Title

More than Mere Deadweight: The Variety of Regulatory Imaginaries that Shape How Regulators, Innovators, and Entrepreneurs Coproduce Disruptive Technological Innovation

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by

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Abstract

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Disruptive technological innovation is the contemporary face of innovation and a dominant force in society. Change is occurring faster and upsetting existing scientific and technical policy systems. Entrepreneurs and innovators, drawing on a folk economic model of regulation, often believe that regulation cannot keep up with the pace of change and therefore policy makers should stay out of their way. Like many folk models, this perception of regulation-as-intrinsic-impediment-to-innovation may sometimes be true but it is not always true. Worse yet, this folk perception of regulators-as-impediment leads entrepreneurs and innovators to ignore opportunities to co-create beneficial regulations and instead create their own bad outcomes by prompting regulators to craft draconian regulations in response to entrepreneurs' malicious non-compliance.

Innovators thus oppose regulation not because they've had bad experiences but because they think they will in the future. A popular version of this folk economic model of regulation brandishes the word "disrupt" while storming the halls of stodgy industries and regulatory agencies. Despite this contemporary *disruptive innovation* narrative, substantial technological change is not a recent invention (though it may be accelerating). The reified economic rhetoric of the folk economic model has convinced disruptive entrepreneurs that regulation is a dirty word synonymous with state inadequacy. Although never perfect and sometimes inadequate, regulators have invariably adapted to technological change. This project explains how regulators have before, are now, and can again become allies of innovators when entrepreneurs look past limiting preconceptions.

Regulatory scholars who study actually-existing regulation will recognize the folk economic model as an extreme version of "capture" within "command and control" regulation. They have repeatedly demonstrated the deceptive inadequacy of totalizing catch-all models of regulation.[1] Nevertheless, scholars who *do not* study actually-existing regulation often use this folk economic capture baseline to judge all work on regulation which hinders scholarly understanding of relationships between regulation and innovation.[2] With these scholarly limitations, lay entrepreneurs' misperceptions are no surprise.

[1] (c.f. Carpenter and Moss 2014b; Slayton and Clark-Ginsberg 2018)
[2] (c.f. Dal Bó 2006; Carrigan and Coglianese 2015)

Contrary to the folk model, I argue regulators have been, are now, and can again be so much more than merely a deadweight loss to innovation if only innovators and entrepreneurs can be guided past self-limiting imaginaries such as the folk economic model of disruptive innovation. To develop this argument, I derive a deductive typology of regulatory imaginaries and discuss how we can use this typology to understand the variety of relationships between regulators, entrepreneurs, and innovators that can lead to better or worse effects on innovation. I then specify my novel methodological approach of Bayesian Type Validation (BayesTV) which combines deductive typological theory with logical Bayesian analysis. Finally, I employ BayesTV to inductively verify my typology using three technological cases in the United States and European Union: autonomous vehicles (AVs), gene editing (GE), and electronic health records (EHR).

The Folk Economic Model imaginary is but one of seven possible regulatory imaginaries of the proper relationship between regulators, entrepreneurs, and innovators. *Regulatory imaginaries*, based on the concept of sociotechnical imaginaries,[3] are collectively held, publicly performed conceptions of desirable relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. Where the Folk Economic Model imaginary sees regulation as only an impediment to be minimized, the other six imaginaries see other potential effects such as moderation, constraint, and catalyst.

Critically, my deductively derived and empirically validated typology also demonstrates that regulatory imaginaries are plural, diverse, and malleable. In presenting three empirical chapters covering multiple imaginaries, I demonstrate that there are plural actually-existing imaginaries around well know technologies. In presenting both similarities and differences in the US and EU implementations of regulation for each disruptive technology, I demonstrate that there is meaningful diversity among regulatory imaginaries in conceptual derivation, expected effect on innovation, and empirical implementation. Finally, in the application of BayesTV to the empirical cases, I demonstrate that regulatory imaginaries are malleable through policy.

This project focuses on regulatory imaginaries because they shape the perceptions of what is possible and desirable about the relationship between regulators, entrepreneurs, and innovators around disruptive innovation. While future studies should build on this focus on imaginaries by exploring their origins and how contending imaginaries shape the outcomes of the policies that are built around them, this project focuses on the imaginaries themselves in order to demonstrate that we need not limit ourselves to the Folk Economic Model which sees regulation, as a rule, as merely deadweight.

[3] (Jasanoff 2015a)

For SL and IvKS,

I may have written it but yall made it possible

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CHAPTER 1

INTRODUCTION

More than Mere Deadweight

SETTING THE STAGE

They promised us jetpacks.[4]

We didn't get jetpacks.[5]

What we got instead was a world populated by both the objects we once imagined and the objects we couldn't yet imagine. Televisions, washing machines, personal communicators, micro-computers, electric appliances; all were imagined labor saving and human-empowering innovations which could release people from drudgery before they became mundane household items.[6] Other innovations followed, building on and elaborating from these now ubiquitous objects. Frozen dinners, video games, mass media, the internet, social media; all first entered the imagination and then became realities building upon widespread technologies which the prior generation had only barely begun to imagine.

We may not have our jetpacks, but we have far outstripped the imagination of the generation who were promised them. The average human now carries around greater processing power than not just the Apollo lunar command module but also greater than the then-supercomputers back in Houston that calculated the trajectories to feed into that simple command module.[7] The average human is now routinely vaccinated against diseases that less than a century ago killed or maimed

[4] Robert F. Courter Jr. from the Bell Aerosystems Corporation flew a jet pack three times a day during the 1964 Worlds Fair and promised onlookers that "in ten years, maybe less, some of you will be up here flying with me." (Abel 2014)

[5] Ok, jet packs actually do exist and have since the 1960s. But they are not the ones we were promised in safety, ubiquity, or capability by Buck Rogers, Boba Fett, or even *The Rocketeer.* As one retrospective put it, "the better question is not "*Who* promised us jetpacks?"—it's "Who promised *us* jetpacks?" (Bosch 2022)," suggesting that while we actually have had jet powered backpacks that can lift a person since the 1960s we were lulled into thinking that ordinary people were ever going to get them.

[6] "progress is people getting released from drudgery and gaining more time to enjoy themselves and build richer lives" is the full quote from the theme song to Walt Disney's Carousel of Progress (Allen [1964] 2015, Walt Disney Records The Legacy Collection: Disneyland:2:59-3:08 min) The composers of the song later called the song "Walt's theme song" in reference to the imagination and optimism of Walt Disney (Anderson 1997).

[7] The Apollo guidance computer was roughly 500 times slower than smartphone *chargers* (48 Mhz) in 2023, much less the phones themselves which are rough 150,000 times faster (although the function of computer processors is very different now, the speed comparisons give a sense of the increase in processing power).(Porter 2020; Heller 2020)

their grandparents.[8] Teenagers today have easy access to more information in their pocket than scholars and experts had a mere 30 years ago.[9] Life today is pretty great!

We may not have our jet-packed supersoldiers,[10] but we have invented fascinating new ways to protect, liberate, oppress, and kill each other as well. Nuclear weapons are the most obvious example, but we didn't stop with fission-initiated fusion bombs. We built gyroscopically guided intercontinental ballistic missiles that could place them within 100 yards of the center of their intended multiple mile immolation zone.[11] We built submarines and supercarriers which can place a missile silo or an entire army base anywhere in the world in a matter of hours. We built first planes then drones armed with missiles capable of decimating cities or eliminating individual people.[12] We imagined, then banned, then fiddled with, and then punished non-compliance around biotechnology including both weapons and genetic alterations.[13] We made information ubiquitous and then built an apparatus to monitor who accesses what to infer what they might do with the information.[14] Life today is pretty terrible?!?!

How did we get all of these wonderful, terrible things? In a word: innovation. We imagined, designed, built, bought, sold, and used all of the things that are wonderful and terrible about life today.

So, is life today pretty great or pretty terrible? Well, we ain't dead yet. "We" are also not a uniform collective; "we" are a collection of many different groups and life experiences; a collection of "me-s", and "you-s", and us-es. So why do some of us live in countries and places that imagine and then create the innovations that built the best the world has to offer? Why do others of us live in countries and places that suffer the downsides of innovation or whose imaginations are not allowed to shape their reality? More perplexingly, why do the places with the "very best" opportunities still fall far short of a reality of access for all and benefit for all? And how have some places and times done better than others at living up to their potential and rhetoric?

In short, where we fall between great and terrible is built on a series of choices. Choices that were made before us, choices we make each day, and choices we must learn to better recognize not as inevitabilities but instead as opportunities. Innovation and the social systems that allow for it are key to all of these choices.

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[8] The most famous example is polio which disabled more than 35,000 people per year in the United States in the 1940s, began widespread vaccination in 1955, by the 1960s there were less than 100 cases annually, 10 cases per year in the 1970s, and complete wild eradication in the United States was certified in 1979. (CDC 2022) This author's grandparents were born in the 1910s, parents in the 1950s, and he was born in the 1980s.

[9] As one study put it, telecommunications capacity roughly doubled every 34 months and information storage capacity doubled every 40 months from 1986 to 2007.(Hilbert and López 2011, 64) And this is not just in rich countries; the internet through mobile devices means developing countries have far more information access than might be guessed by perceptions formed among adults in the 1990s or early 2000s. (c.f. Stork, Calandro, and Gillwald 2013)

[10] Boba Fett, Ironman, and the Rocketeer were all that as well… see footnote 5

[11] (MacKenzie 1993, 1–2)

[12] The MIM-104 Patriot Missile, a surface-to-air "smart missile" was introduced by the US Army in 1981. The AGM-114 Hellfire missile, a complementary air-to-ground "smart missile" was introduced in 1984. Missiles have been mounted on jet fighters since the 1960s and their use on drones became well known during the Obama administration in 2010.

[13] (c.f. Kolata, Wee, and Belluck 2018; Cohen, 2019, and Am 2019; Wee 2019)

[14] (c.f. Zuboff 2015)

While regimes, rulers, and histories vary between times and places, none of these critical social forces is a choice. However, the policies we advocate for, craft, and implement *are* choices we can make. To the problem of a great or terrible future built upon technology, a key choice we face is how we imagine what we desire and then work to institutionalize that imaginary.

When it comes to technological innovation, the key institutional arrangement is the set of rules that entrepreneurs and innovators work within in order to innovate. The most successful systems of wealth and innovation creation in human history have been market societies.[15] While all rich countries use market systems, there is a great variety of implementations of a market system.[16] All successful market societies, however, agree that markets need rules.[17] In fact, economists and political economists have repeatedly pointed out that freer, more dynamic, more successful markets generally have *more* rules not fewer.[18]

Whether public or private, when we are talking about institutionalized rules that govern societies we are talking about regulation. The broader term "governance" is often used to encompass the wider collection of norms, beliefs, practices, and standards in addition to regulation which govern market societies.[19] While the concept of governance certainly helps to expand our views on what contributes to the varieties of market systems, we should not allow it to distract us from the core role that public regulations and the regulators who craft and implement them play in market society.

Combining these points, I argue that a critical factor in crafting technological innovation is the *regulatory imaginary* that defines a desirable relationship between regulators, entrepreneurs, and innovators in a particular time and place around a particular technology. They are based upon the concept of sociotechnical imaginaries and are thus definitionally "collectively held, institutionally stabilized, and publicly performed visions of desirable" relationships between regulators, entrepreneurs, and innovators.[20] They can also be understood as alternative animating logics behind or rival worlds created by regulatory regimes.

A key contribution that this project makes is cataloging and classifying seven varieties of these imaginaries that have before, do now, and can in future shape the relationships between entrepreneurs, innovators, and regulators. Most critically, I identify two imaginaries*, beneficial constraints* and *adoption catalyst*, which demonstrate how regulators can be a positive contribution to innovation beyond the deadweight loss or neutral traffic cops they are sometimes portrayed as. A beneficially constraining regulator seeks to close off known dangerous,

[15] (c.f. DeLong 2022, entire, esp. 2–3)
[16] (c.f. Esping-Andersen 1990; Hall and Soskice 2001b)
[17] (S. K. Vogel 2018, 1–14, and entire). While it should be noted that "laisses faire" or "hands-off" rhetoric is endemic among some politicians in many successful market societies (c.f. Block and Somers 2014), no actually-existing successful market society as measured against 20th or 21st century levels of productivity can function without rules such as property rights, financial systems, contract enforcement, and many more. (S. K. Vogel 2018, 13–14)
[18] (S. K. Vogel 1998; 2007; 2018; Rodrik 1998; 2011)
[19] (S. K. Vogel 2018, 9–14)
[20] (Jasanoff 2015a, 4) is the authoritative source on sociotechnical imaginaries and provides this definition. The concept of regulatory imaginaries and their relationship to sociotechnical imaginaries and other conceptions of ideas, faith, and imagination in political economy is fully explained and derived in chapter 2 on page 35. I have also developed an earlier version of the concept in a slightly different direction with my coauthors in (Mukherjee et al. 2023)

unfruitful, or undesirable paths for innovation in order to funnel entrepreneurs and innovators to focus their energy on less defined but more fruitful avenues. An adoption catalyzing regulator seeks to take a nascent innovation and foster its growth and adoption across the relevant market sector and regulatory jurisdiction. In effect, I demonstrate that regulators *can be* so much more than merely dead-weight by showing how they *have been* so much more than dead-weight.

In order to show how regulation can be more than mere deadweight, this chapter proceeds as follows. First, I discuss disruptive innovation, the modern face of innovation, and the folk economic model regulatory imaginary which sustains it.[21] Next, I discuss three core actor roles which are central to this project: regulators, entrepreneurs, and innovators. The interrelationships between these actor roles then foreshadow the explication of my argument: that regulation can be more than mere dead weight. I develop my argument by presenting the full typological property space[22] of regulatory imaginaries and discussing how we can use it to understand the variety of relationships between regulators, entrepreneurs, and innovators which can lead to better or worse effects on innovation. With my argument developed, I then briefly explain my methodological approach which combines the novel method of Bayesian Type Validation (BayesTV)[23] with elite interviews. I conclude this introductory chapter by discussing how I selected autonomous vehicles (AVs), gene editing (GE), and electronic health records (EHR) as the empirical cases to inductively refine the typology. I close by summarizing how the remaining chapters in the project execute the argument and method introduced in this chapter.

DISRUPTIVE INNOVATION AND THE FOLK ECONOMIC MODEL IMAGINARY OF REGULATION

Disruptive technological innovation is the contemporary face of innovation and a dominant force in society. Change is occurring faster and upsetting existing scientific and technical policy systems. Entrepreneurs and innovators, drawing on a folk economic model of regulation, often believe that regulation cannot keep up with the pace of change and therefore policy makers should stay out of their way. Like many folk models, this perception of regulation-as-intrinsic-impediment-to-innovation may sometimes be true but it is not always true. Worse yet, this folk perception of regulators-as-impediment leads entrepreneurs and innovators to ignore opportunities to co-create beneficial regulations and instead create their own bad outcomes by forcing regulators to create draconian regulations in response to entrepreneurs' malicious non-compliance.

Innovators thus oppose regulation not because they've had bad experiences but because they think they will in the future. A popular version of this folk economic model of regulation brandishes the word "disrupt" while storming the halls of stodgy industries and regulatory agencies. Despite this contemporary disruptive innovation narrative, substantial technological change is not a recent invention (though it may be accelerating). The reified economic rhetoric of the folk economic model has convinced disruptive entrepreneurs that regulation is a dirty word

[21] A genealogy of disruptive innovation and regulatory imaginaries is presented in Chapter 2. The concepts are briefly defined in this chapter only so far as is necessary to understand my argument.

[22] The derivation of this typology is explained in Chapter 3. In this introductory chapter, I present only the implications this theory has for our understanding of regulation and disruptive technological innovation.

[23] The specification of the novel method of Bayesian type validation (BayesTV) in both theory and practice is presented in Chapter 4. In brief, BayesTV combines deductive typological theory with logical Bayesian analysis in order to discipline and clarify how typologies are theoretically defined and empirically validated.

synonymous with state inadequacy. Although never perfect and sometimes inadequate, regulators have invariably adapted to technological change. This project explains how regulators have before, are now, and can again become allies of innovators when entrepreneurs look past limiting preconceptions.

Failure is loud, success quiet. Regulatory failures like the Deepwater Horizon oil spill and 2008 Global Financial Crisis are loudly publicized. Quieter are responses other than failure like American recombinant DNA regulation following the 1975 Asilomar Conference. This mismatch reinforces a folk economic perception of regulators as merely deadweight destined to fail. Worse yet, loudly prognosticating regulators' inevitable failure often fosters failure where alternative rhetoric could encourage success.

Regulatory scholars who study actually existing regulation will recognize the folk economic model as an extreme version of "capture" within "command and control" regulation. They have repeatedly demonstrated the deceptive inadequacy of totalizing catch-all models of regulation.[24] Nevertheless, scholars who *do not* study actually existing regulation often use this folk economic capture baseline to judge all work on regulation which hinders scholarly understanding of relationships between regulation and innovation.[25] With these scholarly limitations, lay entrepreneurs' misperceptions are no surprise.

As with most folk theories, the folk economic model is not always wrong and there are certainly cases where it is correct; if there wasn't some correlation, it wouldn't work as a "statement of the common-sense understandings that people use in ordinary life [rather than] various "specialized" and "scientific" models."[26] This project intends to demonstrate, however, that not always wrong is not the same as always or even often correct by showing that other regulatory imaginaries of innovation exist and provide templates which can help innovators, entrepreneurs, and regulators co-create better outcomes. In short, to show that regulators can be so much more than mere deadweight if only innovators and entrepreneurs choose, as they have before, to co-create better interactions.

This project focuses on regulatory imaginaries because they shape the perceptions of what is possible and desirable about the relationship between regulators, entrepreneurs, and innovators around disruptive innovation. While future studies should build on this focus on imaginaries by exploring their origins and how contending imaginaries shape the outcomes of the policies that are built around them, this project focuses on the imaginaries themselves in order to demonstrate that we need not limit ourselves to the Folk Economic Model which sees regulation, as a rule, as merely deadweight.

Before introducing my typology of the range of regulatory imaginaries, I lay out more formally the distinctions between the core roles of regulators, entrepreneurs, and innovators which actors involved in DTI can take on.

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[24] (Slayton and Clark-Ginsberg 2018) is a good recent review of the inadequacy of the capture model. (Carpenter and Moss 2014b) provides an excellent variety of complexifications of the concept of capture.

[25] For evidence of the folk economic model's endemic reach among academic economists, see (Dal Bó 2006, 203-206 especially) where Stigler (1971) is seen as a jumping off point needing only additional formalization and empirical support rather than as one type among many.

[26] (D'Andrade 1987, 113)

CORE ROLES – REGULATORS, ENTREPRENEURS, & INNOVATORS

As explained in the previous section, this project deals with the various regulatory imaginaries which define collectively held, publicly performed conceptions of desirable[27] relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. Up to this point, I have not detailed who the actors who co-create the imaginaries are other than to name them: regulators, entrepreneurs, and innovators. In naming them, I have, in fact, defined roles rather than actors, a critical distinction I explain below. In this section, I provide role descriptions that define what functions each of these three actor-roles play within the regulatory imaginaries which I argue are at the core of disruptive technological innovation (DTI).

WHY ROLES AND NOT ACTORS

Before defining regulators, entrepreneurs, and innovators, a word about the distinction between actors and roles. The importance of identifying actors, analyzing their interests, and measuring their preferences arises ultimately from "methodological individualism;" from treating the behavior of individuals as the key unit of analysis.[28] While this focus on individual behavior aggregating up as if "led by an invisible hand" to national behavior can quite literally be traced back to Adam Smith (A. Smith [1776] 2021, 43), methodological individualism in contemporary social science is most closely associated with the behavioral revolution and rational choice theory.[29] As formally defined, the rational choice definition of the individual requires a single ranking of interests; individuals are modeled as actors who have a complete list of all their options placed in a single rank order of most to least preferred.[30]

However, this formal methodological assumption of rational choice methodological individualism requires that all preferences be reducible down to a single rank ordering, a difficult proposition to accomplish for even ordinary actually existing people such as the male breadwinner or the working mother. In their very names, the male breadwinner and working mother describe not one type of actor but three roles played by a single person (a gender role, a family role, and a labor market role). While others have demonstrated that these complexities contribute to people behaving irrationally and then attempted to undermine the validity of rational choice theory,[31] the fact that theory does not perfectly mirror reality is not damming. Instead, the arbiter of a whether a simplifying assumption in theory is warranted is whether the loss of exactness is outweighed by the gain in analytical usefulness for a particular purpose. For methodological individualism within rational choice formal modelling, the answer is very often

[27] Note that by desirable this includes such relationships as "stay out of the way" or "don't meddle." Desirable here thus means simply that the imaginary defines the proper role for each of the key actor-roles of regulator, entrepreneur, and innovator not that we are judging the imaginary against any normative standard.

[28] (c.f. Levi 1997; 2009; Hall and Taylor 2016)

[29] (Levi 2009, 133). This is, perhaps ironically, despite the critical findings from rational choice models that naïve aggregations of individual behavior often do NOT explain group behavior (Levi 2009, 117).

[30] Note that rational choice theory is somewhat flexible in how it uses the terms "interest" and "preference" wherein actors are technically defined to have complete and transitive preferences over all of their possible alternative actions/outcomes. Once this preference order has been established, it is often what is referred to as the interest of the particular actor. As discussed in the "Social Construction" section of Chapter 2, the empirical usage of preferences is distinct: interests remain as the result of theoretical analysis but preferences are now what people actually say they want and sometimes called "revealed preferences" for that reason.

[31] (c.f. Levi 2009, 131)

yes but for our purposes of understanding how multiple types of actors fit together into an imaginary, we may not wish to lose the complexity distinguishing between roles and people.

To deal with the complexities of actually existing people, social network scholars Padgett and Powell (2012, 5) shift our focus from methodological individualism to "methodological role-ism." In shifting from a focus on actors to a focus on roles, they disentangle the complexity of actually existing people without assuming it away for simplicity. In this formulation, then, people are not required to be reduced to an actor type with a single set of ranked preferences; instead people are modeled as a collection of roles where each role can have a single set of ranked preferences. From our earlier examples of the male breadwinner and the working mother, it is much more satisfying to say that we can rank a persons preferences in one way when they are in one role and another way when they are in another role than being forced to reduce them down to a single totalizing actor preference order by collapsing alternative roles into a master actor type.

Thus, in defining the key actor roles of entrepreneur, innovator, and regulator in order to specify how their functions fit in to regulatory imaginaries, it is critical to remember that these are *roles and not people*. Remembering that they are roles allows us to capture complexities where single people can play multiple roles, either simultaneously (the founder and CEO; innovator and entrepreneur) or in series (the so-called revolving door between regulators and industry). Regulatory imaginaries therefore consist of different conceptions of how actor roles fit together, not requiring that an actually existing person be shoehorned into only one by reducing them down to simply an actor. We can maintain useful complexity while gaining analytic clarity.

REGULATORS, ENTREPRENEURS, AND INNOVATORS

There are three key roles that define regulatory imaginaries of DTI: entrepreneurs, innovators, and regulators. A regulatory imaginary *is* a collectively held, publicly performed conception of desirable relationships between regulators, entrepreneurs, and innovators which people believe are (or should be) institutionalized within regulatory agencies. While the people who do the defining of a regulatory imaginary include groups of people beyond those that fill these three roles, the content of a regulatory imaginary defines the desirable relationships between the three roles of regulatory, entrepreneur, and innovator. It is useful, now, to explicitly define these three core roles and then consider potential complexities of these definitions.

A **regulator** within a regulatory imaginary is defined by their goal of promoting the public interest. While the classical implementation of such a role is a publicly employed civil servant, that is not a necessary condition. Instead, with a given regulatory imaginary, the regulator is the role charged with defending the interest of groups outside the triad of regulators, entrepreneurs, and innovators who are centrally placed within regulatory imaginaries.[32] The definition of the public interest may also vary between imaginaries; in fact defining what is in public interest is often a critical distinction between different visions of a desirable relationship between regulators, entrepreneurs, and innovators. While the regulator role need not ONLY be concerned

[32] This definition of the public interest as the interest of people outside of the direct interaction draws upon Sorauf's (1957) definition of the public interest as those outside of the influence system envisioned by pluralism. Note that it need not exclude other definitions such as the strict pluralist aggregation of interests or some exogenous value system's definition (e.g. the glorification of a deity, a desire for national unity & growth, etc.). While based in Sorauf's conception, my definition of the public interest is a simple one: the interests of those who are not at the proverbial table of regulators, entrepreneurs, and innovators.

with groups beyond themselves, entrepreneurs, and innovators, they are defined by being ALSO concerned with groups beyond the central triad.

An **entrepreneur** within a regulatory imaginary is defined by their managerial goals to mediate a relationship between the rigid requirements of a technological innovation and the uncertain reality of the social world. Whether thought of as the apocryphal "huckster" in the hacker/hustler dyad[33] or the more formal managerial and institutional functions from J.D. Thompson's theory of instrumental organizations,[34] the entrepreneur is defined by their goal to bridge the gap between a technological innovation and social needs such as a market opportunities or social problem. Their goals include both feeding the inputs (material, investment, personnel, etc.) into the technical core inhabited by the innovator as well as promulgating the outputs (products, services, platforms, etc.) from that core.

An **innovator** within a regulatory imaginary is defined by their technological goals to leverage scientific and technical logic into a novel device, process, or application. They are the complementary "hacker" from the hacker/hustler dyad and the technical core from J.D. Thompson's theory of instrumental organizations.[35] As a role (rather than a complete person) they are solely interested in the needs of the technological innovation at the heart of the technological core and rely upon the mediating functions of the entrepreneur to protect them from the uncertainty of social reality.[36]

When seen as roles, the distinction between entrepreneurs and innovators is less controversial than it may seem to the myth of the self-made entrepreneur[37] because it simply distinguishes between the engineering/design function of creating a new product or process (innovating) and the business function of getting that innovation to scale and to market (entrepreneurship). As role descriptions, a single person could well hold both the innovator and entrepreneur role within a given DTI organization or, at the very least, the roles of innovator and entrepreneur can both be shared by people who are primarily one or the other.[38]

The role of regulator within a regulatory imaginary may seem more contestable, but this contestation is a feature of the regulatory imaginary perspective rather than a bug. Within the folk economic model imaginary described above, the role of the regulator is constrained to function as an impediment upon innovation and entrepreneurship because the regulator within that imaginary is seen as upholding a narrow conception of the public interest. However, the folk economic imaginary is but one of a set of possible regulatory imaginaries which are chiefly distinguished by the functions the regulator can play in co-creating disruptive technological

[33] The phrase "hacker and hustler" comes from founder stereotypes in tech startup culture based on the prototypical pair of Steve Jobs and Steve Wozniak who founded Apple Computer. The hacker is the technological "genius" who can make the product or service possible. The hustler is the business "genius" who can create the investment supply and customer demand to create a business from the hacker's technical knowledge. The adage is broadly treated as common wisdom without direct attribution, but later entrepreneurs such as Rei Inamoto have expanded the dyad to include the "hipster" whose creativity can make the business cool (and thus desirable/sustainable beyond simple technical functionality or financial solvency). (Cabage 2014; Ellwood 2012; Rudic, Hubner, and Baum 2021)

[34] (Thompson [1967] 2003, 10–13)

[35] (Thompson [1967] 2003, 10–13)

[36] (Thompson [1967] 2003, 19)

[37] (S. K. Vogel 2020; 2022)

[38] To borrow the hacker/huckster archetype, Steve Jobs knew more than nothing about the technical side of Apple Computer and Steve Wozinak knew more than nothing about the business side. Yet Jobs clearly specialized in the business/huckster side while Wozniak specialized in the technical/hacker side.

innovation beyond merely that of dead-weight impediment. In the following section, I systematically describe the deductively defined and inductively verified range of these regulatory imaginaries which are the central contribution of this project.

ARGUMENT: MORE THAN MERE DEAD WEIGHT

As the title of this section, chapter, and the overall project suggest, my central argument is deceptively simple: regulators have been and can be so much more than merely a deadweight loss to innovation if only innovators and entrepreneurs can be guided past self-limiting imaginaries such as the folk economic model of disruptive innovation. In order to make this argument, I deductively develop and inductively validate a typology of seven regulatory imaginaries of innovation. These seven imaginaries span from the Folk Economic Model's predictions of an impediment (or deadweight) of regulation on innovation to the catalytic impact of some regulation to drive innovation beyond the limited imagination of market actors. While the deductive derivation of the typology comes in Chapter 3 and the inductive validation comes in Chapters 5, 6, and 7, this section lays out an overview of why such a typology is necessary, how it was constructed, and how it helps us to move beyond the zero from regulatory costs to regulatory benefits. In short, scholars have known for decades to centuries that regulation need not be the enemy of innovation; an exhaustive typology of potential relationships creates a catalog of diversity to hedge against any claims of monotype orthodoxy.

In Chapter 2, I explain how *regulatory imaginaries* of disruptive technological innovation (DTI) are collectively held, publicly performed conceptions of desirable relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. I also explain how the concept of regulatory imaginaries draws on the tradition of ideas, faith, and imagination in political economy scholarship and how employing the concept of sociotechnical imaginaries as defined in STS brings additional clarity to how different conceptions of the relationship between regulation, innovation, and entrepreneurship coproduce disruptive technological innovation. In the prior section, I specified how to distinguish between the core actor roles of entrepreneur, innovator, and regulator while acknowledging that, in practice, multiple roles may be played by one person.

In this section, we move from what regulatory imaginaries are in general to what they are specifically by using a typology derived from variables underlying two seminal works on regulation: Stigler's (1971) "The theory of economic regulation" and Streeck's (1997) "Beneficial Constraints." While the full derivation of the typology is left for Chapter 3, this section explains how the specifics of regulatory imaginaries about DTI fit into the conceptual work laid out in Chapter 2.

To begin on familiar ground, the Folk Economic Model of regulation sees regulators as the classical impediment to innovation. In Christensen's (1997) original formulation of disruptive innovation, regulation is brought up to discuss what old regulations need to be removed and new regulations put in place with a standard narrative that "regulations are toppled only when disruptive innovators find applications or markets beyond the reach of regulators."[39] Thus, regulator's role in DTI is relegated to "ultimately succumbing" to innovators and entrepreneurs who successfully end-run the classically entrenched and inefficient regulator. This view of

[39] (Christensen, Grossman, and Hwang 2009, xlv)

regulators as an incompetent impediment to regulation is a folk theory Christensen derives from Stigler.

With just its title, Stigler's (1971) "The theory of economic regulation" lays claim to parsimoniously defining all that need be thought of economic regulation. The abstract makes clear that the paper will "provide a scheme of the demand for regulation" and "provide elements of a theory of supply of regulation,"[40] neatly promising the canonical supply-and-demand binary necessary and sufficient for any good economic theory. With such a clear purpose, Stigler then proceeds to lay out a systematic list of benefits and costs which regulation can bring to businesses to define the predictable "calculus of the profitability of regulation of an industry."[41]

From this analysis, Stigler has been credited with the concept of 'regulatory capture' because a "central thesis of [his] paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit."[42] So powerful was this parsimonious economic analysis of politics that Carrigan and Coglianese point out that, to the contemporary reader, all of the above seems rather obvious.[43] For many non-regulatory scholars, and most lay people, regulation *is* regulatory capture to greater or lesser degree.

By the time Christensen coined the term "disruptive innovation" in *The Innovator's Dilemma* (1997), the "obviousness" of regulatory capture formed the basis of his analysis. Due to the baseline of capture, regulation is relegated to the role of "ultimately succumbing" to innovators who successfully end-run the classically entrenched and inefficient regulator. Beyond this common wisdom, little discussion of regulators appears in Christensen's formulation.

In building my typology, I challenge Christensen's received wisdom from Stigler's claim that the benefits and costs of regulation should be seen as fixed and universal. By introducing the alternative narrative of beneficial constraints from Streeck (1997), we can begin to unpack the seductive 'common sense' of Stigler's supply and demand model.

Streeck's "Beneficial Constraints: On the Economic Limits of Rational Voluntarism" (1997) provides an alternative to Stigler's classic article not only in message but also in format. Where Stigler set out to provide *the* theory of economic regulation, Streeck's "Beneficial Constraints" explicitly "do[es] not pretend to have a conceptual schema to cover them all."[44] Instead, he presents examples from which he can draw out theoretical and practical implications. Streeck's key advice to colleagues is that "Recognition of the economic benefits of *some* social constraints immunizes against the received wisdom that *all* constraints are counterproductive by definition."[45] For Streeck, sometimes the future is best made by regulators who constrain innovators from their original ambitions forcing them to innovate in line with other ambitions.[46]

To reconcile Christensen and Stigler's single fixed model with Streeck's call for diverse models, I derive five variables which generalize their underlying concepts: relationship, access,

[40] (Stigler 1971, 3) emphasis in original
[41] (Stigler 1971, 7)
[42] Quote from (Stigler 1971, 3), although as (Carrigan and Coglianese 2015, 277) point out, Stigler did not actually coin the term regulatory capture in this article.
[43] (Carrigan and Coglianese 2015, 292)
[44] (Streeck 1997, 200)
[45] (Streeck 1997, 213)
[46] (Streeck 2004, 428)

driver, outcomes, and effect.[47] The first variable is the *relationship* of regulators to the innovative market being regulated, whether an external rulemaker or internal stakeholder who brings their views and priorities to the table. The second variable is the access that regulators have to *information* about the practices and features of an innovative sector, whether lower or higher than firms in that sector. The third variable is where the *driver* of adoption of the disruptive innovation throughout a regulatory domain comes from, whether from the market or from regulators. The fourth variable is the number of optimal regulatory arrangement *outcomes* which the model believes can result from a regulatory response to disruptive technological innovation, whether a laisses faire zero, a Pareto optimal one, or a socially constructed many. The fifth variable is the *effect* of regulation on innovation within the regulatory domain, whether an impediment, moderator, constrainer, or catalyzer.

From these variables, the first four specify aspects of the regulators role in DTI and thus define an exhaustive typological property space[48] which leads to the various effects of regulation on innovation. These regulatory imaginaries have been organized by the amount they diverge from Christensen's (1997) folk theory application of Stigler's (1971) economic model, particularly in the sense that they have a different effect on innovation than the impediment predicted by the folk economic model.

Using this deductive typological theorizing process,[49] I identify seven distinct regulatory imaginaries comprising 18 of the 24 mathematically possible configurations. Of these seven regulatory imaginaries, the Folk Economic Model imaginary, Beneficial Constrainer imaginary, and Adoption Catalyst imaginary are of particular interest because they present theoretically and empirically interesting variations in the expected effect of regulation on innovation. The other four imaginaries are well represented in the literature and do not represent surprising variation.[50] The resulting typological property space may be seen in Table 1.

The first of the three imaginaries core to this project is the Folk Economic Model. Characterized by regulators who consign themselves to be merely rulemakers with low access to information and believe the market provides the drive for adoption thus leaving a single least bad or zero optimal outcome, the Folk Economic Model is the folk theory introduced above which animates many non-regulatory scholars and most laypersons' understanding of regulation.

While it may seem unfair to blame Stigler for the way in which his theory has been reduced to a simple folk understanding of regulation which forgets the complexity of regulatory scholars, identifying and specifying this imaginary is central to this project because it is important to demonstrate that such a folk theory is a self-fulfilling prophecy. If regulators and firms act as if regulators are merely deadweight which must be minimized in order to allow for innovation, then all actors behave to make it so; the folk economic model is the proto regulatory imaginary.

The second core imaginary, Beneficial Constrainer, is characterized by regulators who have higher access to information and believe that there are many possible optimal outcomes but believe that the drive for adoption of an innovation comes from the market. Named for Streeck's

[47] A full discussion of the derivation of these variables from the specific scores in Stigler (1971) and Streeck (1997) may be found in Chapter 3.
[48] (A. L. George and Bennett 2005, 233–62)
[49] (A. L. George and Bennett 2005, 244)
[50] Six of the 24 configurations were identified as trivial or logically impossible. For details on why this is a feature (rather than a bug) of this deductive typology theory process, see Chapter 3.

Table 1: Complete Typological Property Space of Regulatory Imaginaries

		Constitutive Variables (Independent Variables)				Dependent
Name of Imaginary	**#**	**Relationship**	**Info**	**Driver**	**Outcomes**	**Effect**
Folk Economic Model (Christensen 1997)	1	Rulemaker	Lower	Market	Zero	Impediment
	2	Rulemaker	Lower	Market	One	Impediment
Market Ideological*	3	Rulemaker	Higher	Market	Zero	Impediment
	4	Stakeholder	Higher	Market	Zero	Impediment
State-as-Venue (Skocpol 1985)	5	Rulemaker	Lower	Regulator	Many	Moderator
	6	Stakeholder	Lower	Market	Many	Moderator
	7	Stakeholder	Lower	Regulator	Many	Moderator
Capture (Stigler 1971)	8	Stakeholder	Lower	Market	One	Constrainer
	9	Stakeholder	Lower	Regulator	One	Constrainer
Technology-Based Regulation "Conventional Command and Control" (Malloy 2010)	10	Rulemaker	Higher	Market	One	Constrainer
	11	Rulemaker	Lower	Regulator	One	Constrainer
	12	Stakeholder	Higher	Market	One	Constrainer
Beneficial Constrainer (Streeck 1997)	13	Rulemaker	Higher	Market	Many	Constrainer
	14	Stakeholder	Higher	Market	Many	Constrainer
Adoption Catalyst	15	Rulemaker	Higher	Regulator	Many	Catalyzer
	16	Stakeholder	Higher	Regulator	Many	Catalyzer
	17	Rulemaker	Higher	Regulator	One	Catalyzer
	18	Stakeholder	Higher	Regulator	One	Catalyzer
Trivial	19	*Rulemaker*	*Lower*	*Regulator*	*Zero*	*Impediment*
	20	*Stakeholder*	*Lower*	*Regulator*	*Zero*	*Impediment*
	21	*Rulemaker*	*Lower*	*Market*	*Many*	*Impediment*
	22	*Stakeholder*	*Lower*	*Market*	*Zero*	*Impediment*
Logically Inconsistent	23	~~Rulemaker~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~
	24	~~Stakeholder~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~

* (Henderson and Appelbaum 1992) completed Chalmers Johnson's (1982) 2x2 of market|plan x rational|ideological by defining the idea of "market ideological" which privileges market structures for organizing social and economic interaction beyond efficient cost-benefit tradeoffs due to an ideological preference for market structures over planning. More modern ears are more familiar with the term "market fundamentalism" as popularized by George Soros (1998) although the concept is as old as capitalism itself with well-reasoned critique of it at least as old as Polanyi ([1944] 1957). The modern usage is well explained in (Block and Somers 2014).

(1997) "Beneficial Constraints" this model captures the same key point as Malloy's (2010) 'Alternative Construction' of command and control regulation where regulators know more about the overall shape of the market sector in their regulatory jurisdiction than any of the firms do individually or in the aggregate. Streeck based his concept on empirical observations such as a high minimum wage which forces firms to develop high productivity business models which serve as an engine for economic growth in the long term even if they are against the short term economic interests of managers who would prefer to maintain their low productivity, low wage business models rather than invest in long term growth in productivity.[51] This effect of beneficially constrained short term innovation leading to long term innovation benefits is exactly the sort of innovation success arising from an alternative regulatory imaginary that demonstrates the lie of the totalizing Folk Economic Model.

[51] (Streeck 1997, 200–201)

The third core imaginary, Adoption Catalyst, is characterized by regulators with higher information than firms who believe that regulators drive the spread of an innovation and desire either one or many different optimal regulatory outcomes. Completing the divergence from the Folk Economic Model, these regulators push firms to adopt innovations they otherwise would not. An adoption catalyzing regulator looks to spread a disruptive technological innovation throughout its sectoral jurisdiction. It does so by actively encouraging specific steps which regulated entities should take to transition from one state of play (where the DTI exists at the margins of the sector) to another state of play (where the DTI is pervasive throughout the sector). Identifying and specifying this imaginary is a key theoretical contribution of this typology. More than merely dead weight, more than merely a beneficial guiding hand, these regulators are actively driving innovation in a particular direction beyond the vision of firms under their the regulatory jurisdiction.

As a collection of regulatory role descriptions about the relationships between regulation and technological innovation, the models defined in the typology in Table 1 form the basis of regulatory imaginaries. To become fully formed imaginaries, the conceptual models must be demonstrated to be collectively held, publicly performed, and desirable statements of relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. The remainder of this project establishes the degree of belief we can have that these deductively defined models are actually empirically extant imaginaries by fully deriving the typology (Chapter 3) and then inductively validating it (Chapters 5,6, and 7).

While the Folk Economic Model imaginary is the key concept in this introduction and in Chapter 2, the key contribution of the project lies in moving beyond the deadweight loss predicted by the impediments that the Folk Economic Model specifies that regulators will have on innovation. Both the Beneficial Constraints and Adoption Catalyst imaginaries move "beyond the zero" from discussing the costs or burdens of regulation on innovation to imagining and implementing benefits of regulation on innovation. Critically, these benefits are not merely social benefits which might counterbalance the economic costs. Rather, Beneficial Constraints and Adoption Catalyst look to create economic benefits as well in order to demonstrate that we need not see regulation as a tradeoff of economic costs for social benefits. This relationship is explained further in the following section.

BEYOND THE ZERO: SOCIAL VS(?) ECONOMIC REGULATION

This is a project which centers regulation. In such studies of regulation, we often make a distinction between social regulation and economic regulation even though we do so while acknowledging the social impact of economic rules and the economic impact of social rules. Underlying this divide is a fundamental assumption that a rule enforced by the state under authority from the government intends to forward the public interest either primarily toward a social benefit despite the potential economic costs[52] or a rule aims toward an economic benefit despite the potential social cost.[53] When we acknowledge the connection between economic and social regulation, we tend to see it purely as a tradeoff.

[52] e.g., requiring catalytic converters costs car makers and consumers more money but drastically reduces harmful carbon monoxide pollution

[53] e.g., caveat emptor, or allowing many products to be sold without requiring marketers to be liable for their dangers reduces the barriers to market entry for new products at the cost of increased risk to consumers

However, only some forms of regulation are actually best understood, best imagined, as a tradeoff while others may be both a social cost and an economic cost. The folk economic model, as I have explained at the beginning of this chapter, is one such form of regulation which, when implemented, leads to both social costs and economic costs. In the case of Uber, while there is certainly a benefit to consumers of a dramatically more efficient matching of riders with vehicles for hire, there is a cost to both drivers as precariously employed contractors and to the economic viability of the car-hire sector (Uber has still never earned a profit as of this writing) from allowing Uber to continue to operate. Indeed, in Uber's home jurisdiction of California, the fight to properly classify drivers as workers, and thus require Uber to pay its fair share of employee benefits, has cost the State of California, Uber, and lobbyists a great deal of money and still done little to resolve the matter.[54]

While a regulation can clearly have both social and economic costs, other regulations can have both social and economic benefits. Indeed, the primary goal of many of the most important regulatory questions in capitalist political economies are intended to do just that. A higher minimum wage, for example, was recognized by thinkers as antithetical as Wolfgang Steeck and Henry Ford as a key mechanism to benefit industry. For Ford, the benefit was quite basic: pay your workers enough to buy your products (and get the guy across the street to do the same) and you've got not just an employee but a customer.[55] For Streeck, the benefit was not as immediately obvious to regulators and entrepreneurs, but in hindsight a high minimum wage forced entrepreneurs to focus on high value add business models which ultimately led to both very internationally competitive companies and good lifestyles for workers.[56]

We can organize these tradeoff and coincident logics quite easily into a logical pattern as shown in Table 2 below.

As the title plainly states, this project aims to demonstrate how regulators can be so much more than merely dead-weight. As such, I aim to move the folk understanding of regulation away from the Folk Economic Model which casts regulation as a dead weight loss on both the economy and ultimately society (Box C in Table 2). In our journey away from a focus on the potential for deadweight loss, I will move beyond cases in the well-travelled realms of either of the two tradeoffs (boxes B and D in Table 2).[57] This project will thus be firmly centered in the realm of regulations which are both socially and economically beneficial (Box A in Table 2). It will also focus on regulations that have social and economic benefits *by design* rather than merely as unintended consequences.[58] The empirical cases used to validate the typology in chapters 5, 6, and 7 will all fall within this realm of benefit-benefit. The cases differ on whether regulation precedes, is coincident with, or follows widespread market adoption. This temporal

[54] The battle between California AB5, Proposition 22 in 2020 (Padilla 2020, 56–59), and the California Supreme Court is still ongoing as of this writing despite an estimated $224 Million having been spent by Uber and Lyft on Proposition 22 alone.
[55] (Tolliday and Zeitlin 1987, 1–2)
[56] (Streeck 1997, 200–201)
[57] This is not to say that there are not interesting stories to tell in boxes B and D. However, the stories of tradeoffs around technology based regulation are well trod (c.f. Cole and Grossman 1999; Malloy 2010; Vinsel 2019) while the stories around Capture have been exceedingly well compiled in the edited volume (Carpenter and Moss 2014b).
[58] This is not to say that unintended consequences are uniteresting or unimportant. In fact, Streecks observation that high wages unintentionally led to high productivity business models in post-War Germany are the seminal Beneficial Constraint which underlies his work (Streeck 1997) upon which I build my typology in Chapter 3.

Table 2: Four Potential Realms of Socioeconomic Regulation

Social \ Economic	Costs	Benefits
Benefits	(B) *Technology-Based Regulation*	(A) *Adoption Catalyst* *Beneficial Constraints*
Costs	(C) *Folk Economic Model* *Market Ideological*	(D) *Capture*

★ *The State-as-Venue Imaginary sits precisely at the center, as regulators are here imagined to have no other impact than simply to convene the social stakeholders. See Chapter 2 for more details on all imaginaries.*

dimension and other case selection logics will be discussed below. First, I briefly introduce the methods I will use to inductively validate this typology: Bayesian type validation and elite interviews.

METHODS

As the chief contribution of this project is a deductively defined and inductively validated typology of regulatory imaginaries, I employ Bayesian type validation (BayesTV) and elite interviews to investigate three empirical cases central to an understanding of relationships between regulators, entrepreneurs, and innovators that have positive economic benefits. While full specification of BayesTV is provided in Chapter 4, the following section explains the core logic of how I employ logical Bayesianism to update our degree of belief that a particular empirical case is most likely of a particular deductive type. In the section following that, I explain how elite interviews allow us to investigate how actors roles view their regulatory imaginaries, how they form those views, and how those views inform their actions.

BAYESIAN TYPE VALIDATION (BAYESTV): AN OVERVIEW[59]

This project employs a new method called Bayesian Type Validation (BayesTV). BayesTV combines two gold-standard pillars of qualitative methodology, process tracing and typological theory, to produce a completely qualitative method of theory development and testing. While excellent qualitative work has always included theory development and theory testing, the logic of how qualitative theory building works has often been opaque to students and a target for incredulous skeptics. BayesTV uses the deductive logic of typological theory to complement the inductive logic of Bayesian process tracing (BayesPT)[60] to produce a disciplined and clear method of analyzing evidence and communicating results. This section briefly reviews how BayesTV operates in practice as it will be applied to the evidence in each of the three empirical chapters (5, 6, and 7).

To efficiently classify cases and refine the deductive typology, BayesTV incorporates a search process that focuses on the most informative pieces of evidence. The first piece of evidence explicitly[61] analyzed for a case should be the strongest piece of support for the most

[59] Chapter 4 fully develops and explains the logic of BayesTV. Those interested in applying the method should see the theoretical and practical advice in that chapter.
[60] (Fairfield and Charman 2017; 2022)
[61] Explicit Bayesian analysis (whether process tracing of hypotheses or validation of types) refers to the use of mathematical likelihood ratios as developed in (Fairfield and Charman 2017) and refined in (Fairfield and Charman

likely type based on background knowledge of the case.[62] The second piece of evidence should be selected as the strongest piece of support for the nearest rival to the most likely type based on background knowledge of the case *and* analysis of the first piece of evidence. Once the first two pieces of evidence have been explicitly analyzed, BayesTV considers whether additional evidence needs to be analyzed based on the possible priors (naïve, skeptical, etc.) and how loudly the first two pieces of evidence have adjudicated between the possible types. The extreme counterfactual state of the world is also considered and evidence for such a "black swan" event is described and sought. Once the analyst is satisfied that sufficient explicit evidence has been analyzed to build a type validation case, the weight of the evidence is placed against defined sets of priors in order to identify the sensitivity of the classification to a reader's prior beliefs about the world.

As a process of search built on highlighting the most informative pieces of evidence, BayesTV (and all logical Bayesianism) relies on the *information value* of evidence rather than the idiosyncrasies of a specific piece of evidence. While specific pieces of evidence are presented below, they are analyzed as a representative of all "informationally equivalent"[63] evidence which provides insight into the relative likelihood of which type is the true state of the world. Thus, what may appear to be a selective reification of evidence is actually a carefully considered process of which evidence to highlight in the explicit analysis in order to distinguish between possible states of the world in a clear and disciplined manner.

In metaphorical terms, the goal of BayesTV is not to cut a node out of its web of interconnections and carefully study its nodal properties under a microscope but rather to carefully consider which node to lift from a web in order to trace the interconnections. The goal is always to pull on the node which reveals the most information about the web rather than to find the most perfect individual node.

This focus on information value may appear unsettling to traditional qualitative scholars who emphasize the richness of evidence presented in their case narrative built upon deep case knowledge[64] to judge the effectiveness of an argument. Indeed, it may seem like cherry picking only one or two pieces of self-justificatory evidence!

2022). Implicitly, all process tracing and most qualitative research can be described as a Bayesian method of reasoning.(Fairfield and Charman 2017, 1–2) The choice of 'how explicit to get' is a tradeoff between exhaustive transparency and laboriousness which should be decided on how informative additional explicit analysis would be as opposed to an implicit summary of the weight of evidence.

[62] Since BayesTV is concerned with type validation, cases are selected using background information to be representative of a particular type. This is *not* a form of confirmation bias as the disciplined consideration of the likelihood of observing this evidence under *all* alternative types clearly and transparently presents the judgements made by the analyst. While a skeptic could certainly disagree with such judgment, the goal of a logical Bayesian approach is to clearly identify the "locus of contention" (Fairfield and Charman 2017, 16) rather than claim to be beyond contention or to set up an "entirely agree vs. entirely disagree" dichotomy. Where a transparent frequentist would rely upon preregistration of hypotheses and appeal to stochastic analysis to reject or fail to reject a null hypothesis, a Bayesian approach instead seeks to transparently state priors and indicate how evidence is used to update those priors.(Fairfield and Charman 2017, 1,6) The author and reader may ultimately disagree with the conclusions of a logical Bayesian analysis but both should be able to clearly state precisely where they disagree (evidence selection, likelihood ratios, missing hypotheses/theories in the set, etc.) rather than rely on less precise statements of agreement or disagreement based on sum total statements or reverse-engineering of an argument.

[63] (Fairfield and Charman 2017, 5 in Online Appendix)

[64] C.f. (Johnston 2012, 70) and "the importance of local or area knowledge for general theory."

However, as qualitativists have long pointed out to quantitativists when accused of selecting on the dependent variable or having too many variables for too few cases, one cannot naïvely apply frequentist statistical intuition to qualitative work.[65] While other qualitative methods such as analytical narratives and comparative historical analysis place their empirical richness directly into the text of their research reports to demonstrate analytic rigor, BayesTV uses deep case knowledge to rigorously highlight the most informative evidence in their research reports. Akin to Charles Proteus Steinmetz, who was hired by Henry Ford to fix a generator and invoiced $10,000 for a single chalk X and two lines of instructions, only a small bit of evidence may appear in the final writeup ('$0.01 of chalk') but the expertise and deep case knowledge lies in knowing which piece to highlight to maximize information value ('$9,999.99 for knowing where to place the X').[66]

Other qualitativists and typologists may object that we have no need to formalize, discipline, or make transparent our typologies; typologies are tools that matter only in so far as they are useful rather than if they are right.[67] Certainly, many excellent typological works have simply presented the logic of their typologies and applied them to understand something about the world without going to far into the details of how they settled on their final typology.[68] While I certainly agree that theories should be judged by primarily their usefulness rather than some hyperfocus on identification, we should nevertheless be transparent in how we generate and refine our typologies in order to assist future scholars in building on our work as well as to focus critics on which specific judgements they disagree with. The discipline and transparency of BayesTV thus allows us to develop typologies in such a way that we can adapt them to new evidence without forcing ourselves or others into wholesale acceptance or rejection.[69]

Building on deductive typological theory and the inductive logic of logical Bayesian process tracing, Bayesian Type Validation (BayesTV) employs a disciplined process of search for informative evidence in order to provide transparently produced degrees of belief in whether a particular case is most plausibly operating under a particular type rather than the rival types. In this project, this translates into degrees of belief about whether regulators are truly operating under one type of regulatory imaginary (e.g. folk economic constrainer) or another (e.g. beneficial constraint, adoption catalyst, etc.). As the goal of this project is to inductively refine the deductive typology developed in Chapter 3, BayesTV is well suited to demonstrating how confident we can be that real empirical examples exist of the variety of ways that regulators, entrepreneur, and innovators co-create disruptive technological innovation.

ELITE INTERVIEWS

While BayesTV allows us to update the analyst's degree of belief that a particular empirical case fits into a particular deductive type, it cannot provide us a direct view into how regulators,

[65] Compare the logic of (Brady and Collier 2010) to that in (Gary King, Keohane, and Verba 1994). A concise review of the struggles of quantitativists to grapple with qualitative evidentiary standards appears in (Fairfield and Charman 2022, 124–26).
[66] (Gilbert King 2011)
[67] I thank Steve Vogel for making this potential objection so poignantly.
[68] (c.f. Esping-Andersen 1990; Hall and Soskice 2001b)
[69] For example, see the critiques of Esping-Andersen in (Estévez-Abe 2008) and his responses in (Esping-Andersen 1997; 1999) which amount to claims such as an increase from three to four models would lead to "[t]he desired explanatory parsimony [being] sacrificed, and we might as well return to individual comparisons."(Esping-Andersen 1999, 88)

entrepreneurs, and innovators view, form, and use their regulatory imaginaries on the ground. In order to understand how the actors involved view, form, and use regulatory imaginaries in their roles as regulators, entrepreneurs, and innovators, the most straightforward approach is to ask them. While this compounds method upon method, I am able to draw upon data from a related project which does essentially that: asks regulators, entrepreneurs, and innovators how they interact with disruptive innovation.[70] This data is limited to the autonomous vehicles (AVs, Chapter 5) and gene editing (GMO, Chapter 6) cases as those two are occurring contemporaneously with this project while the electronic health records (EHR) case was completed. The interviews in the two available cases nevertheless provide a window into how regulatory imaginaries play out in actually existing innovation regulation.

CASE SELECTION

Cases in this project were selected based on a schema of conceptual derivations which were then filled with specific cases based on their cross-national, cross-sectoral, and non-technological-expert level accessibility. As explained above, the cases were first selected to be within the economic benefits + social benefits quadrant of Table 2. This section then explains how cases were narrowed based on the relative timing of regulation with respect to innovation. Finally, I specify details tertiary criteria (salience, archetype, technological diversity, cross-national impact) and present an overview of each case. This process leads to three core empirical cases: autonomous vehicles (AVs), gene editing (GMO), and electronic health records (EHR).

WHEN DO WE REGULATE DISRUPTIVE TECHNOLOGICAL INNOVATIONS?

In addition to the relationship between social and economic aspects of regulation, a key question regulators face when confronted with a DTI is when to regulate. Regulators, innovators, and entrepreneurs co-create different imaginaries around answers to this question of when to regulate. Fundamentally, there are four possible scenarios for this question:

1. the DTI develops before a mass market with constitutive regulatory regime exists
2. the DTI develops at the same time as the mass market and regulatory regime for it develops
3. the DTI develops after a regulatory regime has defined a mass market for it
4. the technology and market with a regulatory regime are both well established

The fourth option, where a technology exists within a mass market with a well-established regulatory regime is quite literally the case of non-innovation; it's business as usual. The other three scenarios, however, define the three cases which form the empirical core of this project:

- Chapter 5: Autonomous Vehicles (AVs) regulated through a Beneficial Constraints imaginary due to Scenario 3: the DTI develops after a regulatory regime has defined a mass market for it.

[70] These interviews were conducted by the author and a team of researchers led by Ann Keller as part of National Science Foundation's Science of Science and Innovation Policy grant #1735661. The analysis in this section draws upon nineteen interviews with twenty-one interviewees. One interview included three respondents. Human subjects approval for collecting, storing, and analyzing interview data was granted by the Office of Protection of Human Subjects at UC Berkeley. The de-identified data is available at (Posch et al. 2021)

- Chapter 6: Gene-Editing (GMOs) regulated through a Beneficial Constraints imaginary due to Scenario 1: the DTI develops before a mass market with constitutive regulatory regime exists
- Chapter 7: Electronic Health Records (EHR) regulated though an Adoption Catalyst imaginary due to Scenario 2: the DTI develops at the same time as the mass market and regulatory regime for it develops

Together, these three cases map out the full conceptual space of innovation within the benefits-benefits box (A) of socioeconomic regulation as detailed in Table 2. Further details of the cases as well as additional tertiary criteria are discussed in the following section.

THREE DISRUPTIVE TECHNOLOGICAL INNOVATION CASES

In addition to the conceptual criteria discussed in the prior two sections, the characteristic disruptive technological innovation (DTI) cases were chosen for each temporal scenario in order to maximize criteria which increase the relevance of the findings to entrepreneurs and innovators. These criteria were included in the case selection process in order to increase the accessibility and broader impact of the central argument of this project: that regulators can be so much more than merely dead-weight on innovation. These tertiary criteria (and their rationale) are:

- **High Salience, Public Facing Sectors** – The technology should be familiar to typical citizens rather than a narrow elite or industrial community.
- **Archetypal Cases with New Relevance** – to address concerns of unusual cases, exceptional circumstances, or anachronisms.
- **Multiple Types of Basic Technology –** to address concerns of merely an "information technology" or "biotechnology" story.
- **Cross-national Impact –** to isolate the effect of the DTI and response variation from a single national contextual story.

Each case will be studied in the US and European context to explore the cross-context influence of regulatory imaginaries surrounding specific DTIs.

BENEFICIAL CONSTRAINTS BEFORE INNOVATION: AUTONOMOUS VEHICLES (AVS)

Autonomous Vehicles (CAVs) are the application of cutting-edge machine learning and computer vision to vehicles on public roads. As such, they bring together two regulatory regimes (highway safety & information technology), two industrial histories (automotive & software), and two communities (the transportation & tech sectors). These collisions bring to light two very different imaginaries of the proper relationship between regulation and innovation: a transportation sector used to working with powerful regulators in order to gain public acceptance of new technologies through certification and a tech sector used to disrupting regulators in order to win public buy in through whizbang new features. This paper demonstrates that by uniting transportation and tech within a new market segment, AVs force a reckoning between these different imaginaries leading entrepreneurs, innovators, and regulators to craft a new one based on beneficial constraints. In both the US and EU, these new imaginaries unite the need for guardrails against known risks in order to win public acceptance (constraints) with large space for innovative elaboration towards known and unknown potential benefits (beneficial). As an unsettled new sector, a variety of conceptions of the proper road forward; the proper imaginary;

are contending for supporters and institutionalization. All US and EU beneficial constraints imaginaries claim to enhance safety, but they differ on whether AVs increase or decrease safety. To characterize and classify these new imaginaries, this paper draws upon Bayesian Type Validation (BayesTV) of archival evidence as well as elite interviews with stakeholders in the AV sector.

Beneficial Constraints before Marketization: Genetically Modified Organisms (GMOs)

Following the 1973 development of recombinant DNA, American and European regulators sought to place guardrails against its dangers and direct innovators towards its benefits through beneficially constraining regulation. The US Asilomar Conference (1975) gathered scientists and policymakers to define what became the Coordinated Framework: GMOs would be considered 'substantially equivalent' to non-GMOs unless 'fundamentally altered (Berg 2008).' Europe tacked in the opposite direction: based on a 'precautionary principle,' GMOs would be considered intrinsically different from non-GMOs and subjected to heightened scrutiny (D. Vogel 2012, 74–81).

Through interview data and my novel method of Bayesian Type Validation (BayesTV), this paper explores how diametrically opposite regulatory goals arose from the same method: both represent constraints on GMOs which their societies considered beneficial. An impromptu US process gathered a technoscientific subset of stakeholders leading to a technoscientifically defined beneficial outcome. A structured EU process brought together diverse social stakeholders leading to a societally defined beneficial outcome.

Each regime successfully constrained its society into different intended forms. From the technoscientific constraints of the US Coordinated Framework, the R&D of GMO technologies flourished leading to the development of a massive gene editing industry. From Europe's social constraints within the Precautionary Principle, the R&D of GMOs stalled while "natural" or "biologique" industries were able to flourish. The constraints were not just both beneficial based on differing definitions of the public good but were also both beneficial to the economies of the US and EU.

While early recombinant DNA technology lead to biomedical products such as human insulin from E. coli (1978), genetic characterization of complex disorders such as thalassemia (1984), and targeted genetic testing for human disease such as Huntington's disease (1993), CRISPR pushes the boundaries of what is possible further into the precise correction of a disease producing gene in an individual. This future is now, CRISPR has successfully cured its first genetic disease (sickle cell anemia, 2020). CRISPR now makes possible the benefits and dangers which were only specters during the recombinant DNA era of gene editing when regulations were designed.

While CRISPR increases the tensions in the regulatory process between social scientific and technoscientific understandings, the US and EU navigated these different interpretations using the same method toward very different goals, Both the US and EU adopted a set of constraints which they could define as beneficial for their societies leading to the development of billion dollar industries. While the definition of beneficial was very different, this regulatory method of beneficial constraints highlights how some constraints can be beneficial to innovation and thus guards against the folk perception that all constraints are counterproductive by definition (Streeck 1997, 213). Separating regulatory method from regulatory goal allows policymakers,

regulators, entrepreneurs, and innovators to craft regimes that better meet the needs of all stakeholders rather than being trapped by false tradeoffs between safety and innovation or justice and growth.

DRIVER OF ADOPTION BEFORE INNOVATION OR MARKETIZATION: ELECTRONIC HEALTH RECORDS (EHRS)

Tech entrepreneur rhetoric paints regulation as a specter of the past fettering the future. Yet the state had to drive the market to adopt electronic health records (EHR), a technology that lowers cost, improves care, and improves health policy research. From archival research, EHR appears to show how regulators can not only cut their dead-weight loss, not only beneficially constrain the market, but also drive adoption of innovations the market fails to promulgate.

Interviews in this case will isolate the mechanism of regulation-driven innovation adoption using US & EU evidence. The 2009 US HITECH Act pushed medical practices to adopt EHR with first a subsidy carrot and then a reimbursement withholding stick. Directive 2011/24EU added healthcare to the Common Market requiring EU member-states to adopt interoperable EHR.

From archival analysis, most medical practices espoused EHR preferences counter to their supposed economic interests.[71] Early EHR adopters recognized their interest in lower costs and improved care. Yet most practices strongly opposed EHR despite this interest due to *perceptions* that practices would bear transition costs while outsiders (administrators, insurers, analysts) would get the benefits.[72]

Perceptions create preferences long before outcomes breed interests. Innovators distrust regulation not because they've *had* bad experiences but because they *think* they will. EHR overcame poor perception to create good outcomes beyond the imagination of the market in the US & EU showing how innovators can work with regulators rather than against them. Interviews with key stakeholders at Health and Human Services (HHS), medical practices, and the key EHR software development firm Epic as well as their European counterparts will explicate exactly how this process worked. While EHR adoption is not perfect or a panacea to the healthcare system, it nevertheless represents an economically beneficial disruptive innovation which market actors initially failed to adopt but were driven to do so by state action.

CONCLUSION

So we didn't get our jetpacks.[73]

Is life today pretty great or pretty terrible? How about tomorrow? Should we have any hope?

In some of my favorite words from my favorite economist: "it depends."[74]

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[71] (Blumenthal 2010; Blumenthal and Tavenner 2010; Blumenthal 2011a; 2011b)

[72] While practitioners perceived that they were unable to exclude others from benefits, EHR is not truly non-excludable as we have seen with the persistent use of fax machines to prevent sharing of information between EHR systems.(Kliff 2017) EHR was also clearly non-zero marginal cost as the costs of adoption were a key sticking point. Thus EHR is an excellent example of an adoption catalyst case which is *not* a public good.

[73] Jetpacks do exist, "we" didn't get them. See footnote 5.

[74] This is the core proposition of Dani Rodrik's allegory of the fox and the hedgehog as applied to economics: hedgehogs know one thing and shout it loud at every problem ('free market!') while foxes know many often contradictory things and thus always reply "it depends." (Rodrik 2015a, 175)

As I have set up above and will argue for the next seven chapters, it depends on the choices we make about how to imagine and institutionalize the 'proper' relationship between regulators, entrepreneurs, and innovators. Should we remain stuck in the Folk Economic Model around disruptive innovation, we lock ourselves into a self-defeating process of antagonism between regulators and entrepreneurs with innovators and innovation left to wither on the sidelines. If we can instead recognize, craft, and coproduce Beneficial Constraints, we have a real chance of encouraging entrepreneurs to innovate toward socially *and economically* beneficial creations by closing off known dangerous or undesirable short-term cul-de-sacs. If we also recognize, craft, and coproduce Adoption Catalysts, we need no longer lie enthralled to the hope that the market will not fail to spread innovations which have peculiar short term incentives against their adoption but well established medium and long term social *and economic* benefits. What we determine and enforce as 'proper' is a choice; we must choose wisely.

I argue regulators have been, are now, and can again be so much more than merely a deadweight loss to innovation if only innovators and entrepreneurs can be guided past self-limiting imaginaries such as the folk economic model of disruptive innovation. To develop this argument, I first introduced the concepts of disruptive innovation, the modern face of innovation, and the folk economic model regulatory imaginary which sustains it.[75] Next, I discussed three core actor roles which are central to this project: regulators, entrepreneurs, and innovators. I then specified my argument by presenting the full typological property space[76] of regulatory imaginaries and discussing how we can use it to understand the variety of relationships between regulators, entrepreneurs, and innovators which can lead to better or worse effects on innovation. I then briefly explained my methodological approach which combines the novel method of Bayesian Type Validation (BayesTV)[77] with elite interviews. Finally, I discussed how I selected autonomous vehicles (AVs), gene editing (GE), and electronic health records (EHR) as the empirical cases to inductively refine the typology.

Disruptive Innovation leads to a folk model, or common everyday understanding, of regulation as a fundamental impediment to innovation. Disruptive innovation is the contemporary face of innovation which judges innovation by its ability to upset or 'disrupt' existing markets, societies, and ways of life (hopefully for the better). As a face of innovation defined by disruption, disruptive innovation thus holds the rules which establish the status quo (regulation) in the lowest possible regard.

However, this Folk Economic Model imaginary is but one of seven possible regulatory imaginaries of the proper relationship between regulators, entrepreneurs, and innovators. *Regulatory imaginaries*, based on the concept of sociotechnical imaginaries,[78] are collectively held, publicly performed conceptions of desirable relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. Where the Folk Economic Model imaginary sees regulation as only an

[75] A genealogy of disruptive innovation and regulatory imaginaries is presented in Chapter 2. The concepts are briefly defined in this chapter only so far as is necessary to understand my argument.
[76] The derivation of this typology is explained in Chapter 3. In this introductory chapter, I present only the implications this theory has for our understanding of regulation and disruptive technological innovation.
[77] The specification of the novel method of Bayesian type validation (BayesTV) in both theory and practice is presented in Chapter 4.
[78] (Jasanoff 2015a, 4)

impediment to be minimized, the other six imaginaries in Table 1 see other potential effects such as moderation, constraint, and catalyst.

Regulatory imaginaries do not exist in a vacuum; they are coproduced by actors filling three core roles: regulator, entrepreneur, and innovator. Regulator is the role defined by their goal of promoting the public interest.[79] Entrepreneurs are defined by their managerial goals to mediate between the rigid requirements of a technological innovation and the uncertain reality of the social world. Innovators are defined by their technological goals to leverage science and technology into novel devices, processes, and/or applications. Each role must function with the others in order for innovation to happen; how those functions interact is defined by the regulatory imaginary and in turn defines the regulatory imaginary, hence coproduction.

The core contribution of this project is the set of seven deductively derived and inductively validated regulatory imaginaries of disruptive innovation laid out in Table 1. As the name suggests, these regulatory imaginaries are defined from the perspective of the regulator role, but in doing so they specify how entrepreneurs and innovators can and should operate. The *relationship* constitutive variable specifies whether regulators should remain separate from entrepreneurs and innovators or serve as a stakeholder themselves. The *information* variable specifies whether regulators have higher or lower access to information than entrepreneurs and innovators. The *driver* variable specifies whether entrepreneurs or regulators are driving the adoption of a particular innovation across the relevant sector. The *outcomes* variable specifies whether regulators intend to allow zero, one, or many potential outcomes to arise from the interplay of entrepreneurs and innovators. These seven regulatory imaginaries thus specify seven possible worlds for regulators, entrepreneurs, and innovators to coproduce disruptive innovation.

Why might we need a naming of regulatory imaginaries beyond simply the cataloging of diversity? Well, I like clever turns of phrase that invoke imagery: "the golden age lies not behind but ahead of mankind;"[80] the arc of the moral universe is long but it bends toward justice.[81] Some have suggested that such turns of phrase are the purview of speech writers, advertisers, and activists but we need good vocabulary in scholarship too. This project is an attempt to meet that need for perhaps the most overhyped but under-diversified conversation happening now: the relationship between regulation and disruptive innovation.

If you were an entrepreneur in Silicon Valley, you might think we don't need a book on the relationship between regulation, innovation, and entrepreneurship. The answer appears simple: as a rule, regulation is bad.[82] However, without regulation in at least two critical moments, entrepreneurship would not be a coequal pillar with innovation in the Silicon Valley ethos. The first of those moments was the 1956 Consent Decree which forced Bell Labs to license all of its patents (notably including the transistor, the solar cell, and the laser) royalty free rather than

[79] While a fraught and contestable concept, the public interest is nevertheless an important part of what government is meant to govern towards. See the discussion at length in the section "Regulators, Entrepreneurs, and Innovators" on page 7.

[80] (Gerschenkron [1951] 2008, 224)

[81] The quote comes from Dr. Martin Luther King in a speech given at the national Cathedral on March 31, 1968. It became a favorite of President Barack Obama due to the perceptions of hope through adversity, and while it may be a more pessimistic statement in its original formulation by abolitionist minister Theodore Parker in 1853, it has nevertheless been a framing image for two iconic and influential leaders. (see M. D. Smith 2018)

[82] For those of a certain generation, read that in Southpark's Mr. Mackey voice, m'kay.

develop them inhouse.[83] The second moment was the landmark decision in United States v. Microsoft which curtailed monopolistic behavior by Microsoft in leveraging one area of software dominance (operating systems) to dominate another one (web browsers).[84] Roughly speaking, these two governance decisions prevented hardware and software monopolies from stifling entrepreneurship and created the space for an entrepreneurial ecosystem.

In light of these critical market-crafting regulations, it's rather surprising that regulation gets such a bad name in entrepreneurship. If nothing else from this project sticks, I would hope that at least we can all remember that regulation can be so much more than a dead weight loss on the economy, that it can be *more than mere deadweight*.

CHAPTER OVERVIEW

In this first introductory chapter, I have introduced the concepts of regulatory imaginaries, disruptive innovation, and the folk economic model. I have covered the argument in brief: that regulators can be so much more than merely deadweight as shown through a variety of regulatory imaginaries. I have also introduced my Bayesian Type Validation methods along with my three empirical cases: autonomous vehicles, gene editing, and electronic health records.

In chapter 2, I develop a genealogy of disruptive innovation and regulatory imaginaries in order to explain how disruptive technological innovation cast regulation as a villain and how we can undo this. I review key concepts about ideas, faith, and imagination from the science and technology studies (STS) and political economy literature in order to help develop the concept of regulatory imaginaries beyond how it was introduced in this chapter.

In chapter 3, I build upon the conceptual work from chapter 2 to define a deductive typology of regulatory imaginaries. This typology maps the variety of regulatory imaginaries that shape how regulators, innovators, and entrepreneurs coproduce disruptive technological innovation which serves as the key contribution of this project. In the chapters 4, 5, and 6, I use different empirical cases for the United States and European Union in order to inductively validated this deductive typology.

In chapter 4, I fully specify and develop my novel method of Bayesian Type Validation. BayesTV allows us to inductively validate deductive typologies with logical Bayesianism in order to discipline our development and clarify our results. BayesTV allows me to develop a typology without resorting to arbitrary parsimony or obtuse classification as well as providing a flexible scaffold upon which future scholars can build and refine my or other typologies.

In chapter 5, we turn to our first empirical validation of the typology from chapter 3 by analyzing beneficially constraining autonomous vehicle (AV) regulation in the United States & Europe from 2016 to present. This case represents a disruptive innovation (AVs) disrupting a well established regulatory regime (vehicle safety regulation). Its key finding is that although technological innovation can upset fundamental assumptions of longstanding regulatory regimes, those regimes can use the Beneficial Constraints imaginary to adapt because it allows them to place guardrails against known dangers while directing innovation and entrepreneurialism toward potential benefits such as increased safety.

[83] (Watzinger et al. 2020)
[84] (Kollar-Kotelly 2002)

In chapter 6, we turn to our second empirical validation of the typology from chapter 3 by analyzing beneficially constraining gene editing (GE) regulation in the United States & Europe from 1975 to present. This case represents a disruptive innovation (GE) which has developed and is prepared to spread before there is an existing regulatory regime. The regulatory regime is thus defined at the same time as the innovation spreads, leading to a key finding that we should distinguish between regulatory method and regulatory goal. Both the US and EU choose a Beneficial Constraints imaginary to craft their regime around GE technologies, but they differ greatly in their definitions of beneficial. While the literature focuses on these different goals (the US chooses to encourage biotechnology, the EU chooses to curtail biotechnology), I highlight how both chose the method of Beneficial Constraints in order to avoid the greatest dangers that scientists and regulators foresaw while allowing each jurisdiction to develop along very different but nevertheless beneficial paths.

In chapter 7, we turn to our third and final empirical validation of the typology from chapter 3 by analyzing adoption catalyzing regulation of electronic health records (EHR) in the United States and Europe from 2009 to 2021. The key finding in this chapter is the demonstration that a regulator can intentionally drive innovation beyond the imagination of the market using a system of incentives and sanctions. Beyond simply the beneficial constraints of the previous two chapters, this analysis of EHR demonstrates just how far beyond the Folk Economic Model we can travel to once and for all demonstrate how regulators can be so much more than merely deadweight.

Finally, in chapter 8, I conclude by returning to my core argument: regulation can go beyond the zero from minimizing costs to maximizing benefits and produce economically beneficial regulation for innovation. In this chapter, I highlight three key features of regulatory imaginaries: plurality, diversity, and malleability. Regulatory imaginaries are plural in that there are multiple types present in actually existing regulation. They are diverse in that they have meaningful differences between the different types of imaginaries. And they are malleable in that different policies can be built upon different imaginaries and thus co-produce those imaginaries.

Given the novel method I employ and breadth of my typology, I include substantial appendices to allow interested readers to delve more deeply into the method and the empirical analysis. In appendix A, I explain the specific Bayesian type validation evidence selection and analysis criteria for this project. In appendix B, I provide a supplement to chapter 5 comprising the explicit Bayesian Type Validation (BayesTV) of how confident can we be that Perpetual Guidance in the US and Regulation (EU) 2022/1426 represent a Beneficial Constraints imaginary for autonomous vehicles regulation. In appendix C, I provide a supplement to chapter 6 comprising the explicit BayesTV of how confident can we be that the Coordinated Framework (US) and Precautionary Principle (EU) represent a beneficial constraints imaginary for gene editing regulation. Finally, in appendix D, I provide a supplement to chapter 7 comprising the explicit BayesTV of how confident we can be that HITECH (US) and Directive 2011/24/EU represent an adoption catalyst imaginary for electronic health records regulation.

CHAPTER 2

A GENEALOGY OF DISRUPTIVE INNOVATION AND REGULATORY IMAGINARIES

How Disruptive Technological Innovation Cast Regulation as a Villain

As of this writing, disruptive innovation is the face of innovation. Look no further than the name of Silicon Valley's original trade fair: TechCruch Disrupt. While Facebook may have coined Silicon Valley's motto of "Move Fast and Break Things," [85] Uber became the poster child for living this motto as a company so much so that the phrase "Uber for X" became a boilerplate part of startup pitches.[86] To claim to be the "Uber for X" was to claim to be *the* company that would show the latest and greatest success of private entrepreneurship at changing the world.

But, interestingly, Uber's claim of private entrepreneurship and innovation requires a very narrow view of what it means "private." At its core, Uber is a combinatorial innovation[87] rather than a novel technology because it combines preexisting technologies, services, and even assets in new and useful ways rather than building something fundamentally new from basic science. It is certainly an innovation, but one built on other innovations. While Uber may have been conspicuously private and venture-capital funded, these underlying technologies such as GPS, smartphones, roads, maps, and the internet certainly were deeply entwined with public innovation.

So how can Uber and similar disruptive innovators claim to be the triumph of private industry despite depending upon a rash of publicly funded and freely available fundamental technologies? In short, by standing upon a legacy of entrepreneurs before them who submerged the state beneath private industry after World War 2.[88] To understand disruptive innovation, then, requires a brief knowledge of this legacy of postwar innovation.

In this chapter, I connect several different strands of political economy history and theory in order to show how disruptive innovation came to cast regulation as a villain, rather than an ally, to innovation. First, I provide an extremely brief history of innovation after World War 2, showing how the modern concept of "disruptive innovation" arose from an earlier submerging of the public role of innovation beneath the market. Then, I define the core concepts of disruptive technological innovation with regard to the related concept of emerging technologies and disruptive innovation. Next, I build the concept of regulatory imaginaries drawing on the general concept of sociotechnical imaginaries from the science and technology studies (STS) literature as well as related discourse on ideas and faith in political economy literatures. Then, I discuss the importance of perception in understanding policy and governance. I conclude the discussion of

[85] This internal motto at Facebook was referred to by Mark Zuckerberg in his 2012 letter to potential investors ahead of the 2012 IPO of Facebook stock, reprinted in full by (WIRED Staff 2012)
[86] (Webb 2016)
[87] (Brynjolfsson and McAfee 2014)
[88] See (Weiss 2014; Mazzucato 2015) on the submersion of the state with regard to innovation. See (Mettler 2011) on processes of policy submersion in the United States more broadly.

core concepts by discussing how social construction links imaginaries and perception to policy outcomes. I conclude by returning to my central argument in light of this historical and theoretical background: regulators can become the allies of innovators if only entrepreneurs (and innovators and even regulators themselves) can be guided past rigid perceptions of the intrinsic costs of all regulation toward to potential benefits of some regulation.

AN EXTREMELY BRIEF HISTORY OF POSTWAR INNOVATION[89]

Somewhat by accident, the United States emerged from the second world war as the richest and most powerful country in the history of the world.[90] Unlike prior claimants to world domination, however, the United States found themselves in this position not through annexing territory or creating colonial subjects.[91] Instead, the United States, benefiting from not having fought any battles on their own territory, was able to build a winning power base by mobilizing not just people but science, technology, and industry in support of their cause.[92]

The most famous example of scientific and technological achievement in WW2 may be the atomic bomb, but more significantly for the post war period is the massive industrial enterprise which built the planes, ships, and automobiles that swept through the European and Pacific theaters. While atomic bombs certainly changed the calculus of conventional warfare to deterrence rather than total victory,[93] it was the mobilization of ingenuity, people, and expertise to design, construct, and mass produce increasingly advanced and capable machines which more directly contributed to the US's position after the peace was won. Atomic bombs may have

[89] There is a great deal that must be omitted to tell this extremely brief history, not the least of which are the important and careful distinctions between the state regulating technology and innovation and engaging in technology and innovation themselves (e.g. through the National Security State, (Weiss 2014) and the change over time from the state primarily doing their own innovation to contracting out, (c.f. La Porte 1994). Certainly this section does not mean to suggest that all innovation policy is regulation. However, it does attempt to show regulation came to be seen as the enemy of innovation.

[90] The somewhat accidental nature of American post-war dominance was first communicated to me by T.J. Pempel (personal correspondence). However, the question of accident vs. intention in the puzzle of US international power is well explored in *By More Than Providence* (Green 2017). As the title suggests, luck or accident may not have been the *only* element of US postwar dominance, but it was also not an irrelevant factor either. Such observations are, of course, as old as Thucydides' observations about Athens being favored by the gods despite Thucydides' atheism in his history of the Peloponnesian War (Thucydides and Hanson 1998).

[91] A counter to the so-called Thucydides trap whereby a rising power must defeat the current global power in order to take over world domination. In this case, the rising power (US) and the waning power (UK) were allies rather than opponents.(Allison 2017) Note as well that although the United States chose not to pursue conventional colonialism after it dabbled with it in the Philippines following the Spanish American War 1898, that is not to say that the US did not build a domestic system based on racial exploitation and subjugation or to challenge the claims that all capitalism is based in racial exploitation (c.f. D. Jenkins and Leroy 2021). The point here is merely that the US international system after World War 2 was built on economic competition rather than colonial extraction and territorial expansion.

[92] This refers to the Office of Scientific Research and Development (OSRD), founded in 1942 and headed by Vannevar Bush. Near the end of World War 2, President Roosevelt asked Bush to consider whether the scientific and industrial capacity which had won the war could be applied to winning the peace. Bush's response to this letter was a 220 page report called *Science – The Endless Frontier* which became the founding document for the National Science Foundation. (Bush [1945] 2020, iii-iv,xiii-xvi)

[93] Interestingly, some nations choose to forgo nuclear weapons when their possession would create more problems than it solves for them. However, the conventional wisdom that possession of nuclear weapons has a strong deterrence effect is as conventional now as it was in the 1950s during the first round of proliferation. (c.f. Paul 2000, esp. 3-13)

finally brought Emperor Hirohito to the peace table over the objections of his military administration, but it was the scientific laboratories, engineering teams, and assembly lines which had been built or pressed into service throughout the United States which built the post war world.

Vital though these people and machines were, more important were the ideas and vision which united them together in wartime and then peacetime. When victory was declared in Europe in May 1945 and Japan in August 1945, the United States occupied substantial amounts of territory in both Europe and Asia. Had this been the end of the prior world war, the culmination of the age of imperialism, these territorial acquisitions might have been divided up among the victorious nations and the war debt of the victors might have been funded through reparations from the vanquished much as they had been in the Treaty of Versailles in 1919. Whether through enlightenment or enlightened self-interest, the victorious Allies of WW2 decided to rebuild the vanquished nations in the political and economic image of the victors rather than punish them for their defeat.

With the two very different systems of allies (democratic capitalism and Soviet communism), this led to a divided Europe of Soviet-style states in the east and democratic capitalism in the west. The East Asian story took a further revolution to create a similar divide but with the victory of Mao's Communist Party of China in the Chinese Civil War in 1949, East Asian countries as well divided into communist and capitalist systems. In light of the turn of China to communism, the American forces which occupied Japan reversed course from the non-Fascist Japanese leftist politicians who had been part of the initial rebuilding of Japan towards a reintegration of former Imperial Japanese politicians into the new regime.[94]

Thus, by 1950, both the capitalist and communist Allies had rejected the older models of imperial domination of the vanquished in a war in favor of a new approach of rebuilding the systems in the image of the victors. While (democratic) capitalism and (authoritarian) communism differed greatly on many vital dimensions, both agreed on the importance of industrialization and technological development which had been critical to winning WW2.[95] The next 40 years would see Cold War competition between the differences of (democratic) capitalism and communism with democratic capitalism ultimately winning out.

Despite the intense Cold War competition over their differences, it is the similarity between communism and capitalism which is more important: both systems sought to marshal scientific discovery into technological advancement and then industrial production to develop better lives for their citizens. While the success and failures of the communist approaches are interesting and instructive views of industrial organization, we will continue by diving deeper into the history of only the capitalist models as those are the ones which ultimately won out.[96] As we'll see, this book is about variation rather than uniformity, thus it is important to note that there was not *a* capitalist model but a variety of capitalist models.

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[94] (Pyle 2007, 222–23)

[95] Although analyzing earlier rounds of industrialization, this realization about the critical connection between power, prosperity, and industrial & economic development was clearly part of the conversation of the immediate post-war era as shown by work such as (Gerschenkron [1951] 2008) and (Rostow [1960] 2008).

[96] This is not to say that contemporary political economy systems have nothing to learn from a study of specific models and organizations of Soviet and Chinese communism but simply that the themes of this book build on the relationship which stem from the capitalist models which form the varied foundations of the early 21st century political economies of the developed world.

The post-war capitalist models spread to the vanquished Japan and countries in Europe through rebuilding programs. The Japanese were occupied and had western-style democratic capitalism forced upon them, though they would make it their own and become the second largest economy in the world by 1972. The vanquished axis countries in Europe, Germany and Italy, both benefitted from the Marshall Plan which allowed Western Germany to become the second largest economy in the world in the 1960s. Both major defeated powers, Japan and Germany, were not just rebuilt in the image of their victors but learned and adapted the lessons well enough to emerge as the most prosperous countries (after the United States) in the postwar period.

At the end of World War 2 in the Pacific Theatre and 10 years of United States military occupation, Japan emerged as an independent country with a democratic capitalist system known as the 1955 system. While the post-war US occupation wrote the formal tenants of democratic capitalism into the Japanese constitution, it was the Japanese who built on these formal tenants and crafted a functioning political economy system. While the Japanese were required to be a capitalist democracy, they created the "1955 system" which checked both boxes while also creating something new which came to be called the "developmental state" after their model was successful and adapted by South Korea and Taiwan. In the developmental state, Japan wedded a single-party-yet-competitive democratic government to a set of political interest group compromises that ensured long term political stability.[97] This in turn allowed the state to deploy a careful system of "plan rational" economic planning which used a close relationship between government ministers, banks, and export industries to rapidly rebuild and develop internationally competitive companies.[98] It was a democratic capitalist country, it hooked into and depended on the US-led international system for growth, but it was also something new.

At the end of World War 2 in the European Theater and 4 years of Allied military occupation, Germany emerged as two countries each dedicated to rebuilding after WW2. While the industrial history of the German Democratic Republic (DDR, "East Germany") is fascinating in its own right, it is the Wirtshaftswunder in the Federal Republic of Germany ("West Germany")[99] that led West Germany to become the second largest economy in the world in the mid-1960s. The Wirtschaftswunder rebuilt Germany as a capitalist democracy focused on long term growth rather than war fighting prowess as the Nazi Reich and German Empire before WW2 and WW1 had.[100]

During WW2, the United States successfully mobilized both science and industry in addition to the military in order to win the war and recognized the need to carry this success into peacetime. In 1941, the resultant organizing effort became the Office of Scientific Research and Development (OSRD) headed by Dr. Vannevar Bush. With the success of the invasion of Normandy in Europe and the inexorable progress of island hopping in the Pacific, President Franklin Delano Roosevelt wrote to Dr. Bush on November 17, 1944 asking him to outline how

[97] (Johnson 1982, 154,315-317)
[98] (Johnson 1982, entire, esp. 18–34)
[99] In German, East Germany was known as the Deutsche Democraticshe Republik (DDR) and West Germany was known as Bundesrepublik Deutschland. I have retained the German abbreviation for East Germany while using "West Germany" instead of an abbreviation for the Bundesrepublic Deutscheland as this reflects what the countries referred to themselves as. Interestingly, while DDR was the official abbreviation for East Germany, BRD was an unofficial abbreviation used by East Germans to refer to west Germany pejoratively and the Bundesrepublik Deutscheland actively worked to prevent the use of the abbreviation.
[100] (c.f. Tolliday 1995; Sally 1996; Young 2014)

the wartime expertise research and development should be translated into a peacetime program.[101] This report, *Science – the endless frontier*, was submitted in July 1945 to Roosevelt's successor President Harry S. Truman and became the basis for the National Science Foundation.

The National Science Foundation (NSF) formed the basis of a new approach to innovation by using public expertise and money to catalyze a relationship between science and industry. Distinct from all prior approaches to translating scientific discovery into industrial output, the National Science Foundation dedicated substantial funds to the extremely expensive and low profit task of "basic science" while allowing the resulting discoveries and patents to remain the property of the innovators. Where pre-WW2 research, scattered between universities and industry, was primarily funded by the whims of private donors or the promise of immediate profits, the NSF brought the budget of the world's largest economy to bear on scientific discovery without the requirement for immediate applications. The NSF became a "Patron for Pure Science"[102] and allowed its client scientists to flourish and build new industries.

At the 1964-65 New York World's Fair, these innovative scientists and engineers, trained by universities funded by NSF grants and now working with private entrepreneurs, promised us the future; and jetpacks.[103] While we didn't get those jetpacks,[104] many of the imaginative things that American companies presented at the 1964-65 World's Fair did become the basis for now ubiquitous technologies.

More importantly, it was *companies* and not *agencies* that did the presenting of tomorrow at the World's Fair. The literal "City of the Future" miniature constructed for the fair was brought to us not by the innovation, money, or might of the US government (although they certainly all made this possible) but instead by the General Motors Corporation.[105] The aforementioned jet pack may have been flown by a former Air Force pilot but it was brought to you by Bell Aerosystems Corporation.[106] And it was Walt Disney himself who designed, and General Electric who constructed, the "Carousel of Progress" which catalogued the march of American industrial development from the 1890s to the 1960s.[107] By 1964, innovation and "tomorrow" had thus become the province of companies as much or more so than the state, at least in the public imagination.

This glowing image of progress, subsidized by the government but owned and driven by industry, was neither absolute nor perfect. The 1960s are known as the "Space Age" not because

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[101] Roosevelt's letter, Dr. Bush's response, and a 70 year retrospective from the NSF in 2020 on the significance of the letter and the report can be found in the foreword to the republished *Science – the endless frontier* (Bush [1945] 2020, iii-iv,xiii-xvi)

[102] The phrase "A Patron for Pure Science" is the title of the official history of the National Science Foundation by J. Merton England (1982).

[103] Robert F. Courter Jr. from the Bell Aerosystems Corporation flew a jet pack three times a day during the fair and promised onlookers that "in ten years, maybe less, some of you will be up here flying with me." (Abel 2014)

[104] Ok, jet packs actually do exist and have since the 1960s. But they are not the ones we were promised in safety, ubiquity, or capability by Buck Rogers, Boba Fett, or even *The Rocketeer.* As one retrospective put it, "the better question is not "*Who* promised us jetpacks?"—it's "Who promised *us* jetpacks?" (Bosch 2022)," suggesting that while we actually have had jet powered backpacks that can lift a person since the 1960s we were lulled into thinking that ordinary people were ever going to get them.

[105] (Abel 2014)

[106] (Abel 2014)

[107] (Sullivan 2014)

of industry-driven innovation but because of *government* driven innovation to land a man on the moon (and return him safely to the Earth) before the decade was out.[108] And even the more aspirational image of the NASA moon program is tarnished by the fact that this public face of innovation ignored, suppressed, or excludes the contributions of women and people of color.[109] These prominent state-led projects and well-documented discrimination should temper the lionized narrative of private sector innovation driving progress.

Yet despite the imperfections and shadow of the state lurking behind the narrative private innovation led progress, this narrative nevertheless captured the imagination for generations to follow. Whether the famous claims of Ronald Reagan and Thatcher about the triumph of private enterprise,[110] the battle of Microsoft against US anti-trust law,[111] or the full circle claims by SpaceX to be the triumph of private industry in space,[112] the narrative of private industry led innovation has been the dominant narrative of innovation since the 1960s.

By the 1990s, this narrative had evolved into one of *disruptive innovation* which stressed the antagonistic elements of innovation rather than the cooperative elements suggested by progress. As coined by Christensen (1997), disruptive innovations are innovations which disrupt the dominance of existing firms and markets by being "cheaper, simpler, smaller, and, frequently, more convenient to use." While seemingly a subtle evolution from the previous narrative of progress, the evolution to disruptive innovation emphasizes the antagonism between existing firms and new entrants; between existing markets and newly forming ones.

In the 2000s, this narrative of disruptive innovation found its poster boy: Mark Zuckerberg, and its banner slogan: "Move Fast and Break Things."[113] This implementation of disruptive innovation ("disruption") as a way of life took the dilemma that Christensen identified and turned it into a mantra. Innovation was now only innovation if it was breaking someone as well as building something.

While Zuckerberg's Facebook may have been the vanguard of the "disruptor" era, the paradigmatic company was Travis Kalanick's Uber. Where Facebook's slogan was just the tip of a hacker ethos grounded in social change,[114] Uber set out to disrupt for the sake of disruption with no larger goal than enrichment and market dominance. If Facebook set out to move fast and break things in order to not be limited by possible negative consequences, Uber set out to break things as fast as possible with the hope of gathering the shards before anyone else could.

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[108] (Kennedy 1962).

[109] For a contemporaneous take, see "Whitey on the Moon"(Scott-Heron 1970 side 2, track 2); for a modern retrospective, see the movie *Hidden Figures* (Melfi 2017)

[110] (S. K. Vogel 2022)

[111] (Kollar-Kotelly 2002)

[112] In its early press releases, SpaceX like to headline the triumph of private industry while reverting to the term public-private partnership deeper in the document.(Space Exploration Technologies (SpaceX) 2010) The email blasts of the time exaggerated this narrative further by trumpeting the triumph of private industry with no mention of public-private partnerships (personal correspondence of author).

[113] This internal motto at Facebook was referred to by Mark Zuckerberg in his 2012 letter to potential investors ahead of the 2012 IPO of Facebook stock, reprinted in full by (WIRED Staff 2012)

[114] The title of Facebook's 2012 letter was "The Hacker Way" and included "build social value" as one of its five core values (WIRED Staff 2012)

The story of Uber has become a case study of Silicon Valley hubris, success, and toxicity.[115] What started as "everyone's private driver" quickly expanded to decimating the taxi industry. While many would claim that taxis had it coming after decades of stagnation, Uber's disruption did not just blaze a new trail for the car hiring market but actively sought to undermine hard won public safety and employment regulations which had governed the taxi industry.

For students of Christensen's disruptive innovation theory, it may not seem surprising that with innovation comes intentional disruption of regulation. In Christensen's (1997) original formulation of disruptive innovation, regulation is only brought up to be toppled: "regulations are toppled only when disruptive innovators find applications or markets beyond the reach of regulators."[116] Regulation, mired in the past, is constructed as the natural antithesis of innovation, particularly of disruptive innovation.

So Uber's innovators and entrepreneurs overcame regulators in order to change the world; to disrupt the taxi industry and build a better market for car hiring based on independent contractors driving their own cars with their own insurance.

This story seems obvious and inevitable, but it's actually weird that we should think so on a technological level. Uber's technological innovation is based on logistics algorithms which weigh a number of real time data points against a set of rules in order to match drivers to passengers. It would be technologically quite simple to solve the logistical problem of employment benefits compliance for gig workers on a technological level. It could be just another branch of the algorithm that grants partial or pooled benefits. Big tech companies like Uber are good at algorithms; if they can price rides in real time, why can't they calculate benefits in real time?

Along with other platform-based technology companies like Amazon, Uber is perhaps one of the best prepared companies to comply with complex employment and safety regulations, but it does not desire to comply. At the core of platform technology companies are systems of algorithms that calculate solutions to multivariate problems in order to generate real time pricing and logistical information. These same technologies could be (but are not voluntarily) applied to regulatory compliance. In fact, Amazon famously used its political influence to delay sales tax compliance despite acknowledging that it had the technology to automate that compliance.[117] Non-compliance despite technological feasibility is therefore a choice.

So what if we told the Uber story differently? What if the entrepreneurs and innovators behind Uber treated regulators not as an impediment to be toppled but as an ally to be wooed?

In this alternative history, Uber leverages its matching and pricing algorithms to automate compliance with local transportation and employment regulations when it expands to new cities. Rather than develop a playbook based on using public pressure to break regulators, it instead develops a playbook for streamlining and homogenizing regulatory compliance. Rather than developing a Greyball algorithm to shadowban regulators from using the service based on correlated behavior, Uber could use the massive amount of ride data to identify transit issues and underserved communities. Rather than spend 100s of millions of dollars fighting employment classification for its drivers, Uber could use its dominant market position and enviable

[115] (Lashinsky 2017) provides an excellent narrative of Uber's rise and crises. This paragraph and those that follow about Uber in this section draw upon Lashinsky's exhaustively sourced narrative.
[116] (Christensen, Grossman, and Hwang 2009, xlv)
[117] (Stone 2014, 286–319)

algorithmic prowess to design a system of cross-platform partial and pooled employment benefits. Each of these pairs is based on a real choice Uber made and an alternative that was technologically available to them.

So what's different in these two stories? It's not the technology. It's how people think about the technology. It's what they imagine is both possible and desirable.

What's different is what we will define below as the *regulatory imaginary* at work in each alternative story of disruptive innovation. Regulatory imaginaries, based on the concept of sociotechnical imaginaries,[118] are collectively held, publicly performed conceptions of desirable relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. These regulatory imaginaries, as produced both by firms such as Uber and regulators themselves, frame the way the regulators, entrepreneurs, and innovators conceive of what is possible around disruptive innovation.

While the name of the disruptive innovator came from Christensen (1997), the implementation and evolution through first Facebook and then firms such as Uber crafted the imaginary of the "disruptor" distinct from its scholarly roots. Tied up with the story of the disruptive entrepreneur ("disruptor") is a particular imaginary born of a quick simplification of an introductory economic understanding of how regulation distorts the invisible hand of the market. This imaginary is formed around an everyday understanding of how entrepreneurs, innovators, and regulators fit together; it is thus the very definition of a folk model. Because it is based on an everyday reading of economics, I refer to this model as the folk *economic* model throughout this project. As discussed in the introduction, this *folk economic model* imaginary has dominated and formed our understanding of disruptive innovation.

In the following section, I delve more deeply into the intellectual development of the core concepts briefly narrated in this history of postwar innovation and used throughout this project. Together, this history and those concepts explain how we can understand disruptive technological innovation in the context of innovation, entrepreneurship, and the broader political economy of growth. The concepts also explain how we can understand regulatory imaginaries (such as the folk economic model) in the broader context of political science and political economy.

CORE CONCEPTS

In the previous section, I have provided an extremely brief narrative of the postwar world without stopping to delve more deeply into the scholarship that formed and examined each stage in that history. In this section, I now turn directly to formal definitions of the core concepts in this project: *disruptive technological innovation (DTI)* and *regulatory imaginaries*. I also explain how regulatory imaginaries shape the coproduction of DTI by regulators, entrepreneurs, and innovators through the process of *perception* and *social construction*.

DISRUPTIVE TECHNOLOGICAL INNOVATION

This project focuses on disruptive technological innovations (DTIs), innovations which arise from technological change and disrupt the regulatory regime. Building on Cortez's (2014, 183)

[118] (Jasanoff 2015a, 4). I am also deeply indebted to Meghna Mukherjee for the collaborative co-author relationship through which I greatly deepened my understanding of and engagement with the concept of sociotechnical imaginaries. Our work on this subject can be found in (Mukherjee et al. 2023)

concept of regulatory disruption from administrative law, these DTIs disrupt the regulatory regime and elicit a response because they are clearly within an agency's jurisdiction but cannot be addressed by the current regulatory regime. DTIs can disrupt the *operation* of the regulatory regime by changing what is possible within a regulatory domain, often by altering the speed, scale, or complexity of the regulated activity.[119] DTIs can also disrupt the regulatory *paradigm* by challenging regulators' fundamental understanding of their responsibility toward the regulated domain.[120]

DTIs are a subclass of emerging technologies that have moved beyond a *potential* to an *actual* social impact because they are used "in the wild" to shape society thus eliciting a response from society.[121] While informed by Christensen's (1997) concept of disruptive innovation, disruption in this project is observed from the perspective of the regulator and thus focuses on disruption to the *state* rather than to a *market.* This distinction is important because muddling state and market disruption creates entrepreneurial braggadocio that spreads the folk economic model of regulators as an intrinsic impediment to DTIs because it equates changing the market with changing the world.

In Christensen's (1997) original formulation of disruptive innovation, regulation is brought up to discuss what old regulations need to be removed and new regulations put in place with a standard narrative that "regulations are toppled only when disruptive innovators find applications or markets beyond the reach of regulators."[122] Thus, regulatory response is relegated to a mechanism of "ultimately succumbing" to innovators who successfully end-run the classically entrenched and inefficient regulator. This view of regulators as an incompetent impediment to regulation is a folk theory Christensen derives from Stigler. By introducing the alternative narrative of beneficial constraints from Streeck (1997), we can begin to unpack the seductive 'common sense' of this folk theory.

In economics, careful distinctions between radical, disruptive, etc. types of innovation are precisely drawn with single and inviolable definitions.[123] As with all such absolute reductivism, there is a benefit to parsimony and unequivocality. And yet, these hard distinctions can also serve to distract from the imprecise yet influential use of language in common life among practitioners. Thus, disruptive technology within my term disruptive technological innovation is meant to broadly include what "disruptive entrepreneurs" mean when they say disruptive technology whether that may more formally be thought of as radical innovation or some other subtype. The danger of DTI then meaning everything and thus nothing, or at least being defined

[119] There are surely more mechanisms of disruption. Empirical examples suggest that speed (i.e. high frequency trading, (Lewis 2014; Ford 2017)), complexity (i.e. Deep Water Horizon oil rig disaster, (Mills and Koliba 2015)), and scale (i.e. cross-national production networks) are three ways technological change disrupts the existing structure of regulatory regimes by changing the practicalities of the regulated activity.

[120] Genetically Modified Organisms (GMOs) in food are an excellent example of such a challenge as they raise the question of whether the products from GM plants are substantially different from those of their non-GM brethren.

[121] You can think of this as a permutation of Polanyi's ([1944] 1957, 76) double movement in that this response does not require agency but is the natural result of the changes brought by disruptive innovation. In other words, an emerging technology becomes a DTI when it elicits a social response beyond merely anticipatory governance due to effects experienced by a portion of society in their everyday lives.

[122] (Christensen, Grossman, and Hwang 2009, xlv)

[123] I thank Lauren Fahy for introducing me to this economic semantics discussion at the Seventh Biennial Conference of the ECPR Standing Group on Regulatory Governance, Lausanne, Switzerland, 4 - 6 July 2018.

by marketing rather than reality, is mitigated by a check against regulatory disruption; DTIs in this project must be disruptive enough to spark regulatory challenges.

REGULATORY IMAGINARIES

The primary contribution of this project is a set of deductively defined and inductively verified imaginaries of how regulation, innovation, and entrepreneurship fit together. These regulatory imaginaries are derived in Chapter 3. This concept of a set of imaginaries about how disruptive technological innovation is co-produced by regulators, innovators, and entrepreneurs draws its name from the general concept of sociotechnical imaginaries. However, the influence of ideas, faith, and imagination have appeared in several forms from the very beginning of political economy. This section explores these concepts and how they fit into this project.

SOCIOTECHNICAL IMAGINARIES

Sociotechnical Imaginaries are a relatively recent concept from the interdisciplinary field of Science and Technology Studies (STS) which build on a number of related concepts from both STS itself as well as the various fields which it intersects. These background concepts of co-production, translation, and imaginaries more generally have been applied to the interaction between technological artifacts and sociopolitical arrangements to form sociotechnical imaginaries.

In Sheila Jasanoff's generalized definition, sociotechnical imaginaries (SIs) are:

> *"**collectively** held, **institutionally** stabilized, and **publicly** performed visions of **desirable** futures, animated by shared understandings of forms of social life and social order attainable through, and supportive of, advances in science and technology" (Jasanoff 2015a, 4 emphasis added)*

Within this definition, there are three characteristics of particular interest for policy scholars and practitioners: desirability, collectiveness/publicness, and institutionalization. SIs must be **desirable** in that they are used to define goals and recruit followers to build a particular positive future, although that future can be defined as desirable by contrast to both or either of a less desirable present or an undesirable alternative future. While many individuals might hold a vision of a desirable future, SIs must be **collectively** held and **publicly** performed in order to transform the thoughts of individuals into the animating motivations of groups. Since multiple groups may have disparate competing or compatible imaginaries, SIs must be **institutionalized** in order to move from animating motivations of groups into enforceable and enactable plans for social order and social life by taking on the power and influence of institutions which exist apart from the current people who inhabit those institutions.

From a regulatory and policy perspective, institutionalization is especially important in translating the motivated collective desire of a group of individuals to the public good of the society beyond the originating group. This process of institutionalization hinges on gathering power and influence beyond that of the individual members whether through formal or informal means. In Latourian(1987, 119–21) terms, institutionalization would be the closest social reality could get to the fifth translation ("becoming indispensable") in that it uses the structure of society to enforce and enact a particular SI. This does not preclude the prior and continued existence of competing SIs, a point I return to in defining my argument below.

Jasanoff is also quite clear to define what SIs are not:

> *imaginaries are not problem frames (Schon and Rein 1995, Goffman 1974) or policy agendas (Kingdon 1995): they are less explicit, less issue-specific, less goal-directed, and less politically accountable. They are not master narratives (Lyotard 1984), but are more futuristic and less grounded in historical memory. Unlike media packages (Gamson and Modigliani 1989), sociotechnical imaginaries are not mainly defined by discourse but are often associated with active exercises of state power and the management of political dissent."(Jasanoff 2019)*

From this defining discussion, we can see that SIs in their original form are distinguishable from prior concepts by their generalized view, future focus, and active exercise of state authority.

When applied to the regulation of disruptive technological innovation, SIs give us a language to talk about how different actor roles see regulation and innovation fitting together. These regulatory imaginaries thus represent collectively held, publicly performed conceptions of desirable relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies.

IDEAS, FAITH, AND IMAGINATION IN POLITICAL ECONOMY

From the beginning of political economy with Adam Smith, the importance of ideas in structuring political economy interactions and outcomes has been central. Indeed, the purpose of *The Wealth of Nations* was to instill in readers the importance of a market as a desirable way to reorganize society to increase the wealth of nations.[124] Works such as Marx and Engel's *The Communist Manifesto* and List's *The National System of Political Economy* continued this tradition of classical political economy in using conceptual understandings of how the world *does* work to define how the world *should* work.

After this classical period of blurred lines between social scientific understanding and social practice, later scholars turned a critical eye to how the ideas in these works created the market societies they found themselves in. Karl Polanyi ([1944] 1957) explained *The Great Transformation* from feudalism/mercantilism to market society by uncovering the progression of market ideas from Adam Smith through a number of advocates and a series of state policies which led them to become central tenants of how society was organized as England underwent the industrial revolution. Alexander Gerschenkron ([1951] 2008) expanded this story of the first industrializer to a set of "*potentially* relevant factors and… *potentially* significant combinations"[125] of a set of later industrializers. In all of these stories, the authors emphasize the importance of faith that the ideas of market society are necessary parts of a change from current problems to a desirable future.

For Polanyi, the role of faith in the transformation to market society plays out in the "Birth of the Liberal Creed" from early ideas of less bureaucratic controls to the full-fledged faith in a self-regulating market.[126] In laying out this evolution from early calls for marginal reductions in regulation and restrictions under mercantilism to a full-fledged self-regulating market, Polanyi invokes the language of faith to highlight the importance of economic liberalism in forming the

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[124] Though Smith is famous for contending that market behavior is a natural "propensity to truck, barter, and exchange," *The Wealth of Nations* was an impassioned plea to reorganize society so as to unleash this natural propensity both domestically and abroad.(Barma and Vogel 2008a; 2008b, 22)

[125] (Gerschenkron [1951] 2008, 212)

[126] "The Birth of the Liberal Creed" is the title of Chapter 12 in *The Great Transformation* which tells the careful story of the progression of laissez-faire from narrow idea to broad "militant creed." (Polanyi [1944] 1957, 135–50)

basis of (English) market society. Polanyi describes this process as "non-bureaucratic methods…evolve[ing] into a veritable faith in man's secular salvation through a self-regulating market."[127] This faith-based language evolves into the "evangelical fervor"[128] and later into a "crusading passion…and…militant creed."[129] While certainly scholars often choose colorful metaphors to illustrate their claims, the choice of those metaphors is telling especially when they lead to the central arguments of a work. In Polanyi's case, this telling of the evangelical fervor behind laissez-faire economic liberalism culminates in his famous point: "Laissez-faire was planned; planning was not."[130] The early ideas of moderate and selected reductions in certain types of social control of economic activity morphed into a faith, promoted and actively institutionalized by ardent followers, in a self-regulating market which must be protected and released from the burdens of society.

Elaborating on this account of the building of economic liberalism in the first industrial revolution by the first industrializer (England), Gerschenkron ([1951] 2008) focusses on how this process of building a faith in the desirability of market society varies by time and place.[131] For France, Napoleon III ties the process of capitalist industrialization seemingly incongruously to Saint-Simion socialism. For an ununified Germany in 1841, Friedrich List tied industrialization to nationalist sentiment. In Russia, considered by Gerschenkron the most backward of the three countries, such strong faith was needed that the Marxist "iron law of historical development" was needed to spur the country to industrialize.

Why is such faith necessary for Gerschenkron? In his words:

> *To break through the barriers of stagnation in a backward country, to ignite the imaginations of men, and to place their energies in the service of economic development,* ***a stronger medicine is needed than the promise of better allocation of resources or even of the lower price of bread.*** *Under such conditions even the businessman, even the classical daring and innovating entrepreneur, needs a more powerful stimulus than the prospect of high profits. What is needed to remove the mountains of routine and prejudice is faith-****faith,*** *in the words of Saint-Simon,* ***that the golden age lies not behind but ahead of mankind.****(Gerschenkron [1951] 2008, 223–24 emphasis added)*

Intriguingly, Gerschenkron places the importance of faith on overcoming the "barriers of stagnation in a backward country" and exempts advanced countries, specifically England, from the need to supplement rational arguments for industrialization with "quasi-religious fervor."[132] And yet, we can see from the earlier discussion by Polanyi that a faith in economic liberalism was crafted as part of England's transition to market society. To reconcile this seeming contradiction between two influential scholars concerned with the importance of ideas in the building of successfully market societies, we should recognize that Gerschenkron is concerned with "capitalist industrialization": the simultaneous process of industrialization and the creation of market society in countries in which neither arose as separate processes.

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[127] (Polanyi [1944] 1957, 135)
[128] (Polanyi [1944] 1957, 135)
[129] (Polanyi [1944] 1957, 137)
[130] (Polanyi [1944] 1957, 141)
[131] Gerschenkron's entire article deals with the comparative concepts of historical economic development and wins the award, in the words of Steven K. Vogel, for "the most insights per page" making it a challenging but illuminating read in its entirety. The specific discussion of faith in the industrializations of France, Germany, and Russia summarized in this paragraph appears on (Gerschenkron [1951] 2008, 222–25)
[132] (Gerschenkron [1951] 2008, 223–24)

To invoke a possible cliché in political economic history, England was exceptional because England was first. For us, this means that the possibly less-intertwined faith linking industrialization to market transition may look different because the world in which those processes played out in England (1750-1830s) is quite different from the world Germany and France faced (1850s) which is different again from the world that Russia faced in the 1890s. Indeed, Gerschenkron himself makes this point "that, useful as the "lessons" of the nineteenth century may be, they cannot properly be applied without understanding the climate of the present [20th] century."[133] Thus, we can be reassured that although Gerschenkron exempts England from the need for faith in capitalist industrialization, the elements of faith explained by Polanyi may nevertheless be present because the simply look different owing to the different conditions faced by English economic liberals and industrializers.

While this sojourn into the eccentricities of how two formidable scholars of economic development may seem a distraction from our study of regulatory imaginaries, it drives home the important point that the role of ideas, faith, and imagination in political economy can often seem ephemeral and contradictory. And yet, this flexibility lets us capture the ephemeral and contradictory nature of social reality. Thus, while it is important to recognize that words like faith and ideas are not always used consistently by scholars and the nuances should be elucidated, it is at least as important to recognize that scholars continue to reach for these words to capture partially ineffable truths about social reality.

In this project, the concept of regulatory imaginaries draws on this tradition of ideas, faith, and imagination in political economy and employs the concept of sociotechnical imaginaries as defined in STS to bring additional clarity to how different conceptions of the relationship between regulation, innovation, and entrepreneurship coproduce disruptive technological innovation. In the following section, we'll explore how different regulatory imaginaries arise from and shape different perceptions.

PERCEPTION

Perception is of key importance to understanding the regulation of disruptive technological innovation because perceptions create preferences long before outcomes breed interests. For the project as a whole, this is a key motivation for expanding our understanding of regulatory models beyond the folk economic baseline.

Innovators and entrepreneurs distrust regulation not because they've *had* bad experiences but because they *think* they have or think they will. This does *not* mean that regulation and innovation (and thus regulators and innovators) are *never* at odds with each other. Indeed, we all have our just so stories and anecdotes of when regulation hindered innovation. However, while such "anecdata" is data, it is neither comprehensive data, nor exhaustive data, nor perhaps even representative data. In everyday life, we take such anecdata of regulatory failures as confirmation of our baseline (aka "folk") understanding of regulation; it comports with our priors so we don't update those priors. But should we be so comfortable in this confirmation of 'what everyone knows' about regulation?

Much as Ostrom (1990, 183) argued against the over-interpretation of certain endemic rational choice models, I am arguing that models that see regulation as an impediment to innovation "are special models that utilize extreme assumptions rather than general theories."

[133] (Gerschenkron [1951] 2008, 225)

Thus, I am not arguing (and would never claim) that regulation is *always good* for innovation. I am simply saying that the opposite is also not always true: regulation is not *always bad* for innovation even though we can all point to an example where it has been so.

This project argues rather humbly that "not always wrong" is not the same thing as "always right" or even "right most of the time." Given the stakes of successful regulation of innovation for a well-functioning political economy, we should study situations and configurations where regulation can enhance innovation rather than erroneously assume that such a search is an a priori pointless endeavor. We must shift our folk model, our "common-sense understandings,"[134] from a perception of regulation as having one effect on innovation (an impediment) to a perception of regulation as having many possible effects on innovation (from impediment to catalyst of adoption).

SOCIAL CONSTRUCTION

Perceptions create preferences before outcomes create interests. Two critical features of the regulatory imaginaries developed in this project are that they are malleable through policy and that they create more or less desirable outcomes. In other words, regulatory imaginaries are *socially constructed* and *socially construct* different relationships between entrepreneurs, innovators, and regulators. They do so by setting the preferences for regulation based on entrepreneurs, innovators, and even regulators perceptions of what is both possible and desirable and, in so doing, these preferences then reflexively reinforce what is possible and desirable. In order to understand these reciprocal processes, we need to unpack social construction; we do that here.

This project focuses on perceptions because perceptions are the intermediate step between data input and action; between gathering information about the world and shaping our response to that information. Perception, then, more so that "objective reality" is what shapes our behavior. In the simple words of Alexander Wendt, the scholar who brought social constructivism into political science: "we want what we want because of how we think about it."[135]

Social construction, best summed up by Wendt's simple words in the quote above, had many years of history before it was brought into political science. However, the clash between Wendt and Waltz ([1979] 2010) brought a clarity to the importance perception in politics beyond simply the roles of deception/mis-perception/ignorance which are core to concepts such as Marxist "false consciousness."[136] At the core, the importance of social constructivism within political deals with whether we can boil down all political contestation to ultimately a material competition over power and resources or whether there is an irreducible component of politics which arises from how we think about the material and non-material forces involved. As this initial porting of social construction in to political science occurred in the subfield of international relations (IR), we can translate this conceptual question into a more concrete one: are the political struggles between nations really just about guns and money and the ideas and slogans are just some pretty window dressing or are the political struggles between nations really about the ideas and slogans and the guns and money simply help to sort them out.

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[134] (D'Andrade 1987, 113)
[135] (Wendt 1999, 119)
[136] (Engels [1893] 1978, 766)

To turn from this IR origin to political economy, social constructivism lies at the heart of the distinction between interests and preferences. In basic economic parlance, interests are what analysts deductively say groups or actors are supposed to want based on a specified utility (growth, profit, gain) while preferences are what groups or actors say they want.[137] Generally, this distinction is treated somewhat casually in economic and formal modelling circles, where modelers deductively define preference functions for each actor in a model based on what their interests must be given the construction of the model and the reified scenario being formalized. And yet, we know that in important parts political economic history, such as the post-war Japanese developmental state, preferences have consistently and durably been very different from preferences.[138] It seems, then, that in circumstances as central to our understanding of modern political economy as the Japanese developmental state, we must understand when material interests and socially constructed preferences fail to align.

This distinction between interests and preferences becomes additionally significant when we consider the importance of "stakeholder creation" for enduring public policy. As Pierson describes the process, stakeholder creation refers to a feature of public policies, especially social welfare policies, which "confer substantial resources on specific types of groups" which creates an economic interest for those groups in ensuring the continued existence of that policy.[139] Canonical examples of stakeholder creation include Social Security as the third rail of American politics, the rise of teacher unions in the 1960s and 1970s,[140] and the more general new group mobilization in the US during the 1960s and 1970s where "policies came *first*, precipitating the massive expansion of organized citizen activism."[141] In short, stakeholder creation means that policies can form interests.

Linked directly with stakeholder creation leading to interest formation, Pierson is also careful to identify the important backlash force of "countermobilization or backlash [because] [n]ew policies create new threats."[142] Pierson emphasizes that this complementary process is often the more significant one and I argue that this backlash is built on perception of the effect of a policy rather than waiting for that effect to play out. In other words, while policies form interests through stakeholder creation, perceptions of those policies by non-stakeholders lead to the countermobilization of those non-stakeholders against the policies. Policies create interests, perceptions create preferences.

Between the two processes of stakeholder creation and countermobilization, there is a key temporal asymmetry which gets to the heart of the effect of perceptions on preferences. While the process of stakeholder creation involves the conferral of benefits on a particular group, those benefits accrue as the outcome of the implementation of the policy (e.g. Social Security provides security when the checks go out). However, the process of backlash *need not wait* for the benefits to accrue. Instead, actors who perceive that they will not benefit from the policy can mobilize on this perception without waiting for the actual beneficiaries to benefit. This temporal

[137] (S. K. Vogel 1999, 202–3 Endnote 1)
[138] (S. K. Vogel 1999, 187–88, 202–3, entire, especially endnote 1 and 3)
[139] (Pierson 2014, 284–86) which draws upon Pierson's earlier and broader work on many forms of policy feedback, (Pierson 1993)
[140] (Moe 2011; cited in Pierson 2014, 284–85)
[141] Quote from (Pierson 2014, 285) summarizing (Skocpol 2004; 2011; Leech et al. 2005)
[142] (Pierson 2014, 285)

asymmetry means that perceptions can create preferences (what people say they want) *before* policies create economic interests through stakeholder creation.

At this point, the reader may ask "so what; why should we care if people act on an expected future non-benefit rather than after they have seen an outcome generate interests for another group." To answer this, I return to Wendt (1999, 119): "we want what we want because of how we think about it." Thus, when the backlashers act, their backlash creates the preference structure of rival groups based on what they perceive to be the likely landscape of 'winners and losers' from a particular policy. That preference structure then contributes to how the policy implementation plays out and ultimately how interests are formed among the stakeholders. Thus, it is critically important what perception the backlashers (and indeed the stakeholders) have of the policy because those perceptions will shape the policy outcome.

Whether the initial perceptions match the eventual historical record thus *is not determinative* of whether the backlashers were "right" about what would happen because it only means that they acted in such a way as if they were right and those actions had an effect on the outcome. There are certainly limits to what perceptions are plausible enough to for preferences which then affect outcomes, but this does not mean that even if history plays out exactly as the backlashers perceived (and acted as if) it would that an alternative was not possible had the backlashers held (and acted upon) a different set of perceptions.

For this project's concern with regulation of disruptive technological innovation, the temporal asymmetry between perception/preference and outcome/interest becomes critical due to the greater uncertainty of the eventual outcome of the disruptive innovation. This uncertainty creates two compounding effects: a larger set of plausible perceptions and a longer lag between policy enactment and full implementation. Because DTIs are emerging technologies, their eventual social and economic impacts are inherently less well understood than more established and commonplace technologies. This creates a space for a wide range of speculation which can inform perceptions and eventually imaginaries of how the technology can, should, and will play out. This necessarily expands the set of plausible perceptions of what will happen with the technology and how different regulatory policies might impact those trajectories. In addition, this broader set of imaginaries will take longer to coalesce down to the eventual historical outcome allowing for a greater period of time where perception (rather than outcome) leads to preference (rather than interest) shaping behavior.

Thus, while perceptions *always* create preferences before policy outcomes can create interests, the importance of perception is *especially* important for the regulation of disruptive technological innovation (DTI). As defined in this project, DTIs are innovations which have moved beyond the potential impact of a scientific discovery or prototype to an actual impact on society, often through market impacts but decisively through an impact on the regulatory regime. In developing these DTIs and in responding to their disruption, actors form regulatory imaginaries which provide collectively held, publicly performed conceptions of desirable relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. The concept of regulatory imaginaries draws on the tradition of ideas, faith, and imagination in political economy scholarship and employs the concept of sociotechnical imaginaries as defined in STS to bring additional clarity to how different conceptions of the relationship between regulation, innovation, and entrepreneurship coproduce disruptive technological innovation.

Because DTIs increase the temporal asymmetry between stakeholder creation and backlash, perceptions (rather than outcomes) become the key factor which shapes how entrepreneurs, innovators, and regulators interact. Each of these roles wants what they want because of how they think about it and each has a fairly wide set of possible ways to think about it when dealing with DTIs. The final regulatory regime around the DTI is socially constructed based on the perceptions that entrepreneurs, regulators, and innovators build their preferences on. This project is focused on expanding the range of imaginaries which entrepreneurs, regulators, and innovators can draw upon to form their perceptions and preferences by unpacking the structure of regulatory imaginaries around DTIs and defining the range of variation possible.

CONCLUSION

The quintessential disruptive innovator of the past decade, Uber, made their bones by intentionally attacking and subverting regulators and regulation. They did so both directly using tactics such as Greyball which literally locked regulators out of their service[143] as well as rhetorically by publicly calling for passengers and drivers to disobey and heckle regulators.[144] But Uber, a fundamentally combinatorial innovation, was built on the back of massive government investment on technologies such as the internet, GPS, and public infrastructure. Worse yet, the hardware and software standards that Uber relies upon, often for low or no license fees, are only possible due to regulatory rulings which made entrepreneurship possible in Silicon Valley.

If Uber depends on government, if Uber relies on regulation, why does it so hate regulation?

This chapter has argued that the course of post-war innovation in the United States and globally has submerged the role of the state beneath a private sector ultimately resulting in the "disruptor" model of innovation. It has then flipped this model on its head to define *disruptive innovation* as innovation which disrupts the existing regulatory regime in a particular sector or jurisdiction. Disruptive innovation then forms the basis of the Folk Economic Model imaginary: that the proper role for regulators is to stay out of the way of innovators or be toppled aside.[145]

Recognizing that disruptive innovation helps to define a regulatory imaginary, this chapter has then unpacked and developed the concept of regulatory imaginaries: collectively held, publicly performed conceptions of desirable relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. This definition then allows us to proceed in the following chapter to define a typology of seven different imaginaries, the Folk Economic Model and six alternatives.

Before proceeding to define this typology, however, we also explored how the constitutive elements of regulatory imaginaries align with concepts of ideas, faith, and imagination in the political economy literature, particular the works of Polanyi ([1944] 1957) and Gerschenkron ([1951] 2008). These two scholars of capitalist development used concepts like ideas and faith to capture the ephemeral yet vital role of the non-material in shaping the development of the material world. We then built on these empirical theoretical works by discussing the importance

[143] (Isaac 2017)
[144] (Lashinsky 2017, 97) (Stone 2017, 110)
[145] (c.f. Christensen 1997)

of perception and social construction within political science leading us ultimately to a simple yet vital observation: "we want what we want because of how we think about it."[146]

Regulatory imaginaries allow us to capture how we think about the relationships between regulators, entrepreneurs, and innovators in crafting disruptive innovation. One conception is certainly the Folk Economic Model which privileges entrepreneurs and innovators while submerging regulators. Other models such as Beneficial Constraints, which see regulators placing guard rails which guide entrepreneurs and innovators towards more fruitful outcomes, and Adoption Catalyst, which sees regulators driving the adoption of a nascent innovation across sectors where it could have economic and social benefits, are both possible and currently existing. We turn in the following chapter to a conceptual mapping of all possible regulatory imaginaries of disruptive innovation to demonstrate how we can know that such imaginaries are possible. We then turn in chapters 5, 6, and 7 to an empirical validation of the typology developed in chapter 3 for these promising Beneficial Constraints and Adoption Catalyst imaginaries.

[146] (Wendt 1999, 119)

CHAPTER 3

A DEDUCTIVE TYPOLOGY OF REGULATORY IMAGINARIES

The Variety of Regulatory Imaginaries that Shape how Regulators, Innovators, and Entrepreneurs Coproduce Disruptive Technological Innovation

It has become cliché to note the speed of technological change and lament the inability of social institutions to keep up. One phalanx of this narrative brandishes the word "disrupt" while storming the halls of stodgy industries and regulatory agencies intent on dismantling them. Yet despite this modern narrative of disruption, rapid and drastic technological change is not the invention of the past year, decade or generation. And despite the libertarian narratives which prompt disruptors to use regulation as the foulest profanity to decry state inadequacy, regulators do find ways to adapt to technological change each time it arises. Although never perfect and sometimes inadequate, these adaptations nevertheless happen.

Regulatory failures such as the Deepwater Horizon oil spill and the 2008 Global Financial Crisis are loudly publicized. Much quieter are the regulatory responses which are something other than failure. We need to understand the range of regulatory responses not just the spectacular failures.

In Chapter 2, I developed the concept of regulatory imaginaries. In this chapter, I build on that concept to develop a typology of regulatory imaginaries about disruptive technological innovation (DTI). I do so by generalizing the variables which underlie the folk economic model which views regulators as mere dead weight whose impact must be minimized to allow entrepreneurs to innovate. This folk understanding of Stigler's fixed concepts in "The Theory of Economic Regulation" (1971) should more properly be understood as values of variables in light of the alternative understanding of regulation in Streeck's "Beneficial Constraints: On the Economic Limits of Rational Voluntarism"(1997).

By a folk model I mean a "statement of the common-sense understandings that people use in ordinary life [in contrast with] various "specialized" and "scientific" models."[147] Thus, one core contribution of this project is to unpack the folk economic imaginary of DTI regulation in order to demonstrate that while this belief is widespread and *seems* obvious, it is in fact just one possible relationship between regulators, entrepreneurs, and innovation that is empirically present and theoretically explainable.

To resolve the unwarranted certainty of the folk economic model, this chapter places Stigler's original theory in conversation with Streeck's and generalizes common concepts into five variables (relationship, information, driver, outcomes, and effect) which are then used to deductively define a typology of seven distinct imaginaries about how regulators, entrepreneurs,

[147] (D'Andrade 1987, 113)

and innovators co-created DTI. This seven-part typology of regulatory imaginaries forms the basis of a broader understanding of the effects regulators can have on innovation.

While a great deal of excellent work has focused on the varieties of ways that regulation can be implemented and enforced, regulatory imaginaries look earlier in the regulatory process at the stage of what is perceived as possible. Thus, each of the seven types defined in this chapter are not meant to replace concepts such as responsive regulation,[148] flexible regulation,[149] or management based regulation.[150] Each of those concepts focuses on how to regulate while this chapter defines a variety of conceptions of the proper relationship between regulators, entrepreneurs, and innovators and the effects they have on innovation. The distinction is one between means and ends.

In order to develop my typology of regulatory imaginaries, I proceed as follows. First, I specify the portions of Stigler's "The Theory of Economic Regulation" (1971) relevant to regulatory responses to innovation, the folk model that Christensen (1997) derives from Stigler, and the counter-narrative of Streeck's "Beneficial Constraints"(1997). Then, I generalize the specification from Stigler's point scores to the systematized concepts underlying them which allows me to define five variables (relationship, information, driver, outcomes, effect). Using these five variables, I then deductively produce 24 possible configurations of variable scores based on the four independent variables (effect is a dependent variable). Each of these 24 configurations is then scored with the dependent variable outcome it would produce and the configurations are grouped into seven distinct regulatory imaginaries of how regulators, entrepreneurs, and innovators co-create DTI. I then specify the content and relevance of each of these seven imaginaries, arguing that the Folk Economic Model imaginary, Beneficial Constraints imaginary, and Adoption Catalyst imaginary are the most fruitful for further study to allow this project to demonstrate that regulators can be so much more than merely dead weight. I conclude by reflecting on the benefits of my deductive typology for practitioners and further research.

"THE" THEORY OF ECONOMIC REGULATION AND AN ALTERNATIVE

As Christensen's (1997) concept of disruptive innovation was originally developed for American business school audiences, it is no surprise that his discussion of regulation adopts the baseline understanding of regulation from economics: constraints are bad. This baseline understanding is a folk theory derived from Stigler's seminal "The Theory of Economic Regulation" (1971). Streeck's "Beneficial Constraints: On the Economic Limits of Rational Voluntarism" (1997) provides a counternarrative to Stigler's economically deductive model by inductively presenting situations where constraints (regulations) are economically beneficial. As Streeck and Stigler's analyses will form the basis of the constitutive variables for my typology, it is important to understand the two narratives in their own right.

"THE" THEORY OF ECONOMIC REGULATION

[148] (Ayres and Braithwaite 1992)
[149] (Ford 2017)
[150] (Coglianese and Lazer 2003)

George Stigler's "The Theory of Economic Regulation" (1971) is a certifiable classic in the field of regulatory politics. Indeed, it receives a dedicated chapter in *The Oxford Handbook of Classics in Public Policy and Administration* penned by two of the foremost scholars of regulation.[151] With just its title, it lays claim to parsimoniously defining all that need be thought of economic regulation. The abstract makes clear that the paper will "provide a scheme of the demand for regulation" and "provide elements of a theory of supply of regulation,"[152] neatly promising the canonical supply-and-demand binary necessary and sufficient for any good political economic theory. With such a clear purpose, Stigler then proceeds to lay out a systematic list of benefits and costs which regulation can bring to businesses to define the predictable "calculus of the profitability of regulation of an industry."[153] In building my typology, I challenge the claim that these benefits and costs should be seen as fixed. However, it is first useful to see the theory seductively laid out as immutable observations in the classic article.

To lay out the benefits terms in the calculus of the profitability of regulation of an industry, Stigler begins by defining the state by the pure principle it has which no other actor shares: "the power to coerce."[154] This power to coerce is naturally attractive to industry as a means to increase profitability which can be achieved through four means: direct subsidy, "control over the entry by new rivals", encouragement of complementary goods and discouragement of supplementary goods, and price fixing. In short, the state can offer material benefit to firms in ways no other actor or organization can because it has the power to make *rules* and force everyone to follow them.

For the complementary costs terms in the calculus of the profitability of regulation of an industry, Stigler lays out the inefficiencies of seeking profitability through a political process.[155] First is the abrogation of the sacrosanct distribution of market power based purely on market share by the addition of political power in determining market power of firms. Second, "the procedural safeguards required of public processes are costly;" it costs money to play by the rules. Finally, "the political process automatically admits powerful outsiders to the industry's councils;" actors concerned with something other than profit and revenue maximization are now in a position of direct authority over businesses. In short, the state muddles the clean and efficient work of business with other motives, other people, and inefficient information gathering processes to ensure compliance.

Together, these statements by Stigler frame regulation as a supply of coercive sources of profitable benefits at the cost of certain political inefficiencies. For this reason, Stigler has been credited with the concept of 'regulatory capture' because a "central thesis of [his] paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit."[156] So powerful was this parsimonious economic analysis of politics that Carrigan and

[151] (Carrigan and Coglianese 2015)
[152] (Stigler 1971, 3) emphasis in original
[153] (Stigler 1971, 7)
[154] This paragraph is a summary of the benefits detailed in (Stigler 1971, 4–6). Direct quotations in this paragraph come from those pages unless otherwise specified.
[155] This paragraph is a summary of the benefits detailed in (Stigler 1971, 6–7). Direct quotations in this paragraph come from those pages unless otherwise specified.
[156] Quote from (Stigler 1971, 3), although as (Carrigan and Coglianese 2015, 277) point out, Stigler did not actually coin the term regulatory capture in this article.

Coglianese point out that, to the contemporary reader, all of the above seems rather obvious.[157] For many non-regulatory scholars, and most lay people, regulation *is* regulatory capture to greater or lesser degree.

CHRISTENSEN AS A FOLK THEORY DERIVED FROM STIGLER

As Stigler's claims today seem like the trivially obvious common sense understanding people use in ordinary life, they amount to a folk theory of regulatory politics.[158] This folk theory of captured regulators who serve incumbent firms has become the received wisdom of how regulators respond to disruptive innovation. When Christensen coined the term "disruptive innovation" in *The Innovator's Dilemma* (1997), regulation is brought up to discuss what old regulations need to be removed and new regulations put in place with a standard narrative that "regulations are toppled only when disruptive innovators find applications or markets beyond the reach of regulators."[159] Thus, regulatory response is relegated to a mechanism of "ultimately succumbing" to innovators who successfully end-run the classically entrenched and inefficient regulator.

Beyond this folk theory, there is little discussion of *how* regulators respond to disruptive innovation which is why this project proposes to study that regulatory response to fill this gap in understanding. To begin to unravel the implicit acceptance of this folk theory, the next section introduces an alternative narrative of regulation. In this empirically based alternative narrative, we see the limits of assuming the immutably inefficient regulator.

BENEFICIAL CONSTRAINTS: A COUNTER-NARRATIVE OF REGULATION

Wolfgang Streeck's "Beneficial Constraints: On the Economic Limits of Rational Voluntarism" (1997) provides an alternative to Stigler's classic article not only in message but also in format. Where Stigler set out to provide *the* theory of economic regulation, Streeck's "Beneficial Constraints" explicitly "do[es] not pretend to have a conceptual schema to cover them all."[160] Instead, he presents examples from which he can draw out theoretical and practical implications. In so doing, Streeck lays out a natural complement to the understanding of economic policy championed by Stigler both in content and form. While this does not amount to a complete alternative theory, it instead quite literally lays out the "economic limits of rational voluntarism. As this format will be very conducive to our next step of generalizing from Stigler and Streeck to constitutive variables for a typology, it is first useful to review the theoretical and practical implications Streeck laid out even though he does not claim they constitute a complete conceptual schema.

Streeck's key advice to colleagues is that "Recognition of the economic benefits of *some* social constraints immunizes against the received wisdom that *all* constraints are counterproductive by definition."[161] This is an explicit rejection of the Christensen's folk economic model derived from Stigler that sees regulators as "ultimately succumbing" to innovators who make the future. For Streeck, sometimes the future is best made by regulators

[157] (Carrigan and Coglianese 2015, 292)
[158] (D'Andrade 1987, 113)
[159] (Christensen, Grossman, and Hwang 2009, xlv)
[160] (Streeck 1997, 200)
[161] (Streeck 1997, 213)

who constrain innovators from their original ambitions forcing them to innovate in line with other ambitions.[162]

From his key advice, Streeck makes three recommendations about politics and policy based on beneficial constraints: partialness, uncertainty, and complexity.[163] First, not all constraints are beneficial but some economically non-rational social institutions improve economic performance so universal prescriptions against constraints should be avoided when designing policy. Second, *uncertainty* is a defining characteristic of a political economy in practice so the "common sense judgment of the practitioner" must take precedence over the "deductively-based knowledge of the expert" and thus "political skills" are vital to good institutional design and adaptive operation. This uncertainty derives from the fact that economically beneficial social institutions are often unintentional side effects which are difficult to forsee and may vary through time and circumstances as economic actors innovate with the constraints.[164] Third, the institutional conditions of good economic performance are *complex* and so must cast a broad policy net rather than the traditionally narrow one which aims at incentivizing desirable behavior within a carefully demarcated arena. Thus, "at the minimum, good economic policy must be embedded in family policy, social policy, and educational policy."

GENERALIZING STIGLER AND STREECK INTO VARIABLES

The core observation that this project builds on is that what Stigler defined as fixed concepts in "The Theory of Economic Regulation" (1971) should more properly be understood as values of variables. In their fixed form, they led to a folk economic model of the regulatory response to disruptive innovation in Christensen's (1997) original specification. In this section, I show how Stigler's costs and benefits in the calculus of profitability of regulation of an industry can be generalized to variables. Drawing on the counter-narrative from Streeck's "Beneficial Constraints" (1997), I then define the range of variation which is empirically observable for those variables as well as the systematized concept behind these case scores which defines the variable.[165]

FROM THE FOLK ECONOMIC MODEL TO REGULATORY IMAGINARIES

In the section above, I summarized Stigler's explanation of the costs and benefits of economic regulation to regulated firms. These costs and benefits that define Stigler's economic model of regulation can be mapped into five variables. These variables can then be generalized by recognizing the underlying range of variation which Stigler has reduced to a single point

[162] (Streeck 2004, 428)

[163] These three recommendations are summations of (Streeck 1997, 213–15) and all quotations are from there unless otherwise specified. The single word terms are my own reification.

[164] (Streeck 1997, 211–12). Note that I am actually going further than Streeck in my Beneficial Constraints imaginary and claiming that although unintended benefits certainly happen, we can do better; it is possible to design for benefits. Not always, but sometimes. And those times are interesting. See discussion in the introduction about benefits-benefits Quadrant A style regulation (page 13) as well as the discussion of my conception of Beneficial Constraints in Chapter 5 (pages 91 to 93)

[165] For an extremely lucid conceptualization of conceptualization and measurement in the social sciences, see (Adcock and Collier 2001) particularly Figure 1 on page 531. The process I apply to Stigler's economic theory in this section is essentially working backward from level 4 to level 1 to demonstrate that what Stigler calls concepts are, in fact, case scores of underlying systematized concepts which I will identify below.

Table 3: Generation of Variables by Generalizing Stigler's Economic Model

A Regulators…	Economic Model	Generalizes to	Regulatory Imaginaries
Relationship to Market Development	External **Rulemaker**	→	External **Rulemaker** **or** Internal **Stakeholder**
Access to **Information** about Regulated Sector	Intrinsically **Lower** than Firms	→	Range from **Lower** than Firms **to Higher** than Firms without perverse incentives
Driver of Innovation Adoption	**Market**	→	**Market** or **Regulator**
Number of Optimal Regulatory Arrangement **Outcomes**	**One** (the single best "efficient" arrangement) or **Zero** (laissez faire)	→	**Many** Possible Configurations based on definition of "Success" by Stakeholders
Effect on Innovation	Path-Dependent **Impediment**	→	Range from Path-Dependent **Impediment** to **Moderator** between stakeholders to "Beneficial **Constrainer**" to **Adoption Catalyst**

score for his model. The economic model, variable scores, and generalized variation described in this section is summarized in Table 3.

The first variable is the *relationship* of regulators to the innovative market being regulated, whether an external rulemaker or internal stakeholder. Stigler defines regulators as categorically coercive and thus sees regulators as an external rulemaker which imposes rules upon a market sector. These rules become inappropriate and inefficient when the market develops and changes as they were imposed to serve incumbent firms. While Streeck agrees that states have a "distinctive status as wielder of public authority," [166] he advocates for states to use that authority to counter the whims of the market when they do not reproduce society. Thus, to generalize this point score, we need to see regulators as an internal stakeholder in a market which interacts with business, labor, and other social stakeholders[167] to shape the development of that market. As a stakeholder, regulators could choose to act in the more limited role of external rulemaker, but they are not categorically limited to that role.

The second variable is the access that regulators have to *information* about the practices and features of an innovative sector, whether lower or higher than firms in that sector. In calling the "procedural safeguards required of public processes" costly,[168] Stigler's economic model sees regulators as inherently less able to access diverse and distributed information about business practices and thus less able to understand what is 'really going on' than the business firms

[166] (Streeck 1997, 215)
[167] These are generally organized interests represented by NGOs such as environmentalists, gender equity activists, etc. whose involvement depends on the specific domain being regulated due to salience for that particular interest.
[168] (Stigler 1971, 7)

themselves.[169] In order to generalize this variable, we should acknowledge that low information is possible but use it to define one end of a range of information where it is also possible for regulators to have better access to information about an entire sector than any single firm and without the perverse incentives which many industry-wide organizations would have.[170] Streeck agrees that cost-benefit "rational accounting" by market actors is often unable to foresee important contributions to economic success as such factors are often "fuzzy."[171] Thus, where the economic model emphasizes a single low level of access to information, a generalized set of regulatory imaginaries emphasizes a range of possible levels of access to information which makes it important to understand how particular levels of information occur and how more desirable levels can be encouraged.

The third variable is the *driver* of adoption of the disruptive innovation throughout a regulatory domain, whether from the market or from regulators. In talking about the benefit of "control over the entry by new rivals," Stigler adopts the position that innovations spread through market sectors as they are driver by market actors. While certainly one source of the spread of innovation, markets are not the only source. Indeed, the core motivation of Streeck's chapter is to point out such limits to rational voluntarism.[172] To generalize this variable, we must recognize that regulators can also push for the adoption of an innovation, such as a new pollution control mechanism, fuel economy standards, or electronic health records. Thus, either markets or regulators can be the driver of adoption for a disruptive innovation.

The fourth variable is the number of optimal regulatory arrangement *outcomes* which the model predicts can result from a regulatory response to disruptive technological innovation. Drawing on economic notions of efficiency, Stigler's economic model implicitly compares captured regulators against a Pareto optimal arrangement and analyzes real outcomes as imperfectly approaching this single best outcome.[173] Often because of the imperfect ability of regulatory regimes to meet the economic model's standard of Pareto optimality, it also suggests a regulatory pseudo-arrangement of "laissez faire" where the most desirable regulatory arrangement is no regulatory arrangement. As Streeck argues for the importance of an economy

[169] Stigler's (1971, 7) example of procedural costs in the original piece is, in fact, the cost of an agency review to gather information. Malloy (2010) provides an excellent overview of two alternative social constructions of command and control regulation (aka. what most non-regulation scholars generally think of as regulation). His "conventional construction" is consistent with Stigler's economic model understanding while his "alternative construction" is the definition of a regulatory politics model to describe the variations in the command and control form of regulation. Indeed, his three propositions of "rigidity", "homogeneity", and "competency" helped me define my variables of effect, outcomes, and access.

[170] (Malloy 2010, 339–41) points out that industry trade associations are responsible to their members (firms in the sector they represent) and thus have an incentive to benefit their members at the possible expense of other stakeholders (such as social and environmental groups). Less optimistically, most industrial trade associations are lobbying groups whose job is often to weaken any industry-undesirable regulation.

[171] (Streeck 1997, 205–6)

[172] (Streeck 1997, title, entire, but especially 197-200)

[173] While the notion of Pareto optimality does allow for a set of equally Pareto efficient outcomes which might cause the reader to question my claim of a "single best arrangement," the search for a set of Pareto optimal outcomes relies upon the assumption that there is a single calculus by which all outcomes can be unambiguously compared which is agreeable to all parties. Because regulation is a political process, it is not only possible but exceedingly likely that no single agreeable calculus exists for all relevant stakeholders. Thus, no matter how complex the calculus nor the possibility of a set rather than a single Pareto optimal outcome, the notion of Pareto optimality is a search for a way to define a "single best arrangement" because it assumes that all arrangements can be compared by a single set of agreed parameters.

embedded in society and the intrinsic uncertainty of political economic institution functions, there is no one universally optimal outcome but rather an evolving and pragmatic adaptation to circumstances.[174] To generalize from the economic model, the wider group of regulatory imaginaries assumes a range of possible optimal outcomes which are defined with respect to varying measures of success used by different stakeholders.

The outcome axis also reveals a more general insight which distinguishes the economic model from the generalized set of regulatory imaginaries: general or specific notions of 'good' and 'bad' responses. From the perspective of the regulatory imaginaries, the goal of an analysis of a regulatory response to disruptive technological change is *not* to adjudicate whether the response was 'good' or 'bad' but rather to explicate that the response was 'good *for whom*' and 'bad *for whom*.' Symmetrically, this suggests that the economic model's focus on one best outcome comes with (often implicit) assumptions of ranked importance of stakeholders allowing the analyst to create a seemingly neutral judgment of good or bad which is in fact based on contestable underlying assumptions of which stakeholders' needs are most important.

The fifth variable is the *effect* of regulation on innovation within the regulatory domain, whether an impediment, moderator, beneficial constraint, or Adoption Catalyst. Based on Christensen's adoption of Stigler's characterization as a folk theory of regulation, the economic model sees regulators as an impediment to innovation because they are working from a rulebook written to benefit pre-innovation firms. For the folk economic model, these anachronistic rules trap regulators in path-dependent[175] thinking which can only serve as an impediment to the development of a new rules of the game to complement the changes from innovation. To generalize this point value, we can acknowledge the possibility of path dependence leading to regulators as an impediment and expand the focus to a *range of possible effects* which regulators can have on innovation. These effects spans from path-dependent impediment to neutral moderator between interests to Streeck's nurturing beneficial constraint[176] which shapes an innovative sector into a better possible form than it would have achieved without regulatory involvement and finally to the regulator as active driver of innovation. The key to the generalized regulatory imaginaries is that they define a range of effects rather than a single effect that regulators can have on innovation which makes it important to understand how particular effects occur and how more desirable effects can be encouraged.

In sum, the definition of regulatory imaginaries is a generalization of Stigler's economic model based on five variables which define a range of values for each variable rather than assigning a single point score. While Stigler's seminal paper has greater complexity than the lessons that most contemporary authors cite it for, it is the *folk understanding* of this model evinced by Christensen (1997) which is most relevant because that is the one that is running in regulators, entrepreneurs, and other stakeholders' heads when they are responding to disruptive technological innovation.

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[174] (Streeck 1997, 211-212,214) See Streeck section above for the discussion of uncertainty.

[175] Thelen (1999) lays out an excellent overview of origin, development, and application of path dependency as a concept in political science and particularly as part of the historical institutionalist approach.

[176] Streeck (1997) originated the term "Beneficial Constraints" with the classic example of a higher minimum wage pushing German industries to form higher productivity and more diversified industries which lead to strong export competitiveness because it removed the 'subsidy' to labor-inefficient (low productivity) business which a low minimum wage provides.

In light of Streeck's counter-narrative of beneficial constraints, we can expand the range of variation from fixed scores to multivalued ranges. This folk economic model characteristically sees regulators as an external rulemaker who serve as a path dependent impediment to innovation because they have intrinsically lower access to, and ability to process, information than the firms which are the driver of innovation which leads to either a single best (yet unachievable) regulatory arrangement outcome or a pseudo-outcome of laissez faire deregulation. By contrast, generalized regulatory imaginaries can specify regulators as an internal stakeholder who can serve in a range of roles from path-dependent impediment to beneficial constrainer of innovation because they can have lower access to information than firms or higher access to sector-wide information than firms which leads to a range of possible optimal regulatory arrangements which are defined by varying standards used by varying stakeholders and may allow regulators themselves to drive the adoption of innovation beyond the imagination of market actors or forces.

SPECIFICATION OF THE FIVE VARIABLES

Based on the generalization from Stigler's Folk Economic Model in the section above, there are five variables which can be used to define regulatory imaginaries to disruptive technological innovation (DTI). The first four variables (*relationship*, *information, driver*, and *outcomes*) are the independent variables which together produce a particular *effect* on the regulatory domain, the dependent variable. Each of these variables is defined and all possible variables values are specified in Table 4.

A TYPOLOGY OF REGULATORY IMAGINARIES

Typological theorizing is ideally suited to this project because the goal of this project is to define the variety of imaginaries which shape how regulators, entrepreneurs, and innovators co-create DTI. Following the advice of George and Bennett (2005, 233–62), this section will deductively define the complete typological property space using four constitutive variables (relationship, information, driver, outcomes). It will then organize the configurations into empirically interesting groupings and eliminate those configurations which are trivial or empirically impossible. The remaining empirically interesting groupings will be explained and cases will be introduced to exemplify them.

REGULATORY IMAGINARIES

To deductively define a typology, the first step is to identify *constitutive* variables whose ranges of variation will define the typological property space which contains an exhaustive set of types based on the combinations of the scores on the constitutive variables.[177] I have adopted Waldner's more specific 'constitutive'[178] adjective for my typology defining variables rather than independent because, while they may be independent variables,[179] they are relevant to the typology in their constitutive role and their independence or dependence is incidental to the deduction of the typology.

[177] (A. L. George and Bennett 2005, 244)
[178] (Waldner 2015b, 243; 2016, 30)
[179] or dependent variables in principle, although my types do not use the dependent variable "effect" as a constitutive variables

Table 4: Variables and Range of Variation for Typology Generation

	A Regulators…	Definition	Range of Variation
Constitutive (Independent) Variables	**Relationship** to Market Development	How do regulators behave with respect to other stakeholders in a regulatory domain affect by a DTI?	External **Rulemaker** ↓ Internal **Stakeholder**
	Access to **Information** about Regulated Domain	How much information can regulators gather about the DTI and regulatory domain it affects?	**Lower** than Firms ↓ **Higher** than Firms
	Driver of Innovation Adoption	From where did the drive to adopt the DTI across a regulatory domain derive?	**Market** or **Regulator**
	Number of Optimal Regulatory Arrangement **Outcomes**	How many "maximally desirable" outcomes can the regulatory response produce?	**Zero** (i.e. laissez faire) ↓ **One** (i.e. pareto optimality) ↓ **Many** (based on varied definitions of "Success" by Stakeholders)
Dependent	**Effect** on Innovation	What effect does the regulator have on innovation by actors in the regulatory domain?*	Path-Dependent **Impediment** ↓ **Moderator** between stakeholders ↓ "Beneficial **Constrainer**"** ↓ **Catalyst** of Innovation

* From the perspective of the regulator; what effect do they perceive they will have.

** cf. (Streeck 1997)

Based on the four independent variables defined above in Table 4, there are 24 possible configurations of variable scores which form the typology property space for my typology of regulatory imaginaries. Each of those configurations is defined and categorized in Table 5, below. The regulatory imaginaries have been organized by the amount they diverge from Christensen's (1997) folk theory application of Stigler's (1971) economic model, particularly in the sense that they have a different effect on innovation that the impediment predicted by the economic model. Based on this deductive typological theorizing process, seven distinct regulatory imaginaries comprising 18 of the 24 mathematically possible configurations have been identified and will be explained below. Of these seven regulatory imaginaries, the Folk Economic Model, Beneficial Constrainer imaginary, and Adoption Catalyst imaginary are of particular interest because they are empirically interesting variations in effect on innovation while the other four are well represented in the literature and do not represent surprising variation. Six of the 24 configurations were identified as trivial or logically impossible.

FOUR CONVENTIONAL REGULATORY IMAGINARIES

Of the seven imaginaries derived from the deductive typological process, four coincide with standard theories of regulation from the literature. The Market Ideological imaginary is characterized by regulators who have better information about the regulatory domain than firms but never the less observe that the market is driving innovation adoption and believe that there are zero desirable regulatory outcomes because the state is believed to intrinsically be an impediment to innovation. The name comes from Henderson & Appelbaum's (1992) completion of Chalmers Johnson's (1982) 2x2 of market | plan x rational | ideological by defining the idea of "market ideological" which privileges market structures for organizing social and economic interaction beyond efficient cost-benefit tradeoffs due to an ideological preference for market structures over planning. While this privileging of market structures beyond their rational benefit is certainly an interesting research phenomenon, this project is concerned with how regulators respond to DTI rather than why they choose not to. Thus, the market ideological imaginary, while interesting, is of limited importance for the rest of this project.

The State-as-Venue imaginary is characterized by lower access to information and a belief in many desirable outcomes to the regulatory response process. Because these regulators recognize that they lack access to information and do not have a strong preference for a particular outcome, they play the role of moderator between other stakeholders. This regulatory response is consistent with one part of the dual nature of the state from Skocpol (1985) where the state acts as the venue for other actors to settle their conflicting interests. As in Skocpol's original edited volume, this neutral moderator role is the less interesting nature of the state for this project where the state-as-actor nature is more consistent with the research aims to understand how regulators act to respond to DTI.

The Capture imaginary is characterized by regulators who see themselves as stakeholders with low access to information who nevertheless choose to impose a single desirable outcome on the response process. This has the effect of constraining innovation, likely in favor of personal benefit and benefit to a particular incumbent firm which they choose to denote as best practice due to a low access to information. This imaginary is distinct from Stigler's Folk Economic Model because the regulators see themselves as stakeholders who seek to achieve their own benefit, whereas the Folk Economic Model casts regulators as rulemakers. While regulatory capture has captured the interest of many studies of regulation, it is explicitly not of primary

Table 5: Complete Typological Property Space of Regulatory Imaginaries

		Constitutive Variables (Independent Variables)				Dependent
Name of Imaginary	**#**	**Relationship**	**Info**	**Driver**	**Outcomes**	**Effect**
Folk Economic Model (Christensen 1997)	1	Rulemaker	Lower	Market	Zero	Impediment
	2	Rulemaker	Lower	Market	One	Impediment
Market Ideological*	3	Rulemaker	Higher	Market	Zero	Impediment
	4	Stakeholder	Higher	Market	Zero	Impediment
State-as-Venue (Skocpol 1985)	5	Rulemaker	Lower	Regulator	Many	Moderator
	6	Stakeholder	Lower	Market	Many	Moderator
	7	Stakeholder	Lower	Regulator	Many	Moderator
Capture (Stigler 1971)	8	Stakeholder	Lower	Market	One	Constrainer
	9	Stakeholder	Lower	Regulator	One	Constrainer
Technology-Based Regulation "Conventional Command and Control" (Malloy 2010)	10	Rulemaker	Higher	Market	One	Constrainer
	11	Rulemaker	Lower	Regulator	One	Constrainer
	12	Stakeholder	Higher	Market	One	Constrainer
Beneficial Constrainer (Streeck 1997)	13	Rulemaker	Higher	Market	Many	Constrainer
	14	Stakeholder	Higher	Market	Many	Constrainer
Adoption Catalyst	15	Rulemaker	Higher	Regulator	Many	Catalyzer
	16	Stakeholder	Higher	Regulator	Many	Catalyzer
	17	Rulemaker	Higher	Regulator	One	Catalyzer
	18	Stakeholder	Higher	Regulator	One	Catalyzer
Trivial	19	*Rulemaker*	*Lower*	*Regulator*	*Zero*	*Impediment*
	20	*Stakeholder*	*Lower*	*Regulator*	*Zero*	*Impediment*
	21	*Rulemaker*	*Lower*	*Market*	*Many*	*Impediment*
	22	*Stakeholder*	*Lower*	*Market*	*Zero*	*Impediment*
Logically Inconsistent	23	~~Rulemaker~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~
	24	~~Stakeholder~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~

* (Henderson and Appelbaum 1992) completed Chalmers Johnson's (1982) 2x2 of market|plan x rational|ideological by defining the idea of "market ideological" which privileges market structures for organizing social and economic interaction beyond efficient cost-benefit tradeoffs due to an ideological preference for market structures over planning. More modern ears are more familiar with the term "market fundamentalism" as popularized by George Soros (1998) although the concept is as old as capitalism itself with well-reasoned critique of it at least as old as Polanyi ([1944] 1957). The modern usage is well explained in (Block and Somers 2014).

interest to this project because I am concerned with the interesting ways in which regulators do *not* fail to benefit innovation rather than the commonplace ways in which they can.

The Technology-Based Regulation imaginary is characterized by the search for a single optimal regulatory outcome through two patterns. When the regulator has higher information than firms but believes that the market provides the drive for adoption of the innovation, this imaginary has regulators apply a one-size-fits-all rule to ensure that market actors all adopt the "correct" response to an innovation. When the regulator has lower information than firms but believes that regulators drive adoption, then this imaginary is Malloy's (2010) "conventional construction" of command and control regulation which sees a rigid and incompetent rulemaker enforce a homogenous solution on all firms. As the term 'conventional construction' implies, this imaginary represents the standard wisdom about regulators among regulatory scholars as opposed to this project's interest in non-standard constructions of regulators which lead to under-recognized effects on regulation.

Three Imaginaries of Particular Interest: Folk Economic, Beneficial Constrainer, and Adoption Catalyst

The remaining three imaginaries derived from the deductive typological process are the core regulatory imaginaries of interest to this project. The Folk Economic Model, characterized by regulators who consign themselves to be merely rulemakers with low access to information and believe the market provides the drive for adoption thus leaving a single least bad or zero optimal outcome, is the folk theory which animates many non-regulatory scholars and most laypersons understanding of regulation. Although it is not fair to blame Stigler for the way in which his theory has been reduced to a simple folk understanding of regulation which forgets the complexity of regulatory scholars, this imaginary is central to this project because it is important to demonstrate that such a folk theory is a self-fulfilling prophecy. If regulators and firms act as if regulators are merely dead weight to be minimized to allow for innovation, then all actors behave to make it so.

The Beneficial Constrainer imaginary is characterized by regulators who have higher access to information and believe that there are many possible optimal outcomes but believe that the drive for adoption of an innovation comes from the market. Named for Streeck's (1997) "Beneficial Constraints: On The Economic Constraints of Rational Voluntarism," this imaginary captures the same key point as Malloy's (2010) 'Alternative Construction' of command and control regulation where regulators know more about the overall shape of a regulatory domain (cf. market sector) than any of the firms do individually or in the aggregate. Streeck based his concept on empirical observations such as a high minimum wage which forces firms to develop high productivity business models which serve as an engine for economic growth in the long term even if they are against the short term economic interests of managers who would prefer to maintain their low productivity, low wage business models rather than invest in long term growth in productivity.[180] This effect of beneficially constrained short term innovation leading to long term innovation benefits is exactly the sort of interesting regulatory success that my chapter is interested in explicating.

The Adoption Catalyst imaginary is characterized by regulators with higher information than firms who believe that a regulator is the drive for the spread of an innovation and desire either one or many different optimal regulatory outcomes. Completing the divergence from the Folk Economic Model, these regulators push firms to adopt innovations they otherwise would not. Identifying and specifying this imaginary is a key theoretical contribution of this typology. More than merely dead weight, more than merely a beneficial guiding hand, these regulators are actively driving innovation in a particular direction beyond the vision of firms in the regulatory domain.

Trivial and Logically Inconsistent Configurations

As with any deductive theorizing process performed on empirical cases, there are several combinations which are trivial or logically inconsistent with what is empirically possible. Configurations 19 and 20 have no ability to regulate because they have lower information, a belief that regulators would be the driver for adoption but see no optimal outcomes. Configurations 21 and 22 have no desire to regulate because they share a lack of information but observe that the market is innovating without regulatory intercession. Configurations 23 and 24 are logical fallacies because a regulator with higher information than firms who believes

[180] (Streeck 1997, 200–201)

regulators are the driver of innovation adoption cannot believe that there are zero optimal regulatory outcomes because that would be inconsistent with the belief that regulation should cause adoption.

CONCLUSION

Innovators and entrepreneurs distrust regulation not because they've *had* bad experiences but because they *think* they have or think they will. This does *not* mean that regulation and innovation (and thus regulators and innovators) are *never* at odds with each other. Indeed, we all have our just so stories and anecdotes of when regulation hindered innovation. However, while such "anecdata" is data, it is neither comprehensive data, nor exhaustive data, nor perhaps even representative data. In everyday life, we take such anecdata of regulatory failures as confirmation of our baseline (aka "folk") understanding of regulation; it comports with our priors so we don't update those priors. But should we be so comfortable in this confirmation of 'what everyone knows' about regulation?

This chapter has placed Stigler's (1971) "The Theory of Economic Regulation" in conversation with Streeck's "Beneficial Constraints: On the Economic Limits of Rational Voluntarism (1997) and generalized common concepts into five variables (relationship, information, driver, outcomes, and effect). Four of these variables were then used to define seven distinct regulatory imaginaries of disruptive technological innovation (DTI). This seven-model typology of regulatory imaginaries forms the basis of a broader understanding of the effects regulators can have on innovation.

Much as Ostrom (1990, 183) argued against the over-interpretation of certain endemic rational choice models, I am arguing that models that see regulation as an impediment to innovation "are special models that utilize extreme assumptions rather than general theories." Thus, I am not arguing (and would never claim) that regulation is *always good* for innovation. I am simply saying that the opposite is also untrue: regulation is not *always bad* for innovation even though we can all point to examples where it has been so.

Given the stakes of successful regulation of innovation for a well-functioning political economy, we should study situations and configurations where regulation can enhance innovation rather than erroneously assume that such a search is an a priori pointless endeavor. We must shift our folk model, our "common-sense understandings,"[181] from a perception of regulation as having one effect on innovation (an impediment) to a perception of regulation as having many possible effects on innovation (from impediment to catalyst of adoption).

All told, this chapter has analytically derived a way to understand regulators as more than mere dead weight. In Chapters 5, 6, and 7, I explore three different actually existing cases of innovation regulation that demonstrate the Beneficial Constraints and Adoption Catalyst models. I then employ the novel method of Bayesian Type Validation (BayesTV) to validate how confident we can be that the imaginaries derived in this chapter are the most likely state of the world in these three examples of actual existing innovation regulation.

[181] (D'Andrade 1987, 113)

CHAPTER 4

BAYESIAN TYPE VALIDATION

Validating Deductive Typologies with Logical Bayesianism for Discipline and Clarity

Typologies and process tracing are two shining pillars of qualitative methodology used to answer big questions in interesting ways. Thanks to the work of key methodological scholars, process tracing is recognized as the gold standard of within-case causal inference.[182] Similarly, typologies are the most significant contribution of many landmark qualitative studies which even the most skeptical quantitativists agree are best developed through qualitative methodology.[183]

Despite their well-established empirical and theoretical literatures, both are sometimes challenged by non-practitioners as nothing more than intuition and conjecture wrapped up in seductive yet ill-defined terms.[184] While the tone of these challenges may be based in methodological rivalry, the underlying critique illuminates that the process and results of process tracing and typology generation can be opaque to non-practitioners.

In response to these challenges, rigorous process tracers have proposed three formalizations of process tracing based on set theory, directed acyclic graphs (DAGs), and logical Bayesianism while rigorous typological theorists have formally specified inductive and deductive methods to generate typologies. As with all formalizations, both the strengths and limitations of the two methods were brought to light through the formalization.

In this paper, I demonstrate how the strengths of deductive typological theory can alleviate the limitations of logical Bayesian process tracing and vice versa to discipline and clarify the process and results of our methods. By definition, deductive typological theory completely maps a typological property space by constructing a mutually exclusive and exhaustive list of types based on combinations of constitutive variables. While Bayesian process tracing generally solves the requirement for exhaustive hypotheses by reasoned assumption, the process of deductive typological theory allows us to meet the requirement by design. Because Bayesian process tracing disciplines and clarifies how we are using case-specific knowledge and expert analysis, it allows us to transparently validate deductive typologies with inductive empirical knowledge.

The elementary method of process tracing is taught using the metaphor of Sherlock Holmes and uses colloquial names for four process tracing tests (straw in the wind, hoop, smoking gun, and doubly decisive).[185] The set theoretic and DAG approaches both formalize this vivid imagery into graphical representations while the logical Bayesian approach formalizes the informativeness of the evidence into numerical representations of human sensory perception. Bayesian process tracing best disciplines the analytic process and provides clarity to the

[182] (A. L. George and Bennett 2005, 179; Bennett and Checkel 2015, 4)
[183] c.f. (Moore [1966] 1993; Dahl 1971; O'Donnell 1973; Esping-Andersen 1990; Huntington 1993; Hall and Soskice 2001a). For the affirmation of quantitative scholars, see (Dunning 2012, 208–32)
[184] (Bennett and Checkel 2015, 4)
[185] (Collier 2011) documented and popularized this approach originally formulated by (Van Evera 1997)

intermediate and final results in terms consistent with human perception and the real number mathematics which are a part of general rather than specialist education.

One of the key requirements of the Bayesian approach is that it requires a mutually exclusive and exhaustive (MEE) specification of the rival hypotheses in order to properly adjudicate between rival hypotheses because it places odds ratios only on pairs of hypotheses. While MEE hypotheses are universally good research practice, most methods and the other process tracing formalization do not require MEE hypotheses. While leading BayesPT scholars have pointed out that it is always possible to rephrase a given set of hypotheses into an MEE specification, most hypotheses are not initially specified as MEE. Although the respecification is logically straightforward, the extra work and complexity of the final set of hypotheses has led some critics to question the value MEE and BayesPT more broadly due to the "cost of entry." Thus, while MEE is not a logical limitation of BayesPT, it can be a practical one which we can alleviate with deductive typological theory.

When generating typological theories, scholars can either inductively generalize from empirical specifics or deductively combine the scores of generalized concepts to generate a set of types. Inductive typological theory runs the risk of missing logically possible combinations which have not (yet) empirically occurred. Deductive typological theory runs the risk of over specifying possible combinations which are empirically uninteresting or irrelevant. While the final typologies which are published generally involve both of these fundamental theory generating processes to some degree, the way in which they are used is often vague in final research reports.

Together, deductive typological theorizing generates a set of mutually exclusive and exhaustive types which are then tested against empirical cases using logical Bayesianism to say how confident we can be that a particular case fits a given type. The results of this process can then be used inductively to refine the typology and applied iteratively to generate a final typology which balances analytic usefulness against empirical correspondence. Because the types developed by deductive typological theory need not be causal, I call this method Bayesian Type Validation (BayesTV) to distinguish it from the causal claims of Bayesian process tracing (BayesPT).

While BayesTV need not be causal, if only independent variables are used to specify the deductive typology (as is often the case) then the types can be used to generate hypotheses. By design, these hypotheses are MEE and can thus be tested with BayesPT. Because BayesPT is a within-case method, this allows typologies to be tested and refined using a small number of cases which do not require all configurations to have empirically occurred as is necessary for between-case analysis.

In order to show how BayesTV can provide a complete logic of qualitative theory generation and testing, I proceed as follows. First, I review the features of process tracing and three alternative formalizations which arose to make the methods more robust. I compare these three formalizations to the standard of analytic discipline and clarity of results to demonstrate that the logical Bayesian formalization (BayesPT) is the most fruitful. Next, I explain what BayesPT gains from deductive typological theory: an explication of the generation of mutually exclusive and exhaustive (MEE) hypotheses. I continue by specifying BayesTV as a combination of deductive typological theory and the logic of BayesPT which can be, but does not have to be, concerned with causal hypotheses. If causal hypotheses are desired, however, I then explain how

BayesPT allows us to easily deductively specify symmetrical ones and refine the set of hypotheses inductively as suggested by analysis of empirical evidence. I conclude by reviewing how BayesTV combines the deductive theory generation logic of typological theory with the inductive theory testing logic of the logical Bayesian formalization of process tracing (BayesPT) to create a logic of social inquiry which is rigorously and transparently qualitative 'all the way down.'

WHY *BAYESIAN* PROCESS TRACING?

Process tracing is often an opaque method to non-practitioners who criticize it as nothing more than intuition and conjecture wrapped up in a seductive yet ill-defined term.[186] In order to discipline and clarify our conjectures, I argue we should systematize process tracing with logical Bayesian.[187] Process tracing involves using causal process observations to adjudicate between rival causal hypotheses in specific cases.[188] Adding Bayesian logic to process tracing disciplines process tracing by requiring the analyst to clearly identify specific pieces of evidence and explain what they are saying about the likelihood of each rival hypothesis.[189]

In the subsections which follow, I will expand on the how adding Bayesian logic disciplines and clarifies process tracing and why I prefer the logical Bayesian formalization of process tracing to the set-theoretic and directed analytic graph (DAG) alternatives. While I hope you will agree with each of my methodological choices, if you do not at the very least you will be able to identify which one specifically troubles you.

FORMALIZING PROCESS TRACING TO DISCIPLINE ANALYSIS AND CLARIFY RESULTS

While process tracing may be uncontroversial as the gold standard of within case causal analysis, procedures for applying process tracing are much less unified. The elementary method of process tracing is taught using the metaphor of Sherlock Holmes and reference to colloquial names for four process tracing tests (straw in the wind, hoop, smoking gun, and doubly decisive).[190] Yet when publishing articles and books which employ process tracing, these colloquial names are generally dropped as they are thought to detract from the perceived seriousness of the studies.[191] To more rigorously represent the logic behind process tracing, scholars have developed several distinct streams[192] of more formal descriptions of the logic of process tracing based on set theory,[193] directed acyclic graphs (DAGs),[194] and logical Bayesianism.[195] Because set theoretic and DAGs still rely on metaphors, specifically graphical metaphors, I adopt logical Bayesianism to discipline my process tracing while acknowledging that these evolving formalizations of process tracing are still largely compatible and

[186] (Bennett and Checkel 2015, 4)
[187] Those familiar with Bennett's (2015) appendix in (Bennett and Checkel 2015) will recognize that I have paraphrased his title. I can think of no more concise justification for why I have added the Bayesian to my process tracing than that of the man who introduced me to method.
[188] (Collier 2011, 823)
[189] (Fairfield and Charman 2017, 1–2)
[190] Collier both documented and further popularized this excellent if casual approach in (Collier 2011). The tests were originally formulated by Van Evera (1997)
[191] Statement by Andrew Bennett at IQMR 2017.
[192] I am grateful for the census of these alternative formulations in (Bennett 2015, 276)
[193] (Mahoney 2012)
[194] (Waldner 2015a; 2015b)
[195] (Fairfield and Charman 2017; Bennett 2015)

commensurate.[196] In other words, I argue we adopt Bayesian process tracing (BayesPT) because it works best for me both to execute research and to communicate research findings without disregarding that set theoretic approaches or DAGs could provide a similar benefits to other practitioners.

However, as I explain below, the use of continuous rather than discrete mathematics and a logarithmic scale based on human sensory perception suggests to me that what works for me may also be easiest for credulous non-practitioners to understand as well. For the incredulous skeptic, BayesPT is exceptionally clear in how it uses data to form inferences,[197] meaning that we can at least focus critique on adjudicating evidence rather than on unproductive attempts to undermine the legitimacy of other methods.

THE FOUR COLLOQUIAL PROCESS TRACING TESTS

Whereas quantitative methods and natural experiments are intended to be analogous to drug development studies interested in average treatment effects, process tracing is analogous to clinical medicine or a police detective who is interested in understanding causality in a single specific case.[198] The police detective version of this metaphor led to the development of four different tests which evidence can put rival hypotheses through. These four tests are a deductively complete mapping of necessary and sufficient conditions for affirming causal inference of a specific hypothesis.[199] While Figure 1 explains all the details and consequences of each test, for our purposes what is relevant is the conceptual format of the tests: they are presented as a 2x2 graphical representation of a logical relationship. While it may have become cliché to say that the 2x2 is the 'swiss army knife' of social science, this analytic tool is nevertheless a powerful way to order our thinking. However, it is unclear what the next step beyond writing the 2x2 is; how do we carry this order further into our thinking other than to simply apply the four test names consistently?

[196] Bennett (2015, 276) proposes the commensurability and possible lack of methodological consequences to these different approaches. Barrenechea and Mahoney (2017) explicitly and formally elucidate the conceptual compatibility between their set theoretic approach and the Bayesian alternative.

[197] (Fairfield and Charman 2017, 13–17), the pioneers of logical Bayesian process tracing, convincingly make the same argument about the benefits of BayesPT in directing criticism to where it belongs (the data and argument) rather than at scholar's methods.

[198] (Bennett and Checkel 2015, 13–14; Collier 2011)

[199] (Collier 2011, 825)

Figure 1: The Colloquial Process Tracing Tests from (Collier 2011, 825)

		SUFFICIENT FOR AFFIRMING CAUSAL INFERENCE	
		No	Yes
NECESSARY FOR AFFIRMING CAUSAL INFERENCE	No	**1. Straw-in-the-Wind**	**3. Smoking-Gun**
		a. Passing: Affirms relevance of hypothesis, but does not confirm it.	**a. Passing:** Confirms hypothesis.
		b. Failing: Hypothesis is not eliminated, but is slightly weakened.	**b. Failing:** Hypothesis is not eliminated, but is somewhat weakened.
		c. Implications for rival hypotheses: **Passing** *slightly* weakens them. **Failing** *slightly* strengthens them.	**c. Implications for rival hypotheses:** **Passing** *substantially* weakens them. **Failing** *somewhat* strengthens them.
	Yes	**2. Hoop**	**4. Doubly Decisive**
		a. Passing: Affirms relevance of hypothesis, but does not confirm it.	**a. Passing:** Confirms hypothesis and eliminates others.
		b. Failing: Eliminates hypothesis.	**b. Failing:** Eliminates hypothesis.
		c. Implications for rival hypotheses: **Passing** *somewhat* weakens them. **Failing** *somewhat* strengthens them.	**c. Implications for rival hypotheses:** **Passing** *eliminates* them. **Failing** *substantially* strengthens.

Source: Adapted from Bennett (2010, 210), who builds on categories formulated by Van Evera (1997, 31–32).

Set-Theoretic Process Tracing Disciplines Analysis with Limited Clarity of Results

One approach scholars have taken to further ordering our thinking when process tracing is to conceptualize the result of passing or failing as altering the absolute and relative size of the set of possible worlds (H_1) where hypothesis H_1 is true and the complementary set of possible worlds ($\sim H_1$) where H_1 is not true.[200] This *set theoretic* conceptualization of the results of process tracing tests is represented graphically in Figure 2. A piece of evidence (k) is used to eliminate an absolute number of possible worlds which changes the balance between the number of possible worlds consistent with H_1 and $\sim H_1$ which affects our relative degree of belief in whether H_1 is likely to be true. The four different process tracing tests from the colloquial formulation in Figure 1 can be translated into a continuous space (Figure 3) based on the different ways they affect the set of possible worlds.

While the complete details of set theoretic process tracing appear in Figure 3, for our purposes what matters is that set theory elaborates the graphical 2x2 of the colloquial theory with another intrinsically graphical representation of logical relationships. Graphical relationships are, of course, illuminating and set theory's focus on possible worlds is a useful additional metaphor which allows us to understand the results of process tracing tests rather than simply the process of applying them. However, we once again reach a methodological barrier where further elaborating the set-theoretic approach takes us further into the increasingly esoteric mathematical symbols (i.e. ∋,∈,∪,∩) of discrete mathematics which ultimately represent graphical properties

[200] (Barrenechea and Mahoney 2017, 5–12)

rather than the continuous mathematics that even non-quantitative scholars are familiar with.[201] As with any use of symbolic mathematics, this is not wrong but it does decrease the legibility and intelligibility for non-experts. Therefore, as a conceptualization of process tracing, the set-theoretic method disciplines our application but is limited in how far it can go without decreasing the clarity of explanation to non-practitioners of the method.

Figure 2: Set-Theoretic Conceptualization of Process Tracing Test Effects on Possible Worlds from (Barrenechea and Mahoney 2017, 9)

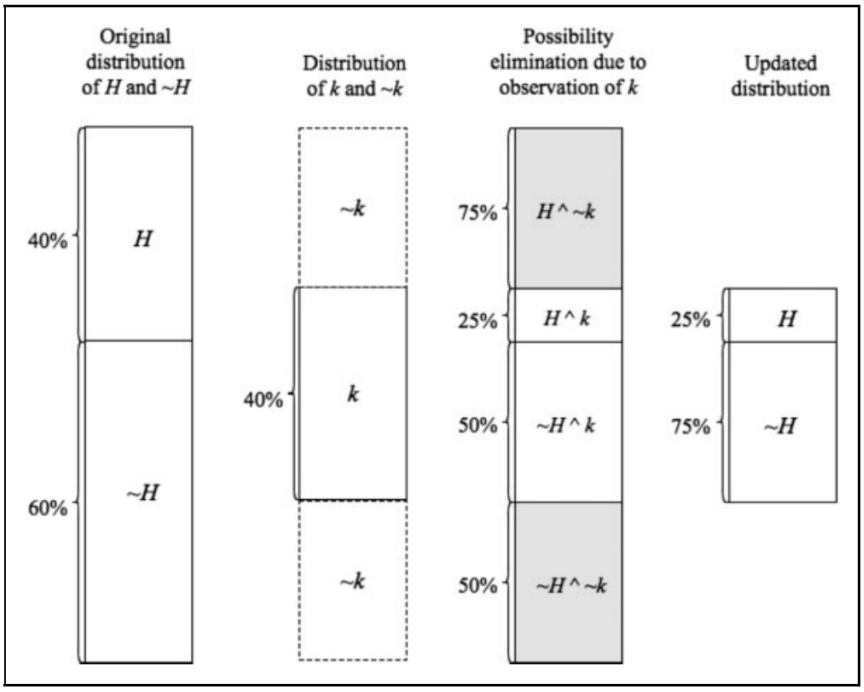
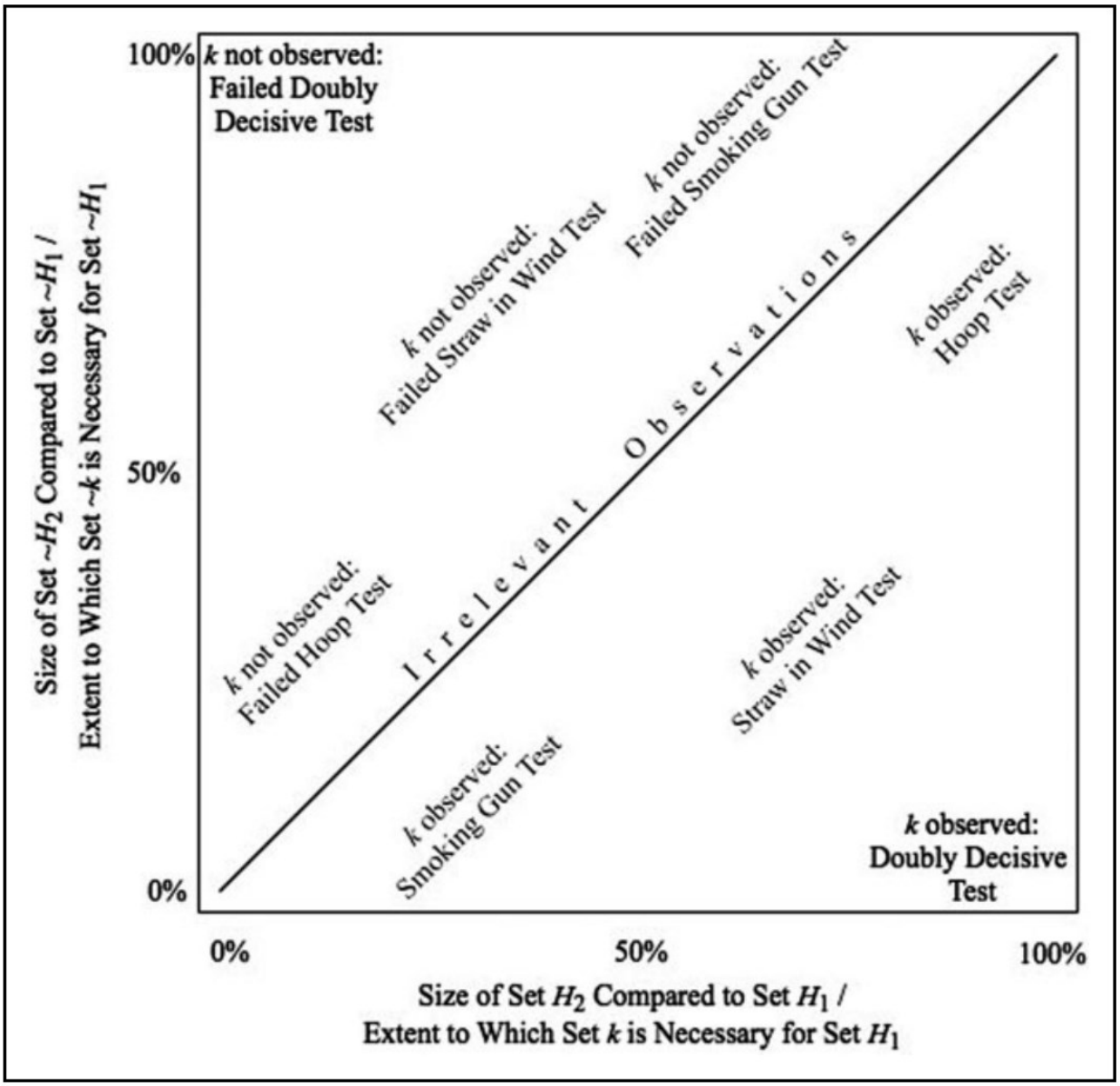


Figure 2. Set diagram illustrating subjective updating through possibility elimination. H = possible worlds in which the hypothesis is true; $\sim H$ = possible worlds in which the hypothesis is false; k = possible worlds with observed evidence; $\sim k$ = possible worlds lacking observed evidence; ^ = logical AND; shaded areas = elimination sets (possible worlds eliminated as impossible).

[201] Continuous mathematics is the "standard" mathematics of real numbers that most students learn in primary and secondary general education while discrete mathematics is typically only taught to those who will use it for their chosen profession, such as certain fields of engineering or computer science. While one could take this as a chance to criticize the state of education in the United States, if our goal is to explain our method and findings to non-experts in our methods then we should meet them on common terms rather than berate them for not meeting some contingent standard of 'proper competency.'

Figure 3: The Set Theoretic Translation of the Colloquial Process Tracing Tests from (Barrenechea and Mahoney 2017, 26)



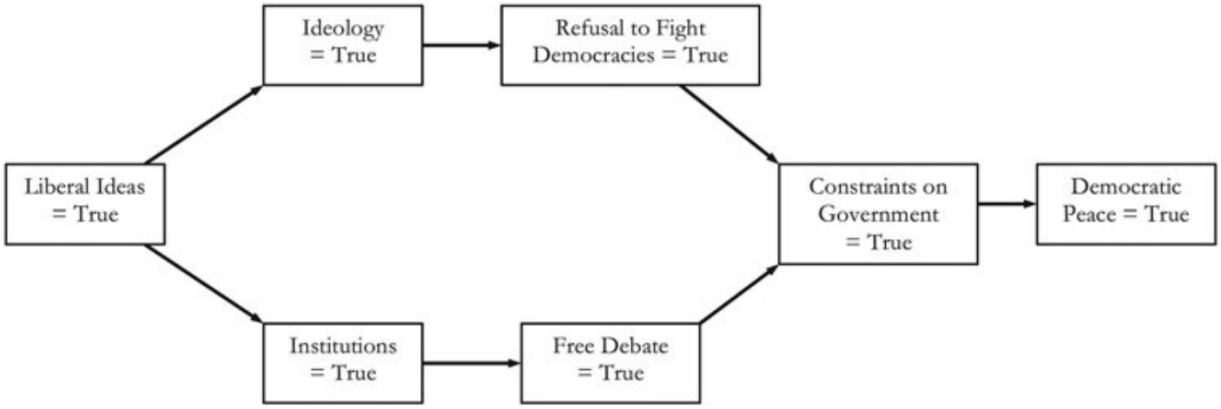
DIRECTED ACYCLIC GRAPHS (DAGS) CLARIFY RESULTS BUT WEAKLY DISCIPLINE ANALYSIS

Hewing closer to descriptive clarity for non-practitioners, directed acyclic graphs (DAGs) focus on clear explication of the final result of the process tracing tests at the expense of black-boxing the practicalities of how the final result was generated. DAGs are the formal name for what many of us know as causal diagrams; they consist of nodes which are specific variable scores and arrows which show how particular scores cause additional observable implications.[202] A fully detailed example of a DAG can be seen in Figure 4, but for our purposes what matters is that the representation of the causal process is again graphical and only represents a single causal

[202] (Waldner 2015b, 247)

process. Whereas the set-theoretic approach emphasizes the process of rejecting rival hypotheses by explicitly discarding alternative possible worlds based on evidence, DAGs simply present the final causal process or processes which result from the analysis. Once again, this methodological choice is not wrong but it does decrease the transparency of the analytic process which reduces the ability of other researchers to understand how the analysis of evidence was disciplined. A DAG is quintessentially a representation of the *result* of scholarly analysis rather than of the analysis itself.

Figure 4: An Example Directed Acyclic Graph (DAG) of Liberal Democratic Peace from (Waldner 2015b, 247) based on (Owen 1994)



BAYESIAN PROCESS TRACING DISCIPLINES ANALYSIS AND CLARIFIES RESULTS

In order to maximize both the discipline of the analytic process as well as the clarity of the final result, Bayesian process tracing (BayesPT) uses logical Bayesianism to iteratively and transparently engage in a "dialogue with the data."[203] This dialog allow the analyst to rationally update her degree of belief in rival hypotheses given the information she possess.[204] Pushing beyond the spatial and graphical representations of logical relationships from the set-theoretic and colloquial formulations, Bayesian process tracing sees "evidentiary confirmation [as] always a matter of degree, not type."[205] This move from graphical representations of the tests to continuous degrees of belief allows BayesPT to retain the standard continuous algebra of real numbers which is widely understood even by practitioners of non-quantitative methodologies. This continuous algebra also allows BayesPT to represent explicitly and formally the iterative interaction between each piece of evidence and our degree of belief in rival hypotheses using standard algebraic operations and symbols. Thus, BayesPT both disciplines process tracing during analysis and clarifies the results by using continuous (rather than discrete) algebra to transparently update our degree of belief in rival hypotheses using clearly identified evidence.

While it is critical for discipline and clarity that BayesPT is based on explicit continuous numbers, in practice it is often useful to abstract back to a metaphorical 'dialog with the data' to avoid an impractical exhaustively explicit application which drowns the reader in data at the

[203] Fairfield and Charman (2017, 1) credit Astrophysicist Stephen Gull quoted in (Sivia 2006) for this definitional characterization of Bayesian probability. They also adopted the phrase for the title of a follow-up paper (Fairfield and Charman 2019).
[204] (Fairfield and Charman 2017, 3)
[205] (Fairfield and Charman 2017, 3)

expense of analysis and the researcher in explication at the expense of synthesis.[206] Because BayesPT has the formal mathematical power to explicitly represent how informative every single quanta of evidence is, there is the danger that a researcher might attempt to do so, that a reviewer might unreasonably demand such an implementation, and that a reader might be overwhelmed with so many minutiae that they will lose clarity on the forest due to the excessive clarity of the trees. However, because BayesPT is based on continuous mathematics, Fairfield and Charman propose that we use the same mathematical power which could sink us to instead tame the underlying complexity into metaphorical clarity by using logarithmic scales and odds ratios to quite literally delineate how 'loudly' each piece of evidence is speaking to us.[207]

Fairfield and Charman recommend that we adopt logarithmic scales and the decibel metaphor for our probabilities in Bayesian process tracing because human sense perception is logarithmic: a perceived doubling of a stimulus intensity (light brightness or sound loudness) requires a 10-fold increase in absolute intensity (as measured by an objective instrument).[208] This psychophysical finding (known as the Weber-Fechner Law) allows us to literally discipline our metaphorical 'dialog with the data' the same way physicists discipline the study of sound: with the decibel, a logarithmic unit used to quantify power ratios. When we say that a particular piece of evidence is whispering or shouting, we are expressing the importance of data using human sense perception literally and figuratively. In both senses, then, it naturally follows that we should discipline that analysis of the data by using the unit developed to describe such sensory perceptions: the decibel. And by translating our expert analysis into a consistent and standard unit, we bring greater clarity to which evidence is saying what and how intensely.

Decibels bring us both discipline and clarity which are consistent with human sense perceptions, but they rely on ratios since they are a unit designed intrinsically to quantify the ratio between two quantities. Once again, this possible snag becomes a blessing because it forces us to recognize that when we say evidence speaks in favor of one hypothesis, we are (implicitly or explicitly) saying that it speaks more strongly for one hypothesis relative to another alternative hypothesis.[209] Because BayesPT is most clearly done in decibels and decibels are a unit based on ratios we are forced to be explicit about this weighing of evidence in light of rival hypotheses. We therefore must be clear about what our rival hypotheses are and how they relate to each other, an element of research design that all empirical social scientists laud.

Because BayesPT forces us to be explicit about our hypotheses and their relationships, it also encourages us to construct hypotheses which are *mutually exclusive* so that when we weigh them against evidence we are able to more easily delineate which hypothesis the evidence supports more (assign and odds ratio in decibels).[210] While this requirement for mutually exclusive hypotheses may sound like yet another pedantic rule for research design, it is actually always possible to translate a set of muddy non-mutually exclusive (non-rival) hypotheses and turn them

[206] (Fairfield and Charman 2017, 14–15)
[207] (Fairfield and Charman 2017, 10–11)
[208] This paragraph is a restatement of (Fairfield and Charman 2017, 10–11) with my comments on how this concept relates to discipline and clarity, my two standards for process tracing as a practical method.
[209] In statistical analysis, researchers refer at the very least to whether their evidence allows them to reject the null alternative hypothesis.
[210] (Fairfield and Charman 2017, 4–5)

into the rivals which our analyses rely on.[211] This can become a combinatorial challenge as hypotheses multiply to become mutually exclusive but this challenge is always implicitly present in our work and BayesPT forces us to be explicit about it.

Mutually exclusive hypotheses combined with testing hypotheses against each other using odds rations leads to the corollary requirement that we have an *exhaustive* set of hypotheses. Without an exhaustive set of hypotheses, deciding which of our hypotheses is most supported by the evidence means very little because we don't know what the other unknown explanations are. In practice, BayesPT often solves this problem by explicitly assuming that the set of mutually exclusive hypotheses are exhaustive[212] in much the same way that rational choice theorists assume rationality or natural experimenters assume "as if random" assignment in their work. As with all assumptions, the less realistic this assumption is to the field of study, the less revelatory the findings are.[213] It also places the onus squarely on the analyst to justify their assumptions, further encouraging ordered thinking and explicit argumentation.

Ultimately, BayesPT is the most fruitful formalization of process tracing because it both disciplines the analytic process and provides clarity to the intermediate and final results in terms consistent with human perception and the real number mathematics which are a part of general rather than specialist education. The four colloquial process tracing tests are a powerful disciplining of within case analysis which can be logically related to each other based on necessary and sufficient conditions but they do not lend themselves to further formalization.

The set-theoretic formalization is a powerful graphical formalization of the process of process tracing but the final result still requires either a picture, a narrative description of a picture, or a specialist understanding of discrete mathematics. While a picture may be worth a thousand words and an incentive to learn a new mathematical toolset is attractive to some, a formalization which is intrinsically graphical ultimately leaves us trying to describe a picture with words which brings to mind the parable of blind men trying to describe an elephant.

Directed acyclic graphs (DAGs) have the same graphical issues as the set theoretic formalization, but without the discipline and clarity in the analytic process because they are ultimately a pure reflection of the results of a process tracing analysis. Especially by non-practitioners, process tracing is criticized as undisciplined conjecture with unclear results. Because it intrinsically encourages and requires both discipline and clarity in analysis and presentation of results, Bayesian process tracing is the most useful formulation of process tracing.

WHAT BAYESPT NEEDS (AND GETS) FROM DEDUCTIVE TYPOLOGICAL THEORY

In the last section, I argued that Bayesian process tracing (BayesPT) provides is the most fruitful formalization of process tracing because it provides discipline and clarity in both the analysis and presentation of results. However, this discipline and clarity comes at the perceived

[211] (Fairfield and Charman 2017, 4) provide an explicit example of rent seeking vs. representation in presidential policy motivations, but the general idea is that we state our two non-exclusive hypotheses as a number of rival exclusive hypotheses which talk about the *relative* importance of one vs. the other non-exclusive hypothesis.
[212] (Fairfield and Charman 2017, 5)
[213] For this specific project, I explain below how I will use a deductive typology to solve the exhaustive hypotheses criteria by design rather than merely as an assumption.

cost of mutually exclusive and exhaustive (MEE) hypotheses. While it would behoove all scholars to lay out MEE hypotheses when testing the causes of an effect, in practice this requirement seems like an undue burden.

In the pioneering specification of BayesPT, Fairfield and Charman clearly explain that it is always possible to rephrase a given set of hypotheses into a MEE specification.[214] However, most hypotheses are not initially specified as MEE. Although the respecification is logically straightforward, the extra work and complexity of the final set of hypotheses has led some critics to question the value MEE and BayesPT more broadly due to the "cost of entry."

Thus, while MEE is not a logical limitation of BayesPT, it can be a practical one which we can alleviate with deductive typological theory. By generating an exhaustive typological property space from constitutive variables, deductive typological theory specifies a set of MEE types. If the variables used as constitutive variables are also independent variables, as they often are, then the types are hypotheses about possible states of the world. In this (very common) case, MEE *types* become MEE *hypotheses* thus providing a clear logic for specifying MEE hypotheses and reducing the perceived cost of entry of BayesPT. In the next section, I take a step back to explain how deductive typological theory works and then explain how the types-to-hypotheses transliteration follows from this process.

BAYESIAN TYPE VALIDATION: CLOSING THE INDUCTIVE-DEDUCTIVE LOOP IN TYPOLOGY CREATION

Process tracing involves using causal process observations to adjudicate between rival causal hypotheses in specific cases.[215] As we saw in the previous sections, adding Bayesian logic to process tracing disciplines the method by requiring the analyst to clearly identify specific pieces of evidence and explain what they are saying about the likelihood of each rival hypothesis.[216] When applied to a typology, the rival hypotheses are instead different types which are constituted (caused to exist)[217] by constituent variables. When empirical cases are examined to validate the typology, we are therefore adjudicating between how likely a type is to be the true state of the world "at work" in that case. In terms of variables and evidence, we are applying logical Bayesianism to the empirical record of what happened in a particular case to inform us about how confident we can be that (1) each of the constitutive variables has a particular value and (2) that particular configurations of those values together mean that one type rather than another is the true state of the world in that case.

Deductive typological theory[218] uses constitutive variables to define a typological property space that contains an exhaustive set of types based on the combinations of the scores on the constitutive variables. As the most disciplined and clear formalization of process tracing, Bayesian process tracing (BayesPT) allows us to explore how confident we can be that these deductively developed types empirically exist. If we find evidence which suggests that there is some new value or additional variable which is relevant to the typology, deductive typological

[214] (Fairfield and Charman 2017, 4)
[215] (Collier 2011, 823)
[216] (Fairfield and Charman 2017, 1–2)
[217] (Waldner 2015b, 243; 2016, 30)
[218] (A. L. George and Bennett 2005, 244)

theory allows us to integrate that finding seamlessly into the typological property space.[219] Together, therefore, deductive typological theory and BayesPT form an inductive-deductive link the theoretical and empirical analyses and contributions.

Beyond the simple practicality of combining the two pillars of qualitative research, deductive typological theory and BayesPT are also methodologically well matched because deductive typological theory solves the mutually exclusive and exhaustive challenge of BayesPT. By definition, deductive typological theory completely maps a typological property space by constructing an exhaustive list of types based on the constitutive variables.[220] While BayesPT generally solves the requirement for exhaustive hypotheses by assumption,[221] this feature of deductive typological theory allows us to meet the requirement by design. By definition, the 24 configurations I derive from my four constitutive variables of relationship, access, impetus, and outcomes and the seven substantive types I group those 24 configurations into are an exhaustive set of regulatory imaginaries.[222]

Note that the types developed by deductive typological theory need not be causal. To separate the requirement for causal claims from the analytic benefits of logical Bayesianism, I call this method *Bayesian Type Validation (BayesTV)*. Yet while BayesTV *need* not be causal, if only independent variables are used to specify the deductive typology (as is often the case) then the types *can* be used to generate hypotheses. By design, these hypotheses are MEE and can thus be tested with BayesPT. Because BayesPT is a within-case method, this allows typologies to be tested and refined using a small number of cases which do not require all configurations to have empirically occurred as is necessary for between-case analysis.[223]

HOW VARIABLES CONSTITUTE TYPES IN A TYPOLOGY

Whether or not it is explicitly a hypothesis, nested within each deductive type is another form of irreducible invariant causality. Baked in by deductive typological theory, the specific scores on the constitutive variables cause the type to exist. This form of the constitutive causality is core to BayesTV because it is the form of causality which asks "How do you know that type X exists?"

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[219] See Chapter 3 for an example of a typological property space (the Typology of Regulatory Imaginaries).

[220] (A. L. George and Bennett 2005, 248)

[221] Although this is always a preliminary rather than canonical assumption; the BayesPT researcher is specifically directed to interrogate this assumption whenever there is reason to believe, in light of evidence, that a new hypothesis is warranted.(Fairfield and Charman 2017) If the BayesPT researcher decides a new hypothesis must be added to maintain the assumption of exhaustive hypotheses, then they must update their entire analysis. However, as all Bayesianism is about updating of priors based on evidence, transparently iterative updating of research design should neither be seen as either a problem nor dissuade prospective Bayesian process tracers from employing the method. See (Fairfield and Charman 2019) for a further elaboration of the iterative nature of all (good) research in the social, natural, and biological sciences and why Bayesianism helps to address concerns that frequentist statisticians have dogmatically perpetuated into all social scientific methodologies about the dangers of mixing deduction and induction.

[222] See Chapter 3 for an example of a typological property space (the Typology of Regulatory Imaginaries).

[223] Note that this does not violate the so-called "Fundamental Problem of Causal Inference" because it does not claim to observe the counterfactual. Rather, it states that even if there are some types which we are unable to validate because they have not happened in the world (and are thus counterfactual) this does not mean we are unable to validate other types which have empirically occurred. This is, in fact, the fundamental purpose of within-case analysis.

This type of causality draws upon Waldner's focus on invariant causal mechanisms which stipulate that the ultimate standard for process tracing should be to reduce all processes down to invariant mechanisms which always produce completely predictable results.[224] Waldner employs the arson vs. fire metaphor: in a specific case of arson, a spark hitting an accelerant may have burned a building down but spark+accelerant=burning a building down is not an invariant causal mechanism because spark and accelerant do not always lead to a building being burned down. Rather, the invariant mechanism is the peculiar interaction of the specific structure of the dioxygen molecule with a fuel source which we call combustion. Waldner argues this need to drill down to invariant causal mechanisms, what he calls the completeness standard, does *not* mean that all other work is pointless but instead endeavors to lay out what a truly complete process tracing should be to claim true causal inference.[225]

As with anything aspiring to be a completeness standard, leading process tracing scholars have pointed out that "It sets the bar so high that it is not clear how anyone can reach it."[226] I absolutely agree with this argument against purity tests in general and the negative incentives it can lead to across a wide variety of process tracing practice. As with Fairfield and Charman's (2017, 14–15) caution against setting a norm requiring explicit BayesPT, this caution against a completeness standard as the only truth of causality is well heeded.

However, the combination of logical Bayesianism with deductive typological theory allows BayesTV to meet the completeness standard. Because the constitutive variables used to construct the typological property space categorically and invariably define the types within that space, they meet the completeness standard. Indeed, I adopted Waldner's more specific 'constitutive'[227] adjective for my typology defining variables rather than independent because, while they may be independent variables,[228] they are relevant to the typology in their constitutive role and their independence or dependence is incidental to the deduction of the typology.

The core of BayesTV is the use of logical Bayesianism from BayesPT to empirically validate our degree of belief that types created by deductive typological theory empirically exist. Due to the complementary characteristics of BayesPT and deductive typological theory, BayesPT is able to meet the completeness standard for invariant mechanisms and solve the mutually exclusive and exhaustive (MEE) rival hypotheses requirement of BayesPT *by design* rather than by reasoned argumentation.

Some readers might argue that this complementary nature is too perfect and there must be a rub. I would argue that this suspicion is no more relevant than suspicion of formal theory because of the assumption of rationality or the suspicion of natural experiments due to the assumption of "as if random" assignment.[229] Each of those assumptions and characteristics are necessary for their methods to be possible and potentially limit the scope of their analysis and the

[224] (Waldner 2015b, 242–43; 2016)
[225] (Waldner 2015a)
[226] (Checkel and Bennett 2015, 265)
[227] (Waldner 2015b, 243; 2016, 30)
[228] or dependent variables in principle, although if you wish to generate hypotheses you cannot use dependent constitutive variables
[229] While some may argue that I have placed BayesTV in controversial company, I would direct the reader to the admonition about models in Elinor Ostrom's (1990, 21–28) Nobel Prize winning work which explains that the pitfalls of any rigorous method lies not in the logic of the method but in the overextrapolation of results. As Dani Rodrik (2015b, 17–44) would put it, formal theory, natural experiments, or any model derived from a rigorous method runs into trouble when it claims to be *the* model rather than *a* model.

generalizability of their results; they are features, not bugs. Why should BayesTV be any less valid because it, too, has intrinsic design restrictions like any other method?

WHAT DEDUCTIVE TYPOLOGICAL THEORY NEEDS (AND GETS) FROM BAYESIAN PROCESS TRACING

As discussed in the previous section, deductive typological theory applies an invariant conceptual structure to systematically lay out all possible combinations of the constitutive variables. This gives a deductively defined theory several beneficial features which can be leveraged to improve research discipline and clarify results. Because all types in a deductive typology are derived from constitutive variables, they contain a consistent embedded narrative logic which allows them to be algorithmically turned into hypotheses. In this section, I demonstrate this process using the empirical case of regulation of disruptive innovation from other work.

In Chapter 3, I developed a seven-part typology of regulatory imaginaries. That chapter placed Stigler's (1971) "The Theory of Economic Regulation" in conversation with Streeck's "Beneficial Constraints: On the Economic Limits of Rational Voluntarism (1997) and generalized common concepts into five variables (relationship, access, impetus, outcomes, and effect). Four of these variables were then used to define seven distinct models which regulators use to respond to disruptive technological innovation (DTI). This seven-model typology of regulatory imaginaries forms the basis of a broader understanding of the effects regulators can have on innovation beyond merely a dead-weight loss.

Because deductive typological theory applies an invariant conceptual structure to systematically lay out all possible combinations of the constitutive variables, every raw type in Table 6 has a consistent relationship between all of the variable scores. Thus, underlying each of the raw types in the typology property space is a hypothesis about how the four constitutive variables create a particular belief about a regulator's effect on innovation (the dependent variable) because each of the constitutive variables are independent variables.

By design of the deductive typological theory, then, each of these hypotheses has the standard and consistent form of:

*In response to a disruptive technological innovation, a regulator who sees themselves as a **[Relationship]** who has **[Information]** access to information than firms in the affected regulatory domain and believes that the **[Driver]** is the impetus for the spread of that innovation sees **[Outcomes]** optimal regulatory arrangements and thus believes that they will be an **[Effect]** of innovation.*

This leads to specific example hypotheses such as:[230]

- Folk Economic$_1$: In response to a disruptive technological innovation, a regulator who sees themselves as a rulemaker who has lower access to information than firms in the affected regulatory domain and believes that the market is the driver for the spread of that innovation sees zero optimal regulatory arrangements and thus believes that they will be an impediment to innovation.

[230]Note, each name is based on the model name and the typology space index number in subscript corresponding to the typology property space in Table 1.

Table 6: Complete Typological Property Space of Regulatory Imaginaries

		Constitutive Variables (Independent Variables)				Dependent
Name of Imaginary	**#**	**Relationship**	**Info**	**Driver**	**Outcomes**	**Effect**
Folk Economic Model (Christensen 1997)	1	Rulemaker	Lower	Market	Zero	Impediment
	2	Rulemaker	Lower	Market	One	Impediment
Market Ideological*	3	Rulemaker	Higher	Market	Zero	Impediment
	4	Stakeholder	Higher	Market	Zero	Impediment
State-as-Venue (Skocpol 1985)	5	Rulemaker	Lower	Regulator	Many	Moderator
	6	Stakeholder	Lower	Market	Many	Moderator
	7	Stakeholder	Lower	Regulator	Many	Moderator
Capture (Stigler 1971)	8	Stakeholder	Lower	Market	One	Constrainer
	9	Stakeholder	Lower	Regulator	One	Constrainer
Technology-Based Regulation "Conventional Command and Control" (Malloy 2010)	10	Rulemaker	Higher	Market	One	Constrainer
	11	Rulemaker	Lower	Regulator	One	Constrainer
	12	Stakeholder	Higher	Market	One	Constrainer
Beneficial Constrainer (Streeck 1997)	13	Rulemaker	Higher	Market	Many	Constrainer
	14	Stakeholder	Higher	Market	Many	Constrainer
Adoption Catalyst	15	Rulemaker	Higher	Regulator	Many	Catalyzer
	16	Stakeholder	Higher	Regulator	Many	Catalyzer
	17	Rulemaker	Higher	Regulator	One	Catalyzer
	18	Stakeholder	Higher	Regulator	One	Catalyzer
Trivial	19	*Rulemaker*	*Lower*	*Regulator*	*Zero*	*Impediment*
	20	*Stakeholder*	*Lower*	*Regulator*	*Zero*	*Impediment*
	21	*Rulemaker*	*Lower*	*Market*	*Many*	*Impediment*
	22	*Stakeholder*	*Lower*	*Market*	*Zero*	*Impediment*
Logically Inconsistent	23	~~Rulemaker~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~
	24	~~Stakeholder~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~

* (Henderson and Appelbaum 1992) completed Chalmers Johnson's (1982) 2x2 of market|plan x rational|ideological by defining the idea of "market ideological" which privileges market structures for organizing social and economic interaction beyond efficient cost-benefit tradeoffs due to an ideological preference for market structures over planning. More modern ears are more familiar with the term "market fundamentalism" as popularized by George Soros (1998) although the concept is as old as capitalism itself with well-reasoned critique of it at least as old as Polanyi ([1944] 1957). The modern usage is well explained in (Block and Somers 2014).

- Beneficial Constrainer$_{13}$: In response to a disruptive technological innovation, a regulator who sees themselves as a Rulemaker who has Higher access to information than firms in the affected regulatory domain and believes that the Market is the driver for the spread of that innovation sees Many optimal regulatory arrangements and thus believes that they will be a Constrainer of innovation.
- Adoption Catalyst$_{17}$: In response to a disruptive technological innovation, a regulator who sees themselves as a Rulemaker who has Higher access to information than firms in the affected regulatory domain and believes that the Regulator is the driver for the spread of that innovation sees One optimal regulatory arrangement and thus believes that they will be a Driver of innovation.

Hypothesis generation is one of the strengths of qualitative research which even quantitative scholars recognize, deductive typological theory provides a method to discipline and clarify this

process. By leveraging logical Bayesianism from BayesPT, BayesTV is also able to qualitatively refine and validate these hypotheses by treating our types as the hypotheses in process tracing. Thus, we can look for the evidence necessary to be confident that a particular regulator, entrepreneur, or other actor holds the constituent beliefs spelled out by a type.

If we find evidence which suggests that there is some new value for a constituent variable or some new variable itself, deductive typological theory allows this inductively gained knowledge from BayesTV to be consistently and easily incorporated. If we need to add additional variation to a constitutive variable, we add new rows to the typological property space (cf. Table 6) representing the additional combinations of variables scores. If we need to add an additional constitutive variable, we add a new column to the typological property space (cf. Table 6), define the possible values, and then add additional rows based on the combinations of variable scores.

BayesTV thus allows us to leverage the two gold-standard qualitative methods of typological theory and process tracing to close the inductive-deductive loop of theory building and theory testing. It also meets the rigorous completeness standard advocated by Waldner (2015a; 2016) by design. Finally, it provides the discipline and clarity necessary to provide a qualitative standard of rigorous transparency by highlighting where expert judgement was used and where decisions are irrefutable logical corollaries of those decisions.

BAYESTV IN PRACTICE: A SEARCH PROCESS

The above sections consider three formalizations of process tracing, argue for Bayesian process tracing (BayesPT) as the most fruitful to discipline analysis and clarify results, and then combines BayesPT with deductive typological theory to theoretically specify a new method called Bayesian type validation (BayesTV). This section moves from the theoretical to the practical specification of BayesTV by providing the concrete steps for deductive creation and inductive refinement of a typology.

AN OVERVIEW OF HOW TO APPLY THE METHOD

To efficiently classify cases and refine the deductive typology, BayesTV incorporates a search process that focuses on the most informative pieces of evidence. The first piece of evidence explicitly[231] analyzed for a case should be the strongest piece of support for the most likely type based on background knowledge of the case.[232] The second piece of evidence should

[231] Explicit Bayesian analysis (whether process tracing of hypotheses or validation of types) refers to the use of mathematical likelihood ratios as developed in (Fairfield and Charman 2017) and refined in (Fairfield and Charman 2022). Implicitly, all process tracing and most qualitative research can be described as a Bayesian method of reasoning.(Fairfield and Charman 2017, 1–2) The choice of 'how explicit to get' is a tradeoff between exhaustive transparency and laboriousness which should be decided on how informative additional explicit analysis would be as opposed to an implicit summary of the weight of evidence.

[232] Since BayesTV is concerned with type validation, cases are selected using background information to be representative of a particular type. This is *not* a form of confirmation bias as the disciplined consideration of the likelihood of observing this evidence under *all* alternative types clearly and transparently presents the judgements made by the analyst. While a skeptic could certainly disagree with such judgment, the goal of a logical Bayesian approach is to clearly identify the "locus of contention" (Fairfield and Charman 2017, 16) rather than claim to be beyond contention or to set up an "entirely agree vs. entirely disagree" dichotomy. Where a transparent frequentist would rely upon preregistration of hypotheses and appeal to stochastic analysis to reject or fail to reject a null hypothesis, a Bayesian approach instead seeks to transparently state priors and indicate how evidence is used to update those priors.(Fairfield and Charman 2017, 1,6) The author and reader may ultimately disagree with the conclusions of a logical Bayesian analysis but both should be able to clearly state precisely where they disagree

be selected as the strongest piece of support for the nearest rival to the most likely type based on background knowledge of the case *and* analysis of the first piece of evidence. Once the first two pieces of evidence have been explicitly analyzed, BayesTV considers whether additional evidence needs to be analyzed based on the possible priors (naïve, skeptical, etc.) and how loudly the first two pieces of evidence have adjudicated between the possible types. The extreme counterfactual state of the world is also considered and evidence for such a "black swan" event is described and sought. Once the analyst is satisfied that sufficient explicit evidence has been analyzed to build a type validation case, the weight of the evidence is placed against defined sets of priors in order to identify the sensitivity of the classification to a reader's prior beliefs about the world.

As a process of search built on highlighting the most informative pieces of evidence, BayesTV (and all logical Bayesianism) relies on the *information value* of evidence rather than the idiosyncrasies of a specific piece of evidence. While specific pieces of evidence are presented below, they are analyzed as a representative of all "informationally equivalent"[233] evidence which provides insight into the relative likelihood of which type is the true state of the world. Thus, what may appear to be a selective reification of evidence is actually a carefully considered process of which evidence to highlight in the explicit analysis in order to distinguish between possible states of the world in a clear and disciplined manner.

In metaphorical terms, the goal of BayesTV is not to cut a node out of its web of interconnections and carefully study its nodal properties under a microscope but rather to carefully consider which node to lift from a web in order to trace the interconnections. The goal is always to pull on the node which reveals the most information about the web rather than to find the most perfect individual node.

This focus on information value may appear unsettling to traditional qualitative scholars who emphasize the richness of evidence presented in their case narrative built upon deep case knowledge[234] to judge the effectiveness of an argument. Indeed, it may seem like cherry picking only one or two pieces of self-justificatory evidence!

However, as qualitativists have long pointed out to quantitativists when accused of selecting on the dependent variable or having too many variables for too few cases, one cannot naïvely apply frequentist statistical intuition to qualitative work.[235] While other qualitative methods such as analytical narratives and comparative historical analysis place their empirical richness directly into the text of their research reports to demonstrate analytic rigor, BayesTV uses deep case knowledge to rigorously highlight the most informative evidence in their research reports. Akin to Charles Proteus Steinmetz, who was hired by Henry Ford to fix a generator and invoiced $10,000 for a single chalk X and two lines of instructions, only a small bit of evidence may appear in the final writeup ('$0.01 of chalk') but the expertise and deep case knowledge lies in

(evidence selection, likelihood ratios, missing hypotheses/theories in the set, etc.) rather than rely on less precise statements of agreement or disagreement based on sum total statements or reverse-engineering of an argument.

[233] (Fairfield and Charman 2017, 5 in Online Appendix)

[234] C.f. (Johnston 2012, 70) and "the importance of local or area knowledge for general theory."

[235] Compare the logic of (Brady and Collier 2010) to that in (Gary King, Keohane, and Verba 1994). A concise review of the struggles of quantitativists to grapple with qualitative evidentiary standards appears in (Fairfield and Charman 2022, 124–26).

knowing which piece to highlight to maximize information value ('$9,999.99 for knowing where to place the X').[236]

Building on deductive typological theory and the inductive logic of logical Bayesian process tracing, Bayesian Type Validation (BayesTV) employs a disciplined process of search for informative evidence in order to provide transparently produced degrees of belief in whether a particular case is most plausibly operating under a particular type rather than the rival types. In this project, this translates into degrees of belief about whether regulators are truly operating under one type of regulatory imaginary (e.g. folk economic impediment) or another (e.g. beneficial constraint, adoption catalyst, etc.). As the goal of this project is to inductively refine the deductive typology developed in Chapter 3, BayesTV is well suited to demonstrating how confident we can be that real empirical examples exist of the variety of ways that regulators, entrepreneur, and innovators co-create disruptive technological innovation.

POSSIBLE TYPES AND PRIORS

Before analyzing evidence, however, Bayesianism requires that you consider priors. In the case of BayesTV, these priors should be weights of evidence for each of the six alternative imaginaries in the typology (Table 6) relative to the most likely type.[237] These seven models present the rival worlds under which BayesTV must evaluate the evidence in order to conclude which model the evidence speaks most strongly for.[238]

We can assign several possible prior probabilities to the case being of a particular type.[239] If we are to adopt a *naïve* assumption, we would weight all seven imaginaries equally with no weight-of-evidence (WoE) for any of them (0 dB across all imaginaries, see Table 7).

We could also consider what priors *common background information* and *case-specific background knowledge* might suggest. Common background knowledge refers to background knowledge about the characteristics of the technology or of the specific imaginary. For example, biotechnology may always lead us to think of catastrophic outcomes and presume that a more constraining type needs a stronger prior. Case specific background knowledge relies upon our historical analysis of the case; if a particular type is often assigned in the literature[240] or by actors and informants in the case, then we should assign some weight to this background information. The background info column in Table 7 shows a prior of moderate weight (10 dB) in favor of Market Ideological relative to Beneficial Constraints, of strong weight (20 dB) in favor of State

[236] (Gilbert King 2011)

[237] The most likely type is generally selected based on what type we are attempting to validate in our case. Methodologically and mathematically, it does not actually matter what type we use as the common comparator because all of the comparisons could be converted to an equivalent set based on comparisons to an alternative comparator, but choosing the one of substantive interest makes practical sense. In the examples which follow in this chapter, Beneficial Constraints will serve as the comparator (numerator).

[238] (Fairfield and Charman 2017, 1,10)

[239] Following the advice of (Fairfield and Charman 2017, 3-4 in online appendix), this paragraph presents extremes and a paradigmatic midpoint. The reader could adopt whatever priors they see fit, but it is most instructive to think in classes of priors rather than a continuum because we can then concentrate on tipping points. Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival.

[240] For example, US Gene Editing regulations is often accused of being Captured by biotechnology companies. See Chapter 6 for further discussion.

Table 7: Prior Weights of Evidence Examples (in dB)

Weight of Evidence (WoE)*	Naïve	Background Info	Skeptical
$\frac{\textbf{Beneficial Constraints}}{\textbf{Adoption Catalyst}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Capture}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Technology Based Regulation}}$	0 dB	-30 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{State as Venue}}$	0 dB	-20 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Folk Economic Model}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Market Ideological}}$	0 dB	-10 dB	-50 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

as Venue relative to Beneficial Constraints, and of very strong weight (30 dB) in favor of Technology Based Regulation relative to Beneficial Constraints.[241]

Finally, to satisfy a frequentist logic to wrap up all objections in a weight against the model of interest, we may adopt a strong *skeptic*'s approach which would put a strong disadvantage to the most likely type (Beneficial Constraints in the example in Table 7 and then equally weight each of the other models. Following Fairfield and Charman's (2022, 133) advice, "a very high prior log-odds in favor of a well-established hypothesis relative to a far less plausible rival might reasonably be set at around 50 dB."[242] Thus, we represent the strong skeptic's position by placing 50 dB against Beneficial Constraints for each of the comparisons in Table 7.

While priors are a vital part of Bayesian reasoning, the most important analysis in logical Bayesianism at the heart of BayesTV is the *sensitivity*[243] of the results to the priors rather than choosing precise priors before the analysis. For type validation, we are interested in how confident we can be that a particular case fits a particular type rather than weighing between plausible hypotheses. For that reason, while the author is likely to have a strong prior for one type (the type being validated) and the reader may have indifferent (naïve) or strongly contrarian (skeptical) priors, what matters is how loudly the evidence needs to speak to convince different

[241] Note that the weights are all expressed in negative numbers in order to show that they favor the denominator over the numerator. This direction also matches our intuition of weighting "against" the most likely type (the numerator in all of the comparisons). Positive dB would be in favor of the most likely type, negative are in favor of the rival type (denominator).

[242] Note that Fairfield & Charman propose this threshold for non-arbitrary reasons; they cite Bayesian mathematician Jaynes (2003, 99–100) as the origin of 50dB based on mathematical logic of probability thresholds used in quantitative work.

[243] (Fairfield and Charman 2017)

types of readers. Thus, while it is proper to think about priors before analyzing evidence, they then only return in the conclusion of a BayesTV analysis (explained in the Presenting Your Results section). Heading into the analysis of evidence, the reader should select their most likely type and concentrate on the reasoning behind the weights of evidence they .

Following the advice of Fairfield and Charman (2022, 124–70), the weights of evidence are determined qualitatively but consistently through six paired comparisons of types (most likely vs. each of the six rivals) with the evidence evaluated in the order most logically coherent to the analyst. Note that because it *mathematically* does not matter in what order we incorporate evidence, we can choose the order most logical to the *substantive* comparisons at hand.[244] We can also reduce the number of comparisons by recognizing that *mathematically* a paired comparison of the six rival types against the same type is equivalent to comparing each of the rival types to each other.[245] Thus, we need only six total comparisons in order to consider all possible pairs and we are free to pick which type will be the comparator for all six rivals based on the *substance* of the case.

In the original specification of the method, Fairfield and Charman (2017, 6 in online appendix) recommended that the pairs of types are assigned weights of evidence (WoEs) in decibels (dB) based on the auditory metaphor of "how loudly the data is speaking." As the evidence is best interpreted *relative* to how much 'quieter' they are than the type which the evidence speaks the 'loudest' for, the relative loudness should be gauged in decibels (dB) to keep with the auditory sense-perception of the analytic metaphor at work. This choice of decibels helps to consistently quantify subjective qualitative analysis because it follows the same logarithmic logic as human sense perception: one dB equals a 10% change in *absolute* loudness which means that 10 dB is equivalent to "twice as loud" because it represents 100% additional *perceived* loudness (even though the actual sound pressure has increased by 1000%). Common reference sounds are reproduced from (Fairfield and Charman 2017, 10) in Table 8.

In the final refinement of their application of logical Bayesianism to social inquiry, Fairfield and Charman (2022, 129–36, esp. p.134) recommend that paired comparisons of types should be assigned weights of evidence (WoEs) in decibels (dB) based on a plain language description of relative differences. While earlier approaches relied on an auditory metaphor of "how loudly the data is speaking,"[246] the final specification recommends a generalized use of the logarithmic decibel (dB) scale to match the logarithmic nature of human sense perception without a reliance on a particular sense metaphor.[247] In keeping with the intuitive human sense perception metaphor, the lower bound for discernable differences is set at 3 dB ("smallest meaningful difference," "very weak," 2:1) while the upper bound is set at 30 dB ("eight times louder," "very strong," 1000:1). A set of qualitative-to-quantitative reference levels, their perceptual references, a natural language description of the relationship, as well as the corresponding odds or likelihood ratios is reproduced from (Fairfield and Charman 2022, 133) in Table 9.

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[244] We can also redo our analysis with the evidence in a different order as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 139–40)

[245] We can also redo our analysis with different comparator type as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 140–42)

[246] (Fairfield and Charman 2017, esp. p.6 in online appendix)

[247] Both the senses of sight and sound, for example, evolved logarithmically in humans; a tenfold increase in absolute light power or sound intensity is perceived as a doubling in "brightness" or "loudness" by human senses. See (Fairfield and Charman 2022, 129–30) for further explanation of the appropriateness of the logarithmic scale across the physical, biological, and social sciences.

Table 8: Common Reference Sounds for Decibel Levels

Decibels (dB)	Reference Sound
10	Adult hearing threshold; rustling leaves, pin drop
20	Whisper
30	Quiet bedroom or library, ticking watch
45	Sufficient to wake a sleeping person
50	Moderate rainstorm
60	Typical conversation
70	Noisy restaurant, common TV level
80	Busy curbside, alarm clock
90	Passing diesel truck or motorcycle
100	Dance club, construction site
115	Rock concert, baby screaming
194	Threshold where sound waves become shock waves

Based on (Fairfield and Charman 2017, 10)

Table 9: Qualitative-to-Quantitative Reference Levels for the decibel (dB) Comparison Scale

dB	Acoustic Perception	Plain Language Description	Equivalent Odds or Likelihood Ratio (approx.)
3	Smallest meaningful difference	Very weak	2:1
6	Clearly noticeable difference	Weak	4:1
10	Twice as loud	Moderate	10:1
20	Four times louder	Strong	100:1
30	Eight times louder	Very Strong	1000:1

Based on (Fairfield and Charman 2022, 133, Table 4.1), Note: Some digital audio files that illustrate these different decibel levels are available at: https://tashafairfield.wixsite.com/home/bayes-book

SHOWING YOUR WORK

To actually execute the six paired comparisons for each piece of evidence, you must inhabit the world of the rival type (denominator) and analyze how likely we would be to see that evidence relative to how likely we would be to see this evidence in the world of the most likely type (numerator). This takes the form of one or several paragraphs of narrative drawing on case knowledge, knowledge of the literature, and logical comparison. While such nuance is vital to honestly establishing weights of evidence, it should be left to an appendix to avoid cluttering the main text.

The comparisons should be summarized in a table such as Table 10. As the layout of Table 10 suggests, the comparisons can and should be reasoned though based on which constitutive variables from the typology are critical distinctions between the most likely type and the six rival types. For example, the Adoption Catalyst row in Table 10 shows that the critical distinction between the most likely type (Beneficial Constraints) and the rival type (Adoption Catalyst) lies in the Driver constitutive variable. There is a moderate (10 dB) distinction based on the content of the evidence ($E_{Example}$) which is also supplemented by case knowledge as show by the information in the Effect column of this same row. If a reader were interested in exactly how these conclusions were drawn and the evidence weighted, they could go to the relevant appendix to that chapter to see an explanation for every row explained in narrative form.

Finally, each piece of evidence should have a final "weight of evidence" summary in narrative form for all six paired comparisons of most likely type and rival type. For the same sample row from Table 10, we could explain it as follows:

> *For the comparison to Adoption Catalyst, the reliance on the market to spread the innovation within the [Evidence] speaks moderately against Adoption Catalyst as the true state of the world (see Driver column in Adoption Catalyst row of Table 10*

For more complicated comparisons and reasoning, more complicated information and citations to the literature should be brought in from the appendix. The goal, as always, is to be both disciplined and clear in the qualitative judgement calls which are being made in order to allow the reader to weigh the evidence and analysis and locate and potential loci of contention.[248]

[248] (Fairfield and Charman 2017, 16)

Table 10: Example BayesTV Constitutive Variable Comparison Summary for $E_{Example}$*

Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Reliance on existing laws affirms access to sufficient information	Strong statement of market-as-driver re: "industry certainty"	Specific acknowledgement of many potential outcomes	Moderate/ Implicit statement of constraint	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Clear reliance on market not regulator to drive adoption	*No distinguishing relevance*	Pro-adoption spirit but non-direct method	10 dB
Capture	*No distinguishing relevance*	"provide certainty for industry" = Higher regulator access to information than firms	*No distinguishing relevance*	Specific encouragement of many rather than one desirable outcome	*No distinguishing relevance*	20 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Intentional flexibility of Coordinated Framework contradicts single preferred outcome of TBR	Constraint is performance not technology based	30 dB
State as Venue	OSTP clearly taking stakeholder role	Clear assertion of informed competence of regulators	*No distinguishing relevance*	*No distinguishing relevance*	More than moderation within Coordinated Framework	30 dB
Folk Economic Model	OSTP clearly sees themselves as informed stakeholder	Statement of Regulator competence anathema to Folk Economic Model	*No distinguishing relevance*	*No distinguishing relevance*	Coordinated Framework explicitly pro-innovation rather than impediment	60 dB
Market Ideological	*No distinguishing relevance*	"provide certainty for industry" = higher regulator access to information than firms	Market is the driver but with regulatory guidance "industry certainty"	Clear description of more than zero desirable outcomes	Coordinated Framework explicitly pro-innovation rather than impediment	54 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table could be found in the appendix sections labeled $WoE_{Example}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column were this not just an example table.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 7 for further explanation.

PRESENTING YOUR RESULTS

Once all pieces of evidence have been analyzed for all geographic cases in a particular chapter or paper, the final classification should be explained in both tabular (Table 11) and narrative form. For the table, all comparisons should be racked up with the various priors from Table 7 and cross-tabulated with the weights of each piece of evidence from their individual tables (such as the last column of Table 10). The narrative should then discuss the overall weights of evidence for each paired comparison, relative to each type of priors (naïve, background information, skeptical) as well as draw out any case specific information that is not obvious from the summary tables that help us to draw conclusions about how confident we can which type is the most likely state of the world.[249]

In the narrative discussion of overall weights of evidence, the key reasoning is based on how confident we can be with reference to reasonable standards: decisive (80+dB), well-established (50-70 dB), and clear (30dB). Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival. Fairfield and Charman (2022, 162–63) proceed to explain that a more stringent threshold of 50-70 decibels equates to the thresholds of confidence used by quantitative Bayesian statisticians in the physical and biological sciences; they note that 62 dB is roughly equivalent to the 5 sigma threshold for discovering a new particle in Physics and 67 dB the chance that any given commercial airplane flight will crash vs. land safely. While Fairfield and Charman (2022, 162, footnote 34) also caution us that you cannot truly mathematically convert Bayesian odds to frequentist p-values because they are different ontological statements, most quantitative social scientists are happy with $p<0.1$ (~27 dB) and $p<0.05$ (~30 dB) for publication and are ebullient about $p<0.01$ (~37 dB). Fairfield and Charman ultimately recommend a threshold of 80-100 dB to consider a qualitative research question "settled" both to guard against potential unaccounted for bias as well as to deal with the reality that quantitative social scientists often show higher skepticism toward qualitative evidence than they do towards their own thresholds of significance.

The possible shape of counterfactual evidence should also be specified. This generally takes the form of inhabiting the world of the *least* likely type (based on the tabulation such as Table 11) and specifying what evidence we would expect to see if that were the true state of the world. While this is an exercise in counterfactual thinking, such exercises are not beyond the skills of an analyst with enough case knowledge to carry out a qualitative analysis such as Bayesian type validation.[250]

[249] Examples of how this narrative is executed can be seen in Chapters 5, 6, and 7. No generic version would be intelligible because the narrative must be specific to the case information. See the "Final Type Classification and Sensitivity to Priors" sections in each of these chapters for examples.

[250] See (Levy 2008; 2015) if you need guidance on meaningful counterfactual thinking.

Table 11: BayesTV Example Prior and Posterior Weights of Evidence (in dB)

	a				b				c			
Weight of Evidence (WoE)*	**Naïve**				**Background Info**				**Skeptical**			
	Prior	E_1 Post	E2 Post	Combo Posterior	Prior	E_1 Post	E2 Post	Combo Posterior	Prior	E_1 Post	E2 Post	Combo Posterior
$\frac{Beneficial\ Constraints}{Adoption\ Catalyst}$	0	4	150	154	-10	-6	140	144	-50	-46	100	104
$\frac{Beneficial\ Constraints}{Capture}$	0	70	3	73	-10	60	-7	63	-50	20	-47	23
$\frac{Beneficial\ Constraints}{Technology\ Based\ Regulation}$	0	50	16	66	-10	40	6	56	-50	0	-34	16
$\frac{Beneficial\ Constraints}{State\ as\ Venue}$	0	50	110	160	-10	40	100	150	-50	0	60	110
$\frac{Beneficial\ Constraints}{Folk\ Economic\ Model}$	0	110	180	290	0	110	180	290	-50	60	130	130
$\frac{Beneficial\ Constraints}{Market\ Ideological}$	0	114	130	244	0	114	130	244	-50	64	80	80

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically $(-\infty,\infty)$ although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

CONCLUSION

This chapter proposes a new method called Bayesian Type Validation (BayesTV). BayesTV combines two gold-standard pillars of qualitative methodology, process tracing and typological theory, to produce a completely qualitative method of theory development and testing. While excellent qualitative work has always included theory development and theory testing, the logic of how this was executed has often been questioned by incredulous skeptics. My explication of BayesTV in this paper demonstrates how the deductive logic of typological theory complements the inductive logic of Bayesian process tracing (BayesPT) to produce a disciplined and clear method of analysis and communicating results.

This discipline and clarity is possible because the strengths of deductive typological theory satisfy the constraints of logical Bayesian process tracing and vice versa. By definition, deductive typological theory completely maps a typological property space by constructing a mutually exclusive and exhaustive (MEE) list of types based on combinations of constitutive variables. While Bayesian process tracing generally solves the requirement for MEE hypotheses by reasoned assumption, the process of deductive typological theory allows us to meet the requirement by design. Because Bayesian process tracing disciplines and clarifies how we are using case-specific knowledge and expert analysis, it allows us to transparently validate deductive typologies with inductive empirical knowledge.

In the following chapters, I will use BayesTV to analyze how confident we can be that a variety of regulatory imaginaries beyond the Folk Economic Model are present in actually existing disruptive technological innovation regulation. In chapter 5, I show how confident we can be that autonomous vehicles are regulated by Beneficial Constraints. In chapter 6, I show how confident we can be that gene editing is regulated by Beneficial Constraints. In chapter 7, I show how confident we can be that electronic health records are regulated by Adoption Catalyst imaginary based regulation. Together, these three empirical cases both inductively validate the typology from Chapter 3 as well as demonstrating the application of the method developed in this chapter.

As with the three alternative formalizations of process tracing discussed above, the power of BayesTV lies in its ability to discipline analysts when conducting research and clarify the results of that research. In agreement with Fairfield & Charman (2017, 14–15) about BayesPT and Checkel & Bennett (2015, 265) about Waldner's (2015a) completeness standard, I strongly caution that an over-emphasis on formalization can lead to an unproductive obsession with minutae. Methods should never be so formalized as to distract from the substance that should be the core of scientific inquiry, social, physical, biological or otherwise. Thus cautioned, I nevertheless argue that a formalization to fall back on allows us to do better research on substance and fend off critics looking to undermine qualitative methodological rigor. With BayesTV, you can stay qualitative 'all the way down' although you should never go further down in practice than is necessary for discipline and clarity.

CHAPTER 5

SOMEDAY WE'LL BE SAFER

Beneficially Constraining Autonomous Vehicle Regulation in the United States & Europe, 2016 to Present

The automobile is one of the oldest complex industrial mass-produced and mass-marketed consumer products. It has been shaped by, and in turn shaped, regulation from its very beginning.[251] By comparison, while the semiconductor industry arose from a regulatory decision,[252] the history of the companies built on those chips has been defined by attempts to evade and avoid regulation. This evasive approach has a number of famous cases and faces, whether they are US v. Microsoft,[253] the Facebook ethos of "move fast and break things," Uber and Lyft's successful campaign to evade employment regulation in California,[254] or simply the broader "disruptor" movement. What happens when these two histories collide in the forging of AVs?

Autonomous Vehicles (AVs) are the application of cutting edge machine learning and computer vision to vehicles. As such, they bring together not only the two regulatory regimes, the two industrial histories, and the two communities of the transportation and tech sectors but also two very different visions of the desirable relationship between regulation and innovation. At this intersection lies the forging of a new regulatory imaginary for how regulators and regulatees should interact as cars begin to drive themselves while generating valuable data for the companies which produce them.

Fundamentally, AVs disrupt the meaning of safety for motor vehicles. When it comes to safety, AVs present a central challenge: while they hold great promise of ultimately replacing dangerous, distractable human drivers with dependable and dedicated computers, the development phases of the technology pose potentially increased dangers to bystanders and other drivers.

Regulators, entrepreneurs, and innovators in the United States and Europe have approached AVs from a Beneficial Constraints imaginary. A beneficially constraining regulator, respectful of the inherent complexity of their task and uncertainty of the future, seeks to design constraints that focus entrepreneurial and innovative energy towards solving problems which will lead to more desirable economic outcomes. In the United States, this has taken the form of a set of five guidance documents from 2016-2021. In Europe, this has taken the form of a new type-approval for AVs: Regulation (EU) 2022/1426.

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[251] (Vinsel 2019, 3)

[252] This refers to the 1956 Consent Decree with the US Justice Department which forced Bell Labs to license all of its patents (notably including the transistor, the solar cell, and the laser) royalty free rather than develop them inhouse. See (Watzinger et al. 2017)

[253] (Kollar-Kotelly 2002)

[254] (Padilla 2020, 56–59)

To demonstrate the Beneficial Constraints at work in the case of autonomous vehicles (AVs), I proceed as follows. First, I explain what AVs are and why they are disruptive to existing regulatory imaginaries and regimes because they raise conflicting standards of safety. I then explain what a Beneficial Constraints regulatory imaginary is, focusing on how regulators operating under this imaginary seek to focus the dynamism of the market toward more economically beneficial outcomes than market forces alone could achieve while navigating around socially dangerous shoals. Next, I explain why AVs are a good exemplar case for Beneficial Constraints by reviewing the history of the US and EU AV regimes: Perpetual Guidance in the US (2016-Present) and Regulation (EU) 2022/1426. Then, I proceed to execute a Bayesian Type Verification (BayesTV) to elucidate how confident we can be that AVs are, in fact, a case of Beneficial Constraints. After verifying the type, I present interview evidence about why actor roles within the regulatory regimes view the regulation as beneficial, how they form these views, and how these views inform their actions. I conclude by explaining why it matters that AVs are an example of Beneficial Constraints, focusing on how the US and EU experiences in this consumer industrial sector can serve as a model for entrepreneurs, innovators, and regulators in other sectors where complex, dangerous, yet vital machines with long histories of regulatory practice are upended by promising new innovations which blur existing lines of safety and authority.

WHAT ARE AVS AND WHY ARE THEY DISRUPTIVE?

Autonomous vehicles (AVs) are the application of machine sensing and learning technologies to the task of safely operating a motor vehicle. They are traditionally organized based on their level of automation (from Level 0 to Level 5) with levels 3, 4, and 5 being considered highly or fully automated vehicles. They disrupt existing automotive safety regulatory regimes because they allow the vehicle to do tasks which were previously the responsibility of the driver, upsetting current understandings of safety built into vehicle certification schemes. The following sections explain in more detail the technology of AVs as sorted into different levels, the critical level 3+ distinction of highly to fully autonomous, and the regulatory disruption that highly and fully autonomous vehicles pose to existing vehicle safety certification regimes.

TECHNOLOGICAL INNOVATION: COMPUTER VISION & MACHINE LEARNING APPLIED TO TRANSPORTATION VEHICLES

Autonomous vehicles (AVs) are the latest development in the application of machine sensing and processing technology to operating motor vehicles. They are a subset of the broader category of connected and autonomous vehicles (CAVs) which includes technologies which focus on the exchange of data between vehicles and from vehicles to stationary points in addition to the technologies necessary for vehicles to perform the task of driving. While there are a great deal of interesting legal, regulatory, and normative questions to be considered around the wider category of CAVs,[255] this chapter focuses on only the regulation of highly and fully autonomous vehicles because those levels focus directly on the technical certification of vehicles as safe to operate on

[255] See, for example, the discussions of liability, privacy, and cybersecurity in (Taeihagh and Lim 2019) and the questions of authority, novelty, and risk in (Mukherjee et al. 2023) for the wider questions of CAVs

Figure 5: Levels of Automation (Adapted from United States NHTSA Chart)

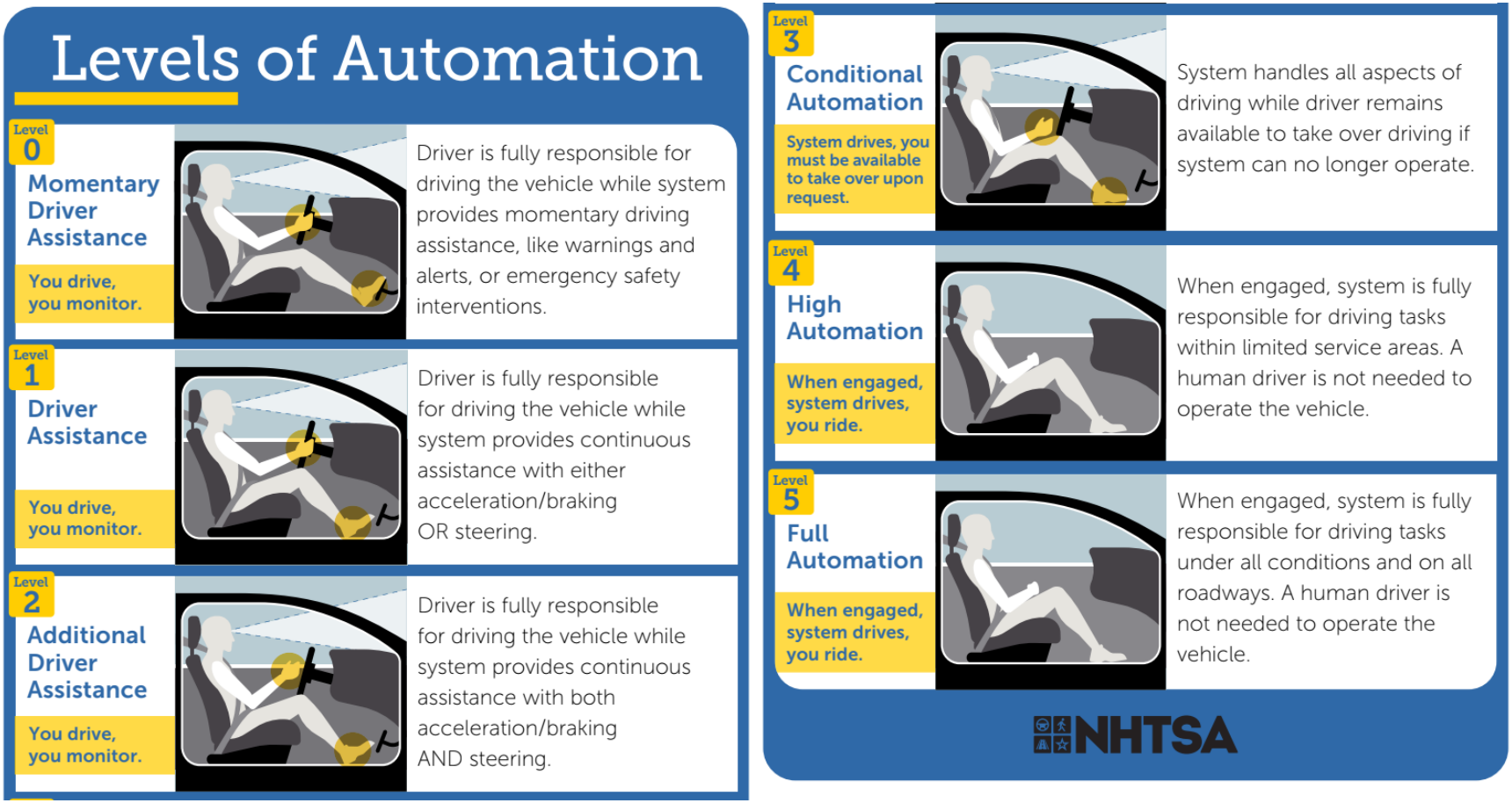
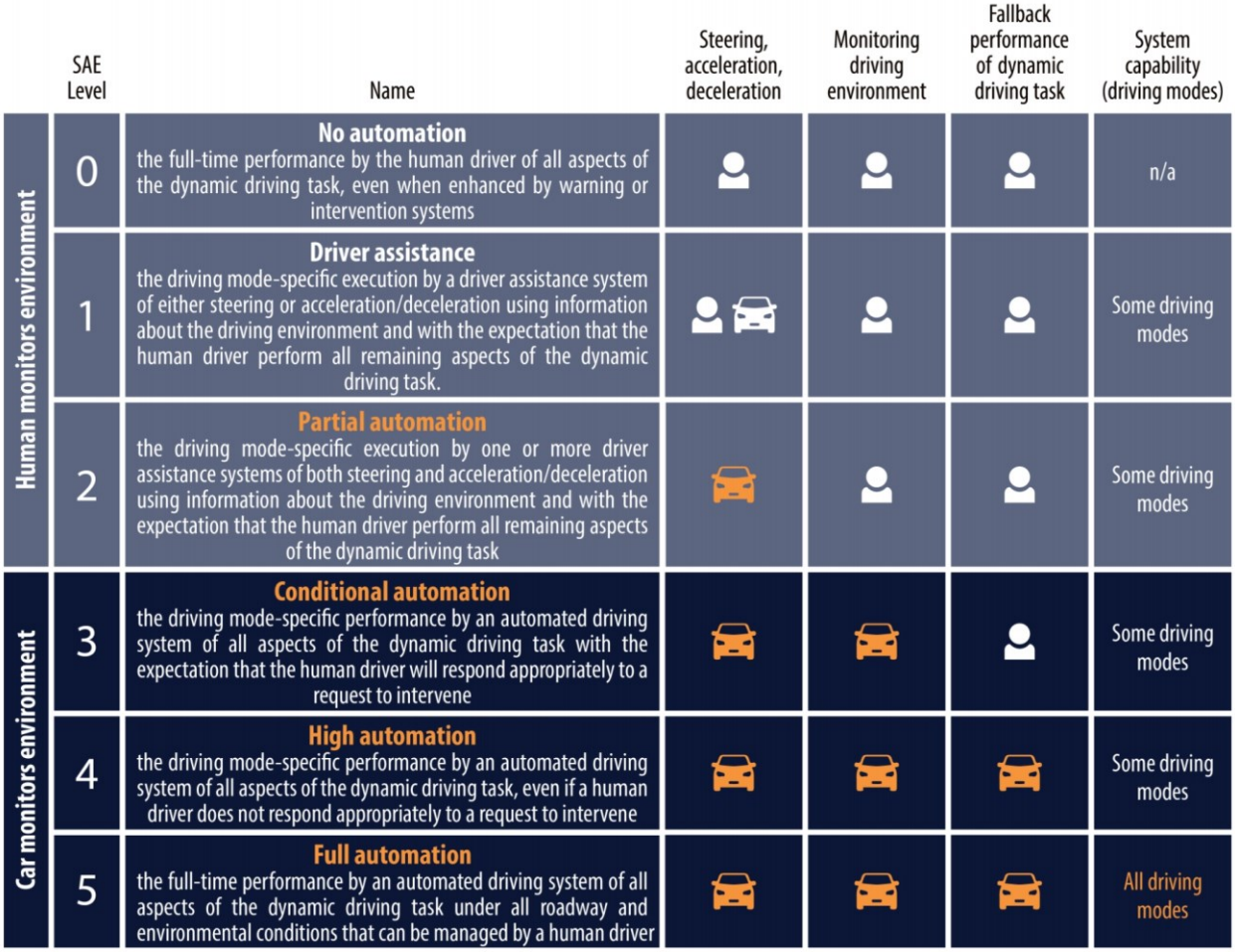


Figure 6: European Union Levels of Automation (from (Pillath 2016, 4 who adapts and credits; ITF 2015, 14))



Source: Automated and Autonomous Driving, OECD/ITF, 2015 (adapted from SAE Standard J3016, SAE International 2014).

public roads. The wider category of CAVs certainly raises interesting and important questions, but they would be beyond the scope of what this chapter focuses on (a disruptive innovation to a well established regulatory regime) because they raise novel interactions more akin to those discussed in the following chapter about gene editing.

Both US and EU regulatory and technical communities have settled on a classification scheme for AVs which follows the recommendations of the Society of Automotive Engineers (SAE J3016). As we can see in Figure 5, the US focuses on the responsibilities of the driver (at levels 4 and 5, the primary passenger) by drawing attention to where the hands, feet, and eyes are on the controls which are increasingly not present as the level of automation increases. As we see in Figure 6, the EU draws a similar comparison between the responsibilities of the vehicle and the driver, but it chooses to highlight three key driving tasks (steering, monitoring, and fallback/failsafe). This focus in the EU figure on whether the person or vehicle performs the key tasks highlights the important cutoff between Levels 0-2 (driver assistance) and 3+ (automation) where the vehicle begins to takeover some and then all of the driving tasks.

In the lower levels of merely "driver assistance," both US and EU framings highlight that the vehicle is still primarily a standard configuration with addon features. Level 0 was defined primarily to clarify what doesn't actually count as automation at all: warnings or buzzers that simply provide information to the driver who still controls all driving tasks. This distinction was initially important to prevent over-advertising of very early features by automakers. Levels 1 and 2 are distinguished by whether the vehicle controls steering OR braking/acceleration (Level 1) or whether the vehicle controls steering AND braking/acceleration (Level 2). At the moment of this writing, there are no mass market vehicles which exceed Level 2, although some attempt to push the definition of Level 2 to 'Level 2.5' in order to suggest they are nearly to Level 3.

Level 3 (Conditional Automation) is the generally accepted threshold when a vehicle crosses over from driver assistance to actually driving itself, if only in limited conditions. From the US NHTSA diagram (Figure 5), we can see that at Level 3 there are periods when the driver's hands and feet may be off the controls but they are still expected to monitor their environment, even if that monitoring is intended as fallback redundancy as is made clear by the icons in the task columns of the EU diagram (Figure 6). The key distinction with Level 3 as opposed to Level 2 is most clear from the EU diagram: within defined and limited conditions, the vehicle is actually able to monitor its environment sufficient to sometimes be in total control of the vehicle (middle column of Figure 6).

Although Level 3 is the threshold to actual automation, both the US and EU have taken the further step of defining Levels 4 and 5 as "high" and "full" automation as these are the vehicles where the design components begin to change. From the US diagram (Figure 5, Level 4 cell), we can see that at Level 4 a steering wheel and pedals are no longer installed although the vehicle is still confined to operating in limited circumstances. Level 5, or full automation, has the same lack of human interface controls but is no longer limited to particular places or routes; it is a true self driving vehicle that is expected operate in all conditions that a human driver would be allowed to (See the bottom row of Figure 6).

In this chapter, we are concerned with the regulation of vehicle design safety, a highly developed regulatory regime in all jurisdictions.[256] Because we are interested in vehicle design safety, the regulatory disruption comes at Level 4 (high automation) and Level 5 (full automation) in the SAE-based US and EU charts. Thus the technological disruption is the application of machine sensors and processing sufficient to carry out all three of the core driving tasks: steering & speed, monitoring of the environment, and failsafe mechanisms sufficient to end the driving task safely if it is not safe to drive. The technologies to execute all three of these tasks in consumer vehicles have exploded in development and testing beginning in the 2010s and public road prototypes were testing at least as early as 2015.[257] While there are no vehicles currently widely available with higher than Level 2 automation, the 2024 Mercedes EQS Sedan and S Class has been approved as the first Level 3 system to be sold to the public in the United States[258] while General Motors' Cruise was authorized to operate fully autonomous (Level 4) vehicles as a taxi service for hire in San Francisco beginning in June 2022.[259] The disruption to

[256] (c.f. Vinsel 2019)
[257] See (Holland-Letz et al. 2021; Yeruva 2022) for investment trends and (e.g. Kang 2017; Wakabayashi 2018; Harris 2018) for public road testing.
[258] (Stafford 2023)
[259] (The Associated Press 2022)

vehicle design safety regulation comes as we pass the threshold from human to autonomous drivers. We will discuss the specific content of this disruption in the following section.

REGULATORY DISRUPTION: TRANSPORTATION SAFETY CULTURE VS. CONSUMER PRODUCT SAFETY

Although the technology behind AVs raises important questions of disruption beyond that of the vehicles themselves,[260] the disruption to vehicle safety regulation provides a critical insight into how a well-established regulatory regime deals which a technological change to the fundamental realities it was originally based upon. When automotive regulation began, not incidentally when mass automobile ownership began, there was no question that human drivers were primarily responsible for operating the vehicle while manufactures were responsible for providing a set of reliable tools to reasonably accomplish the driving task.[261] This generally came down to providing safe and reliable controls (steering, braking, lighting etc.).[262] However, highly (Level 4) and fully (Level 5) autonomous vehicles disrupt this divide between manufacturer and driver by reopening what it means to be safe and how it can and should best be accomplished. At a more basic level, it forces vehicle safety regulators to reassess what it means and what it takes for a vehicle to be safe enough to sell to and be operated by the public.

Both proponents and opponents of AVs claim to be concerned with safety because AVs disrupt current regimes for dealing with road safety. This disruption arises from two questions:

1) Risk: Are AVs more or less risky than human drivers?
2) Consent vs. Inevitability: Will AVs inevitably become required equipment (like turn signals, headlights, airbags and backup cameras before them) or will they remain a choice (like cruise control or GPS navigation systems)?

Answering both questions creates four perspectives on safety which are named in Table 12. These possible conceptions of safety build outward from two distinct legacies of safety regulation: consumer protection and safety culture. By bringing these two regulatory histories into conversation, AVs create a disruption by creating contestation over what it means to be safe.

Table 12: Four Perspectives on "Safety" for AV

	AV More Risky than Human Drivers	**AV Less Risky than Human Drivers**
Consent: AV are a Choice	Consumer Protection Precautionary *"Punishing Backseat Tesla Bro"*[263]	Safety Culture Ideal *"AV are a safer option consumers should have"*
Inevitability: AV are Inevitable	Consumer Protection Ideal *"Certified Safe and Reliable AV"*	Safety Culture Precautionary *"Trolley Problem Arms Race"*

[260] See footnote 255
[261] (Vinsel 2019, 15–74)
[262] (Vinsel 2019, 75–150)
[263] The 2020-2021 trend of Tesla car owners who illegally ride in the backseat of their cars while set to autopilot. (Torchinsky 2021; "'I Am A Gold-Collar;' Driverless Tesla Backseat Rider Param Sharma Basks In Social Media Notoriety As He Flaunts His Wealth" 2021; "UPDATE: CHP Announce Arrest of Man Who Rode in Back Seat of Driverless Tesla Across Bay Bridge" 2021)

The rise of *safety culture* is an important part of late 20th century automobile regulation. Safety culture is a set of attitudes which prioritize safety as the chief deciding factor in organizational decision-making (Guldenmund 2000, 222, 227–29). As with seatbelts, airbags, anti-lock brakes, and electronic stability control, AV technologies are seen as the latest way to enhance safety culture in the transportation sector.

From a safety culture perspective, human drivers are the chief fallible component in the transportation system and a swift introduction of AVs is the resolution.[264] AVs follow a set of programmed rules that avoid common human frailties behind the wheel such as drunkenness, drowsy driving, and texting. This perception of decreased risk, however, relies on a long-term vison of fully developed, highly reliable, and widely adopted AVs.

Among those who adopt the safety culture perspective, there are two possible futures: the ideal world where AV are a choice, and the precautionary world where AV technologies are either mandated or "an arms race." In the ideal world, AV can be a safety-optimized choice for consumers, designed to intermingle with human-operated vehicles to increase the safety of drivers, AV operators, and pedestrians. In the precautionary world, AV technologies can be developed as a convenience-optimized choice which privileges the experience and safety of the AV operator at the potential expense of human drivers and pedestrians.[265] Here, safety culture adherents foresee the danger of an arms race where consumers are pressured to pay for AV and risk is de-prioritized in transportation systems, leading them to advocate that AV technologies be mandated for all new cars. This follows the trend with previous technologies such as airbags, seatbelts, crash worthiness, and driver assist technologies which were initially options that became mandated as they demonstrated safety benefits.

A *consumer protection* perspective reflects more reactive approaches to roadway regulation. From this perspective, AV raise questions during the development and testing phase, as they are vehicles without drivers and may endanger others before they are fully developed. The safety of consumers who both do and do not purchase an AV reflects two worlds: the ideal world where safe AVs inevitably come to market, and the precautionary world where regulators must choose to ban or permit AVs. Where AVs are seen as inevitable, the focus becomes on testing, licensing, and labeling AV products to allow for informed purchasing decisions and operation. Where AVs may be banned or allowed, the question of safety focuses on the current testing phase of "does the technology really work?" In both scenarios, the question of safety in the consumer protection perspective is about the near-term, individualized, and product-related risk. The untested and still-evolving nature of these technologies thus leads to a perception that they raise new risks on top of the standard risks of human-operated vehicles.

AVs disrupt the conception of safety around vehicles. Contemplating the risk of AVs (do they increased risk or decrease it? Are AV inevitable or a choice?) leads to four potential perspectives on safety: Consumer Protection Ideal, Consumer Protection Precautionary, Safety Culture Ideal, and Safety Culture Precautionary. Each of these perspectives claim to be the most

[264] One interviewee argues that 90% of crashes stem from human error (Posch et al. 2021, interview 25) This reflects a consensus among systematic studies (c.f. Taeihagh and Lim 2019) This is also reflected in US (NHTSA 2016, 5; 2017, ii; NSTC and USDOT 2020, 2) and EU (Pillath 2016, 2) regulatory documents and can be traced back to the study by Singh (2015).

[265] These are versions of the "trolley problem" where the car must be programmed to choose between who to kill in an unavoidable collision. See (Nyholm and Smids 2016) for a discussion of how AVs relate.

safety conscious; but each lead to a different conception of what is most risky and what constraints are necessary in order to achieve the "safest" outcome.

WHAT IS A "BENEFICIALLY CONSTRAINING" REGULATOR?

Before proceeding to verify that connected and autonomous vehicles (AVs) are a good exemplar of Beneficially Constraining regulation, we should first be clear about what the Beneficial Constraints imaginary is. Based on the variables in the typology derived in Chapter 3, a regulator following the Beneficial Constraints imaginary has *higher* access to *information* than firms, believes that the *market is the driver* for the spread of an innovation and is content with *many* different optimal regulatory *outcomes*. Put plainly, a beneficially constraining regulator is defined by careful negation: they identify certain undesirable practices or outcomes and place constraints on regulated firms which are intended not just to reduce harm but to spur innovation towards other desirable practices and outcomes. Critically, these constraints are not simply beneficial to society (as regulation generally is intended to be) but are also economically beneficial to the regulated firms; this form of regulation seeks not to curb the excesses of the market but instead to direct the dynamism of the market toward more economically beneficial outcomes while also serving the social ends of regulation.[266]

The name "Beneficial Constraints" is a direct and intentional reference to the title of Wolfgang Streeck's "Beneficial Constraints: On the Economic Limits of Rational Voluntarism" (1997). As we saw in Chapter 3, Steeck's article serves as a direct foil to Stigler's "The theory of economic regulation," the article which created the concept of capture and was eventually reified into the folk economic model discussed in Chapter 1 and Chapter 2. The attempt to reconcile Streeck and Stigler generated the conceptual puzzle which led to the typological property space developed in Chapter 3 and presented in Table 5 (reprinted below as Table 13).

Yet despite the formative contributions from Streeck, his description of "beneficial constraints" explicitly "do[es] not pretend to have a conceptual schema to cover [all of his claims about social constraints on economic performance]."[267] Instead, he presents examples from which he can draw out theoretical and practical implications. Streeck's key advice to his readers is that the "Recognition of the economic benefits of *some* social constraints immunizes against the received wisdom that *all* constraints are counterproductive by definition."[268]

Elaborating his key advice, Streeck makes three recommendations about politics and policy based on beneficial constraints which I label *partialness, uncertainty, and complexity*.[269] First, not all constraints are beneficial but *some* economically non-rational social institutions improve economic performance so universal prescriptions against constraints should be avoided when designing policy. Second, *uncertainty* is a defining characteristic of a political economy in

[266] If capitalism is about creative destruction, as Schumpeter ([1943] 2010, 93–94) famously claimed, the beneficial constrainer seeks not to reduce the destruction but instead focus it on destroying current problems while finding creative solutions which are both economically productive and socially beneficial beyond the narrow dictates and time horizon of cyclical market forces.

[267] (Streeck 1997, 200)

[268] (Streeck 1997, 213)

[269] These three recommendations are summations of (Streeck 1997, 213–15) and all quotations are from there unless otherwise specified. The single word terms are my own reification.

Table 13: Complete Typological Property Space of Regulatory Imaginaries

		Constitutive Variables (Independent Variables)				Dependent
Name of Imaginary	**#**	**Relationship**	**Info**	**Driver**	**Outcomes**	**Effect**
Folk Economic Model (Christensen 1997)	1	Rulemaker	Lower	Market	Zero	Impediment
	2	Rulemaker	Lower	Market	One	Impediment
Market Ideological*	3	Rulemaker	Higher	Market	Zero	Impediment
	4	Stakeholder	Higher	Market	Zero	Impediment
State-as-Venue (Skocpol 1985)	5	Rulemaker	Lower	Regulator	Many	Moderator
	6	Stakeholder	Lower	Market	Many	Moderator
	7	Stakeholder	Lower	Regulator	Many	Moderator
Capture (Stigler 1971)	8	Stakeholder	Lower	Market	One	Constrainer
	9	Stakeholder	Lower	Regulator	One	Constrainer
Technology-Based Regulation "Conventional Command and Control" (Malloy 2010)	10	Rulemaker	Higher	Market	One	Constrainer
	11	Rulemaker	Lower	Regulator	One	Constrainer
	12	Stakeholder	Higher	Market	One	Constrainer
Beneficial Constrainer (Streeck 1997)	13	Rulemaker	Higher	Market	Many	Constrainer
	14	Stakeholder	Higher	Market	Many	Constrainer
Adoption Catalyst	15	Rulemaker	Higher	Regulator	Many	Catalyzer
	16	Stakeholder	Higher	Regulator	Many	Catalyzer
	17	Rulemaker	Higher	Regulator	One	Catalyzer
	18	Stakeholder	Higher	Regulator	One	Catalyzer
Trivial	19	*Rulemaker*	*Lower*	*Regulator*	*Zero*	*Impediment*
	20	*Stakeholder*	*Lower*	*Regulator*	*Zero*	*Impediment*
	21	*Rulemaker*	*Lower*	*Market*	*Many*	*Impediment*
	22	*Stakeholder*	*Lower*	*Market*	*Zero*	*Impediment*
Logically Inconsistent	23	~~Rulemaker~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~
	24	~~Stakeholder~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~

* (Henderson and Appelbaum 1992) completed Chalmers Johnson's (1982) 2x2 of market|plan x rational|ideological by defining the idea of "market ideological" which privileges market structures for organizing social and economic interaction beyond efficient cost-benefit tradeoffs due to an ideological preference for market structures over planning. More modern ears are more familiar with the term "market fundamentalism" as popularized by George Soros (1998) although the concept is as old as capitalism itself with well-reasoned critique of it at least as old as Polanyi ([1944] 1957). The modern usage is well explained in (Block and Somers 2014).

practice so the "common sense judgment of the practitioner" must take precedence over the "deductively-based knowledge of the expert" and thus "political skills" are vital to good institutional design and adaptive operation. This uncertainty derives from the fact that economically beneficial social institutions are often unintentional side effects which are difficult to foresee and may vary through time and circumstances as economic actors innovate within their constraints.[270] Third, the institutional conditions of good economic performance are *complex* and so must cast a broad policy net rather than the traditionally narrow one which aims at incentivizing desirable behavior within a carefully demarcated arena. Thus, "at the minimum, good economic policy must be embedded in family policy, social policy, and educational policy."

[270] (Streeck 1997, 211–12).

My Beneficial Constraints imaginary accepts the inherent partialness, uncertainty, and complexity Streeck identifies but it comes to a rather stronger conclusion in response: regulators can *design* Beneficial Constraints rather than merely recognize unintentional ones after the fact. To elaborate, I draw upon Streeck's own key example: the high minimum wage in post war Germany. Streeck based his concept on the empirical observation that a high minimum wage forces firms to develop high productivity business models that then generate long run economic growth even though they are against the short term economic interests of managers who would prefer to maintain low productivity, low wage business models rather than invest in long term productivity growth.[271]

In the moment, Streeck is absolutely right that "common sense judgment of the practitioner" must take precedence over the "deductively-based knowledge of the expert" and thus "political skills" will be vital to craft a compromise between owners, managers, and workers such that a high minimum wage is feasible policy.[272] Yet, just because all parties may only recognize the economic rationality of the compromise in hindsight should not suggest that we cannot learn from the prior uncertainty after history has borne out a series of events which reduce the specific uncertainty of that situation. Experts may not have known that a high minimum wage would lead to high productivity business models before it succeeds in Streeck's German example, but we certainly now can use that example in future expert analysis to intentionally craft beneficial constraints.

This is not to say that past is simply prologue and once a compromise has been successful (once a constraint has proven economically beneficial) it is necessarily always going to be beneficial. But it is fair to say that regulators can learn from past successes and carefully apply those lessons to new situations. Thus, while partialness, uncertainty, and complexity cannot be eliminated, their presence does not make it impossible for regulators to learn from past successes and failures and apply those lessons to new challenges.

The key to the Beneficial Constraints regulatory imaginary of disruptive technological innovation lies between the folk economic model's despondency that regulators can do nothing right and Streeck's original critique of that despondency that sometimes something goes right, although unintentionally. A beneficially constraining regulator, respectful of the inherent complexity of their task and uncertainty of the future, seeks to design constraints that focus entrepreneurial and innovative energy towards solving problems which will lead to more desirable economic outcomes. While not all attempts to focus regulation will succeed in their goals, neither should all fail or those that succeed merely do so by chance; you cannot design out uncertainty but you can design with it in mind and learn from past experiences.

CHANGING PERCEPTION: DISENTANGLING CONSTRAINT FROM NEGATIVE CONNOTATIONS

As discussed in Chapter 1, perception is of key importance to understanding the regulation of disruptive technological innovation because perceptions create preferences long before outcomes breed interests. For the project as a whole, this is a key motivation for expanding our understanding of regulatory imaginaries beyond the folk economic baseline. In the Beneficial Constraints regulatory imaginary, the most significant shift in perception is the disentangling of "constraint" from the negative connotations it has taken on within the context of regulation of

[271] (Streeck 1997, 200–201)
[272] (Streeck 1997, 213–15)

innovation; that constraint is necessarily economically bad.[273] When Christensen coined the term "disruptive innovation" in *The Innovator's Dilemma* (1997), regulation was brought up to discuss what old regulations need to be removed: "regulations are toppled only when disruptive innovators find applications or markets beyond the reach of regulators."[274] To answer this perception, we can turn to Streeck himself: "Recognition of the economic benefits of *some* social constraints immunizes against the received wisdom that *all* constraints are counterproductive by definition."[275] Thus, the beneficially constraining regulator will seek to demonstrate that constraints need not be seen as bad a priori. In their turn, entrepreneurs and innovators would do well to ask themselves whether the constraints they are faced with are truly due to a pernicious imaginary such as capture or technology based regulation (c.f Table 13, lines 8-12) or whether they might truly be under a set of beneficial constraints (lines 13 & 14) which allow them to focus their creative and competitive prowess on creating better economic outcomes rather than undermining regulation or racing to the bottom due to short term competitive thinking. In the following section, we will see how certain constraints came to be defined as beneficial to both the businesses and consumers of the US and EU in response to the disruption of AV technology.

WHY ARE AVS A GOOD EXEMPLAR CASE FOR BENEFICIAL CONSTRAINTS?

In brief, connected and autonomous vehicles (AVs) are a good exemplar case for the Beneficial Constraints regulatory imaginary because the well-established regimes for regulating automobiles meant that a major new technology could not enter without guardrails. In the United States, these guardrails took the form of five guidance documents issued between 2016 and 2021. In the EU, these guardrails took the form of an orderly regulatory process beginning in 2016 and culminating in the introduction of a new type-approval process for AVs in Regulation (EU) 2022/1426 in 2022. The following sections explain first why AVs are a useful case for the overall project's interests in exploring regulatory imaginaries, then provide a case overview narrative for the US and EU cases, and concludes by comparing these narratives in preparation for a BayesTV of how confident we can be that each narrative actually represents a Beneficial Constraints imaginary.

EMPIRICAL CASE SELECTION: MAJOR DISRUPTIVE TECHNOLOGY IN ESTABLISHED REGULATORY SECTOR (TRANSPORTATION)

The two specific cases selected for comparison in this chapter were selected because they represent a simultaneous challenge to two different regulatory regimes around a set of traditional regulatory functions. In other words, vehicles, roads, and drivers have been regulated from the very earliest days of modern administrative states.[276] Transportation also represents a sector with a long history of public good regulation around safety. Finally, the introduction of machine learning and computer vision to replace the driver represents an integration of traditionally separate regulatory domains (roads, vehicles, drivers, data). AVs are also a current growth sector with a great deal of investment in both the United States and Europe.[277] In short, AVs take a classic set of regulatory institutions and disrupt them with a new technological innovation which

[273] (Malloy 2010, 281–88)
[274] (Christensen, Grossman, and Hwang 2009, xlv)
[275] (Streeck 1997, 213)
[276] (Vinsel 2019, 3–4)
[277] (c.f Holland-Letz et al. 2021; Yeruva 2022)

is the core unit of analysis for this project. The following two sections lay out the narratives of the US and EU cases.

PERPETUAL GUIDANCE IN THE UNITED STATES (2016-PRESENT)

The United States develops standards for vehicles sold and operated in the US through the federal Department of Transportation (USDOT). To date, the USDOT and its agency the National Highway Transportation Safety Administration (NHTSA) have regulated AVs through a successive series of five guidance documents from 2016 to 2021.[278] While the first document reserved the right to use both existing authority and new tools,[279] each successive document has been careful to re-emphasize the US government's intent to guide the development of "automated driving systems (ADS)" (their term for AVs) through voluntary compliance.[280] While these guidance documents are officially non-binding, the represent the understanding and intent of the relevant regulatory agency for a particular jurisdiction of how the law should be understood. As such, these guidance documents serve as a constraint on the actions of entrepreneurs and innovators, whether simply as persuasive authority[281] or as actions in lieu of (or in preparation for) binding regulatory rulemaking.[282]

The first action taken by USDOT (thru NHTSA) to shape emerging AV technology was the 2016 *Federal Automated Vehicles Policy* (FAVP).[283] This guidance document was published in September 2016 following extensive consultation with stakeholders in industry, academia, and the public.[284] The resulting policy guidance was a rather standard claim to jurisdiction and authority what laid out four principles to "facilitate[e] the safe introduction and deployment of HAVs…:

1. Vehicle performance guidance for Automated Vehicles
2. Model State Policy
3. NHTSA's Current Regulatory Tools
4. New Tools and Authorities"[285]

While cross-national analysts have focused on the formal voluntary nature of this initial guidance document,[286] within the context of the US Administrative State and the successive rounds of AV guidance below (AV 2.0, 3.0, 4.0, and the AVCP), the FAVP was a relatively *more* constraining document. As compared to later guidance documents, the FAVP laid specific claim to both the applicability of existing regulation to this new innovation (item 3 above) and

[278] In this section and throughout, I use the acronyms that USDOT and NHTSA use for each of the five guidance documents: FAVP (NHTSA 2016), AV 2.0 (NHTSA 2017), AV 3.0 (USDOT 2018), AV 4.0 (NSTC and USDOT 2020), and AVCP (USDOT 2021). Although not named as such, you may think of FAVP as "AV 1.0" and AVCP as "AV 5.0" as the progression between the documents is explained in this section. The full name for each acronym is introduced in the relevant paragraph in this section where the document is discussed.
[279] (NHTSA 2016, 7–8)
[280] (NHTSA 2017; USDOT 2018; NSTC and USDOT 2020; USDOT 2021)
[281] (Aman 1994)
[282] (Newman and Bach 2004; Meyer 2013)
[283] (NHTSA 2016)
[284] (NHTSA 2016, 3)
[285] (NHTSA 2016, 6 list itemization in original, bullets replaced with numbers for clarity)
[286] (Taeihagh and Lim 2019, 108)

the likely need to develop new tools and rules (item 4 above). While guidance documents are not technically rules with the full force of law, scholars agree that they have become increasingly influential since the 1960s and are certainly central to how agencies govern in the last 20 years.[287] In laying claim to both the application of existing rules and the "likely [need for] additional regulatory tools],"[288] NHTSA in this guidance document is therefore clearly staking its claim over regulating and constraining AV development.

To reflect the stated priorities of the incoming Republican Trump Administration in 2017, the USDOT published a new voluntary guidance in September 2017: *Automated Driving Systems 2.0: A Vision for Safety* (AV 2.0).[289] AV 2.0 was intentionally and explicitly framed as "clearer, more streamlined, less burdensome and contains additional, more helpful information for states"[290] than the FAVP from the prior Obama Administration. In the document, AV 2.0 claims not to "hamper" the development of the AV industry,[291] claims to be "a nonregulatory approach to automated vehicle technology safety," [292] and excessively uses the term "*Voluntary Guidance."*[293]

Despite the cacophony of claims to the contrary, AV 2.0 nevertheless reiterates NHTSA's and USDOT's jurisdiction over AV regulation. In other words, it may claim to be "developing a regulatory framework that encourages, rather than hampers, the safe development, testing and deployment of automated vehicle technology" but it's still developing a regulatory framework despite also claiming to be "a nonregulatory approach."[294] However, we need not rely simply on the inconsistent rhetoric as we can see a clear parallel structure in the body of the document as well.

In the body of AV 2.0, we can see the same four principles as laid out in FAVP.[295] Section 1 may be called "Voluntary Guidance," but page 3 makes extremely clear, at the request of several states, that "NHTSA's enforcement authority concerning safety-related defects in motor vehicles and motor vehicle equipment extends and applies equally to current and emerging ADSs [aka AVs]."[296] In other words, NHTSA's current regulatory tools still apply just like in FAVP, component 3. The rest of section 1 includes a good deal of guidance on how to develop and test

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[287] The disagree, however, about whether this increasing use of informal guidance documents is a "good" (c.f. Aman 1994; Rakoff 2000), "bad" (c.f. Crews, Jr. 2017; C. J. Walker 2017, 662–64), or simply practical reality (c.f. Raso 2010). In this disagreement, however, they agree that guidance documents have an effect of constraining the actions of regulatees.

[288] (NHTSA 2016, 8)

[289] (NHTSA 2017)

[290] (NHTSA 2023,while the page was captured in 2023, the relevant text about AV 2.0 was on the site as of 2018 per the 2018-12-12 capture on Archive.org and has not been changed since then)

[291] (NHTSA 2017, i, the introductory letter from USDOT Secretary Elaine L. Chao)

[292] (NHTSA 2017, ii)

[293] Voluntary Guidance appears 6 times on the single-page Executive Summary and is the title of the first section which makes up the majority of the document (16 of 24 substantive pages) *despite* the fact that it is entirely redundant; as previously noted FAVP 2016 and AV 2.0 2017 are both guidance documents that call for voluntary compliance.

[294] Yes, indeed, AV 2.0 really does say "a regulatory approach" on page i and "a nonregulatory approach" on page ii (NHTSA 2017, i–ii)

[295] In fact, this parallelism will serve as our first piece of highlighted evidence ($E_{4\text{-Principles}}$) in the BayesTV, beginning on page 107.

[296] (NHTSA 2017, 3)

AVs that perform safely (FAVP component 1). While more muted, AV 2.0 acknowledges that "laws and regulations will inevitably change over time [and thus AV business] entities should consider developing processes to update and adapt"[297] just as FAVP component 4 identified the likely need for new tools and authorities. Section 2 of AV 2.0 (Technical Assistance to States) clearly mirrors FAVP component 2 (Model State Policy). In fact, despite what one might expect from the rhetoric of a 'small government/states rights' Republican Administration, AV 2.0 is *more* explicit in its calls for States to cede any potential authority over AV technology to USDOT through NHTSA, thus "allowing NHTSA alone to regulate the safety design and performance aspects of ADS technology." Although framed at the top level as a simplification and reduction, the content of AV 2.0 does more to reflect (rather than undo) the constraining authority of USDOT.

In the subsequent two years of the Trump Administration, the conversation about AVs in the US moves up from NHTSA to USDOT leading to two additional guidance documents which build upon AV 2.0 both outward across multiple modes of transit (AV 3.0) and internationally (AV 4.0). In October 2018, USDOT released *Preparing for the Future of Transportation: Automated Vehicles 3.0* (AV 3.0) which "builds upon—but does not replace—voluntary guidance provided in [AV 2.0]."[298] In effect, AV 3.0 expands the principles from AV 2.0 (and by extension, FAVP, as explained above) beyond just automobile transportation to trucking, aviation, maritime, and railways.[299] While it slips in additional phrasing about "removing unnecessary barriers and issuing voluntary guidance, rather than regulations that could stifle innovation" it also "[re]affirms U.S. DOT's authority to establish motor vehicle safety standards" just as it did in AV 2.0 and FAVP.

In January 2020, USDOT collaborated with National Science and Technology Council (NSTC) to release *Ensuring American Leadership in Automated Vehicle Technologies: Automated Vehicles 4.0* (AV 4.0) which builds upon AV 3.0, AV 2.0 (and thus FAVP) by emphasizing the economic importance of AV technology in addition to safety. Where prior documents written by NHTSA and USDOT had focused on safety as paramount as in line with the mission of USDOT and more specifically NHTSA (safety is in their name), AV 4.0 made explicit the importance of economic development of the AV industry. In AV 2.0 and AV 3.0, there were clear references to the need for innovation and entrepreneurship but these had been framed secondarily to the mission for safety.[300] In FAVP as well, the economic importance of AVs was acknowledged if in far more subdued language about the "socioeconomic impacts" and the importance of the automobile industry.[301] While AV 4.0 centered economic considerations much more than prior guidance documents, this was neither entirely novel nor particularly surprising considering that the document was no longer the exclusive domain of USDOT and instead added the NSTC, a group of political appointees within the Executive Office of the President.

Finally, on January 11, 2021, during the lame duck period of the Trump Administration and 5 days after the January 6th insurrection, USDOT released the *Automated Vehicles* –

[297] (NHTSA 2017, 15) In fact, this language is nearly a word-for-word copy from FAVP (NHTSA 2016, 26)
[298] (USDOT 2018, viii)
[299] (USDOT 2018, viii–xi)
[300] (NHTSA 2017, c.f. i and ii)
[301] (NHTSA 2016, 3, references to industry appear throughout)

Comprehensive Plan (AVCP) which serves as a capstone to the previous 4 guidance documents. While framed as a comprehensive plan, the AVCP is primarily a reiteration of the principles in AV 2.0, 3.0, and 4.0 as well as an explicit effort to claim credit for the efforts of the previous 5 years. As noted above, although it makes no mentions of the FAVP which had been published in September 2016 at the end of the Obama Administration (but before that president's lame duck period), as explained above AV 2.0 incorporates the principles, and in some cases the exact language, of the FAVP. This makes AVCP the last guidance document in a series of guidance document which asserted the authority of NHTSA and USDOT over AVs both using existing regulations and the potential for new regulations, asks states to recognize the supremacy of the federal government and avoid passing conflicting regulations, and commits USDOT to facilitating the introductions of AVs for both safety and economic reasons.

Though AVCP may seem redundant, particularly in light of when it was released, we can see it as an attempt to justify the first attempt at actual rulemaking from NHTSA: an Advanced Notice of Proposed Rulemaking (ANPRM) entitled "Framework for Automated Driving System Safety."[302] While it may seem that this formal rulemaking should be the focus of this case, rather than the series of guidance documents, there are two reasons to consider this a false lead. First, the ANPRM and request for comments was posted on December 2, 2020, nearly one month *after* Donald Trump had been declared the loser of the 2020 Presidential election and during the height of the election denialism by the Trump campaign which gripped national political coverage. This makes the ANPRM both a lame duck policymaking as well as particularly under-reported given the national political news focus on a historic attempt to subvert a fair and free election in the United States. Second, the comment period was slated to close *after* the new Biden Administration took power (January 31, 2021) which would have brought with it a new Transportation Secretary and likely a new agenda for the Department of Transportation. These logical likelihoods appear to have played out as, at the moment of this writing, the ANPRM from December 2020 has not led to any rulemaking.[303] An ANPRM is not even an NPRM, but even if we generously consider this action to have been a step towards rulemaking that step went no further; we can also observe the neither USDOT nor NHTSA make reference to this ANPRM in

[302] (NHTSA 2020) Note that due to a peculiarity of the Administrative Procedures Act (APA) which governs how regulation is made in the US, what we might consider making a "formal" rule is not actually formal rulemaking, a rarely used procedure where and administrative law judge must hold a hearing to define a regulatory change. Instead, rulemaking is most commonly used to what is officially known as the "informal rulemaking" procedure where an agency publishes a Notice of Proposed Rulemaking (NPRM), collects comments from the public, reviews those comments, and then publishes the final rule making reference to comments it considers relevant and noteworthy. Under this regular process of rulemaking (technically known as informal but quite formal compared to guidance documents), there is no such thing as an ANPRM. Technically, an ANPRM is simply a request for comments without a rule yet being proposed, but, as the name suggests, it is intended to be a step further along the path to actual rulemaking (which begins legally with an NPRM). Thus, this action by NHTSA in December 2020 was not even, truly, a beginning of the actual rulemaking but, as it was an ANPRM, it was an attempt to signal a move from guidance to rulemaking. For more details on the peculiarities of the US rulemaking process, see https://www.regulations.gov/learn and https://www.reginfo.gov/public/jsp/Utilities/faq.jsp or consult the latest edition of any textbook on US Administrative Law (e.g. Kristin E. Hickman and Richard J. Pierce 2014).

[303] Although the Biden administration extended the comment period on January 29th until April 1, 2021 (NHTSA 2021), there has been no further action based on the ANPRM.

the AV sections of their websites where they lay out their views of the current best guidance on federal AV policy.[304]

If the December 2020 ANPRM failed, one might reasonably wonder if USDOT or NHTSA have passed *any* actual rules related to AVs. The answer is yes, exactly one of very limited scope relative to the five guidance documents above: "Occupant Protection for Vehicles with Automated Driving Systems" (NHTSA-2021-0003) published in March 2022.[305] As the summary makes clear about this rule: "this final rule is limited to the crashworthiness standards… applicable to vehicles with and without ADS [aka AV] functionality."[306] Where the ANPRM was not the proper definition for the case because it was a dead-end, NHTSA-2021-003 is not the proper definition for the case because it is explicitly too limited in scope.

In the United States since 2016, the US Department of Transportation (USDOT) has made it clear that it, and its subsidiary agency the National Highway Transportation Administration (NHTSA) have jurisdiction of AVs. Through a series of five guidance documents developed and refined in consultation with stakeholders, USDOT and NHTSA have laid out constraints on AV manufacturers intended to allow this beneficial technology to be safely introduced and develop into a major economic sector in the United States and internationally. Although these five guidance documents (FAVP, AV 2.0, AV 3.0, AV 4.0, and AVCP) are all legally voluntary guidance, each asserts and builds on the principle that existing NHTSA regulations, procedures, and statutory already give NHTSA and USDOT the authority to make legally binding rules and enforcement actions should they choose to do so. Thus these are true, if flexible, constraints as they are the only clarification that the relevant regulators (USDOT and NHTSA) have provided to regulatees. In the context of the US Administrative State, in the absence of rulemaking, these technically voluntary guidance documents function as constraints upon regulatee actions whether simply as persuasive authority[307] or as actions in lieu of (or in preparation for) more formal regulatory rules.[308]

REGULATION (EU) 2022/1426 IN THE EU (2016-PRESENT)

As its member states are signatories to Vienna Convention on Road Traffic of 1968 ("Vienna Convention"), the EU develops safety regulations for vehicles at the EU level that comply with international standards that are then implemented into member state law.[309] Following a 2015 announcement by transport ministers in the G7[310] about the need for coordinated international regulations on AVs, the European Parliamentary Research Service undertook a study[311] to inform its members of the current status and suggested changes needed for AV regulation. From this study, it was clear that the EU would require a new *type-approval* protocol in order to introduce a new type of vehicle, an autonomous vehicle, onto the road. This new type-approval was enacted as Regulation (EU) 2022/1426.

[304] (NHTSA 2023; USDOT 2022)
[305] (NHTSA 2022)
[306] (NHTSA 2022, 18560)
[307] (Aman 1994)
[308] (Newman and Bach 2004; Meyer 2013)
[309] (Pillath 2016, 6)
[310] (European Commission 2015)
[311] That study is (Pillath 2016); this brief overview narrative is greatly indebted to her work.

The EU's implementation of type-approval to comply with the Vienna Convention was enacted and revised several times before AVs were added as Regulation (EU) 2022/1426. Initial compliance as the European Union (EU) was enacted as Directive 2007/46/EC, which repealed and replaced the much amended 1970 Council Directive 70/156/EEC from the predecessor European Economic Community (EEC).[312] This implementation was itself frequently amended over the following 11 years and eventually replaced with Regulation (EU) 2018/858 in 2018 which became the new framework for type-approval for all motor vehicles and trailers with a revision and updating again in 2019 as Regulation (EU) 2019/2144.[313] Each of these documents in their turn served as the basis for the EU and member-states approaches to motor vehicle approval for operation on public roads.

Autonomous Vehicles (aka Automated Driving Systems or ADSes) were added to the then-current general regulation (Regulation (EU) 2019/2144) by Regulation 2022/1426 on August 5, 2022. In this regulation, the EU spelled out a very short and simple scope ("manufacturer may apply for …type-approval under this Regulation of the automated driving system of vehicles … provided that those vehicles fulfil the requirements of this Regulation.")[314] That short scope is followed by a similarly short, legally speaking, set of definitions (only 3 pages) and then a single page that details the real heart of the regulation: the 4 Annexes which spell out the technical specifications and compliance procedures required of AVs to seek and receive type-approval to operate in the EU.[315]

CROSS-CASE COMPARISON

In comparing the US and EU cases, it's clear that both US and EU transportation communities agree on the dangers of humans behind the wheel and the potential for highly autonomous vehicles (Levels 4 and 5) to greatly reduce traffic dangers. In the US, a combination of administration changes and a national hesitancy about preemptive regulation led to a series of perpetual guidance documents between 2016 and 2021. In the EU, a system without any such hesitancy about preemptive regulation,[316] they proceed along a similar timeline (2016-2022) but ended with a new type-approval category for autonomous vehicles (Regulation (EU) 2022/1426). While the EU process was straightforward, orderly, and has terminated in final regulation, the US process was characterized by a continual set of guiding constraints couched in shifting rhetoric based on administration goals. However, both represent clear constraints placed upon the development and marketing of AVs which the US and EU considered beneficial to both the development of a vital national safety resource (fewer road deaths due to human drivers) as well as a lucrative market for automotive technologies.

Returning to the disruption caused by AVs,[317] it is clear that both US and EU regulators saw AVs as a vital technology for future reduction of harm placing them firmly in the Safety Culture worlds from Table 12. However, while it remains unclear where US and EU approaches will eventually fall, it is clear that at the current time both fall into the Safety Culture Ideal world ("AV are a safer option consumers should have") and have thus enacted constraints seeking to

[312] (European Parliament and Council of the European Union 2007, 263/1)
[313] (European Parliament and Council of the European Union 2018; 2019)
[314] (European Commission 2022, 221:221/3)
[315] (European Commission 2022, 221:221/3-221/6)
[316] (Taeihagh and Lim 2019, 109; Nicola, Behrmann, and Mawad 2018)
[317] See page 89

avoid the dangers of unsafe products reaching the market without taking the further step of mandating that all new vehicles must have AV technologies.[318] We are thus not yet approaching in either case the Safety Culture Precautionary world ("Trolley Problem Arms Race") but neither does it seem that there is much real doubt among vehicle standards regulators that the technology has a compelling potential to realize real safety gains rather than safety threats. News coverage and conceptual analysis may very well reveal a potential tradeoff between immature technological threat and mature technological safety,[319] but it is clear that for regulators charged with vehicle safety regulation, the question is clear: the huge safety potential (and the economic potential of the new industry) clearly and decisively outweigh the transitory difficulties of properly introducing the AV technology to the market.

How Confident Can We Be that Perpetual Guidance in the US and Regulation (EU) 2022/1426 represent a Beneficial Constraints Model?

Based on the historical narratives above, the US and EU enactment of constraints on AVs which were considered beneficial by their constituencies suggest that AVs are a good illustrative case for the Beneficial Constraints regulatory imaginary applied to a disruptive technology in a well-established regulatory regime. However, we need not simply rely on asserting this judgment, we can place boundaries on our degree of confidence. Thus, as the illustrative case for Beneficial Constraints in which technological innovation disrupts an established market and regulatory regime, AV is subjected in this section to a Bayesian Type Validation (BayesTV) in order to demonstrate how confident we can be that it does, indeed, represent a distinctive regulatory imaginary of disruptive innovation.[320] This section explains how BayesTV was applied to AVs in the US (Perpetual Guidance, 2016 to Present) and the EU (Regulation (EU) 2022/1426) cases by first discussing relevant priors, then analyzing the weight of statutory intent and near rival evidence, characterize potential black swan evidence, and then concludes with a final type classification and sensitivity to priors.[321] It concludes by explaining that, for any reasonable set of priors, we can be meaningfully to decisively confident that AV regulation is indeed a case of Beneficial Constraints while also identifying the specific loci of contention where the reader can evaluate their level of agreement or departure from this conclusion.

Possible Types and Priors for AV

The possible regulatory imaginaries which the AV case could assume are detailed in the deductive typology developed in Chapter 3 and presented in Table 3 in that chapter (reproduced above as Table 13). From the deductive typology and the reasoning in Chapter 2, we have seven distinct types which are plausible: the Folk Economic Model, Market Ideological, State-as-Venue, Capture, Technology-Based Regulation, Beneficial Constrainer, and Adoption Catalyst.

[318] As they eventually did with seatbelts, airbags, rear view cameras, and catalytic converters.

[319] (c.f. "'I Am A Gold-Collar;' Driverless Tesla Backseat Rider Param Sharma Basks In Social Media Notoriety As He Flaunts His Wealth" 2021; Torchinsky 2021; Taeihagh and Lim 2019) see also discussions and concerns from state-level regulators in the United States in (Mukherjee et al. 2023)

[320] See Chapter 4 for a full explanation of Bayesian Type Validation, particularly the sections on BayesTV in Practice for an explanation of how the analysis in this section was performed.

[321] The full explicit application of BayesTV for the AV cases may be found in Appendix B.

These seven models present the rival worlds under which BayesTV must evaluate the evidence in order to conclude which model the evidence speaks most strongly for.[322]

We can assign several possible prior probabilities to the case being of a particular type.[323] If we are to adopt a *naïve* assumption, we would weight all seven imaginaries equally with no weight-of-evidence (WoE) for any of them (0 dB across all imaginaries, see Table 14). If, instead, we use *common background information* about the AV cases, we might be led to believe that the State-as-Venue model is more likely given explicit reliance on technical specifications and classifications by the Society of Automotive Engineers in defining what AVs are as discussed in the "What are AVs and Why are They Disruptive" section of this chapter. Additionally, if we refer to the *case-specific background knowledge* in each case narrative, the USDOT's stated desire to "[act] as a convener and facilitator"[324] makes the State-as-Venue imaginary more likely in the US case. At the extreme, the USDOT desire under the Trump Administration to excessively promulgate the voluntary nature of the already voluntary guidance documents may lead us to think that the Market Ideological model is at work because of the repeated invocations of the dynamism of the private sector and the need to remove burdensome regulations. In the EU case, the narrative suggests that we might expect Technology-Based Regulation to be more likely because the EU went directly to type-approval, a step the USDOT considered to be overly constraining and technologically limiting.[325] We can represent each of these background information-based priors by placing a moderate amount of evidence (10 dB) against Beneficial Constraints for each of the three relevant comparisons in Table 14.[326]

Finally, to satisfy a frequentist logic to wrap up all objections in a weight against the model of interest, we may adopt a strong *skeptic*'s approach which would put a strong disadvantage to the Beneficial Constraints imaginary because it is the focus of this chapter and then equally weight each of the other models. Following Fairfield and Charman's (2022, 133) advice, "a very high prior log-odds in favor of a well-established hypothesis relative to a far less plausible rival might reasonably be set at around 50 dB."[327] Thus, we represent the strong skeptic's position by placing 50 dB against Beneficial Constraints for each of the comparisons in Table 14.

Based on the title of this chapter and discussion so far, it should not surprise the reader that my prior is that AV regulation is a characteristic Beneficial Constraints case for a disruptive technology introduced into a highly developed sector with a highly developed regulatory

[322] (Fairfield and Charman 2017, 1,10)
[323] Following the advice of (Fairfield and Charman 2017, 3-4 in online appendix). This paragraph presents extremes and a paradigmatic midpoint. The reader could adopt whatever priors she sees fit, but it is most instructive to think in classes of priors rather than a continuum because we can then concentrate on tipping points. Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival.
[324] (USDOT 2022)
[325] (USDOT 2018, ix)
[326] note that State-as-Venue gets two portions of counterweight as we might hold a prior about it for both common and case specific reasons.
[327] Note that Fairfield & Charman propose this threshold for non-arbitrary reasons; they cite Bayesian mathematician Jaynes (2003, 99–100) as the origin of 50dB based on mathematical logic of probability thresholds used in quantitative work.

Table 14: Prior Weights of Evidence for Perpetual Guidance and Regulation (EU) 2022/1426 (in dB)

Weight of Evidence (WoE)*	Naïve	Background Info	Skeptical
$\frac{\textbf{Beneficial Constraints}}{\textbf{Adoption Catalyst}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Capture}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Technology Based Regulation}}$	0 dB	-10 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{State as Venue}}$	0 dB	-20 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Folk Economic Model}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Market Ideological}}$	0 dB	-10 dB	-50 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

regime.[328] To state this precisely, it should be noted that each row in Table 13 can be read as a sentence[329] and thus the Beneficial Constrainer would read as follows: a regulator following the Beneficial Constraints model has *higher* access to *information* than firms, believes that the *market* is the *driver* for the spread of an innovation and would be content with *many* different optimal regulatory *outcomes*. Put plainly, a beneficially constraining regulator is defined by careful negation: they identify certain undesirable practices or outcomes and place constraints on regulated firms which are intended not just to reduce harm but to spur innovation towards *undefined desirable* practices and outcomes and away from *defined undesirable* ones. Critically, these constraints are not simply beneficial to society (as regulation generally is intended to be) but are also beneficial to the regulated firms; this form of regulation seeks not to curb the excesses of the market but instead to direct the dynamism of the market toward more economic (and socially) beneficial outcomes.[330] The presentation of evidence below in the execution of BayesTV is meant to give the reader, whatever their priors, an updated belief in whether or not this paragraph is the most plausible state of the world in the two AV cases.

[328] See the next chapter on GE editing regulation for a case of Beneficial Constraints of a disruptive technology introduced into a as-yet undefined regulatory regime and market sector.

[329] This is a result of the consistency of a deductive typology, discussed in detail in Chapter 3. Note that in that discussion the grammar of the sentence is exactly consistent for all 24 lines in Table 5 while in this chapter I have simplified the grammar to highlight the defining features of the Beneficial Constraints type.

[330] If capitalism is about creative destruction, as Schumpeter ([1943] 2010, 93–94) famously claimed, the beneficial constrainer seeks not to reduce the destruction but instead focus it on destroying current problems while finding creative solutions which are both economically productive and socially beneficial beyond the narrow dictates and time horizon of current market forces.

While priors are a vital part of Bayesian reasoning, the most important analysis in logical Bayesianism at the heart of BayesTV is the *sensitivity*[331] of the results to the priors rather than choosing precise priors before the analysis. For type validation, we are interested in how confident we can be that a particular case fits a particular type rather than weighing between plausible hypotheses. For that reason, while the author is likely to have a strong prior for one type (the type being validated) and the reader may have indifferent (naïve) or strongly contrarian (skeptical) priors, what matters is how loudly the evidence needs to speak to convince different types of readers. Thus, we will return to the discussion of priors in the conclusion of this section (Final Type Classification and Sensitivity to Priors). For now, the reader should file away what regulatory imaginary she thinks best fits the AV cases and concentrate on the reasoning behind the weights of evidence presented below and more fully explained in the Appendix.

BAYESTV OF AVS IN THE US PERPETUAL GUIDANCE AND EU REGULATION (EU) 2022/1426

In validating that autonomous vehicles are an example of the Beneficial Constraints regulatory imaginary, the key constituent variables are information, driver, and outcomes. A Beneficial Constraint conception of innovation regulation is defined by a regulator who is conceived as having higher access to information about a regulated domain combined with a belief that the market is the driver of adoption and who is content with many definitions of "optimal" outcomes rather than a single definition of optimality. The two following sections on each of the empirical AV cases will present evidence to update our belief in whether that is the most likely conception of regulators within each case. The evidence will focus on statements within the legislation or made by the regulators who implemented the regulations and how likely they are to be observed in the seven rival states of the world (see Table 13).

Following the advice of Fairfield and Charman (2022, 124–70), the weights of evidence are determined qualitatively but consistently through six paired comparisons of types (most likely vs. each of the six rivals) with the evidence evaluated in the order most logically coherent to the analyst. Note that because it *mathematically* does not matter in what order we incorporate evidence, we can choose the order most logical to the *substantive* comparisons at hand.[332] We can also reduce the number of comparisons by recognizing that *mathematically* a paired comparison of the six rival types against the same type is equivalent to comparing each of the rival types to each other.[333] Thus, we need only six total comparisons in order to consider all possible pairs and we are free to pick which type will be the comparator for all six rivals based on the *substance* of the case.

In their application of logical Bayesianism to social inquiry, Fairfield and Charman (2022, 129–36, esp. p.134) recommend that paired comparisons of types should be assigned weights of evidence (WoEs) in decibels (dB) based on a plain language description of relative differences. While earlier approaches relied on an auditory metaphor of "how loudly the data is speaking,"[334] the final specification recommends a generalized use of the logarithmic decibel (dB) scale to match the logarithmic nature of human sense perception without a reliance on a particular sense

[331] (Fairfield and Charman 2017)
[332] We can also redo our analysis with the evidence in a different order as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 139–40)
[333] We can also redo our analysis with different comparator type as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 140–42)
[334] (Fairfield and Charman 2017, esp. p.6 in online appendix)

Table 15: Qualitative-to-Quantitative Reference Levels for the decibel (dB) Comparison Scale

dB	Acoustic Perception	Plain Language Description	Equivalent Odds or Likelihood Ratio (approx.)
3	Smallest meaningful difference	Very weak	2:1
6	Clearly noticeable difference	Weak	4:1
10	Twice as loud	Moderate	10:1
20	Four times louder	Strong	100:1
30	Eight times louder	Very Strong	1000:1

Based on (Fairfield and Charman 2022, 133, Table 4.1), Note: Some digital audio files that illustrate these different decibel levels are available at: https://tashafairfield.wixsite.com/home/bayes-book

Table 16: Weights of Evidence for the Perpetual Guidance and Regulation (EU) 2022/1426 (in dB)

Weight of Evidence (WoE)*	Initial Evidence		Near Rival Evidence	
	US $E_{4\text{-Principles}}$	EU $E_{\text{Type-Approval}}$	US $E_{\text{Non-Regulatory}}$	EU $E_{\text{Recital Qualification}}$
$\frac{\textit{Beneficial Constraints}}{\textit{Adoption Catalyst}}$	20 dB	20 dB	40 dB	10 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Capture}}$	30 dB	30 dB	20 dB	30 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Technology Based Regulation}}$	40 dB	40 dB	30 dB	60 dB
$\frac{\textit{Beneficial Constraints}}{\textit{State as Venue}}$	10 dB	60 dB	0 dB[335]	10 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Folk Economic Model}}$	37 dB	40 dB	20 dB	40 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Market Ideological}}$	16 dB	60 dB	10 dB	60 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically $(-\infty,\infty)$ although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

[335] See the extensive reasoning in the Weight of $E_{\text{Non-Regualtory}}$ below (page 116) as well as Appendix B on pages 269 to 276

metaphor.[336] In keeping with the intuitive human sense perception metaphor, the lower bound for discernable differences is set at 3 dB ("smallest meaningful difference," "very weak," 2:1) while the upper bound is set at 30 dB ("eight times louder," "very strong," 1000:1). A set of qualitative-to-quantitative reference levels, their perceptual references, a natural language description of the relationship, as well as the corresponding odds or likelihood ratios is reproduced from (Fairfield and Charman 2022, 133) in Table 15.

Table 16 provides a summary of the weight of each of the pieces of evidence. The reasoning behind these weights of evidence are summarized in the sections which follow while the full explicit BayesTV analysis may be found in the Appendix. The possible contours of counterfactual evidence is explicitly defined after the analysis of the actually-existing evidence. The final interpretation and comparison with priors occurs in Table 22 on page 122.

INITIAL EVIDENCE: STATUTORY INTENT

The first piece of evidence highlighted for each case is based on the highest likelihood to correspond with the Beneficial Constraints model. As the GE cases were selected in order to validate the Beneficial Constraints model, their overarching statements of legislative intent shall be used to make the initial case for Beneficial Constraints over rival types as the most probable state of the world. In the US case, this evidence comes not from legislation but from regulator action in lieu of legislation: four matched principles from the Executive Summaries of the FAVP 2016 and AV 2.0 2017. In the EU case, this evidence comes from Regulation (EU) 2022/1426 where the European Commission and Council crafted a regulation which added a specific type-approval process for AVs to the vehicle code. The following sections discuss each of these two pieces of statutory intent evidence in turn.

Perpetual Guidance in the United States (2016-present)

While the BayesTV method recommends highlighting statutory intent from the enacting legislation as the initial evidence, the US regulation of AV technology has not been crafted through legislation. Rather, the US Department of Transportation (USDOT) issued a successive series of guidance documents indicating their jurisdiction to govern AVs under existing statutory authority while reserving the right to enact new rules as needed.[337] Since the first piece of evidence should capture the most informative statement of the intent of the ultimate statutory authority for the regulatory action, the following paired comparison between the principles of FAVP in 2016 from the Obama Administration and the supposed departure represented by AV 2.0 in 2017 from the Trump Administration serves to illustrated the consistent strain of guidance issued through this series of guidance documents.[338] This statement of statutory intent states:

[336] Both the senses of sight and sound, for example, evolved logarithmically in humans; a tenfold increase in absolute light power or sound intensity is perceived as a doubling in "brightness" or "loudness" by human senses. See (Fairfield and Charman 2022, 129–30) for further explanation of the appropriateness of the logarithmic scale across the physical, biological, and social sciences.

[337] (NHTSA 2016; 2017; USDOT 2018; NSTC and USDOT 2020; USDOT 2021)

[338] The reasoning behind this pairing between these two documents by different administrations from different political parties is explained above in the US case narrative section on page 95

Table 17: Specification of $E_{4\text{-principles}}$

#	**Federal Automated Vehicle Policy (FAVP)** (NHTSA 2016)	**Automated Driving Systems 2.0: A Vision for Safety (AV 2.0)** (NHTSA 2017)
1	Vehicle performance guidance for Automated Vehicles	Section 1: Voluntary Guidance on ADS Safety Elements (p.1-16 of 24)
2	Model State Policy	Section 2: Technical Assistance to States
3	NHTSA's Current Regulatory Tools	"NHTSA's enforcement authority… extends and applies equally to current and emerging ADSs [aka AVs]." (p. 3)
4	New Tools and Authorities	"laws and regulations will inevitably change over time" (p15)

A summary of the explicit Bayesian type validation (BayesTV) of $E_{4\text{-principles}}$ for each of the regulatory imaginaries in Table 13 is presented below in Table 18. The full narrative prose explaining these summaries of how likely we would be to see this evidence ($E_{4\text{-principles}}$) under the assumption that each potential regulatory imaginary was the true state of the world may be found in Appendix B. The significance of this analysis is discussed in the following section on the weight of evidence $E_{4\text{-principles}}$.

The Weight of Evidence 4-Principles

As seen by the weights of evidence in the last column of Table 18, the piece of evidence presented above ($E_{4\text{-Principles}}$) increases our confidence that Beneficial Constraints is the true state of the world in the US Coordinated Framework case. At 37 dB, this piece of evidence shouts against the Folk Economic Models which sees regulators as simply an impediment to innovation since it is a strong demonstration of regulatory competence with the detailed policy and technical guidance provided in the body of the document (information and effect columns of last two rows of Table 18). At 16 dB, this piece of evidence speaks moderately strongly against the Market Ideological imaginary due to the dissonance between the Trump Administrations condemnation of regulation in the framing of the documents[339] and the actual content of the documents which clearly demonstrates the importance of regulation working with innovators and entrepreneurs in the four principles detailed above..

The real stakes of the Beneficial Constraints model, however, lies in regulators placing constraints on firms intended to be *beneficial* to industry but not at the expense of society. As the other two constraint-effect imaginaries, Capture (30 dB) and Technology-Based Regulation (40 dB) are nevertheless spoken very strongly against because the specific content of the constraints do not match the specification of those imaginaries. For Capture, FAVP and AV 2.0 very clearly do *not* side with incumbent industry (the automobile industry) at the expense of new upstarts. Instead, they simply apply existing rules to new firms which wish to make vehicles for operation

[339] Desire not to "hamper" (NHTSA 2017, i, the introductory letter from USDOT Secretary Elaine L. Chao), the pretense of a regulatory guidance document that claims to be "a nonregulatory approach to automated vehicle technology safety (NHTSA 2017, ii)."

on public roads.[340] For Technology-based Regulation, the guidance in all five documents as evidenced by the principles in $E_{4\text{-Principles}}$ are principle based rather than technology constraining. Indeed, AV 3.0 makes clear that USDOT "will remain technology neutral,"[341] a clear contradiction of the expectations in a Technology-Based Regulation world which would expect a set of firm technical constraints (see Technology-Based Regulation row, Effect column of Table 18).

When compared to the other beneficial effect of regulation on innovation imaginary, this piece of evidence speaks strongly against the Adoption Catalyst world (20 dB) as the USDOT and NHTSA are taking no incentive or punishment based actions through which regulators could drive adoption of AV technology. While the final guidance document, AVCP in 2021, does lay claim to several research grants and investments, these are far from the direct incentive/punishment (carrot and stick) based approach we would expect of a regulator who wishes to drive innovation beyond the imagination of the market.[342]

Finally, this piece of evidence speaks only moderately against the State as Venue model (10 dB) due to the conflicting indicators of successive guidance documents (rather than rulemaking) and explicit framings of DOT & NHTSA's roles as "a convener and facilitator"[343] (rather than a stakeholder) as juxtaposed with the actual content of the documents themselves which demonstrate clear technical and policy competence as well as a distinct stakeholder view of how things should proceed. We can reconcile this apparent contradiction by viewing career USDOT and NHTSA employees as "doing truth to power."[344] While the concept of an American "deep state" is overblown, it is entirely reasonable to expect career civil servants in technical positions would be especially likely to tell the Trump Administration what they wanted to hear while maintaining technical competence in the body of their guidance documents.[345] We should also recall that guidance documents serve a true constraining[346] role despite being technically non-binding; in a demonstrably anti-rulemaking Administration (Trump), it would not be surprising to see reliance on this less contestable approach to governance.

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[340] For the potential of capture by "business/the economy itself," see the discussion in the appendix about cultural capture (Kwak 2014) and the privileged position of business (Lindblom 1977, 170–88). In short, these are better understood as contestations of the public good rather than subversions (capture) of the public good.

[341] (USDOT 2018, iv)

[342] We turn to an example of an actual Adoption Catalyst regulatory imaginary in the case of Electronic Health Records in Chapter 7.

[343] The quote "a convener and facilitator" comes from the topline description of USDOT's webpage on AV Activities, which is listed as last updated on March 28, 2022 although the text dates back to the publication of AV 4.0 (2020) and the AVCP (2021), see (USDOT 2022)

[344] Todd Laporte often used the phrase "Doing Truth to Power" to describe the professional motivation of many public servants to serve the mission of their organization (personal conversation). Although there does not appear to be a direct publication of this phrase, the ideas behind it are discussed at length in many of his works, c.f. (La Porte 1971)

[345] There is remarkably clearly evidence of the Trump Administration struggling not with a deep state but with simply the State: "But the same way the administration's media problems come not from "fake news" but simply from news, so its bureaucratic problems come not from an insidious, undemocratic "deep state" but simply from the state-the large, complex hive of people and procedures that constitute the U.S.
federal government." (Michaels 2017, 52–53)

[346] See footnote 29 in the main chapter and surrounding discussion on page 96

Table 18: BayesTV Constitutive Variable Comparison Summary for $E_{4\text{-principles}}$*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Detailed statements on Performance Guidance demonstrates high access to info	Explicit recognition that industry is driving AV spread & that this drive is desirable	Specific acknowledgement of many potential exciting outcomes	Both explicit regulatory constraints & implicit technical "guidance" constraints	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Clear recognition & reliance on market not regulator as driver	*No distinguishing relevance*	Pro-adoption spirit but non-direct method, no incentives or punishments	20 dB
Capture	*No distinguishing relevance*	Guidance documents both lay out clear claims to high info	*No distinguishing relevance*	Specific encouragement of many rather than one desirable outcome	*No distinguishing relevance*	30 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Outcomes are explicitly technology agnostic and principle-based	Constraint is performance not technology based	40 dB
State as Venue	Regulator concessions to "convening & facilitating" but clearly acting as a stakeholder	While acknowledging stakeholder contributions, clear statement of high info	*No distinguishing relevance*	*No distinguishing relevance*	More than moderation, model policy and technical guidance is constraining	10 dB
Folk Economic Model	Regulator concessions to "convening & facilitating" but clearly acting as a stakeholder	Demonstration of specific regulator competence anathema to Folk Economic Model	*No distinguishing relevance*	*No distinguishing relevance*	All five guidance documents explicitly pro-innovation rather than impediment	37 dB
Market Ideological	*No distinguishing relevance*	Guidance documents both lay out clear claims to high info	Market is the driver but with regulatory guidance critical to coordination	NHTSA reaffirms that regulation is a necessary and vital part of all potential outcomes	Coordinated Framework explicitly pro-innovation rather than impediment	16 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{4\text{-principles}}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 16 for further explanation and Chapter 4 for complete methodological specification.

Regulation (EU) 2022/1426 in the EU (2016-Present)

The statutory intent for the EU Regulation (EU) 2022/1426 approach to AV regulation comes from the regulation itself: the fact that it is a type-approval process specifically for autonomous vehicles. Although this piece of evidence incorporates both the fact that this is a vehicle type approval (rather than guidance document or other method of regulation) as well as the content of that type approval, the full title of the regulation can serve as an illustrative demonstration of the content of this evidence:

> *Commission Implementing Regulation (EU) 2022/1426*
>
> *of 5 August 2022*
>
> *laying down rules for the application of Regulation (EU) 2019/2144 of the European Parliament and of the Council as regards uniform procedures and technical specifications for the type-approval of the automated driving system (ADS) of fully automated vehicles (Text with EEA relevance)*
>
> *- (European Commission 2022, 221:221/1)*

As noted in this title, the EU took the rather straightforward and ordinary step when confronted with a new vehicle technology of specifying how it would be reviewed and approved as part of the vehicle code.[347] This choice to create a type-approval process and the content of that process forms $E_{\text{Type-Approval}}$, our initial evidence for the EU case.

A summary of the explicit Bayesian type validation of $E_{\text{Type-Approval}}$ for each of the regulatory imaginaries in Table 13 which were narratively explained above is presented below in Table 19. The full narrative prose explaining these summaries are omitted here for clarity and brevity but may be found Appendix B. The significance of this analysis is discussed in the following section on the weight of evidence $E_{\text{Type-Approval}}$.

The Weight of Evidence Type-Approval

As seen by the weights of evidence in the last column of Table 19, the piece of evidence presented above ($E_{\text{Type-Approval}}$) increases our confidence that Beneficial Constraints is the true state of the world in the EU Regulation (EU) 2022/1426 case. At 40 and 60 dB, this piece of evidence speaks very strongly against the two models which see regulators as simply an incompetent (Folk Economic Model) or undesirable (Market Ideological) impediment to the market because the constraints enacted follow the EU more cooperative style of regulation which places rules, but flexible ones, on technologies of interest.[348] This evidence also speaks very strongly (60 dB) against the State as venue imaginary as the EU is clearly taking a much more proactive role than merely the neutral moderator since it has created detailed guidelines and test procedures in Annexes II and III of the regulation.[349]

In our priors, we expected that Technology Based Regulation might be a near rival imaginary to Beneficial Constraints to the technologically involved type approval process. However, as we dive more deeply into the actual specification of the type-approval standards (Annex II) and the evaluation process (Annex III), it is clear that these are principle based rather than specific

[347] The latest amendment of which was Regulation (EU) 2019/2144, see case narrative on page 99

[348] (c.f. Kagan [2001] 2009) for a comparison between US and EU approaches to administrative law, particularly the cooperative nature of the EU as compared to the adversarial nature of the US.

[349] (European Commission 2022, 221:221/11-221/61)

Table 19: BayesTV Constitutive Variable Comparison Summary for $E_{Type\text{-}Approval}$ *

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	detailed technical appendices demonstrate high competence	Allowance for type-approval with member state variation places onus on market	explicit toleration for member state variation means many outcomes could be desirable	Type-approval requirements and procedure clearly place guardrails while allowing innovation to proceed	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is not driving adoption, no incentive or punishment	*No distinguishing relevance*	Clearly Constraining rather than Catalyzing although positive hopes for AV technology	20 dB
Capture	*No distinguishing relevance*	No claims of low information, in fact the opposite	*No distinguishing relevance*	Open to many potential outcomes which meet the type-approval standards	Constraining to type approval process, but not to the level of an uneven playing field	30 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Despite our prior, type-approval is principle rather than tech based	A focus on principles rather than required technology is constraining but not TBR	40 dB
State as Venue	*No distinguishing relevance*	EU stakes clear claim to high access to information	*No distinguishing relevance*	*No distinguishing relevance*	Far more than a neutral moderator, type-approval process sets out EU's perspective	60 dB
Folk Economic Model	*No distinguishing relevance*	Clear demonstrations of technical competence in Annexes II and III	*No distinguishing relevance*	*No distinguishing relevance*	Far from an impediment, EU wants AVs developed to these standards to increase safety	40 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	EU certainly does not abrogate authority to the market	Not an impediment but constraints intended to spur innovation	60 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{Type\text{-}Approval}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 16 for further explanation and Chapter 4 for complete methodological specification

technology solution based. Technology based regulation is characteristically a one size fits all "command and control" approach to a regulatory problem that specifies not what needs to be solved but how it must be solved (solution rather than principles).[350] This allows us to place a very very strong weight of evidence (40 dB) against Technology Based Regulation as despite being about a technological process, the criteria are principle rather than solution based.

Finally, we are left with two extremely different imaginaries as the closest comparators: Adoption Catalyst and Capture. Importantly, neither of these clos*est* comparators is actually a *close* comparator as both have strong or very strong weights of evidence against them from $E_{\text{Type-Approval}}$. In the case of Capture, we have a very strong weight of evidence (30 dB) in favor of Beneficial Constraints over Capture because we lack both any reasonable capturing entity and any distinctly uneven playing field created to benefit such an entity. The most plausible capture story would rely on an AV industry attempting to foist unsafe and immature products on an unsuspecting public. While the media enjoys this narrative, there is little technical disagreement in either the US or EU that AVs represent a significant promise to increase safety (and sell vehicles).[351] Adoption Catalyst then becomes our nearest rival, although there is still strong evidence (20 dB) against it in favor of Beneficial Constraints because the type-approval process offers neither incentives for adoption nor punishments for non-adoption of AVs.

NEAR RIVAL EVIDENCE:

As can be seen from the weight of evidence summary in Table 16, the initial evidence was least decisive (fewest decibels) about a different alternative type for each of the cases. In the US Perpetual Guidance case, the nearest rival model is the State as Venue model because the USDOT regulated AVs through guidance documents emphasizing voluntary compliance rather than through rulemaking. The principles in the initial evidence ($E_{\text{4-Principles}}$) are clearly consistent with a regulator who wishes to be seen as merely a "a convener and facilitator"[352] although it is relatively less likely than Beneficial Constraints because the content of the principles demonstrate a much more active role for the regulator than claimed by the State as Venue model. In the EU Regulation (EU) 2022/1426 case, the nearest rival model is the Adoption Catalyst model due to largely to the fact that this initial evidence ($E_{\text{Type-Approval}}$) spoke so loudly against all other rival types. Although Adoption Catalyst was still strongly (20 dB) spoken against by the initial evidence, the fact that the generally overly cautious EU regulatory system[353] created a type-approval process for a technology which is nearly, but not quite, actually ready for mass adoption could conceivably be seen as nearly catalyzing by comparison to the EU's usual reticence.

In this section, we highlight an additional piece of evidence which is most supportive of the respective nearest rival type for each of the two empirical cases. For the US Perpetual Guidance

[350] (c.f. Malloy 2010, entire, but esp. 283-296) about the rigidity and homogeneity characterization of the "conventional construction" of command and control regulation.

[351] The US (NHTSA 2016, 5; 2017, ii; NSTC and USDOT 2020, 2) and EU (Pillath 2016, 2) both repeatedly use the statistic that greater than 90% of crashes come from human error which can be seriously mitigated by proposed AV technologies. The technology is not quite here but it is also not off in the distant future (immature) from these estimates.

[352] The quote "a convener and facilitator" comes from the topline description of USDOT's webpage on AV Activities, which is listed as last updated on March 28, 2022 although the text dates back to the publication of AV 4.0 (2020) and the AVCP (2021), see (USDOT 2022)

[353] Or "precautious," see extensive discussion in Chapter 6 about the Precautionary Principle.

case, this evidence is the frequent claims, especially in the later documents, to be merely a facilitator among stakeholders. The evidence comprises a collection of statements from the AV 2.0, AV 3.0, AV 4.0, and the AVCP. For the Regulation (EU) 2022/1426 case, this evidence comes from the frequent references to expected revision and updating in the recitals that lead Regulation (EU) 2022/1426 because they demonstrate that although the EU sees this regulation as a step forward in approval, they still feel that there is much left to be defined.

Perpetual Guidance in the United States (2016-Present)

Of marked significance in the US regulation of AVs is the change of administration during the process from the Democratic Obama Administration to the Republican Trump Administration in 2017.[354] While and change in administration can have a significant impact on policy, the change from Obama to Trump was particularly significant to the administrative state due to both the rhetoric and the demonstrable competence of the two administrations. The Obama Administration, in line with most modern Democratic administrations, attempted to craft landmark policy (most famously the Affordable Care Act in 2010). At a more day-to-day level, the Democratic party platform of last 20 years has been built upon implementing public policy while the modern Republican party platform has been built upon a rhetoric of "smaller government" and a policy agenda of decreasing taxation on the wealthy.[355] Building on this rhetoric and agenda, the Trump administration came to power claiming to "drain the swamp" and looking to slash regulation for the sake of it. It quickly became clear, however, that in addition to being against regulation and administration on a rhetorical and principle level, the Trump Administration was exceptionally bad at actually executing their rhetoric.[356]

With the change of administration came a change in the rhetoric of AV policy, at least in the cover letters and framing from Trump Administration appointed Secretary of Transportation Elaine Chao. While I have argued above that this shift in framing was more rhetoric than substance,[357] taking seriously the nearest rival type analysis means that I will highlight evidence that is most supportive of the counterargument: that claim was more than rhetoric and was in fact a substantive change which has shaped US AV regulation toward the nearest rival type: State as Venue. The quotes below are illustrative of this trend in rhetoric shift, while the entire strain of rhetoric forms the evidence for the nearest rival type ($E_{\text{Non-Regualtory}}$)

[354] The 2016 election resulted in a transition in power in January 2017. The Obama Administration thus authored the FAVP, but the Trump Administration authored AV 2.0, AV 3.0, AV 4.0, and the AVCP. For more details, see the case narrative in Perpetual Guidance in the United States (2016-Present) on page 95.

[355] This divide can be traced back to the 1990s with Newt Gingrich and Grover Norquist moving the Republican Party to an absolutist position against public spending to achieve public policy (or even back to Ronald Reagan's decrying of the supposed worst sentence in the English language "I'm from the government and I'm here to help"). It took real center stage, however, with the Tea Party movement which began in 2008 in response to Barack Obama's election and the perception that he would be a "tax and spend" Democrat. Excellent explanations of this rhetorical and policy divide can be found in (Skocpol and Williamson 2012; Hacker and Pierson 2020).

[356] (Michaels 2017)

[357] See, for example, the discussion above about $E_{\text{4-Principles}}$ (page 107) and the discussion in the case narrative (pages 95 to 99) as well as the explicit BayesTV in Appendix B for $E_{\text{4-Principles}}$ (pages 256 to 263)

The most expressive statement of the supposed shift appears in AV 2.0 from 2017:

> *"[AV 2.0:] A Vision for Safety replaces the Federal Automated Vehicle Policy released in 2016…The Federal Government wants to ensure it does not impede progress with unnecessary or unintended barriers to innovation…In this document, NHTSA offers a nonregulatory approach to automated vehicle technology safety."(NHTSA 2017, i–ii)*

This is echoed later in AV 3.0:

> *"Automation technologies are new and rapidly evolving. The right approach to achieving safety improvements begins with a focus on removing unnecessary barriers and issuing voluntary guidance, rather than regulations* ***that could stifle innovation****." (USDOT 2018, viii, emphasis in original)*

Although not explicitly highlighted in AV 4.0, the rhetoric reappears in a subdued form in the AVCP on January 11, 2021; just 9 days before the Trump Administration transition to the Biden Administration:

> ***"2. Modernize the Regulatory Environment*** *– U.S. DOT will modernize regulations to remove unintended and unnecessary barriers to innovative vehicle designs, features, and operational models, and will develop safety focused frameworks and tools to assess the safe performance of ADS technologies." (USDOT 2021, ii, emphasis in original)*

Together, these statements and the sentiments like them that suffuse the Trump Administration documents (AV 2.0, AV 3.0, AV 4.0, AVCP) comprise the Near Rival evidence for the US Case, $E_{\text{Non-Regulatory}}$.

A summary of the explicit Bayesian type validation (BayesTV) of $E_{\text{Non-Regulatory}}$ for each of the regulatory imaginaries in Table 13 is presented below in Table 20. The full narrative prose explaining these summaries of how likely we would be to see this evidence ($E_{\text{Non-Regulatory}}$) under the assumption that each potential regulatory imaginary was the true state of the world may be found in Appendix B. The significance of this analysis is discussed in the following section on the weight of evidence $E_{\text{Non-Regulatory}}$.

The Weight of Evidence Non-Regulatory

As seen by the weights of evidence in the last column of Table 20, the piece of evidence presented above ($E_{\text{Non-Regulatory}}$) increases our confidence that Beneficial Constraints is the most likely state of the world in the US Perpetual Guidance case over all imaginaries except the State as Venue imaginary. As expected, given the selection criteria for the near rival evidence, this evidence is least decisive between Beneficial Constraints (the most likely type) and State as Venue (the nearest rival type). However, perhaps damningly, even when highlighting the strongest evidence for State as Venue, that evidence is not informative (0 dB) in favor of the State as Venue imaginary over the Beneficial Constraints imaginary because there are two rival explanations which are, most skeptically, equally plausible.[358]

The two rival explanations of this evidence, critical to the distinction between Beneficial Constraints and State as Venue, hinge on whether we believe the statements of AV 2.0, 3.0, 4.0,

[358] I have chosen to err on the side of skepticism and assign 0 dB to this evidence. However, I also think there are strong reasons to believe that this skepticism is excessive in the specific context of the Trump Administration as explained in the following paragraph and at great length in Appendix B (beginning on page 270)

and AVCP as "a nonregulatory approach" can be taken at face value or instead should be understood as subterfuge. While logical Bayesian analysis often directs us to consider any need to assume subterfuge as inherently less likely than a rival world where no subterfuge is needed,[359] there are good grounds to believe that subterfuge is the *more* likely actual state of the world during the Trump Administration specifically on the issue of economic regulation. As explained in the case narrative,[360] the Trump Administration was exceptionally bad at running the administrative state and the career civil servants who worked below the level of the political appointees often "did truth to power"[361] in keeping the apparatus of the government functioning despite the rhetoric of the administration.

In that specific time and place, it would be *more* surprising to see career USDOT and NHTSA employees radically change the direction dictated by their technical expertise and experience in favor of a mission-threatening abrogation of authority. In other words, while subterfuge is generally a less likely event than compliance with formal authority for government actors, the comparison here should be between subterfuge in service of the agency mission and authentic change of direction in contradiction of the agency mission. And public agencies are categorically mission-driven organizations.[362] The mission of the USDOT and especially NHTSA is:

> *"Save lives, prevent injuries, and reduce economic costs due to road traffic crashes, through education, research, safety standards, and enforcement activity" - (NHTSA 2017, 1, Note: this is a Trump Administration document)*

Beyond simply the logic of pro-mission subterfuge and anti-mission veracity, the prior piece of evidence, $E_{4\text{-Principles}}$ demonstrates that the core principles of the actual regulatory guidance are consistent between the Trump and Obama Administration Documents. Thus, combining both logical and empirical reasons, we can conservatively say that this piece of evidence ($E_{\text{Non-Regulatory}}$) is at least a plausible in the specific Beneficial Constraints world of the Trump Administration as it would be were the state actually be to be acting from a State as Venue imaginary.

With respect to the two models which see regulators as simply an impediment to innovation (Folk Economic Model and Market Ideological), we can moderately (10 dB) and strongly (20 dB) conclude, respectively, that this evidence speaks in favor of Beneficial Constraints over them. The anti-mission pro-Administration interpretation of the rhetoric in this evidence is clearly consistent with the Market Ideological imaginary because the Trump Administration's intended approach *is itself* a relatively bald statement a Market Ideological approach.[363]

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[359] (Fairfield and Charman 2022, 109-111,451-454)

[360] See the discussion in the Chapter 5 case narrative (pages 95 to 99) as well as in the section above on State as Venue for $E_{4\text{-Principles}}$, see page 259 in Appendix B. Note as well, methodologically, that incorporating background knowledge such as this case narrative and the reasoning in other comparisons is *exactly* what it means to be a Bayesian rather than a frequentist (who might require you to analyze all evidence in isolation in order to avoid a frequentist notion of bias).

[361] c.f. (La Porte 1971), see discussion in footnote 704 on page 259.

[362] (Goodsell 2010, 2)

[363] Although the Trump Administration's rhetoric can be economically populist (protectionism, anti-globalization), its actions clearly follow the old doublespeak of prior market fundamentalists like Ronald Reagan and Margaret Thatcher and do the opposite (Block and Somers 2017, 389).

Table 20: BayesTV Constitutive Variable Comparison Summary for $E_{Non\text{-}Regulatory}$ *

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	Regulators "doing truth to power" (parroting Administration rhetoric while acting pro agency mission) or they may be authentically pro-administration and anti-mission.[364]		*No specific relevance*	*No specific relevance*	Rhetoric: Remove Constraints Content: maintain constraints	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Both interpretations of the MLT and nearest rival make it clear that market is driver	*No distinguishing relevance*	The conflicting honest/dishonest interpretations would be shocking in a proactive AC world.	40 dB
Capture	*No distinguishing relevance*	The regulators still have important information, it's just "voluntary"	*No distinguishing relevance*	Clearly not in favor of a single outcome; very pro-innovation & new entrant firms.	*No distinguishing relevance*	20 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Clearly not in favor of a single outcome; very pro-innovation & new entrant firms.	If there are constraints, they're principle not technology based.	30 dB
State as Venue	Weighing mission-affirming subterfuge against mission-violating authentic rhetoric, we must conservatively consider this a wash		*No distinguishing relevance*	*No distinguishing relevance*	No distinction Due to viable conflicting motivations for regulators saying what they said	0 dB[365]
Folk Economic Model	Regulator is not abrogating responsibility, competence, or authority		*No distinguishing relevance*	*No distinguishing relevance*	Not an impediment to innovation, even if anti-regulatory rhetoric	20 dB
Market Ideological	The conflicting interpretations are MI vs. BC.		*No distinguishing relevance*	Not a 'no desirable outcomes' world	Not an impediment to innovation, even if anti-regulatory rhetoric	10 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{Non\text{-}Regulatory}$ Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 7 for further explanation and Chapter 4 for complete methodological specification.

[364] Note: The Relationship and Information cells have been combined in this analysis because the distinguishing information in both cells would be the same , thus it is more space efficient to span both and provide additional clarity.

[365] See the extensive reasoning in Appendix B on pages 269 to 276

However, based on the analysis of $E_{4\text{-Principles}}$,[366] the actual content of the guidance does not match the rhetoric and thus undermines the support for the Market Ideological world interpretation. In other words, it may claim to be "developing a regulatory framework that encourages, rather than hampers, the safe development, testing and deployment of automated vehicle technology" but it's still developing a regulatory framework despite other sections of the documents which claim this to be "a nonregulatory approach."[367] Combined with a lack of impediment to innovation and instead an encouragement of innovation through regulatory guidance, we can be confident the evidence is moderately to strongly surprising in these two worlds.

Both Capture and Technology Based Regulation see regulators as a constraint on innovation, although of a different character than Beneficial Constraints. The Capture imaginary sees regulators as a constraint in favor of existing regulated entities who have 'captured' regulatory to serve their interests while this evidence explicitly rejects the language of capture to encourage new entrant firms to build on this guidance and innovate.[368] This contradiction makes us strongly (20 dB) confident that Capture is not the true state of the world for this evidence. The Technology Based Regulation imaginary sees regulators as a constraint requiring or banning a particular implementation of a technology while the content of the voluntary guidance as well as the rhetoric in this evidence very strongly (30 dB) endorses "technology neutral[ity]."[369]

Finally, this evidence is very clearly paradigmatically unlikely (40 dB) in an Adoption Catalyst world because the drive for adoption by the regulator is explicitly lacking and the rhetoric is anti-regulatory. All together then, this near rival evidence which was selected to highlight the best possible case for the nearest rival imaginary (State as Venue) provides no support (0 dB) for that imaginary over Beneficial Constraints while moderately to extremely strongly increasing our confidence in Beneficial Constraints over the other five rival imaginaries.

Regulation (EU) 2022/1426 in the EU (2016-Present)

As discussed in the analysis of the initial evidence ($E_{\text{Type-Approval}}$), there is not a true near-rival imaginary to Beneficial Constraints for the Regulation (EU) 2022/1426 case because all rival imaginaries have strong (20 dB) or more weight against them. However, the near*est* rival is that of Adoption Catalyst because although the regulation lacks an incentive or punishment structure to catalyze adoption, Regulation (EU) 2022/1426 is still uncharacteristically anticipatory of a not-quite-ready technology for the classically precautionary EU.[370] Thus, somewhat by default and somewhat by contrast, we can take the EU moving before the technology is "ready" as a relatively catalytic rather than constraining step.

[366] See pages 107 to 110 in Chapter 5 and 256 to 263 in Appendix B.
[367] Yes, indeed, AV 2.0 really does say "a regulatory approach" on page i and "a nonregulatory approach" on page ii (NHTSA 2017, i–ii)
[368] "there is no need for U.S. DOT to favor particular locations or to pick winners and losers." (USDOT 2018, ix)
[369] (USDOT 2018, iv)
[370] See the extensive discussion of the EU's precautionary principle in Chapter 6 as well as a discussion of the general cooperative regulatory culture in the EU as compared to the adversarial one in the United States in (Kagan [2001] 2009).

Evidence that the EU believes it is enacting the type-approval standard in Regulation (EU) 2022/1426 comes from the frequent references in the recitals[371] to the need for frequent revaluation, quick updating, and constant monitoring. Although this near rival evidence ($E_{\text{Recital Qualification}}$) includes the qualifications and hesitancy which suffuse all nine recitals in their entirety, we can illustrate it with statements such as:

> *(2) …As next stage, the Commission will continue the work to further develop and adopt by July 2024…*
>
> *(3) …The review of such use cases, and their amendment if required, to cover additional use cases should be conducted on a regular basis…*
>
> *(5) …Given the complexity of automated driving systems, it is necessary to supplement the performance requirements and tests of this Regulation by manufacturer documentation…*
>
> *(European Commission 2022, 221:221/1-2)*

Taken together, these statements illustrate an EU that is moving to create a type approval ahead of the full maturity of AV technology because they qualify the detailed provisions which follow by setting up both immediate follow-on amendments as well as general guidance to monitor and revise the guidelines as the technology develops and matures. They thus define the Near Rival evidence for the EU case: $E_{\text{Recital Qualification}}$.

A summary of the explicit Bayesian type validation of $E_{\text{Recital Qualification}}$ for each of the regulatory imaginaries in Table 13 which were narratively explained above is presented below in Table 21. The full narrative prose explaining these summaries are omitted here for clarity and brevity but may be found in the Appendix. The significance of this analysis is discussed in the following section on the weight of evidence $E_{\text{Recital Qualification}}$.

The Weight of Evidence Recital Qualification

As seen by the weights of evidence in the last column of Table 21, the piece of evidence presented above ($E_{\text{Recital Qualification}}$) increases our confidence that Beneficial Constraints is the most plausible state of the world against all rivals including the nearest rival, Adoption Catalyst. Although this evidence was selected to speak as strongly as possible for Adoption Catalyst, we are still left with at least moderate (10 dB) support for Beneficial Constraints over Adoption Catalyst because despite the relatively proactive and non-precautionary approach of moving to approve the technology before it is fully developed, there are none of the incentives for adoption (or punishments for non-adoption) we would expect to see in an Adoption Catalyst world.

While this evidence also speaks less loudly against State as Venue than the initial evidence ($E_{\text{Type-Approval}}$), we can nevertheless see that this does not suggest that we should consider State as Venue as a near rival overall. Although the hesitancy and qualification in this piece of evidence might be consistent State as Venue, it is clear that the EU believes "it is necessary to adopt the implementing legislation for the type-approval of the automated driving system of fully automated vehicles" even if "[a]s next stage, the Commission will continue to work to further develop… necessary requirements."[372] Thus while a cold look at the weight of evidence of only

[371] "Recitals" refer to the numbered statements which follow the "Whereas" in an EU Regulation but proceed the actual text of the Regulation. While they do not carry the weight of law, they are intended to reflect the EU's reasoning behind the Regulation. (Publications Office of the European Union 2022, 35–36)
[372] (European Commission 2022, 221:221/1)

Table 21: BayesTV Constitutive Variable Comparison Summary for $E_{\text{Recital Qualification}}$*

Constitutive Variables (Independent Variables)					Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Hesitant, qualified, but confident there is enough information to take initial moves	Clearly not the regulator, thus relying on the market	Closing off known dangers while allowing for adaptation to multiples possible final configurations	Clearly constraining within the principles and optimistic but not pushing for adoption	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Clearly not the regulator, thus relying on the market	*No distinguishing relevance*	Clearly no incentives or punishments to drive or catalyze adoption	10 dB
Capture	*No distinguishing relevance*	Implausible low information interpretation in light of Annexes II and III	*No distinguishing relevance*	Clear allowance for multiple outcomes	Constraining of known dangers but allowance for development of multiple potential benefits	30 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Clear reliance on principles rather than "one-size-fits-all" solution	Principles based constraint based on Annex II and III rather than solution based constraint	60 dB
State as Venue	*No distinguishing relevance*	Hesitancy might be consistent except in the context of the rest of the recitals	*No distinguishing relevance*	*No distinguishing relevance*	Although clearly recognizing that changes may be needed, EU taking more than a moderating role	10 dB
Folk Economic Model	*No distinguishing relevance*	Ironically, the qualifications are not strong enough for expected low information	*No distinguishing relevance*	*No distinguishing relevance*	Regulators are clearly not standing in the way of innovation by providing a path to approval	40 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Despite qualifications and hesitancy, EU moves forward with initial regulation	Market Ideological would expect inaction under uncertainty, exact opposite occurs	60 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $\text{WoE}_{\text{Recital Qualification}}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 16 for further explanation and Chapter 4 for complete methodological specification

this piece of evidence might suggest a closer look at State as Venue, the background information discussed in the case narrative as well as the analysis of the initial evidence leave us confident that the Beneficial Constraints explanation for the qualification (an embrace of curtailing known dangers while embracing unknown future developments) is more plausible overall.

We can also rule out both the Folk Economic Model (40 dB) and Market Ideological (60 dB) imaginaries because, ironically, these qualified and hesitant statements do not strongly enough decry the 'incompetence' of regulators. The Folk Economic Model world would expect blustery denial or defensive overconfidence rather than the measured qualifications we actually see here. The Market Ideological world would expect a regulator who makes these qualified claims to take no action because they would recognize, in such a world, that any action could never be as good as the wisdom of the market especially when faced with a not-quite-mature technology.

Finally, the other two constraint-effect imaginaries of Capture (30 dB) and Technology Based Regulation (60 dB) can both be ruled out because although Regulation (EU) 2022/1426 is constraining, the constraints it puts in place do not match the constraints these worlds would expect. In a Capture world, the constraints would need to be based on a low access toinformation essentially ceding decision making to the capturing entity. Although we can be quite confident that there is no capturing entity,[373] even if there were the constrains put in place are much more plausibly those of Beneficial Constraints: closing of known dangers while allowing for many avenues potentially beneficial developments. The constraints are not consistent with Technology Based Regulation because they are not solution (aka single technological implementation) based but instead are principle based. On top of that, the hesitancy, qualification, and adaptation of this evidence would not be seen in the characteristically rigid statements of blanket mandates expected in the Technology Based Regulation imaginary.[374]

BLACK SWAN EVIDENCE AND THE COUNTERFACTUAL

Before adjudicating the final type classification and sensitivity to priors, due diligence requires us to consider what evidence would be consistent with the extreme opposite of the suggested type classification being the most probable state of the world; the so-called "black swan" evidence. As Beneficial Constraints is the most likely type for the autonomous vehicle cases and the nearest rivals are State as Venue and Adoption Catalyst, the question of extreme opposite is a complex one. If we consider the neutral moderator State as Venue imaginary, we could consider either 'extreme' direction (top or bottom of Table 13) to be the black swan. However, as the actual analyzed imaginaries are one extreme (Beneficial Constraints and Adoption Catalyst) that would leave us with only the other extreme (Folk Economic Model).

If we look only at the proactive imaginaries of Beneficial Constraints and Adoption Catalyst, the extreme opposite of them would be the Folk Economic Model. Market Ideological would generally also be considered the opposite, but the complexity of the US Perpetual Guidance case makes it less clear that we can consider that an extreme opposite as it may be consistent with the near rival evidence ($E_{\text{Non-Regualtory}}$). However, as explained at length in the weight of $E_{\text{Non-Regualtory}}$ section as well as in Appendix D, we are able place moderate to strong weight against Market

[373] See the discussion around the initial evidence, $E_{\text{Type-Approval}}$, which explains that the most plausible capturing entity contradicts well known technical consensus on the promise of AVs for social good (public safety).

[374] (c.f. Malloy 2010, 283–85) on the "rigidity proposition" and "homogeneity proposition" of the conventional construction of command and control (aka. Technology-based) regulation.

Ideological because the rhetoric of the Trump Administration documents did not match the content of those documents. While that rhetoric may be consistent with the Folk Economic Model, the actions taken within the guidance documents to place guiding constraints on AV entrepreneurs and innovators certainly do not match the Folk Economic Model Imaginary. We can thus make only the Folk Economic Model a true "black swan" imaginary.

From both sets of analyses, we are left with the Folk Economic Model as the black swan imaginary, and there is simply little reason to expect evidence in favor of it. In a Folk Economic Model world, we would expect to see regulators acting lost due to lower access to information than market participants and either recusing themselves from regulation in order to stay out of the way until the market has innovated[375] or implementing harsh and inappropriate anti-innovative regulations. We instead see even the US case, which may be somewhat consistent with the neighboring Market Ideological imaginary, making a strong claim to high information access in order to provide technical guidance to innovators and entrepreneurs.[376] Although we can be confident that such evidence consistent with the Folk Economic Model is unlikely to exist in either the US or EU cases, a skeptical reader should contact the author with such evidence so that it may be incorporated into analysis and allow us to radically update our priors.

FINAL TYPE CLASSIFICATION AND SENSITIVITY TO PRIORS

For final classification based on updating our beliefs in which regulatory imaginary is most probably animating the regulatory framework around autonomous vehicles, we add the decibel comparisons between the Beneficial Constraints imaginary and each of the alternative models from each piece of evidence and then add those to the priors discussed at the beginning of this section. These comparisons are presented in Table 22.

Consistent with the design and intent of Bayesian type validation, the evidence can tell several disciplined and clear stories depending on how it is combined with priors and across cases. If we combine all of the evidence for both the US and EU cases, we find decisive evidence[377] to believe that AV technology is regulated from the Beneficial Constraints imaginary (all imaginaries 80+ dB, Combo Posterior Column under a in Table 22). If we look just at the US case (Table 22, column a "US Post"), we find very well-established evidence (50-70 dB) for

[375] While this may seem fanciful, this "wait and see" attitude was exactly how the US Federal Reserve approached mobile payment apps for years. (Lowry 2016, 384)

[376] See the discussion of $E_{\text{Non-Regulatory}}$ (page 116) and the much lengthier discussion of same in Appendix B (page 269 to 278) for why the rhetoric of the Trump Administration documents in the United States is not Black Swan evidence despite an anti-regulatory tone to their regulatory guidance.

[377] Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival. Fairfield and Charman (2022, 162–63) proceed to explain that a more stringent threshold of 50-70 decibels equates to the thresholds of confidence used by quantitative Bayesian statisticians in the physical and biological sciences; they note that 62 dB is roughly equivalent to the 5 sigma threshold for discovering a new particle in Physics and 67 dB the chance that any given commercial airplane flight will crash vs. land safely. While Fairfield and Charman (2022, 162, footnote 34) also caution us that you cannot truly mathematically convert Bayesian odds to frequentist p-values because they are different ontological statements, most quantitative social scientists are happy with $p<0.1$ (~27 dB) and $p<0.05$ (~30 dB) for publication and are ebullient about $p<0.01$ (~37 dB). Fairfield and Charman ultimately recommend a threshold of 80-100 dB to consider a qualitative research question "settled" both to guard against potential unaccounted for bias as well as to deal with the reality that quantitative social scientists often show higher skepticism toward qualitative evidence than they do towards their own thresholds of significance.

Table 22: BayesTV Prior and Posterior Weights of Evidence for the AV Cases, US Perpetual Guidance and Regulation(EU) 2022/1426 evidence (in dB)

	a				b				c			
Weight of Evidence (WoE)*	**Naïve**				**Background Info**				**Skeptical**			
	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior
$\frac{Beneficial\ Constraints}{Adoption\ Catalyst}$	0	60	30	90 dB	0	60	30	90 dB	-50	10	-20	40 dB
$\frac{Beneficial\ Constraints}{Capture}$	0	50	60	110 dB	0	50	60	110 dB	-50	0	10	60 dB
$\frac{Beneficial\ Constraints}{Technology\ Based\ Regulation}$	0	70	100	170 dB	-10	60	90	160 dB	-50	20	50	120 dB
$\frac{Beneficial\ Constraints}{State\ as\ Venue}$	0	10	70	80 dB	-20	-10	50	60 dB	-50	-40	20	30 dB
$\frac{Beneficial\ Constraints}{Folk\ Economic\ Model}$	0	57	80	137 dB	0	57	80	137 dB	-50	7	30	87 dB
$\frac{Beneficial\ Constraints}{Market\ Ideological}$	0	26	120	146 dB	-10	16	110	136 dB	-50	-24	70	96 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

Beneficial Constraints over the Folk Economic Model, Adoption Catalyst, Capture, and Technology Based Regulation imaginaries. We also see strong (26 dB) evidence over Market Ideological and moderate (10 dB) evidence over State as Venue. If we look at just the EU case (Table 22, column a "EU Post"), we find decisive evidence (80+ dB) for Beneficial Constraints over Technology Based Regulation, Folk Economic Model, and Market Ideological imaginaries. We see very well-established evidence (50-70 dB) in favor of Beneficial Constraints over the Capture and State as Venue imaginaries and very strong (30 dB) evidence against Adoption Catalyst. These overall weights of evidence should then each be considered against the reader's priors to update our belief in what the most probable state of the world is.

If the reader adopted naïve priors with equal weights (0 dB for or against Beneficial Constraints) for the combined case of AVs in the US and EU (Table 22, column a "combo posterior"), then the evidence presented above would create decisive (80+ dB) to overwhelming (100+ dB) in favor of Beneficial Constraints over alternative regulatory imaginaries. While there are fair reasons to disaggregate the data to a per-case level as that is where the regulation actually occurred (at the US/EU levels), this combined weight of evidence is useful for us to understand how AVs are imagined to be regulated cross-nationally. The evidence thus aggregated tells us that AVs are regulated from the Beneficial Constraints imaginary regardless of priors (Naïve, Background Information, or Skeptical). Indeed, it would take a prior far stronger than the likelihood of any commercial airplane flight crashing (~67 dB) in favor of State as Venue (the nearest cross-case rival) in order to break even with Beneficial Constraints at this level of aggregation.

However, as the actual US Perpetual Guidance and Regulation (EU) 2022/1426 approaches to AV regulation were decided through separate processes, it is also useful to disaggregate down to the US/EU level and compare against priors. In the US Perpetual Guidance case, we see that the evidence remains well-established (50-70 dB) against all models except State as Venue and Market Ideological Imaginaries across Background Info priors (Table 22, column b "US Post"). With skeptical priors (Table 22, column c "US Post"), the US case maintains only strong evidence against Technology Based Regulation, moderate evidence against Adoption Catalyst, and weak evidence against the Folk Economic Model. The extreme weight of the skeptical priors (50 dB) also make Capture a wash (0 dB) and put Market Ideological and State as Venue up as favored alternatives.

Although it is worth noting that the weight in favor of State as Venue and Market Ideological are solely due to strong priors, we should not be surprised that blanket skepticism would lead the rhetoric of the US Perpetual Guidance case to override the content. As discussed at length in the weight of $E_{\text{Non-Regulatory}}$ section as well as in the analysis in Appendix D, the Trump Administration clearly set out to wrap their guidance documents around AVs in a rhetoric of non-regulation, both as a neutral moderator (State as Venue) and as a market advocate (Market Ideological). However, the actual content of each of the Trump Administration documents remained remarkable consistent with the constraining technical guidance and assertions of authority first laid out in the FAVP from the Obama Administration.[378] While a strongly

[378] Review the discussions above about the weight of $E_{\text{4-principles}}$ as well as the extensive reasoning in Appendix D on each pair comparison on $E_{\text{4-Principles}}$ and $E_{\text{Non-Regulatory}}$

skeptical reader may remain unconvinced despite the evidence, the evidence both in the explicit highlighting and discussed in the case narrative are clear that the Trump Administration documents were far more a rhetoric of non-regulation than a substance of non-regulation.

In the Regulation (EU) 2022/1426 case, we see that the evidence weighted against Background Info priors (Table 22, column b "EU Post") remains decisive (80+ dB) against Technology Based Regulation, Folk Economic Model, and Market Ideological imaginaries and very well established (50-70 dB) for Capture and State as Venue. Adoption Catalyst remains the near*est* rival (but far from near) at a very strong (30 dB) weight of evidence. Weighted against Skeptical priors (Table 22, column c "EU Post"), the EU case maintains well-established evidence (50-70 dB) against Technology Based Regulation and Market Ideological Imaginaries and moderate to very strong evidence (10-30 dB) against Capture, State as Venue, and the Folk Economic Model imaginaries. The Adoption Catalyst imaginary for Skeptical priors does manage to maintain a strong weight of evidence over Beneficial Constraints, but this is again driven by the excessive skepticism of the skeptical priors. In other words, skeptical priors *should* represent a very well informed theory against a very new rival[379] but in order to define an extreme set of priors as an example to the reader, we set *all* alternative models at 50 dB rather than relying on Background Information or some other method of setting priors. For a reader to interpret substantive meaning from this prior-driven result, they would need to have a very good reason to believe that the EU was actually trying to catalyze the adoption of AVs hidden within the more hesitant language of Regulation (EU) 2022/1426. Possible, but highly unlikely.

Based on these four pieces of evidence, we see that how clearly AVs can be considered a case of Beneficial Constraints depends on the priors you adopt and the aggregation you are interested in. In isolation for any set of priors, these four pieces of evidence (4-Principles, Type-Approval, Non-Regulatory, Recital Qualification) are overwhelmingly convincing in favor of Beneficial Constraints over all alternative models for the general approach to AV regulation across the US and EU.

However, at the individual regulatory domain level, we see divergent conclusions based on priors that nevertheless may be undermined by additional case information. In the US, the State as Venue and Market Ideological imaginaries become moderately (10, -16 dB) and strongly (40, 24 dB) more likely than Beneficial Constraints for Background Info and Skeptical priors respectively, although this can only be supported were a reader to be seduced by the framing rhetoric to the exclusion of the content of the regulation. In the EU, the Beneficial Constraints imaginary confidently survives all levels of priors except for the somewhat non-sensical prior that privileges the Adoption Catalyst imaginary. As explained above, either a review of the content of the regulation, or an analysis of the EU way of law,[380] or additional explicit BayesTV could drive this spurious prior-driven weight away.

All told, though, this analysis draws our attention to the misalignment between rhetoric and reality in the US case and allows us to be exceptionally confident in Beneficial Constraints in the EU case. In the following section, we will explore some suggestive interview evidence which can shed light on how the US case is experiencing AV regulation, how regulators, entrepreneurs,

[379] See the discussion on page 101 about the assignment of priors.

[380] Cooperative but precautionary, as compared to the adversarial approach in the United States, (c.f Kagan [2001] 2009 for the contrasting American way of law; and D. Vogel 2012 for the precautionary principle)

and innovators see and experience the imaginaries, and how those imaginaries shape their actions.

VIEWS OF AV REGULATION FROM VARIOUS ROLES

As we saw in the previous section where BayesTV highlighted statutory intent and near rival evidence, the US case brings to the forefront an interesting story of regulation under a hostile administration and the Market Ideological imaginary. In this section, I draw on interview data from a related project[381] to explore how actors in various roles view AV regulation. We completed the interviews in the repository I am drawing upon between July 2018 and December 2019, placing these respondents right in the middle of the Perpetual guidance case. They could conceivably have been exposed to the FAVP Policy of 2016, AV 2.0 in 2017, and AV 3.0 in 2018.[382] These interviews allow me to explore whether actors involved in the regulatory regime view it as beneficially constraining, how they deal with the Market Ideological rhetoric of the administration which challenges their fundamental mission, how they form their views about AV constraints (beneficial or otherwise), and how those views inform their actions under the regulatory regime. While the previous sections have focused on archival data about the imaginary demonstrated by the intent of each regulatory regime, this section draws on contemporaneous interviews to unpack suggestive evidence of how this imaginary has played out in practice. By examining what actors such as regulators, AV innovators, and AV entrepreneurs have to say about their regulatory regimes, we can better understand how the beneficial constraints imaginary plays out in actually existing regulatory regimes.

While it is beyond the scope for this project to provide definitive causal proof that the Beneficial Constraints imaginary, or any other imaginary, actually has the effects that the imaginary specifies (see effects column, Table 13), this interview evidence provides at least suggestive evidence about how regulatory outcomes are shaped by the imaginaries which I argue frame regulatory intent. Future projects should investigate how imaginaries play out in practice, particularly with a focus on how alignments and misalignments between the imaginaries different roles hold or different actors in the same role hold lead to variations in outcomes. In the following section, though, we get an illustrative picture from some actors involved in the US AV case.

WHAT DO ACTOR ROLES VIEW AS BENEFICIAL ABOUT THE CONSTRAINTS AROUND AVS?

While the interviews I am drawing upon take place in the middle of the series of guidance documents (FAVP, AV 2.0, AV 3.0 but not AV 4.0 or AVCP), they nevertheless allow us to see what different actors hoped for and saw taking shape as the guidance documents were being promulgated. Their comments primarily concerned the need for some sort of standard set of technical measurements and requirements which would allow innovators to design for compliance, entrepreneurs to project the costs and market opportunities to do so, and regulators

[381] These interviews were conducted by the author and a team of researchers led by Ann Keller as part of National Science Foundation's Science of Science and Innovation Policy grant #1735661. The analysis in this section draws upon nineteen interviews with twenty-one interviewees. One interview included three respondents. Human subjects approval for collecting, storing, and analyzing interview data was granted by the Office of Protection of Human Subjects at UC Berkeley. The de-identified data is available at (Posch et al. 2021)

[382] (NHTSA 2016; 2017; USDOT 2018)

at different levels to monitor and enforce as well as construct infrastructure which would work with the intended performance standards.

As one former federal transportation regulator and former AV industry representative put it, the early days of AV regulation at USDOT was all about finding technical expertise that was not biased by proprietary concerns: "we needed a technically competent organization that was completely neutral, wasn't selling products per se" (Posch et al. 2021, interview 3). The same interviewee went on to detail the many steps that USDOT took to create this competence, and we can see that reflected in the lengthy technical guidance of FAVP, AV 2.0, AV 4.0, and AVCP. This constraint was sought and desired by industry in order to give them unbiased standards which would not privilege on firm over another.[383]

A state transportation regulatory echoed this emphasis on standards as a vital step in shaping the emerging AV industry:

> *The hardest part right now is the standard. We don't want to just sit and wait for what it needs to be. So, we're kind of at that point where, first, we have to decide what the standard is and then we decide how we actually send it out and how to integrate it. (CAV Interview 10) (Posch et al. 2021, interview 16)*

Although the guidance documents do not have the formal authority of law, each made sure to reiterate that NHTSA and the USDOT *already* had the authority to police anything on the roads through recalls.[384] Certainly it may have been more desirable to pass standards, but in their absence guidance could signal something constraining.

How do Actor Roles Form their Views about AV Constraints?

As part of the separate project which generated these interviews, Meghna Mukherjee and I were struck by a particularly evocative interview where a state level transportation regulator literally described how they imagined their role in the regulation of AVs.[385] This state level regulator described how their job is to, in essence, form an imaginary:

> *We have this big floor to ceiling window [in our office] that when it's time to daydream I turn around and I look out at the freeway. And a lot of what's in our regulations are a result of time spent just staring out at the freeway wondering, how would we address this? How would we address that [autonomous] cars need to obey the traffic rules? [...] And is it something that we need to think about that companies need to plan how they're going to interact with police officers and things like that? So, … it was a fascinating process for me because a lot of it was just sitting staring out the window and basically spit-balling ideas. (Posch et al. 2021, interview 11)*

This process of spit-balling ideas about how to shape and constrain AVs demonstrates that, at least for this regulator, their job is to form an imaginary. Suggestive, yes. But deeply evocative.

Another respondent who was a former AV industry representative and current state transportation regulator described a more ordinary, but still vital, process of ongoing consultation

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[383] For an example of firms attempting to weaponize standards, see Tesla's offers to freely license (but not make open license) it's charging connector, leading to two competing high speed charging standards, one widely shared and one for Tesla, at charging stations. (c.f. Hundal 2022)

[384] See the discussion of $E_{4\text{-principles}}$ (page 107) and the principles in the case narrative (page 95)

[385] We developed these ideas about sociotechnical imaginaries around a comparison of AV and gene therapy regulation into the paper (Mukherjee et al. 2023). We had both been separately flirting with the concept of sociotechnical imaginaries before this interview, but this statement really cemented the relevance for regulation of emerging and disruptive technologies for us.

and engagement with NHTSA in order to form their views on what constraints might be beneficial:

> *"The operation of the vehicle and the equipment on the vehicle are all in this gray area… So, we had to work really closely with NHTSA on this muddied piece of responsibility. And we went back and forth with NHTSA on what should we require? What can we require? What would you guys be okay with, with regard to our [state level] regulations? And so, there was quite a bit of back and forth [...].(Posch et al. 2021, interview 14)*

Recall from the discussion of $E_{4\text{-Principles}}$ that NHTSA's guidance include a request for regulators to essentially step back and allow NHTSA to regulate the technology in the vehicle in order to prevent a Galapagos of different state and local standards. However, as this state level regulator respondent is pointing out, there are more aspects to AV operations on public roads than just the technology in the vehicle. They thus were keenly interested in understanding how a uniform set of guidance on the performance requirements of the vehicle fits in with their state level desires to design and operate infrastructure and vehicle registration, for example.

HOW DO ACTOR ROLES' VIEWS INFORM THEIR ACTIONS?

While the AV case, particularly in the United States, is defined by being nearly, but not quite, actually here, we can still see regulators projecting ahead what they anticipate entrepreneurs and innovators will be asking for. The federal transportation regulator below clearly believes that the Folk Economic Model (or perhaps even the Market Ideological imaginary) will shape the demands entrepreneurs and innovators will place on them:

> *Looking ahead, maybe two to three to five years, we can expect [CAV] companies to submit requests for waivers from regulations that they argue will hinder their technologies. The question is whether the agencies in DOT will be ready to do that. […] We might not yet have metrics or tools to evaluate systems of systems instead of individual vehicles. (Posch et al. 2021, interview 1)*

Interestingly, as we saw above in the prior section, these expectations were perhaps premature (the interview is from July 2018) since entrepreneurs and innovators actually were eager for a standard that they could then conform to (rather than an undefined principle of safety which could become a moving goalpost). The respondent continued:

> *So, the question for [federal regulators] is to figure out how one might test that when it comes to thinking about what makes [CAV] more or less safe than traditional vehicles (CAV Interview 1). (Posch et al. 2021, interview 1)*

Clearly, what this respondent thought was needed based on their understanding of federal regulators role was not just a standard but a promulgated test standard. Interestingly, this is exactly what the EU produced in Regulation (EU) 2022/1426 in Annexes II (technical standard) and III (testing procedures).[386] It turns out, then, that while the EU approach may have been more straightforward, more boring even, boring might be exactly what some stakeholders want.

[386] See discussion of $E_{\text{Type-Approval}}$ and $E_{\text{Recital Qualification}}$ in the EU case.

CONCLUSION: WHY DOES IT MATTER THAT AVS ARE REGULATED THROUGH A BENEFICIAL CONSTRAINTS REGULATORY IMAGINARY?

This chapter demonstrated how confident we can be that autonomous vehicle regulation in the US and EU was derived from a Beneficial Constraints imaginary. Based on the Bayesian Type Validation (BayesTV), we can be decisively confident that GE regulation was not operating from a Folk Economic or Technology-based Regulation imaginaries while the comparisons with the other imaginaries are more complicated and case-dependent. This finding contributes to our understanding of how a very well established regulatory regime, vehicle safety regulation, deals with a disruptive innovation (AVs). While the complexity of the messages imaginaries beyond these two will be discussed below, this top line finding is important because it demonstrates that even a very well know, very well established, and famously restrictive regulatory regime such as automotive safety regulation is able to respond to disruptive innovation without resorting to either command and control Technology-based Regulation (like they did with catalytic converters, seatbelts, and airbags)[387] or reproducing the Folk Economic Model of hapless impediment to be avoided.

In the US case, the evidence allows to rule out Adoption Catalyst and Capture at the well-established level, focusing our attention on the State as Venue and Market Ideological imaginaries given the antiregulatory rhetoric of the Trump Administration documents[388] as well as the choice to use guidance rather than rulemaking. Logical Bayesian analysis specifically directs us to interrogate how confident we can be that "X said A as opposed to B," meaning that we interrogate not just what our evidence says but why it might be saying it by inhabiting the various alternative worlds of each imaginary.[389] In the US Perpetual Guidance case, this allows us to see the fascinating divide between the introductory pages of the Trump Administration documents and the much more extensive and detailed bodies of the guidance. While the introductory pages demonstrated a pervasive and increasing desire to first have the state serve merely as a facilitator for private sector innovation (State as Venue) and then became more doctrinaire about the dangers of innovation-stifling regulation (Market Ideological), the bodies of the guidance documents continued to demonstrate a more mainstream set of detailed technical and performance guidelines intended to affirm the authority of the USDOT and NHTSA over innovators and entrepreneurs and guide them to compliance rather than enforcement of sanctions.

The consistency of the evidence in the US Perpetual Guidance case with Market Ideological imaginary also speaks to the theoretical questions of "doing truth to power"[390] The Trump Administration was a moment of significant challenge for the administrative state as they were faced with an administration that at once was asking them to execute policy which seriously threatened career civil servants understanding of their mission and was also distinctively unable to follow through on their high level policy rhetoric.[391] This placed career civil servants, both administrative and technical, in the position of leaving or continuing to do what was needed to serve their mission behind the scenes and with reduced authority while waiting out the

[387] (Vinsel 2019, 75–150)
[388] (NHTSA 2017; USDOT 2018; NSTC and USDOT 2020; USDOT 2021)
[389] (Fairfield and Charman 2022, 109-111,451-454)
[390] c.f. (La Porte 1971)
[391] (Michaels 2017)

administration. Both strategies of dealing with a mission-violating administration raise interesting questions about how political expediency clashes with longer-run technical innovation policy. While the US AVs case is far less settled than the EU case, it will be fascinating to watch how rulemaking ultimately does (or does not) develop around AVs as level 4 and level 5 products begin to come to market.

Relatedly, the consistency of the evidence with the State-as-Venue imaginary speaks to regulation in the shadow of hierarchy.[392] Especially in a situation where more concrete rulemaking procedures are closed off to them due to administration opposition, regulators in the US were able to continue to produce guidance documents on a nearly annual basis to stay relevant in the entrepreneurial and innovative conversation around AVs. In staying relevant, they were also able to remind entrepreneurs and innovators that they had enforcement authority should they be forced to use it. Indeed, Tesla and it's CEO Elon Musk continue to market "Full Self Driving" as the brand name for their level 2 (perhaps 2.5) AV technology which has led to a recent enforcement decision and recall against their vehicles.[393] While this may seem to undermine the constraints of the guidance documents, I would suggest that it actually demonstrates them: when push comes to shove, if you don't follow the guidance you get the stick.

As flashy and interesting as the US case is, the EU case highlights a more ordinary alternative world that is most significant in its banality: the EU recognized AVs as a new type of vehicle technology and they passed a new type-approval process for them. This banality is reflected in the weights of evidence on all imaginaries other than Beneficial Constraints being strong to paradigmatic. For students of EU regulation, it is likely not shocking that a regulatory culture built on cooperation[394] between regulators and stakeholders would have a relatively orderly process to evaluate, weight, and integrate concerns into straightforward rulemaking. For students of regulation more broadly, it's worth nothing that quiet can be good. Successful regulation, like successful design, is generally quiet and invisible.[395]

In closing, this chapter has sought to demonstrate how a well-established regulatory regime deals with a disruptive innovation which challenges some of its fundamental assumptions. In doing so, it has demonstrated both that such regimes can avoid what we might expect to be classical responses: command and control-style Technology Based Regulation and the Folk Economic Model of incompetent impediment. Further, from the US case, we have seen that well established regimes faced with a mission-challenging political administration can engage in "doing truth to power," although this is often through less direct means such as working in the shadow of hierarchy. Finally, from the EU case, we can see what we might call ordinary regulation akin to ordinary science; even as disruptive an innovation as cars that drive themselves are just processed through the EU regulatory system without much fuss to allow them to place reasonable constraints on known dangers in order to encourage innovators to seek out undefined but hoped for benefits (safety and lucrative industries). For these reasons, this chapter demonstrates two very different paths to a future of hoped for safety, although both employ

[392] (Newman and Bach 2004)
[393] (Krisher 2023)
[394] As compared to the US's famous reliance on adversarial legalism in administrative law, see (Kagan [2001] 2009)
[395] This is the title of and conceit behind the design-based podcast, 99 Percent Invisible (https://99percentinvisible.org/)

guardrails intended to direct that path away from known hazards and towards multiple, undefined, but just visible benefits.

CHAPTER 6

RECOMBINANT PASTS AND CRISPR FUTURES

Beneficially Constraining Gene Editing Regulation in the United States & Europe, 1975 to Present

Following the 1973 development of recombinant DNA, American and European regulators sought to corral gene editing technology's dangers and encourage its benefits through beneficially constraining regulation. The US Asilomar Conference (1975) gathered scientists and policymakers to define what became the Coordinated Framework: genetically modified organisms (GMOs) would be considered 'substantially equivalent' to non-GMOs unless 'fundamentally altered.'[396] Europe took the opposite tack: based on a 'precautionary principle,' GMOs would be considered intrinsically different from non-GMOs and subjected to heightened scrutiny.[397]

Through Bayesian Type Validation (BayesTV), this chapter explores how diametrically opposite regulatory outcomes arose from the same regulatory imaginary:[398] both represent constraints on GMOs which their societies considered economically *beneficial for their markets* in addition to the social benefits behind all regulation. This chapter thus makes three claims: (1) some regulatory constraints can be economically beneficial for the constrained entities in addition to the social benefits to the public good, (2) the same regulatory method may be employed by different regulators to very different goals, and (3) recognizing that we can separate regulatory method from regulatory goal means that we can break down false dichotomies such as those between safety and innovation or justice and growth; in short, we need not buy into a tradeoff between regulatory constraints and innovation.

This focus on method also illuminates a new dimension of similarity of regulatory method at odds with the well-known narrative of regulatory divergence in regulatory outcome in the US/EU GMO story.[399] This claim of similarity in method does not reject the well-established fact that the US and EU took fundamentally opposite positions on GMOs: the US fostered their growth while the EU sharply restricted them. However, it does point out that both political economies chose to do so through a technique which constrained their markets towards economically and socially beneficial goals. They differed not on method but on the definition of beneficial.

In the case of gene editing (GE), and the GMOs produced thereby, an impromptu US process gathered a technoscientific subset of stakeholders leading to a technoscientifically beneficial outcome which defined market benefits based on producer and expert views. By contrast, a

[396] (Berg 2008)
[397] (D. Vogel 2012, 74–81)
[398] The concept of regulatory imaginaries is explained at length in Chapter 1. For reference here, a regulatory imaginary is a collectively held, publicly performed, and desirable statement of relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. In practice for a specific regulatory regime, a regulatory imaginary describes the animating logic behind that regime.
[399] (Urry 1997; Pollack and Shaffer 2001; 2009; D. Vogel 2012; Entine 2005)

structured EU process brought together diverse social stakeholders leading to a socially acceptable outcome which defined market benefits based on perceptions of consumer interest.

Each regime successfully constrained its society into different intended forms. From the technoscientific principles of the US Coordinated Framework, the R&D of gene editing technologies and GMO products flourished. Less emphasized were social costs such as inequalities in global exports of 'suicide gene' crops from rich *companies* to developing *countries*. From Europe's social scientific Precautionary Principle, the R&D of GMOs stalled yet European society remained content with how GMOs were (not) integrated into their political economy and instead a natural foods market flourished.[400]

Gene editing's benefits are technoscientific while their dangers are social scientific. Since CRISPR-Cas9 magnifies the power of gene editing, this mismatch is being readdressed. In the first round of gene editing regulation around recombinant DNA technology, the EU chose to constrain the technoscientific benefits in favor of reducing potential social risks while the US chose to constrain the social risks in favor of increasing the technoscientific benefits. Interviews with GE stakeholders reveal how the recombinant pasts affect their CRISPR futures of the US in the Food and Drug Administration (FDA) Investigatory New Drug (IND) review process. While stakeholders agree that the process is challenging, they also perceive it to be a necessary challenge in order to both meet the socially necessary safety standards as well as push scientists to develop the standardization and protocols necessary for scientific findings to become commercial products.

While recombinant DNA led to biomedical products such as human insulin from E. coli (1978), genetic characterization of complex disorders such as thalassemia (1984), and targeted genetic testing for human disease such as Huntington's disease (1993), CRISPR-Cas9 pushes the boundaries of what is possible further into the precise correction of disease producing genes in an individual. By making possible the benefits and dangers which were only specters during the recombinant DNA era of gene editing, CRISPR-Cas9 thus increases the tensions in the regulatory process between social scientific and technoscientific understandings. This created an exceptional opportunity to observe how these often separate communities collide in the process of crafting regulations which navigate the benefits and dangers of gene editing technologies.

To demonstrate the Beneficial Constraints at work in the case of gene editing technology, I proceed as follows. First, I explain what gene editing is and why it is disruptive to the social and technoscientific systems due to the increase precision and decreased difficulty and cost of shaping life to human intention. I then explain what a Beneficial Constraints regulatory imaginary is, focusing on how regulators operating under this imaginary seek to focus the dynamism of the market toward more economic (and socially) beneficial outcomes than market forces alone could achieve. Next, I explain why gene editing is a good exemplar case for Beneficial Constraints by reviewing the history of the US and EU gene editing regulatory regimes: the US Coordinated Framework and the EU Precautionary Principle. Then, I proceed to execute a Bayesian Type Validation (BayesTV) to elucidate how confident we can be that gene editing is, in fact, a case of Beneficial Constraints. After validating the type, I present interview evidence about why actor roles within the regulatory regimes view the regulation as beneficial, how they form these views, and how these views inform their actions. I conclude by explaining

[400] (Pollack and Shaffer 2001, 79)

why it matters that gene editing is an example of Beneficial Constraints, focusing on how the US and EU experiences in this biotechnology sector can serve as a model for entrepreneurs, innovators, and regulators in other sectors which are defined by dynamic innovative potential benefits that come with socially unacceptable possible risks.

WHAT IS GENE EDITING AND WHY IS IT DISRUPTIVE?

While humans have unknowingly, but intentionally, shaped the genetic code of many organisms since the invention of agriculture, gene editing is the term given to the creation of increasingly precise tools to control the shape and function of organisms. By allowing genetic engineers to now directly affect genetic code, genetic editing techniques have created a new set of common tools for practices which had previously been siloed in seemingly unrelated fields such as agriculture and medicine. This section explains how gene editing disrupts the status quo in two ways: technoscientific and social scientific. Technoscientifically, gene editing makes concerns and opportunities which had previously been beyond direct human control into a real possibility; it is now possible to edit the code of life directly for good or ill. Social scientifically, gene editing raises questions over the legal claims and ownership of life both between companies and between countries.

TECHNOLOGICAL INNOVATION: INCREASING PRECISION AND CONTROL OVER LIFE

Genetic manipulation is not new. Farmers, herders, ranchers, cat fanciers, and dog breeders are but a few names for the genetic engineers of prior centuries and millennia. When recombinant DNA technology was first demonstrated in 1973, what changed was the precision with which people could manipulate the shape and function of life. What had previously been managed through selective breeding of desirable mutations, intentional irradiation to increase mutation,[401] crossbreeding, and other imprecise forms of genetic manipulation could now be achieved more directly. Where previous attempts to shape life were akin to a hammer or an axe, recombinant DNA technology handed would be genetic engineers a knife.

With the 2012 publication of the clustered regularly interspaced short palindromic repeats associated protein 9 (CRISPR-Cas9) gene editing technique by Jennifer Doudna and Emmanuelle Charpentier at the University of California, Berkeley and Feng Zhang at Harvard/MIT's Broad Institute, that knife became a scalpel.[402] Earlier recombinant DNA techniques such as restriction enzymes, viral vectors, zinc finger nucleases, and transcription activator-like effector nucleases (TALENs) allowed genetic engineers to target specific sequences to cut and splice DNA between genomes but were limited to targeting DNA sequences which could be painstakingly edited into the specific structure of the tool.[403]

CRISPR-Cas9 is far faster, easier, and more versatile than prior tools. Rather than needing to carefully edit the structure of the tools, CRISPR-Cas9 uses a guide RNA sequence which is easily programable without potentially affecting the function of the tool itself. This guide RNA sequence makes CRISPR-Cas9 a "cost-effective and easy-to-use technology to precisely and

[401] (International Atomic Energy Agency 2016)
[402] (Doudna and Charpentier 2014; Park 2006)
[403] (Doudna and Charpentier 2014, 1258096–1)

efficiently target, edit, modify, regulate, and mark genomic loci of a wide array of cells and organisms."[404]

What began as an idea first successfully demonstrated in 1973 using comparatively primitive restriction enzymes on bacteria has now become a highly configurable reality since 2012. The millennia of painstaking breeding of fortuitous mutations to create such wonders as corgis from wolves, naval oranges from the ancestral citrus species (citron, pomelo, and mandarins),[405] and broccoli from cabbage have given way first to the late 20th century creation of transgenic human insulin and now to the highly targetable tool of CRISPR-Cas9. The innovation of gene editing is not in the task to be undertaken (the shaping of life) but rather in the degree of greater precision and intentionality with which it can be carried out. This greater precision through the overt shaping of life, which had previously been obscured through millennia of imprecise traditional practice, gave rise first to technoscientifically-framed disruptions such as "Frankenstein foods"[406] and the Non-GMO Project.[407] Later, additional social-scientific disruptions arose over how the intentionality involved in wielding these tools affected the legal status of the resulting organism: could their design be owned and by whom? The following two sections will explore each of these disruptions caused by the innovation of gene editing.

TECHNOSCIENTIFIC DISRUPTION: INCREASED PRECISION MAKES PREVIOUSLY HYPOTHETICAL BENEFITS AND DANGERS MANIFEST REALITY

The technology of gene editing built upon the science of genetics disrupted the ability of humanity to shape biological life in the most aspirational sense of the word disruption: it opened an entirely new field of possibilities. This makes it exactly the sort of disruptive innovation that entrepreneurs and innovators picture when they call themselves disruptors. We should not forget the potential for great good inherent in the disruption gene editing brings to the yokes of genetic disease, shortages of biological medical supplies such as insulin, and agricultural underproduction.

Yet this positive vision brought by an ever-increasing mastery over the code of biological life is not inherent to the tools; they simply increase what is possible. Since the first conceptions of recombinant DNA in 1973, scientists have worried about the potential for misuse.[408] These concerns brought them to the Asilomar Conference Center in Pacific Grove, California in 1975 to hash out guidelines for the development of the technology.[409]

The uncertainty between the promise of gene editing for human progress and the real and imagined fears of misuse has been a fruitful well for journalism,[410] skepticism,[411] political organizing,[412] and science fiction[413]. Yet despite the evocative success of these narratives, the

[404] (Doudna and Charpentier 2014, 1077)
[405] (Klein 2014)
[406] (Pollack and Shaffer 2001, 165)
[407] c.f. https://www.nongmoproject.org/
[408] (Berg 2008, 290)
[409] (Berg 2008, 290), the details of this conference are discussed at length below in Perpetual Guidance in the United States (2016-Present) as they form the generative moment of what becomes the Coordinated Framework.
[410] e.g (Scientific American Custom Media for Kavli Prize n.d.; Urry 1997; Park 2006)
[411] c.f. the "Frankenstein Food" protests (Pollack and Shaffer 2001, 165)
[412] e.g. the Non-GMO Project (www.nongmoproject.org), and Organic Movement (Guthman 1998)
[413] e.g. *Gattaca,* (Niccol 1997)

events they fear have not come to pass because the very small potential for very great harm is overwhelmingly outweighed by the much more lucrative actuality of diffuse good. Why have these narratives persisted despite the technoscientific reality?

The most useful allegory comes from a technology developed after gene editing: nanotechnology: grey goo. In a seminal work in the field, K. Eric Drexler coined the term "gray goo problem" to describe a dystopian specter of a world (perhaps accidentally) consumed by nanoscopic machines, broken into component atoms, and then rebuilt as simple replications of the machines themselves.[414] The evocative image of a world returned to a primordial soup of undifferentiated and unthinking goo has haunted the field of nanotechnology from its start leading Drexler to rue the day he coined it.[415] Why has the image persisted? *Because* it is so evocative despite being very unlikely.[416]

To be fair to those haunted by specters of GE misuse, there was a case of two children born in China who were edited as embryos by He Jainkui used CRISPR-Cas9 which has caused considerable stir in the GE community and wider public.[417] However, these missteps were noticed, sanctioned, and publicly debated, not just in the West but within China as well. This transgression did not spread like wildfire through the world erasing and outweighing treatments for thalassemia or GMO produced insulin. There are, indeed, real questions about how swiftly, effectively, and comprehensively the He affair was handled and whether all affiliates at non-Chinese universities were appropriately punished *but* these are social scientific questions of whether the tools of gene editing should be used in certain ways *not technoscientific* questions about inherent dangers of using the tools.

The technoscientific benefits of gene editing are clear and clearly disruptive to prior limitations on humanity's ability to shape biology. The negative disruptions, however, come not from inherent dangers of using the tools of gene editing but from misuse of those tools. Deciding what constitutes misuse is a social scientific question, not a technoscientific one. We turn to that question in the following section.

SOCIAL SCIENTIFIC DISRUPTION: PATENTS, SOCIAL REVOLTS, AND GEOPOLITICS

While gene editing is a technoscientific innovation, the disruption splits between technoscientific good and social scientific uncertainty. Concerns about gene editing and the genetically modified organisms (GMOs) produced have no basis in the nuts and bolts of the process; unlike more commonplace tools such as automobiles or table saws, using them does not raise an intrinsic danger to safety of the operator or those around them.[418] However, there is a great deal of controversy around *how* the tools *should or should not* be used. These concerns are real, and thus gene editing is disruptive to the social systems around technology, but they are not technoscientific concerns; no evidence has ever been shown that GMOs are unsafe simply

[414] (Drexler 1986, 172–73)
[415] (Giles 2004, 591)
[416] (Clarke 2005, 121)
[417] C.f. (Cyranoski 2020)
[418] There is a concern about "off-targets" where the technique being used splices DNA not just at the intended location in a genome but also at other locations which are off-target. However, this concern is well recognized and measures for it are part of the scientific and medical R&D process.

because they are GMOs.[419] The social disruptions from gene editing concern socio-political constructs such as patents, social opposition movements, and the geopolitics of rich country companies selling to developing country individuals.

Despite the technoscientific safety/social scientific concern dichotomy explained above, many of the critics of GMOs and gene editing couch their concerns in seemingly scientific or "scientistic" language. Rather than address the roots of their concerns directly as (often quite legitimate) contestations over power and control, both genetic engineers (scientific and corporate) and social activists frame their discussion as one over the science of GMO and gene editing safety. One core argument of this chapter is that such arguments over power and control should be contested on their own merits rather than couched in misleading terms of technoscientific safety. In the following section, this argument is developed by exploring how "beneficial" is defined within Beneficial Constraints.

WHAT IS A "BENEFICIALLY CONSTRAINING" REGULATOR?

Before proceeding to validate that gene editing (GE) is a good exemplar of Beneficially Constraining regulation, we should first be clear about what the Beneficial Constraints imaginary is. Based on the variables in the typology derived in Chapter 3 a regulator following the Beneficial Constraints imaginary has *higher* access to *information* than firms, believes that the *market is the driver* for the spread of an innovation and is content with *many* different optimal regulatory *outcomes*. Put plainly, a beneficially constraining regulator is defined by careful negation: they identify certain undesirable practices or outcomes and place constraints on regulated firms which are intended not just to reduce harm but to spur innovation towards other desirable practices and outcomes. Critically, these constraints are not simply beneficial to society (as regulation generally is intended to be) but are also economically beneficial to the regulated firms; this form of regulation seeks not to curb the excesses of the market but instead to direct the dynamism of the market toward more economically beneficial outcomes while also serving the social ends of regulation.[420]

The name "Beneficial Constraints" is a direct and intentional reference to the title of Wolfgang Streeck's "Beneficial Constraints: On the Economic Limits of Rational Voluntarism" (1997). As we saw in Chapter 3, Steeck's article serves as a direct foil to Stigler's "The theory of economic regulation," the article which created the concept of capture and was eventually reified into the folk economic model discussed in Chapter 1 and Chapter 2. The attempt to reconcile Streeck and Stigler generated the conceptual puzzle which led to the typological property space developed in Chapter 3 and presented in Table 5 (reprinted below as Table 23).

Yet despite the formative contributions from Streeck, his description of "beneficial constraints" explicitly "do[es] not pretend to have a conceptual schema to cover [all of his claims

[419] The most famous studies which claimed to show GMOs were harmful (the Pusztai and Séralini Affairs) were also famously retracted and discredited. Despite their rejection by peer review, the persistence of their misinformation has, itself, become an object of study. See (Xia et al. 2015)

[420] If capitalism is about creative destruction, as Schumpeter ([1943] 2010, 93–94) famously claimed, the beneficial constrainer seeks not to reduce the destruction but instead focus it on destroying current problems while finding creative solutions which are both economically productive and socially beneficial beyond the narrow dictates and time horizon of cyclical market forces.

Table 23: Complete Typological Property Space of Regulatory Imaginaries

		Constitutive Variables (Independent Variables)				Dependent
Name of Imaginary	**#**	**Relationship**	**Info**	**Driver**	**Outcomes**	**Effect**
Folk Economic Model (Christensen 1997)	1	Rulemaker	Lower	Market	Zero	Impediment
	2	Rulemaker	Lower	Market	One	Impediment
Market Ideological*	3	Rulemaker	Higher	Market	Zero	Impediment
	4	Stakeholder	Higher	Market	Zero	Impediment
State-as-Venue (Skocpol 1985)	5	Rulemaker	Lower	Regulator	Many	Moderator
	6	Stakeholder	Lower	Market	Many	Moderator
	7	Stakeholder	Lower	Regulator	Many	Moderator
Capture (Stigler 1971)	8	Stakeholder	Lower	Market	One	Constrainer
	9	Stakeholder	Lower	Regulator	One	Constrainer
Technology-Based Regulation "Conventional Command and Control" (Malloy 2010)	10	Rulemaker	Higher	Market	One	Constrainer
	11	Rulemaker	Lower	Regulator	One	Constrainer
	12	Stakeholder	Higher	Market	One	Constrainer
Beneficial Constrainer (Streeck 1997)	13	Rulemaker	Higher	Market	Many	Constrainer
	14	Stakeholder	Higher	Market	Many	Constrainer
Adoption Catalyst	15	Rulemaker	Higher	Regulator	Many	Catalyzer
	16	Stakeholder	Higher	Regulator	Many	Catalyzer
	17	Rulemaker	Higher	Regulator	One	Catalyzer
	18	Stakeholder	Higher	Regulator	One	Catalyzer
Trivial	19	*Rulemaker*	*Lower*	*Regulator*	*Zero*	*Impediment*
	20	*Stakeholder*	*Lower*	*Regulator*	*Zero*	*Impediment*
	21	*Rulemaker*	*Lower*	*Market*	*Many*	*Impediment*
	22	*Stakeholder*	*Lower*	*Market*	*Zero*	*Impediment*
Logically Inconsistent	23	~~Rulemaker~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~
	24	~~Stakeholder~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~

* (Henderson and Appelbaum 1992) completed Chalmers Johnson's (1982) 2x2 of market|plan x rational|ideological by defining the idea of "market ideological" which privileges market structures for organizing social and economic interaction beyond efficient cost-benefit tradeoffs due to an ideological preference for market structures over planning. More modern ears are more familiar with the term "market fundamentalism" as popularized by George Soros (1998) although the concept is as old as capitalism itself with well-reasoned critique of it at least as old as Polanyi ([1944] 1957). The modern usage is well explained in (Block and Somers 2014).

about social constraints on economic performance]."[421] Instead, he presents examples from which he can draw out theoretical and practical implications. Streeck's key advice to his readers is that the "Recognition of the economic benefits of *some* social constraints immunizes against the received wisdom that *all* constraints are counterproductive by definition."[422]

Elaborating his key advice, Streeck makes three recommendations about politics and policy based on beneficial constraints which I label *partialness, uncertainty, and complexity*.[423] First, not all constraints are beneficial but *some* economically non-rational social institutions improve economic performance so universal prescriptions against constraints should be avoided when

[421] (Streeck 1997, 200)
[422] (Streeck 1997, 213)
[423] These three recommendations are summations of (Streeck 1997, 213–15) and all quotations are from there unless otherwise specified. The single word terms are my own reification.

designing policy. Second, *uncertainty* is a defining characteristic of a political economy in practice so the "common sense judgment of the practitioner" must take precedence over the "deductively-based knowledge of the expert" and thus "political skills" are vital to good institutional design and adaptive operation. This uncertainty derives from the fact that economically beneficial social institutions are often unintentional side effects which are difficult to foresee and may vary through time and circumstances as economic actors innovate within their constraints.[424] Third, the institutional conditions of good economic performance are *complex* and so must cast a broad policy net rather than the traditionally narrow one which aims at incentivizing desirable behavior within a carefully demarcated arena. Thus, "at the minimum, good economic policy must be embedded in family policy, social policy, and educational policy."

My Beneficial Constraints imaginary accepts the inherent partialness, uncertainty, and complexity Streeck identifies but it comes to a rather stronger conclusion in response: regulators can *design* Beneficial Constraints rather than merely recognize unintentional ones after the fact. To elaborate, I draw upon Streeck's own key example: the high minimum wage in post war Germany. Streeck based his concept on the empirical observation that a high minimum wage forces firms to develop high productivity business models that then generate long run economic growth even though they are against the short term economic interests of managers who would prefer to maintain low productivity, low wage business models rather than invest in long term productivity growth.[425]

In the moment, Streeck is absolutely right that "common sense judgment of the practitioner" must take precedence over the "deductively-based knowledge of the expert" and thus "political skills" will be vital to craft a compromise between owners, managers, and workers such that a high minimum wage is feasible policy.[426] Yet, just because all parties may only recognize the economic rationality of the compromise in hindsight should not suggest that we cannot learn from the prior uncertainty after history has borne out a series of events which reduce the specific uncertainty of that situation.

This is not to say that past is simply prologue and once a compromise has been successful (one a constraint has proven economically beneficial) it is necessarily always going to be beneficial. But it is fair to say that regulators can learn from past successes and carefully apply those lessons to new situations. Thus, while partialness, uncertainty, and complexity cannot be eliminated, their presence does not make it impossible for regulators to learn from past successes and failures and apply those lessons to new challenges.

The key to the Beneficial Constraints regulatory imaginary of disruptive technological innovation lies between the folk economic model's despondency that regulators can do nothing right and Streeck's original critique of that despondency that sometimes something goes right, although unintentionally. A beneficially constraining regulator, respectful of the inherent complexity of their task and uncertainty of the future, seeks to design constraints that focus entrepreneurial and innovative energy towards solving problems which will lead to more desirable economic outcomes. While not all attempts to focus regulation will succeed in their

[424] (Streeck 1997, 211–12).
[425] (Streeck 1997, 200–201)
[426] (Streeck 1997, 213–15)

goals, neither should all fail or those that succeed merely do so by chance; you cannot design out uncertainty but you can design with it in mind and learn from past experiences.

CHANGING PERCEPTION: DISENTANGLING CONSTRAINT FROM NEGATIVE CONNOTATIONS

As discussed in Chapter 1, perception is of key importance to understanding the regulation of disruptive technological innovation because perceptions create preferences long before outcomes breed interests. For the project as a whole, this is a key motivation for expanding our understanding of regulatory imaginaries beyond the folk economic baseline. In the Beneficial Constraints regulatory imaginary, the most significant shift in perception is the disentangling of "constraint" from the negative connotations it has taken on within the context of regulation of innovation; that constraint is necessarily economically bad.[427] When Christensen coined the term "disruptive innovation" in *The Innovator's Dilemma* (1997), regulation was brought up to discuss what old regulations need to be removed: "regulations are toppled only when disruptive innovators find applications or markets beyond the reach of regulators."[428] To answer this perception, we can turn to Streeck himself: "Recognition of the economic benefits of *some* social constraints immunizes against the received wisdom that *all* constraints are counterproductive by definition."[429] Thus, the beneficially constraining regulator will seek to demonstrate that constraints need not be seen as bad a priori. In their turn, entrepreneurs and innovators would do well to ask themselves whether the constraints they are faced with are truly due to a pernicious imaginary such as capture or technology based regulation (c.f Table 23, lines 8-12) or whether they might truly be under a set of beneficial constraints (lines 13 & 14) which allow them to focus their creative and competitive prowess on creating better economic outcomes rather than undermining regulation or racing to the bottom due to short term competitive thinking. In the following section, we will see how certain constraints came to be defined as beneficial to both the businesses and consumers of the US and EU in response to the disruption of gene editing technology.

WHY IS GENE EDITING A GOOD EXEMPLAR CASE FOR BENEFICIAL CONSTRAINTS?

In brief, gene editing is a good exemplar case for the Beneficial Constraints regulatory imaginary because it was regulated in both the US and the EU based on what their respective polities believed were rules that constrained dangerous behavior and encouraged beneficial behavior. To be completely clear, while the EU and US approaches to gene editing (GE) regulation have famously been considered *opposites* based on their content (US: permissive, EU: precautionary),[430] I assert that they are actually operating from the same regulatory imaginary: Beneficial Constraints. I claim they are the same because both GE regulatory regimes, while respectful of the inherent complexity of their task and uncertainty of the future, sought to design constraints that focus entrepreneurial and innovative energy towards solving problems which will lead to more desirable outcomes (although they differed on what was desired). In the US, the Coordinated Framework sought to focus energy toward developing GE technology while in the EU the precautionary principle-based regime sought to focus energy toward developing stringent

[427] (Malloy 2010, 281–88)
[428] (Christensen, Grossman, and Hwang 2009, xlv)
[429] (Streeck 1997, 213)
[430] (D. Vogel 2012, 9–10)

testing of (and alternatives to) GE technologies. The following sections more deeply explain the history and context of these two empirical cases to justify my assertion that while they had different goals ("benefits"), they employed the same regulatory method: Beneficial Constraints.[431]

EMPIRICAL CASE SELECTION: TWO MAJOR POLICY POLES THROUGHOUT HISTORY

The two specific cases selected for comparison in this chapter were selected because they represent an archetypical contrast in regulation (precaution vs. "sound science")[432] of a highly salient disruptive technological innovation (gene editing) which has a long and storied track record (significant disruption from 1973 until present) that continues to spark public and regulatory engagement. The following two sections lay out the narratives of the US and EU cases.

COORDINATED FRAMEWORK IN THE UNITED STATES (1986-PRESENT)

The story of the creation of the Coordinated Framework for regulating GE in the United States begins at the Asilomar Conference in 1975 and is often summarized with the phrase "substantially equivalent." While this story has traditionally been told as a triumph of science-based over precautionary or fear-based regulation (or, symmetrically, as the loss of protection at the altar of science), we have underappreciated how substantially equivalent served as a beneficial constraint on the development of GE technology and products. With the continual improvement of GE techniques from 1973 to 2015 culminating in the invention of CRISPR-Cas9, our understanding of the well-told story is worth unpacking in order to inform deliberation over whether and how the next chapter might be written.

The first stages of the Beneficial Constraints surrounding GE technology happened at the International Congress on Recombinant DNA Molecules held at the Asilomar Conference Center, February 24-27 1975.[433] So influential was this conference in the history of scientific policy that the name of the conference center has become synonymous with this specific conference (e.g. "The Asilomar Conference" refers to the events of February 24-27, 1975).[434] The conference was organized by Paul Berg, David Baltimore, Sydney Brenner, Richard Roblin, and Maxine Singer following an earlier letter from a 1974 committee led by Berg. This letter had called for in immediate moratorium on further research on recombinant DNA until a conference could be held which evaluated the risks of recombinant DNA technology and devise the proper ways to regulate it. Asilomar was that conference.

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[431] Vogel (2012, 18–19) makes a related point about underappreciated similarity between the US and EU with regard to the precautionary principle, but his claim is that both the US and EU are equally precautionary but in different policy domains (US is precautionary on terrorism/security while EU is precautionary on health, safety, and environmental risks). Other authors have also commented on this intriguing cross-domain similarity (e.g. (Fossati 2006)). My claim is distinct in that these scholars have pointed to a similarity in desired outcome (precaution) across domains while I am focused on a similarity of method (Beneficial Constraints) within the same domain.

[432] (D. Vogel 2012, 9–10; Wiener 2003, 214–15) and Alan Larson, former US Under Secretary of State quoted in (Eli 1987, 85) and re-quoted in (D. Vogel 2012, 9)

[433] This narration of the events and impact of the Asilomar conference draws heavily upon the narration in (Berg 2008). Specifics in this paragraph come from that article.

[434] Unless otherwise specified, references to the Asilomar Conference in this chapter refer to these events of February 24-27, 1975.

The Asilomar Conference intentionally drew together diverse stakeholders with the explicit task of assessing the potential risks of recombinant DNA and devising regulatory approaches to allow research into the benefits while constraining the risks. "[T]he approximately 140 participants included scientists, lawyers, journalists, and government officials…15% of the participants at Asilomar were from the media".[435] While discussions were fierce, the participants agreed on the final day that "research should continue, but under stringent restrictions[;] the[se] recommendations formed the basis of the official US guidelines on research involving recombinant DNA, issued in July 1976."

In the 46 years since Asilomar, research has continued within these stringent restrictions. While the benefits took "longer than anticipated" to be developed into viable technologies, since the 1980's GE products, diagnostics, and therapies have increasingly come onto the market.[436] However, these earlier methods of GE were limited in their ability to "identif[y] the genes responsible for producing certain products or conditions… and learning how to manipulate them usefully."[437] Yet despite these limitations, the constraints drafted at Asilomar and made official in 1976 have allowed "researchers around the world [to carry] out countless experiments with recombinant DNA without reported incident… none has been a hazard to public health.[438]"

When research led to commercializable products in 1986, the Office of Science and Technology Policy (OSTP) issued a "Coordinated Framework for the Regulation of Biotechnology" whose primary objective was to promote the development of a biotechnology industry. [439] This Coordinated Framework spanned three agencies (the Food and Drug Administration (FDA), the US Department of Agriculture (USDA) and the Environmental Protection Agency (EPA)) and created a baseline assumption of "substantial equivalence" between GE foods and conventional foods. Under this standard, pre-market approval and potential labeling would only be required if GE foods were substantially different in composition, nutrition, or safety. Development was thus constrained to producing products which were "substantially equivalent" but within these bounds business and scientific practices were quite free to innovate. Indeed, "the planting of GM crops in the United States represents "the most rapid adoption of a new technology in the history of agriculture."[440]

However, while the constraints placed on GE research by the Asilomar Conference recommendations have led to a glowing record for research, and the implementation of the Coordinated Framework has expanded this research into commercializable technologies, the technoscientific framing of these constraints have allowed gaps in their social benefits. Because the Coordinated Framework privileges commercialization of biotechnology, it has "relegated non-business constituencies to a marginal role in this policy arena."[441] Domestically, this has meant that when GE products become salient in public discussion (often around a particular product or incident) the result has been either to contain the discussion to a "one-off" needing

[435] (Berg 2008, 290–91)
[436] (Berg 2008, 291)
[437] (Berg 2008, 291)
[438] (Berg 2008, 290–91)
[439] The summary of the Coordinated Framework in this paragraph draws substantially upon the analysis in (D. Vogel 2012, 73)
[440] (Pollack and Shaffer 2009, 1) quoted in (D. Vogel 2012, 81)
[441] (D. Vogel 2012, 74)

more stringent enforcement of existing regulations[442] or to a discussion of voluntary labeling[443] standards and other business self-regulatory actions.[444] Internationally, this has led to conflicts with the EU in the World Trade Organization (WTO) over the perceived protectionist motivation of anti-GMO regulation[445] and clashes with developing countries over resistance to planting GE crops.[446]

With the development of CRISPR-Cas9, the Coordinated Framework and its social holes become newly salient because CRISPR-Cas9 makes GE easier, faster, and ultimately more powerful. The limitations on identifying and editing genes which slowed the progress in the recombinant days of Asilomar are specifically overcome by CRISPR-Cas9.[447] In addition, the shunting of the discussion about social impacts of GE and GMO products to industry self-regulation and non-governmental organizations such as The Non-GMO Project has created a constituency of stakeholders activated around the social issues (validated and perceived) with GE technologies. As Berg observed in 2008, "so many issues in science and technology today are beset by economic self-interest and, increasingly, by nearly irreconcilable ethical and religious conflicts, as well as by challenges to deeply held social values" which would make it "much more difficult to organize such an event [as Asilomar] today."[448] In shunting these discussions of social issues out of the Coordinated Framework, it remains a question whether regulation can respond to the technoscientific and social scientific challenges amplified by CRISPR-Cas9. As we will see in the interviews below (see on page 101), medical biotechnologists and doctors remain confident that the FDA retains the capacity to regulate CRISPR-Cas9 but those perceptions may be a result of the privileged position of technoscientific actors such as themselves within the existing Coordinated Framework.

PRECAUTIONARY PRINCIPLE IN THE EU (2001-PRESENT)

While the precautionary principle predates the invention of gene editing technology by decades, the controversy which arose around the EU's stringent application of the precautionary principle to GE has become a defining archetype of the principle. Thus, while there are a number of European regulations surrounding GE and GMO, they are united under a shared principle of precaution.

While defining the precautionary principle is not without its own set of controversies, the parties can agree that it increases the power of regulators to constrain technologies which might be risky before such risks are proven (or disproven). Critics of the precautionary principle see it allowing "phantom risks" to drive a review process to "convinc[e] even the most irrational consumer of the absences of even the most hypothetical risk of the most remote theoretical

[442] (Jasanoff 2007, 136) cited in (D. Vogel 2012, 83)
[443] (D. Vogel 2012, 83–84)
[444] (D. Vogel 2012, 86)
[445] (D. Vogel 2012, 87; Drezner 2008, 165–67; Urry 1997)
[446] (D. Vogel 2012, 88; Paarlberg 2001; Entine 2005)
[447] See What are AVs and Why are they Disruptive? section on page 85 for more details on the technology of CRISPR-Cas9
[448] (Berg 2008, 291)

uncertainty."[449] Proponents of the precautionary principle see it as erring on the side of the potential for risk rather than waiting for actual risk.[450]

With GE regulation, the precautionary principle led Europe to err on the side of caution, although it initially lacked the authority to do so. In the 1980's, the EU lacked authority to regulate GE crops, leaving the task to the member states which created a lack of harmonized regulations which Directorate-General (DG) Science feared would make it difficult for European biotechnology firms to compete with the booming American industry.[451] In 1990, the EU was able to gain the authority to regulate biotechnology as part of the Single Market initiative, but this new authority reversed the direction from pro-industry to a more precautionary attitude because it was placed with DG Environment rather than DG Science.[452]

This precautionary shift began to be realized in following the technoscientifically unrelated (but socially connected) bovine spongiform encephalopathy (BSE) or "Mad Cow" scare in Britain in 1996.[453] As the very public regulatory failure of BSE had raised public concerns of novel agricultural processes, when the European Commission began to approve GE crops for sale in 1996 the public became suspicious that the safety concerns of these new crops were being suppressed. Public sentiment in Europe continued to rise steeply against GE crops.

Based on this socially connected (but technoscientifically unrelated) Mad Cow scare, six member states (including the largest agricultural producer, France) used their power within the Council of Ministers to prevent the approval of any new GMO products leading to a de facto moratorium on the sale of GMO products.[454] From the beginning of this de facto moratorium in 1998, no new GMO products were approved for sale in the EU. This moratorium reduced production and sale of already approved crops and led biotech investors to flee the European market.[455] This de facto moratorium decided by the political log jamming of a small number of members states rather than through the legislative and regulatory process of the EU threatened both the EU core principle of a Single Market as well as the biotech market.

First in 2001, and then finally in 2003, the EU adopted explicitly precautionary regulation meant to constrain GMOs in order to satisfy the six GMO-moratorium member states and repeal the de facto ban. In 2001, the European Council and European Parliament adopted Directive 2001/18/EC to regulate GMOs which explicitly required the precautionary principle to be invoked (and a product to be restricted) whenever "politically negative effects had been identified, but scientific evaluations were unable to determine "with sufficient certainty" the seriousness of those risks."[456] When this 2001 Directive proved insufficiently stringent for member states who had enacted bans on GMOs, the Commission, Council, and Parliament crafted two 2003 Regulations (EC No 1829/2003 and EC No 1830/2003) which required specific

[449] Alan Larson, former US Under Secretary of State quoted in (Eli 1987, 85) and re-quoted in (D. Vogel 2012, 9)
[450] Wiener, "Whose Precaution After All?" 213–14 cited in (D. Vogel 2012, 10)
[451] (D. Vogel 2012, 74)
[452] (D. Vogel 2012, 75) citing (Jasanoff 2007, 92) and (Falkner 2007)
[453] See details of BSE in (D. Vogel 2012, 63–64) and the non-technoscientific but public/social connection to GMOs in (D. Vogel 2012, 75–77)
[454] (D. Vogel 2012, 78–79 citing; Pollack and Shaffer 2009, 238,240). The member states were France, Italy, Austria, Denmark, Greece, and Luxembourg.(Pollack and Shaffer 2009, 361 text of footnote 15 from pg. 240)
[455] (Pollack and Shaffer 2009, 79)
[456] (D. Vogel 2012, 78–79) (European Parliament and Council of the European Union 2001)

regulatory approval for anything grown from GMO seeds and "established the world's most stringent and comprehensive labeling requirements" based on tight tolerances and comprehensive tracing procedures.[457]

While the 2001 Directive and 2003 Regulations have allowed new GE crops to be approved for sale in Europe since their enactment, the stringent labeling requirements have led to virtually all food producers and retailers abstaining from selling GMOs as they fear consumer backlash against products which would need to bear the labels.[458] While this abstention may seem at odds with "science-based" regulation, it nevertheless demonstrates that the constraints which were put in place directed European products in the direction that European public opinion considered beneficial (the absence of GE crops in food)[459] while also repealing the outright de facto ban on GE crop approval which had existed prior to the 2001 Directive and 2003 Regulations.

CROSS-CASE COMPARISON

Paradigmatically, the case of GE regulation in the US and EU has been seen as one of divergence. The US took the pro-biotech and "pro-science" approach a Coordinated Framework which considers products to be "substantially similar" provided the genetic alterations had not changed the substance of the product. On the other hand, the EU adopted an increasingly stringent Precautionary Principle based approach of considering GE products inherently different if there was any concern raised about them, requiring labeling and stringent tracking.

Yet, these approaches differ not in method but in definition of goal: both the US and EU enacted constraints on the production and sale of GE products to direct development along the avenues they considered beneficial socially (as all regulation does) but more important economically. For the US, this meant preventing risky experiments under the 1976 Research Guidelines and later constraining innovation of commercialized products in the 1986 Coordinated Framework to those which could be considered technoscientifically "substantially equivalent" to products produced by other means. This led to a booming US biotechnology industry. For the EU, this meant increasingly recognizing the resistance of member states to GE products and working to create a harmonized regulatory standard which codified this resistance into a stringent evaluation standard while overturing a de facto outright ban.

While the EU case may seem to be the triumph of social benefits at the expense of economic benefits (as required by Beneficial Constraints), there are four ways to see economic benefits from the EU precautionary restraints. First, the de factor moratorium imposed on the EU by only six member states violated the principle of a Single Market with harmonized standards through official procedure which 2001 Directive and 2003 Regulations overturned. Second, the overwhelming abstention from production and sale of GMO products even after the ban created a market for "natural" foods which has become a billion Euro industry since the 1990s. While this second market benefit has some evidence of intentional industry action based on regionally specific agricultural products and small producers,[460] it's much more likely a true Streeckian accidental beneficial constraint where a market was created by a policy's social intent rather than

[457] (D. Vogel 2012, 79) (European Parliament and Council of the European Union 2003a; 2003b)
[458] (D. Vogel 2012, 81; Kurzer and Cooper 2007a)
[459] (European Parliament and Council of the European Union 2003a, 3; Kurzer and Cooper 2007a)
[460] (Kurzer and Cooper 2007b)

economic planning.[461] Third, the EU de facto abstention can be seen as a form of protectionism as the majority of GMO products come from US designers and producers, although there is substantial evidence that the protectionism followed genuine public concern rather than the other way around.[462] Finally, the stringent regulation of GE agriculture could be seen as a way of constraining politically unpopular aspects of GE in order to allow more popular aspects such as GE medical therapies to flourish without heightened scrutiny. Indeed, medical procedures were explicitly exempted from Directive 2001/18/EC and the follow up Regulations EC No 1829/2003 and EC No 1830/2003.[463]

Whichever framing of the EU case you prefer, it is clear economic benefits were baked into both the US Coordinated Framework and the EU Precautionary Principle. In the US, the benefits were intentionally technoscientific and pro-commercialization of GMOs. In the EU, the benefits were intentionally political and social-scientific and anti-commercialization of GMO foods although this created four possible alternative economic benefits. Thus, despite the diametrically opposite outcomes (US dominates GE product production and consumption, EU is virtually absent by comparison), both polities enacted constraints they considered beneficial on GE technology.

How Confident Can We Be that the Coordinated Framework and Precautionary Principle represent a Beneficial Constraints Model?

Based on the historical narratives above, the US and EU enactment of constraints on gene editing which were considered beneficial by their constituencies suggest that gene editing is a good illustrative case for Beneficial Constraints regulatory imaginary. However, we need not simply rely on asserting this judgment, we can place boundaries on our degree of confidence. Thus, as the illustrative case for Beneficial Constraints in which technology innovation precedes the development of a market and regulatory regime, gene editing is subjected in this section to a Bayesian Type Validation (BayesTV) in order to demonstrate how confident we can be that it does, indeed, represent a distinctive regulatory imaginary of disruptive innovation.[464] This section explains how BayesTV was applied to gene editing in the US (Coordinated Framework) and the EU (Precautionary Principle) cases by first discussing relevant priors, then analyzing the weight of statutory intent and near rival evidence, characterize potential black swan evidence, and then concludes with a final type classification and sensitivity to priors.[465] It concludes by explaining that, for any reasonable set of priors, we can be meaningfully to decisively confident that gene editing is indeed a case of Beneficial Constraints while also identifying the specific loci of contention where the reader can evaluate their level of agreement or departure from this conclusion.

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[461] (Streeck 1997, 213–15)

[462] (Pollack and Shaffer 2009, 285)

[463] The medical exemptions in Directive 2001/18/EC is visible below in $E_{ANNEX\ I}$ while the Regulations are specifically applied only to Food and Feed per their titles.

[464] See Chapter 4 for a full explanation of Bayesian Type Validation, particularly the sections on BayesTV in Practice for an explanation of how the analysis in this section was performed.

[465] The full explicit application of BayesTV for the GE cases may be found in the Appendix.

POSSIBLE TYPES AND PRIORS FOR GE

The possible regulatory imaginaries which the GE case could assume are detailed in the deductive typology developed in Chapter 3 and presented in Table 3 in that chapter (reproduced above as Table 1). From the deductive typology and the reasoning in Chapter 2, we have seven distinct types which are plausible: the Folk Economic Model, Market Ideological, State-as-Venue, Capture, Technology-Based Regulation, Beneficial Constrainer, and Adoption Catalyst. These seven models present the rival worlds under which BayesTV must evaluate the evidence in order to conclude which model the evidence speaks most strongly for.[466]

We can assign several possible prior probabilities to the case being of a particular type.[467] If we are to adopt a *naïve* assumption, we would weight all seven imaginaries equally with no weight-of-evidence (WoE) for any of them (0 dB across all imaginaries, see Table 24). If, instead, we use *common background information* about the gene editing cases, we might be led to believe that either the Technology-Based Regulation or Beneficial Constraints models are more likely given the technology-specific constraints enacted by the state in the US and EU and the interrelatedness of these models discussed in the Beneficial Constraints model specification section of this chapter. Additionally, if we refer to the *case-specific background knowledge* in each case narrative, the strong public and incumbent agricultural and retail industry resistance to GE products makes the Capture imaginary more likely in the EU case while the strong public apathy and agricultural industry acceptance of GE products makes the Adoption Catalyst imaginary more likely in the US case. We can represent each of these background information-based priors by placing a moderate amount of evidence (10 dB) against Beneficial Constraints for each of the four relevant comparisons in Table 24.

Finally, to satisfy a frequentist logic to wrap up all objections in a weight against the model of interest, we may adopt a strong *skeptic*'s approach which would put a strong disadvantage to the Beneficial Constraints imaginary because it is the focus of this chapter and then equally weight each of the other models. Following Fairfield and Charman's (2022, 133) advice, "a very high prior log-odds in favor of a well-established hypothesis relative to a far less plausible rival might reasonably be set at around 50 dB."[468] Thus, we represent the strong skeptic's position by placing 50 dB against Beneficial Constraints for each of the comparisons in Table 24.

Based on the title of this chapter and discussion so far, it should not surprise the reader that my prior is that GE is a characteristic Beneficial Constraints case. To state this precisely, it

[466] (Fairfield and Charman 2017, 1,10)

[467] Following the advice of (Fairfield and Charman 2017, 3-4 in online appendix). This paragraph presents extremes and a paradigmatic midpoint. The reader could adopt whatever priors she sees fit, but it is most instructive to think in classes of priors rather than a continuum because we can then concentrate on tipping points. Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival.

[468] Note that Fairfield & Charman propose this threshold for non-arbitrary reasons; they cite Bayesian mathematician Jaynes (2003, 99–100) as the origin of 50dB based on mathematical logic of probability thresholds used in quantitative work.

Table 24: Prior Weights of Evidence for the Coordinated Framework and Precautionary Principle (in dB)

Weight of Evidence (WoE)*	Naïve	Background Info	Skeptical
$\frac{\textit{Beneficial Constraints}}{\textit{Adoption Catalyst}}$	0 dB	-10 dB	-50 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Capture}}$	0 dB	-10 dB	-50 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Technology Based Regulation}}$	0 dB	-10 dB	-50 dB
$\frac{\textit{Beneficial Constraints}}{\textit{State as Venue}}$	0 dB	-10 dB	-50 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Folk Economic Model}}$	0 dB	0 dB	-50 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Market Ideological}}$	0 dB	0 dB	-50 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically $(-\infty,\infty)$ although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

should be noted that each row in Table 1 can be read as a sentence[469] and thus the Beneficial Constrainer would read as follows: a regulator following the Beneficial Constraints model has *higher* access to *information* than firms, believes that the *market* is the *driver* for the spread of an innovation and would be content with *many* different optimal regulatory *outcomes*. Put plainly, a beneficially constraining regulator is defined by careful negation: they identify certain undesirable practices or outcomes and place constraints on regulated firms which are intended not just to reduce harm but to spur innovation towards undefined desirable practices and outcomes and away from defined undesirable ones. Critically, these constraints are not simply beneficial to society (as regulation generally is intended to be) but are also beneficial to the regulated firms; this form of regulation seeks not to curb the excesses of the market but instead to direct the dynamism of the market toward more economic (and socially) beneficial outcomes.[470] The presentation of evidence below in the execution of BayesTV is meant to give the reader, whatever their priors, an updated belief in whether or not this paragraph is the most plausible state of the world in the two GE cases.

[469] This is a result of the consistency of a deductive typology, discussed in detail in Chapter 3. Note that in that discussion the grammar of the sentence is exactly consistent for all 24 lines in Table 5 while in this chapter I have simplified the grammar to highlight the defining features of the Beneficial Constraints type.

[470] If capitalism is about creative destruction, as Schumpeter ([1943] 2010, 93–94) famously claimed, the beneficial constrainer seeks not to reduce the destruction but instead focus it on destroying current problems while finding creative solutions which are both economically productive and socially beneficial beyond the narrow dictates and time horizon of current market forces.

While priors are a vital part of Bayesian reasoning, the most important analysis in logical Bayesianism at the heart of BayesTV is the *sensitivity*[471] of the results to the priors rather than choosing precise priors before the analysis. For type validation, we are interested in how confident we can be that a particular case fits a particular type rather than weighting between plausible hypotheses. For that reason, while the author is likely to have a strong prior for one type (the type being validated) and the reader may have indifferent (naïve) or strongly contrarian (skeptical) priors, what matters is how loudly the evidence needs to speak to convince different types of readers. Thus, we will return to the discussion of priors in the conclusion of this section (Final Type Classification and Sensitivity to Priors). For now, the reader should file away what regulatory imaginary she thinks best fits the GE cases and concentrate on the reasoning behind the weights of evidence presented below and more fully explained in Appendix C.

BAYESTV OF GENE EDITING IN THE US COORDINATED FRAMEWORK AND EU PRECAUTIONARY PRINCIPLE

In validating that gene editing is an example of the Beneficial Constraints regulatory imaginary, the key constituent variables are information, driver, and outcomes. A Beneficial Constraint conception of innovation regulation is defined by a regulator who is conceived as having higher access to information about a regulated domain combined with a belief that the market is the driver of adoption and who is content with many definitions of "optimal" outcomes rather than a single definition of optimality. The two following sections on each of the empirical gene editing cases will present evidence to update our belief in whether that is the most likely conception of regulators within each case. The evidence will focus on statements within the legislation or made by the regulators who implemented the regulations and how likely they are to be observed in the seven rival states of the world (see Table 23).

Following the advice of Fairfield and Charman (2022, 124–70), the weights of evidence are determined qualitatively but consistently through six paired comparisons of types (most likely vs. each of the six rivals) with the evidence evaluated in the order most logically coherent to the analyst. Note that because it *mathematically* does not matter in what order we incorporate evidence, we can choose the order most logical to the *substantive* comparisons at hand.[472] We can also reduce the number of comparisons by recognizing that *mathematically* a paired comparison of the six rival types against the same type is equivalent to comparing each of the rival types to each other.[473] Thus, we need only six total comparisons in order to consider all possible pairs and we are free to pick which type will be the comparator for all six rivals based on the *substance* of the case.

In their application of logical Bayesianism to social inquiry, Fairfield and Charman (2022, 129–36, esp. p.134) recommend that paired comparisons of types should be assigned weights of evidence (WoEs) in decibels (dB) based on a plain language description of relative differences. While earlier approaches relied on an auditory metaphor of "how loudly the data is speaking,"[474]

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[471] (Fairfield and Charman 2017)

[472] We can also redo our analysis with the evidence in a different order as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 139–40)

[473] We can also redo our analysis with different comparator type as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 140–42)

[474] (Fairfield and Charman 2017, esp. p.6 in online appendix)

Table 25: Qualitative-to-Quantitative Reference Levels for the decibel (dB) Comparison Scale

dB	Acoustic Perception	Plain Language Description	Equivalent Odds or Likelihood Ratio (approx.)
3	Smallest meaningful difference	Very weak	2:1
6	Clearly noticeable difference	Weak	4:1
10	Twice as loud	Moderate	10:1
20	Four times louder	Strong	100:1
30	Eight times louder	Very Strong	1000:1

Based on (Fairfield and Charman 2022, 133, Table 4.1), Note: Some digital audio files that illustrate these different decibel levels are available at: https://tashafairfield.wixsite.com/home/bayes-book

Table 26: Weights of Evidence for the Coordinated Framework and Precautionary Principle (in dB)

Weight of Evidence (WoE)*	Initial Evidence		Near Rival Evidence	
	US $E_{OSTP1986}$	EU $E_{ANNEX\ I}$	US $E_{Blue\ Book\ Repo.}$	EU $E_{Recitals\ 21+22}$
$\frac{Beneficial\ Constraints}{Adoption\ Catalyst}$	10	60	-6	90
$\frac{Beneficial\ Constraints}{Capture}$	20	6	50	-3
$\frac{Beneficial\ Constraints}{Technology\ Based\ Regulation}$	30	10	20	6
$\frac{Beneficial\ Constraints}{State\ as\ Venue}$	30	50	20	60
$\frac{Beneficial\ Constraints}{Folk\ Economic\ Model}$	60	90	50	90
$\frac{Beneficial\ Constraints}{Market\ Ideological}$	54	40	60	90

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically $(-\infty,\infty)$ although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

the final specification recommends a generalized use of the logarithmic decibel (dB) scale to match the logarithmic nature of human sense perception without a reliance on a particular sense metaphor.[475] In keeping with the intuitive human sense perception metaphor, the lower bound for discernable differences is set at 3 dB ("smallest meaningful difference," "very weak," 2:1) while the upper bound is set at 30 dB ("eight times louder," "very strong," 1000:1). A set of qualitative-to-quantitative reference levels, their perceptual references, a natural language description of the relationship, as well as the corresponding odds or likelihood ratios is reproduced from (Fairfield and Charman 2022, 133) in Table 25.

Table 26 provides a summary of the weight of each of the pieces of evidence. The reasoning behind these weights of evidence are summarized in the sections which follow while the full explicit BayesTV analysis may be found in Appendix C. The possible contours of counterfactual evidence is explicitly defined after the analysis of the actually-existing evidence. The final interpretation and comparison with priors occurs in Table 31 on page 165.

Initial Evidence: Legislative Intent

The first piece of evidence highlighted for each case is based on the highest likelihood to correspond with the Beneficial Constraints model. As the GE cases were selected in order to validate the Beneficial Constraints model, their overarching statements of legislative intent shall be used to make the initial case for Beneficial Constraints over rival types as the most probable state of the world. In the US case, this evidence comes not from legislation but from regulator action in lieu of legislation: the preamble to the 1986 Coordinated Framework for Regulation of Biotechnology. In the EU case, this evidence comes from Annex I of Directive 2001/18/EC where the European Commission, Council, and Parliament crafted a directive requiring specific regulatory approval for any product this a GMO or made from a GMO which is to be released into the environment (placed on the market). The following sections discuss each of these two pieces of "legislative intent" evidence in turn.

Coordinated Framework in the United States (1986-present)

While the BayesTV method generally highlights legislative intent as the initial evidence, the US regulation of GE technology was not crafted through legislation. Rather, the USDA, FDA, and EPA came together at the behest of the White House Office of Science and Technology Policy (OSTP) to craft a coordinated framework under existing statutory authorities.[476] Since the first piece of evidence should capture the most informative statement of the intent of the ultimate authority for the regulatory action, it is this statement in the Federal Register rather than a piece of legislation which best captures this information because there *was no legislation* passed to address the regulatory disruption of GE technology in the United States. This statement of regulatory intent seeks:

> *"to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry… Upon examination of the existing laws available for the regulation of*

[475] Both the senses of sight and sound, for example, evolved logarithmically in humans; a tenfold increase in absolute light power or sound intensity is perceived as a doubling in "brightness" or "loudness" by human senses. See (Fairfield and Charman 2022, 129–30) for further explanation of the appropriateness of the logarithmic scale across the physical, biological, and social sciences.

[476] (Office of Science and Technology Policy 1986, 23303)

> *products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately… The existing health and safety laws had the advantage that they could provide more immediate regulatory protection and certainty for the industry than possible with the implementation of new legislation…. The regulatory framework anticipates that future scientific developments will lead to further refinements."*
>
> *-- (Office of Science and Technology Policy 1986, 23302–3)*

A summary of the explicit Bayesian type validation (BayesTV) of $E_{OSTP1986}$ for each of the regulatory imaginaries in Table 23 is presented below in Table 27. The full narrative prose explaining these summaries of how likely we would be to see this evidence ($E_{OSTP1986}$) under the assumption that each potential regulatory imaginary was the true state of the world may be found in the appendix. The significance of this analysis is discussed in the following section on the weight of evidence $E_{OSTP1986}$.

The Weight of Evidence OSTP1986

As seen by the weights of evidence in the last column of Table 27, the piece of evidence presented above ($E_{OSTP1986}$) increases our confidence that Beneficial Constraints is the true state of the world in the US Coordinated Framework case. At 60 dB and 54 dB, this piece of evidence speaks overwhelmingly against the two models which see regulators as simply an impediment to innovation since it is a strong statement of belief in regulatory competence (information and effect columns of last two rows of Table 27).

The real stakes of the Beneficial Constraints model, however, lies in regulators placing constraints on firms intended to be beneficial to industry but not at the expense of society. It is thus not surprising that this piece of evidence speaks less loudly against the Capture (20 dB) and Technology Based Regulation (30 dB) models as each of these models also see the regulator as a constrainer. However, as explained at length in the Appendix, a world of Capture would not likely see evidence of three powerful existing agencies (FDA, EPA, USDA) assert their existing ability to adapt to a newly emerging industrial technology (rather than assert need to protect incumbent industry, see Information column in Capture row of Table 27). So too with Technology Based Regulation, the Coordinated Framework as explained in this preamble is neither requiring nor forbidding a specific technology but is rather establishing a flexible set of guidelines across agencies (see Outcomes and Effect columns in Technology-Based Regulation row of Table 27).

At the other extreme of state action, Adoption Catalyst, the reliance on the market to spread the innovation within the Coordinated Framework speaks moderately against Adoption Catalyst as the true state of the world (see Driver column in Adoption Catalyst row of Table 27). Finally, this piece of evidence speaks very strongly against the neutral moderator role of the State as Venue model relative to Beneficial Constraints given that the Coordinated Framework went beyond moderating the stakeholder discussions at both the Asilomar Conference and the OSTP working group in order tto actually specify a set of rules and principles shared between the three agencies covered by the framework (see State as Venue row of Table 27).

Table 27: BayesTV Constitutive Variable Comparison Summary for $E_{OSTP1986}$*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Reliance on existing laws affirms access to sufficient information	Strong statement of market-as-driver re: "industry certainty"	Specific acknowledgement of many potential outcomes	Moderate/ Implicit statement of constraint	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Clear reliance on market not regulator to drive adoption	*No distinguishing relevance*	Pro-adoption spirit but non-direct method	10 dB
Capture	*No distinguishing relevance*	"provide certainty for industry" = Higher regulator access to information than firms	*No distinguishing relevance*	Specific encouragement of many rather than one desirable outcome	*No distinguishing relevance*	20 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Intentional flexibility of Coordinated Framework contradicts single preferred outcome of TBR	Constraint is performance not technology based	30 dB
State as Venue	OSTP clearly taking stakeholder role	Clear assertion of informed competence of regulators	*No distinguishing relevance*	*No distinguishing relevance*	More than moderation within Coordinated Framework	30 dB
Folk Economic Model	OSTP clearly sees themselves as informed stakeholder	Statement of Regulator competence anathema to Folk Economic Model	*No distinguishing relevance*	*No distinguishing relevance*	Coordinated Framework explicitly pro-innovation rather than impediment	60 dB
Market Ideological	*No distinguishing relevance*	"provide certainty for industry" = higher regulator access to information than firms	Market is the driver but with regulatory guidance "industry certainty"	Clear description of more than zero desirable outcomes	Coordinated Framework explicitly pro-innovation rather than impediment	54 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{OSTP1986}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 26 for further explanation and Chapter 4 for complete methodological specification.

Precautionary Principle in the EU (2001-Present)

The legislative intent for the EU Precautionary Principle approach to gene editing regulation comes from the establishing Directive, Directive 2001/18/EC. As with all EU Directives, 2001/18/EC opens with a list of numbered recitals including notable references to "the precautionary principal,"[477] "respect for ethical principles,"[478] "case-by-case evaluation,"[479] and "step by step" introduction of each GMO.[480] While these recitals do not carry the force of law, they may be used by member states in interpreting and clarifying provisions of the Directive when implementing them in national law and often contain a statement of principles which motivate the enactment of the directive.[481]

The objective of Directive 2001/18/EC, stated in Article 1, is to protect human health and the environment when releasing genetically modified organisms within the Community specifically "in accordance with the precautionary principle".[482] Notably, however, the EU clearly specifies what is not considered to be genetic modification in Annex I A Part 2 and I B:

> *[Annex I A] PART2*
>
> *Techniques referred to in Article 2(2)(b) which are* ***not considered to result in genetic modification****, on condition that they* ***do not involve the use of recombinant nucleic acid molecules*** *or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:*
>
> *(1) in vitro fertilisation,*
>
> *(2) natural processes such as: conjugation, transduction, transformation,*
>
> *(3) polyploidy induction.*
>
> *ANNEX I B*
>
> *TECHNIQUES REFERRED TO IN ARTICLE 3*
>
> *Techniques/methods of genetic modification yielding* ***organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules*** *or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:*
>
> *(1) mutagenesis,*
>
> *(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through* ***traditional breeding methods****.*
>
> -- (European Parliament and Council of the European Union 2001, OJ L:17–18 emphasis added)

[477] (European Parliament and Council of the European Union 2001, OJ L:1, recital 8)
[478] (European Parliament and Council of the European Union 2001, OJ L:1, recital 9)
[479] (European Parliament and Council of the European Union 2001, OJ L:2, recitals 18 & 19)
[480] (European Parliament and Council of the European Union 2001, OJ L:2, recital 24)
[481] (Publications Office of the European Union 2022, 35–36)
[482] (European Parliament and Council of the European Union 2001, OJ L:4)

Although buried somewhat in negation language, the line between genetically modified organism (GMO) and not is clearly defined here not based on **whether** the genetic code of an organism has been modified but **how** that code has been modified. For Directive 2001/18/EC, and thus the EU Precautionary Principle case, genetic modification is only of concern when it is does not occur "naturally" and is not induced through "traditional breeding methods." The line is defined based on technique, not outcome.

A summary of the explicit Bayesian type validation of $E_{ANNEX\ I}$ for each of the regulatory imaginaries in Table 23 which were narratively explained above is presented below in Table 28. The full narrative prose explaining these summaries are omitted here for clarity and brevity but may be found in the Appendix. The significance of this analysis is discussed in the following section on the weight of evidence $E_{ANNEX\ I.}$

The Weight of Evidence ANNEX I

As seen by the weights of evidence in the last column of Table 28, the piece of evidence presented above ($E_{ANNEX\ I}$) increases our confidence that Beneficial Constraints is the true state of the world in the EU Precautionary Principle case. At 90 dB and 40 dB, this piece of evidence speaks overwhelmingly against the two models which see regulators as simply an incompetent (Folk Economic Model) or undesirable (Market Ideological) impediment to the market because the constraints enacted specifically were done to repeal a de facto ban create by powerful member states prior to Directive 2001/18/EC.[483]

Nevertheless, the real stakes of the Beneficial Constraints model lie in the placing of constraints as well as the intention for those constraints to be beneficial to both industry and society. It is thus not surprising that this piece of evidence speaks less loudly against the Capture (6 dB) and Technology Based Regulation (10 dB) models as each of these models also see the regulator as a constrainer. However, as explained at length in the Appendix, while the technoscientifically arbitrary line between recombinant DNA and "traditional methods" of gene editing are congruent with capture by traditional agricultural producers, the background information of the case makes clear that *consumers* pressed for this line, not incumbent *industry* as would be required for any meaningful specification of capture theory.[484] With regard to Technology Based Regulation, the Precautionary Principle does not forbid a specific technology but rather establish a stringent set of protocols for its use. For similar reasons, this evidence speaks vehemently against the Adoption Catalyst model as the Precautionary Principle uses state action to slow the adoption of GE technology rather than enable it. Finally, the neutral moderator role of the State as Venue model is extremely incongruent with this piece of evidence given the strong stance these definitions take in favor of traditional gene editing techniques over recombinant DNA techniques.

[483] (D. Vogel 2012, 78–79)

[484] See (D. Vogel 2012, 80–81) for the discussion of the dominance of "consumer interest" and "public support" over agricultural industry lobbying in the GM debate around Directive 2001/18/EC and Regulations EC No 1829/2003 and EC No 1830/2003 and (Carpenter and Moss 2014a, 20) for a discussion of capture theory

Table 28: BayesTV Constitutive Variable Comparison Summary for $E_{ANNEX\ I}$*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Careful specification of what is/isn't "considered to result in genetic modification"	Directive overturned de facto ban[485] so market could drive GE adoption	Implicit acceptance of multiple outcomes due to labeling replacing prior de facto ban	Constraint based on careful weaving of techno-/social-scientific criteria	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Clearly constraining not catalyzing.	60 dB
Capture	*No distinguishing relevance*	Regulator claimed information about consumers beyond that of regulated firms	*No distinguishing relevance*	*No distinguishing relevance*	Constraints demanded by consumers, not by regulated industry	6 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Multiple outcomes possible due to categorization rather than ban/mandate	Constraints based on categorization (rather than ban/mandate) for specific technology	10 dB
State as Venue	*No distinguishing relevance*	Regulator claimed information about consumers beyond that of regulated firms	*No distinguishing relevance*	*No distinguishing relevance*	Clearly constraints and not mere moderation.	50 dB
Folk Economic Model	Regulator clearly acting as precautionary stakeholder not reserved rulemaker	Proactive precaution of regulator based on assessment of consumer demand would be anathema to FEM	*No distinguishing relevance*	*No distinguishing relevance*	Constraints on GE to repeal a de facto ban (removed impediment)	90 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Precautionary principle heretical to Market Ideological world	Constraints on GE to repeal a de facto ban (removed impediment)	40 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{ANNEX\ I}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 26 for further explanation and Chapter 4 for complete methodological specification

[485] (D. Vogel 2012, 81)

NEAR RIVAL EVIDENCE:

As can be seen from the weight of evidence summary in Table 26, the initial evidence was least decisive (fewest decibels) about a different alternative type for each of the cases. In the US Coordinated Framework case, the nearest rival model is the Adoption Catalyst model because the structure of the Coordinated Framework as expressed in this preamble ($E_{OSTP1986}$) is clearly consistent with the broad strokes of a regulator who wishes to promote the adoption of GE technology although it is relatively less likely than Beneficial Constraints because the mechanism used is left to the market rather than catalyzed by the state. In the EU Precautionary Principle case, the nearest rival model is the Capture model due the explicit exception of "traditional breeding methods" from regulation as well as the careful semantics that simultaneously acknowledge that genes are modified in other ways than those covered by Annex I A Part 1 but then define them as "not considered to result in genetic modification."[486]

In this section, we highlight an additional piece of evidence which is most supportive of the respective nearest rival type for each of the two empirical cases. For the US Coordinated Framework case, this evidence comes from the International Aspects section of the Preamble to the Coordinated Framework because, in line with the Adoption Catalyst imaginary, it explicitly lays out the desire of the OSTP and coordinating Agencies (USDA, FDA, EPA) to encourage development of and reduce barriers to trade in GMO products.[487] For the EU Precautionary Principle case, this evidence comes from Recitals 21+22 of Regulation EC No 1829/2003 because they explicitly lay out the deference to consumer distrust of GMO products against the advice of experts which is consistent with a (cultural) capture imaginary.

Coordinated Framework in the United States (1986-Present)

In the leadup to the drafting of the Coordinated Framework, there were a number of US and international meetings of scientists and other stakeholders to discuss what was scientifically known of, economically possible from, and socially (un)desirable about gene editing technology and the resulting GMO products. One such meeting was the previously discussed 1975 Asilomar Conference.[488] Another meeting, specifically referenced in the published Coordinated Framework, was the Ad Hoc Group of Government Experts convened by the Organization for Economic Cooperation and Development (OECD) which was reported in "Recombinant DNA Safety Considerations, Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques,"[489] colloquially known as the "Blue Book."[490]

In the final section of the preamble to the Coordinated Framework, OSTP reproduced the entirety of the "Summary and Recommendations" guidelines from the OECD Blue Book. This reproduction was presaged with a statement from OSTP where they paraphrased what they saw as the message of the OECD's report:

> *"**The United States seeks to promote international scientific cooperation and understanding of scientific considerations in biotechnology** on a range of technical*

[486] (European Parliament and Council of the European Union 2001, OJ L:17–18)
[487] (Office of Science and Technology Policy 1986, 23308)
[488] See the discussion of several such meetings in the US Case background section (Perpetual Guidance in the United States (2016-Present)) on page 95, above.
[489] (Office of Science and Technology Policy 1986, 23308; OECD 1986)
[490] (Schiemann 2006)

matters. These activities add to scientific knowledge and ultimately contribute to protection of health and the environment.

***The United States also seeks to reduce barriers to international trade**. U.S. agencies apply the same regulation and approval procedures on domestic and foreign biotechnological products.*

*We are seeking recognition among nations of the need to harmonize, to the maximum extent possible, national regulatory oversight activities concerning biotechnology. **Barriers to trade in biotechnological products should be avoided** as nations join together in working toward this mutual goal.*

The U.S. agencies that have published separate policy statements as part of this notice are committed to the policy described in this section on international harmonization and have incorporated by reference the language in this International Aspects section as part of their respective agency policy statements.

Organization for Economic Cooperation and Development (OECD)

The approach of the comprehensive framework contained in this notice takes into account, inter alia*, the broad goals described by an Ad Hoc Group of Government Experts convened by OECD in their recent report entitled, "Recombinant DNA Safety Considerations, Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques." **The United States is pleased to have had the opportunity for its experts to work with those of other governments in the preparation of this report**."*

-- (Office of Science and Technology Policy 1986, 23308 emphasis added)

With strong and repeated emphasis on lowering barriers, promoting scientific cooperation and understanding, and driving international trade in GMOs, the introduction to the reproduction of the Summary and Recommendations from the OECD Blue Book is a piece of evidence which would be very consistent with the Adoption Catalyst imaginary identified by the legislative intent evidence ($E_{OSTP1986}$) as a near rival to the Beneficial Constraints imaginary in the US Coordinated Framework case.

A summary of the explicit Bayesian type validation of $E_{OSTP1986}$ for each of the regulatory imaginaries in Table 23 which were narratively explained above is presented below in Table 29. The full narrative prose explaining these summaries are omitted here for clarity and brevity but may be found in the Appendix. The significance of this analysis is discussed in the following section on the weight of evidence $E_{\text{Blue Book Reproduction.}}$

Table 29: BayesTV Constitutive Variable Comparison Summary for $E_{\text{Blue Book Reproduction}}$*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Content of OECD Blue Book asserts high information that "no scientific basis for specific legislation"	*No specific relevance*	*No specific relevance*	Reducing constraints in favor of US-led shared constraints which encouraged "future developments"	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Aspirational language encouraging adoption	*No distinguishing relevance*	Hard to produce international catalyst due to no international state.	-6 dB
Capture	*No distinguishing relevance*	State claimed knowledge of information beyond firms (thus guidance)	*No distinguishing relevance*	Flexibility and encouragement of innovative outcomes.	Constraints were pro-competition and pro new-entrant firms	50 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Endorsement of multiple outcomes and international competition	Principle based (rather than prescriptive) constraint	20 dB
State as Venue	OSTP acting as stakeholder even if OECD was simply rulemaker	OSTP experts and OECD experts asserting high information in authoring guidance	*No distinguishing relevance*	*No distinguishing relevance*	OECD moderated but OSTP used output to constrain	20 dB
Folk Economic Model	OSTP clearly a stakeholder (guidance) and not a withdrawn rulemaker	Strong claims of regulatory competence to adequately evaluate and regulate GE	*No distinguishing relevance*	*No distinguishing relevance*	OSTP is reducing impediments and encouraging lower barriers to trade	50 dB
Market Ideological	*No distinguishing relevance*	Strong claims of regulatory competence to adequately evaluate and regulate GE	*No distinguishing relevance*	Flexibility and encouragement of innovative outcomes.	OSTP is reducing impediments and encouraging lower barriers to trade	60 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $\text{WoE}_{\text{Blue Book Reproduction}}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 26 for further explanation and Chapter 4 for complete methodological specification.

The Weight of Evidence Blue Book Reproduction

As seen by the weights of evidence in the last column of Table 29, the piece of evidence presented above ($E_{\text{Blue Book Reproduction}}$) increases our confidence that Beneficial Constraints is the most likely state of the world in the US Coordinated Framework case over all imaginaries except the Adoption Catalyst imaginary. As expected, given the selection criteria for the near rival evidence, we would be more likely to see this piece of evidence in the nearest rival world (Adoption Catalyst) than the Beneficial Constraints world because they are seeking to promote the adoption of US-congruent standards (which are also OECD congruent) for biotechnology so as to reduce the barriers to trade in biotechnology. Yet, given the Adoption Catalyst imaginary's focus on state action to drive the adoption of a technology, the lack of a true state in the international arena makes this evidence only slightly (6 dB) more likely in the Adoption Catalyst world than the Beneficial Constraints world.

With respect to the two models which see regulators as simply an impediment on innovation (Folk Economic Model and Market Ideological), the endorsement of regulatory competence in the content of the OECD recommendation reproduced by the OSTP cannot be drowned out by the pro-market language of lowering trade barriers. Indeed, for this pro-market language to be plausible observed along with the rest of the evidence discussed in the case narrative as well as that highlighted in the legislative intent section (E_{OSTP1986}), we would have to believe that regulators were either deeply incompetent (for the Folk Economic Model) or engaged in some sort of devious subterfuge intended to allow the power of international capitalism to undo all of the rest of the careful constraints defined in the Coordinated Framework. Such beliefs might help to turn out Libertarian voters but they are extremely (50 dB and 60 dB) unlikely relative to the much more plausible narrative of the US seeking to evangelize their way of regulating GE which is all we would need to accept for a Beneficial Constraints world.

Interesting though the extreme imaginaries are, the real stakes of the Beneficial Constraints model lie in placing constraints on markets to benefit both industry and society. Thus, the crux lies in distinguishing between the other two models which see the regulator as a constrainer: Technology-based Regulation and Capture. Relative to the initial evidence (E_{OSTP1986}), this piece of evidence slightly more quietly yet still decisively against Technology-Based Regulation (20 dB) but *much louder* against Capture (50 dB). As Capture was strongly yet not overwhelmingly weighed against in E_{OSTP1986}, this piece of evidence allows us to more forcefully reject Capture because the *lowering* of barriers to an emerging technology sector (biotechnology) is antithetical to the core concept of capture which hinges on protecting the interests of *incumbent* industry (or, internationally, domestic industry) at the expense of consumers and new challenger firms (c.f. Carpenter and Moss 2014b). As with the prior evidence, $E_{\text{Blue Book Reproduction}}$ speaks against Technology-Based Regulation because the OECD recommendations reproduced by the OSTP are not requiring or forbidding a specific technology but are rather establishing a flexible set of guidelines.

Finally, the neutral moderator role of the State as Venue model is a normal conversation in a quiet room quieter than Beneficial Constraints given that, while the OECD may have reproduced the views and recommendations of the stakeholders on the ad-hoc committee, the OSTP in its introduction to the reproduction clearly states what they see as the correct interpretation of those principles.

Precautionary Principle in the EU (2001- Present)

As discussed in the case introduction (p.142), when Directive 2001/18/EC proved insufficiently stringent for member states who had enacted bans on GMOs, the Commission, Council, and Parliament crafted two 2003 Regulations (EC No 1829/2003 and EC No 1830/2003) which required specific regulatory approval for anything grown from GMO seeds and "established the world's most stringent and comprehensive labeling requirements" based on tight tolerances and comprehensive tracing procedures.[491] These stringent labeling requirements have led to a de facto moratorium across virtually all food producers and retailers as they fear consumer backlash against products which would need to bear the labels.[492] These guidelines were developed with specific reference to what European public opinion considered beneficial: the absence of GE crops in food, as expressed in the 21st recital of EC No 1829/2003:

> *(21) The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling,* ***irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers****, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.*
>
> -- (European Parliament and Council of the European Union 2003a, 3 emphasis added)

Further clarification for the intent behind this labeling is provided in the immediately following 22nd recital of EC No 1829/2003:

> *(22) In addition, the labelling should* ***give information about any characteristic or property which renders a food or feed different from its conventional counterpart*** *with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as* ***any characteristic or property which gives rise to ethical or religious concerns***
>
> -- (European Parliament and Council of the European Union 2003a, 3 emphasis added)

Together, these two recitals specify that the labelling enacted through this binding Regulation[493] is based on consumer demand arising from a suspicion that GMO products are different from conventional counterparts, specifically in ways which may be medically, ethically, or religiously relevant. Further, this labelling is explicitly "irrespective of the detectability" of any difference in the final GMO product relative to "traditionally" produced alternative products.

This concern with an inherent difference between GMO and "non-GMO" products (which include products which have been altered using "traditional" non-Recombinant DNA techniques, per $E_{ANNEX\ I}$) may reflect the special place of farmers and agriculture within all societies, but particularly within European society and European Law.[494] Although the demands in Recital 21

[491] (D. Vogel 2012, 79) (European Parliament and Council of the European Union 2003a; 2003b)
[492] (D. Vogel 2012, 81)
[493] In European law, *Directives* are guidance for the member states while *Regulations* are binding requirements, (European Union 2016)
[494] (Ciciora 2019)

are explicitly attributed to consumers and not agricultural producers, it is possible that the special place of (traditional) farmers constitutes a form of cultural capture[495] of European consumers. In effect, traditional incumbent agriculture has captured regulators not through lobbying of bureaucrats but through the capturing of the hearts and minds of consumers.[496]

With this strong statement of support for incumbent "traditional" agricultural production over the potential concerns spurred by GMO "irrespective of detectability," Recitals 21 & 22 of EC 1829/2003 together comprise a piece of evidence ($E_{\text{Recitals 21+22}}$) which would be highly likely under a Capture regulatory imaginary which was identified as the nearest rival to the Beneficial Constraints imaginary in the EU Precautionary Principle case.

A summary of the explicit Bayesian type validation of E_{OSTP1986} for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 21. The full narrative prose explaining these summaries are omitted here for clarity and brevity but may be found in the Appendix. The significance of this analysis is discussed in the following section on the weight of evidence $E_{\text{Recitals 21+22.}}$

The Weight of Evidence Recitals 21+22

As seen by the weights of evidence in the last column of Table 21, the piece of evidence presented above ($E_{\text{Recitals 21+22}}$) increases our confidence that Beneficial Constraints is the most plausible state of the world against all rivals except Capture. At 90 dB for each, this piece of evidence speaks overwhelmingly against the two models which see regulators as simply an incompetent (Folk Economic Model) or undesirable (Market Ideological) impediments to the market. The neutral moderator role of the State as Venue model is also extremely incongruent with this piece of evidence given the firm position the EU takes on the side of stringent labeling for GMO products "irrespective of the detectability" and in line with "the demands expressed in numerous surveys by a large majority of consumers." The placing of impediments to adoption makes also makes it extremely unlikely (90 dB) to see this evidence in an Adoption Catalyst world.

The real stakes of the Beneficial Constraints model, however, lies in the placing of constraints as well as the intention for those constraints to be beneficial to both industry and society. It is thus not surprising that this piece of evidence speaks less loudly against Technology Based Regulation (6 dB) models and in favor of Capture (-3 dB) as each of these models also see the regulator as a constrainer. With regard to Technology-based Regulation, this piece of evidence contains specifications which are primarily about principles (e.g. "ethical and religious") rather than specific measures which is more in line with Beneficial Constraints although other parts of EC No 1829/2003 and EC No 1830/2003 do include specific measures, narrowing the distinction to only a clearly noticeable difference (6 dB).

As explained at length in the Appendix, while the technoscientifically arbitrary line between recombinant DNA and "traditional methods" of gene editing are congruent with capture by traditional agricultural producers, the background information on the case makes clear that consumers pressed for this line, not incumbent industry as specified in capture theory. In essence, for this piece of evidence to be highly likely to be seen in a world where Capture is the

[495] (Carpenter and Moss 2014a, 19–20; Kwak 2014)

[496] I thank Matthew Stenberg for stridently making this point on an earlier version of this chapter. It echoes the third and fourth core arguments of (Ciciora 2019)

Table 30: BayesTV Constitutive Variable Comparison Summary for $E_{Recitals\ 21+22}$*

(Independent Variables)					Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	EU forgoes claims to expertise in favor of consumer surveys but not firm advocacy	*No specific relevance*	While labeling can be flexible, this labeling regime is very stringent and comprehensive[497]	Constraint was actual a repeal of prior de facto ban[498]	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Market is the driver, labeling scheme	*No distinguishing relevance*	Clearly constraining not catalyzing adoption	90 dB
Capture	*No distinguishing relevance*	Regulators claim higher information but from consumers, possibility of cultural capture but better understood as FEM or Market Ideological[499]	*No distinguishing relevance*	While labeling can be flexible, this labeling regime is very stringent and comprehensive	Constraints demanded by consumers, not by regulated industry, but possibility of "cultural capture"[500]	-3 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Strict specification of protocols but primarily principle rather than technical	Constraints are principle not technology based	6 dB
State as Venue	*No distinguishing relevance*	EU claims knowledge of consumer needs and expertise to evaluate compliance with them	*No distinguishing relevance*	*No distinguishing relevance*	Not simply moderating, constraining from a clear precautionary perspective	60 dB
Folk Economic Model	Precautionary Principle inherently creates stakeholder relations	EU claims knowledge of consumer needs and expertise to evaluate compliance with them	*No distinguishing relevance*	*No distinguishing relevance*	Constraints on GE to repeal a de facto ban (removed impediment)	90 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Consumer interest supersedes firm interest AND the state should make this adjudication; contradicts supremacy of the market.	Constraints on GE to repeal a de facto ban (removed impediment)	90 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{Recitals\ 21+22\ vs.}$ Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.
† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 26 for further explanation and Chapter 4 for complete methodological specification.

[497] (D. Vogel 2012, 79)
[498] (D. Vogel 2012, 78–79)
[499] Some evidence of Green-Green coalitions between consumers and producers (Kurzer and Cooper 2007b), but this is better understood as a "plausible reading of the public interest" (Kwak 2014, 79) and better examined through Folk Economic Model or Market Ideological imaginaries.
[500] (Carpenter and Moss 2014a, 19–20; Kwak 2014)

true state and where we do *not* see *deliberate* action by agricultural firms[501] to divert regulation toward their private interest at the expense of the public interest, we must define capture as cultural capture: how non-material factors such as identity, status, and relationships can lead to regulatory outcomes which favor the interests of regulated firms at the expense of the public interest.[502] However, cultural capture is often indistinguishable from plausible contestation of the public interest.[503] Thus, while we would be likely to see this evidence in a Capture world, it raises at least as many questions about the nature of capture than it answers about the true state of the world.[504] To that end, while this evidence is more likely to be observed in a Capture world than a Beneficial Constraints world, the difference is not as extreme as it may appear because the reliance on a very weak form of cultural capture means that this evidence can reasonably be seen as a legitimate contestation of what is beneficial to the public interest (and thus might be a Beneficial Constraint rather than capture) meaning we can go no higher than the smallest meaningful difference in the weight of evidence (-3 dB).[505]

BLACK SWAN EVIDENCE AND THE COUNTERFACTUAL

Before adjudicating the final type classification and sensitivity to priors, due diligence requires us to consider what evidence would be consistent with the extreme opposite of the suggested type classification being the most probable state of the world; the so-called "black swan" evidence. As Beneficial Constraints is the most likely type for the gene editing cases and the nearest rivals are Adoption Catalyst and Capture, the extreme opposites (from Table 23) are either the Folk Economic Model or Market Ideological because they reject the competence and/or legitimacy of regulation (lower access to information, one or zero desirable outcomes).[506] In a Folk Economic or Market Ideological world, we would expect to see regulators acting lost due to lower access to information than market participants and either recusing themselves from regulation in order to stay out of the way until the market has innovated[507] or implementing harsh and inappropriate anti-innovative regulations. While no evidence has been found that carries this information,[508] a skeptical reader should contact the author with such evidence so that it may be incorporated into analysis and allow us to radically update our priors.

[501] See (D. Vogel 2012, 80–81) for the discussion of the dominance of "consumer interest" and "public support" over agricultural industry lobbying in the GM debate around Directive 2001/18/EC and Regulations EC No 1829/2003 and EC No 1830/2003.

[502] (Kwak 2014, 79–80)

[503] (Kwak 2014, 79)

[504] A finding that is by no means surprising in the intellectually rigorous capture literature, see (Carpenter and Moss 2014b), particularly (Carpenter and Moss 2014a, 2-5,13-16; 2014c; Novak 2014; Posner 2014)

[505] Recall that negative WoE means that the evidence speaks more loudly for the challenger imaginary (in this case Capture) than the comparator imaginary (in this chapter, Beneficial Constraints)

[506] Note that the black swan imaginaries are selected conceptually rather than empirically but the extremely high decibel scores for the Folk Economic Model and Market Ideological on all four pieces of evidence highlighted with explicit BayesTV increases our confidence that these two imaginaries are extremely unlikely to be the true state of the world.

[507] While this may seem fanciful, this "wait and see" attitude was exactly how the US Federal Reserve approached mobile payment apps for years. (Lowry 2016, 384)

[508] See Appendix section on $WoE_{OSTP1986}$ Beneficial Constraints vs. Market Ideological) for discussion of why the "substantially equivalent" standard in the Coordinated Framework is not an example of this hands off attitude.

FINAL TYPE CLASSIFICATION AND SENSITIVITY TO PRIORS

For final classification based on updating our beliefs in which regulatory imaginary is the most probably animating the regulatory framework around gene editing, we add the decibel comparisons between the Beneficial Constraints imaginary and each of the alternative models from each piece of evidence and then add those to the priors discussed at the beginning of this section. These comparisons are presented in Table 31.

Consistent with the design and intent of Bayesian type validation, the evidence can tell several disciplined and clear stories depending on how it is combined with priors and across cases. If we combine all of the evidence for both the US and EU cases, we find overwhelming reason to believe that GE technology is regulated from the Beneficial Constraints imaginary (from a rock concert to more than twice the shockwave threshold). If we look just at the US case (Table 31, column a "US Post"), we find decisive evidence [509] (80+ dB) for Beneficial Constraints over the Folk Economic Model and Market Ideological imaginaries. We also see evidence which is above the threshold of a very well established theory (50-70 dB) for Beneficial Constraints over Capture, State as Venue, and Technology-based Regulation. For Adoption Catalyst in the US case, we find a meaningful difference (4 dB) in favor of Beneficial Constraints. If we look at just the EU case (Table 31, column a "EU Post"), we find decisive evidence (80+ dB) for Beneficial Constraints over all alternative imaginaries except Capture where we find merely meaningful evidence (3 dB) and Technology-based Regulation where we find moderately strong evidence (16 dB). These overall weights of evidence should then each be considered against the reader's priors to update our belief in what the most probable state of the world is.

If the reader adopted naïve priors with equal weights (0 dB in favor of or against Beneficial Constraints) for the combined case of GE in the US and EU (Table 31, column a "combo posterior"), then the evidence presented above would create well-established (50-70 dB) or decisive (80+ dB) in favor of Beneficial Constraints over alternative regulatory imaginaries. While there are fair reasons to disaggregate the data to a per-case level as that is where the regulation actually occurred (at the US/EU levels), this combined weight of evidence is useful for us to understand how GE is imagined to be regulated cross-nationally. The evidence thus aggregated tells us that GE is regulated from the Beneficial Constraints imaginary regardless of priors (Naïve, Background Information, or Skeptical). Indeed, it would take a prior roughly equivalent to the likelihood of any commercial airplane flight crashing (~67 dB) in favor of

[509] Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival. Fairfield and Charman (2022, 162–63) proceed to explain that a more stringent threshold of 50-70 decibels equates to the thresholds of confidence used by quantitative Bayesian statisticians in the physical and biological sciences; they note that 62 dB is roughly equivalent to the 5 sigma threshold for discovering a new particle in Physics and 67 dB the chance that any given commercial airplane flight will crash vs. land safely. While Fairfield and Charman (2022, 162, footnote 34) also caution us that you cannot truly mathematically convert Bayesian odds to frequentist p-values because they are different ontological statements, most quantitative social scientists are happy with $p<0.1$ (~27 dB) and $p<0.05$ (~30 dB) for publication and are ebullient about $p<0.01$ (~37 dB). Fairfield and Charman ultimately recommend a threshold of 80-100 dB to consider a qualitative research question "settled" both to guard against potential unaccounted for bias as well as to deal with the reality that quantitative social scientists often show higher skepticism toward qualitative evidence than they do towards their own thresholds of significance.

Table 31: BayesTV Prior and Posterior Weights of Evidence for the GE Cases, US Coordinated Framework and EU Precautionary Principle evidence (in dB)

	a				b				c			
Weight of Evidence (WoE)*	**Naïve**				**Background Info**				**Skeptical**			
	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior
$\frac{Beneficial\ Constraints}{Adoption\ Catalyst}$	0	4	150	154	-10	-6	140	144	-50	-46	100	104
$\frac{Beneficial\ Constraints}{Capture}$	0	70	3	73	-10	60	-7	63	-50	20	-47	23
$\frac{Beneficial\ Constraints}{Technology\ Based\ Regulation}$	0	50	16	66	-10	40	6	56	-50	0	-34	16
$\frac{Beneficial\ Constraints}{State\ as\ Venue}$	0	50	110	160	-10	40	100	150	-50	0	60	110
$\frac{Beneficial\ Constraints}{Folk\ Economic\ Model}$	0	110	180	290	0	110	180	290	-50	60	130	130
$\frac{Beneficial\ Constraints}{Market\ Ideological}$	0	114	130	244	0	114	130	244	-50	64	80	80

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

Technology-based Regulation (the nearest cross-case rival) in order to break even with Beneficial Constraints at this level of aggregation.

However, as the actual Coordinated Framework and Precautionary Principle approaches to GE regulation were decided through separate processes, it is also useful to disaggregate down to the US/EU level and compare against priors. In the US Coordinated Framework case, we see that the evidence remains very very strong (40+ dB), well-established (50-70 dB) or decisive (80+ dB) against all models except Adoption Catalyst across Background Info priors (Table 31, column b "US Post"). With skeptical priors (Table 31, column c "US Post"), the US case has only well-established evidence for Beneficial Constraints over Folk Economic and Market Ideological imaginaries while Capture has merely strong evidence (20 dB) against it and Technology-based Regulation and State-as-Venue are indistinguishable from Beneficial Constraints. With these skeptical priors, Adoption catalyst remains very very strongly favored (46 dB) not due to the evidence but due to the priors.

In the US case, the Adoption Catalyst result for background information and Skeptical priors is not surprising and consistent with the common understanding of the Coordinated Framework as encouraging the adoption of GE technology. It was identified as the nearest rival model after the initial piece of evidence and thus used as the selection criteria for the second piece of evidence which suggests that it may be "spoken for" a bit too loudly by design. However, were the BayesTV process to continue for additional evidence selected to specifically adjudicate between the two models, Beneficial Constraints would ultimately be more likely based on thecase narrative above because the Coordinated Framework did not cross from encouraging GE technology into catalyzing adoption through incentives or proactive programs.[510]

In the EU Precautionary Principle case, we see that the evidence remains decisive (80+ dB) against all models except Capture and Technology-based Regulation for Background Info priors (Table 31, column b "EU Post") and either very well established (50-70 dB) or decisive against all models except Capture and Technology-based Regulation for Skeptical priors (Table 31, column c "EU Post"). In the EU case, the classification of the case is less clear given the strong appearance of capture given the anti-GE and "pro-traditional" content of Directive 2001/18/EC and Regulations EC No 1829/2003 and EC No 1830/2003. However, the strength of the evidence in favor of Capture relies on the concept of cultural capture which ultimately reduces down to contested definitions of the public good.[511] As discussed above in the description of GE technology and its regulation, these sorts of contests over what is "beneficial" are better understood and analyzed as definitions of desired goals than as inherent features of a particular regulatory approach. To remain transparent, the BayesTV process scores the ambiguity of support for Capture into the analysis. However, it is up to the reader to consider when and why cultural capture is a more useful lens to understand what is happening with EU GE regulation than Beneficial Constraints where the benefit is defined as pro-"traditional" (non-GMO) products. For the author, separating out regulatory method from regulatory goal is more

[510] How this background information figures into the evidence presented is discussed at length in the Appendix where the BayesTV is explicitly carried out for each piece of evidence. See the discussion in the Appendix section $P(E_{OSTP1986} | T_{Adoption\ Catalyst} I)$.

[511] See the discussion above in What is a "Beneficially Constraining" Regulator? as well as the far more detailed discussion of cultural capture in the Appendix section $WoE_{Recitals\ 21+22}$ Beneficial Constraints vs. Capture.

analytically useful because it allows us to recognize interesting similarities in method (Beneficial Constraints) which would be obscured by purely a focus on outcomes (pro vs. anti-GMO).

Based on these four pieces of evidence, we see that how clearly GE can be considered a case of Beneficial Constraints depends on the priors you adopt and the aggregation you are interested in. In isolation for any set of priors, these four pieces of evidence (OSTP 1986, Annex I, Blue Book Reproduction, and Recitals 21+22) are overwhelmingly convincing in favor of Beneficial Constraints over all alternative models for the general approach to GE regulation across the US and EU.

However, at the individual regulatory domain level, we see divergent conclusions based on priors that nevertheless may be undermined by additional case information. In the US, the Adoption Catalyst model becomes noticeably (6 dB) and very very strongly (46 dB) more likely than Beneficial Constraints for Background Info and Skeptical priors respectively, although it is likely that this would disappear if further evidence were highlighted in the explicit analysis analysis based on the narrative analysis in the case background. In the EU, the Capture model stands out as noticeably (7 dB) and very very strongly (47 dB) more likely than Beneficial Constraints based on the "cultural capture" understanding of capture although I argue that this is analytically misleading here as it confuses regulatory goal with regulatory method.

All told, though, we can decisively reject the negative imaginaries of the Folk Economic Model and Market Ideological with decisive (80+ dB) evidence no matter which priors or level of aggregation one chooses (see the bottom two rows of Table 22). We also have very very strong (40 dB) to decisive (80+ dB) against the neutral imaginary of State-as-Venue in all except the skeptical prior US case (Table 31, column c "US Post"), although this US exception is again driven not by the evidence but by the extremely strong (likely unrealistic) prior. This allows us to focus our consideration on the proactive state models of Adoption Catalyst and Beneficial Constraints as well as drawing out attention to analytically complex and empirically interesting refinements of the Capture imaginary.

VIEWS OF GENE EDITING REGULATION FROM VARIOUS ROLES

As explained in the previous section, we can reasonably agree that proactive regulatory imaginaries were at work in both the US and EU cases and that there is suggestive to conclusive (depending on priors) evidence that both regulators were working from the Beneficial Constraints imaginary. In this section, I draw on interview data from a related project[512] to explore whether actors involved in the regulatory regime view it as beneficially constraining, how they form their views about GE constraints (beneficial or otherwise), and how those views inform their actions under the regulatory regime. While the previous sections have focused on archival data about the recombinant pasts where each regulatory regime was formed, this section draws on contemporaneous interviews concerning the CRISPR present. By examining what actors such as regulators and biomedical researchers have to say about their regulatory regimes,

[512] These interviews were conducted by the author and a team of researchers led by Ann Keller as part of National Science Foundation's Science of Science and Innovation Policy grant #1735661. The analysis in this section draws upon nineteen interviews with twenty-one interviewees. One interview included three respondents. Human subjects approval for collecting, storing, and analyzing interview data was granted by the Office of Protection of Human Subjects at UC Berkeley. The de-identified data is available at (Posch et al. 2021)

we can better understand how the beneficial constraints imaginary plays out in actually existing regulatory regimes.

Understandably, many readers may be interested in how imaginaries affect policy outcomes and how they frame policy debates leading to enactment. I agree these are fascinating questions that should be given a full and fair treatment as projects in their own right. However, with these interviews, I am able to provide some suggestive starts for such an investigation.

For this discussion, the data is based on the United States Food and Drug Administration's (FDA) Investigative New Drug (IND) review process. The FDA is one of the three core agencies granted jurisdiction over GE regulation by the Coordinated Framework.[513] The FDA IND process [explain how it works]. Key actors in this process are the applicants (academic and industrial scientific researchers submitting a study, drug, or therapy for approval) and the reviewers (FDA employees with scientific backgrounds who judge whether the applications meet agency standards). These two core roles are complemented by a number FDA employees which contribute to the expertise of the agency in reviewing applications by engaging in the scientific community as practitioners and consumers of scientific knowledge. The sections below discuss how these various actor roles view the FDA IND process as constraining and whether (and how) those constraints are beneficial.

WHAT DO ACTOR ROLES VIEW AS BENEFICIAL ABOUT THE CONSTRAINTS AROUND GENE EDITING?

Across the breadth of interview respondents including industry scientists, academic scientists, patient advocates, and current and former FDA employees, the characteristic feature of the FDA is that they are *the* game in town for anyone who hopes to create a medical product based on gene editing. Without FDA approval, no product can be sold. This places the FDA in the position of having an inescapable gatekeeping role which allows them to exercise constraints on the application of new GE technologies such as CRISPR-Cas9. While various respondents had many specific views on their interactions with the FDA review process, they inescapably acknowledged the necessary authority of the FDA.

With this inescapable authority, the FDA then provides a number of constraints which respondents considered beneficial, particularly expertise in the processes and necessities of changing a scientific study into a commercializable product. For one scientist respondent, the FDA demonstrated "a lot of expertise in manufacturing and controls and ways to ensure reproducibility" while relying on the applicants to provide the "vagaries" of specific GE technologies (CRISPR-Cas9 Interview 7, p.6). This sentiment was echoed and expanded on in great detail by a former FDA employee who described the importance of FDA approved manufacturing protocols in consumer acceptance of ubiquitous drugs such as ibuprofen (CRISPR Interview 17, p.17). As the Beneficial Constraints imaginary is built around economic benefits from a social process, the FDA's expertise in commercializability is clearly perceived to provide a benefit as part of the review process which complements the scientific expertise of applicants.

HOW DO ACTOR ROLES FORM THEIR VIEWS ABOUT GENE EDITING CONSTRAINTS?

As the other face of the FDA's inescapable gatekeeper role, respondents widely expressed views that the IND process was complex and stressful. Given the high stakes that FDA approval

[513] See discussion in Perpetual Guidance in the United States (2016-Present) on page 95

carries to continuing research and development of new products, new scientist applicants are socialized into the process by more experienced applicants and by regulatory offices within research organizations both academic and industry. Through this process of socialization, an acceptance of the FDA's constraining role as well as an appreciation for the benefits this process may have (to offset the costs of complexity and stress) spreads to new applicants.

In reflecting on their first experience with the review process, one respondent explained the deep integration of regulatory engagement within organizations such as theirs (CRISPR Interview 13, p.11-12). Applications to the FDA are drafted in consultation with experienced "people who have gone through the process." This experience is also institutionalized within research organizations as a "regulatory office," "regulatory officer," or "VP of regulatory." The respondent was clear that these informal and formal processes transmit not just rules about what to include but also a "sort of know[ing] what goes into it and what needs to be considered" and advice like "trying to keep it less jargony." Together, these reflections suggest that perceptions of the regulatory imaginary are passed as tacit knowledge by informal and semi-formalized interactions within applicant organizations as well as gathered through direct interactions with the FDA.

HOW DO ACTOR ROLES' VIEWS INFORM THEIR ACTIONS?

Because the FDA review process is so high stakes and inescapable, and the applicants are socialized into their expected behavior based on perceptions of what the FDA wants, the chief way that the views of actor roles inform their actions is through their attempts to anticipate what the FDA will need, want, or demand from them in order to complete the review process. This need to satisfy the FDA based on perceptions of what they will want contributes to a shared view among respondents that while the process is difficult and stressful it is ultimately a constraint that is beneficial to the safety of new drugs as well as a constraint that serves to optimize toward commercializability.

Of the nineteen interviews, eighteen mentioned at least once that the FDA is well regarded as up to speed on the scientific expertise needed to evaluate the applications before them.[514] One respondent summarized the status of the FDA review process succinctly as: "There is no such thing as a facile interaction with the FDA. And that is exactly how it should be (Interview 13, p. 6)." One respondent was clear, though, that the process was not without its frustrations, particularly with the opacity of information between different applications which may have been fruitfully put into conversation with each other. However, that same respondent also explained that the opaqueness also worked in favor of the applicants because it gave them room to co-define the process and the FDA room to be flexible with application without being accused of inconsistency (Interview 28, pg 2-3). Together, these responses present and FDA which respondents perceive as competent while challenging and a process which they therefore engage with in good faith.

[514] In fact, most respondents gave two or more examples, and one respondent gave ten examples. See (Keller et. Al. forthcoming) for a full discussion of these endorsements.

CONCLUSION: WHY DOES IT MATTER THAT GENE EDITING IS REGULATED THROUGH A BENEFICIAL CONSTRAINTS REGULATORY IMAGINARY?

This chapter demonstrated how confident we can be that gene-editing regulation in the US and EU was derived from a Beneficial Constraints imaginary. Based on the Bayesian Type Validation (BayesTV), we can be decisively confident that GE regulation was not operating from a Folk Economic, Market Ideological, or State-as-Venue imaginary while the comparisons with Capture and Adoption Catalyst are more complicated. This finding contributes to reframing our understanding of a well-known case (GE/GMO), focusing our attention on specific rival imaginaries for specific cases, disentangling regulatory method from regulatory goal or outcome, and providing a great deal of empirical explication to an important challenge to the assumption that all regulatory constraints are inherently a cost on economic activity.

For the gene editing (GE or GMO) case, this illuminates a new dimension of similarity of regulatory method at odds with the well-known narrative of regulatory goal divergence. This does not reject the well-established fact that the US and EU took fundamentally opposite positions on GMOs: the US fostered their growth while the EU sharply restricted them. However, it does point out that both political economies chose to do so through a technique which constrained their markets towards economically and socially beneficial goals. They differed not on method but on the definition of beneficial.

This distinction between regulatory method and regulatory purpose, goal, or outcome is important beyond just the well-known GMO case. As the discussion of the Folk Economic Model in the introductory chapter drives home, assuming that all regulation is an inherent impediment on innovation constructs self-confirming pernicious outcomes. The lesson of the GE case shows that we should also be careful about assuming a simple correlation between regulatory method and desired or determined outcome. Certain methods will certainly be more conducive to certain outcomes, but the limits and flexibility of these configurations should be mapped and studied rather than assumed.

The need to nuance an argument based on level of aggregation is also a contribution; the US and EU cases both have very different nearest rival imaginaries. In the US Coordinated Framework (1986-Present) case, the Adoption Catalyst model becomes meaningfully (6 dB) more likely than Beneficial Constraints for Background Info priors, although it is likely that this would disappear if further evidence were explicitly highlighted in the BayesTV analysis. In the EU, the Capture model stands out as meaningfully (7 dB) more likely than Beneficial Constraints based on the "cultural capture" understanding of capture although I argue that this is analytically misleading here as it confuses regulatory goal with regulatory method.[515] As discussed above in the description of GE technology and its regulation, these sorts of contests over what is "beneficial" are better understood and analyzed as definitions of desired goals than as inherent features of a particular regulatory approach (such as Capture of any specification, cultural or otherwise).

From the interview data about the current FDA review process for CRISPR gene editing therapies, we see that the Beneficial Constraints imaginary present in the design stage of the

[515] See the discussion in the Final Type Classification and Sensitivity to Priors as well as the much more extensive reasoning presented in the Appendix C section $WoE_{Recitals\ 21+22}$, Beneficial Constraints vs. Capture = -3 dB for further details.

Coordinated Framework remains visibly present in the contemporary operation of the system at one of the core three agencies. The FDA review process is an inescapable constraint on any GE therapy which wishes to enter the market in the United States, but this constraint is experienced by researchers and developers as beneficial, particularly with regard to the FDA's knowledge of commercializability and process standardization. We also see the beneficial constraints of the Coordinated Framework as implemented at the FDA propagates as an imaginary through informal socialization between researchers and formal regulatory offices within research organizations both academic and industrial. This perception of beneficial constraints, propagated through relevant actors in the GE space, comes full circle to reinforce the view that applicants hold of the FDA's review of GE products as challenging yet appropriate by an honest collaborator in the bring-to-market process for these complicated products.

In honor of Wolfgang Streeck, originator of the term beneficial constraints, I close with his lesson: "Recognition of the economic benefits of *some* social constraints immunizes against the received wisdom that *all* constraints are counterproductive by definition." [516] Thus, the beneficially constraining regulator will seek to demonstrate that constraints should not be seen as a cost to be minimized. In their turn, entrepreneurs and innovators would do well to ask themselves whether the constraints they are faced with are truly due to pernicious impediments such as capture, technology-based regulation or the folk economic model or whether they might truly be under a set of beneficial constraints which allow them to focus their creative and competitive prowess on creating better outcomes rather than undermining regulation or racing to the bottom due to short term competitive thinking. In the case of gene editing technology, a reader with any set of priors should conclude that it is plausible that the constraints were animated by the beneficial constraints imaginary. They should then ask themselves whether it is in their interest to counterproductively fight the constraints or to work within those guardrails towards the beneficial goal encouraged by those constraints.

[516] (Streeck 1997, 213)

CHAPTER 7

INNOVATION BEYOND THE IMAGINATION OF THE MARKET

Catalyzing the Adoption of Electronic Health Records in the United States and Europe, 2009 to 2021

The tech industry's entrepreneurial rhetoric has tarred regulation as the specter of the past holding back the future. Yet, in the case of electronic health records (EHR), concerted state action was required to drive market participants to adopt a technology which decreases costs, improves patient care, and has the potential to revolutionize public health and policy research.[517] EHR therefore demonstrates that regulators can not only reduce their dead-weight loss to industry, not only beneficially constrain market actors to coordinate on better equilibria, but also move past the zero to driving the adoption of innovations which the market has failed to spread catalyzing the move to a new state of play based on pervasive adoption of a disruptive technological innovation.

This chapter illuminates the mechanism by which regulation drives innovation adoption using Bayesian type verified evidence from the United States and European Union. In the US, the HITECH act of 2009 pushed the laggard medical community to adopt EHR with first a carrot (subsidy) and then a stick (withholding of Medicare reimbursements). In the EU, Directive 2011/24EU interpreted the Single Market to include cross-border healthcare and required EU member-states to adopt interoperable EHR although implementation details were left to member-state governments.

The mechanism behind the regulation-driven innovation adoption of EHR is particularly interesting because actors espoused preferences counter to their purported interests. Among US and EU states, there were both early adopter and laggard medical practices that led governments to push for system-wide adoption in order to realize gains from scale and pervasiveness. Early adopters recognized that adopting EHR was in their economic interest: once the transition from paper charts was complete, EHR lowered costs and improved patient care.[518]

Yet despite these clear practice level benefits, the vast majority of medical practices espoused strong preferences against adopting EHR even though these preferences were against their "thick" economic interest.[519] This resistance centered on *perceptions* of who had to bear the costs of transition (doctors) and who received the benefits (administrators, insurers, researchers).[520]

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[517] (Institute of Medicine 2000, 177–78) (Institute of Medicine 2001, 164–80), both of which are cited in (Washington et al. 2017, 904) to make the same point about the benefits of EHR.
[518] (Institute of Medicine 2000, 177–78) (J. Walker et al. 2005)
[519] (S. K. Vogel 1999, 187–88, 202–3, entire, especially endnote 1 and 3) explores this distinction between interests and preferences; for our purposes interests are what analysts deductively say groups or actors are supposed to want based on a specified utility (growth, profit, gain) while preferences are what groups or actors say they want.
[520] (Uribe et al. 2002, 275–76; Jeffe et al. 2004; Garrett et al. 2006, 2)

That patients and public health would eventually experience the majority of the benefits was deeply downplayed; patients were employed in effigy to support both pro and anti EHR camps but did not actively enter the debate.

Mandated EHR adoption in the US and EU demonstrates the power of perception in public policy: policies live and die on whether people *think* they will work. Perceptions create preferences long before outcomes can breed interests.[521] Innovators and entrepreneurs distrust new regulations not because they've *had* bad experiences with those regulations but because they *think* they will.[522] EHR is a case where public policy overcame poor perception to create good outcomes beyond the imagination of the market in Europe and the United States. Understanding how regulators catalyzed the adoption of EHR helps us build on that success to allow innovators to work with regulators rather than against them.

To demonstrate the existence of the adoption catalyst regulatory imaginary in the case of EHR, I proceed as follows. First, I briefly define EHR and how its focus on interoperability disrupts the security and privacy of protected health information. Then, I explain what the Adoption Catalyst imaginary is and what it is not by explaining that it seeks not only to cause pervasive adoption of a disruptive technological innovation (DTI) but also to create a state change where that DTI forms a new state of play in the affected sector. Next, I explain why EHR is a good test case for the adoption catalyst imaginary based on the empirical narrative of the US and EU implementations of the technology as well as the conceptual qualities that bridge these narratives. Then, I execute a Bayesian type validation (BayesTV) of how confident we can be that EHR is a case of adoption catalyst using empirical evidence from the US HITECH Act of 2009 and Article 14 of Directive 2011/24/EU. I conclude by addressing why it matters that EHR represents an Adoption Catalyst imaginary, suggesting both case ramifications and general contributions to the understanding of regulation of disruptive innovation.

WHAT IS EHR AND WHY IS IT DISRUPTIVE?

Electronic health records (EHR) are the application of information technology (IT) tools to healthcare data. By taking information which was formerly fragmented and hidden within paper medical encounter and financial records, EHR increases the accessibility of this information and disrupts the status quo security and privacy system of security-through-inconvenience. This section explains how EHR disrupts the healthcare system by both changing the day-to-day recordkeeping operations of healthcare as well as forcing a re-evaluation of security and privacy practices around health information.

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[521] My distinction between perceptions and outcomes versus preferences and interests is both counter-to and consistent-with Pierson's (2014, 284–86) discussion of "stakeholder creation" because it is counter to the initial process of policies "confer[ing] substantial resources on specific types of groups" while it is consistent with the complementary process of "countermobilization or backlash [because] [n]ew policies create new threats." Pierson emphasizes that this complementary process is often the more significant one and I argue that this backlash is built on perception of the effect of a policy rather than waiting for that effect to play out.

[522] Note, this does NOT mean that regulation and innovation (and thus regulators and innovators) are *never* at odds with each other. I am not arguing that regulation is *always good* for innovation. I am simply saying that the opposite is also not always true: regulation is not *always bad* for innovation even though we can all point to example where it has been so. This is discussed further in the "Changing Perception" section on page 93.

TECHNOLOGICAL INNOVATION: APPLICATION OF IT TO HEALTHCARE INFORMATION

Electronic health records (EHR) are fundamentally the application of "computing technology that has transformed virtually every other aspect of human endeavor"[523] to health information. Once referred to as eCharts, EHRs are in fact more than simply a digitization of the patient encounter information which would traditionally have been stored in a paper chart. Instead, EHRs combine all information involved in healthcare to serve eight core functionalities: clinical documentation and health information display, results management, computerized provider order entry and management (CPOE), clinical decision support (CDS), electronic communication and connectivity, patient support, administrative processes, and reporting and population health management.[524] Together, these functions allow EHR to not only replicate the functions of paper charts but provide additional possibilities to leverage medical data.

INTEROPERABILITY DISRUPTS THE SECURITY & PRIVACY OF HEALTH INFORMATION

Like all collections of digitized information, EHR offers the benefits of speed, ease of access, and the promise of comprehensiveness at the risk that non-approved parties could benefit from these capabilities as well as approved stakeholders. Interoperability, the ability for information to move between stakeholders quickly and efficiently, promises the ability for health information to follow patients to different providers in place and time. This increase in the ease of movement of information disrupted the existing status quo for protecting protected health information (PHI) because it removes the security-through-inconvenience of paper charts.

There are two aspects to interoperability: interoperability between different types of actors within the medical system (codification) and interoperability between different actors of the same type within the medical system (desiloization). These two types of interoperability are inter-related, and increased codification can increase the ability of information to be shared among the same types of actors just as desiloization can increase the ability of different types of actors to access medical information. Despite this overlap, each form of interoperability has a distinct spectrum and can primarily be understood separately in order to better understand EHR systems.

Codification refers to the creation of standardized, machine manipulable data which can be accessed in different configurations and formats from that in which it is generated. This spectrum of interoperability ranges from lowest to highest as:[525]

1. Unstructured, viewable electronic data (i.e., PDF files)
2. Structured, viewable electronic data (i.e., electronic text)
3. Computable electronic data (i.e., keyword coded electronic information)

Codification thus emphasizes the 'Big Data' version of interoperability where the degree of interoperability is measured by the degree to which the data can be processed and manipulated by ICT. Codification is therefore the aspect of interoperability which can allow EHR to become a sectoral general-purpose technology upon which increasing innovation can be built.

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[523] (Blumenthal 2010, 385)
[524] This sentence is a brutally brief summary of the excellent and exhaustive description in (Hoffman 2016, 9–14)
[525] This spectrum is taken from GAO figure reproduced in (Hufnagel 2009, 36)

On the other hand, desiloization refers to the more mundane version of interoperability where-in patient data is able to travel with the patient to different providers. This spectrum of interoperability ranges from lowest to highest as:

1. Heterogeneity (data which can travel between providers, but not in any systemic or universal way)
2. Constructed interoperability (i.e., a common standard for information interchange between different systems)
3. Intrinsic Interoperability (a single EHR system).

While all levels of desiloization start with the minimum interoperability requirement of allowing a patient's information to travel with them, this requirement is never-the-less imperfectly met by current EHR systems. Although desiloization may seem like the most basic form of interoperability,[526] no approach yet has actually achieved this level of interoperability system wide. In fact, there are incentives for competing EHR software companies to make interoperability as low as possible to lock in customers,[527] which has allowed the landscape after widespread EHR adoption to continue to be fragmented by EHR vendor.[528] Nevertheless, the desire for desiloization is the aspect of interoperability which make EHR potentially disruptive (for good and ill) if it could be adopted system wide because it would change how medical data is handled within the medical system. EHR thus opens the door for deeper consideration of security and privacy of PHI which had previously been hidden behind a literal mountain of paper.

WHAT IS AN "ADOPTION CATALYZING" REGULATOR?

Before verifying that the adoption of EHR is a good exemplar of an Adoption Catalyst type regulator, we should first be clear what the Adoption Catalyst imaginary is. Based on the variables in the typology derived in Chapter 3 (see Table 32 repeated from Chapter 3), a regulator following the adoption catalyst imaginary has *higher information* than firms, believes that a *regulator is the driver* for the spread of an innovation and desires either *one or many* different optimal regulatory *outcomes*. Put plainly, an adoption catalyzing regulator looks to spread a disruptive technological innovation throughout its relevant sector by actively encouraging a specific set of steps to take to transition from one state of play where the DTI exists at the margin of the sector to another one where the DTI is pervasive throughout the sector.

While the beneficial constraints imaginary discussed in chapters 5 and 6 shares the "pro-innovation" motivation of the adoption catalyst imaginary, the two can be distinguished by the

[526] In (Hufnagel 2009, 35), the ability to travel between providers is provided simply as a basic justification for interoperability. In (Castillo, Martínez-García, and Pulido 2010, 10,13-14), the authors cite concerns over interoperability as one of the primary concerns of adopting physicians as well as one of the primary assumed benefits.
[527] (Kliff 2017)
[528] (Holmgren and Adler-Milstein 2017; Holmgren, Adler-Milstein, and McCullough 2018)

Table 32: Complete Typological Property Space of Regulatory Models

		Constitutive Variables (Independent Variables)				Dependent
Model Name	**#**	**Relationship**	**Info**	**Driver**	**Outcomes**	**Effect**
Folk Economic Model (Christensen 1997)	1	Rulemaker	Lower	Market	Zero	Impediment
	2	Rulemaker	Lower	Market	One	Impediment
Market Ideological*	3	Rulemaker	Higher	Market	Zero	Impediment
	4	Stakeholder	Higher	Market	Zero	Impediment
State-as-Venue (Skocpol 1985)	5	Rulemaker	Lower	Regulator	Many	Moderator
	6	Stakeholder	Lower	Market	Many	Moderator
	7	Stakeholder	Lower	Regulator	Many	Moderator
Capture (Stigler 1971)	8	Stakeholder	Lower	Market	One	Constrainer
	9	Stakeholder	Lower	Regulator	One	Constrainer
Technology-Based Regulation "Conventional Command and Control" (Malloy 2010)	10	Rulemaker	Higher	Market	One	Constrainer
	11	Rulemaker	Lower	Regulator	One	Constrainer
	12	Stakeholder	Higher	Market	One	Constrainer
Beneficial Constrainer (Streeck 1997)	13	Rulemaker	Higher	Market	Many	Constrainer
	14	Stakeholder	Higher	Market	Many	Constrainer
Adoption Catalyst	15	Rulemaker	Higher	Regulator	Many	Driver
	16	Stakeholder	Higher	Regulator	Many	Driver
	17	Rulemaker	Higher	Regulator	One	Driver
	18	Stakeholder	Higher	Regulator	One	Driver
Trivial	19	*Rulemaker*	*Lower*	*Regulator*	*Zero*	*Impediment*
	20	*Stakeholder*	*Lower*	*Regulator*	*Zero*	*Impediment*
	21	*Rulemaker*	*Lower*	*Market*	*Many*	*Impediment*
	22	*Stakeholder*	*Lower*	*Market*	*Zero*	*Impediment*
Logically Inconsistent	23	~~Rulemaker~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~
	24	~~Stakeholder~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~

* (Henderson and Appelbaum 1992) completed Chalmers Johnson's (1982) 2x2 of market|plan x rational|ideological by defining the idea of "market ideological" which privileges market structures for organizing social and economic interaction beyond efficient cost-benefit tradeoffs due to an ideological preference for market structures over planning. More modern ears are more familiar with the term "market fundamentalism" as popularized by George Soros (1998) although the concept is as old as capitalism itself with well-reasoned critique of it at least as old as Polanyi ([1944] 1957). The modern usage is well explained in (Block and Somers 2014).

how regulators aim to encourage innovation. The beneficial constrainer identifies a problem and places specific constraints upon the regulated sector to force competitive firms to innovate in order to excel within this changed landscape of threats and opportunities towards solving the identified problem.[529] By contrast, the adoption catalyzer identifies both a problem and an existing solution and sets up a set of incremental criteria and performance metrics which require adoption of an existing solution while encouraging innovation beyond that minimum towards potential solutions which outperform the identified minimum. A beneficial constrainer identifies a problem and mandates that a solution be found while an adoption catalyzer identifies a problem and requires a minimum solution while incentivizing a better solution.

[529] As discussed further in chapter 4, "technology-forcing regulation" is a specific type of beneficial constraint which "sets a standard that is unattainable with existing technology, at least at an acceptable cost." (Gerard and Lave 2005, 762)

For those familiar with regulatory scholarship, the adoption catalyst regulator clearly intersects with the concept of "performance-based" regulation. Indeed, the adoption catalyst process I describe in the prior paragraph is consistent with May's (2011, 377) hybrid prescriptive/performance regulatory regime in the mixing of prescribed actions with objective outcomes, determinations of compliance based on both actions and results, and combinations of particularistic and goal-oriented specifications. As explained in chapter 3, the adoption catalyst regulator from Table 32 serves as a sociotechnical imaginary or motivating cognitive model which can lead a regulator to undertake a hybrid performance-based implementation for a particular regulatory domain. In addition to being a background to the choice of performance based regulation, the adoption catalyst imaginary may also be seen as a special case of performance based regulation applied to disruptive technological innovation where a desire to focus on outcomes is challenged by the uncertainties of technological innovation.

The adoption catalyst imaginary is also distinct from that of Technology-based regulation due to the catalyst's characteristic constitutive belief that the regulator has higher access to information than the regulated firms as well as it's allowance for one or many intended regulatory regime outcomes.[530] As discussed in chapter 2, Technology-Based Regulation characteristically desires one outcome: the adoption of a specified technology. While this may take two forms, either inducement through the market or command through the state, both pathways begin and end with the adoption of a specified technology. For the Adoption Catalyzing regulator, adoption is but the first step towards an innovative new world. The next section expands on the importance of this "new world" in distinguishing the adoption catalyzing regulator from other types.

CHANGING PERCEPTION

As discussed in the introduction to this chapter as well as the introductory chapter, perception is of key importance to understanding the regulation of disruptive technological innovation because perceptions create preferences long before outcomes breed interests. For the project as a whole, this is a key motivation for expanding our understanding of regulatory imaginaries beyond the Folk Economic Model baseline. Beyond this research motivation, however, perception also plays a substantive role in the Adoption Catalyst imaginary. For an Adoption Catalyzing regulator, adoption of the initially specified minimally sufficient solution is meant to shift the perception of the regulated sector from whether to adopt a solution to a focus on how to improve upon the minimally sufficient solution and then build additional innovation within the new state of play. Before expanding on this substantive role of perception in Adoption Catalyzing regulation, a clarifying note on perception as research motivation.

Innovators and entrepreneurs distrust regulation not because they've *had* bad experiences but because they *think* they have or think they will. This does *not* mean that regulation and innovation (and thus regulators and innovators) are *never* at odds with each other. Indeed, we all have our just so stories and anecdotes of when regulation hindered innovation. However, while such "anecdata" is data, it is neither comprehensive data, nor exhaustive data, nor perhaps even

[530] Compare relevant lines in Table 1 for Technology-Based Regulation and Adoption Catalyst. The plausibility of a regulator having more information than firms in the regulated sector is discussed at length in Chapter 2 and benefit's greatly from Malloy's (2010, especially 335-343) careful study of social construction of regulation that counters the arguments of information asymmetry scholars by pointing out that regulators often have more systemic and sectoral information even if firms may have a greater sum total of firm-specific knowledge.

representative data. In everyday life, we take such anecdata of regulatory failures as confirmation of our baseline (aka "folk") understanding of regulation; it comports with our priors so we don't update those priors. But should we be so comfortable in this confirmation of 'what everyone knows' about regulation?

Much as Ostrom (1990, 183) argued against the over-interpretation of certain endemic rational choice models, I am arguing that imaginaries that see regulation as an impediment to innovation "are special models that utilize extreme assumptions rather than general theories." Thus, I am not arguing (and would never claim) that regulation is *always good* for innovation. I am simply saying that the opposite is also not always true: regulation is not *always bad* for innovation even though we can all point to an example where it has been so.

This chapter and this project argue rather humbly that "not always wrong" is not the same thing as "always right" or even "right most of the time." Given the stakes of successful regulation of innovation for a well-functioning political economy, we should study situations and configurations where regulation can enhance innovation rather than erroneously assume that such a search is an a priori pointless endeavor. We must shift our folk model, our "common-sense understandings,"[531] from a perception of regulation as having one effect on innovation (an impediment) to a perception of regulation as having many possible effects on innovation (from impediment to catalyst of adoption).

Akin to how this project aspires to shift the perceptions behind our folk model of regulation, the adoption catalyzing regulator looks to shift the perception of what is possible and desirable around a disruptive technological innovation within the regulated sector. More than simply setting new performance metrics through beneficial constraints, more than simply mandating the adoption of a particular technology intended to serve the public good, the adoption catalyzing regulator looks to catalyze a state change from a world with one set of baseline understandings to a world with a different set of baseline understandings. The goal is to mandate the adoption of the identified minimally sufficient existing DTI solution in order to spur the regulated sector to innovate not only to optimize the solution they are stuck with but also to innovate on top of the new capabilities that the DTI unlocks.

For students of the history of science, this focus on catalyzing a state change may sound familiar. Just as Kuhn ([1962] 1996, 10) spoke of ordinary science between successive paradigm shifts, the adoption catalyzing regulator aims to shift business-as-usual within the regulated sector from one where the minimally sufficient DTI exists on the margins to a new business-as-usual where the DTI is pervasive. As with most pervasive technologies in a market, an optimization process begins to reduce costs and increase benefits through incremental innovations in the core technology of the DTI. However, the major innovation benefits come when the DTI can begin to serve as a sectoral general purpose technology upon which other practices and opportunities can be built due to the pervasiveness of the technology and the possibility for "innovational complementarities,"[532] innovations which are made on top of the capabilities unlocked by the initial DTI's newfound pervasiveness.

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[531] (D'Andrade 1987, 113)

[532] (Bresnahan and Trajtenberg 1995) Note that I am narrowing their definition of GPTs from an entire political economy down to the regulated sector, but the importance of pervasiveness and innovational complementarities still hold at this level for the adoption catalyzing regulator and regulatee.

In sum, an Adoption Catalyst imaginary of disruptive technological innovation is defined by its focus on the regulator as a driver of innovation adoption where the regulator has higher access to information than firms in the regulated sector and seeks to catalyze the change from one state of business as usual with the DTI at the margins of the sector to another where the DTI has become a sectoral general purpose technology. This imaginary is distinct both from beneficial constraints (which use rules to encourage innovation towards a beneficial end) and technology based innovation (which requires merely the adoption of a specified technology) in that it combines the mandated adoption of the second with the expansive focus on later innovation of the first and then adds a strong drive for pervasiveness which aims to create follow-on innovative complementarities. As the name suggests, the adoption catalyzing regulator aims not just for DTI adoption but also to catalyze a new state of play for the regulated sector.

WHY IS EHR A GOOD EXEMPLAR CASE FOR ADOPTION CATALYST?

In brief, electronic health records (EHR) is a case where concerted state action was required to drive market participants to adopt a technology which decreases costs, improves patient care, and has the potential to revolutionize public health and policy research.[533] EHR therefore demonstrates that regulators can not only reduce their dead-weight loss to industry, not only beneficially constrain market actors to coordinate on better equilibria, but also move past the zero to driving the adoption of innovations which the market has failed to spread and catalyze a new state-of-play with economic and social benefits.

EHR was implemented in two advanced industrial societies, the United States and the European Union. The 2009 US HITECH Act pushed medical practices to adopt EHR with first a subsidy carrot and then a reimbursement withholding stick. Directive 2011/24EU added healthcare to the Common Market requiring EU member-states to adopt interoperable EHR. Both of these actual implementations of an EHR adoption catalyst happened in the aftermath of the 2008 Global Financial Crisis and tied the inherent features of EHR technology to the specific economic conditions at that time. How this link between "Economic and Clinical Health" was forged for "Health Information Technology" in each case is described in the following sections.[534]

EMPIRICAL CASE SELECTION: PERVASIVE ADOPTION

Before diving into the narratives of the two specific EHR implementations selected, a word on why these were selected rather than alternative EHR examples. Since a key defining characteristic of EHR is interoperability leading to health information portability,[535] the empirical cases were selected for being the first attempts to create political economy-wide adoption of EHR. The US HITECH Act of 2009 and Directive 2011/24/EU were not the first moments when some providers in their respective political economies adopted electronic health records. However, they were the first explicit drives to take isolated low levels of adoption and make EHR pervasive throughout the healthcare industry. Both empirical cases were explicitly

[533] (Institute of Medicine 2000, 177–78) (Institute of Medicine 2001, 164–80), both of which are cited in (Washington et al. 2017, 904) to make the same point about the benefits of EHR.
[534] The HITECH Act stands for Health Information Technology for Economic and Clinical Health Act, showing this connection in the very name adopted as a backronym for the US case.
[535] See section "Technological Innovation: " above.

targeted at shifting the normal operating procedure from paper-based charting to electronic health records throughout their entire national medical system.

HITECH ACT IN THE UNITED STATES (2009-2015)

In the US, the Health Information Technology for Economic and Clinical Health Act (HITECH) Act of 2009 pushed the laggard medical community to adopt EHR with first a carrot (subsidy) and then a stick (withholding of Medicare reimbursements). While the United States had seen pockets of EHR implementation prior to the HITECH Act, overall adoption remained limited to pockets of the medical care system as well as in the parallel but separate Veterans' Health Administration (VHA) system. At the moment of passing the HITECH Act, 17% of doctors and 10% of hospitals were thought to have any sort of EHR.[536] By 2015, office-based physicians (doctors) had increased to 78% certified EHR (88% "Any EHR") while hospitals had increased to 98% certified EHR.[537] The HITECH Act, then, was not the beginning of EHR use in the United States medical system but it was the policy which made that technology pervasive. This section reviews the precursors, leadup, and implementation of the HITECH Act.

Long before the HITECH Act spread EHR throughout the US medical system, the parallel Veterans Health Administration developed and implemented a distinct EHR system. From 1968 to 1999, the United States Department of Veteran's Affairs (VA) designed and implemented a variety of computerization programs which were consolidated into the Veterans Health Information Systems and Technology Architecture (VistA). By 1999, VistA had been implemented system-wide within the VHA as a common data system which managed medical, financial, and operational data across the myriad facilities.[538] Intriguingly, VistA did not become the basis for HITECH but it does demonstrate the long tail of EHR development which failed to spread throughout the civilian healthcare system that serves the overwhelming majority of the United States.[539]

Between 1968 and 1982, two parallel strains of development outlined conflicting centralized and decentralized development strategies. Beginning in 1968, the VA operated an Office of Data Management and Telecommunications (ODM&T) which practiced a characteristically centralized and top-down design and implementation logic which led to slow progress.[540] In a parallel development beginning in 1969, many VHA facilities began to independently acquire computers to run research studies and rapidly develop solutions to local issues without needing or seeking centralized approval.[541] Although these facility-level investments were ardently decentralized, a number of conferences were held to discuss developments. These conferences eventually led to the creation of a Computer Assisted System Staff (CASS) Office in 1977 which

[536] (Blumenthal 2009, 1477) N.B. this article was written by the NCHIT to introduce HITECH to the medical community. The numbers provided indicate his office's understanding of the landscape in the moment.
[537] (Washington et al. 2017) The definitions of "Any EHR," "Basic EHR," and "Certified EHR" are discussed below.
[538] The following timeline of events summarizes the excellent historical overview assembled by (Brown et al. 2003)
[539] The VHA is a study in contrasts; while it is the largest integrated healthcare system in the US with 1255 healthcare facilities (including 170 medical centers and 1,074 outpatient sites of care) it only serves the 9 million enrolled veterans out of a US population of 330 million. It is thus both the largest system while serving a relatively small and select number of people in the communities it operates in distributed around the country.
[540] (Brown et al. 2003, 136)
[541] (Brown et al. 2003, 137)

was tasked with the recruitment and training of staff around common architectural principles. The principles were later codified as the Decentralized Hospital Computer Program (DHCP).

From 1982 to 1996, the DHCP spread to cover the VHA medical system and expanded its functionality to include a suite of medical, financial, and administrative functions. In 1982, the VA discontinued the centralized ODM&T development plans in favor of the decentralized but interoperable DHCP development plans.[542] By 1985, the "full core" of services specified under the DHCP had been nationally implemented within the VHA.[543] By 1989, an additional set of applications were nationally implemented which added additional clinical functionality in addition to financial and hospital management features.[544] In 1996, the name of the DHCP was changed to the Veterans Health Information Systems and Technology Architecture (VistA) to reflect the expanded and deepened functionality which was continuing to develop.[545]

From 1996 to 1999, the VHA developed and nationally deployed the Computerized Patient Record System (CPRS), completing the foundational implementation of their EHR program by providing a replacement for paper charts. CPRS draws upon the wide array of data which is already organized and stored within the VistA system and presents it to users as a "tabbed chart metaphor."[546] Providers are able to both retrieve data from the system and enter it as computer identifiable information. The system is able to automatically check entered and stored data to verify medically relevant information such as orders and allergies.[547]

At the beginning of the new millennium, two books published by the US Institute of Medicine called for the EHR to be widely implemented across the US medical system in order to improve quality and cost of care.[548] The authors of one seemed keenly aware of the activities in the VHA when they noted that "[d]espite the computer-based patient record being "almost here" for 45 years, it has still not arrived."[549] In their sections which discussed EHR, both books clearly asserted the positive benefits of EHR: one stating that "IT must play a central role in the redesign of the health care system if a substantial improvement in health care quality is to be achieved during the coming decade"[550] while the other asserted that "the computer-based patient record['s]… advantages are clear."[551] In the early 2000s, those studying the US medical system clearly believed in the potential benefits of EHR.

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[542] (Brown et al. 2003, 138)

[543] (Brown et al. 2003, 138) This "full core" includes "[Admission, Discharge, Transfer] ADT, scheduling, outpatient pharmacy,… clinical labs, inpatient pharmacy, and some radiology functions." National implementation included 169 of 172 VHA facilities, with the other three required to use alternative commercial systems by Congressional Mandate.

[544] (Brown et al. 2003, 138) These additional applications include "dietetics, fiscal/supply, medical center management, medical records tracking, mental health, nursing, radiology, and surgery).

[545] (Brown et al. 2003, 138)

[546] (Brown et al. 2003, 140)

[547] (Brown et al. 2003, 141)

[548] (Institute of Medicine 2000, 177–78) (Institute of Medicine 2001, 164–80) both of which were cited as influential on the medical system's understanding in (Washington et al. 2017, 904)

[549] (Institute of Medicine 2000, 178)

[550] (Institute of Medicine 2001, 165)

[551] (Institute of Medicine 2000, 178) the authors then proceed to list quick information access, continuity of care, data aggregation, outcome measurement, and drug interaction tracking in a 73 word exhortation on the benefits of EHR based on a contemporaneous study (Leape et al. 1998)

However, EHR advocates were aware that new technologies are often met with resistance from medical professionals, especially physicians, who may not perceive a personal benefit a priori. Based on studies of medical error reporting procedures, physicians were reluctant to upset "tried and true" workflows unless they could clearly see a benefit.[552] More promising, however, these studies showed that reluctant physicians could be persuaded to adopt new technologies and procedures when they were made to "see the personal utility of the new technology."[553] Managing perception was thus believed to be key to the successfully realization of the system and patient level benefits through the implementation of EHR.

In recognizing the importance of perception for successful adoption, EHR advocates in the 2000s came to focus on a key potential challenge: patient privacy concerns.[554] While patients would not be the ones buying or implementing EHR systems, the perception by doctors that privacy-concerned patients may opt-out of EHR systems could have become a potential reason to resist EHR. Owing to the peculiar consumer-based medical system in the United States, this concern with consumer opposition highlighted the complex "relationships between individuals' perceptions and behaviors; health care organizations' policies and practices; their sectors' guidelines; national regulatory frameworks; and global factors."[555] Yet, as with the malleable resistance of physicians on procedural grounds, studies showed "that high privacy concerns can be balanced off by strong positive perceptions about a certain activity that individuals perceive as beneficial."[556] Thus, while privacy remains a key technological concern as explained above in the description of EHR technology, they key policy impact of privacy is in the *perception* of benefits and risk which EHR brings which can be affected by how EHR is explained to stakeholders.

With these understandings and advocacy for EHR from the National Academy of Medicine, President George W. Bush used Executive Order 13335 in 2004 to create the Office of the National Coordinator for Health Information Technology (the ONC headed by the NCHIT) to "shepherd the health care sector into the digital age."[557] As the name suggests, the ONC was originally intended to play a coordinating role to help the healthcare market implement and adopt EHR and telemedicine technologies. While this coordinating role did not do much to spur adoption of EHR, it did begin to gather data about just how low adoption of EHR in the non-VHA US medical system was: in 2004, 20% of physicians reported having "Any EHR" but in 2006 when a functional description was added, "Any EHR" was reported at 30% while "Basic EHR" which could perform basic charting functions such as patient intake demographics, physician notes, labs and imaging, and prescriptions was significantly lower at only 10% of physician's offices.[558] Clearly, coordination was a step towards EHR adoption but primarily served to capture just how poorly defined EHR adoption truly was at this time.

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[552] (Garrett et al. 2006, 2)
[553] (Garrett et al. 2006, 2) who cites (Uribe et al. 2002, 275–76), (Jeffe et al. 2004) as the studies of medical error reporting.
[554] (Dinev et al. 2016, 21–24)
[555] (Dinev et al. 2016, 23)
[556] (Dinev et al. 2016, 23) citing (Angst and Agarwal 2006a; 2006b; 2009)
[557] (Washington et al. 2017, 904) provides the quote and the description of the early days of the ONC as a predecessor to its expanded role after HITECH.
[558] (Washington et al. 2017, 905)

The HITECH Act was passed in 2009 as part of the American Recovery and Reinvestment Act (ARRA).[559] Along with creating statutory authority for the NCHIT in the ONC on top of the prior executive order, HITECH's purpose was to stimulate the adoption of EHR by private sector medical providers through the use of incentive payments and eventually penalties tied to a set of information technology (IT) outcomes known as "meaningful use."[560] These IT outcome measures were chosen over clinical outcome measures or direct subsidization of adoption costs because the goal of HITECH was to encourage the implementation of particular features which IT could bring to medicine rather than to generally improve clinical outcomes or encourage simply purchasing current EHR software products.[561]

As part of the post-financial crisis stimulus, HITECH was as much a technology development and adoption program as it was a public health program. In addition to the basic replication of paper chart functionality in EHR, meaningful use introduced criteria focused on regulatory reporting and compliance. In order to encourage technology development towards these criteria, HITECH required EHR to submit to a certification program to ensure regulatory compliance with the new standards of meaningful use.[562]

HITECH was thus a regulatory program designed to push both the adoption and further development of EHR technology. The US Department of Health and Human Services expanded its regulatory jurisdiction to include technology development which disrupted the market for EHR. With the inclusion of reporting and regulatory compliance criteria (in addition to clinical criteria) in the certification program, technological development was pushed specifically towards the use of technological means to ensure compliance with existing and expanding healthcare regulations such as privacy and security of medical data. Together, this push for both adoption and inclusion of algorithmic regulatory compliance disrupted both the regulatory paradigm and the regulatory regime which had previously governed clinical data management.

As of January 2015, the HITECH program phased in the scheduled penalties of 1% on Medicare reimbursements for eligible providers who had not demonstrated meaningful use. This January 2015 deadline effectively represents the "end of the beginning" of the implementation of a new regulatory regime based on the use of EHR in the United States. Additional stages of compliance and deadlines are included in the program and continue to be refined and implemented.

DIRECTIVE 2011/24/EU IN THE EU (2011-2021[563])

In the EU, Directive 2011/24/EU interpreted the Single Market to include cross-border healthcare and required EU member-states to adopt interoperable EHR although implementation details were left to member-state governments. While several member-states had already implemented a national EHR system prior to EU action, Article 14 of Directive 2011/24/EU directed the Commission to "adopt the necessary measures for the establishment, management and transparent functioning" of an EHR system operating among the nations of the EU and

[559] The ARRA was colloquially known as the "stimulus" bill, a response to the aftermath of the financial crisis and recession of 2008.
[560] (Washington et al. 2017, 904)
[561] (Blumenthal 2011a, 2325–26)
[562] (Blumenthal 2011b, 2428)
[563] Projected completion of "gradual implementation" in 22 EU countries is 2021 (European Commission 2019) although it was originally slated for 2020 in (European Commission 2012).

Norway. While 2011/24/EU leaves the language as "voluntary," it does require that the Union shall support and encourage the participation of the member states.[564] This has led to various stages of implementation in EU member states ranging from full implementation in Denmark in 2003 to proposals still at the legislative stage in Germany and Ireland. While there are EHR systems operating in all countries in the EU, only some countries have nationally organized systems which are the building blocks for an EU wide integrated system championed by Directive 2011/24/EU.[565]

Compared to the US case, the EU EHR case is thus an interesting mixture of well-established systems and un-established systems commensurate with the interesting character of the EU as something more than just a supranational organization. For the purposes of this study, this heterogeneity gives the EU EHR case established regulatory history (i.e., in Sweden or the UK), early stage implementation (i.e. Austria or Belgium) and an evolving regulatory environment (i.e. Germany or Ireland).[566] Analytically, this heterogeneity provides an excellent window into how the EU regulatory system, made up of supranational rules and national implementation, deals with disruptive technological innovation.

Much like the US HITECH case, the EU level push for EHR began before the final push for widespread adoption with Directive 2011/24/EU. While the supranational level was characterized by "national peculiarities" and the heterogeneity of member state stories introduced above, the core narrative of the EU level push was one of EU-wide interoperability.[567] EHR first rose to the EU level agenda in 2000 as part of the European Union i2010 Strategy but a detailed agenda was not laid out until 2004 with the e-Health Action Plan.[568] In this Action Plan, the European Commission explicitly tied e-Health to European market concerns by asserting that "e-Health is today's tool for substantial productivity gains" and "is key to achieving stronger growth and creating highly qualified jobs in a dynamic, knowledge-based economy – the vision set out by [the European Union i2010 Strategy] in March 2000."[569] This link between e-Health and economic concerns was affirmed in the European Commission's 2009 Digital agenda where eHealth, specifically interoperable patient records (i.e. EHR), were established as a goal which would help alleviate obstacles to the "economic and social benefits from a digital single market."[570] Achieving widespread adoption of interoperable EHR thus

[564] (European Parliament and Council of the European Union 2011, OJ L:88/63)
[565] (Milieu Ltd. and Time.lex 2014, 7)
[566] A complete list of EU countries (and Norway) and their status on implementing EHR can be found in brief in (Milieu Ltd. and Time.lex 2014, 18–22) and in exhaustive depth in the country-level reports which that document serves as the final report of which may be found at:
http://ec.europa.eu/health/ehealth/projects/nationallaws_electronichealthrecords_en.htm .
[567] (Dumortier and Verhenneman 2013, 26) make this summarizing point as well as providing an excellent overview of the legal and regulatory framework for US and EU EHR through 2013. This section's historical account draws upon this excellent history of these formative years.
[568] (European Commission 2004) Note that the EU uses the term e-Health to refer to the full scope of information and communication technology based tools which can, have, and might be implemented. They explicitly list "electronic health records" as a key example.(European Commission 2004, 4) Because of this core placement of EHR within e-Health, discussions of the EU case in this chapter will use e-Health and EHR interchangeably unless a distinction needs to be made for a specific purpose.
[569] (European Commission 2004, 4–5)
[570] (Dumortier and Verhenneman 2013, 26)

became a policy goal tied to the EU's strategy for a digital single market, linking it to one of the core objectives of the EU: a European Single Market.

Now linked to the single market, EHR implementation was codified through Article 14 of Directive 2011/24/EU which directed the Commission to "adopt the necessary measures for the establishment, management and transparent functioning" of an EHR system operating among the nations of the EU and Norway.[571] While Article 14 of Directive 2011/24/EU did refer to member state participation as "voluntary," the Union was required to support and encourage the participation of the member states by " adopt[ing] the necessary measures for the establishment, management, and transparent functioning of the [EHR] network."[572] To undertake this task, the EU first consulted with relevant stakeholders[573] and then published a new eHealth Action Plan for 2012-2020.[574] Since the adoption of this action plan, EU-wide adoption of EHR has increased from 39% in 2012 to 82% in 2016, although the 2016 member state adoption rates vary with 10 states at 95-100%, 3 states at 80-89%, 2 states at 70-78%, and 3 low-adopters at 40%, 30%, and 3%.[575] All told, the adoption of EHR in the EU has remarkably increased as the culmination of a series of policies and agendas linking eHealth (and EHR) to the Single Market beginning in 2000 with the EU i2010 Strategy, enacted through Directive 2011/24/EU, and implemented following eHealth Action Plan 2012-2020.

CROSS-CASE COMPARISON

The championing of EHR in Directive 2011/24/EU has similar characteristics of disruption as HITECH in the USA in that it uses regulation to push for the widespread adoption of a technology which will change the nature of the regulated jurisdiction. As with the USA, the EU also includes public health and economic concerns in the requirements for EHR implementation, pushing for further technology development in order to achieve existing regulatory goals on top of simply adoption of EHR.

The mechanism behind the regulation driven innovation adoption of EHR is particularly interesting because actors espoused preferences counter to their purported interests. Among US and EU states, there were both early adopter and laggard medical practices that led governments to push for system-wide adoption in order to realize gains from scale and pervasiveness. Early adopters recognized that adopting EHR was in their economic interest: once the transition from paper charts was complete, EHR lowered costs and improved patient care.[576]

Yet despite these clear practice level benefits, the vast majority of medical practices espoused strong preferences against adopting EHR even though these preferences were against their "thick" economic interest.[577] This resistance centered on *perceptions* of who had to bear the costs of transition (doctors) and who received the benefits (administrators, insurers, researchers). That

[571] (European Parliament and Council of the European Union 2011, OJ L:88/63)
[572] (European Parliament and Council of the European Union 2011, OJ L:88/63)
[573] (DG INFSO 2011)
[574] (European Commission 2012)
[575] EU numbers are based on author's population correction to raw percentages for 15 EU countries in 2012 (before) and 2016 (after) reported in (OECD and European Union 2018, 193). Countries include the EU 15 as well as Iceland, Norway, and Switzerland.
[576] (Institute of Medicine 2000, 177–78) (Institute of Medicine 2001, 164–80), both of which are cited in (Washington et al. 2017, 904) to make the same point about the benefits of EHR.
[577] See footnote 519 on page 175

patients and public health would eventually experience the majority of the benefits was deeply downplayed; patients were employed in effigy to support both pro and anti EHR camps (c.f. the discussion of privacy) but did not actively enter the debate.[578]

Mandated EHR adoption in the US and EU demonstrates the power of perception in public policy: policies live and die on whether people *think* they will work. Perceptions create preferences long before outcomes can breed interests.[579] Innovators and entrepreneurs distrust regulation not because they've *had* bad experiences but because they *think* they have or think they will. While it is certainly possible for regulators to behave in accordance with the Folk Economic Model imaginary, it is also possible and indeed plausible that they could behave based on one of the alternatives in Table 32. However, such an alternative outcome relies on innovators, entrepreneurs, and regulators perceiving the alternative.

EHR is such a case where public policy overcame poor perception to create good outcomes beyond the imagination of the market in Europe and the United States. As such, it is a clear case where the state was not merely reactive to a new innovation in a regulated sector but clearly undertook proactive actions to foster the adoption of an innovation. These characteristics of distinctive state action (HITECH, Directive 2011/24/EU) and innovation adoption success (from 17%[580] to 90%[581] uptake in the US, 39% to 82% in the EU[582]) make EHR a strong case to empirically verify that the state can, indeed, drive the adoption of an innovation as an adoption catalyst.

How Confident Can We Be that HITECH and Directive 2011/24/EU represent an Adoption Catalyst Model?

Based on the historical narratives above, the US and EU mandates for adoption of EHR in the late 2000's and early teens suggest that EHR is a good illustrative case for the adoption catalyst regulatory imaginary. However, we need not simply rely on asserting this judgment, we can place boundaries on our degree of confidence. Thus, as the illustrative case for adoption catalyst, EHR is subjected in this section to a Bayesian Type Validation (BayesTV) in order to demonstrate how confident we can be that it does, indeed, represent a distinctive regulatory imaginary of disruptive innovation.[583] This section explains how BayesTV was applied to EHR in the US (HITECH Act of 2009) and the EU (Directive 2011/24/EU) cases by first discussing relevant priors, then analyzing the weight of statutory intent and near rival evidence, characterize potential black swan evidence, and then concludes with a final type classification and sensitivity

[578] Notably, the Australian Personally Controlled Electronic Health Record (PCEHR) was distinctive for attempting to put patients in control of medical records rather than doctors as has been the traditional approach in US and European medical systems. (c.f. Almond, Cummings, and Turner 2013; Gajanayake, Sahama, and Iannella 2013; Pearce and Bainbridge 2014)

[579] See footnote 521 on page 176

[580] (Blumenthal 2009, 1477)

[581] (Washington et al. 2017)

[582] EU numbers are based on author's population correction to raw percentages for 15 EU countries in 2012 (before) and 2016 (after) reported in (OECD and European Union 2018, 193).

[583] See Chapter 4 for a full explanation of Bayesian Type Validation, particularly the sections on BayesTV in Practice for an explanation of how the analysis in this section was performed.

to priors.[584] It concludes by explaining that, for any reasonable set of priors, we can be reasonably to overwhelmingly confident that EHR is indeed a case of adoption catalyst.

POSSIBLE TYPES AND PRIORS FOR EHR

The possible regulatory imaginaries which could characterize the EHR case are detailed in the deductive typology developed in Chapter 3 and presented in Table 5 in that chapter (reproduced in this chapter as Table 32). From the deductive typology and the reasoning in Chapter 3, we have seven distinct types which are plausible: the Folk Economic Model, Market Ideological Model, State-as-Venue, Capture, Technology-Based Regulation, Beneficial Constrainer, and Adoption Catalyst. These seven imaginaries present the rival worlds under which BayesTV must evaluate the evidence in order to conclude which imaginary the evidence speaks most strongly for.[585]

We can assign several possible prior probabilities to the case being of a particular type.[586] If we are to adopt a naïve assumption, we would weight all seven imaginaries equally with no weight-of-evidence (WoE) for any of them (0 dB across all imaginaries, see Table 33). If, instead, we use background information about the EHR cases, we might be led to believe that either the Technology-Based Regulation or Beneficial Constraints imaginaries are more likely given the proactive actions of the state in the US and EU and the interrelatedness of these imaginaries discussed in the Adoption Catalyst imaginary specification section of this chapter. We can represent this background information with a moderate weight of evidence (10 dB) for each of these imaginaries over Adoption Catalyst. Finally, we may adopt a strong skeptic's approach which would put a strong disadvantage (50 dB)[587] to the Adoption Catalyst imaginary because it is the focus of this chapter and then equally weight each of the other imaginaries.

Based on the title of this chapter and discussion so far, it should not surprise the reader that my prior is that EHR is a characteristic Adoption Catalyst case. To state this precisely, it should be noted that each row in Table 32 can be read as a sentence[588] and thus the Adoption Catalyst would read as follows: the adoption catalyst conceives of a regulator with higher access to knowledge about the regulated domain who is the primary driver for adoption of an innovation while being agnostic about whether that regulator is viewed as a rulemaker or stakeholder or whether there are one or many perceived ideal outcomes. The presentation of evidence below in the execution of BayesTV is meant to give the reader, whatever their priors, an updated belief in whether or not the prior sentence is the true state of the world in the EHR case.

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[584] The full explicit application of BayesTV for the EHR cases may be found in Appendix D.

[585] (Fairfield and Charman 2017, 1,10)

[586] Following the advice of (Fairfield and Charman 2017, 3-4 in online appendix). This paragraph presents extremes and a paradigmatic midpoint. The reader could adopt whatever priors she sees fit, but it is most instructive to think in classes of priors rather than a continuum because we can then concentrate on tipping points.

[587] "a very high prior log-odds in favor of a well-established hypothesis relative to a far less plausible rival might reasonably be set at around 50 dB (Fairfield and Charman 2022, 133)." Fairfield & Charman propose this threshold for non-arbitrary reasons, citing Bayesian mathematician Jaynes (2003, 99–100) as the origin of 50dB based on the mathematical logic of probability thresholds which are used in quantitative work.

[588] This is a result of the consistency of a deductive typology, discussed at greater length in Chapter 3. Note that in that discussion the grammar of the sentence is exactly consistent for all 24 lines in Table 5 while in this chapter I have simplified the grammar to highlight the defining features of the adoption catalyst type.

Table 33: Prior Weights of Evidence for Perpetual Guidance and Regulation (EU) 2022/1426 (in dB)

Weight of Evidence (WoE)*	Naïve	Background Info	Skeptical
$\frac{\textbf{Adoption Catalyst}}{\textbf{Beneficial Constraints}}$	0 dB	-10 dB	-50 dB
$\frac{\textbf{Adoption Catalyst}}{\textbf{Capture}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Adoption Catalyst}}{\textbf{Technology Based Regulation}}$	0 dB	-10 dB	-50 dB
$\frac{\textbf{Adoption Catalyst}}{\textbf{State as Venue}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Adoption Catalyst}}{\textbf{Folk Economic Model}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Adoption Catalyst}}{\textbf{Market Ideological}}$	0 dB	0 dB	-50 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

While priors are a vital part of Bayesian reasoning, the most important analysis in logical Bayesianism at the heart of BayesTV is the *sensitivity*[589] of the results to the priors rather than choosing precise priors before the analysis. For type validation, we are interested in how confident we can be that a particular case fits a particular type rather than weighing between plausible hypotheses. For that reason, while the author is likely to have a strong prior for one type (the type being validated) and the reader may have indifferent (naïve) or strongly contrarian (skeptical) priors, what matters is how loudly the evidence needs to speak to convince different types of readers. Thus, we will return to the discussion of priors in the conclusion of this section ("Final Type Classification and Sensitivity to Priors"). For now, the reader should consider what regulatory imaginary she thinks best fits the EHR case.

BAYESTV OF EHR IN HITECH AND DIRECTIVE 2011/24/EU

In verifying that EHR is an example of the Adoption Catalyst regulatory imaginary, the key constituent variables are information and driver. An Adoption Catalyst conception of innovation regulation is defined by a regulator who is conceived as having higher access to information about a regulated domain and a belief that the regulator is the adoption catalyst rather than (or due to the failure of) the market. The two following sections on each of the empirical EHR cases will present evidence to update our belief in whether that is the true conception of regulators within each case. The evidence will focus on statements within the legislation or made by the regulators who implemented the regulations and how likely they are to be observed in rival states of the world (see Table 42).

[589] (Fairfield and Charman 2017)

Following the advice of Fairfield and Charman (2022, 124–70), the weights of evidence are determined qualitatively but consistently through six paired comparisons of types (most likely vs. each of the six rivals) with the evidence evaluated in the order most logically coherent to the analyst. Note that because it *mathematically* does not matter in what order we incorporate evidence, we can choose the order most logical to the *substantive* comparisons at hand.[590] We can also reduce the number of comparisons by recognizing that *mathematically* a paired comparison of the six rival types against the same type is equivalent to comparing each of the rival types to each other.[591] Thus, we need only six total comparisons in order to consider all possible pairs and we are free to pick which type will be the comparator for all six rivals based on the *substance* of the case.

In their application of logical Bayesianism to social inquiry, Fairfield and Charman (2022, 129–36, esp. p.134) recommend that paired comparisons of types should be assigned weights of evidence (WoEs) in decibels (dB) based on a plain language description of relative differences. While earlier approaches relied on an auditory metaphor of "how loudly the data is speaking,"[592] the final specification recommends a generalized use of the logarithmic decibel (dB) scale to match the logarithmic nature of human sense perception without a reliance on a particular sense metaphor.[593] In keeping with the intuitive human sense perception metaphor, the lower bound for discernable differences is set at 3 dB ("smallest meaningful difference," "very weak," 2:1) while the upper bound is set at 30 dB ("eight times louder," "very strong," 1000:1). A set of qualitative-to-quantitative reference levels, their perceptual references, a natural language description of the relationship, as well as the corresponding odds or likelihood ratios is reproduced from (Fairfield and Charman 2022, 133) in Table 34.

Table 35 provides a summary of the weight of each of the pieces of evidence. The reasoning behind these weights of evidence is summarized in the sections which follow while the full explicit BayesTV analysis may be found in the Appendix. The possibility of counterfactual evidence is explicitly defined after analysis of the evidence. The final interpretation and comparison with priors occurs in Table 40 on page 202.

[590] We can also redo our analysis with the evidence in a different order as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 139–40)

[591] We can also redo our analysis with different comparator type as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 140–42)

[592] (Fairfield and Charman 2017, esp. p.6 in online appendix)

[593] Both the senses of sight and sound, for example, evolved logarithmically in humans; a tenfold increase in absolute light power or sound intensity is perceived as a doubling in "brightness" or "loudness" by human senses. See (Fairfield and Charman 2022, 129–30) for further explanation of the appropriateness of the logarithmic scale across the physical, biological, and social sciences.

Table 34: Qualitative-to-Quantitative Reference Levels for the decibel (dB) Comparison Scale

dB	Acoustic Perception	Plain Language Description	Equivalent Odds or Likelihood Ratio (approx.)
3	Smallest meaningful difference	Very weak	2:1
6	Clearly noticeable difference	Weak	4:1
10	Twice as loud	Moderate	10:1
20	Four times louder	Strong	100:1
30	Eight times louder	Very Strong	1000:1

Based on (Fairfield and Charman 2022, 133, Table 4.1), Note: Some digital audio files that illustrate these different decibel levels are available at: https://tashafairfield.wixsite.com/home/bayes-book

Table 35: Weights of Evidence for HITECH and Directive 2011/24/EU (in dB)

Odds Ratio*	Initial Evidence		Near Rival Evidence	
	US E_{NCHIT}	EU E_{ART14}	US $E_{Meaningful\ Use}$	EU E_{INFSO_PC}
$\frac{Adoption\ Catalyst}{Beneficial\ Constraints}$	6 dB	10 dB	3 dB	10 dB
$\frac{Adoption\ Catalyst}{Capture}$	54 dB	30 dB	40 dB	10 dB
$\frac{Adoption\ Catalyst}{Technology\ Based\ Regulation}$	10 dB	20 dB	20 dB	30 dB
$\frac{Adoption\ Catalyst}{State\ as\ Venue}$	40 dB	3 dB	60 dB	-3 dB
$\frac{Adoption\ Catalyst}{Folk\ Economic\ Model}$	90 dB	50 dB	60 dB	60 dB
$\frac{Adoption\ Catalyst}{Market\ Ideological}$	90 dB	50 dB	60 dB	50 dB

* Note that the comparisons are properly labeled as odds ratios since they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WOE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically $(-\infty,\infty)$ although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WOE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WOE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

INITIAL EVIDENCE: STATUTORY INTENT

The first piece of evidence for each case is selected based on the highest likelihood to correspond with the adoption catalyst imaginary. As the EHR cases were selected in order to verify the adoption catalyst imaginary, their overarching statements of statutory intent shall be used to make the initial case for adoption catalyst over rival types as the true state of the world. In the US case, this evidence comes from the introduction to the first of a series of articles where the National Coordinator for Health Information Technology (NCHIT) David Blumenthal laid out case for the statutory authority given to regulators under the HITECH Act. In the EU case, this evidence comes from Article 14 of Directive 2011/24/EU which directs the European Commission to adopt EHR which interoperates between the member states.

HITECH Act in the United States (2009-2015)

In launching the HITECH act, a series of articles were published in the New England Journal of Medicine by David Blumenthal, the National Coordinator for Health Information Technology (NCHIT).[594] In these articles, Blumenthal explicitly laid out the origin and intent of the HITECH Act of 2009 to the medical profession. In the first of the series, he made clear claims about how regulators perceived their actions and how the medical community should understand them:

> *"The HIT components of the stimulus package — collectively labeled HITECH in the law — reflect a shared conviction among the fledgling Obama administration, the Congress, and many health care experts that electronic information systems are essential to improving the health and health care of Americans. However, proponents of HIT expansion face substantial problems. Few U.S. doctors or hospitals — perhaps 17% and 10%, respectively — have even basic EHRs, and there are significant barriers to their adoption and use: their substantial cost, the perceived lack of financial return from investing in them, the technical and logistic challenges involved in installing, maintaining, and updating them, and consumers' and physicians' concerns about the privacy and security of electronic health information. HITECH addresses these obstacles head on, but huge challenges await efforts to implement the law and fulfill President Barack Obama's promise that every American will have the benefit of an EHR by 2014." (Blumenthal 2009, 1477)*

A summary of the explicit Bayesian type validation (BayesTV) of E_{NCHIT} for each of the regulatory imaginaries in Table 32 is presented below in Table 36. The full narrative prose explaining these summaries of how likely we would be to see this evidence (E_{NCHIT}) under the assumption that each potential regulatory imaginary was the true state of the world may be found in Appendix D. The significance of this analysis is discussed in the following section on the weight of evidence E_{NCHIT}.

[594] (Blumenthal 2009; 2010; Blumenthal and Tavenner 2010; Blumenthal 2011a; 2011b)

Table 36: BayesTV Constitutive Variable Comparison Summary for E_{NCHIT}*

Constitutive Variables (Independent Variables)					Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Adoption Catalyst	*No specific relevance*	Regulator provides high level analysis of opportunities and challenges of EHR; beyond that of regulated entities	HITECH clearly pushes for adoption through incentives & punishments	*No specific relevance*	Evidence clearly states that under-adoption is a problem this regulation seeks to solve; catalyze adoption	
Beneficial Constraints	*No distinguishing relevance*	*No distinguishing relevance*	Incentives for adoption of identified tech, not guardrails for innovation	*No distinguishing relevance*	Beyond simply constraints, HITECH pushes for adoption beyond existing barriers	6 dB
Capture	*No distinguishing relevance*	Clear demonstration of knowledge through outreach in highly respected journals	*No distinguishing relevance*	*No distinguishing relevance*	Regulator seeks to push adoption beyond constraints rather than constrain	54 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Although regulator pushes a specific set of technological principles, they do not constrain the implementation to a single tech solution	10 dB
State as Venue	*No distinguishing relevance*	High level analysis of barriers to adoption represents high rather than low level of systemic information	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is pushing far beyond a moderating role to change the perceptions of regulated entities	40 dB
Folk Economic Model	*No distinguishing relevance*	Regulator clearly stakes claim to high level of knowledge beyond that of market actors	HITECH pushes for adoption beyond market desires	*No distinguishing relevance*	Far from creating an impediment, HITECH seeks to remove impediments to adoption and innovation around EHR	90 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	HITECH pushes for adoption beyond market desires	Clearly not laisses faire		90 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled WoE_{NCHIT}, Adoption Catalyst vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 35 for further explanation and Chapter 4 for complete methodological specification.

The Weight of Evidence NCHIT

As seen by the weights of evidence in the last column of Table 36, the piece evidence presented above (E_{NCHIT}) increases our belief that the Adoption Catalyst is the true regulatory imaginary conceived by the HITECH Act. It provides unsurprisingly strong support for the Adoption Catalyst imaginary over the three least proactive regulatory imaginaries (Folk Economic Model (90 dB), Market Ideological (90 dB), Capture (54 dB)) making this evidence a strong bulwark against any claim that regulators are always an impediment to innovation. At 40 dB difference, this evidence provides an exceptionally strong level of evidence against the state as venue imaginary because the regulator is clearly pushing far beyond merely serving as a moderator. At 10 dB difference, this evidence moderately increases our belief that Adoption Catalyst rather than Technology Based Regulation is at work here because although HITECH does seek to catalyze the adoption of EHR technology, that technology is principle based (e.g. Meaningful Use) rather than solution or implementation based.[595] Finally, at 6 dB, this evidence weakly but clearly increases our belief that Adoption Catalyst rather than Beneficial Constraints is the more plausible imaginary because although both imaginaries seek to encourage innovation, only Adoption Catalyst looks to push beyond the imagination of the market with incentives and punishments.

Directive 2011/24/EU in the EU (2011-2021[596])

While several member-states had already implemented a national EHR system prior to EU action, Article 14 of Directive 2011/24/EU directed the Commission to "adopt the necessary measures for the establishment, management and transparent functioning" of an EHR system operating among the nations of the EU and Norway. While Directive 2011/24/EU leaves the language as "voluntary," it does require that the Union shall support and encourage the participation of the member states.[597]

A summary of the explicit Bayesian type validation (BayesTV) of E_{ART14} for each of the regulatory imaginaries in Table 32 is presented below in Table 37. The full narrative prose explaining these summaries of how likely we would be to see this evidence (E_{ART14}) under the assumption that each potential regulatory imaginary was the true state of the world may be found in Appendix D. The significance of this analysis is discussed in the following section on the weight of evidence E_{ART14}.

[595] See the discussion below around $E_{Meaningful\ Use}$ for a discussion of this distinction between principles and solution based technological specification.

[596] Projected completion of "gradual implementation" in 22 EU countries is 2021 (European Commission 2019) although it was originally slated for 2020 in (European Commission 2012).

[597] (European Parliament and Council of the European Union 2011, OJ L:88/63)

Table 37: BayesTV Constitutive Variable Comparison Summary for E_{ART14}*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Adoption Catalyst	*No specific relevance*	*No specific relevance*	The EU is driving adoption by directing the Commission to facilitate adoption	*No specific relevance*	Commission is directed to facilitate establishment and functioning	
Beneficial Constraints	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is driving establishment and adoption	*No distinguishing relevance*	No constraints are mentioned or implemented	10 dB
Capture	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	No constraints mentioned, especially not those consistent with medical business interests	30 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Principle-based guidelines (such as they are) not implementation based.	20 dB
State as Venue	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Regulator taking a proactive rather than moderating approach	3 dB
Folk Economic Model	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is driving establishment and adoption	*No distinguishing relevance*	Regulator driving innovation not impeding it	50 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is driving establishment and adoption	Clearly *not* laisses faire	Regulator driving innovation not impeding it	50 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled WoE_{ART14}, Adoption Catalyst vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 35 for further explanation and Chapter 4 for complete methodological specification.

The Weight of Evidence ART14

As seen by the weights of evidence in the last column of Table 37, the evidence provided by Article 14 of Directive 2011/24/EU (E_{ART14}) is most likely in the Adoption Catalyst world, although it speaks only weakly louder than for the State-as-Venue imaginary due to the broad and general principles it seeks to drive the adoption of which could reasonably be read as simply drawing together stakeholders. As there are no constraints given in the very general wording, Adoption Catalyst is a moderately (10 dB) more likely than Beneficial Constraints since there is also not a strong drive for adoption other than a directive to adopt. Finally, the remaining imaginaries would all be rather unlikely to have this piece of evidence and thus provide strong (20 dB) to exceptionally strong (50 dB) weight of evidence against each imaginary.

NEAR RIVAL EVIDENCE:

As can be seen from the weight of evidence summary in Table 35, the initial evidence was least decisive about a different alternative type for each of the cases. In the US HITECH case, the nearest rival imaginary is the Beneficial Constrainer imaginary because the prevalence of economic barriers and overcoming perception is compatible with both Adoption Catalyst and Beneficial Constrainer regulatory imaginaries. In the EU Directive 2011/24/EU case, the nearest rival imaginary is the State as Venue imaginary due to the broad and voluntary language of the directive.

In this section, we consider a piece of evidence which is most supportive of the respective nearest rival type for each of the two empirical cases. For the US HITECH case, this evidence comes from the core mechanism of the implementation, the Meaningful Use standard, because it represents a constraint which was meant to beneficially incite innovation. For the EU case, this evidence comes from public consultation on the eHealth Action Plan 2012-2020 because it represents the state acting as a venue rather than as an active driver of innovation.

HITECH Act in the United States (2009-2015)

As initially envisioned and introduced to the medical community, the HITECH Act's key goal was to achieve not just adoption of any EHR but the "meaningful use" of "certified EHR."[598] These two key terms were formally defined through the notice and comment procedure leading to a standard of meaningful use which included "a set of core objectives that constitute an essential starting point for meaningful use of EHRs and a separate menu of additional important activities from which providers will choose several to implement."[599] In the words of the regulatory architects reaching out to the regulatees:

> *"The meaningful use rule strikes a balance between acknowledging the urgency of adopting EHRs to improve our health care system and recognizing the challenges that adoption will pose to health care providers. The regulation must be both ambitious and achievable. Like an escalator, HITECH attempts to move the health system upward toward improved quality and effectiveness in health care. But the speed of ascent must be calibrated to reflect both the capacities of providers who face a multitude of real-world challenges and the maturity of the technology itself." (Blumenthal and Tavenner 2010, 504)*

By establishing a constraint meant to drive beneficial challenges, the Meaningful Use regulation is a piece of evidence which would be highly likely under the Beneficial Constrainer imaginary identified as a near rival to the Adoption Catalyst imaginary in the US HITECH case.

[598] (Blumenthal 2009, 1479)
[599] (Blumenthal and Tavenner 2010, 502–3)

A summary of the explicit Bayesian type validation (BayesTV) of $E_{Meaningful\ Use}$ for each of the regulatory imaginaries in Table 32 is presented below in Table 38. The full narrative prose explaining these summaries of how likely we would be to see this evidence ($E_{Meaningful\ Use}$) under the assumption that each potential regulatory imaginary was the true state of the world may be found in Appendix D. The significance of this analysis is discussed in the following section on the weight of evidence $E_{Meaningful\ Use}$.

The Weight of Evidence Meaningful Use

As seen by the weights of evidence in the last column of Table 38, the piece evidence presented above ($E_{Meaningful\ Use}$) increases our belief that the Adoption Catalyst is the true regulatory imaginary conceived by the HITECH Act. While it was selected to align most closely with the nearest rival imaginary (Beneficial Constraints), it provides weakly stronger support for the Adoption Catalyst rather than Beneficial Constraints (3dB). Unsurprisingly, it also reinforces support for the Adoption Catalyst imaginary over the two least proactive regulatory imaginaries (Folk Economic Model and Market Ideological) which, at 60 dB difference, makes this evidence an exceptionally strong bulwark against any claim that regulators are always an impediment to innovation. At 40 dB, we also have very very strong evidence against Capture as the Meaningful Use standard is a difficult one for any conceivable capturing entity (medical or IT) to meet. At 60 dB difference, this evidence also provides extremely strong evidence against the state as venue imaginary because despite the use of the notice and comment process to draft meaningful use, the final specification was clearly influenced by the agenda of CMMS rather than simply an aggregate of the stakeholders. Finally, at 20 dB), this evidence strongly increases our belief that adoption catalyst rather than technology based regulation is at work here because the standard in meaningful use is performance and principle based rather than particular implementation or technology based.

Table 38: BayesTV Constitutive Variable Comparison Summary for $E_{\text{Meaningful Use}}$*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Adoption Catalyst	*No specific relevance*	The principles and standards laid out in the meaningful use standard demonstrate clear claims to high information	The meaningful use standard comes with carrots and sticks to drive adoption	*No specific relevance*	Archetypical catalyst: using incentives and punishments to drive adoption	
Beneficial Constraints	*No distinguishing relevance*	*No distinguishing relevance*	The regulator rather than the market is the driver (incentives)	*No distinguishing relevance*	Meaningful use can be seen as either a constraint or a set of adoption principles	3 dB
Capture	*No distinguishing relevance*	Regulator set a firm and "meaningful" standard that was beyond the wishes of market actors	*No distinguishing relevance*	*No distinguishing relevance*	Drove adoption of an innovation rather than allowing short term economic calculus to constrain it.	40 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	A principle (performance) based standard rather than a solution based one	20 dB
State as Venue	*No distinguishing relevance*	State gathered information from Notice and Comment then adjudicated & prioritized it	*No distinguishing relevance*	*No distinguishing relevance*	Far more than moderating, CMMS regulator clearly set out its own agenda for meaningful use.	60 dB
Folk Economic Model	*No distinguishing relevance*	Principles and standards demonstrate competence	Regulator is driving adoption with carrots and sticks	*No distinguishing relevance*	Regulator catalyzing adoption and innovation, not impeding it	60 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is driving adoption with carrots and sticks	Far from standing back, regulator is driving	Regulator catalyzing adoption and innovation, not impeding it	60 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{\text{Meaninful Use}}$, Adoption Catalyst vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 35 for further explanation and Chapter 4 for complete methodological specification.

Directive 2011/24/EU in the EU (2011-2021)

As part of passing any major EU initiative, a public consultation is required. This process involves a 90 day period of soliciting responses to a questionnaire by the directorate-general (DG). Following promulgation of Directive 2011/24/EU, the Information Society and Media Directorate-General (DG INFSO) was tasked with creating the eHealth Action Plan for 2012-2020 (2012). This action plan laid out the steps towards implementing the required eHealth Network as laid out in Directive 2011/24/EU.[600] As part of implementation, DG INFSO undertook a public consultation with the following four proposed objectives:

> *"Objective 1: Increase awareness of the benefits and opportunities of eHealth, and empower citizens, patients and healthcare professionals.*
>
> *Objective 2: Address issues currently impeding eHealth interoperability*
>
> *Objective 3: Improve legal certainty for eHealth*
>
> *Objective 4: Support research and innovation in eHealth and development of a competitive European market." (DG INFSO 2011, 2)*

Leading to the following three summary recommendations from respondents:

> *"1) The need to support systematic evaluation of the benefits and costs, effectiveness/usefulness of eHealth solutions;*
>
> *2) Improving interoperability and strengthening the evidence-based approach; and*
>
> *3) Facilitating cooperation between Member States and regions and, exploring innovative financing and reimbursement schemes." (DG INFSO 2011, 2)*

By focusing on awareness, standard setting, and facilitating cooperation, this framing of both the objectives and the responses is a piece of evidence which would be highly likely under the State-as-Venue imaginary which was identified as a near rival to the Adoption Catalyst imaginary in the Directive 2011/24/EU case.

A summary of the explicit Bayesian type validation (BayesTV) of E_{INFSO_PC} for each of the regulatory imaginaries in Table 32 is presented below in Table 39. The full narrative prose explaining these summaries of how likely we would be to see this evidence (E_{INFSO_PC}) under the assumption that each potential regulatory imaginary was the true state of the world may be found in Appendix D. The significance of this analysis is discussed in the following section on the weight of evidence E_{INFSO_PC}.

[600] (European Commission 2012, 3)

Table 39: BayesTV Constitutive Variable Comparison Summary for E_{INFSO_PC} *

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Adoption Catalyst	*No specific relevance*	Regulator is gathering information but muddy on how much it has	Regulator is increasing awareness and facilitating adoption; driving but weakly	*No specific relevance*	Actions are consistent with catalyst but not strongly indicative of it	
Beneficial Constraints	*No distinguishing relevance*	*No distinguishing relevance*	Not waiting for the market to drive, facilitating	*No distinguishing relevance*	If there are constraints, they are not very constraining	10 dB
Capture	*No distinguishing relevance*	Regulators gather information and spreading it as well	*No distinguishing relevance*	*No distinguishing relevance*	Implausible capturing entity (EHR tech firms) who are in their infancy at this time. Tech more promise than reality	10 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Gathering principles rather than mandating specific implementations	30 dB
State as Venue	*No distinguishing relevance*	Regulator gathering information is axiomatic State as Venue	*No distinguishing relevance*	*No distinguishing relevance*	Although axiomatically consistent, it is also consistent with Adoption Catalyst	- 3 dB
Folk Economic Model	*No distinguishing relevance*	Regulator gathering and spreading info, no low access	Regulator weakly driving adoption	*No distinguishing relevance*	Regulator is proactively educating and spreading the innovation, rather than impeding its development	60 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	Regulator weakly driving adoption	Certainly not leaving the outcome up to the market		50 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled WoE_{INFSO_PC}, Adoption Catalyst vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 35 for further explanation and Chapter 4 for complete methodological specification.

The Weight of Evidence INFSO_PC

As we can see from the last column of Table 39, the information provided by INFSO_PC (E_{INFSO_PC}) increases our belief that the Adoption Catalyst is the true regulatory imaginary conceived by the Directive 2011/24/EU. As it was selected to align most closely with the nearest rival imaginary (state-as-venue), it provides weakly stronger support (3dB) for the State-as-Venue imaginary over the Adoption Catalyst imaginary because it derives from a mandated procedure to facilitate stakeholder interaction and feedback. Unsurprisingly, it also reinforces support for the Adoption Catalyst imaginary over two of the three least proactive regulatory imaginaries (Folk Economic Model and Market Ideological) which, at 60 and 50 dB difference, makes this evidence an exceptional strong barrier against any claim that regulators are always an impediment to innovation.

Intriguingly, at only 10 dB, this evidence only moderately speaks against the capture imaginary due to concessions it makes to established market actors (professional organizations) and the educating work it does to spread the benefits of EHR. However, this support also shows the analytical limits of Stiglerian capture within corporatist[601] or coordinated[602] market societies as the language emphasizing market stakeholders in such contexts is observationally equivalent between the negative sentiment suggested by Stiglerian capture and the positive sentiment of public consultation. At 10 dB difference, this evidence provides a moderate increase in our belief in favor of Adoption Catalyst over Beneficial constraints as there is no explicit discussion of constraints in the objectives or responses from DG INFSO's public consultation even if we might generously attempt to read them in between the lines. At 30 dB difference, this evidence provides a very strong weight in favor of Adoption Catalyst over Technology Based Regulation because the discussions are general principle rather than specific implementation based.

BLACK SWAN EVIDENCE AND THE COUNTERFACTUAL

Before adjudicating the final type classification and sensitivity to priors, due diligence requires us to consider what evidence would be consistent with the extreme opposite of the suggested type classification being the true state of the world; the so called "black swan" evidence. As adoption catalyst is the most likely type for the EHR case, the extreme opposite (from Table 32) is the Folk Economic Model imaginary because it is at the extreme other end of the effect spectrum. In a folk economic world, we would expect to see regulators acting lost due to lower access to information than market participants and either recusing themselves from regulation in order to stay out of the way until the market has innovated[603] or implementing harsh and inappropriate anti-innovative regulations. While no evidence has been found that carries this information, a skeptical reader should contact the author with such evidence so that it may be incorporated into analysis and allow us to radically update our priors.

FINAL TYPE CLASSIFICATION AND SENSITIVITY TO PRIORS

For final classification based on an update of belief in which imaginary is the true state of the world, we add the decibel comparisons between the Adoption Catalyst imaginary and each of

[601] (c.f. Esping-Andersen 1990), although he preferred the term Christian Democratic after the parties that often construct such societies and others have described them as continental or conservative welfare capitalist societies.
[602] (c.f. Hall and Soskice 2001a)
[603] While this may seem fanciful, this "wait and see" attitude was exactly how the Federal Reserve approached mobile payment apps for years. (Lowry 2016, 384)

alternative imaginaries from each piece of evidence and then add those to the priors discussed at the beginning of this section. These comparisons are presented in Table 40.

Consistent with the design and intent of Bayesian Type Validation, the evidence can tell several disciplined and clear stories depending on how it is combined with priors and across cases. If we combine all of the evidence for both the US and EU cases, we find decisive evidence[604] to believe that EHR technology is regulated from the Adoption Catalyst imaginary (80+ dB, Combo Posterior Column under a in Table 40) for all rival imaginaries except Beneficial Constraints, where we see very strong (29 dB) evidence. If we look just at the US case (Table 40, column a "US Post"), we find decisive (80+ dB) for Adoption Catalyst over the Capture , State as Venue, Folk Economic Model, and Market Ideological imaginaries, strong (30 dB) evidence over Technology Based Regulation, and moderate (9 dB) evidence over Beneficial Constraints. If we look at just the EU case (Table 40, column a "EU Post"), we find decisive evidence (80+ dB) for Adoption Catalyst over the Folk Economic Model and Market Ideological imaginaries, well-established evidence (50-70 dB) over the Technology Based Regulation imaginary, exceptionally strong (40 dB) evidence against Capture, and strong (20 dB) evidence against Beneficial Constraints. The State as Venue imaginary ends up equally as plausible as the Adoption Catalyst imaginary for the EU Directive 2011/24/EU case. These overall weights of evidence should then each be considered against the reader's priors to update our belief in what the most probable state of the world is.

If the reader adopted naïve priors with equal weights (0 dB for or against Adoption Catalyst) for the combined case of AVs in the US and EU (Table 40, column a "combo posterior"), then the evidence presented above would create decisive (80+ dB) to overwhelming (100+ dB) in favor of Adoption Catalyst over all alternative regulatory imaginaries except Beneficial Constraints where it would be only very strong (29 dB). While there are fair reasons to disaggregate the data to a per-case level as that is where the regulation actually occurred (at the US/EU levels), this combined weight of evidence is useful for us to understand how EHR is imagined to be regulated cross-nationally. The evidence thus aggregated tells us that EHR is regulated from the Adoption Catalyst imaginary for Naïve and Background Information priors while the Skeptical priors are able to tile the scale towards Beneficial Constraints.

However, as the actual US HITECH Act and EU Directive 2011/24/EU approaches to EHR regulation were decided through separate processes, it is also useful to disaggregate down to the US/EU level and compare against priors. In the US HITECH Act case, we see that the evidence

[604] Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival. Fairfield and Charman (2022, 162–63) proceed to explain that a more stringent threshold of 50-70 decibels equates to the thresholds of confidence used by quantitative Bayesian statisticians in the physical and biological sciences; they note that 62 dB is roughly equivalent to the 5 sigma threshold for discovering a new particle in Physics and 67 dB the chance that any given commercial airplane flight will crash vs. land safely. While Fairfield and Charman (2022, 162, footnote 34) also caution us that you cannot truly mathematically convert Bayesian odds to frequentist p-values because they are different ontological statements, most quantitative social scientists are happy with $p<0.1$ (~27 dB) and $p<0.05$ (~30 dB) for publication and are ebullient about $p<0.01$ (~37 dB). Fairfield and Charman ultimately recommend a threshold of 80-100 dB to consider a qualitative research question "settled" both to guard against potential unaccounted for bias as well as to deal with the reality that quantitative social scientists often show higher skepticism toward qualitative evidence than they do towards their own thresholds of significance.

Table 40: BayesTV Prior and Posterior Weights of Evidence for the EHR Cases, US HITECH and EU Directive 2011/24/EU (in dB)

	a				b				c			
Weight of Evidence (WoE)*	**Naïve**				**Background Info**				**Skeptical**			
	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior
$\frac{\textit{Adoption Catalyst}}{\textit{Beneficial Constraints}}$	0	9	20	29 dB	-10	-1	10	19 dB	-50	-41	-30	-21 dB
$\frac{\textit{Adoption Catalyst}}{\textit{Capture}}$	0	94	40	134 dB	0	94	40	40 dB	-50	44	-10	84 dB
$\frac{\textit{Adoption Catalyst}}{\textit{Technology Based Regulation}}$	0	30	50	80 dB	-10	20	40	70 dB	-50	-20	0	30 dB
$\frac{\textit{Adoption Catalyst}}{\textit{State as Venue}}$	0	100	0	100 dB	0	100	0	100 dB	-50	50	-50	50 dB
$\frac{\textit{Adoption Catalyst}}{\textit{Folk Economic Model}}$	0	150	110	260 dB	0	150	110	260 dB	-50	100	60	210 dB
$\frac{\textit{Adoption Catalyst}}{\textit{Market Ideological}}$	0	150	100	250 dB	0	150	100	250 dB	-50	100	50	200 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

remains decisive (80+ dB) against all imaginaries except Beneficial Constraints and Technology Based Regulation across Background Info priors (Table 40, column b "US Post"). Technology Based Regulation slips to strong (20 dB) evidence against it while Beneficial Constraints becomes indistinguishable (-1 dB).[605] With skeptical priors (Table 40, column c "US Post"), the US case maintains decisive (80+ dB) evidence against Folk Economic Model and Market Ideological imaginaries, well established (50-70 dB) evidence against State as Venue, and exceptionally strong (44 dB) evidence against Capture. The extreme weight of the skeptical priors (50 dB) allows Beneficial Constraints and Technology Based Regulation to rise above Adoption Catalyst as favored alternatives.

Although the weight in favor of Beneficial Constraints and Technology Based Regulation are primarily driven by overly strong skeptical priors, we should not be surprised that these two imaginaries are the nearest rivals as both share elements with Adoption Catalyst. Beneficial Constraints shares the proactive nature of the Adoption Catalyst imaginary which seeks to encourage innovation. Technology Based Regulation shares the drive for adoption of a technology with Adoption Catalyst, although Adoption Catalyst is more pro innovation and flexible than the blanket mandate of Technology Based Regulation. Beyond merely the weights of evidence, however, if we dive into the analysis and case narrative of the HITECH act, we see that this regulation lacks the constraining aspects of both Beneficial Constraints and Technology Based Regulation. HITECH uses incentives and punishments rather than constraints or mandates in order to drive the innovation and adoption of EHR beyond the imagination of the market.

In the Directive 2011/24/EU case, we see that the evidence weighted against Background Info priors (Table 40, column b "EU Post") remains decisive (80+ dB) against Folk Economic Model and Market Ideological imaginaries, very strong (40 dB) against Capture and Technology Based Regulation, moderate (10 dB) against Beneficial Constraints, and indecisive (0 dB) between State as Venue and Adoption Catalyst. Weighted against Skeptical priors (Table 40, column c "EU Post"), the EU case maintains well-established evidence (50-70 dB) against the Folk Economic Model and Market Ideological imaginaries but flips to favoring or indifference between all other imaginaries over Adoption Catalyst. This flip against all but the most anathema imaginaries demonstrates that the EU case is at best a weak representation of Adoption Catalyst but is not particularly indicative of which of the rivals may be preferable. From the narrative analysis in Appendix D, it is clear that the coordinated market economy engagement with stakeholders muddies the waters in favor of the State as Venue imaginary.

Based on these four pieces of evidence, we see that how clearly EHR can be considered a case of Adoption Catalyst depends on the priors you adopt and the aggregation you are interested in. In isolation for any set of priors, these four pieces of evidence (NCHIT, ART14, Meaningful Use, INFSO_PC) are overwhelmingly convincing in favor of Adoption Catalyst over all alternative models for the general approach to EHR regulation across the US and EU except for Beneficial Constraints, where the evidence is very strongly in favor of Adoption Catalyst.

However, at the individual regulatory domain level, we see divergent conclusions based on priors that nevertheless may be undermined by additional case information. In the US, the Beneficial Constraints and Technology Based Regulation imaginaries become increasingly likely relative to Adoption Catalyst as we increase the weight of the prior against Adoption Catalyst, although this relies on a lack of deeper reading of the HITECH act where the consistency with

[605] Recall that 3 dB is the smallest meaningful difference, see Table 34

the constraint worlds breaks down due to the lack of constraints in favor of incentives and punishments. In the EU, the Adoption Catalyst is universally less strongly supported except against the extreme opposite imaginaries of Folk Economic Model and Market Ideological because the EU aimed to facilitate adoption through outreach and education which is also highly consistent with a State as Venue imaginary. At the very least, however, EHR in both cases, combined and isolated, allows us to soundly reject the Folk Economic Model and Market Ideological imaginaries in favor of imaginaries which are more proactive and beneficial to innovation.

CONCLUSION: WHY DOES IT MATTER THE EHR IS REGULATED THROUGH AN ADOPTION CATALYST MODEL?

In some respects, this chapter has an exceptionally humble goal: to demonstrate that there is at least one disruptive technological innovation (DTI) where regulators draw upon the Adoption Catalyst imaginary. As with all claims, whether this is boring or insightful depends on the reader's prior beliefs about what is possible for regulators when faced with DTI. Thus, this chapter adopted a Bayesian Type Validation (BayesTV) approach which presents evidence in a disciplined way in order to clearly identify possible loci of contention. It also weighed that evidence against three possible sets of priors based on likely reader profiles: naïve, informed on the background of the cases, and skeptical. To conclude, we should therefore reflect on what the weight of the evidence and the sets of priors tell us about how regulators respond to disruptive technological innovation more broadly as well as case-specific outstanding questions.

Beyond these two specific cases of EHR, what does BayesTV of this case tell us about the regulation of disruptive technological innovation more broadly? The EHR cases are defined by the application of information technology (IT) to the healthcare sector and both of these two characteristics might be relevant to the scope of the finding that the state can drive innovation adoption beyond the imagination of the market. As compared to biotechnology or hardware engineering, IT is often distinguished as having zero marginal cost which might make it easier for regulation to make an "unfunded mandate" to adopt a new technology. Yet in both the HITECH and Directive 2011/24/EU cases, the mandated adoption is not unfunded but instead strongly supported by the state. In the US, this took the form of direct payments to practices (and then penalties for non-compliance) to offset adoption costs while in the EU this took the form of substantial in-kind payments coordinating between different member states on standards, laws, and implementations.[606] EHR also do not have zero marginal cost, costing practices an estimated $10-20,000 per physician to be covered in the period when HITECH was designed.[607] Both of these facts suggest that adoption catalyst is not an imaginary limited to only information technology and other supposedly low-capital intensive technologies.

However, the intrinsically regulated and highly consolidated nature of health care may suggest that adoption catalyst is limited to regulatory domains where regulation is accepted as simply a cost of doing business.[608] Yet, as market institutionalists have pointed out, all markets are made by rules.[609] A fundamental contention of this dissertation is that regulation is actually

[606] See (Blumenthal 2011a) for an overview of US payments scheme and (European Commission 2018) for an overview of the EU in-kind provision of standards and coordination.
[607] (Menachemi and Brooks 2006, 161–62)
[608] Thanks to Andrew Kelley for pointing this out at WPSA 2019 in San Diego, CA.
[609] (c.f. S. K. Vogel 1998; 2007; Barma and Vogel 2008c; S. K. Vogel 2018)

present, often neutrally or even beneficially so, in all domains of market activity although the perception of regulation varies widely by domain. Failure is loud, success quiet. Regulatory failures like the Deepwater Horizon oil spill and 2008 Global Financial Crisis are loudly publicized. Quieter are responses other than failure like American recombinant DNA regulation following the 1975 Asilomar Conference.[610]

Mandated EHR adoption in the US and EU demonstrates the power of perception in public policy: policies live and die on whether people *think* they will work. Perceptions create preferences long before outcomes can breed interests.[611] Innovators and entrepreneurs distrust new regulations not because they've *had* bad experiences with those regulations but because they *think* they will because, "as a rule," [612] regulation is bad. This does not mean that regulation is *always good* for innovation; it simply means that regulation is not *always bad* for innovation even though the Folk Economic Model encourages innovators and entrepreneurs to think so. If we can guide entrepreneurs and innovators to think better of regulation as it is being adopted, we can have more innovative outcomes: HITECH took the US from 17%[613] of practices with EHR to 90%[614] in six years while Directive 2011/24/EU took the EU from 39% to 82% in four years.[615]

This chapter and this project thus humbly argue that, for the folk economic model, "not always wrong" is not the same thing as "always right" or even "right most of the time." Given the stakes of successful regulation of innovation for a well-functioning political economy, we must study situations and configurations where regulation can enhance innovation rather than erroneously assume that such a search is a Sisyphean endeavor. EHR is such a case where public policy overcame poor perception to create good outcomes beyond the imagination of the market in Europe and the United States. Understanding how the state catalyzed the pervasive adoption of an economically and socially beneficial technology helps us build on that success to allow innovators to work with regulators rather than against them to design and implement statutes which further the public welfare by encouraging and enabling innovation in line with public and private goals.

[610] (Berg 2008)
[611] See footnote 521 on page 176.
[612] Recall that "[a] central thesis of [Stigler's "The theory of economic regulation] paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit." (Stigler 1971, 3)
[613] (Blumenthal 2009, 1477)
[614] (Washington et al. 2017)
[615] EU numbers are based on author's population correction to raw percentages for 15 EU countries in 2012 (before) and 2016 (after) reported in (OECD and European Union 2018, 193).

CHAPTER 8

CONCLUSION

Beyond the Zero – Economically Beneficial Regulation for Innovation

They promised us jetpacks.[616]

We didn't get jetpacks.[617]

But, as we saw in chapters 5, 6, and 7, we did get gene editing technology (GE) and electronic health records (EHR) while autonomous vehicles (AVs) are rapidly pushing upwards from level 2 (partially autonomous) to level 3+ (conditionally to fully autonomous).

Beyond those current innovations, we've certainly seen a great many innovations other than jetpacks since we were promised them back at the 1964 New York World's Fair.[618] The computers which guided the Apollo program to the moon shrank from the size of a room to the size of our pockets.[619] Automobiles which made a great deal of (glorious) noise using 409 cu. in (6.7 L) of displacement to turn out 409 horsepower[620] have shrunk to 6.2 L while rising to 808 horsepower[621] or even to a displacement of zero while outputting 1,020 horsepower to the sound of a gentle hum.[622] And yes, our 800 kiloton W59 warhead-armed Minuteman I missiles from 1962 had also grown into the LGM-118 Peacekeeper by 1986 which was capable of carrying twelve 300 kiloton W87 warheads (total yield of 3600 kilotons). Not all of these innovations were great, but all are quite literally awesome.

All of these innovations were also *not in spite of regulation but because of regulation*. I've discussed AVs, GE, and EHR at great length in the chapters 5, 6, and 7 as well as their respective appendices (B, C, and D). The computer revolution between the 1960s and today owes the availability of its basic hardware to the 1956 Consent Decree which forced Bell Labs to license all of its patents (notably including the transistor, the solar cell, and the laser) royalty free rather

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[616] Robert F. Courter Jr. from the Bell Aerosystems Corporation flew a jet pack three times a day during the 1964 World's Fair and promised onlookers that "in ten years, maybe less, some of you will be up here flying with me." (Abel 2014)

[617] Ok, jet packs actually do exist and have since the 1960s. But they are not the ones we were promised in safety, ubiquity, or capability by Buck Rogers, Boba Fett, or even *The Rocketeer.* As one retrospective put it, "the better question is not "*Who* promised us jetpacks?"—it's "Who promised *us* jetpacks?" (Bosch 2022)," suggesting that while we actually have had jet powered backpacks that can lift a person since the 1960s we were lulled into thinking that ordinary people were ever going to get them.

[618] See footnote 4.

[619] In fact, much smaller than our pockets, since our smartphones are significantly more powerful than the command module computers. The Apollo guidance computer was roughly 500 times slower than smartphone *chargers* (48 Mhz) in 2023, much less the phones themselves which are rough 150,000 times faster (although the function of computer processors is very different now, the speed comparisons give a sense of the increase in processing power).(Porter 2020; Heller 2020)

[620] This is the famous "409" Big-Block Chevy engine from The Beach Boy's song "409" (The Beach Boys 1962)

[621] This is the 2018 Dodge Challenge SRT Demon, a comparable muscle car to the hot rods and muscle cars the Chevy Big-block 409 would have been put into in the 1960s. It is a special edition of a mass production car but still legal to be driven on public roads.

[622] This is the 2021 Tesla Model S Plaid, and all electric mass produced sports sedan legal to be driven on public roads and sold to the general public.

than develop them inhouse.[623] The computer revolution owes its "open but owned" software ecosystem pioneered by Microsoft and Intel to the landmark decision in United States v. Microsoft which curtailed monopolistic behavior by Microsoft in leveraging one area of software dominance (operating systems) to dominate another one (web browsers).[624] The doubling of internal combustion engine output (400 to 800 hp on 6 liters) and the development of practical high output electric vehicles owe their development to emissions and oil consumption regulations which began with Corporate Average Fuel Economy (CAFE) standards in 1975.[625] And missile technologies and yields are not only built by and for the state, they are constrained by international treaties.

Throughout this project, I have argued that regulation can be good for innovation; that it can move 'beyond the zero' from the costs of regulation to the benefits of regulation for entrepreneurs and innovators. Note that I am not making the important but easier point that regulation has *social* benefits that outweigh its *economic* costs. Instead I am claiming that we must recognize that regulation can have both social and economic benefits. It is certainly true that regulation should not *only* be about economic benefits. But it is also true that regulation should be understood as having both economic costs and economic benefits to complement the full range of social costs and social benefits. The range should, metaphorically, extend not from zero to negative infinity (costs only) but from negative infinity to positive infinity. We can represent this relationship graphically as Table 41:

Table 41: Four Potential Realms of Socioeconomic Regulation

Social \ Economic	Costs	Benefits
Benefits	(B) *Technology-Based Regulation*	(A) *Adoption Catalyst* *Beneficial Constraints*
Costs	(C) *Folk Economic Model* *Market Ideological*	(D) *Capture*

★ *The State-as-Venue Imaginary sits precisely at the center, as regulators are here imagined to have no other impact than simply to convene the social stakeholders. See Chapter 2 for more details on all imaginaries.*

Certainly regulation can come with costs. In the worst of all possible worlds, we end up with both social costs (negative impacts on the public interest)[626] and economic costs (decreases in economic efficiency, performance, or other metrics). It is precisely this costs-costs world (Box C in Table 41) that the Folk Economic Model imagines is the ordinary and endemic way of doing things that leads it to see regulation as something to be avoided.

More typically, the rhetoric around social and economic regulation tends to center on tradeoffs between social and economic benefits (Boxes B and D in Table 41). In a Technology-

[623] (Watzinger et al. 2020)
[624] See (Kollar-Kotelly 2002) for the United States v. Microsoft decision. See (Borrus and Zysman 1997) for an explanation of the Wintelism system of "open but owned" standards.
[625] (c.f. Vinsel 2019, 221–39; Posch 2014; Austin and Dinan 2005)
[626] While a fraught and contestable concept, the public interest is nevertheless an important part of what government is meant to govern towards. See the discussion at length in the section Regulators, Entrepreneurs, and Innovators in Chapter 1.

Based Regulation world, regulators, entrepreneurs, and innovators tend to see the constraints of regulation as a price that must be paid for a social benefit (e.g. catalytic converters are costly and reduce engine power but are needed to reduce smog). In a Capture world, regulators are seen by entrepreneurs and innovators as providing economic benefits to some firms while distributing costs to others ('picking winners and losers'). This is generally seen as a potential economic benefit (e.g. from protection of infant industries, (c.f. List [1841] 2021)) but at some social cost ('free markets,' 'justice,' 'fairness,' etc.). The ease with which we can identify classical examples of tradeoffs demonstrates that it's not always wrong to see the world through this lens.

However, rarely do regulatory scholars (much less regulators, entrepreneurs, and innovators), focus on the potential for social *and* economic benefits simultaneously (Box A in Table 41). Thus, this project has done so. Beneficial Constraints on autonomous vehicles (chapter 5), Beneficial Constraints on gene editing (chapter 6), and Adoption Catalyst of electronic health records (chapter 7) all live squarely in the benefits-benefits box. They all move beyond the zero in the sense that we can see Table 41 as a classical Cartesian coordinate system where costs are negative numbers and benefits are positive numbers. They also move beyond the zero figuratively in emphasizing the net benefits of regulation rather than focusing on the net costs as the Folk Economic Model would have us do.

This project has demonstrated that the critical fourth quadrant (Box A) of Table 41 is deductively possible and inductively extant. In so doing, it makes three claims which are useful to focus our concluding thoughts. First, that regulatory imaginaries are *plural;* multiple different regulatory imaginaries are conceptually possible and empirically present in actually existing regulation of well-known technologies. Second, regulatory imaginaries are *diverse;* there are meaningful differences in their conceptual specification, expected effect on innovation, and actually observed empirical approaches to innovation regulation design. Third, regulatory imaginaries are *malleable*; different actually existing policies can be drawn from and coproduce different regulatory imaginaries and imaginaries and their intended effects on innovation can be shaped by policy.

These three insights of plurality, diversity, and malleability are key to the question of choice with which we began this project. If regulatory imaginaries were simply technologically determined or tied to long time scale immutable factors such as regimes and histories, then it may not mean much to catalogue and classify their diversity or plurality. But because they are mutable through policy, we are empowered to coproduce and reproduce the relationships we desire between regulators, entrepreneurs, and innovators. At its best, this should embolden regulators and innovators to recruit entrepreneurs into better possible worlds; into better boxes of Table 41. At it's worst, though, we should remain inured against any claims that regulation is, "as a rule,"[627] any one fixed thing such as merely a deadweight loss.

To demonstrate and expand upon these three key insights of plurality, diversity, and mutability, this chapter proceeds as follows. First, I take a step back from my passion for regulation of technological innovation to explain why technological innovation should be *central* to the study of politics rather than seen as an aberration. Next, I review my argument as developed in the introduction, deductively derived in chapter 3, and inductively validated in chapters 5, 6, and 7. Finally, I close by returning to our core questions of choice and moving

[627] Recall that "[a] central thesis of [Stigler's] paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit." (Stigler 1971, 3)

beyond the zero of social and economic costs to the world of social and economic benefits from regulation. But before we dive into the three key insights we can take from this project, a word first on why students of politics should care about technological innovation and its regulation.

WHY SHOULD STUDENTS OF POLITICS CARE ABOUT TECHNOLOGICAL INNOVATION?

While it is far less common than it used to be, the number one question my colleagues often ask me is "How is *this* political science?" The better-behaved among them tend to preface this with some acknowledgement of my knowledge and excitement while the worse-behaved tend to frame my interests as an insult to their own. But whether they are better or worse at framing my interests, many seem convinced that a focus on technology and innovation cannot possibly of central interest to a *political* scientist or even a political economist. Sure, *economists* may dally with technology, but that's not the purview of those of us who choose to study who gets what, when, and how as mediated by power.[628]

Clearly I disagree. Technological innovation should be *central* to a study of politics, not just now and not just in developed countries but especially now and especially in developed countries, because technological innovation is the basis of the radically rising levels of human prosperity[629] which first gave rise to the questions at the center of political science. As our colleagues in political theory can easily remind us, politics certainly existed prior to the industrial revolution. But a politics and political science focused on understanding how we generate, maintain, and distribute abundance is certainly characteristic of the core interests of many political scientists and political economists and is only possible when the technology to generate abundance is invented.

Prior to the industrial revolution, it was not surprising that some people had a little and most people had very little at all.[630] It certainly also was neither just nor good that this was the case, but it critically was not *surprising* or *puzzling*: the people with coercive power could and did take what little there was and reproduced relationships that produced what little that could be produced. This is not to say that everything was universally terrible and pre-industrial societies have nothing to contribute to an understanding of politics. But it is to say that many of the core questions of politics and political science would not have been questions.

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[628] This rhetorical construction draws upon the title of Harold Lasswell's (1936) book *Who Gets What, When, and How.* In order to avoid the disciplinary seduction into seeing all politics through the electoral nexus, I often use this phrase to derive my definition of political issues: political issues are those issues we agree are to important to leave to others to solve for us yet disagree on how to solve them and on what the desirable solution is and are still unwilling to simply step back and leave for others to resolve them for us. This definition of political focuses us on many issues, whether electorally salient at the moment or not, as well as requiring us to take seriously the resources, structures, and pathways which mediate the outcomes of these disputes without artificially limiting ourselves to a small subset of institutions such as elections and legislatures.

[629] The radical increase in material abundance due to the industrial revolution should not be a question, but see the following for but a few good presentations of the facts and figures: (Hobsbawm 1968; Zysman 1983; 1994; Mazzucato 2015; 2021; DeLong 2022)

[630] This sentence might have alternatively read 'some people had a lot and others had very little,' but the pre-industrial world was not characterized by extreme inequality because there just wasn't very much to have. (c.f. DeLong 2022, entire, esp. 2–3)

Modern politics and political science focus on asking and answering questions,[631] and many of those questions ultimately rely on a presumption of technological innovation to really be puzzling. If you are asking questions about development, employment, healthcare, or welfare policy, you are asking questions about the proper and improper allocations of resources around different potential interventions which ultimately rely on technologies for implementation. If you are asking questions at a higher level of abstraction about inequality, equity, and justice, you may be tapping into conversations as old as society itself, but you are talking about them in the context of what is now technologically possible (for both good and ill). If you are asking questions at a higher level of generalization about power, institutions and organization, you are not just heavily influenced in your answers by what is technologically possible[632] but you are also fundamentally talking about social technologies. Our questions are questions, our puzzles are puzzles, because we observe that societies *can* marshal resources to affect outcomes and yet we also observe that they often *do not* do so or do not do so *very well*.

While I am saying that technological innovation should be of central interest to politics and political science, I am not saying that nothing else matters. Of course there are other interesting questions and puzzles out there. I am simply saying that we should not be shocked or appalled that scholars interested in questions of who gets what, when, and how (politics) would be interested in a fundamental social force which shapes what is possible (technological innovation).

ARGUMENT: REGULATORY IMAGINARIES ARE PLURAL, DIVERSE, & MALLEABLE

My central argument throughout has been deceptively simple: regulators have been and can be so much more than merely a deadweight loss to innovation if only innovators and entrepreneurs can be guided past self-limiting imaginaries such as the folk economic model of disruptive innovation. To sustain this argument, I deductively developed and inductively validated a typology of seven regulatory imaginaries of innovation (Table 42). These seven imaginaries span from the Folk Economic Model's predictions of an impediment (or deadweight) of regulation on innovation to the catalytic impact of some regulation to drive innovation beyond the limited imagination of market actors.[633] I this section, I return to the typology in light of the empirical validation to discuss how what we learned about Beneficially Constraining autonomous vehicle regulation (AVs, Chapter 5), Beneficially Constraining gene editing regulation (GEs, Chapter 6), and Adoption Catalyzing electronic health record regulation (EHR,

[631] Yes, I am cognizant that many methodologists prefer to use the term puzzle or problem rather than question. While an important methodological guide, the distinction is less relevant here as the common use of the word question incorporates the puzzling aspect of puzzle and the (re)solution aspect of problem. I will predominantly use the term question, but the reader may substitute puzzle or problem if that is more in fitting with their methodological priors. See (Booth et al. 2016, 33–64) for a methodologically and field agnostic discussion of research questions, research puzzles, and research problems. In fact, Brady and Collier's definition of research problem in the glossary of *Rethinking Social Inquiry* literally defines research problem as "see research question." (Seawright and Collier 2010, 347)

[632] Information technology, for example, radically changes the costs of different forms of organization as well as reinforcing or undermining different institutional structures.

[633] Return to Chapter 3 for the full deductive derivation of the typology. See the inductive validation in Chapters 5, 6, and 7.

Chapter 7) allows us to make three key claims about regulatory imaginaries: that they are plural, diverse, and malleable.

In Chapter 2, I explained how *regulatory imaginaries* of disruptive technological innovation (DTI) are collectively held, publicly performed conceptions of desirable relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. I also explain how the concept of regulatory imaginaries draws on the tradition of ideas, faith, and imagination in political economy scholarship and how employing the concept of sociotechnical imaginaries as defined in STS[634] brings additional clarity to how different conceptions of the relationship between regulation, innovation, and entrepreneurship coproduce disruptive technological innovation.

Chapter 3 moved from what regulatory imaginaries are in general to what they are specifically by developing a typology derived from variables underlying two seminal works on regulation: Stigler's (1971) "The theory of economic regulation," which sees regulation as a coercive tool for private profit, and Streeck's (1997) "Beneficial Constraints," which warns that there is a potential for at least some regulation to have general economic benefits. Stigler's paper, generally credited with originating the concept of regulatory capture,[635] was diluted and broadened by Christensen (1997) into an economic folk model[636] which sees regulation as little more than an impediment to be avoided in order for innovation to occur.[637]

To reconcile Christensen and Stigler's single fixed model with Streeck's call for diverse models, I derived five variables generalizing underlying concepts: relationship, access, driver, outcomes, and effect.[638] The first variable is the *relationship* of regulators to the innovative market being regulated, whether an external rulemaker or internal stakeholder who brings their views and priorities to the table. The second variable is the access that regulators have to *information* about the practices and features of an innovative sector, whether lower or higher than firms in that sector. The third variable is where the *driver* of adoption of the disruptive innovation throughout a regulatory domain comes from, whether from the market or from regulators. The fourth variable is the number of optimal regulatory arrangement *outcomes* which the model believes can result from a regulatory response to disruptive technological innovation, whether a laisses faire zero, a Pareto optimal one, or a socially constructed many. The fifth variable is the *effect* of regulation on innovation within the regulatory domain, whether an impediment, moderator, constrainer, or catalyzer.

From these variables, the first four specify aspects of the regulators role in DTI and thus define an exhaustive typological property space[639] which leads to the various effects of regulation on innovation. These regulatory imaginaries have been organized by the amount they diverge

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[634] (c.f. Jasanoff and Kim 2009; Jasanoff 2015b; 2019)

[635] "A central thesis of this paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit." (Stigler 1971, 3), although as (Carrigan and Coglianese 2015, 277) point out, Stigler did not actually coin the term regulatory capture in this article.

[636] A folk model is a "statement of the common-sense understandings that people use in ordinary life [in contrast with] various "specialized" and "scientific" models." (D'Andrade 1987, 113)

[637] This is best stated as: "regulations are toppled only when disruptive innovators find applications or markets beyond the reach of regulators." (Christensen, Grossman, and Hwang 2009, xlv)

[638] A full discussion of the derivation of these variables from the specific scores in Stigler (1971) and Streeck (1997) may be found in Chapter 3.

[639] (A. L. George and Bennett 2005, 233–62)

Table 42: Complete Typological Property Space of Regulatory Imaginaries

		Constitutive Variables (Independent Variables)				Dependent
Name of Imaginary	**#**	**Relationship**	**Info**	**Driver**	**Outcomes**	**Effect**
Folk Economic Model (Christensen 1997)	1	Rulemaker	Lower	Market	Zero	Impediment
	2	Rulemaker	Lower	Market	One	Impediment
Market Ideological*	3	Rulemaker	Higher	Market	Zero	Impediment
	4	Stakeholder	Higher	Market	Zero	Impediment
State-as-Venue (Skocpol 1985)	5	Rulemaker	Lower	Regulator	Many	Moderator
	6	Stakeholder	Lower	Market	Many	Moderator
	7	Stakeholder	Lower	Regulator	Many	Moderator
Capture (Stigler 1971)	8	Stakeholder	Lower	Market	One	Constrainer
	9	Stakeholder	Lower	Regulator	One	Constrainer
Technology-Based Regulation "Conventional Command and Control" (Malloy 2010)	10	Rulemaker	Higher	Market	One	Constrainer
	11	Rulemaker	Lower	Regulator	One	Constrainer
	12	Stakeholder	Higher	Market	One	Constrainer
Beneficial Constrainer (Streeck 1997)	13	Rulemaker	Higher	Market	Many	Constrainer
	14	Stakeholder	Higher	Market	Many	Constrainer
Adoption Catalyst	15	Rulemaker	Higher	Regulator	Many	Catalyzer
	16	Stakeholder	Higher	Regulator	Many	Catalyzer
	17	Rulemaker	Higher	Regulator	One	Catalyzer
	18	Stakeholder	Higher	Regulator	One	Catalyzer
Trivial	19	*Rulemaker*	*Lower*	*Regulator*	*Zero*	*Impediment*
	20	*Stakeholder*	*Lower*	*Regulator*	*Zero*	*Impediment*
	21	*Rulemaker*	*Lower*	*Market*	*Many*	*Impediment*
	22	*Stakeholder*	*Lower*	*Market*	*Zero*	*Impediment*
Logically Inconsistent	23	~~Rulemaker~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~
	24	~~Stakeholder~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~

* (Henderson and Appelbaum 1992) completed Chalmers Johnson's (1982) 2x2 of market|plan x rational|ideological by defining the idea of "market ideological" which privileges market structures for organizing social and economic interaction beyond efficient cost-benefit tradeoffs due to an ideological preference for market structures over planning. More modern ears are more familiar with the term "market fundamentalism" as popularized by George Soros (1998) although the concept is as old as capitalism itself with well-reasoned critique of it at least as old as Polanyi ([1944] 1957). The modern usage is well explained in (Block and Somers 2014).

from Christensen's (1997) folk theory application of Stigler's (1971) economic model, particularly in the sense that they have a different effect on innovation than the impediment predicted by the folk economic model.

Using this deductive typological theorizing process,[640] I identified seven distinct regulatory imaginaries comprising 18 of the 24 mathematically possible configurations. Of these seven regulatory imaginaries, the Folk Economic Model imaginary, Beneficial Constrainer imaginary, and Adoption Catalyst imaginary were of particular interest because they presented theoretically and empirically interesting variations in the expected effect of regulation on innovation. The

[640] (A. L. George and Bennett 2005, 244)

other four imaginaries are well represented in the literature and do not represent surprising variation.[641] The resulting typological property space may be seen in Table 42.

The first of the three imaginaries core to this project is the Folk Economic Model. Characterized by regulators who consign themselves to be merely rulemakers with low access to information and believe the market provides the drive for adoption thus leaving a single least bad or zero optimal outcome, the Folk Economic Model is the folk theory introduced above which animates many non-regulatory scholars and most laypersons' understanding of regulation.

While it may seem unfair to blame Stigler for the way in which his theory has been reduced to a simple folk understanding of regulation which forgets the complexity of regulatory scholars, identifying and specifying this imaginary is central to this project because it is important to demonstrate that such a folk theory is a self-fulfilling prophecy. If regulators and firms act as if regulators are merely deadweight which must be minimized in order to allow for innovation, then all actors behave to make it so; the folk economic model is the proto regulatory imaginary.

The second core imaginary, Beneficial Constrainer, is characterized by regulators who have higher access to information and believe that there are many possible optimal outcomes but believe that the drive for adoption of an innovation comes from the market. Named for Streeck's (1997) "Beneficial Constraints" this model captures the same key point as Malloy's (2010) 'Alternative Construction' of command and control regulation where regulators know more about the overall shape of the market sector in their regulatory jurisdiction than any of the firms do individually or in the aggregate. Streeck based his concept on empirical observations such as a high minimum wage which forces firms to develop high productivity business models which serve as an engine for economic growth in the long term even if they are against the short term economic interests of managers who would prefer to maintain their low productivity, low wage business models rather than invest in long term growth in productivity.[642] This effect of beneficially constrained short term innovation leading to long term innovation benefits is exactly the sort of innovation success arising from an alternative regulatory imaginary that demonstrates the lie of the totalizing Folk Economic Model.

The third core imaginary, Adoption Catalyst, is characterized by regulators with higher information than firms who believe that regulators drive the spread of an innovation and desire either one or many different optimal regulatory outcomes. Completing the divergence from the Folk Economic Model, these regulators push firms to adopt innovations they otherwise would not. An adoption catalyzing regulator looks to spread a disruptive technological innovation throughout its sectoral jurisdiction. It does so by actively encouraging specific steps which regulated entities should take to transition from one state of play (where the DTI exists at the margins of the sector) to another state of play (where the DTI is pervasive throughout the sector). Identifying and specifying this imaginary is a key theoretical contribution of this typology. More than merely dead weight, more than merely a beneficial guiding hand, these regulators are actively driving innovation in a particular direction beyond the vision of firms under their the regulatory jurisdiction.

Based on the deductive derivation and inductive validation of my typology (Table 1), we can conclude three key points about regulatory imaginaries:

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[641] Six of the 24 configurations were identified as trivial or logically impossible. For details on why this is a feature (rather than a bug) of this deductive typology theory process, see Chapter 3.

[642] (Streeck 1997, 200–201)

1. **Plural:** Multiple different regulatory imaginaries are conceptually possible and empirically present in actually existing regulation of well known technologies.
2. **Diverse:** There are meaningful differences between regulatory imaginaries in their conceptual specification (relationship, information, driver, outcomes), expected effect on innovation, and actually observed empirical approaches to innovation regulation design.
3. **Malleable:** Different actually existing policies can be drawn from and coproduce different regulatory imaginaries; imaginaries and their intended effects on innovation can be shaped by policy and are not dictated by either technological determinism or strict national regulatory cultures.

Although perhaps the most basic of the three points, the fact that regulatory imaginaries are *plural* in both deductive derivation and empirical reality is absolutely critical because it guards against simple assumptions such as Stigler's and Christensen's that regulation, "as a rule,"[643] is any one thing. The most basic support for this fact is that chapters 5,6, and 7 deal with two very different imaginaries: Beneficial Constraints and Adoption Catalyst. Beyond the BayesTV validation in those three chapters, the fact that both imaginaries dealt with in the empirical chapters are *not* the Folk Economic Model imaginary which undergirds the rhetoric of disruptive innovation lends additional credence to the claim that multiple different imaginaries are both logically possible and empirically extant. There are clearly multiple different imaginaries of the desirable relationship between regulators, entrepreneurs, and innovators around disruptive innovation.

Building upon the plural imaginaries, it is critical to recognize that there is meaningful *diversity* in the content, expected effect on innovation, and actually implemented regulatory designs from different regulatory imaginaries. As explained at length in Chapter 3 and summarized above, the four constitutive variables (relationship, information, driver, outcomes) define a meaningfully diverse set of relationships between regulators, entrepreneurs, and innovators (see Table 42). These differences in constitutive variables lead to different predicted effects (the effects variable in Table 42) which can be descriptively named and aligned with regulatory imaginaries both in the literature[644] as well as uncovering the critical model of Adoption Catalyst. In the execution of the BayesTV for each of the empirical cases in chapters 5 (AVs), 6 (GE), and 7 (EHR), we can see that these distinctions between constitutive variables and the effect variable allow us to make distinctions between how likely we would be to see each of the highlighted pieces of empirical evidence were each rival imaginary the true state of the world.[645] Each of the three core imaginaries (Folk Economic Model, Beneficial Constraints, and Adoption Catalyst) have clearly distinct specifications, expectations, and regulatory implementations.

[643] Recall that "[a] central thesis of [Stigler's] paper is that, as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit." (Stigler 1971, 3)

[644] As indicated in the first column of Table 42, the Market Ideological imaginary lines up with (Henderson and Appelbaum 1992), the State-as-Venue imaginary lines up with (Skocpol 1985), and the Technology-Based Regulation imaginary lines up with the conventional construction of command and control regulation from (Malloy 2010). See chapter 3 for further discussion of how these imaginaries match to the literature.

[645] See the summary tables (one for each piece of evidence) in each empirical chapter (Chapters 5,6, and 7) as well as the extensive narrative explanations of the BayesTV reasoning in the related appendices for each empirical chapter (Appendices B, C, and D, respectively).

Finally, building on the established multiple meaningfully diverse imaginaries, we should observe that these differences are due to policy design choices and thus that regulatory imaginaries are *malleable* through policy. Based on the design of the three empirical chapters (holding technology and imaginary constant and looking at two different places, the US and EU), some readers might suspect that there is a form of technological determinism at play. For example, it may seem that because AVs were regulated with Beneficial Constraints in both the US and EU, that means that Beneficial Constraints must be the 'natural' imaginary to regulate this specific technology from. However, if we return to the case narratives in chapter 5, we see that although both the US and EU placed constraints upon AVs, the mechanisms they chose (guidance in the US, type-approval in the EU) were very different. Both were certainly intended to be economically and socially beneficial but prioritized these factors differently.

We can see further evidence of the malleability of imaginaries through policy by the paradoxical cases of gene editing regulation in Chapter 6 where the US and EU both employed the means Beneficial Constraints but towards very different ends. In the US, the technoscientifically shaped process aimed to close of the most dangerous anticipated avenues in order to encourage the development of uncertain but promising positive avenues ultimately leading to gene therapies and GMO products which both save lives and generate billions of dollars of economic activity. This "substantial equivalence" standard met the definition of beneficial within the US context. In the EU, the precautionary principle initially lead to a de facto ban on GE products and the stunting of the burgeoning GE companies following bad publicity around a biology scandal about mad cow disease.[646] The EU later used the precautionary principle to enact a heightened form of review for GE products effectively repealing the de facto ban and replacing it with a higher level of scrutiny that assumed that GE products were inherently different from their non-GE counterparts. The US was thus seen as relatively permissive while the EU was seen as relatively stringent toward GE products and companies *but* both regulatory regimes drew upon the Beneficial Constraints imaginary to create a regulatory regime that constrained regulated entities from certain risky behaviors while encouraging others that were considered beneficial. Critical to our rejection of technological determinism, GE technology led to two very different definitions of beneficial even though it was subjected to (different) constraints in both the US and EU context.

The primary contribution this project makes is the deductively derived and inductively validated typology of regulatory imaginaries (Table 42). Derived from a deconstruction of the underlying variables of two seminal works in regulation scholarship, this typology maps out a range of regulatory imaginaries which demonstrates that they are plural, diverse, and malleable. It can serve as both a bulwark against any claims that, "as a rule," regulation is every just one thing as well as a set of templates which regulators, entrepreneurs, and innovators can draw upon in order to shape more fruitful interactions around technological innovation.

The next natural questions that should be asked are where do these regulatory imaginaries come from and where do they go; in other words their origins and how they shape outcomes. This project has focused exactly in between the pre-enactment legislative and stakeholder battles and the post enactment effects on outcomes to demonstrate the plurality, diversity, and malleability of imaginaries. These three points needed to be made, in a clear and disciplined way

[646] See details of BSE in (D. Vogel 2012, 63–64) and the non-technoscientific but public/social connection to GMOs in (D. Vogel 2012, 75–77). See further discussion about the EU precautionary principle case in chapter 6.

that focuses the loci of contention, because despite claims to the contrary by many scholars (of regulation and otherwise), if you walk in any direction from your office and go into the first shop you find, the owner would be happy to tell you how regulation is such an impediment to their entrepreneurial ideas and innovations they just can't way to bring to their customers.

I, and I hope other scholars, will build on this work to study the outcomes and origins of regulatory imaginaries. In particular, I think a fruitful first step would be to see how the actors who fulfil the three roles (regulators, entrepreneurs, innovators) that are cast into certain proper relationships within a regulatory imaginary agree, disagree, or interpret their roles within the imaginary. I have provided suggestive evidence of some of these possible relationships using the interviews in chapter 5 and chapter 6 but a full treatment would require another project or series of projects. I hope that the typology I have created here and validated with the empirical evidence of the intent of the regulations provides a useful set of hypotheses and framings to begin this work.

CONCLUSION: BEYOND THE ZERO

So we didn't get our jetpacks.[647]

We did get some pretty wonderful and some pretty terrible things in the 60 years since we were promised those jetpacks. But were those things because of regulation or in spite of it? Should we tell a story of the triumph of the market and the subversion of the state? And would that be a triumphant or cautionary tale?

In the words of foxy (political) economists everywhere: "it depends."[648]

As I have argued for the last seven chapters, it depends on the choices we make about how to imagine and institutionalize the 'proper' relationship between regulators, entrepreneurs, and innovators. Should we remain stuck in the Folk Economic Model around disruptive innovation, we lock ourselves into a self-defeating process of antagonism between regulators and entrepreneurs with innovators and innovation left to wither on the sidelines. We may get to tell a tale of the triumph of entrepreneurial heroes over the dastardly incompetence of hapless regulators, but it would be just that, a self-fulfilling prophecy with losers on every side.

As I've demonstrated in Chapters 5, 6, and 7, if we tell a different story and build regulation around that alternative imaginary, we can build a different reality. If we can instead recognize, craft, and coproduce Beneficial Constraints, we have a real chance of encouraging entrepreneurs to innovate toward socially *and economically* beneficial horizons by closing off known dangerous or undesirable short-term cul-de-sacs. If we also recognize, craft, and coproduce Adoption Catalysts, we need no longer lie enthralled to the hope that the market will not fail to spread innovations which have peculiar short-term incentives against their adoption but well established medium and long term social *and economic* benefits. What we determine and enforce as 'proper' is a choice; we must choose wisely.

I argue regulators have been, are now, and can again be so much more than merely a deadweight loss to innovation if only innovators and entrepreneurs can be guided past self-

[647] Jetpacks do exist, "we" didn't get them. See footnote 5.

[648] This is the core proposition of Dani Rodrik's allegory of the fox and the hedgehog as applied to economics: hedgehogs know one thing and shout it loud at every problem ('free market!') while foxes know many often contradictory things and thus always reply "it depends." (Rodrik 2015a, 175)

limiting imaginaries such as the folk economic model of disruptive innovation. To develop this argument, I first introduced the concepts of disruptive innovation, the modern face of innovation, and the Folk Economic Model regulatory imaginary which sustains it.[649] I then specified my argument by presenting the full typological property space[650] of regulatory imaginaries and discussing how we can use it to understand the variety of relationships between regulators, entrepreneurs, and innovators which can lead to better or worse effects on innovation. I then derived and explained my methodological approach of Bayesian Type Validation (BayesTV).[651] Finally, I employed BayesTV in order to inductively verify my typology using three technological cases in the US and EU: autonomous vehicles (AVs), gene editing (GE), and electronic health records (EHR).

Disruptive innovation leads to a folk model, or common everyday understanding, of regulation as a fundamental impediment to innovation. Disruptive innovation is the contemporary face of innovation which judges innovation by its ability to upset or 'disrupt' existing markets, societies, and ways of life (hopefully for the better). As a face of innovation defined by disruption, disruptive innovation thus holds the rules which establish the status quo (regulation) in the lowest possible regard.

However, this Folk Economic Model imaginary is but one of seven possible regulatory imaginaries of the proper relationship between regulators, entrepreneurs, and innovators. *Regulatory imaginaries*, based on the concept of sociotechnical imaginaries,[652] are collectively held, publicly performed conceptions of desirable relationships between regulation and technological innovation which actors believe are (or should be) institutionalized within regulatory agencies. Where the Folk Economic Model imaginary sees regulation as only an impediment to be minimized, the other six imaginaries in Table 42 see other potential effects such as moderation, constraint, and catalyst.

Regulatory imaginaries do not exist in a vacuum; they are coproduced by actors filling three core roles: regulator, entrepreneur, and innovator. Regulator is the role defined by their goal of promoting the public interest.[653] Entrepreneurs are defined by their managerial goals to mediate between the rigid requirements of a technological innovation and the uncertain reality of the social world. Innovators are defined by their technological goals to leverage science and technology into novel devices, processes, and/or applications. Each role must function with the others in order for innovation to happen; how those functions interact is defined by the regulatory imaginary and in turn defines the regulatory imaginary, hence coproduction.

The core contribution of this project is the set of seven deductively derived and inductively validated regulatory imaginaries of disruptive innovation laid out in Table 42. As the name suggests, these regulatory imaginaries are defined from the perspective of the regulator role, but in doing so they specify how entrepreneurs and innovators can and should operate. The

[649] Return to the genealogy of disruptive innovation and regulatory imaginaries in Chapter 2 for a fuller explanation.
[650] The derivation of this typology is fully explained in Chapter 3 and reviewed above in the Argument section of this chapter on page 213.
[651] The specification of the novel method of Bayesian type validation (BayesTV) in both theory and practice is presented in Chapter 4.
[652] (Jasanoff 2015a, 4)
[653] While a fraught and contestable concept, the public interest is nevertheless an important part of what government is meant to govern towards. See the discussion at length in the section "Regulators, Entrepreneurs, and Innovators" in Chapter 1.

relationship constitutive variable specifies whether regulators should remain separate from entrepreneurs and innovators or serve as a stakeholder themselves. The *information* variable specifies whether regulators have higher or lower access to information than entrepreneurs and innovators. The *driver* variable specifies whether entrepreneurs or regulators are driving the adoption of a particular innovation across the relevant sector. The *outcomes* variable specifies whether regulators intend to allow zero, one, or many potential outcomes to arise from the interplay of entrepreneurs and innovators. These seven regulatory imaginaries thus specify seven possible worlds for regulators, entrepreneurs, and innovators to coproduce disruptive innovation.

Critically, this typology and my empirical validation of it also demonstrates that regulatory imaginaries are plural, diverse, and malleable.[654] In presenting three empirical chapters covering multiple imaginaries, I demonstrated that there are plural actually existing imaginaries around well know technologies. In presenting both similarities and differences in the US and EU implementations of regulation for each disruptive technology, I demonstrated that there is meaningful diversity among regulatory imaginaries in conceptual derivation, expected effect on innovation, and empirical implementation. Finally, in the application of BayesTV to the empirical cases as well as the extensive reasoning in Appendices B, C, and D I demonstrated that regulatory imaginaries are malleable through policy. Together, once again, these three properties of regulatory imaginaries return us to the importance of choice because they demonstrate that our choices have meaningfully different effects.

Why might we need a naming of regulatory imaginaries beyond simply the cataloging of diversity? Well, I like clever turns of phrase that invoke imagery: "the golden age lies not behind but ahead of mankind;"[655] the arc of the moral universe is long but it bends toward justice.[656] While I've been told that such turns of phrase are the purview of speech writers, advertisers, and activists, we need good vocabulary in scholarship too. Perceptions shape preferences long before outcomes can create interests, for both scholars and practitioners.[657] This project is an attempt to meet that need for perhaps the most overhyped but under-diversified conversation happening now: the relationship between regulation and disruptive innovation.

If you were an entrepreneur in Silicon Valley, you might think we don't need a book on the relationship between regulation, innovation, and entrepreneurship.

The answer appears simple: as a rule, regulation is bad.[658]

However, without regulation in at least two critical moments, entrepreneurship would not be seen as a coequal pillar with innovation in the Silicon Valley ethos. The first of those moments was the 1956 Consent Decree which forced Bell Labs to license all of its patents (notably including the transistor, the solar cell, and the laser) royalty free rather than develop them inhouse.[659] The second moment was the landmark decision in United States v. Microsoft which

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[654] Return to the Argument section of this chapter for further details (page 213)
[655] (Gerschenkron [1951] 2008, 224)
[656] The quote comes from Dr. Martin Luther King in a speech given at the national Cathedral on March 31, 1968. It became a favorite of President Barack Obama due to the perceptions of hope through adversity, and while it may be a more pessimistic statement in its original formulation by abolitionist minister Theodore Parker in 1853, it has nevertheless been a framing image for two iconic and influential leaders. (see M. D. Smith 2018)
[657] Think no further than the methodological and empirical fads that grip our profession. Return to the section on "Perception" in Chapter 2 for further discussion.
[658] For those of a certain generation, read that in Southpark's Mr. Mackey voice, m'kay.
[659] (Watzinger et al. 2020)

curtailed monopolistic behavior by Microsoft in leveraging one area of software dominance (operating systems) to dominate another one (web browsers).[660] Roughly speaking, these two governance decisions prevented hardware and software monopolies from stifling entrepreneurship and created the space for an entrepreneurial ecosystem.

In these two moments, regulation clearly went 'beyond the zero' from merely minimizing the costs that regulation has upon the economy to clearly creating unequivocal economic benefits. Every hardware firm founded on transistor technology (so every hardware firm) owes its business plan to the space created by the 1956 Consent Degree which forced Bell to license the transistor rather than allowing it to maintain market dominance. Every software firm founded on a set of shared standards and platforms (so nearly every software firm) owes its business plan to the space created by United States v. Microsoft which prevented the original giant tech company from being able to monopolize other emerging types of software. Both decisions clearly crossed from the negative quadrant of costs into the positive quadrant of benefits.

Barrington Moore famously gave us "No bourgeois, no democracy"[661] and scholars have argued ever since about how right or wrong that critical link between capitalism and democracy really was.

In light of these critical market-crafting regulations, and my own empirical work in Chapters 5,6, and 7, let me propose the following:

No Regulation, No Entrepreneurship (and Weaker Innovation).

If that statement is too strong an ending, then let's at least remember to be surprised that regulation gets such a bad name among entrepreneurs in light of the critical role that regulation has played in those two key historical moments and in the three current innovations I used to validate my typology (AV, GE, and EHR). If you then remember nothing else, please at least remember that regulation, as a rule, can be so much more than a dead weight loss on the economy, that it can be *more than mere deadweight*.

[660] (Kollar-Kotelly 2002)
[661] (Moore [1966] 1993, 418)

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APPENDIX A: SPECIFIC BAYESIAN TYPE VALIDATION EVIDENCE SELECTION AND ANALYSIS CRITERIA FOR THIS PROJECT

The following table provides a schematic layout of how to execute a Bayesian Type Validation in this project. Note that while it is possible to convert decibel weights of evidence (WoE) to probabilities, and the math to do so is presented below, there is no real purpose in doing so as the comparisons on probabilistic terms are far less meaningful and comparable than the log odds decibel WoE.

Table 43: Search Process for Incorporating Evidence into Bayesian Type Validation (BayesTV)

Step	Description	Goal	Examples
0	Priors	Lay out possible priors (in decibels) for how likely each type is to be the true state of the world. As this is type validation, we must also identify the most likely type ($Type_{ML}$) which will be our comparative referent throughout this process. [662]	• Naïve (0 dB for all) • Background Information (30 dB in favor of each reasonable alternative to $Type_{ML}$) • Skeptic (60 dB in favor of every type except $Type_{ML}$)
1	Select Initial Piece of Evidence (E_1)	Select piece of evidence that appears to most strongly favor the most likely type	• Preamble to Legislation • Preamble to Final Rule
1.1	Justify the How Likely E_1 is to be observed in the world of the Most Likely Type ($Type_{ML}$)	Assuming that the suspected type is the true state of the world, justify how likely one would be to observe E_1. This generally draws upon the constitutive variables of the typology for $Type_{ML}$ as well as the case background narrative.	A narrative prose of several paragraphs reasoning through why E_1 is likely to be seen in $Type_{ML}$ as well as how likely that would be (e.g. very, moderately, etc). Decibels are not assigned as they require a comparator

[662] Since BayesTV is concerned with type validation, cases are selected using background information to be representative of a particular type. This is *not* a form of confirmation bias as the disciplined consideration of the likelihood of observing this evidence under *all* alternative types clearly and transparently presents the judgements made by the analyst. While a skeptic could certainly disagree with such judgment, the goal of a logical Bayesian approach is to clearly identify the "locus of contention" (Fairfield and Charman 2017, 16) rather than claim to be beyond contention or to set up an "entirely agree vs. entirely disagree" dichotomy. Where a transparent frequentist would rely upon preregistration of hypotheses and appeal to stochastic analysis to reject or fail to reject a null hypothesis, a Bayesian approach instead seeks to transparently state priors and indicate how evidence is used to update those priors.(Fairfield and Charman 2017, 1,6) The author and reader may ultimately disagree with the conclusions of a logical Bayesian analysis but both should be able to clearly state precisely where they disagree (evidence selection, likelihood ratios, missing hypotheses/theories in the set, etc.) rather than rely on less precise statements of agreement or disagreement based on sum total statements or reverse-engineering of an argument.

1.2.1	Assess Weight of Evidence (WOE) for E_1 based on the comparison of the most likely type to <u>each of</u> the other types in typology	Using the Decibel reference sounds, assess how much quieter E_1 speaks for the type in question ($Type_i$) relative to the most likely type ($Type_{ML}$)	• 3 dB – Smallest discernable difference • 6 dB – Weak • 10 dB – Moderate • 20 dB – Strong • 30 dB – Very Strong
1.2.1a	(Optional, not recommended)[663] Calculate absolute likelihood of seeing E_1 given all other types	WOE in decibels can be converted to absolute probability of observing E_1 for $Type_i$ using: $$P(E_1\|Type_i) = \frac{P(E_1\|Type_{ML})}{10^{\frac{WOE_1}{10}}}$$	• 30dB with 80% initial probability leads to $Type_i$ probability of 0.08% probability
1.2.2	Tabulate the overall Weight of Evidence for $Type_{ML}$ compared to	Gather each of the likelihood ratios (in dB) from the comparisons into a chart which includes all of the possible type pairs between the most likely type ($Type_{ML}$) and the other types.	*A list of n likelihood ratios where n = total number of types – 1* *each row is labeled as:* $$\frac{Type_{ML}}{Type_i}$$ *for all types, i-end.*
2	Select 2nd Piece of Evidence (E_2)	Based on the result of Step 1, select the piece of evidence which most strongly supports the nearest rival type ($Type_{NR}$) to the most likely type ($Type_{ML}$) which was used to select evidence in Step 1.	*Depends heavily on specifics of typology and case* • Key Feature of legislation which seems against $Type_{ML}$ • Key feature of regulation which seems against $Type_{ML}$

[663] While it is possible to convert decibel comparisons mathematically to probability percentages, the ontological truth behind a Bayesian comparison and a frequentist absolute probability are different (Fairfield and Charman 2022, 162, footnote 34). This formula is provided merely for completeness for the curious. Logical Bayesians reasoning is done in decibels for a reason (because it better represents human sense perception) and they should be kept in decibels until converted back into prose. See Chapter 4 for extensive explanation of Bayesian Type Validation, its rationale, and its application.

2.1	Reason about how likely E_2 is to be observed in the world of the Most Likely Type ($Type_{ML}$)	Assuming that the most likely type is the true state of the world, discuss how likely one would be to observe E_2. Since we must also condition on other evidence, this percentage should be chosen WITH RESPECT TO the likelihood in 1.1 as well. Note too, that this this evidence may be rather surprising in $Type_{ML}$ as E_2 was selected to be most likely under $Type_{NR}$ not $Type_{ML}$	A narrative prose of several paragraphs reasoning through why E_2 is likely to be seen in $Type_{ML}$ as well as how likely that would be (e.g. very, moderately, etc). Decibels are not assigned as they require a comparator
2.2.1	Assess Weight of Evidence (WOE) for E_2 based on the comparison of $Type_{ML}$ to <u>each of</u> the other types in typology	Using the Decibel reference sounds, assess how much <u>quieter</u> E_2 speaks for the type in question ($Type_i$) relative to the most likely type ($Type_{ML}$). Since reference is to $Type_{ML}$, if the evidence speaks more loudly to $Type_i$ then the decibels would be *negative*. We expect to see at least one such case since E_2 was selected to correspond with $Type_{NR}$ over $Type_{ML}$	• 3 dB – Smallest discernable difference • 6 dB – Weak • 10 dB – Moderate • 20 dB – Strong • 30 dB – Very Strong
2.2.1a	(Optional, not recommended)[664] Calculate absolute likelihood of seeing E_2 given all other types	WOE in decibels can be converted to absolute probability of observing E_1 for $Type_i$ using: $$P(E_2\|Type_i) = \frac{P(E_2\|Type_{ML})}{10^{\frac{WOE_2}{10}}}$$	• 30dB with 80% initial probability leads to $Type_i$ probability of 0.08% probability
2.2.2	Tabulate the overall Weight of Evidence for $Type_{ML}$ compared to	Add each of WOE_2 likelihood ratios (in dB) from the comparisons to the chart from 1.2.2 which includes all of the possible type pairs between the most likely type ($Type_{ML}$) and the other types.	*A list of n likelihood ratios where n = total number of types – 1.* *Each row is labeled as:* $$\frac{Type_{ML}}{Type_i}$$ *for all types, i-end.*

[664] See footnote 663

…	Consider if more evidence is needed	Repeat steps 2-2.2.2 for additional evidence if there are still near rivals. Consider if there is evidence for a "black swan" event; evidence that the most likely type which led to this case being selected was in fact exceptionally wrong. Write out this counterfactual and then consider if there is evidence for it Decision criteria should include whether current evidence adequately updates all priors as well as what level of informativeness is needed to satisfactorily conclude the analysis (in dB with referents; i.e. is a typical conversation or an alarm clock needed to be confident in type classification?)	*As above*
3	Overall Weight of Evidence	Add summary column to Weight of Evidence table from 2.2.2 which tabulates across all the evidence for each likelihood ratio	*Add the decibels across the rows*
3.1	Describe the Overall Weight Narratively	Using the decibel referents, interpret the overall weight of evidence for the likelihood ratio comparisons to the most likely type.	*If the sum is 60db for* $\frac{Type_{ML}}{Type_i}$*:* "With an overall weight of 60 dB, the evidence lends a typical conversational level of support for the most likely type over $Type_i$."

4	Sensitivity Analysis (Updating Priors)	Take the overall weight of evidence from 3 and add it to each of the priors to calculate the posterior (all in decibels)	*A list of n likelihood ratios where n = total number of types – 1.* *Each row is labeled as:* $\frac{Type_{ML}}{Type_i}$ *for all types, i-end.* *A pair of columns for each set of priors, one for the prior (in dB) and one for the posterior (in dB)*
4.1	Describe the sensitivity to priors narratively	Using the new table created in 4, interpret the decibel posteriors in light of the decibel priors using the decibel referents	*For Background Information priors for* $Type_i$ *and if the sum is 60db for* $\frac{Type_{ML}}{Type_i}$*:* "If you entered this analysis with a background understanding that $Type_i$ was a reasonable alternative to the most likely type, then you should leave with a quiet room's level of information in favor of the most likely type. While not conclusive, this should put you with reasonable confidence that the most likely type is more likely the true state of the world than $Type_i$.

APPENDIX B: SUPPLEMENT TO CHAPTER 5 – EXPLICIT BAYESIAN TYPE VALIDATION (BAYESTV) OF HOW CONFIDENT CAN WE BE THAT PERPETUAL GUIDANCE IN THE US AND REGULATION (EU) 2022/1426 REPRESENT A BENEFICIAL CONSTRAINTS IMAGINARY FOR AUTONOMOUS VEHICLES REGULATION

Based on the historical narratives above, the US and EU enactment of constraints on AVs which were considered beneficial by their constituencies suggest that AVs are a good illustrative case for the Beneficial Constraints regulatory imaginary applied to a disruptive technology in a well-established regulatory regime. However, we need not simply rely on asserting this judgment, we can place boundaries on our degree of confidence. Thus, as the illustrative case for Beneficial Constraints in which technological innovation disrupts an established market and regulatory regime, AV is subjected in this section to a Bayesian Type Validation (BayesTV) in order to demonstrate how confident we can be that it does, indeed, represent a distinctive regulatory imaginary of disruptive innovation.[665] This appendix briefly reviews what BayesTV is and then explains how it was applied to AVs in the US (Perpetual Guidance, 2016 to Present) and the EU (Regulation (EU) 2022/1426) cases by first discussing relevant priors, then analyzing the weight of statutory intent and near rival evidence, characterize potential black swan evidence, and then concludes with a final type classification and sensitivity to priors.[666] It concludes by explaining that, for any reasonable set of priors, we can be meaningfully to decisively confident that AV regulation is indeed a case of Beneficial Constraints while also identifying the specific loci of contention where the reader can evaluate their level of agreement or departure from this conclusion.

BAYESIAN TYPE VALIDATION (BAYESTV): AN OVERVIEW

As explained in chapter 4, this project employs a new method called Bayesian Type Validation (BayesTV). BayesTV combines two gold-standard pillars of qualitative methodology, process tracing and typological theory, to produce a completely qualitative method of theory development and testing. While excellent qualitative work has always included theory development and theory testing, the logic of how qualitative theory building works has often been the target of incredulous skeptics. BayesTV uses the deductive logic of typological theory to complement the inductive logic of Bayesian process tracing (BayesPT)[667] to produce a disciplined and clear method of analyzing evidence and communicating results. This section briefly reviews how BayesTV operates in practice before it is applied to the evidence in this case.

To efficiently classify cases and refine the deductive typology, BayesTV incorporates a search process that focuses on the most informative pieces of evidence. The first piece of evidence explicitly[668] analyzed for a case should be the strongest piece of support for the most

[665] See Chapter 4 for a full explanation of Bayesian Type Validation, particularly the sections on BayesTV in Practice for an explanation of how the analysis in this section was performed.
[666] The full explicit application of BayesTV for the AV cases may be found in Appendix B.
[667] (Fairfield and Charman 2017; 2022)
[668] Explicit Bayesian analysis (whether process tracing of hypotheses or validation of types) refers to the use of mathematical likelihood ratios as developed in (Fairfield and Charman 2017) and refined in (Fairfield and Charman 2022). Implicitly, all process tracing and most qualitative research can be described as a Bayesian method of

likely type based on background knowledge of the case.[669] The second piece of evidence should be selected as the strongest piece of support for the nearest rival to the most likely type based on background knowledge of the case *and* analysis of the first piece of evidence. Once the first two pieces of evidence have been explicitly analyzed, BayesTV considers whether additional evidence needs to be analyzed based on the possible priors (naïve, skeptical, etc.) and how loudly the first two pieces of evidence have adjudicated between the possible types. The extreme counterfactual state of the world is also considered and evidence for such a "black swan" event is described and sought. Once the analyst is satisfied that sufficient explicit evidence has been analyzed to build a type validation case, the weight of the evidence is placed against defined sets of priors in order to identify the sensitivity of the classification to a reader's prior beliefs about the world.

As a process of search built on highlighting the most informative pieces of evidence, BayesTV (and all logical Bayesianism) relies on the *information value* of evidence rather than the idiosyncrasies of a specific piece of evidence. While specific pieces of evidence are presented below, they are analyzed as a representative of all "informationally equivalent"[670] evidence which provides insight into the relative likelihood of which type is the true state of the world. Thus, what may appear to be a selective reification of evidence is actually a carefully considered process of which evidence to highlight in the explicit analysis in order to distinguish between possible states of the world in a clear and disciplined manner.

In metaphorical terms, the goal of BayesTV is not to cut a node out of its web of interconnections and carefully study its nodal properties under a microscope but rather to carefully consider which node to lift from a web in order to trace the interconnections. The goal is always to pull on the node which reveals the most information about the web rather than to find the most perfect individual node.

This focus on information value may appear unsettling to traditional qualitative scholars who emphasize the richness of evidence presented in their case narrative built upon deep case knowledge[671] to judge the effectiveness of an argument. Indeed, it may seem like cherry picking only one or two pieces of self-justificatory evidence!

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reasoning.(Fairfield and Charman 2017, 1–2) The choice of 'how explicit to get' is a tradeoff between exhaustive transparency and laboriousness which should be decided on how informative additional explicit analysis would be as opposed to an implicit summary of the weight of evidence.

[669] Since BayesTV is concerned with type validation, cases are selected using background information to be representative of a particular type. This is *not* a form of confirmation bias as the disciplined consideration of the likelihood of observing this evidence under *all* alternative types clearly and transparently presents the judgements made by the analyst. While a skeptic could certainly disagree with such judgment, the goal of a logical Bayesian approach is to clearly identify the "locus of contention" (Fairfield and Charman 2017, 16) rather than claim to be beyond contention or to set up an "entirely agree vs. entirely disagree" dichotomy. Where a transparent frequentist would rely upon preregistration of hypotheses and appeal to stochastic analysis to reject or fail to reject a null hypothesis, a Bayesian approach instead seeks to transparently state priors and indicate how evidence is used to update those priors.(Fairfield and Charman 2017, 1,6) The author and reader may ultimately disagree with the conclusions of a logical Bayesian analysis but both should be able to clearly state precisely where they disagree (evidence selection, likelihood ratios, missing hypotheses/theories in the set, etc.) rather than rely on less precise statements of agreement or disagreement based on sum total statements or reverse-engineering of an argument.

[670] (Fairfield and Charman 2017, 5 in Online Appendix)

[671] C.f. (Johnston 2012, 70) and "the importance of local or area knowledge for general theory."

However, as qualitativists have long pointed out to quantitativists when accused of selecting on the dependent variable or having too many variables for too few cases, one cannot naïvely apply frequentist statistical intuition to qualitative work.[672] While other qualitative methods such as analytical narratives and comparative historical analysis place their empirical richness directly into the text of their research reports to demonstrate analytic rigor, BayesTV uses deep case knowledge to rigorously highlight the most informative evidence in their research reports. Akin to Charles Proteus Steinmetz, who was hired by Henry Ford to fix a generator and invoiced $10,000 for a single chalk X and two lines of instructions, only a small bit of evidence may appear in the final writeup ('$0.01 of chalk') but the expertise and deep case knowledge lies in knowing which piece to highlight to maximize information value ('$9,999.99 for knowing where to place the X').[673]

Building on deductive typological theory and the inductive logic of logical Bayesian process tracing, Bayesian Type Validation (BayesTV) employs a disciplined process of search for informative evidence in order to provide transparently produced degrees of belief in whether a particular case is most plausibly operating under a particular type rather than the rival types. In this project, this translates into degrees of belief about whether regulators are truly operating under one type of regulatory imaginary (e.g. folk economic constrainer) or another (e.g. beneficial constraint, adoption catalyst, etc.). As the goal of this project is to inductively refine the deductive typology developed in Chapter 3, BayesTV is well suited to demonstrating how confident we can be that real empirical examples exist of the variety of ways that regulators, entrepreneur, and innovators co-create disruptive technological innovation.

POSSIBLE TYPES AND PRIORS

The possible regulatory imaginaries which the AV case could assume are detailed in the deductive typology developed in Chapter 3 and presented in Table 5 in that chapter. From the deductive typology and the reasoning in Chapter 2, we have seven distinct types which are plausible: the Folk Economic Model, Market Ideological, State-as-Venue, Capture, Technology-Based Regulation, Beneficial Constrainer, and Adoption Catalyst. These seven models present the rival worlds under which BayesTV must evaluate the evidence in order to conclude which model the evidence speaks most strongly for.[674]

We can assign several possible prior probabilities to the case being of a particular type.[675] If we are to adopt a *naïve* assumption, we would weight all seven imaginaries equally with no weight-of-evidence (WoE) for any of them (0 dB across all imaginaries, see Table 44). If,

[672] Compare the logic of (Brady and Collier 2010) to that in (Gary King, Keohane, and Verba 1994). A concise review of the struggles of quantitativists to grapple with qualitative evidentiary standards appears in (Fairfield and Charman 2022, 124–26).

[673] (Gilbert King 2011)

[674] (Fairfield and Charman 2017, 1,10)

[675] Following the advice of (Fairfield and Charman 2017, 3-4 in online appendix). This paragraph presents extremes and a paradigmatic midpoint. The reader could adopt whatever priors she sees fit, but it is most instructive to think in classes of priors rather than a continuum because we can then concentrate on tipping points. Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival..

Table 44: Prior Weights of Evidence for the Coordinated Framework and Precautionary Principle (in dB)

Weight of Evidence (WoE)*	Naïve	Background Info	Skeptical
$\frac{\textbf{Beneficial Constraints}}{\textbf{Adoption Catalyst}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Capture}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Technology Based Regulation}}$	0 dB	-10 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{State as Venue}}$	0 dB	-20 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Folk Economic Model}}$	0 dB	0 dB	-50 dB
$\frac{\textbf{Beneficial Constraints}}{\textbf{Market Ideological}}$	0 dB	-10 dB	-50 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

instead, we use *common background information* about the AV cases, we might be led to believe that the State-as-Venue model is more likely given explicit reliance on technical specifications and classifications by the Society of Automotive Engineers in defining what AVs are as discussed in the "What are AVs and Why are They Disruptive" section of this chapter. Additionally, if we refer to the *case-specific background knowledge* in each case narrative, the USDOT's stated desire to "[act] as a convener and facilitator"[676] makes the State-as-Venue imaginary more likely in the US case. At the extreme, the USDOT desire under the Trump Administration to excessively promulgate the voluntary nature of the already voluntary guidance documents may lead us to think that the Market Ideological model is at work because of the repeated invocations of the dynamism of the private sector and the need to remove burdensome regulations. In the EU case, the narrative suggests that we might expect Technology-Based Regulation to be more likely because the EU went directly to type-approval, a step the USDOT considered to be overly constraining and technologically limiting.[677] We can represent each of these background information-based priors by placing a moderate amount of evidence (10 dB) against Beneficial Constraints for each of the three relevant comparisons in Table 44.[678]

Finally, to satisfy a frequentist logic to wrap up all objections in a weight against the model of interest, we may adopt a strong *skeptic*'s approach which would put a strong disadvantage to the Beneficial Constraints imaginary because it is the focus of this chapter and then equally

[676] (USDOT 2022)
[677] (USDOT 2018, ix)
[678] note that State-as-Venue gets two portions of counterweight as we might hold a prior about it for both common and case specific reasons.

weight each of the other models. Following Fairfield and Charman's (2022, 133) advice, "a very high prior log-odds in favor of a well-established hypothesis relative to a far less plausible rival might reasonably be set at around 50 dB."[679] Thus, we represent the strong skeptic's position by placing 50 dB against Beneficial Constraints for each of the comparisons in Table 44.

Based on the title of this chapter and discussion so far, it should not surprise the reader that my prior is that AV regulation is a characteristic Beneficial Constraints case for a disruptive technology introduced into a highly developed sector with a highly developed regulatory regime.[680] To state this precisely, it should be noted that each row in Table 5 can be read as a sentence[681] and thus the Beneficial Constrainer would read as follows: a regulator following the Beneficial Constraints model has *higher* access to *information* than firms, believes that the *market* is the *driver* for the spread of an innovation and would be content with *many* different optimal regulatory *outcomes*. Put plainly, a beneficially constraining regulator is defined by careful negation: they identify certain undesirable practices or outcomes and place constraints on regulated firms which are intended not just to reduce harm but to spur innovation towards *undefined desirable* practices and outcomes and away from *defined undesirable* ones. Critically, these constraints are not simply beneficial to society (as regulation generally is intended to be) but are also beneficial to the regulated firms; this form of regulation seeks not to curb the excesses of the market but instead to direct the dynamism of the market toward more economic (and socially) beneficial outcomes.[682] The presentation of evidence below in the execution of BayesTV is meant to give the reader, whatever their priors, an updated belief in whether or not this paragraph is the most plausible state of the world in the two AV cases.

While priors are a vital part of Bayesian reasoning, the most important analysis in logical Bayesianism at the heart of BayesTV is the *sensitivity*[683] of the results to the priors rather than choosing precise priors before the analysis. For type validation, we are interested in how confident we can be that a particular case fits a particular type rather than weighing between plausible hypotheses. For that reason, while the author is likely to have a strong prior for one type (the type being validated) and the reader may have indifferent (naïve) or strongly contrarian (skeptical) priors, what matters is how loudly the evidence needs to speak to convince different types of readers. Thus, we will return to the discussion of priors in the conclusion of this section (Final Type Classification and Sensitivity to Priors). For now, the reader should file away what regulatory imaginary she thinks best fits the AV cases and concentrate on the reasoning behind the weights of evidence presented below.

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[679] Note that Fairfield & Charman propose this threshold for non-arbitrary reasons; they cite Bayesian mathematician Jaynes (2003, 99–100) as the origin of 50dB based on mathematical logic of probability thresholds used in quantitative work.

[680] See the next chapter on GE editing regulation for a case of Beneficial Constraints of a disruptive technology introduced into a as-yet undefined regulatory regime and market sector.

[681] This is a result of the consistency of a deductive typology, discussed in detail in Chapter 3. Note that in that discussion the grammar of the sentence is exactly consistent for all 24 lines in Table 1 while in this chapter I have simplified the grammar to highlight the defining features of the Beneficial Constraints type.

[682] If capitalism is about creative destruction, as Schumpeter ([1943] 2010, 93–94) famously claimed, the beneficial constrainer seeks not to reduce the destruction but instead focus it on destroying current problems while finding creative solutions which are both economically productive and socially beneficial beyond the narrow dictates and time horizon of current market forces.

[683] (Fairfield and Charman 2017)

BAYESTV OF AVS IN THE US PERPETUAL GUIDANCE AND EU REGULATION (EU) 2022/1426

In validating that autonomous vehicles are an example of the Beneficial Constraints regulatory imaginary, the key constituent variables are information, driver, and outcomes. A Beneficial Constraint conception of innovation regulation is defined by a regulator who is conceived as having higher access to information about a regulated domain combined with a belief that the market is the driver of adoption and who is content with many definitions of "optimal" outcomes rather than a single definition of optimality. The two following sections on each of the empirical AV cases will present evidence to update our belief in whether that is the most likely conception of regulators within each case. The evidence will focus on statements within the legislation or made by the regulators who implemented the regulations and how likely they are to be observed in the seven rival states of the world (see Table 1).

Following the advice of Fairfield and Charman (2022, 124–70), the weights of evidence are determined qualitatively but consistently through six paired comparisons of types (most likely vs. each of the six rivals) with the evidence evaluated in the order most logically coherent to the analyst. Note that because it *mathematically* does not matter in what order we incorporate evidence, we can choose the order most logical to the *substantive* comparisons at hand.[684] We can also reduce the number of comparisons by recognizing that *mathematically* a paired comparison of the six rival types against the same type is equivalent to comparing each of the rival types to each other.[685] Thus, we need only six total comparisons in order to consider all possible pairs and we are free to pick which type will be the comparator for all six rivals based on the *substance* of the case.

In their application of logical Bayesianism to social inquiry, Fairfield and Charman (2022, 129–36, esp. p.134) recommend that paired comparisons of types should be assigned weights of evidence (WoEs) in decibels (dB) based on a plain language description of relative differences. While earlier approaches relied on an auditory metaphor of "how loudly the data is speaking,"[686] the final specification recommends a generalized use of the logarithmic decibel (dB) scale to match the logarithmic nature of human sense perception without a reliance on a particular sense metaphor.[687] In keeping with the intuitive human sense perception metaphor, the lower bound for discernable differences is set at 3 dB ("smallest meaningful difference," "very weak," 2:1) while the upper bound is set at 30 dB ("eight times louder," "very strong," 1000:1). A set of qualitative-to-quantitative reference levels, their perceptual references, a natural language description of the relationship, as well as the corresponding odds or likelihood ratios is reproduced from (Fairfield and Charman 2022, 133) in Table 45.

Table 46 provides a summary of the weight of each of the pieces of evidence. The reasoning behind these weights of evidence is summarized in the sections which follow while the full explicit BayesTV analysis may be found in the Appendix. The possible contours of

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[684] We can also redo our analysis with the evidence in a different order as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 139–40)

[685] We can also redo our analysis with different comparator type as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 140–42)

[686] (Fairfield and Charman 2017, esp. p.6 in online appendix)

[687] Both the senses of sight and sound, for example, evolved logarithmically in humans; a tenfold increase in absolute light power or sound intensity is perceived as a doubling in "brightness" or "loudness" by human senses. See (Fairfield and Charman 2022, 129–30) for further explanation of the appropriateness of the logarithmic scale across the physical, biological, and social sciences.

Table 45: Qualitative-to-Quantitative Reference Levels for the decibel (dB) Comparison Scale

dB	Acoustic Perception	Plain Language Description	Equivalent Odds or Likelihood Ratio (approx.)
3	Smallest meaningful difference	Very weak	2:1
6	Clearly noticeable difference	Weak	4:1
10	Twice as loud	Moderate	10:1
20	Four times louder	Strong	100:1
30	Eight times louder	Very Strong	1000:1

Based on (Fairfield and Charman 2022, 133, Table 4.1), Note: Some digital audio files that illustrate these different decibel levels are available at: https://tashafairfield.wixsite.com/home/bayes-book

Table 46: Weights of Evidence for the Perpetual Guidance and Regulation (EU) 2022/1426 (in dB)

Weight of Evidence (WoE)*	Initial Evidence		Near Rival Evidence	
	US $E_{4\text{-Principles}}$	EU $E_{\text{Type-Approval}}$	US $E_{\text{Non-Regulatory}}$	EU $E_{\text{Recital Qualification}}$
$\frac{\textit{Beneficial Constraints}}{\textit{Adoption Catalyst}}$	20 dB	20 dB	40 dB	10 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Capture}}$	30 dB	30 dB	20 dB	30 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Technology Based Regulation}}$	40 dB	40 dB	30 dB	60 dB
$\frac{\textit{Beneficial Constraints}}{\textit{State as Venue}}$	10 dB	60 dB	0 dB[688]	10 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Folk Economic Model}}$	37 dB	40 dB	20 dB	40 dB
$\frac{\textit{Beneficial Constraints}}{\textit{Market Ideological}}$	16 dB	60 dB	10 dB	60 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically $(-\infty,\infty)$ although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

[688] See the extensive reasoning in the Weight of $E_{\text{Non-Regualtory}}$ below (page 116) as well as Appendix B on pages 269 to 276

counterfactual evidence is explicitly defined after the analysis of the actually-existing evidence. The final interpretation and comparison with priors occurs in Table 52 on page 280.

INITIAL EVIDENCE: STATUTORY INTENT

The first piece of evidence highlighted for each case is based on the highest likelihood to correspond with the Beneficial Constraints model. As the GE cases were selected in order to validate the Beneficial Constraints model, their overarching statements of legislative intent shall be used to make the initial case for Beneficial Constraints over rival types as the most probable state of the world. In the US case, this evidence comes not from legislation but from regulator action in lieu of legislation: four matched principles from the Executive Summaries of the FAVP 2016 and AV 2.0 2017. In the EU case, this evidence comes from Regulation (EU) 2022/1426 where the European Commission and Council crafted a regulation which added a specific type-approval process for AVs to the vehicle code. The following sections discuss each of these two pieces of statutory intent evidence in turn.

Perpetual Guidance in the United States (2016-present)

While the BayesTV method recommends highlighting statutory intent from the enacting legislation as the initial evidence, the US regulation of AV technology has not been crafted through legislation. Rather, the US Department of Transportation (USDOT) issued a successive series of guidance documents indicating their jurisdiction to govern AVs under existing statutory authority while reserving the right to enact new rules as needed.[689] Since the first piece of evidence should capture the most informative statement of the intent of the ultimate statutory authority for the regulatory action, the following paired comparison between the principles of FAVP in 2016 from the Obama Administration and the supposed departure represented by AV 2.0 in 2017 from the Trump Administration serves to illustrated the consistent strain of guidance issued through this series of guidance documents.[690] This statement of statutory intent states:

Table 47: Specification of $E_{4\text{-principles}}$

#	**Federal Automated Vehicle Policy (FAVP)** (NHTSA 2016)	**Automated Driving Systems 2.0: A Vision for Safety (AV 2.0)** (NHTSA 2017)
1	Vehicle performance guidance for Automated Vehicles	Section 1: Voluntary Guidance on ADS Safety Elements (p.1-16 of 24)
2	Model State Policy	Section 2: Technical Assistance to States
3	NHTSA's Current Regulatory Tools	"NHTSA's enforcement authority… extends and applies equally to current and emerging ADSs [aka AVs]." (p. 3)
4	New Tools and Authorities	"laws and regulations will inevitably change over time" (p15)

[689] (NHTSA 2016; 2017; USDOT 2018; NSTC and USDOT 2020; USDOT 2021)

[690] The reasoning behind this pairing between these two documents by different administrations from different political parties is explained above in the US case narrative section on page 95

The explicit Bayesian type validation (BayesTV) of $E_{4\text{-principles}}$ for each of the regulatory imaginaries in Table 1 is presented in the following sections and summarized in Table 18 in the main text (repeated as Table 48 below).

Justification for $E_{4\text{-principles}}$ as Evidence for the Most Likely Type (Beneficial Constraints)

In a world where USDOT and its daughter agency NHTSA were truly operating from a Beneficial Constraints imaginary of regulation, these set of consistent principles from two different administrations would be very likely to be observed. Both specifications (FAVP and AV 2.0) lay out clear guidance on how to pursue the desirable safety gains of AVs (principle 1) while also endorsing the importance of allowing private sector innovation to drive the exact development of the direction of the technology.[691] Both also place clear explicit constraints (principles 3 and 4) as well as the implicit constraints of the performance guidance.

With regard to access to information, USDOT & NHTSA are providing these guidance documents is clearly expressing that while there may be many unknowns about the eventual development of the technology, USDOT & NHTSA have a great deal of access to expertise, more than both states (as shown in principle 2) and than any individual private sector form (as shown by the extensive technical guidance in principle 1).[692]

With regard to whether the market drives innovation, both FAVP and AV 2.0 are clear that the market *is* driving adoption of prototype AV technologies *and that this is a desirable thing* because AVs have the potential to greatly increase road safety. Both FAVP and AV 2.0 cite the figure that 94% of road crashes can be attributed to human error as a motivating factor for encouraging and allowing AV technologies to be adopted.[693] They also both refer to the driving force behind the spread of the innovation being industry actors.[694]

Thus with a strong statement of beneficial, both an explicit and implicit statement of constraints, and an acknowledgement of the many potential desirable outcomes as the technology develops, $E_{4\text{-principles}}$ is most likely in a world where USDOT & NHTSA saw themselves as operating to beneficially constrain AV innovators.

$WoE_{4\text{-principles}}$, Beneficial Constraints vs. Adoption Catalyst = 20 dB

In the world of Adoption Catalyst, this evidence would be quite surprising because it relies on the market rather than regulators to drive the adoption of the innovation (Driver Variable). The key distinguishing variable between Beneficial Constraints and Adoption Catalyst is this incentive/punishment based program to drive adoption beyond the imagination of the market. In fact, even in the FAVP from the Obama administration where we might expect proactive government action to drive adoption of this key safety technology ("94 percent of crashes can be tied to a human choice or error"[695]), the 4 principles are guidance, model state policy, 'current rules still apply,' and 'new rules may be needed but we aren't there yet.' This hesitancy and deference to market driven spread of an innovation is strongly more consistent with Beneficial Constraints than with Adoption Catalyst, hence 20 dB.

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[691] (NHTSA 2017, c.f. i and ii), (NHTSA 2016, 3, references to industry appear throughout)
[692] There are 26 pages of technical guidance (25.7% % of total substantive document) in FAVP and 16 pages of technical guidance (66% of total substantive document) in AV 2.0.
[693] (NHTSA 2016, 5; 2017, i)
[694] (NHTSA 2016, 5; 2017, ii)
[695] (NHTSA 2016, 5 citing Singh 2015)

$WoE_{4\text{-}principles}$, Beneficial Constraints vs. Capture = 30 dB

The key conceptual distinction of a capture world is that capture must occur by some interest group, often times incumbent industry (sector or firm(s)) and sometimes just 'business' more broadly. We might not be surprised to see the Trump Administration documents (AV 2.0, 3.0, 4.0, AVCP)[696] exhort the beneficence of business ("QUOTE"). However, the content of both the Obama Administration document (FAVP) and all four of the Trump Administration documents beyond the cover letters makes clear that NHTSA and DOT will be exercising their regulatory authority in a deliberately technology neutral and company neutral way.[697] Combined with the clear invocation of the safety motive of AV technology which aligns with NHTSA's mission, we would be quite surprised to see this evidence in a Capture world specifically because it upends the dominance of the existing incumbent automotive industry and introduces the possibility for new challengers to enter.

If we think of capture by 'business itself,' we might be less surprised to see this evidence since we would have to frame capture as "cultural capture" [698] or "the privileged position of business."[699] However, both frames are more meaningfully understood as a contestation over the definition of the public good rather than "capture" of the public good. In other words, reasonable people may disagree on how highly we should prioritize the economy in public policy, but that is very different from the subversion of the public good for individual benefit which is central to capture.

Strictly from the typology, a Capture Imaginary would require a regulator to demonstrate and/or claim their ignorance and defer to the expertise of industry *in designing regulation* (the Information variable). Both FAVP and AV 2.0 (as well as AV 3.0, 4.0, and AVCP) clearly demonstrate the technical and regulatory competence of NHTSA and DOT with their detailed vehicle design guidance which would be extremely surprising in a captured world. Based on this competence, NHTSA in both the Obama and Trump Administrations clearly indicate that they would welcome many potential final outcomes rather than the zero or one predicted by the Capture Imaginary.

As there are strong conceptual and typological reasons to be surprised by this evidence in a Capture world, I rate it 30 dB (Very Strong)

$WoE_{4\text{-}principles}$, Beneficial Constraints vs. Technology-Based Regulation = 40 dB

While both FAVP and AV 2.0 in this piece of evidence are 'pro-technology' in the sense that they are encouraging the development of AV technology for both safety and economic reasons, that is not what Technology-Based Regulation means. As explained in Chapter 3, Technology-Based Regulation is defined by setting a classic mandate or ban for a particular technology (e.g. catalytic converters). This is represented in the typology as a single outcome for the Outcomes constitutive variable, but this evidence clearly is open to many possible implementations and outcomes so long as they conform to the principles in the guidance documents.

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[696] (NHTSA 2017; USDOT 2018; NSTC and USDOT 2020; USDOT 2021)
[697] See the discussion around footnote 296 and 297 on page 96 in the main chapter
[698] (Kwak 2014, 79–80)
[699] (Lindblom 1977, 170–88)

As this $E_{4\text{-Principles}}$ is definitionally principle-based rather than technology based *and* those principles are explicitly flexible and adaptable, we would be truly shocked to see this evidence in a Technology-Based Regulation World. Even more, the guidance is intrinsically and explicitly "technology neutral"[700] which affirms that these are not principles by accident. Our shock would be registered as something moderately stronger than very-strong, hence 40 dB.

$WoE_{4\text{-principles}}$, Beneficial Constraints vs. State as Venue = 10 dB

In the abstract, we would certainly be more surprised to see successive guidance documents (rather than rulemaking) and explicit framings of DOT & NHTSA's roles as "a convener and facilitator"[701] (rather than a stakeholder) in a Beneficial Constraints world than in a State as Venue world. However, the USDOT and NHTSA demonstrate high access to information through the detailed provision of technical guidance in both Obama (FAVP) and Trump (AV 2.0, 4.0, AVCP) rather than low access as expected in a State as Venue world. Indeed, the detailed guidance (principle 1) and model state policy (principle 2) demonstrate a clear engagement as a stakeholder with a particular agenda rather than simply as a rulemaker trying to bring concerned parties to the table as would be predicted by State as Venue.

However, it is clear that the Trump Administration USDOT especially wished to be seen as "non-regulatory" [702] and "less burdensome" [703] in their approach to AVs due to their frequent and persistent assertions of same. Yet, as explained in the main chapter (p.95), these assertions are largely confined to the Secretary of Transportation Cover Letters and Executive Summaries of the documents. In the actual text of the guidance documents, the USDOT employees who wrote the technical and policy content are largely consistent between administrations, between documents, and with the regulatory authority of NHTSA and USDOT.

To see this potentially conflicting evidence in a Beneficial Constraints world, we would have to think that career USDOT and NHTSA employees were "doing truth to power."[704] While the concept of an American "deep state" is overblown, it is entirely reasonable to expect career civil servants in technical positions would be especially likely to tell the Trump Administration what they wanted to hear while maintaining technical competence in the body of their guidance documents.[705] As discussed at length above as well, guidance documents often exist in lieu or in preparation for rulemaking; in a particularly anti-rulemaking Administration (Trump), it would not be surprising to see reliance on this less contestable approach to governance.

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[700] (USDOT 2018, iv)

[701] The quote "a convener and facilitator" comes from the topline description of USDOT's webpage on AV Activities, which is listed as last updated on March 28, 2022 although the text dates back to the publication of AV 4.0 (2020) and the AVCP (2021), see (USDOT 2022)

[702] (NHTSA 2017, ii)

[703] (NHTSA 2023,while the page was captured in 2023, the relevant text about AV 2.0 was on the site as of 2018 per the 2018-12-12 capture on Archive.org and has not been changed since then)

[704] Todd Laporte often used the phrase "Doing Truth to Power" to describe the professional motivation of many public servants to serve the mission of their organization (personal conversation). Although there does not appear to be a direct publication of this phrase, the ideas behind it are discussed at length in many of his works, c.f. (La Porte 1971)

[705] There is remarkably clearly evidence of the Trump Administration struggling not with a deep state but with simply the State: "But the same way the administration's media problems come not from "fake news" but simply from news, so its bureaucratic problems come not from an insidious, undemocratic "deep state" but simply from the state-the large, complex hive of people and procedures that constitute the U.S.
federal government." (Michaels 2017, 52–53)

Thus, while there are superficial reasons[706] this evidence would not be surprising in State-as-Venue world, the specific content of $E_{4\text{-Principles}}$ that asserts technical competence and a clear agenda (stakeholder) give us moderate evidence in favor of Beneficial Constraints.

$WoE_{4\text{-principles}}$, Beneficial Constraints vs. Folk Economic Model = 37 dB

As repeatedly discussed previously, the explicit technical and policy competence as well as the explicit desire to welcome innovation around AV technology would make it very surprising to see this evidence in a Folk Economic Model world. However, to truly inhabit the world, the rhetoric surrounding a "non-regulatory" approach discussed in the State-as-venue section above slightly tempers the overwhelming weight against Folk Economic Model, thus giving us 37 dB (the extremity of the Technology-Based Regulation less the smallest discernible difference, 3 dB)

$WoE_{4\text{-principles}}$, Beneficial Constraints vs. Market Ideological = 16 dB

The rhetoric expressed by the Trump Administration about not to "hampering" the development of the AV industry,[707] to be presenting "a nonregulatory approach to automated vehicle technology safety,"[708] and excessively using the term "*Voluntary Guidance"*[709] are clearly very consistent with a Market Ideological world. However, the actual content of the principles in $E_{4\text{-Principles}}$, and thus the actual content of the guidance documents themselves, do not show the same abrogation of regulatory competence, power, and authority reflected by this rhetoric. Thus, while there are elements of the conflict present in the State as Venue discussion for this evidence above, there is at least weakly more evidence for Beneficial Constraints relative to Market Ideological because the Market Ideological imaginary makes strong claims about lower information *and* a desire for no regulatory outcome both of which contradict the existence and content of the guidance documents. The moderate WoE of State as Venue (10 dB) plus a weak difference (6 dB) gives us 16 dB.

A summary of the explicit Bayesian type validation of $E_{4\text{-Principles}}$ for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 48. The significance of this analysis is discussed in the following section on the weight of evidence $E_{4\text{-Principles}}$.

[706] These reasons will form the basis of the nearest rival evidence in the following section
[707] (NHTSA 2017, i, the introductory letter from USDOT Secretary Elaine L. Chao)
[708] (NHTSA 2017, ii)
[709] Voluntary Guidance appears 6 times on the single-page Executive Summary and is the title of the first section which makes up the majority of the document (16 of 24 substantive pages) *despite* the fact that it is entirely redundant; as previously noted FAVP 2016 and AV 2.0 2017 are both guidance documents that call for voluntary compliance.

Table 48: BayesTV Constitutive Variable Comparison Summary for $E_{4\text{-principles}}$ *

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Detailed statements on Performance Guidance demonstrates high access to info	Explicit recognition that industry is driving AV spread & that this drive is desirable	Specific acknowledgement of many potential exciting outcomes	Both explicit regulatory constraints & implicit technical "guidance" constraints	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Clear recognition & reliance on market not regulator as driver	*No distinguishing relevance*	Pro-adoption spirit but non-direct method, no incentives or punishments	20
Capture	*No distinguishing relevance*	Guidance documents both lay out clear claims to high info	*No distinguishing relevance*	Specific encouragement of many rather than one desirable outcome	*No distinguishing relevance*	30
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Outcomes are explicitly technology agnostic and principle-based	Constraint is performance not technology based	40
State as Venue	Regulator concessions to "convening & facilitating" but clearly acting as a stakeholder	While acknowledging stakeholder contributions, clear statement of high info	*No distinguishing relevance*	*No distinguishing relevance*	More than moderation, model policy and technical guidance is constraining	10
Folk Economic Model	Regulator concessions to "convening & facilitating" but clearly acting as a stakeholder	Demonstration of specific regulator competence anathema to Folk Economic Model	*No distinguishing relevance*	*No distinguishing relevance*	All five guidance documents explicitly pro-innovation rather than impediment	37
Market Ideological	*No distinguishing relevance*	Guidance documents both lay out clear claims to high info	Market is the driver but with regulatory guidance critical to coordination	NHTSA reaffirms that regulation is a necessary and vital part of all potential outcomes	Coordinated Framework explicitly pro-innovation rather than impediment	16

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{4\text{-principles}}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 7 for further explanation and Chapter 4 for complete methodological specification.

The Weight of Evidence 4-Principles

As seen by the weights of evidence in the last column of Table 48, the piece of evidence presented above ($E_{4\text{-Principles}}$) increases our confidence that Beneficial Constraints is the true state of the world in the US Coordinated Framework case. At 37 dB, this piece of evidence shouts against the Folk Economic Models which sees regulators as simply an impediment to innovation since it is a strong demonstration of regulatory competence with the detailed policy and technical guidance provided in the body of the document (information and effect columns of last two rows of Table 48). At 16 dB, this piece of evidence speaks moderately strongly against the Market Ideological imaginary due to the dissonance between the Trump Administrations condemnation of regulation in the framing of the documents[710] and the actual content of the documents which clearly demonstrates the importance of regulation working with innovators and entrepreneurs in the four principles detailed above..

The real stakes of the Beneficial Constraints model, however, lies in regulators placing constraints on firms intended to be *beneficial* to industry but not at the expense of society. As the other two constraint-effect imaginaries, Capture (30 dB) and Technology-Based Regulation (40 dB) are nevertheless spoken very strongly against because the specific content of the constraints do not match the specification of those imaginaries. For Capture, FAVP and AV 2.0 very clearly do *not* side with incumbent industry (the automobile industry) at the expense of new upstarts. Instead, they simply apply existing rules to new firms which wish to make vehicles for operation on public roads.[711] For Technology-based Regulation, the guidance in all five documents as evidenced by the principles in $E_{4\text{-Principles}}$ are principle based rather than technology constraining. Indeed, AV 3.0 makes clear that USDOT "will remain technology neutral,"[712] a clear contradiction of the expectations in a Technology-Based Regulation world which would expect a set of firm technical constraints (see Technology-Based Regulation row, Effect column of Table 48).

When compared to the other beneficial effect of regulation on innovation imaginary, this piece of evidence speaks strongly against the Adoption Catalyst world (20 dB) as the USDOT and NHTSA are taking no incentive or punishment based actions through which regulators could drive adoption of AV technology. While the final guidance document, AVCP in 2021, does lay claim to several research grants and investments, these are far from the direct incentive/punishment (carrot and stick) based approach we would expect of a regulator who wishes to drive innovation beyond the imagination of the market.[713]

Finally, this piece of evidence speaks only moderately against the State as Venue model (10 dB) due to the conflicting indicators of successive guidance documents (rather than rulemaking)

[710] Desire not to "hamper" (NHTSA 2017, i, the introductory letter from USDOT Secretary Elaine L. Chao), the pretense of a regulatory guidance document that claims to be "a nonregulatory approach to automated vehicle technology safety (NHTSA 2017, ii)."

[711] For the potential of capture by "business/the economy itself," see the discussion in the appendix about cultural capture (Kwak 2014) and the privileged position of business (Lindblom 1977, 170–88). In short, these are better understood as contestations of the public good rather than subversions (capture) of the public good.

[712] (USDOT 2018, iv)

[713] We turn to an example of an actual Adoption Catalyst regulatory imaginary in the case of Electronic Health Records in Chapter 7.

and explicit framings of DOT & NHTSA's roles as "a convener and facilitator"[714] (rather than a stakeholder) as juxtaposed with the actual content of the documents themselves which demonstrate clear technical and policy competence as well as a distinct stakeholder view of how things should proceed. We can reconcile this apparent contradiction by viewing career USDOT and NHTSA employees as "doing truth to power."[715] While the concept of an American "deep state" is overblown, it is entirely reasonable to expect career civil servants in technical positions would be especially likely to tell the Trump Administration what they wanted to hear while maintaining technical competence in the body of their guidance documents.[716] We should also recall that guidance documents serve a true constraining[717] role despite being technically non-binding; in a demonstrably anti-rulemaking Administration (Trump), it would not be surprising to see reliance on this less contestable approach to governance.

Regulation (EU) 2022/1426 in the EU (2016-Present)

The statutory intent for the EU Regulation (EU) 2022/1426 approach to AV regulation comes from the regulation itself: the fact that it is a type-approval process specifically for autonomous vehicles. Although this piece of evidence incorporates both the fact that this is a vehicle type-approval (rather than guidance document or other method of regulation) as well as the content of that type-approval, the full title of the regulation can serve as an illustrative demonstration of the content of this evidence:

> *Commission Implementing Regulation (EU) 2022/1426*
>
> *of 5 August 2022*
>
> *laying down rules for the application of Regulation (EU) 2019/2144 of the European Parliament and of the Council as regards uniform procedures and technical specifications for the type-approval of the automated driving system (ADS) of fully automated vehicles (Text with EEA relevance)*
>
> *- (European Commission 2022, 221:221/1)*

As noted in this title, the EU took the rather straightforward and ordinary step when confronted with a new vehicle technology of specifying how it would be reviewed and approved as part of the vehicle code.[718] This choice to create a type-approval process and the content of that process forms $E_{\text{Type-Approval}}$, our initial evidence for the EU case.

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[714] The quote "a convener and facilitator" comes from the topline description of USDOT's webpage on AV Activities, which is listed as last updated on March 28, 2022 although the text dates back to the publication of AV 4.0 (2020) and the AVCP (2021), see (USDOT 2022)

[715] Todd Laporte often used the phrase "Doing Truth to Power" to describe the professional motivation of many public servants to serve the mission of their organization (personal conversation). Although there does not appear to be a direct publication of this phrase, the ideas behind it are discussed at length in many of his works, c.f. (La Porte 1971)

[716] There is remarkably clearly evidence of the Trump Administration struggling not with a deep state but with simply the State: "But the same way the administration's media problems come not from "fake news" but simply from news, so its bureaucratic problems come not from an insidious, undemocratic "deep state" but simply from the state-the large, complex hive of people and procedures that constitute the U.S.
federal government." (Michaels 2017, 52–53)

[717] See footnote 287 in the main chapter and surrounding discussion on page 96

[718] The latest amendment of which was Regulation (EU) 2019/2144, see case narrative on page 99

The explicit Bayesian type validation of $E_{Type\text{-}Approval}$ for each of the regulatory imaginaries in Table 1 is presented in the following sections and summarized in Table 19 in the main text (repeated below as Table 49).

Justification for $E_{Type\text{-}Approval}$ as Evidence for the Most Likely Type (Beneficial Constraints)

The characteristic constitutive variables of the Beneficial Constraints imaginary are that a regulatory has higher access to information than any individual regulated innovating entity, that they nevertheless believe that the market should be the driver of adoption for the innovation, and that they are willing to accept multiple potential configurations of outcomes so long as they fit within the principles of what the regulators define as "beneficial." The decision of the EU to create a type-approval process specifically for AVs is very consistent with the information and driver constitutive variable scores and at least somewhat consistent with the outcomes variable score. The intended effect, constraint which is beneficial to both the industry and public interest, is very consistent with this type-approval process which creates a clear certification scheme for AV technology.

The publication of a type-approval document with substantial Annexes clearly demonstrates that the EU was confident that they had access to a high enough level of information that they could set an extensive set of requirements that manufacturers should meet. In particular, Annex II sets out a detailed list of Performance Requirements (9 pages) that tie into existing laws and regulations as well as setting out general principles of operation.[719] In addition, Annex III lays out the full compliance assessment procedures (41 pages) against which the performance requirements from Annex II will be tested.[720] Together, both Annexes demonstrate that the EU was confident it had the level of comprehensive data necessary to define how AVs need to perform in order to seek type-approval.

With regard to the market as driver and acceptance of many possible outcomes, this evidence is quite consistent when considering both variables together. The preamble to the type-approval makes clear that while this regulation specifies the type approval, "this regulation is without prejudice to the right of Member States to regulate the circulation and the safety of operation of fully automated vehicles."[721] In other words, while the EU Commission and Parliament are here creating the process for AVs to be approved, they are not requiring that member states allow them or that additional constraints cannot be added by those member states. This amounts to a reliance on the market (and additional potential regulators) to drive the spread of AVs as well as an acceptance of many potential outcomes, so long as they comply with the principle-based technical requirements in Annex II as evaluated in Annex III.

Together with this match on constitutive variables, the expected effect of type approval (permission to sell within constraints intended to minimize predictable harms and maximize potential benefits) is very consistent with Beneficial Constraints, making it a good match for the most likely type.

$WoE_{Type\text{-}Approval}$, Beneficial Constraints vs. Adoption Catalyst = 20 dB

In an Adoption Catalyst world, we would be rather surprised to see this evidence because it rather hesitantly allows manufacturers to seek type-approval rather than encouraging the

[719] (European Commission 2022, 221:221/11-221/19)
[720] (European Commission 2022, 221:221/20-221/61)
[721] (European Commission 2022, 221:221/2)

adoption of AVs. In addition, as discussed in the previous section, the EU was clearly ok with allowing the market to drive adoption (rather than the regulator as expected in an Adoption Catalyst world) and also explicitly allowed member states to place additional requirements on AVs. This lack of a characteristic push to catalyze the adoption of the innovation with either incentives or punishments leaves us with a strong weight of evidence (20 dB) in favor of Beneficial Constraints over Adoption Catalyst.

$WoE_{Type\text{-}Approval}$, Beneficial Constraints vs. Capture = 30 dB

In a Capture world, we would be truly shocked to see this evidence as it represents a generalized process for any manufacturer to seek type approval based on uniform standards rather than some sort of privilege for the capturing entity (whoever that may be, another key missing character for this evidence to be observed). The most plausible explanation for seeing this evidence in a Capture world would be that the dastardly automobile industry, intent on forcing dangerous AVs upon us, had convinced regulators to allow through an inherently suspect technology. However, as both US[722] and EU[723] regulators are quick to point out, the most dangerous and dastardly technology associated with automobiles is the human driver while AVs have a very real and recognized promise to greatly reduce the dangers of this most harmful component. We could choose to believe that technical experts both inside and outside regulatory agencies are deeply mistaken or over-enamored of AVs promise despite its potentially immature state, but such a belief would require us to doubt engineers on principles of engineering. Possible, but not particularly plausible given the widespread consensus about the potential safety benefits of AVs. We are left with a very strong (30 dB) weight of evidence for the plausible Beneficial Constraints world over the shocking Capture world.

$WoE_{Type\text{-}Approval}$, Beneficial Constraints vs. Technology Based Regulation = 40 dB

Similar to the reasoning in the US case where technical principles rather than specific solutions were specified, we would be paradigmatically shocked to see a type-approval process such as Regulation (EU) 2022/1426 in a Technology Based Regulation world because the specifications in Annex II and evaluation procedures in Annex III are principles based rather than mandating a particular approach. Although we initially included a prior in favor of Technology-Based Regulation based on the creation of type-approval, it is clear from this evidence that the actual type-approval process here is principles rather than technology based. This paradigmatic shock thus equals our shock in the US case $E_{4\text{-}Principles}$ (40 dB).

$WoE_{Type\text{-}Approval}$, Beneficial Constraints vs. State as venue = 60 dB

The critical distinguishing constitutive variable between State as Venue and Beneficial Constraints is that of access to information; State as Venue is based upon a regulator who believes they lack the information to make the call themselves and thus relegate themselves to merely a moderating role between stakeholders. This evidence (creation of a type-approval process) would be simply flabbergasting in such a world as the EU has clearly taken a strong stance on their competence to provide a blanket type-approval process. This level of unexpectedness should be beyond that of paradigmatic shock (40 dB), much stronger than very strong (30 dB). Thus, we land at very strongly stronger than very strong, or 60 dB.

[722] In the US, the oft-repeated statistic is greater than 90% of crashes come from human error. (NHTSA 2016, 5; 2017, ii; NSTC and USDOT 2020, 2)

[723] The EU also uses the 90% statistic (Pillath 2016, 2)

$WoE_{Type\text{-}Approval}$, Beneficial Constraints vs. Folk Economic Model = 40 dB

The critical constitutive variable for the Folk Economic Model world is that the regulator must demonstrate or believe that they lack the information to regulate and thus they become an impediment to innovation (which must be evaded). The clear competence of Annexes II and III violates this fundamental expectation and would make this evidence truly shocking in a Folk Economic Model world. These specifications might be constraining but they are far from an impediment to an innovation that the EU clearly has high hopes for (AVs). Our shock can register as 40 dB.

$WoE_{Type\text{-}Approval}$, Beneficial Constraints vs. Market Ideological = 60 dB

Similar to our reasoning in State as Venue, if the this evidence would be surprising in a world where regulators think they have too little information to regulate properly, it would be exceptionally shocking to seem them create this sort of detailed type-approval process in a Market Ideological world where regulators claim they have enough information to know that no regulation should be undertaken because the best possible outcome is to let the market decide all. This is always an unlikely imaginary for the EU given their regulatory culture of cooperative regulation.[724] We will register this very very strong surprise as 60 dB.

A summary of the explicit Bayesian type validation of $E_{Type\text{-}Approval}$ for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 49. The significance of this analysis is discussed in the following section on the weight of evidence $E_{Type\text{-}Approval}$.

[724] (c.f. Kagan [2001] 2009) for a comparison between US and EU approaches to administrative law, particularly the cooperative nature of the EU as compared to the adversarial nature of the US.

Table 49: BayesTV Constitutive Variable Comparison Summary for $E_{Type\text{-}Approval}$ *

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	detailed technical appendices demonstrate high competence	Allowance for type-approval with member state variation places onus on market	explicit toleration for member state variation means many outcomes could be desirable	Type-approval requirements and procedure clearly place guardrails while allowing innovation to proceed	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is not driving adoption, no incentive or punishment	*No distinguishing relevance*	Clearly Constraining rather than Catalyzing although positive hopes for AV technology	20 dB
Capture	*No distinguishing relevance*	No claims of low information, in fact the opposite	*No distinguishing relevance*	Open to many potential outcomes which meet the type-approval standards	Constraining to type approval process, but not to the level of an uneven playing field	30 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Despite our prior, type-approval is principle rather than tech based	A focus on principles rather than required technology is constraining but not TBR	40 dB
State as Venue	*No distinguishing relevance*	EU stakes clear claim to high access to information	*No distinguishing relevance*	*No distinguishing relevance*	Far more than a neutral moderator, type-approval process sets out EU's perspective	60 dB
Folk Economic Model	*No distinguishing relevance*	Clear demonstrations of technical competence in Annexes II and III	*No distinguishing relevance*	*No distinguishing relevance*	Far from an impediment, EU wants AVs developed to these standards to increase safety	40 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	EU certainly does not abrogate authority to the market	Not an impediment but constraints intended to spur innovation	60 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{Type\text{-}Approval}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 16 for further explanation and Chapter 4 for complete methodological specification

The Weight of Evidence Type-Approval

As seen by the weights of evidence in the last column of Table 49, the piece of evidence presented above ($E_{Type\text{-}Approval}$) increases our confidence that Beneficial Constraints is the true state of the world in the EU Regulation (EU) 2022/1426 case. At 40 and 60 dB, this piece of evidence speaks very strongly against the two models which see regulators as simply an incompetent (Folk Economic Model) or undesirable (Market Ideological) impediment to the market because the constraints enacted follow the EU more cooperative style of regulation which places rules, but flexible ones, on technologies of interest.[725] This evidence also speaks very strongly (60 dB) against the State as venue imaginary as the EU is clearly taking a much more proactive role than merely the neutral moderator since it has created detailed guidelines and test procedures in Annexes II and III of the regulation.[726]

In our priors, we expected that Technology Based Regulation might be a near rival imaginary to Beneficial Constraints to the technologically involved type approval process. However, as we dive more deeply into the actual specification of the type-approval standards (Annex II) and the evaluation process (Annex III), it is clear that these are principle based rather than specific technology solution based. Technology based regulation is characteristically a one size fits all "command and control" approach to a regulatory problem that specifies not what needs to be solved but how it must be solved (solution rather than principles).[727] This allows us to place a very very strong weight of evidence (40 dB) against Technology Based Regulation as despite being about a technological process, the criteria are principle rather than solution based.

Finally, we are left with two extremely different imaginaries as the closest comparators: Adoption Catalyst and Capture. Importantly, neither of these clos*est* comparators is actually a *close* comparator as both have strong or very strong weights of evidence against them from $E_{Type\text{-}Approval}$. In the case of Capture, we have a very strong weight of evidence (30 dB) in favor of Beneficial Constraints over Capture because we lack both any reasonable capturing entity and any distinctly uneven playing field created to benefit such an entity. The most plausible capture story would rely on an AV industry attempting to foist unsafe and immature products on an unsuspecting public. While the media enjoys this narrative, there is little technical disagreement in either the US or EU that AVs represent a significant promise to increase safety (and sell vehicles).[728] Adoption Catalyst then becomes our nearest rival, although there is still strong evidence (20 dB) against it in favor of Beneficial Constraints because the type-approval process offers neither incentives for adoption nor punishments for non-adoption of AVs.

NEAR RIVAL EVIDENCE:

As can be seen from the weight of evidence summary in Table 46, the initial evidence was least decisive (fewest decibels) about a different alternative type for each of the cases. In the US

[725] (c.f. Kagan [2001] 2009) for a comparison between US and EU approaches to administrative law, particularly the cooperative nature of the EU as compared to the adversarial nature of the US.
[726] (European Commission 2022, 221:221/11-221/61)
[727] (c.f. Malloy 2010, entire, but esp. 283-296) about the rigidity and homogeneity characterization of the "conventional construction" of command and control regulation.
[728] The US (NHTSA 2016, 5; 2017, ii; NSTC and USDOT 2020, 2) and EU (Pillath 2016, 2) both repeatedly use the statistic that greater than 90% of crashes come from human error which can be seriously mitigated by proposed AV technologies. The technology is not quite here but it is also not off in the distant future (immature) from these estimates.

Perpetual Guidance case, the nearest rival model is the State as Venue model because the USDOT regulated AVs through guidance documents emphasizing voluntary compliance rather than through rulemaking. The principles in the initial evidence ($E_{4\text{-Principles}}$) are clearly consistent with a regulator who wishes to be seen as merely a "a convener and facilitator"[729] although it is relatively less likely than Beneficial Constraints because the content of the principles demonstrate a much more active role for the regulator than claimed by the State as Venue model. In the EU Regulation (EU) 2022/1426 case, the nearest rival model is the Adoption Catalyst model due to largely to the fact that this initial evidence ($E_{\text{Type-Approval}}$) spoke so loudly against all other rival types. Although Adoption Catalyst was still strongly (20 dB) spoken against by the initial evidence, the fact that the generally overly cautious EU regulatory system[730] created a type-approval process for a technology which is nearly, but not quite, actually ready for mass adoption could conceivably be seen as nearly catalyzing by comparison to the EU's usual reticence.

In this section, we highlight an additional piece of evidence which is most supportive of the respective nearest rival type for each of the two empirical cases. For the US Perpetual Guidance case, this evidence is the frequent claims, especially in the later documents, to be merely a facilitator among stakeholders. The evidence comprises a collection of statements from the AV 2.0, AV 3.0, AV 4.0, and the AVCP. For the Regulation (EU) 2022/1426 case, this evidence comes from the frequent references to expected revision and updating in the recitals that lead Regulation (EU) 2022/1426 because they demonstrate that although the EU sees this regulation as a step forward in approval, they still feel that there is much left to be defined.

Perpetual Guidance in the United States (2016-Present)

Of marked significance in the US regulation of AVs is the change of administration during the process from the Democratic Obama Administration to the Republican Trump Administration in 2017.[731] While and change in administration can have a significant impact on policy, the change from Obama to Trump was particularly significant to the administrative state due to both the rhetoric and the demonstrable competence of the two administrations. The Obama Administration, in line with most modern Democratic administrations, attempted to craft landmark policy (most famously the Affordable Care Act in 2010). At a more day-to-day level, the Democratic party platform of last 20 years has been built upon implementing public policy while the modern Republican party platform has been built upon a rhetoric of "smaller government" and a policy agenda of decreasing taxation on the wealthy.[732] Building on this rhetoric and agenda, the Trump administration came to power claiming to "drain the swamp" and

[729] The quote "a convener and facilitator" comes from the topline description of USDOT's webpage on AV Activities, which is listed as last updated on March 28, 2022 although the text dates back to the publication of AV 4.0 (2020) and the AVCP (2021), see (USDOT 2022)

[730] Or "precautious," see extensive discussion in Chapter 6 about the Precautionary Principle.

[731] The 2016 election resulted in a transition in power in January 2017. The Obama Administration thus authored the FAVP, but the Trump Administration authored AV 2.0, AV 3.0, AV 4.0, and the AVCP. For more details, see the case narrative in Perpetual Guidance in the United States (2016-Present) on page 95.

[732] This divide can be traced back to the 1990s with Newt Gingrich and Grover Norquist moving the Republican Party to an absolutist position against public spending to achieve public policy (or even back to Ronald Reagan's decrying of the supposed worst sentence in the English language "I'm from the government and I'm here to help"). It took real center stage, however, with the Tea Party movement which began in 2008 in response to Barack Obama's election and the perception that he would be a "tax and spend" Democrat. Excellent explanations of this rhetorical and policy divide can be found in (Skocpol and Williamson 2012; Hacker and Pierson 2020).

looking to slash regulation for the sake of it. It quickly became clear, however, that in addition to being against regulation and administration on a rhetorical and principle level, the Trump Administration was exceptionally bad at actually executing their rhetoric.[733]

With the change of administration came a change in the rhetoric of AV policy, at least in the cover letters and framing from Trump Administration appointed Secretary of Transportation Elaine Chao. While I have argued above that this shift in framing was more rhetoric than substance,[734] taking seriously the nearest rival type analysis means that I will highlight evidence that is most supportive of the counterargument: that claim was more than rhetoric and was in fact a substantive change which has shaped US AV regulation toward the nearest rival type: State as Venue. The quotes below are illustrative of this trend in rhetoric shift, while the entire strain of rhetoric forms the evidence for the nearest rival type ($E_{\text{Non-Regualtory}}$)

The most expressive statement of the supposed shift appears in AV 2.0 from 2017:

> *"[AV 2.0:] A Vision for Safety replaces the Federal Automated Vehicle Policy released in 2016…The Federal Government wants to ensure it does not impede progress with unnecessary or unintended barriers to innovation…In this document, NHTSA offers a nonregulatory approach to automated vehicle technology safety."(NHTSA 2017, i–ii)*

This is echoed later in AV 3.0:

> *"Automation technologies are new and rapidly evolving. The right approach to achieving safety improvements begins with a focus on removing unnecessary barriers and issuing voluntary guidance, rather than regulations* ***that could stifle innovation****." (USDOT 2018, viii, emphasis in original)*

Although not explicitly highlighted in AV 4.0, the rhetoric reappears in a subdued form in the AVCP on January 11, 2021; just 9 days before the Trump Administration transition to the Biden Administration:

> ***"2. Modernize the Regulatory Environment*** *– U.S. DOT will modernize regulations to remove unintended and unnecessary barriers to innovative vehicle designs, features, and operational models, and will develop safety focused frameworks and tools to assess the safe performance of ADS technologies." (USDOT 2021, ii, emphasis in original)*

Together, these statements and the sentiments like them that suffuse the Trump Administration documents (AV 2.0, AV 3.0, AV 4.0, AVCP) comprise the Near Rival evidence for the US Case, $E_{\text{Non-Regulatory}}$. The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be, relative to Beneficial Constraints, to see this evidence ($E_{\text{Non-Regulatory}}$) under the assumption that each potential regulatory imaginary was the true state of the world.

Reasoning about $E_{\text{Non-Regulatory}}$ under the Comparator Type (Beneficial Constraints)[735]

As we are highlighting $E_{\text{Non-Regulatory}}$ specifically to explore the nearest rival to the most likely type, it is unsurprising that this evidence, taken at face value, would be rather surprising to see in a Beneficial Constraints world. However, as explained at length in the analysis of the

[733] (Michaels 2017)

[734] See, for example, the discussion above about $E_{\text{4-Principles}}$ (page 107) and the discussion in the case narrative (pages 95 to 99) as well as the explicit BayesTV in Appendix B for $E_{\text{4-Principles}}$ (pages 256 to 257)

[735] To avoid excessive repetition in the paired comparisons which follow, this first section in the explicit BayesTV analysis covers the reasoning for how (un)surprising this piece of evidence is under the most likely type (which will also serve as the comparator type for ease of final tabulation).

initial statutory intent evidence, in order to see this rhetoric about the federal government 'stepping back,' "removing unnecessary and unintended barriers," and "a nonregulatory approach to automated vehicle technology safety" we must believe that the agencies are merely telling the administration what they want to hear while enacting constraints in practice. In other words, USDOT and NHTSA must be speaking in the language that their politically appointed head (The Trump Administration Secretary of Transportation, Elaine Chao) wants to hear while the body of their guidance document is, in fact, constraining upon entrepreneurs and innovators in their jurisdiction.

While logical Bayesian analysis often directs us to consider any need to assume subterfuge as inherently less likely than a rival world where no subterfuge is needed,[736] there are good grounds to believe that subterfuge is the *more* likely actual state of the world during the Trump Administration specifically on the issue of economic regulation. As explained in the case narrative,[737] as well as in the section above on State as Venue for $E_{4\text{-Principles}}$,[738] the Trump Administration was exceptionally bad at running the administrative state and the career civil servants who worked below the level of the political appointees often "did truth to power" in keeping the apparatus of the government functioning despite the rhetoric of the administration.

In this specific time and place, it would be *more* surprising to see career USDOT and NHTSA employees radically change the direction dictated by their technical expertise and experience in favor of a mission-threatening abrogation of authority. In other words, while subterfuge is generally a less likely event than compliance with formal authority for government actors, the comparison here should be between subterfuge in service of the agency mission and authentic change of direction in contradiction of the agency mission. And public agencies are categorically mission-driven organizations.[739] The mission of the USDOT and especially NHTSA is:

> *"Save lives, prevent injuries, and reduce economic costs due to road traffic crashes, through education, research, safety standards, and enforcement activity" - (NHTSA 2017, 1, Note: this is a Trump Administration document)*

Beyond simply the logic of pro-mission subterfuge and anti-mission veracity, the prior piece of evidence, $E_{4\text{-Principles}}$ demonstrates that the core principles of the actual regulatory guidance are consistent between the Trump and Obama Administration Documents. Thus, combining both logical and empirical reasons, we can conservatively say that this piece of evidence is at least a plausible in the specific Beneficial Constraints world of the Trump Administration as it would be were the state actually be to be acting from a State as Venue imaginary. Thus this evidence will score 0 dB in the comparison between State as Venue and Beneficial Constraints (see below).

$WoE_{Non\text{-}Regulatory}$, Beneficial Constraints vs. Adoption Catalyst = 40 dB

While the reasoning how this evidence would be seen in a Beneficial Constraints world might apply to the even more proactive Adoption Catalyst world (doing truth to power), it would

[736] (Fairfield and Charman 2022, 109-111,451-454)
[737] See the discussion in the Chapter 5 case narrative (pages 95 to 99). Note as well, methodologically, that incorporating background knowledge such as this case narrative is *exactly* what it means to be a Bayesian rather than a frequentist (who might require you to analyze all evidence in isolation in order to avoid a frequentist notion of bias).
[738] See page 259.
[739] (Goodsell 2010, 2)

be truly paradigm shattering to see that big a stretch of doing truth to power. Where Beneficial Constraints 'merely' requires that a regulator enact constraints often based on firmly established statutory authority, Adoption Catalyst requires a regulator to step beyond guiderails into actually propelling the adoption of an innovation using incentives and punishments (the Driver and Effect variables). As this drive for adoption by the regulator is *explicitly* lacking *and* we have the additional layer of anti-regulatory rhetoric, we can safely conclude that this evidence would be much more surprising in an Adoption Catalyst world, which we can record as similar to our shock (40 dB) at seeing $E_{4\text{-Principles}}$ in a Technology-Based Regulation world.

$WoE_{Non\text{-}Regulatory}$, Beneficial Constraints vs. Capture = 20 dB

In a world of Capture, this evidence may seem consistent with the idea of capture by AV entrepreneurs. However, true Capture requires that the regulators concede that regulated entities have more information than regulators and dictate that there is a preferred outcome in favor of the capturing entity. In this case, while this evidence does show a strong rhetorical desire to defer to entrepreneurs and innovators, it's clear in the context $E_{4\text{-Principles}}$ that this rhetoric does not match the content of the guidance which displays a high level of information beyond that of any single firm. In addition, the rhetoric in this piece of evidence explicitly states that "there is no need for U.S. DOT to favor particular locations or to pick winners and losers."[740] With clear distinction on higher information and an explicit counter-indication on Outcomes (pro-innovation and firm agnostic), this evidence strongly (20 dB) supports Beneficial Constraints over Capture.

$WoE_{Non\text{-}Regulatory}$, Beneficial Constraints vs. Technology Based Regulation = 30 dB

For similar reasons to those explained on the initial statutory intent evidence ($E_{4\text{-Principles}}$),[741] this piece of evidence would be extremely surprising in a technology based regulation world because it is clearly principle (rather than technology) based and clearly favor technology agnosticism. In fact, under either interpretation discussed in the reasoning under the comparator type section above (pro-mission subterfuge and anti-mission veracity), we would be much much more likely to see this evidence in a Beneficial Constraints or State as Venue world than a Technology based regulation world because whether we believe that this is Beneficial Constraints flying under the radar or State as Venue taking a hands off approach, its clearly *not* the mandate or ban of a specific implementation of a technology as expected in a Technology Based Regulation world. We can thus assign a very strong weight of evidence (30 dB), although moderately weaker than the veritable shock of $E_{4\text{-Principles}}$ due to the ambiguity of the two interpretations.

$WoE_{Non\text{-}Regulatory}$, Beneficial Constraints vs. State as venue = 0 dB

Narratively, and based on the explicit analysis of the statutory intent evidence ($E_{4\text{-Principles}}$), the nearest rival type for the US AV case is the State as Venue imaginary. However, as carefully explained in the section above about how likely this piece of evidence ($E_{Non\text{-}Regulatory}$) would be in a Beneficial Constraints world,[742] we are forced to consider the likelihood that the USDOT and NHTSA would violate their mission in order to comply with the stated goals of the Trump

[740] (USDOT 2018, ix)
[741] See page 258
[742] See page 270.

administration versus the likelihood that career civil servants would place mission above strict honesty and thus would choose to "do truth to power."[743]

While there are good logical and empirical reasons to believe that USDOT and NHTSA employees would have place mission above strict compliance with a mission-threating administration, the most conservative score would be to place a judgment of "non-determinative" on this evidence for this pairing, thus 0 dB.

$WoE_{Non\text{-}Regulatory}$, Beneficial Constraints vs. Folk Economic Model = 20 dB

In a Folk Economic Model world, we might expect to see this evidence because it appears consistent with the idea that regulators should simply get out of the way. However, the Folk Economic Model world requires that regulators step aside due to low information and a desire to be a simple rulemaker. While this evidence does demonstrate a desire to "avoid stifling innovation," it does so from a position of higher rather than lower knowledge as show by the lengthy content of the guidance discussed in the case narrative.[744] Indeed, although there is clear anti-regulatory rhetoric in the Trump Administration documents, it is wedded to a pro-innovation message of the actions these guidance documents represent. In other words, it may claim to be "developing a regulatory framework that encourages, rather than hampers, the safe development, testing and deployment of automated vehicle technology" but it's still developing a regulatory framework despite other sections of the documents which claim this to be "a nonregulatory approach."[745] The tensions between interpretations as Beneficial Constraints and State as Venue notwithstanding, we can strongly (20 dB) conclude that this evidence favors both over the Folk Economic Model.

$WoE_{Non\text{-}Regulatory}$, Beneficial Constraints vs. Market Ideological = 10 dB

The anti-mission pro-Administration interpretation of this evidence is clearly consistent with the Market Ideological imaginary because the Trump Administration's intended approach *is itself* a relatively bald statement a Market Ideological approach.[746] However, for the same reasons discussed above about the Folk Economic Model (which we can see as simply a more extreme version of Market Ideological), the actual actions do not match the rhetoric and thus undermine the support for the Market Ideological world interpretation. Despite their endorsement of the market as the driver of adoption, there is no active abrogation of regulatory authority. Indeed, despite anti-regulatory rhetoric, every document still endorses the USDOT and NHTSA roles in promoting innovation through guidance instead of creating an impediment. Thus, although we must be moderately weaker than the 20 dB assigned to the Folk Economic Model comparison due to the rhetorical similarity to a Market Ideological world, we can still be moderately in favor (10 dB) of the Beneficial Constraints world over the Market Ideological world because the actions do not match the rhetoric.

A summary of the explicit Bayesian type validation of $E_{Non\text{-}Regulatory}$ for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 50.

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[743] See discussion of "doing truth to power" in footnote 704

[744] See page 95 in Chapter 5.

[745] Yes, indeed, AV 2.0 really does say "a regulatory approach" on page i and "a nonregulatory approach" on page ii (NHTSA 2017, i–ii)

[746] Although the Trump Administration's rhetoric can be economically populist (protectionism, anti-globalization), its actions clearly follow the old doublespeak of prior market fundamentalists like Reagan and Thatcher and do the opposite (Block and Somers 2017, 389)

The significance of this analysis is discussed in the following section on the weight of evidence $E_{\text{Non-Regulatory}}$.

The Weight of Evidence Non-Regulatory

As seen by the weights of evidence in the last column of Table 50, the piece of evidence presented above ($E_{\text{Non-Regulatory}}$) increases our confidence that Beneficial Constraints is the most likely state of the world in the US Perpetual Guidance case over all imaginaries except the State as Venue imaginary. As expected, given the selection criteria for the near rival evidence, this evidence is least decisive between Beneficial Constraints (the most likely type) and State as Venue (the nearest rival type). However, perhaps damningly, even when highlighting the strongest evidence for State as Venue, that evidence is not informative (0 dB) in favor of the State as Venue imaginary over the Beneficial Constraints imaginary because there are two rival explanations which are, most skeptically, equally plausible.[747]

The two rival explanations of this evidence, critical to the distinction between Beneficial Constraints and State as Venue, hinge on whether we believe the statements of AV 2.0, 3.0, 4.0, and AVCP as "a nonregulatory approach" can be taken at face value or instead should be understood as subterfuge. While logical Bayesian analysis often directs us to consider any need to assume subterfuge as inherently less likely than a rival world where no subterfuge is needed,[748] there are good grounds to believe that subterfuge is the *more* likely actual state of the world during the Trump Administration specifically on the issue of economic regulation. As explained in the case narrative,[749] the Trump Administration was exceptionally bad at running the administrative state and the career civil servants who worked below the level of the political appointees often "did truth to power"[750] in keeping the apparatus of the government functioning despite the rhetoric of the administration.

In that specific time and place, it would be *more* surprising to see career USDOT and NHTSA employees radically change the direction dictated by their technical expertise and experience in favor of a mission-threatening abrogation of authority. In other words, while subterfuge is generally a less likely event than compliance with formal authority for government actors, the comparison here should be between subterfuge in service of the agency mission and authentic change of direction in contradiction of the agency mission. And public agencies are

[747] I have chosen to err on the side of skepticism and assign 0 dB to this evidence. However, I also think there are strong reasons to believe that this skepticism is excessive in the specific context of the Trump Administration as explained in the following paragraph and at great length in Appendix B (beginning on page 270)

[748] (Fairfield and Charman 2022, 109-111,451-454)

[749] See the discussion in the Chapter 5 case narrative (pages 95 to 99) as well as in the section above on State as Venue for $E_{\text{4-Principles}}$, see page 259 in Appendix B. Note as well, methodologically, that incorporating background knowledge such as this case narrative and the reasoning in other comparisons is *exactly* what it means to be a Bayesian rather than a frequentist (who might require you to analyze all evidence in isolation in order to avoid a frequentist notion of bias).

[750] c.f. (La Porte 1971), see discussion in footnote 704 on page 259.

Table 50: BayesTV Constitutive Variable Comparison Summary for $E_{Non\text{-}Regulatory}$ *

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	Regulators "doing truth to power" (parroting Administration rhetoric while acting pro agency mission) or they may be authentically pro-administration and anti-mission.[751]		*No specific relevance*	*No specific relevance*	Rhetoric: Remove Constraints Content: maintain constraints	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Both interpretations of the MLT and nearest rival make it clear that market is driver	*No distinguishing relevance*	The conflicting honest/dishonest interpretations would be shocking in a proactive AC world.	40 dB
Capture	*No distinguishing relevance*	The regulators still have important information, it's just "voluntary"	*No distinguishing relevance*	Clearly not in favor of a single outcome; very pro-innovation & new entrant firms.	*No distinguishing relevance*	20 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Clearly not in favor of a single outcome; very pro-innovation & new entrant firms.	If there are constraints, they're principle not technology based.	30 dB
State as Venue	Weighing mission-affirming subterfuge against mission-violating authentic rhetoric, we must conservatively consider this a wash		*No distinguishing relevance*	*No distinguishing relevance*	No distinction Due to viable conflicting motivations for regulators saying what they said	0 dB[752]
Folk Economic Model	Regulator is not abrogating responsibility, competence, or authority		*No distinguishing relevance*	*No distinguishing relevance*	Not an impediment to innovation, even if anti-regulatory rhetoric	20 dB
Market Ideological	The conflicting interpretations are MI vs. BC.		*No distinguishing relevance*	Not a 'no desirable outcomes' world	Not an impediment to innovation, even if anti-regulatory rhetoric	10 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{Non\text{-}Regulatory}$ Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 7 for further explanation and Chapter 4 for complete methodological specification.

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[751] Note: The Relationship and Information cells have been combined in this analysis because the distinguishing information in both cells would be the same , thus it is more space efficient to span both and provide additional clarity.

[752] See the extensive reasoning in Appendix B on pages 269 to 276

categorically mission-driven organizations.[753] The mission of the USDOT and especially NHTSA is:

> *"Save lives, prevent injuries, and reduce economic costs due to road traffic crashes, through education, research, safety standards, and enforcement activity" - (NHTSA 2017, 1, Note: this is a Trump Administration document)*

Beyond simply the logic of pro-mission subterfuge and anti-mission veracity, the prior piece of evidence, $E_{4\text{-Principles}}$ demonstrates that the core principles of the actual regulatory guidance are consistent between the Trump and Obama Administration Documents. Thus, combining both logical and empirical reasons, we can conservatively say that this piece of evidence ($E_{\text{Non-Regulatory}}$) is at least a plausible in the specific Beneficial Constraints world of the Trump Administration as it would be were the state actually be to be acting from a State as Venue imaginary.

With respect to the two models which see regulators as simply an impediment to innovation (Folk Economic Model and Market Ideological), we can moderately (10 dB) and strongly (20 dB) conclude, respectively, that this evidence speaks in favor of Beneficial Constraints over them. The anti-mission pro-Administration interpretation of the rhetoric in this evidence is clearly consistent with the Market Ideological imaginary because the Trump Administration's intended approach *is itself* a relatively bald statement a Market Ideological approach.[754] However, based on the analysis of $E_{4\text{-Principles}}$,[755] the actual content of the guidance does not match the rhetoric and thus undermines the support for the Market Ideological world interpretation. In other words, it may claim to be "developing a regulatory framework that encourages, rather than hampers, the safe development, testing and deployment of automated vehicle technology" but it's still developing a regulatory framework despite other sections of the documents which claim this to be "a nonregulatory approach."[756] Combined with a lack of impediment to innovation and instead an encouragement of innovation through regulatory guidance, we can be confident the evidence is moderately to strongly surprising in these two worlds.

Both Capture and Technology Based Regulation see regulators as a constraint on innovation, although of a different character than Beneficial Constraints. The Capture imaginary sees regulators as a constraint in favor of existing regulated entities who have 'captured' regulatory to serve their interests while this evidence explicitly rejects the language of capture to encourage new entrant firms to build on this guidance and innovate.[757] This contradiction makes us strongly (20 dB) confident that Capture is not the true state of the world for this evidence. The Technology Based Regulation imaginary sees regulators as a constraint requiring or banning a

[753] (Goodsell 2010, 2)
[754] Although the Trump Administration's rhetoric can be economically populist (protectionism, anti-globalization), its actions clearly follow the old doublespeak of prior market fundamentalists like Ronald Reagan and Margaret Thatcher and do the opposite (Block and Somers 2017, 389).
[755] See pages 107 to 110 in Chapter 5 and 256 to 263 in Appendix B.
[756] Yes, indeed, AV 2.0 really does say "a regulatory approach" on page i and "a nonregulatory approach" on page ii (NHTSA 2017, i–ii)
[757] "there is no need for U.S. DOT to favor particular locations or to pick winners and losers." (USDOT 2018, ix)

particular implementation of a technology while the content of the voluntary guidance as well as the rhetoric in this evidence very strongly (30 dB) endorses "technology neutral[ity]."[758]

Finally, this evidence is very clearly paradigmatically unlikely (40 dB) in an Adoption Catalyst world because the drive for adoption by the regulator is explicitly lacking and the rhetoric is anti-regulatory. All together then, this near rival evidence which was selected to highlight the best possible case for the nearest rival imaginary (State as Venue) provides no support (0 dB) for that imaginary over Beneficial Constraints while moderately to extremely strongly increasing our confidence in Beneficial Constraints over the other five rival imaginaries.

Regulation (EU) 2022/1426 in the EU (2016-Present)

As discussed in the analysis of the initial evidence ($E_{\text{Type-Approval}}$), there is not a true near-rival imaginary to Beneficial Constraints for the Regulation (EU) 2022/1426 case because all rival imaginaries have strong (20 dB) or more weight against them. However, the near*est* rival is that of Adoption Catalyst because although the regulation lacks an incentive or punishment structure to catalyze adoption, Regulation (EU) 2022/1426 is still uncharacteristically anticipatory of a not-quite-ready technology for the classically precautionary EU.[759] Thus, somewhat by default and somewhat by contrast, we can take the EU moving before the technology is "ready" as a relatively catalytic rather than constraining step.

Evidence that the EU believes it is enacting the type-approval standard in Regulation (EU) 2022/1426 comes from the frequent references in the recitals[760] to the need for frequent revaluation, quick updating, and constant monitoring. Although this near rival evidence ($E_{\text{Recital Qualification}}$) includes the qualifications and hesitancy which suffuse all nine recitals in their entirety, we can illustrate it with statements such as:

> *(2) …As next stage, the Commission will continue the work to further develop and adopt by July 2024…*
>
> *(3) …The review of such use cases, and their amendment if required, to cover additional use cases should be conducted on a regular basis…*
>
> *(5) …Given the complexity of automated driving systems, it is necessary to supplement the performance requirements and tests of this Regulation by manufacturer documentation…*
>
> *(European Commission 2022, 221:221/1-2)*

Taken together, these statements illustrate an EU that is moving to create a type approval ahead of the full maturity of AV technology because they qualify the detailed provisions which follow by setting up both immediate follow-on amendments as well as general guidance to monitor and revise the guidelines as the technology develops and matures. They thus define the Near Rival evidence for the EU case: $E_{\text{Recital Qualification}}$. The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be, relative to Beneficial Constraints, to see this evidence

[758] (USDOT 2018, iv)

[759] See the extensive discussion of the EU's precautionary principle in Chapter 6 as well as a discussion of the general cooperative regulatory culture in the EU as compared to the adversarial one in the United States in (Kagan [2001] 2009).

[760] "Recitals" refer to the numbered statements which follow the "Whereas" in an EU Regulation but proceed the actual text of the Regulation. While they do not carry the weight of law, they are intended to reflect the EU's reasoning behind the Regulation. (Publications Office of the European Union 2022, 35–36)

($E_{\text{Recital Qualification}}$) under the assumption that each potential regulatory imaginary was the true state of the world.

Reasoning about $E_{\text{Recital Qualification}}$ under the Comparator Type (Beneficial Constraints)[761]

Although we are highlighting $E_{\text{Recital Qualification}}$ in order to give the strongest possible support to the Adoption Catalyst nearest rival imaginary, this evidence would be at least as likely (if not more likely) to appear in the Beneficial Constraints world. Because Beneficial Constraints often looks to place guardrails against identifiable risks before an innovation has fully matured, these hesitant and qualifying statements could simply represent the EU recognizing that they are moving early in the innovation process. This "early move" is consistent with both Adoption Catalyst and Beneficial Constraints.

The key distinction between Adoption Catalyst and Beneficial Constraints lies in whether the market or the regulator is driving the adoption of the innovation across the relevant market/regulatory jurisdiction. For Beneficial Constraints, the market is the driver while regulators place guardrails. For Adoption Catalyst, the regulator is the driver and they place incentives for adoption and punishments for non-adoption.

As Regulation (EU) 2022/1426 lacks any incentives or punishments to drive adoption, it is clear that it envisions the market as the driver of adoption (driver constitutive variable). Thus, we can be moderately confident that this evidence of hesitancy is consistent with a Beneficial Constraints world.

$WoE_{\text{Recital Qualification}}$, Beneficial Constraints vs. Adoption Catalyst = 10 dB

As discussed in the analysis of the initial evidence as well as the layout of the near*est* (but not near) rival, Adoption Catalyst is not particularly likely to be the true state of the world around Regulation (EU) 2022/1426. However, this evidence could be considered consistent with an Adoption Catalyst imaginary if we consider that, for the EU, this early movement is surprising and somewhat against their general precautionary approach to regulation. However, this framing is moderately less likely than the more straightforward reading explained in the prior section where a Beneficial Constraints imaginary leads regulators to craft a regulation that places constraints on known dangers while acknowledging that the final shape of the benefits and development of the technology could take many forms. We can thus place a moderate weight of evidence (10 dB) on Beneficial Constraints over Adoption Catalyst.

$WoE_{\text{Recital Qualification}}$, Beneficial Constraints vs. Capture = 30 dB

In a Capture world, we would be quite surprised to see this evidence. The possible rationale for seeing this evidence under the assumption that Capture is the true state of the world would be that the regulator is attempting to demonstrate their lack of access to information and intent to rely on industry or other regulated entities to drive the shape of the regulation. However, we clearly know from the initial evidence that Annex II and Annex III demonstrate that the EU is very confident that they have a great deal of information to take these initial moves. Thus, the background information allows us to conclude that the Capture interpretation is far less likely than the Beneficial Constraints interpretation above which attributes the hesitancy to moving early but confidently to close of known dangers and allow for future developments. We can

[761] To avoid excessive repetition in the paired comparisons which follow, this first section in the explicit BayesTV analysis covers the reasoning for how (un)surprising this piece of evidence is under the most likely type (which will also serve as the comparator type for ease of final tabulation).

represent this comparison with a very strong (30 dB) weight in favor of the far more likely Beneficial Constraints imaginary.

$WoE_{Recital\ Qualification}$, Beneficial Constraints vs. Technology Based Regulation = 60 dB

This evidence would be extremely surprising in a Technology based Regulation world even in isolation from all other analysis because the qualification, adaptation, and hesitancy would be anathema to a regulatory imaginary which places a blanket solution-based rule in place. This blanket solution is generally characterized with a statement like 'we've weighed it all and discussion is closed' which would contradict the reevaluation and hesitancy in this evidence. In context of the other analysis, while a Technology Based Regulation world could have regulators that have either lower or higher information, it is characterized by a reliance on a single blanket outcome ("one-size-fits-all")[762] rather than allowance for multiple solutions that meet a set of guidelines or principles. As discussed in the analysis of the initial evidence, Annexes II and III clearly demonstrate that Regulation (EU) 2022/1426 is principle rather than single-solution based. As both the evidence in isolation and in context of the analysis already executed speak against Technology Based Regulation, we can place an anathema-like 60 dB (very strongly very strong) against Technology Based regulation in favor of Beneficial Constraints.

$WoE_{Recital\ Qualification}$, Beneficial Constraints vs. State as Venue = 10 dB

In a State as Venue world, these statements seeking continued input and adaptation to evolving conditions are somewhat consistent. However, taking even just the recitals in their entirety (much less the entire structure of the regulation), it is clear that the EU believes "it is necessary to adopt the implementing legislation for the type-approval of the automated driving system of fully automated vehicles" even if "[a]s next stage, the Commission will continue to work to further develop… necessary requirements."[763] In other words, the EU is ready to take this initial step even knowing that there is more that can be known and that future developments mean that "review of such use cases… should be conduced on a regular basis."[764] The EU is clearly staking a claim to being ready to move forward with their current even while acknowledging that future developments may adjust that understanding. This is far more active than merely the moderating role the State as Venue imaginary would expect. We can place a moderate (10 dB) weight of evidence in favor of Beneficial Constraints due to this more active than moderator role even though we might see such qualified language used by a mere moderator.

$WoE_{Recital\ Qualification}$, Beneficial Constraints vs. Folk Economic Model = 40 dB

While a strong believer in the truth of the Folk Economic Model might latch onto these equivocal and qualified statements as proof of the incompetence of regulators in a Folk Economic Model world, we would actually expect a much stronger statement of either defensive prescription ('this is our final statement, here is the rule') or blustering denial ('we need no additional information, we know all we need to'). In a Folk Economic Model world, then, this evidence would be paradoxically moderate and measured rather than blustery denial or defensive prescription. This measured approach is far more consistent with a Beneficial Constraints world, which we can represent with an extremely strong (40 dB) weight of evidence.

[762] (c.f. Malloy 2010, 283–85) related to the "rigidity proposition" and "homogeneity proposition."
[763] (European Commission 2022, 221:221/1)
[764] (European Commission 2022, 221:221/2)

$WoE_{Recital\ Qualification}$, Beneficial Constraints vs. Market Ideological = 60 dB

Piling on an additional level of ideological commitment to non-regulation, the Market Ideological imaginary world would seen the same perspective as the analysis of the Folk Economic Model and find this evidence to measured of a qualification. In addition, the decision to move forward with regulation despite the measured qualification would be deeply anathema to a Market Ideological world where regulators would ideally choose never to regulate under such ambiguity and uncertainty. We can represent this anathema level of surprise with 60 dB against Market Ideological and in favor of the much more plausible Beneficial Constraints interpretation.

A summary of the explicit Bayesian type validation of $E_{Recital\ Qualification}$ for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 51. The significance of this analysis is discussed in the following section on the weight of evidence $E_{Recital\ Qualification}$.

Table 51: BayesTV Constitutive Variable Comparison Summary for $E_{\text{Recital Qualification}}$ *

Constitutive Variables (Independent Variables)					Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Hesitant, qualified, but confident there is enough information to take initial moves	Clearly not the regulator, thus relying on the market	Closing off known dangers while allowing for adaptation to multiples possible final configurations	Clearly constraining within the principles and optimistic but not pushing for adoption	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Clearly not the regulator, thus relying on the market	*No distinguishing relevance*	Clearly no incentives or punishments to drive or catalyze adoption	10 dB
Capture	*No distinguishing relevance*	Implausible low information interpretation in light of Annexes II and III	*No distinguishing relevance*	Clear allowance for multiple outcomes	Constraining of known dangers but allowance for development of multiple potential benefits	30 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Clear reliance on principles rather than "one-size-fits-all" solution	Principles based constraint based on Annex II and III rather than solution based constraint	60 dB
State as Venue	*No distinguishing relevance*	Hesitancy might be consistent except in the context of the rest of the recitals	*No distinguishing relevance*	*No distinguishing relevance*	Although clearly recognizing that changes may be needed, EU taking more than a moderating role	10 dB
Folk Economic Model	*No distinguishing relevance*	Ironically, the qualifications are not strong enough for expected low information	*No distinguishing relevance*	*No distinguishing relevance*	Regulators are clearly not standing in the way of innovation by providing a path to approval	40 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Despite qualifications and hesitancy, EU moves forward with initial regulation	Market Ideological would expect inaction under uncertainty, exact opposite occurs	60 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{\text{Recital Qualification}}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 16 for further explanation and Chapter 4 for complete methodological specification

The Weight of Evidence Recital Qualification

As seen by the weights of evidence in the last column of Table 51, the piece of evidence presented above ($E_{\text{Recital Qualification}}$) increases our confidence that Beneficial Constraints is the most plausible state of the world against all rivals including the nearest rival, Adoption Catalyst. Although this evidence was selected to speak as strongly as possible for Adoption Catalyst, we are still left with at least moderate (10 dB) support for Beneficial Constraints over Adoption Catalyst because despite the relatively proactive and non-precautionary approach of moving to approve the technology before it is fully developed, there are none of the incentives for adoption (or punishments for non-adoption) we would expect to see in an Adoption Catalyst world.

While this evidence also speaks less loudly against State as Venue than the initial evidence ($E_{\text{Type-Approval}}$), we can nevertheless see that this does not suggest that we should consider State as Venue as a near rival overall. Although the hesitancy and qualification in this piece of evidence might be consistent State as Venue, it is clear that the EU believes "it is necessary to adopt the implementing legislation for the type-approval of the automated driving system of fully automated vehicles" even if "[a]s next stage, the Commission will continue to work to further develop… necessary requirements."[765] Thus while a cold look at the weight of evidence of only this piece of evidence might suggest a closer look at State as Venue, the background information discussed in the case narrative as well as the analysis of the initial evidence leave us confident that the Beneficial Constraints explanation for the qualification (an embrace of curtailing known dangers while embracing unknown future developments) is more plausible overall.

We can also rule out both the Folk Economic Model (40 dB) and Market Ideological (60 dB) imaginaries because, ironically, these qualified and hesitant statements do not strongly enough decry the 'incompetence' of regulators. The Folk Economic Model world would expect blustery denial or defensive overconfidence rather than the measured qualifications we actually see here. The Market Ideological world would expect a regulator who makes these qualified claims to take no action because they would recognize, in such a world, that any action could never be as good as the wisdom of the market especially when faced with a not-quite-mature technology.

Finally, the other two constraint-effect imaginaries of Capture (30 dB) and Technology Based Regulation (60 dB) can both be ruled out because although Regulation (EU) 2022/1426 is constraining, the constraints it puts in place do not match the constraints these worlds would expect. In a Capture world, the constraints would need to be based on a low access to information essentially ceding decision making to the capturing entity. Although we can be quite confident that there is no capturing entity,[766] even if there were the constrains put in place are much more plausibly those of Beneficial Constraints: closing of known dangers while allowing for many avenues potentially beneficial developments. The constraints are not consistent with Technology Based Regulation because they are not solution (aka single technological implementation) based but instead are principle based. On top of that, the hesitancy, qualification, and adaptation of this evidence would not be seen in the characteristically rigid statements of blanket mandates expected in the Technology Based Regulation imaginary.[767]

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[765] (European Commission 2022, 221:221/1)

[766] See the discussion around the initial evidence, $E_{\text{Type-Approval}}$, which explains that the most plausible capturing entity contradicts well known technical consensus on the promise of AVs for social good (public safety).

[767] (c.f. Malloy 2010, 283–85) on the "rigidity proposition" and "homogeneity proposition" of the conventional construction of command and control (aka. Technology-based) regulation.

BLACK SWAN EVIDENCE AND THE COUNTERFACTUAL

Before adjudicating the final type classification and sensitivity to priors, due diligence requires us to consider what evidence would be consistent with the extreme opposite of the suggested type classification being the most probable state of the world; the so-called "black swan" evidence. As Beneficial Constraints is the most likely type for the autonomous vehicle cases and the nearest rivals are State as Venue and Adoption Catalyst, the question of extreme opposite is a complex one. If we consider the neutral moderator State as Venue imaginary, we could consider either 'extreme' direction (top or bottom of Table 1) to be the black swan. However, as the actual analyzed imaginaries are one extreme (Beneficial Constraints and Adoption Catalyst) that would leave us with only the other extreme (Folk Economic Model).

If we look only at the proactive imaginaries of Beneficial Constraints and Adoption Catalyst, the extreme opposite of them would be the Folk Economic Model. Market Ideological would generally also be considered the opposite, but the complexity of the US Perpetual Guidance case makes it less clear that we can consider that an extreme opposite as it may be consistent with the near rival evidence ($E_{\text{Non-Regualtory}}$). However, as explained at length in the weight of $E_{\text{Non-Regualtory}}$ section as well as in Appendix D, we are able place moderate to strong weight against Market Ideological because the rhetoric of the Trump Administration documents did not match the content of those documents. While that rhetoric may be consistent with the Folk Economic Model, the actions taken within the guidance documents to place guiding constraints on AV entrepreneurs and innovators certainly do not match the Folk Economic Model Imaginary. We can thus make only the Folk Economic Model a true "black swan" imaginary.

From both sets of analyses, we are left with the Folk Economic Model as the black swan imaginary, and there is simply little reason to expect evidence in favor of it. In a Folk Economic Model world, we would expect to see regulators acting lost due to lower access to information than market participants and either recusing themselves from regulation in order to stay out of the way until the market has innovated[768] or implementing harsh and inappropriate anti-innovative regulations. We instead see even the US case, which may be somewhat consistent with the neighboring Market Ideological imaginary, making a strong claim to high information access in order to provide technical guidance to innovators and entrepreneurs.[769] Although we can be confident that such evidence consistent with the Folk Economic Model is unlikely to exist in either the US or EU cases, a skeptical reader should contact the author with such evidence so that it may be incorporated into analysis and allow us to radically update our priors.

FINAL TYPE CLASSIFICATION AND SENSITIVITY TO PRIORS

For final classification based on updating our beliefs in which regulatory imaginary is most probably animating the regulatory framework around autonomous vehicles, we add the decibel comparisons between the Beneficial Constraints imaginary and each of the alternative models from each piece of evidence and then add those to the priors discussed at the beginning of this section. These comparisons are presented in Table 52.

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[768] While this may seem fanciful, this "wait and see" attitude was exactly how the US Federal Reserve approached mobile payment apps for years. (Lowry 2016, 384)

[769] See the discussion of $E_{\text{Non-Regulatory}}$ (page 116) and the much lengthier discussion of same in Appendix B (page 269 to 271) for why the rhetoric of the Trump Administration documents in the United States is not Black Swan evidence despite an anti-regulatory tone to their regulatory guidance.

Consistent with the design and intent of Bayesian type validation, the evidence can tell several disciplined and clear stories depending on how it is combined with priors and across cases. If we combine all of the evidence for both the US and EU cases, we find decisive evidence[770] to believe that AV technology is regulated from the Beneficial Constraints imaginary (all imaginaries 80+ dB, Combo Posterior Column under a in Table 52). If we look just at the US case (Table 52, column a "US Post"), we find very well-established evidence (50-70 dB) for Beneficial Constraints over the Folk Economic Model, Adoption Catalyst, Capture, and Technology Based Regulation imaginaries. We also see strong (26 dB) evidence over Market Ideological and moderate (10 dB) evidence over State as Venue. If we look at just the EU case (Table 52, column a "EU Post"), we find decisive evidence (80+ dB) for Beneficial Constraints over Technology Based Regulation, Folk Economic Model, and Market Ideological imaginaries. We see very well-established evidence (50-70 dB) in favor of Beneficial Constraints over the Capture and State as Venue imaginaries and very strong (30 dB) evidence against Adoption Catalyst. These overall weights of evidence should then each be considered against the reader's priors to update our belief in what the most probable state of the world is.

If the reader adopted naïve priors with equal weights (0 dB for or against Beneficial Constraints) for the combined case of AVs in the US and EU (Table 52, column a "combo posterior"), then the evidence presented above would create decisive (80+ dB) to overwhelming (100+ dB) in favor of Beneficial Constraints over alternative regulatory imaginaries. While there are fair reasons to disaggregate the data to a per-case level as that is where the regulation actually occurred (at the US/EU levels), this combined weight of evidence is useful for us to understand how AVs are imagined to be regulated cross-nationally. The evidence thus aggregated tells us that AVs are regulated from the Beneficial Constraints imaginary regardless of priors (Naïve, Background Information, or Skeptical). Indeed, it would take a prior far stronger than the likelihood of any commercial airplane flight crashing (~67 dB) in favor of State as Venue (the nearest cross-case rival) in order to break even with Beneficial Constraints at this level of aggregation.

However, as the actual US Perpetual Guidance and Regulation (EU) 2022/1426 approaches to AV regulation were decided through separate processes, it is also useful to disaggregate down to the US/EU level and compare against priors. In the US Perpetual Guidance case, we see that the evidence remains well-established (50-70 dB) against all models except State as Venue and Market Ideological Imaginaries across Background Info priors (Table 52, column b "US Post"). With skeptical priors (Table 52, column c "US Post"), the US case maintains only strong

[770] Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival. Fairfield and Charman (2022, 162–63) proceed to explain that a more stringent threshold of 50-70 decibels equates to the thresholds of confidence used by quantitative Bayesian statisticians in the physical and biological sciences; they note that 62 dB is roughly equivalent to the 5 sigma threshold for discovering a new particle in Physics and 67 dB the chance that any given commercial airplane flight will crash vs. land safely. While Fairfield and Charman (2022, 162, footnote 34) also caution us that you cannot truly mathematically convert Bayesian odds to frequentist p-values because they are different ontological statements, most quantitative social scientists are happy with $p<0.1$ (~27 dB) and $p<0.05$ (~30 dB) for publication and are ebullient about $p<0.01$ (~37 dB). Fairfield and Charman ultimately recommend a threshold of 80-100 dB to consider a qualitative research question "settled" both to guard against potential unaccounted for bias as well as to deal with the reality that quantitative social scientists often show higher skepticism toward qualitative evidence than they do towards their own thresholds of significance.

Table 52: BayesTV Prior and Posterior Weights of Evidence for the AV Cases, US Perpetual Guidance and Regulation(EU) 2022/1426 evidence (in dB)

	a				b				c			
Weight of Evidence (WoE)*	**Naïve**				**Background Info**				**Skeptical**			
	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior
Beneficial Constraints / ***Adoption Catalyst***	0	60	30	90 dB	0	60	30	90 dB	-50	10	-20	40 dB
Beneficial Constraints / ***Capture***	0	50	60	110 dB	0	50	60	110 dB	-50	0	10	60 dB
Beneficial Constraints / ***Technology Based Regulation***	0	70	100	170 dB	-10	60	90	160 dB	-50	20	50	120 dB
Beneficial Constraints / ***State as Venue***	0	10	70	80 dB	-20	-10	50	60 dB	-50	-40	20	30 dB
Beneficial Constraints / ***Folk Economic Model***	0	57	80	137 dB	0	57	80	137 dB	-50	7	30	87 dB
Beneficial Constraints / ***Market Ideological***	0	26	120	146 dB	-10	16	110	136 dB	-50	-24	70	96 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

evidence against Technology Based Regulation, moderate evidence against Adoption Catalyst, and weak evidence against the Folk Economic Model. The extreme weight of the skeptical priors (50 dB) also make Capture a wash (0 dB) and put Market Ideological and State as Venue up as favored alternatives.

Although it is worth noting that the weight in favor of State as Venue and Market Ideological are solely due to strong priors, we should not be surprised that blanket skepticism would lead the rhetoric of the US Perpetual Guidance case to override the content. As discussed at length in the weight of $E_{\text{Non-Regulatory}}$ section as well as in the analysis in Appendix D, the Trump Administration clearly set out to wrap their guidance documents around AVs in a rhetoric of non-regulation, both as a neutral moderator (State as Venue) and as a market advocate (Market Ideological). However, the actual content of each of the Trump Administration documents remained remarkable consistent with the constraining technical guidance and assertions of authority first laid out in the FAVP from the Obama Administration.[771] While a strongly skeptical reader may remain unconvinced despite the evidence, the evidence both in the explicit highlighting and discussed in the case narrative are clear that the Trump Administration documents were far more a rhetoric of non-regulation than a substance of non-regulation.

In the Regulation (EU) 2022/1426 case, we see that the evidence weighted against Background Info priors (Table 52, column b "EU Post") remains decisive (80+ dB) against Technology Based Regulation, Folk Economic Model, and Market Ideological imaginaries and very well established (50-70 dB) for Capture and State as Venue. Adoption Catalyst remains the near*est* rival (but far from near) at a very strong (30 dB) weight of evidence. Weighted against Skeptical priors (Table 52, column c "EU Post"), the EU case maintains well-established evidence (50-70 dB) against Technology Based Regulation and Market Ideological Imaginaries and moderate to very strong evidence (10-30 dB) against Capture, State as Venue, and the Folk Economic Model imaginaries. The Adoption Catalyst imaginary for Skeptical priors does manage to maintain a strong weight of evidence over Beneficial Constraints, but this is again driven by the excessive skepticism of the skeptical priors. In other words, skeptical priors *should* represent a very well informed theory against a very new rival[772] but in order to define an extreme set of priors as an example to the reader, we set *all* alternative models at 50 dB rather than relying on Background Information or some other method of setting priors. For a reader to interpret substantive meaning from this prior-driven result, they would need to have a very good reason to believe that the EU was actually trying to catalyze the adoption of AVs hidden within the more hesitant language of Regulation (EU) 2022/1426. Possible, but highly unlikely.

Based on these four pieces of evidence, we see that how clearly AVs can be considered a case of Beneficial Constraints depends on the priors you adopt and the aggregation you are interested in. In isolation for any set of priors, these four pieces of evidence (4-Principles, Type-Approval, Non-Regulatory, Recital Qualification) are overwhelmingly convincing in favor of Beneficial Constraints over all alternative models for the general approach to AV regulation across the US and EU.

[771] Review the discussions above about the weight of $E_{\text{4-principles}}$ as well as the extensive reasoning in Appendix D on each pair comparison on $E_{\text{4-Principles}}$ and $E_{\text{Non-Regulatory}}$

[772] See the discussion on page 245 about the assignment of priors.

However, at the individual regulatory domain level, we see divergent conclusions based on priors that nevertheless may be undermined by additional case information. In the US, the State as Venue and Market Ideological imaginaries become moderately (10, -16 dB) and strongly (40, 24 dB) more likely than Beneficial Constraints for Background Info and Skeptical priors respectively, although this can only be supported were a reader to be seduced by the framing rhetoric to the exclusion of the content of the regulation. In the EU, the Beneficial Constraints imaginary confidently survives all levels of priors except for the somewhat non-sensical prior that privileges the Adoption Catalyst imaginary. As explained above, either a review of the content of the regulation, or an analysis of the EU way of law,[773] or additional explicit BayesTV could drive this spurious prior-driven weight away.

All told, though, this analysis draws our attention to the misalignment between rhetoric and reality in the US case and allows us to be exceptionally confident in Beneficial Constraints in the EU case. In the following section, we will explore some suggestive interview evidence which can shed light on how the US case is experiencing AV regulation, how regulators, entrepreneurs, and innovators see and experience the imaginaries, and how those imaginaries shape their actions.

[773] Cooperative but precautionary, as compared to the adversarial approach in the United States, (c.f Kagan [2001] 2009 for the contrasting American way of law; and D. Vogel 2012 for the precautionary principle)

APPENDIX C: SUPPLEMENT TO CHAPTER 6 – EXPLICIT BAYESIAN TYPE VALIDATION (BAYESTV) OF HOW CONFIDENT CAN WE BE THAT THE COORDINATED FRAMEWORK (US) AND PRECAUTIONARY PRINCIPLE (EU) REPRESENT A BENEFICIAL CONSTRAINTS IMAGINARY FOR GENE EDITING REGULATION

Based on the historical narratives above, the US and EU enactment of constraints on gene editing which were considered beneficial by their constituencies suggest that gene editing is a good illustrative case for Beneficial Constraints regulatory imaginary. However, we need not simply rely on asserting this judgment, we can place boundaries on our degree of confidence. Thus, as the illustrative case for Beneficial Constraints in which technology innovation precedes the development of a market and regulatory regime, gene editing is subjected in this section to a Bayesian Type Validation (BayesTV) in order to demonstrate how confident we can be that it does, indeed, represent a distinctive regulatory imaginary of disruptive innovation. This section briefly reviews what BayesTV is, explains how it is applied, and then summarizes how it was applied to gene editing in the US (Coordinated Framework) and the EU (Precautionary Principle) cases. It concludes by explaining that, for any reasonable set of priors, we can be reasonably to overwhelmingly confident that gene editing is indeed a case of Beneficial Constraints while also identifying the specific loci of contention where the reader can evaluate their level of agreement or departure from this conclusion.

BAYESIAN TYPE VALIDATION (BAYESTV): AN OVERVIEW

As explained in chapter 3, this project employs a new method called Bayesian Type Validation (BayesTV). BayesTV combines two gold-standard pillars of qualitative methodology, process tracing and typological theory, to produce a completely qualitative method of theory development and testing. While excellent qualitative work has always included theory development and theory testing, the logic of how qualitative theory building works has often been the target of incredulous skeptics. BayesTV uses the deductive logic of typological theory to complement the inductive logic of Bayesian process tracing (BayesPT)[774] to produce a disciplined and clear method of analyzing evidence and communicating results. This section briefly reviews how BayesTV operates in practice before it is applied to the evidence in this case.

To efficiently classify cases and refine the deductive typology, BayesTV incorporates a search process that focuses on the most informative pieces of evidence. The first piece of evidence explicitly[775] analyzed for a case should be the strongest piece of support for the most likely type based on background knowledge of the case.[776] The second piece of evidence should

[774] (Fairfield and Charman 2017; 2022)

[775] Explicit Bayesian analysis (whether process tracing of hypotheses or validation of types) refers to the use of mathematical likelihood ratios as developed in (Fairfield and Charman 2017) and refined in (Fairfield and Charman 2022). Implicitly, all process tracing and most qualitative research can be described as a Bayesian method of reasoning.(Fairfield and Charman 2017, 1–2) The choice of 'how explicit to get' is a tradeoff between exhaustive transparency and laboriousness which should be decided on how informative additional explicit analysis would be as opposed to an implicit summary of the weight of evidence.

[776] Since BayesTV is concerned with type validation, cases are selected using background information to be representative of a particular type. This is *not* a form of confirmation bias as the disciplined consideration of the likelihood of observing this evidence under *all* alternative types clearly and transparently presents the judgements

be selected as the strongest piece of support for the nearest rival to the most likely type based on background knowledge of the case *and* analysis of the first piece of evidence. Once the first two pieces of evidence have been explicitly analyzed, BayesTV considers whether additional evidence needs to be analyzed based on the possible priors (naïve, skeptical, etc.) and how loudly the first two pieces of evidence have adjudicated between the possible types. The extreme counterfactual state of the world is also considered and evidence for such a "black swan" event is described and sought. Once the analyst is satisfied that sufficient explicit evidence has been analyzed to build a type validation case, the weight of the evidence is placed against defined sets of priors in order to identify the sensitivity of the classification to a reader's prior beliefs about the world.

As a process of search built on highlighting the most informative pieces of evidence, BayesTV (and all logical Bayesianism) relies on the *information value* of evidence rather than the idiosyncrasies of a specific piece of evidence. While specific pieces of evidence are presented below, they are analyzed as a representative of all "informationally equivalent"[777] evidence which provides insight into the relative likelihood of which type is the true state of the world. Thus, what may appear to be a selective reification of evidence is actually a carefully considered process of which evidence to highlight in the explicit analysis in order to distinguish between possible states of the world in a clear and disciplined manner.

In metaphorical terms, the goal of BayesTV is not to cut a node out of its web of interconnections and carefully study its nodal properties under a microscope but rather to carefully consider which node to lift from a web in order to trace the interconnections. The goal is always to pull on the node which reveals the most information about the web rather than to find the most perfect individual node.

This focus on information value may appear unsettling to traditional qualitative scholars who emphasize the richness of evidence presented in their case narrative built upon deep case knowledge[778] to judge the effectiveness of an argument. Indeed, it may seem like cherry picking only one or two pieces of self-justificatory evidence!

However, as qualitativists have long pointed out to quantitativists when accused of selecting on the dependent variable or having too many variables for too few cases, one cannot naïvely apply frequentist statistical intuition to qualitative work.[779] While other qualitative methods such as analytical narratives and comparative historical analysis place their empirical richness directly

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made by the analyst. While a skeptic could certainly disagree with such judgment, the goal of a logical Bayesian approach is to clearly identify the "locus of contention" (Fairfield and Charman 2017, 16) rather than claim to be beyond contention or to set up an "entirely agree vs. entirely disagree" dichotomy. Where a transparent frequentist would rely upon preregistration of hypotheses and appeal to stochastic analysis to reject or fail to reject a null hypothesis, a Bayesian approach instead seeks to transparently state priors and indicate how evidence is used to update those priors.(Fairfield and Charman 2017, 1,6) The author and reader may ultimately disagree with the conclusions of a logical Bayesian analysis but both should be able to clearly state precisely where they disagree (evidence selection, likelihood ratios, missing hypotheses/theories in the set, etc.) rather than rely on less precise statements of agreement or disagreement based on sum total statements or reverse-engineering of an argument.

[777] (Fairfield and Charman 2017, 5 in Online Appendix)

[778] C.f. (Johnston 2012, 70) and "the importance of local or area knowledge for general theory."

[779] Compare the logic of (Brady and Collier 2010) to that in (Gary King, Keohane, and Verba 1994). A concise review of the struggles of quantitativists to grapple with qualitative evidentiary standards appears in (Fairfield and Charman 2022, 124–26).

into the text of their research reports to demonstrate analytic rigor, BayesTV uses deep case knowledge to rigorously highlight the most informative evidence in their research reports. Akin to Charles Proteus Steinmetz, who was hired by Henry Ford to fix a generator and invoiced $10,000 for a single chalk X and two lines of instructions, only a small bit of evidence may appear in the final writeup ('$0.01 of chalk') but the expertise and deep case knowledge lies in knowing which piece to highlight to maximize information value ('$9,999.99 for knowing where to place the X').[780]

Building on deductive typological theory and the inductive logic of logical Bayesian process tracing, Bayesian Type Validation (BayesTV) employs a disciplined process of search for informative evidence in order to provide transparently produced degrees of belief in whether a particular case is most plausibly operating under a particular type rather than the rival types. In this project, this translates into degrees of belief about whether regulators are truly operating under one type of regulatory imaginary (e.g. folk economic constrainer) or another (e.g. beneficial constraint, adoption catalyst, etc.). As the goal of this project is to inductively refine the deductive typology developed in Chapter 2, BayesTV is well suited to demonstrating how confident we can be that real empirical examples exist of the variety of ways that regulators, entrepreneur, and innovators co-create disruptive technological innovation.

POSSIBLE TYPES AND PRIORS

The possible regulatory imaginaries which the GE case could assume are detailed in the deductive typology developed in Chapter 3 and presented in Table 5. From the deductive typology and the reasoning in Chapter 2, we have seven distinct types which are plausible: the Folk Economic Model, Market Ideological, State-as-Venue, Capture, Technology-Based Regulation, Beneficial Constrainer, and Adoption Catalyst. These seven models present the rival worlds under which BayesTV must evaluate the evidence in order to conclude which model the evidence speaks most strongly for.[781]

We can assign several possible prior probabilities to the case being of a particular type.[782] If we are to adopt a *naïve* assumption, we would weight all seven imaginaries equally with no weight-of-evidence (WoE) for any of them (0 dB across all imaginaries, see Table 53). If, instead, we use *common background information* about the gene editing cases, we might be led to believe that either the Technology-Based Regulation or Beneficial Constraints models are more likely

[780] (Gilbert King 2011)

[781] (Fairfield and Charman 2017, 1,10)

[782] Following the advice of (Fairfield and Charman 2017, 3-4 in online appendix). This paragraph presents extremes and a paradigmatic midpoint. The reader could adopt whatever priors she sees fit, but it is most instructive to think in classes of priors rather than a continuum because we can then concentrate on tipping points. Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival..

Table 53: Prior Weights of Evidence for the Coordinated Framework and Precautionary Principle (in dB)

Weight of Evidence (WoE)*	Naïve	Background Info	Skeptical
$\frac{Beneficial\ Constraints}{Adoption\ Catalyst}$	0 dB	-10 dB	-50 dB
$\frac{Beneficial\ Constraints}{Capture}$	0 dB	-10 dB	-50 dB
$\frac{Beneficial\ Constraints}{Technology\ Based\ Regulation}$	0 dB	-10 dB	-50 dB
$\frac{Beneficial\ Constraints}{State\ as\ Venue}$	0 dB	-10 dB	-50 dB
$\frac{Beneficial\ Constraints}{Folk\ Economic\ Model}$	0 dB	0 dB	-50 dB
$\frac{Beneficial\ Constraints}{Market\ Ideological}$	0 dB	0 dB	-50 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

given the technology-specific constraints enacted by the state in the US and EU and the interrelatedness of these models discussed in the Beneficial Constraints model specification section of this chapter. Additionally, if we refer to the *case-specific background knowledge* in each case narrative, the strong public and incumbent agricultural and retail industry resistance to GE products makes the Capture imaginary more likely in the EU case while the strong public apathy and agricultural industry acceptance of GE products makes the Adoption Catalyst imaginary more likely in the US case. We can represent each of these background information-based priors by placing a moderate amount of evidence (10 dB) against Beneficial Constraints for each of the four relevant comparisons in Table 53.

Finally, to satisfy a frequentist logic to wrap up all objections in a weight against the model of interest, we may adopt a strong *skeptic*'s approach which would put a strong disadvantage to the Beneficial Constraints imaginary because it is the focus of this chapter and then equally weight each of the other models. Following Fairfield and Charman's (2022, 133) advice, "a very high prior log-odds in favor of a well-established hypothesis relative to a far less plausible rival might reasonably be set at around 50 dB."[783] Thus, we represent the strong skeptic's position by placing 50 dB against Beneficial Constraints for each of the comparisons in Table 53.

Based on the title of this chapter and discussion so far, it should not surprise the reader that my prior is that GE is a characteristic Beneficial Constraints case. To state this precisely, it

[783] Note that Fairfield & Charman propose this threshold for non-arbitrary reasons; they cite Bayesian mathematician Jaynes (2003, 99–100) as the origin of 50dB based on mathematical logic of probability thresholds used in quantitative work.

should be noted that each row in Table 5 can be read as a sentence[784] and thus the Beneficial Constrainer would read as follows: a regulator following the Beneficial Constraints model has *higher* access to *information* than firms, believes that the *market* is the *driver* for the spread of an innovation and would be content with *many* different optimal regulatory *outcomes*. Put plainly, a beneficially constraining regulator is defined by careful negation: they identify certain undesirable practices or outcomes and place constraints on regulated firms which are intended not just to reduce harm but to spur innovation towards undefined desirable practices and outcomes and away from defined undesirable ones. Critically, these constraints are not simply beneficial to society (as regulation generally is intended to be) but are also beneficial to the regulated firms; this form of regulation seeks not to curb the excesses of the market but instead to direct the dynamism of the market toward more economic (and socially) beneficial outcomes.[785] The presentation of evidence below in the execution of BayesTV is meant to give the reader, whatever their priors, an updated belief in whether or not this paragraph is the most plausible state of the world in the two GE cases.

While priors are a vital part of Bayesian reasoning, the most important analysis in logical Bayesianism at the heart of BayesTV is the *sensitivity*[786] of the results to the priors rather than choosing precise priors before the analysis. For type validation, we are interested in how confident we can be that a particular case fits a particular type rather than weighting between plausible hypotheses. For that reason, while the author is likely to have a strong prior for one type (the type being validated) and the reader may have indifferent (naïve) or strongly contrarian (skeptical) priors, what matters is how loudly the evidence needs to speak to convince different types of readers. Thus, we will return to the discussion of priors in the conclusion of this section (Final Type Classification and Sensitivity to Priors). For now, the reader should file away what regulatory imaginary she thinks best fits the GE cases and concentrate on the reasoning behind the weights of evidence presented below.

BayesTV of Gene Editing in the US Coordinated Framework and EU Precautionary Principle

In validating that gene editing is an example of the Beneficial Constraints regulatory imaginary, the key constituent variables are information, driver, and outcomes. A Beneficial Constraint conception of innovation regulation is defined by a regulator who is conceived as having higher access to information about a regulated domain combined with a belief that the market is the driver of adoption and who is content with many definitions of "optimal" outcomes rather than a single definition of optimality. The two following sections on each of the empirical gene editing cases will present evidence to update our belief in whether that is the most likely conception of regulators within each case. The evidence will focus on statements within the

[784] This is a result of the consistency of a deductive typology, discussed in detail in Chapter 2. Note that in that discussion the grammar of the sentence is exactly consistent for all 24 lines in Table 5 while in this chapter I have simplified the grammar to highlight the defining features of the Beneficial Constraints type.

[785] If capitalism is about creative destruction, as Schumpeter ([1943] 2010, 93–94) famously claimed, the beneficial constrainer seeks not to reduce the destruction but instead focus it on destroying current problems while finding creative solutions which are both economically productive and socially beneficial beyond the narrow dictates and time horizon of current market forces.

[786] (Fairfield and Charman 2017)

legislation or made by the regulators who implemented the regulations and how likely they are to be observed in the seven rival states of the world (see Table 1).

Following the advice of Fairfield and Charman (2022, 124–70), the weights of evidence are determined qualitatively but consistently through six paired comparisons of types (most likely vs. each of the six rivals) with the evidence evaluated in the order most logically coherent to the analyst. Note that because it *mathematically* does not matter in what order we incorporate evidence, we can choose the order most logical to the *substantive* comparisons at hand.[787] We can also reduce the number of comparisons by recognizing that *mathematically* a paired comparison of the six rival types against the same type is equivalent to comparing each of the rival types to each other.[788] Thus, we need only six total comparisons in order to consider all possible pairs and we are free to pick which type will be the comparator for all six rivals based on the *substance* of the case.

In the original specification of the method, Fairfield and Charman (2017, 6 in online appendix) recommended that the pairs of types are assigned weights of evidence (WoEs) in decibels (dB) based on the auditory metaphor of "how loudly the data is speaking." As the evidence is best interpreted *relative* to how much 'quieter' they are than the type which the evidence speaks the 'loudest' for, the relative loudness should be gauged in decibels (dB) to keep with the auditory sense-perception of the analytic metaphor at work. This choice of decibels helps to consistently quantify subjective qualitative analysis because it follows the same logarithmic logic as human sense perception: one dB equals a 10% change in *absolute* loudness which means that 10 dB is equivalent to "twice as loud" because it represents 100% additional *perceived* loudness (even though the actual sound pressure has increased by 1000%). Common reference sounds are reproduced from (Fairfield and Charman 2017, 10) in Table 54.

In the final refinement of their application of logical Bayesianism to social inquiry, Fairfield and Charman (2022, 129–36, esp. p.134) recommend that paired comparisons of types should be assigned weights of evidence (WoEs) in decibels (dB) based on a plain language description of relative differences. While earlier approaches relied on an auditory metaphor of "how loudly the data is speaking,"[789] the final specification recommends a generalized use of the logarithmic decibel (dB) scale to match the logarithmic nature of human sense perception without a reliance on a particular sense metaphor.[790] In keeping with the intuitive human sense perception metaphor, the lower bound for discernable differences is set at 3 dB ("smallest meaningful difference," "very weak," 2:1) while the upper bound is set at 30 dB ("eight times louder," "very strong," 1000:1). A set of qualitative-to-quantitative reference levels, their perceptual references, a natural language description of the relationship, as well as the corresponding odds or likelihood ratios is reproduced from (Fairfield and Charman 2022, 133) in Table 55.

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[787] We can also redo our analysis with the evidence in a different order as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 139–40)

[788] We can also redo our analysis with different comparator type as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 140–42)

[789] (Fairfield and Charman 2017, esp. p.6 in online appendix)

[790] Both the senses of sight and sound, for example, evolved logarithmically in humans; a tenfold increase in absolute light power or sound intensity is perceived as a doubling in "brightness" or "loudness" by human senses. See (Fairfield and Charman 2022, 129–30) for further explanation of the appropriateness of the logarithmic scale across the physical, biological, and social sciences.

Table 54: Common Reference Sounds for Decibel Levels

Decibels (dB)	Reference Sound
10	Adult hearing threshold; rustling leaves, pin drop
20	Whisper
30	Quiet bedroom or library, ticking watch
45	Sufficient to wake a sleeping person
50	Moderate rainstorm
60	Typical conversation
70	Noisy restaurant, common TV level
80	Busy curbside, alarm clock
90	Passing diesel truck or motorcycle
100	Dance club, construction site
115	Rock concert, baby screaming
194	Threshold where sound waves become shock waves

Based on (Fairfield and Charman 2017, 10)

Table 55: Qualitative-to-Quantitative Reference Levels for the decibel (dB) Comparison Scale

dB	Acoustic Perception	Plain Language Description	Equivalent Odds or Likelihood Ratio (approx.)
3	Smallest meaningful difference	Very weak	2:1
6	Clearly noticeable difference	Weak	4:1
10	Twice as loud	Moderate	10:1
20	Four times louder	Strong	100:1
30	Eight times louder	Very Strong	1000:1

Based on (Fairfield and Charman 2022, 133, Table 4.1), Note: Some digital audio files that illustrate these different decibel levels are available at: https://tashafairfield.wixsite.com/home/bayes-book

Table 56: Weights of Evidence for the Coordinated Framework and Precautionary Principle (in dB)

Weight of Evidence (WoE)*	Initial Evidence		Near Rival Evidence	
	US $E_{OSTP1986}$	EU $E_{ANNEX\ I}$	US $E_{Blue\ Book\ Repo.}$	EU $E_{Recitals\ 21+22}$
$\frac{Beneficial\ Constraints}{Adoption\ Catalyst}$	10	60	-6	90
$\frac{Beneficial\ Constraints}{Capture}$	20	6	50	-3
$\frac{Beneficial\ Constraints}{Technology\ Based\ Regulation}$	30	10	20	6
$\frac{Beneficial\ Constraints}{State\ as\ Venue}$	30	50	20	60
$\frac{Beneficial\ Constraints}{Folk\ Economic\ Model}$	60	90	50	90
$\frac{Beneficial\ Constraints}{Market\ Ideological}$	54	40	60	90

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically $(-\infty,\infty)$ although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

Table 56 provides a summary of the weight of each of the pieces of evidence. The reasoning behind these weights of evidence are fully explained in the sections which follow and each section is then summarized in a table for quick comparison (Table 57 thru Table 60). The possible contours of counterfactual evidence is explicitly defined after analysis of the actually-existing evidence. The final interpretation and comparison with priors occurs in Table 61 on page 316.

INITIAL EVIDENCE: LEGISLATIVE INTENT

The first piece of evidence highlighted for each case is based on the highest likelihood to correspond with the Beneficial Constraints model. As the GE cases were selected in order to validate the Beneficial Constraints model, their overarching statements of legislative intent shall be used to make the initial case for Beneficial Constraints over rival types as the most probable state of the world. In the US case, this evidence comes not from legislation but from regulator action in lieu of legislation: the preamble to the 1986 Coordinated Framework for Regulation of Biotechnology. In the EU case, this evidence comes from Annex I of Directive 2001/18/EC where the European Commission, Council, and Parliament crafted a directive requiring specific regulatory approval for any product this a GMO or made from a GMO which is to be released into the environment (placed on the market). The following sections discuss each of these two pieces of "legislative intent" evidence in turn.

Coordinated Framework in the United States (1986-present)

While the BayesTV method generally highlights legislative intent as the initial evidence, the US regulation of GE technology was not crafted through legislation. Rather, the USDA, FDA, and EPA came together at the behest of the White House Office of Science and Technology Policy (OSTP) to craft a coordinated framework under existing statutory authorities.[791] Since the first piece of evidence should capture the most informative statement of the intent of the ultimate authority for the regulatory action, it is this statement in the Federal Register rather than a piece of legislation which best captures this information because there *was no legislation* passed to address the regulatory disruption of GE technology in the United States. This statement of regulatory intent seeks:

> *"to achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry… Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately… The existing health and safety laws had the advantage that they could provide more immediate regulatory protection and certainty for the industry than possible with the implementation of new legislation…. The regulatory framework anticipates that future scientific developments will lead to further refinements."*
>
> *-- (Office of Science and Technology Policy 1986, 23302–3)*

The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be to see this evidence ($E_{OSTP1986}$) under the assumption that each potential regulatory imaginary was the true state of the world.

[791] (Office of Science and Technology Policy 1986, 23303)

Justification for $E_{OSTP1986}$ as Evidence for the Most Likely Type (Beneficial Constraints)

In a world where the regulators brought together by the OSTP were truly operating from a Beneficial Constraints imaginary of regulation, this statement in the preamble to the Coordinated Framework would be very consistent but slightly less vehement than an archetypical statement of Beneficial Constraints. A beneficially constraining regulator characteristically claims higher access to information about the disruptive innovation but believes the market is the driver of innovation adoption. This leads them to seek to put constraints on socially and economically undesirable avenues of innovation and direct the forces of the market to socially and economically beneficial avenues of innovation.

The statement in $E_{OSTP1986}$ clearly believes in the market as driver of innovation in voicing a concern for 'infant industry' and explaining that the framework desires to "provide more immediate regulatory protection and certainty for the industry" than would be likely from alternative approaches. This clearly business and market friendly language also satisfies the economically beneficial intent of Beneficial Constraints.

However, the statement of constraint is left more implicit as a reliance on "existing health and safety laws." Yet this approach is clearly a constraint in the sense that it requires the new tools of GE to be used with the rules which judge final products. It also represents a claim of competence and expertise on the part of existing regulators that they have access to the information they need to properly regulate within existing statutes. There is also a clear "anticipat[ion] that future scientific developments will lead to further refinements" of the specific constraints, an acknowledgement of many compatible potential regulatory outcomes to the constraints enacted.

Thus with a strong statement of beneficial, an implicit but present statement of constraints, and a specific acknowledgement of many potential outcomes, $E_{OSTP1986}$ is most likely in a world where the OSTP saw itself as operating to beneficially constrain GE innovators.

$WoE_{OSTP1986}$, Beneficial Constraints vs. Adoption Catalyst = 10 dB

While the classical interpretation of the US Coordinated Framework as 'pro-science and pro-industry at the expense of consumer safety' is overly reductive, there is certainly evidence compatible with an understanding of US OSTP as privileging a technoscientific evaluation in regulatory decision making. The structure of the Coordinated Framework as expressed in this preamble is clearly consistent with the broad strokes of a regulator who wishes to promote the adoption of GE technology. However, given the reliance on the market to promote adoption rather than state action (such as pilot projects, subsidies, or penalties for non-adoption), this piece of evidence relatively surprising in a world where the regulator is operating from an adoption catalyst imaginary because it has the effect of constraining (rather than catalyzing) innovation, albeit in a tech promoting direction. As this is an alignment in spirit (tech promotion) but a non-alignment on means (market based), this evidence weights moderately against adoption catalyst and thus is 10 dB in favor of the alternative (Beneficial Constraints).

$WoE_{OSTP1986}$, Beneficial Constraints vs. Capture = 20 dB

In a world where the regulators have been captured by regulated industry, we might expect to see this evidence because it is explicitly pro-industry and chooses to rely on existing regulations rather than seeking to enact a new framework. However, in such a world, we would need to consider the statements ensuring "adequate… health and environmental safety" to be simply lip

service. We would also expect to see a call for one preferred regulatory outcome (see Table 1 in the main article) rather than an explicit choice to "anticipate that future scientific developments will lead to further refinements." Further, for regulatory capture by industry to be more than just an epithet, it needs to be able to identify which incumbent firms are capturing which regulators.[792] As the Coordinated Framework spans three agencies (FDA, USDA, EPA) who each regulate distinct firms and sectors, the claim that the coordinated framework is the result of capturing all three would be hard to support. While the three agencies' purviews are not completely mutually exclusive (hence the need for a Coordinated Framework), the amount of coordination and collusion necessary for capture to be the true state of the world while paying lip service to all of language contrary to capture in $E_{OSTP1986}$ would be quite substantial especially for a newly developing field where the incumbent firms themselves are not firmly established. The explicit desire to "provide certainty for industry" demonstrates, as well, that regulators are claiming a greater degree of information about the technology and balance with the public interest than firms have been able to. In short, a lack of strong incumbent firms, the presence of explicit calls for flexibility, and the careful consideration of health and safety in balance with industry needs above and beyond what firms have been able to claim speaks a strongly against capture as the true state of the world and thus is 20 dB in favor of the alternative (Beneficial Constraints).

$WoE_{OSTP1986}$, Beneficial Constraints vs. Technology-Based Regulation = 30 dB

The characteristic feature of technology-based regulation is the mandate to adopt a particular technology as the only accepted solution to an identified problem. While that simply isn't the case here, even the more generalized form (a single preferred outcome, see Table 1 in the main chapter, rows 10-12) would be strongly contradicted by the intentional flexibility of the Coordinated Framework expressed in this piece of evidence. As the characteristic features of technology-based regulation are explicitly rejected in the coordinated framework, this piece of evidence would be very surprising in a Technology-Based Regulation world, and thus we have 30 dB in favor of the alternative (Beneficial Constraints) world.

$WoE_{OSTP1986}$, Beneficial Constraints vs. State as Venue = 30 dB

While the Coordinated Framework arose from a classic example of the state drawing together stakeholders to discuss their needs and desires at the 1975 Asilomar Conference, the Framework itself is clearly a step beyond simply moderating between interests. The OSTP is taking on a stakeholder rather than rulemaker relationship with the stakeholder firms and public interest. In a world where the state was simply a venue, we would expect to see deference to the stated needs of stakeholders not claims of evaluation and specific existing regulatory competence to evaluate and direct needs based on access to information about the firms and technology. As the evidence is thus a contradiction of the expected relationship of the regulator to regulated firms in the State as Venue world, this evidence would be very surprising, and thus we have 30 dB in favor of the alternative (Beneficial Constraints).

$WoE_{OSTP1986}$, Beneficial Constraints vs. Folk Economic Model = 60 dB

Quite simply, the Coordinated Framework as explained in this preamble is a statement of regulatory competence within a complicated and changing field. It represents an explicit claim by powerful and established agencies to be able to properly balance industry and public needs

[792] (Carpenter and Moss 2014a, 20)

around an emerging technology as a highly informed stakeholder rather than a proverbially ossified rulemaker envisioned by the Folk Economic Model.[793] Such a statement is anathema to a Folk Economic Model world and thus we should adopt the extreme end of our scale beyond even that in Table 55. As it would be earthshattering to see such a strong and influential statement of competence in the world imagined by the Folk Economic Model, not even the 50 dB we gave to the skeptical priors will do. Instead, we shall assign twice our very strong (60 dB), akin to a million-to-one odds or likelihood ratio.

$WoE_{OSTP1986}$, Beneficial Constraints vs. Market Ideological = 54 dB

Similar to the explanation for the Folk Economic Model, were the Market Ideological model to be the true state of the world, we would not expect to see such a bold claim of regulatory competence to supersede the almighty power of the market to guide innovation to it's most efficient ends. Instead, we would expect to see much stronger language about needing to step back and allow the market to take its course (zero desirable outcomes). Not quite as unlikely as the Folk Economic Model, we would have to believe that this was all lip service to some powerful but unobserved group who would needed to be quelled, but still quite unlikely. We'll thus score it as a clearly noticeable difference less than the Folk Economic Model, and thus put it at merely 54 dB in favor of the Beneficial Constraints imaginary.

A summary of the explicit Bayesian type validation of $E_{OSTP1986}$ for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 57. The significance of this analysis is discussed in the following section on the weight of evidence $E_{OSTP1986}$.

The Weight of Evidence OSTP1986

As seen by the weights of evidence in the last column of Table 57, the piece of evidence presented above ($E_{OSTP1986}$) increases our confidence that Beneficial Constraints is the true state of the world in the US Coordinated Framework case. At 60 dB and 54 dB, this piece of evidence speaks overwhelmingly against the two models which see regulators as simply an impediment to innovation since it is a strong statement of belief in regulatory competence (information and effect columns of last two rows of Table 57).

The real stakes of the Beneficial Constraints model, however, lies in regulators placing constraints on firms intended to be beneficial to industry but not at the expense of society. It is thus not surprising that this piece of evidence speaks less loudly against the Capture (20 dB) and Technology Based Regulation (30 dB) models as each of these models also see the regulator as a constrainer. However, as explained at length in the Appendix, a world of Capture would not likely see evidence of three powerful existing agencies (FDA, EPA, USDA) assert their existing ability to adapt to a newly emerging industrial technology (rather than assert need to protect incumbent industry, see Information column in Capture row of Table 57). So too with Technology Based Regulation, the Coordinated Framework as explained in this preamble is netiher requiring nor forbidding a specific technology but is rather establishing a flexible set of guidelines across agencies (see Outcomes and Effect columns in Technology-Based Regulation row of Table 57).

[793] (Yackee and Yackee 2011)

Table 57: BayesTV Constitutive Variable Comparison Summary for $E_{OSTP1986}$*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Reliance on existing laws affirms access to sufficient information	Strong statement of market-as-driver re: "industry certainty"	Specific acknowledgement of many potential outcomes	Moderate/ Implicit statement of constraint	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Clear reliance on market not regulator to drive adoption	*No distinguishing relevance*	Pro-adoption spirit but non-direct method	10 dB
Capture	*No distinguishing relevance*	"provide certainty for industry" = Higher regulator access to information than firms	*No distinguishing relevance*	Specific encouragement of many rather than one desirable outcome	*No distinguishing relevance*	20 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Intentional flexibility of Coordinated Framework contradicts single preferred outcome of TBR	Constraint is performance not technology based	30 dB
State as Venue	OSTP clearly taking stakeholder role	Clear assertion of informed competence of regulators	*No distinguishing relevance*	*No distinguishing relevance*	More than moderation within Coordinated Framework	30 dB
Folk Economic Model	OSTP clearly sees themselves as informed stakeholder	Statement of Regulator competence anathema to Folk Economic Model	*No distinguishing relevance*	*No distinguishing relevance*	Coordinated Framework explicitly pro-innovation rather than impediment	60 dB
Market Ideological	*No distinguishing relevance*	"provide certainty for industry" = higher regulator access to information than firms	Market is the driver but with regulatory guidance "industry certainty"	Clear description of more than zero desirable outcomes	Coordinated Framework explicitly pro-innovation rather than impediment	54 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{OSTP1986}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 53 for further explanation and Chapter 4 for complete methodological specification.

At the other extreme of state action, Adoption Catalyst, the reliance on the market to spread the innovation within the Coordinated Framework speaks moderately against Adoption Catalyst as the true state of the world (see Driver column in Adoption Catalyst row of Table 57). Finally, this piece of evidence speaks very strongly against the neutral moderator role of the State as Venue model relative to Beneficial Constraints given that the Coordinated Framework went beyond moderating the stakeholder discussions at both Asilomar and the OSTP working group to actually specify a set of rules and principles shared between three agencies (see State as Venue row of Table 57).

Precautionary Principle in the EU (2001-Present)

The legislative intent for the EU Precautionary Principle approach to gene editing regulation comes from the establishing Directive, Directive 2001/18/EC. As with all EU Directives, 2001/18/EC opens with a list of numbered recitals including notable references to "the precautionary principal,"[794] "respect for ethical principles,"[795] "case-by-case evaluation,"[796] and "step by step" introduction of each GMO.[797] While these recitals do not carry the force of law, they may be used by member states in interpreting and clarifying provisions of the Directive when implementing them in national law and often contain a statement of principles which motivate the enactment of the directive.

The objective of Directive 2001/18/EC, stated in Article 1, is to protect human health and the environment when releasing genetically modified organisms within the Community specifically "in accordance with the precautionary principle".[798] Notably, however, the EU clearly specifies what is not considered to be genetic modification in Annex I A Part 2 and I B:

> *[Annex I A] PART2*
>
> *Techniques referred to in Article 2(2)(b) which are* ***not considered to result in genetic modification****, on condition that they* ***do not involve the use of recombinant nucleic acid molecules*** *or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:*
>
> *(1) in vitro fertilisation,*
>
> *(2) natural processes such as: conjugation, transduction, transformation,*
>
> *(3) polyploidy induction.*
>
> *ANNEX I B*
>
> *TECHNIQUES REFERRED TO IN ARTICLE 3*
>
> *Techniques/methods of genetic modification yielding* ***organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules*** *or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:*

[794] (European Parliament and Council of the European Union 2001, OJ L:1, recital 8)
[795] (European Parliament and Council of the European Union 2001, OJ L:1, recital 9)
[796] (European Parliament and Council of the European Union 2001, OJ L:2, recitals 18 & 19)
[797] (European Parliament and Council of the European Union 2001, OJ L:2, recital 24)
[798] (European Parliament and Council of the European Union 2001, OJ L:4)

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through ***traditional breeding methods****.*

-- (European Parliament and Council of the European Union 2001, OJ L:17–18 emphasis added)

Although buried somewhat in negation language, the line between genetically modified organism (GMO) and not is clearly defined here not based on **whether** the genetic code of an organism has been modified but **how** that code has been modified. For Directive 2001/18/EC, and thus the EU Precautionary Principle case, genetic modification is only of concern when it is does not occur "naturally" and is not induced through "traditional breeding methods." The line is defined based on technique, not outcome. The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be to see this evidence ($E_{ANNEX\ I}$) under the assumption that each potential regulatory imaginary was true.

Justification for $E_{ANNEX\ I}$ as Evidence for the Most Likely Type (Beneficial Constraints)

As argued throughout the chapter, the Precautionary Principal is a case of Beneficial Constraints based on the definition of beneficial set by the European Union (strict scrutiny of new "unnatural" GMOs). If Beneficial Constraints is the true state of the world, then we would be very likely to see the definitions of what is and is not a GMO seen in $E_{ANNEX\ I}$ which carefully draws the line for genetic modification based on the technique of modification. The acknowledgement and exclusion of "traditional breeding methods" as well as the careful semantics that simultaneously acknowledge that genes are modified in other ways than those covered but then define them as "not considered to result in genetic modification" is exactly the sort of careful submersion of social scientific/subjective goals beneath seemingly technoscientific/objective criteria that we would expect to see in a world where the regulator aims to have a constraining effect on recombinant GE techniques because those techniques are seen as needing extra precaution.

In terms of the constitutive variables in the typology, the content of Annex I is a clear claim by regulators to have higher information than GE agriculture firms, specifically their claim to define what is and is not "considered to result in genetic modification." Directive 2001/18/EC was also enacted by the EU in order to overturn a de facto moratorium on GE products due to member state bans, showing that they intended for the market rather than the regulator to drive innovation adoption.[799] While perhaps only implicit in this specific excerpt, there is also space left for a variety of desirable outcomes by trying to delineate what is and is not considered to be GE, rather than what is and is not allowed. We know from the case narrative that this flexibility will eventually lead to the follow-up Regulations EC No 1829/2003 and EC No 1830/2003 which create a labeling scheme rather than an outright ban.

$WoE_{ANNEX\ I}$, Beneficial Constraints vs. Adoption Catalyst = 60 dB

As the EU is clearly putting in place strong constraints on the adoption of GE technology, we would be very unlikely to see this piece of evidence in an Adoption Catalyst world. In order for us to observe this evidence in such a world, regulators would need to be quite literally saying one

[799] (D. Vogel 2012, 81)

thing (precaution about GE technology and GMOs) while actually intending to encourage the opposite (the rapid adoption of GE and GMOs). We know from the background information that no such subterfuge ever took form nor is it likely that regulators were so incompetent as to not realize what they were saying. This leaves us with we more than twice our very strong weight of evidence (60 dB) in favor of Beneficial Constraints over adoption catalyst, akin to a million-to-one odds or likelihood ratio.

$WoE_{ANNEX\ I}$, Beneficial Constraints vs. Capture = 6 dB

In a world where the EU Commission and Parliament have been captured by traditional agricultural producers, this evidence would appear at first to not be very surprising. However, given the EU case narrative presented in the case introduction explaining why GE is a good exemplar for Beneficial Constraints, it is clear that the demand for a technique-based distinction came not from the producers but from consumers.[800] Thus, despite the alignment between $E_{ANNEX\ I}$ and the Capture model, background information from evidence presented narrative rather than highlighted here with explicit BayesTV allows us to create a clearly noticeable difference against Capture as industry did not push for this distinction. In a Beneficial Constraints world, this evidence would be even less surprising because the attempt to constrain based on a consumer definition of what is beneficial is more consistent with Beneficial Constraints than Capture. We will return to the distinction between Beneficial Constraints and Capture in the EU case based on how we define "beneficial" at much greater length in the discussion of $E_{Recitals\ 21+22}$.[801] For now, we can record a clearly noticeable 6 dB of support for Beneficial Constraints over Capture.

$WoE_{ANNEX\ I}$, Beneficial Constraints vs. Technology Based Regulation = 10 dB

While technology-based regulation generally mandates the use of a specific technology, it can just as logically ban the use of a specific technology. From this perspective, this piece of evidence might be seen in a Technology-based regulation world, but it is more likely in a Beneficial Constraints one because it neither requires nor bans particular technologies, instead explicitly choosing to distinguish between acceptable exclusions and heightened scrutiny inclusions of technology. This categorization rather than a ban or mandate also affirms the possibility of multiple desirable outcomes (no GMO products, well labeled GMO products, mix of label and restraint) rather than the single desirable outcome specified in a technology-based regulation. Thus, we get a moderate weight of this evidence (10 dB) in favor of Beneficial Constraints over Technology-based Regulation.

$WoE_{ANNEX\ I}$, Beneficial Constraints vs. State as venue = 50 dB

Given the clear language in the recitals and the careful semantics of acknowledgement and negation in Annex I, it is clear that the EU is not simply convening stakeholders here but instead taking a firm position on the side of precaution over alternative means of evaluation. Such a firm position would be shocking in a State-as-Venue world where regulators are characteristically

[800] See (D. Vogel 2012, 80–81) for the discussion of the dominance of "consumer interest" and "public support" over agricultural industry lobbying in the GM debate around Directive 2001/18/EC and Regulations EC No 1829/2003 and EC No 1830/2003.

[801] Note, by the way, that this sort of crosstalk between evidence is not violation or "bug" in logical Bayesian analysis but a feature. See (Fairfield and Charman 2022, 139–40) for a discussion of the ordering of evidence in logical and substantive perspectives.

detached from discussions of stakeholders. This shock can be represented by the 50 dB of our extreme skeptic's aversion to believing that such evidence would be observed in such a world.

$WoE_{ANNEX\ I}$, Beneficial Constraints vs. Folk Economic Model = 90 dB

The concept of a precautionary principal which explicitly animated this law as well as the specific inclusions/exclusions in this list simply would not appear in a world where regulators did not believe it was possible for them to properly manage the introduction of a new technology. Strictly speaking of the Effect constitutive variable, the EU is placing constraints on GE and GMO but these are in repeal of a de facto ban [802] (an impediment) which is precisely the opposite of what we would expect to see in a Folk Economic Model world. At this extreme a level of unlikeliness relative to Beneficial Constraints the precise number of decibels becomes more fluid, but as this is perhaps the most earth-shatteringly contradictory evidence in a Folk Economic World, we are forced to push very strongly above our previous strongest distinction. This would make us 30 dB beyond the 60 dB in the $E_{OSTP1986}$(Beneficial Constraints vs. Folk Economic Model) leaving us at 90 dB for Beneficial Constraints over the Folk Economic Model for $E_{ANNEX\ I}$.[803]

$WoE_{ANNEX\ I}$, Beneficial Constraints vs. Market Ideological = 40 dB

Given the appeals to ethics and the precautionary principle in the preamble, as well as the specific language of "traditional methods" in Annex I B, we would be highly unlikely to see this piece of evidence in a world where the market was valued as the arbiter for its own sake (a Market Ideological world). While this is certainly far from the true anathema of this evidence in the Folk Economic Model, never the less this evidence speaks more than very strongly (30 dB) in favor of Beneficial Constraints over Market Ideological because it heretically set limits outside of market rationale. We'll put "more than very strongly" at 10 dB above 30 dB, leaving us with a WoE of 40 dB.

A summary of the explicit Bayesian type validation of $E_{ANNEX\ I}$ for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 58. The significance of this analysis is discussed in the following section on the weight of evidence $E_{ANNEX\ I}$.

The Weight of Evidence ANNEX I

As seen by the weights of evidence in the last column of Table 58, the piece of evidence presented above ($E_{ANNEX\ I}$) increases our confidence that Beneficial Constraints is the true state of the world in the EU Precautionary Principle case. At 90 dB and 40 dB, this piece of evidence speaks overwhelmingly against the two models which see regulators as simply an incompetent (Folk Economic Model) or undesirable (Market Ideological) impediment to the market because the constraints enacted specifically were done to repeal a de facto ban create by powerful member states prior to Directive 2001/18/EC.[804]

Nevertheless, the real stakes of the Beneficial Constraints model lie in the placing of constraints as well as the intention for those constraints to be beneficial to both industry and

[802] (D. Vogel 2012, 78–79)
[803] A reminder: these sorts of cross-evidentiary comparisons in qualitatively determining decibels are EXACTLY the point of logical Bayesian inference: being consistent about how we are making and recording out qualitative judgements. See (Fairfield and Charman 2022, 124–26) for further discussion.
[804] (D. Vogel 2012, 78–79)

Table 58: BayesTV Constitutive Variable Comparison Summary for $E_{ANNEX\ I}$*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Careful specification of what is/isn't "considered to result in genetic modification"	Directive overturned de facto ban[805] so market could drive GE adoption	Implicit acceptance of multiple outcomes due to labeling replacing prior de facto ban	Constraint based on careful weaving of techno-/social-scientific criteria	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Clearly constraining not catalyzing.	60 dB
Capture	*No distinguishing relevance*	Regulator claimed information about consumers beyond that of regulated firms	*No distinguishing relevance*	*No distinguishing relevance*	Constraints demanded by consumers, not by regulated industry	6 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Multiple outcomes possible due to categorization rather than ban/mandate	Constraints based on categorization (rather than ban/mandate) for specific technology	10 dB
State as Venue	*No distinguishing relevance*	Regulator claimed information about consumers beyond that of regulated firms	*No distinguishing relevance*	*No distinguishing relevance*	Clearly constraints and not mere moderation.	50 dB
Folk Economic Model	Regulator clearly acting as precautionary stakeholder not reserved rulemaker	Proactive precaution of regulator based on assessment of consumer demand would be anathema to FEM	*No distinguishing relevance*	*No distinguishing relevance*	Constraints on GE to repeal a de facto ban (removed impediment)	90 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Precautionary principle heretical to Market Ideological world	Constraints on GE to repeal a de facto ban (removed impediment)	40 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{ANNEX\ I}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 53 for further explanation and Chapter 4 for complete methodological specification

[805] (D. Vogel 2012, 81)

society. It is thus not surprising that this piece of evidence speaks less loudly against the Capture (6 dB) and Technology Based Regulation (10 dB) models as each of these models also see the regulator as a constrainer. However, as explained at length in the Appendix, while the technoscientifically arbitrary line between recombinant DNA and "traditional methods" of gene editing are congruent with capture by traditional agricultural producers, the background information of the case makes clear that *consumers* pressed for this line, not incumbent *industry*as would be required for any meaningful specification of capture theory.[806] With regard to Technology Based Regulation, the Precautionary Principle does not forbid a specific technology but rather establish a stringent set of protocols for its use. For similar reasons, this evidence speaks vehemently against the Adoption Catalyst model as the Precautionary Principle uses state action to slow the adoption of GE technology rather than enable it. Finally, the neutral moderator role of the State as Venue model is extremely incongruent with this piece of evidence given the strong stance these definitions take in favor of traditional gene editing techniques over recombinant DNA techniques.

NEAR RIVAL EVIDENCE:

As can be seen from the weight of evidence summary in Table 56, the initial evidence was least decisive (fewest decibels) about a different alternative type for each of the cases. In the US Coordinated Framework case, the nearest rival model is the Adoption Catalyst model because the structure of the Coordinated Framework as expressed in this preamble ($E_{OSTP1986}$) is clearly consistent with the broad strokes of a regulator who wishes to promote the adoption of GE technology although it is relatively less likely than Beneficial Constraints because the mechanism used is left to the market rather than catalyzed by the state. In the EU Precautionary Principle case, the nearest rival model is the Capture model due the explicit exception of "traditional breeding methods" from regulation as well as the careful semantics that simultaneously acknowledge that genes are modified in other ways than those covered by Annex I A Part 1 but then define them as "not considered to result in genetic modification."[807]

In this section, we highlight an additional piece of evidence which is most supportive of the respective nearest rival type for each of the two empirical cases. For the US Coordinated Framework case, this evidence comes from the International Aspects section of the Preamble to the Coordinated Framework because, in line with the Adoption Catalyst imaginary, it explicitly lays out the desire of the OSTP and coordinating Agencies (USDA, FDA, EPA) to encourage development of and reduce barriers to trade in GMO products.[808] For the EU Precautionary Principle case, this evidence comes from Recitals 21+22 of Regulation EC No 1829/2003 because they explicitly lay out the deference to consumer distrust of GMO products against the advice of experts which is consistent with a (cultural) capture imaginary.

Coordinated Framework in the United States (1986-Present)

In the leadup to the drafting of the Coordinated Framework, there were a number of US and international meetings of scientists and other stakeholders to discuss what was scientifically known of, economically possible from, and socially (un)desirable about gene editing technology

[806] See (D. Vogel 2012, 80–81) for the discussion of the dominance of "consumer interest" and "public support" over agricultural industry lobbying in the GM debate around Directive 2001/18/EC and Regulations EC No 1829/2003 and EC No 1830/2003 and (Carpenter and Moss 2014a, 20) for a discussion of capture theory

[807] (European Parliament and Council of the European Union 2001, OJ L:17–18)

[808] (Office of Science and Technology Policy 1986, 23308)

and the resulting GMO products. One such meeting was the previously discussed 1975 Asilomar Conference. [809] Another meeting, specifically referenced in the published Coordinated Framework, was the Ad Hoc Group of Government Experts convened by the Organization for Economic Cooperation and Development (OECD) which was reported in "Recombinant DNA Safety Considerations, Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques,"[810] colloquially known as the "Blue Book."[811]

In the final section of the preamble to the Coordinated Framework, OSTP reproduced the entirety of the "Summary and Recommendations" guidelines from the OECD Blue Book. This reproduction was presaged with a statement from OSTP where they paraphrased what they saw as the message of the OECD's report:

> *"**The United States seeks to promote international scientific cooperation and understanding of scientific considerations in biotechnology** on a range of technical matters. These activities add to scientific knowledge and ultimately contribute to protection of health and the environment.*
>
> ***The United States also seeks to reduce barriers to international trade**. U.S. agencies apply the same regulation and approval procedures on domestic and foreign biotechnological products.*
>
> *We are seeking recognition among nations of the need to harmonize, to the maximum extent possible, national regulatory oversight activities concerning biotechnology. **Barriers to trade in biotechnological products should be avoided** as nations join together in working toward this mutual goal.*
>
> *The U.S. agencies that have published separate policy statements as part of this notice are committed to the policy described in this section on international harmonization and have incorporated by reference the language in this International Aspects section as part of their respective agency policy statements.*
>
> *Organization for Economic Cooperation and Development (OECD)*
>
> *The approach of the comprehensive framework contained in this notice takes into account,* inter alia*, the broad goals described by an Ad Hoc Group of Government Experts convened by OECD in their recent report entitled, "Recombinant DNA Safety Considerations, Safety Considerations for Industrial, Agricultural and Environmental Applications of Organisms Derived by Recombinant DNA Techniques." **The United States is pleased to have had the opportunity for its experts to work with those of other governments in the preparation of this report**."*
>
> *-- (Office of Science and Technology Policy 1986, 23308 emphasis added)*

[809] See the discussion of several such meetings in the US Case background section (Perpetual Guidance in the United States (2016-Present)) on page 95, above.
[810] (Office of Science and Technology Policy 1986, 23308; OECD 1986)
[811] (Schiemann 2006)

With strong and repeated emphasis on lowering barriers, promoting scientific cooperation and understanding, and driving international trade in GMOs, the introduction to the reproduction of the Summary and Recommendations from the OECD Blue Book is a piece of evidence which would be very consistent with the Adoption Catalyst imaginary identified by the legislative intent evidence ($E_{OSTP1986}$) as a near rival to the Beneficial Constraints imaginary in the US Coordinated Framework case. The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be, relative to Beneficial Constraints, to see this evidence ($E_{\text{Blue Book Reproduction}}$) under the assumption that each potential regulatory imaginary was the true state of the world.

Reasoning about $E_{\text{Blue Book Reproduction}}$ under the Comparator Type (Beneficial Constraints)[812]

As we are highlighting $E_{\text{Blue Book Reproduction}}$ in order to give the strongest possible support to the Adoption Catalyst imaginary, it is no surprise that it would be rather more surprising to see in a world where the OSTP is actually acting from the Beneficial Constraints imaginary. The emphasis on reducing and avoiding barriers to trade seems to be in direct contravention of the concept of constraint, beneficial or otherwise. Nevertheless, it is not impossible to see how a beneficially constraining regulator might advocate for a particular (low) set of constraints established by US experts and US led "understanding of scientific considerations in biotechnology." Indeed, in the actual recommendations from the OECD which were reprinted by the OSTP to form this piece of evidence, we see statements such as "There is no scientific basis for specific legislation for the implementation of rDNA techniques and applications" and "Any approach to implementing guidelines should not impede future developments in rDNA techniques"[813] which strongly reflect the OSTP Coordinated Framework's structure as discussed in $E_{OSTP1986}$. So, while looking just at the text of $E_{\text{Blue Book Reproduction}}$ might suggest a much lower likelihood of observing it in a Beneficial Constraints world, in light of background information (such as the actual content of the OECD's recommendations) we can safely conclude that the evidence is somewhat likely to be observed.

$WoE_{\text{Blue Book Reproduction}}$, Beneficial Constraints vs. Adoption Catalyst = -6 dB

Unsurprisingly, $E_{\text{Blue Book Reproduction}}$ is exactly what we would expect to see in a world where the OSTP is working as an adoption catalyzing regulator as they are seeking to promote the adoption of US-congruent standards (which are also OECD congruent) for biotechnology so as to reduce the barriers to trade in biotechnology. Yet, as discussed in the prior section, this evidence would not be all that surprising in a Beneficial Constraints and the language remains symbolic and aspirational rather than a specification for strong incentives to encourage international adoption. In addition, Adoption Catalyst, given its focus on state action, is necessarily harder to reproduce in the international arena as there is no "world state" to take as active a role as might be expected in an adoption catalyzing regulator. Nevertheless, the participation of US experts in the drafting of the OECD guidelines is consistent with an attempt to take state action in a stateless (but not purely anarchic) international arena and we can speak at least weakly in favor of Adoption Catalyst over Beneficial Constraints (-6 dB).

[812] To avoid excessive repetition in the paired comparisons which follow, this first section in the explicit BayesTV analysis covers the reasoning for how (un)surprising this piece of evidence is under the most likely type (which will also serve as the comparator type for ease of final tabulation).

[813] (OECD 1986, 42; reproduced in Office of Science and Technology Policy 1986, 23308)

$WoE_{Blue\ Book\ Reproduction}$, Beneficial Constraints vs. Capture = 50 dB

Although there are many faces of regulatory capture (c.f. (Carpenter and Moss 2014b)), the encouragement of *lowering* barriers to an emerging technology sector (biotechnology) is antithetical to the core concept of capture which hinges on protecting the interests of *incumbent* industry (or, internationally, domestic industry) at the expense of consumers and new challenger firms. This piece of evidence is thus diametrically opposed to capture, excepting perhaps a concept of "capture by capitalism" (a concept explored in the Folk Economic Model and Market Ideological imaginary) or the pernicious forms of "the privileged position of business".[814] In addition, the guidance in the OECD blue book and reprinted by the OSTP makes clear claims by regulators to be highly informed as well as stating their desires to allow for many innovative outcomes. It would thus be extremely surprising to see regulators ENCOURAGING new entrant firms and countries into a sector not already dominated by powerful American incumbent firms if Capture were the true state of the world. We can thus place extremely strong weight (50 dB) in favor of the comparator (Beneficial Constraints) where this evidence would not be particularly surprising.

$WoE_{Blue\ Book\ Reproduction}$, Beneficial Constraints vs. Technology Based Regulation = 20 dB

Technology based regulation on the international stage is axiomatically difficult to impossible as there is no global state to enforce the blanket command. However, attempts to emulate command and control regulation (of which Technology-based regulation is sub-type) in international arenas often takes the form of adopting shared standards and specifications. While the OECD language reproduced in the Coordinated Framework might be seen as such, the content of that language is principle-based rather than prescriptive, making it much less likely to be seen in a world where the regulators are operating from a Technology Based Regulation imaginary. The statement also endorses international competition under uniform evaluation for domestic and international products, allowing for many possible outcomes based on the vicissitudes of the competitive market, a stance at odds with the single mandated outcome of the Technology-based Regulation imaginary. We can therefore put a very strong weight of evidence (30 dB) in favor of the comparator hypothesis because this evidence would be very surprising in a Technology-based Regulation world while it would be somewhat consistent with a Beneficial Constraints world.

$WoE_{Blue\ Book\ Reproduction}$, Beneficial Constraints vs. State as venue = 20 dB

While the Ad Hoc committee which wrote the Blue Book does represent an international organization (the OECD) operating as a venue to gather and collate stakeholder views, the reproduction of the output from that action ($E_{Blue\ Book\ Reproduction}$) goes beyond simply a reproduction of the views of stakeholders. Instead, while the OECD may have reproduced the views and recommendations of the stakeholders on the ad-hoc committee, the OSTP (when introducing the reproduction of the OECD's views) clearly states what they see as the correct *interpretation* of those principles. In interpreting and framing the OECD, the OSTP is taking on a stakeholder rather than moderating rulemaker relationship. This goes significantly beyond simply convening and collating, making this evidence relatively less likely in a state-as-venue world. In addition, the presentation of this expertise demonstrates that the OSTP is claiming

[814] C.f. (Lindblom 1977, 170–88 (aka. Chpt 13)) for a discussion of the Privileged Position of Business, although note as well that this framework go so far beyond capture that reducing Lindblom's argument to merely "capture" is to lose vital detail on an altar of parsimony.

access to a very high level of information about the regulated domain and underlying technology rather than the low level of information which helps to define the State as Venue imaginary. We can thus place strong weight (20 dB) for Beneficial Constraints over State as Venue because the OSTP is clearly acting as a high information stakeholder even if one believes the OECD was only acting as a low information rulemaker.

$WoE_{Blue\ Book\ Reproduction}$, Beneficial Constraints vs. Folk Economic Model = 50 dB

While the lowering of barriers and constraints is consistent with the Folk Economic Model's perception of regulators as an inherent impediment, in light of background information of what the Coordinated Framework contains in its entirety as well as what the OECD recommendations include (such as a reliance on regulatory evaluation as a competent means of ensuring safety) we can safely say that this call to conform to and encourage international harmonization does not represent an abdication of regulatory competence and authority. Instead, this pro-market stance is based in claims of regulatory competence to spread the US approach internationally which would be much much more surprising in a Folk Economic Model world than a Beneficial Constraints world because the Folk Economic Model presumes incompetence while the Beneficial Constraints model presumes competence. The OSTP is also acting in a guiding way and thus as a stakeholder rather than simply a withdrawn rulemaker. Taken together, this is very very strong evidence (50 dB) in favor of Beneficial Constraints over the Folk Economy Model.

$WoE_{Blue\ Book\ Reproduction}$, Beneficial Constraints vs. Market Ideological = 60 dB

Similar to the reasoning of the Folk Economic Model, the content of the OECD's recommendations makes it clear that the authors of the OECD and OSTP reports both believe that the state is fundamentally competent to assess risk and adequately constrain GE technology while still promoting its development and trade. This belief in the competence of state regulation contradicts the Market Ideological approach which would allow the market to decide rather than tying itself to international organization guidelines. In order for us to observe this evidence in a Market Ideological world, we would have to think that this passage is intended as a "poison pill" to allow the power of international capitalism to undo all of the rest of the careful constraints defined in the Coordinated Framework (and highlighted in $E_{OSTP1986}$). Whether or not we believe that there are people who hold such views in government from time to time, it is clear that this is an exceptionally unlikely set of circumstances relative to the more probable reasoning under Beneficial Constraints in the first section about this piece of evidence. Thus, we want to place a weight somewhat higher than that on the Folk Economic Model vs. Beneficial Constraints here because that comparison relied on incompetence of the regulators while this comparison would rely on malfeasance and subterfuge if we were to inhabit the Market Ideological world. Moderately higher weight (10 dB) than the very very strong evidence (50 dB) leads us to a reasonable 60 dB for Beneficial Constraints over Market Ideological.

A summary of the explicit Bayesian type validation of $E_{OSTP1986}$ for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 59. The significance of this analysis is discussed in the following section on the weight of evidence $E_{Blue\ Book\ Reproduction}$.

Table 59: BayesTV Constitutive Variable Comparison Summary for $E_{\text{Blue Book Reproduction}}$*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	Content of OECD Blue Book asserts high information that "no scientific basis for specific legislation"	*No specific relevance*	*No specific relevance*	Reducing constraints in favor of US-led shared constraints which encouraged "future developments"	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Aspirational language encouraging adoption	*No distinguishing relevance*	Hard to produce international catalyst due to no international state.	-6 dB
Capture	*No distinguishing relevance*	State claimed knowledge of information beyond firms (thus guidance)	*No distinguishing relevance*	Flexibility and encouragement of innovative outcomes.	Constraints were pro-competition and pro new-entrant firms	50 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Endorsement of multiple outcomes and international competition	Principle based (rather than prescriptive) constraint	20 dB
State as Venue	OSTP acting as stakeholder even if OECD was simply rulemaker	OSTP experts and OECD experts asserting high information in authoring guidance	*No distinguishing relevance*	*No distinguishing relevance*	OECD moderated but OSTP used output to constrain	20 dB
Folk Economic Model	OSTP clearly a stakeholder (guidance) and not a withdrawn rulemaker	Strong claims of regulatory competence to adequately evaluate and regulate GE	*No distinguishing relevance*	*No distinguishing relevance*	OSTP is reducing impediments and encouraging lower barriers to trade	50 dB
Market Ideological	*No distinguishing relevance*	Strong claims of regulatory competence to adequately evaluate and regulate GE	*No distinguishing relevance*	Flexibility and encouragement of innovative outcomes.	OSTP is reducing impediments and encouraging lower barriers to trade	60 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $\text{WoE}_{\text{Blue Book Reproduction}}$, Beneficial Constraints vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 53 for further explanation and Chapter 4 for complete methodological specification.

The Weight of Evidence Blue Book Reproduction

As seen by the weights of evidence in the last column of Table 59, the piece of evidence presented above ($E_{\text{Blue Book Reproduction}}$) increases our confidence that Beneficial Constraints is the most likely state of the world in the US Coordinated Framework case over all imaginaries except the Adoption Catalyst imaginary. As expected, given the selection criteria for the near rival evidence, we would be more likely to see this piece of evidence in the nearest rival world (Adoption Catalyst) than the Beneficial Constraints world because they are seeking to promote the adoption of US-congruent standards (which are also OECD congruent) for biotechnology so as to reduce the barriers to trade in biotechnology. Yet, given the Adoption Catalyst imaginary's focus on state action to drive the adoption of a technology, the lack of a true state in the international arena makes this evidence only slightly (6 dB) more likely in the Adoption Catalyst world than the Beneficial Constraints world.

With respect to the two models which see regulators as simply an impediment on innovation (Folk Economic Model and Market Ideological), the endorsement of regulatory competence in the content of the OECD recommendation reproduced by the OSTP cannot be drowned out by the pro-market language of lowering trade barriers. Indeed, for this pro-market language to be plausible observed along with the rest of the evidence discussed in the case narrative as well as that highlighted in the legislative intent section (E_{OSTP1986}), we would have to believe that regulators were either deeply incompetent (for the Folk Economic Model) or engaged in some sort of devious subterfuge intended to allow the power of international capitalism to undo all of the rest of the careful constraints defined in the Coordinated Framework. Such beliefs might help to turn out Libertarian voters but they are extremely (50 dB and 60 dB) unlikely relative to the much more plausible narrative of the US seeking to evangelize their way of regulating GE which is all we would need to accept for a Beneficial Constraints world.

Interesting though the extreme imaginaries are, the real stakes of the Beneficial Constraints model lie in placing constraints on markets to benefit both industry and society. Thus, the crux lies in distinguishing between the other two models which see the regulator as a constrainer: Technology-based Regulation and Capture. Relative to the initial evidence (E_{OSTP1986}), this piece of evidence slightly more quietly yet still decisively against Technology-Based Regulation (20 dB) but *much louder* against Capture (50 dB). As Capture was strongly yet not overwhelmingly weighed against in E_{OSTP1986}, this piece of evidence allows us to more forcefully reject Capture because the *lowering* of barriers to an emerging technology sector (biotechnology) is antithetical to the core concept of capture which hinges on protecting the interests of *incumbent* industry (or, internationally, domestic industry) at the expense of consumers and new challenger firms (c.f. Carpenter and Moss 2014b). As with the prior evidence, $E_{\text{Blue Book Reproduction}}$ speaks against Technology-Based Regulation because the OECD recommendations reproduced by the OSTP are not requiring or forbidding a specific technology but are rather establishing a flexible set of guidelines.

Finally, the neutral moderator role of the State as Venue model is a normal conversation in a quiet room quieter than Beneficial Constraints given that, while the OECD may have reproduced the views and recommendations of the stakeholders on the ad-hoc committee, the OSTP in it's introduction to the reproduction clearly states what they see as the correct interpretation of those principles.

Precautionary Principle in the EU (2001- Present)

As discussed in the case introduction (p.99 in the main chapter), when Directive 2001/18/EC proved insufficiently stringent for member states who had enacted bans on GMOs, the Commission, Council, and Parliament crafted two 2003 Regulations (EC No 1829/2003 and EC No 1830/2003) which required specific regulatory approval for anything grown from GMO seeds and "established the world's most stringent and comprehensive labeling requirements" based on tight tolerances and comprehensive tracing procedures.[815] These stringent labeling requirements have led to a de facto moratorium across virtually all food producers and retailers as they fear consumer backlash against products which would need to bear the labels.[816] These guidelines were developed with specific reference to what European public opinion considered beneficial: the absence of GE crops in food, as expressed in the 21st recital of EC No 1829/2003:

> *(21) The labelling should include objective information to the effect that a food or feed consists of, contains or is produced from GMOs. Clear labelling, irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product, meets the demands expressed in numerous surveys by a large majority of consumers, facilitates informed choice and precludes potential misleading of consumers as regards methods of manufacture or production.* -- (European Parliament and Council of the European Union 2003a, 3 emphasis added)

Further clarification for the intent behind this labeling is provided in the immediately following 22nd recital of EC No 1829/2003:

> *(22) In addition, the labelling should* ***give information about any characteristic or property which renders a food or feed different from its conventional counterpart*** *with respect to composition, nutritional value or nutritional effects, intended use of the food or feed and health implications for certain sections of the population, as well as* ***any characteristic or property which gives rise to ethical or religious concerns*** *-- (European Parliament and Council of the European Union 2003a, 3 emphasis added)*

Together, these two recitals specify that the labelling enacted through this binding Regulation[817] is based on consumer demand arising from a suspicion that GMO products are different from conventional counterparts, specifically in ways which may be medically, ethically, or religiously relevant. Further, this labelling is explicitly "irrespective of the detectability" of any difference in the final GMO product relative to "traditionally" produced alternative products.

This concern with an inherent difference between GMO and "non-GMO" products (which include products which have been altered using "traditional" non-Recombinant DNA techniques, per $E_{ANNEX\ I}$) may reflect the special place of farmers and agriculture within all societies, but particularly within European society and European Law.[818] Although the demands in Recital 21 are explicitly attributed to consumers and not agricultural producers, it is possible that the special place of (traditional) farmers constitutes a form of cultural capture[819] of European consumers. In

[815] (D. Vogel 2012, 79) (European Parliament and Council of the European Union 2003a; 2003b)
[816] (D. Vogel 2012, 81)
[817] In European law, *Directives* are guidance for the member states while *Regulations* are binding requirements, (European Union 2016)
[818] (Ciciora 2019)
[819] (Carpenter and Moss 2014a, 19–20; Kwak 2014)

effect, traditional incumbent agriculture has captured regulators not through lobbying of bureaucrats but through the capturing of the hearts and minds of consumers.[820]

With this strong statement of support for incumbent "traditional" agricultural production over the potential concerns spurred by GMO "irrespective of detectability," Recitals 21 & 22 of EC 1829/2003 together comprise a piece of evidence ($E_{Recitals\ 21+22}$) which would be highly likely under a Capture regulatory imaginary which was identified as the nearest rival to the Beneficial Constraints imaginary in the EU Precautionary Principle case. The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be, relative to Beneficial Constraints, to see this evidence ($E_{Recitals\ 21+22}$) under the assumption that each potential regulatory imaginary was the true state of the world.

Reasoning about $E_{Recitals\ 21+22}$ under the Comparator Type (Beneficial Constraints)[821]

As we are highlighting $E_{Recitals\ 21+22}$ in order to give the strongest possible support to the Capture imaginary, it is no surprise that it would be rather more surprising to see in a world where the Parliament and the Council of the European Union (hereafter EU) is actually acting from the Beneficial Constraints imaginary. The key distinction between Capture and Beneficial Constraints lies in their scores on the information and outcomes constitutive variables (see Table 1 in main chapter text). Regulators working from both the Capture imaginary and the Beneficial Constraints imaginary see their effect on innovation as constraining, but the key difference lies in what they intended the *outcome* of constraint to be and the level of access to *information* about the regulated sector regulators believe they have relative to regulated firms. The Capture imaginary sees regulators as seeking one preferred outcome (that which benefits the capturing interest group) and relying on the higher access to information of the regulated entities (and thus relatively lower information of regulators) to dictate what that preferred outcome is; in essence *capturing* the regulatory process to dictate preferred outcomes. By contrast, the Beneficial Constraints imaginary sees regulators as having higher access to information than the regulated firms and thus setting constraints not to benefit one specific firm or interest group but instead to beneficially direct the market away from undesirable outcomes towards many possible more desirable ones.

Based on these explications of the difference between Capture and Beneficial Constraints on the axes of information and outcomes, it would seem somewhat surprising to see $E_{Recitals\ 21+22}$ in a Beneficial Constraints world. In terms of information, the EU specifically foregoes claims to scientific or administrative expertise in favor of the "the demands expressed in numerous surveys by a large majority of consumers." In terms of outcomes, the EU is rather explicitly delineating "the world's most stringent and comprehensive labeling requirements" based on tight tolerances and comprehensive tracing procedures.[822] Both of these speak in favor of Capture over Beneficial Constraints as the most probable state of the world.

However, were we to inhabit the world of Beneficial Constraints (as BayesTV dictates we must here), it is not completely implausible for us to see $E_{Recitals\ 21+22}$. While the EU defers claims

[820] I thank Matthew Stenberg for stridently making this point on an earlier version of this chapter. It echoes the third and fourth core arguments of (Ciciora 2019)

[821] To avoid excessive repetition in the paired comparisons which follow, this first section in the explicit BayesTV analysis covers the reasoning for how (un)surprising this piece of evidence is under the most likely type (which will also serve as the comparator type for ease of final tabulation).

[822] (D. Vogel 2012, 79)

of high access to information, they do so to "a large majority of consumers" and not to regulated firms. So too with outcomes, the stringent and comprehensive labeling requirements are not a ban on GMO products (even if they have the effect of serving as one for consumer products). In fact, the enactment of these labeling standards overturned a de-facto moratorium on GMO products while the regulatory design was being negotiated in the Parliament, Council, Commission, and Member States.[823] Thus, there is some chance we would observe this evidence in a Beneficial Constraints world, but lower than the chance of any other piece of evidence in this chapter. This high level of surprisingness (and thus low level of conformity) will affect our reasoning in the following paired comparisons of imaginaries against the Beneficial Constraints imaginary.

$WoE_{Recitals\ 21+22}$, Beneficial Constraints vs. Adoption Catalyst = 90 dB

As the EU is clearly placing strong constraints on the adoption of GE technology, we would be very unlikely to see this piece of evidence in a world where Adoption Catalyst is the true state of the world because regulators are expected to drive adoption in an adoption catalyst world not constrain it with a labeling scheme. We thus would be truly shocked by the incompetence of assumed catalyzers who instead enact an anti-catalyst, meaning we should assign a weight on par with the highest level of discrimination assigned in this chapter (90 dB)

$WoE_{Recitals\ 21+22}$, Beneficial Constraints vs. Capture = -3 dB

As explained in the reasoning section above, we are highlighting $E_{Recitals\ 21+22}$ as both the strongest piece of evidence for Capture in the EU Precautionary Principle case and as evidence that is very informative about the distinction between Beneficial Constraints and Capture based on the constitutive variables of information and outcomes. Thus, it is not surprising that if we assume Capture to be the true state of the world we would be very likely to observe this piece of evidence.

However, in a world where Capture is the true state of the world and yet we do not see intentional and active attempts by the regulated firms (agricultural producers) to influence policy outcomes[824], we are forced to rely on a cultural rather than material specification of capture. As originally defined by Kwak, cultural capture is a way of discussing how non-rational, non-material factors such as identity, status, and relationships can lead to regulatory outcomes which favor the interests of regulated firms at the expense of the public interest.[825] In the case of the Precautionary Principle in the EU and the information in this piece of evidence, cultural capture tells us to ask about the role of traditional agricultural producers who are benefiting from the exemption of their practices from those being stringently regulated as "GMO".

Indeed, we do see evidence in background information about the case of the special place of agriculture[826] leading to cultural capture through shaping the public interest. Kurzer and Cooper (2007b) point to the influence of green-green alliances between small farmers groups and environmental groups in countries with vigorous eco-farming or regional food specialties sectors.

[823] See (D. Vogel 2012, 78–79) for a discussion of how six powerful agricultural member-states banned GM products domestically leading to a de-facto ban throughout the common market.
[824] See (D. Vogel 2012, 80–81) for the discussion of the dominance of "consumer interest" and "public support" over agricultural industry lobbying in the GM debate around Directive 2001/18/EC and Regulations EC No 1829/2003 and EC No 1830/2003.
[825] (Kwak 2014, 79–80)
[826] (Ciciora 2019)

Notably, this influence comes through the avenue of heightening public resistance to GM crops in order to influence policy rather than lobbying of policymakers directly. This fits the spirit Kwak's (2014, 79) cultural capture as "the industry position is arguably a plausible reading of the [expressed] public interest."

Kwak is also clear to point out that while he calls cultural capture a form of capture, it is often something more diffuse than any consistent definition of capture. For example, in the same edited volume, editors Carpenter and Moss (2014a, 20 emphasis added) measure cultural capture against the same standard as more traditional forms of capture leading them to specify that cultural shifts must "be shown to be deleterious to the public and stem from the *deliberate* efforts of firms to shape the intellectual climate for their own private benefit." In other words, for cultural capture to actually be capture it must be more than just competing definitions of the public interest, it must be an intentional departure from public interest in favor of private interests due to *deliberate* actions of the firms.

In essence, for this piece of evidence to be highly likely to be seen in a world where capture is the true state and we do not see deliberate action by agricultural firms to divert regulation toward their private interest at the expense of the public interest, we must define capture as cultural capture. However, cultural capture is often indistinguishable from plausible contestation of the public interest. Thus, while we would be likely to see this evidence in a Capture world, it raises at least as many questions about the nature of capture as it answers about the most plausible state of the world.[827] To that end, while this evidence is more likely to be observed in a Capture world than a Beneficial Constraints world, the difference is not as extreme as it may appear because the reliance on a very weak form of cultural capture means that this evidence can reasonably be seen as a legitimate contestation of what is beneficial to the public interest (and thus might be a Beneficial Constraint rather than capture). We will thus give it our smallest meaningful difference (3 dB) in favor of Capture over Beneficial Constraint.

$WoE_{Recitals\ 21+22}$, Beneficial Constraints vs. Technology Based Regulation = 6 dB

While this piece of evidence has the relatively strict specifications of protocol which often occur in a Technology-based Regulation world, those specifications are primarily about principles (e.g. "ethical and religious") rather than specific measures which is more in line with Beneficial Constraints. Nevertheless, there are other portions of Regulations EC No 1829/2003 and EC No 1830/2003 from which these recitals come which do specify specific measures and limits, making this piece of evidence more likely to be observed in a Technology-based Regulation world than the other piece of evidence in this case ($E_{ANNEX\ I}$). Thus, we need a narrower weight of evidence than the comparison on $E_{ANNEX\ I}$ but we still place the weight on balance toward Beneficial Constraints because the discussion of principles is more consistent with that world than with Technology-based Regulations; 6 dB seems to fit these criteria.

$WoE_{Recitals\ 21+22}$, Beneficial Constraints vs. State as Venue = 60 dB

Given the declarative language in the recitals, the EU is clearly not simply convening stakeholders here but instead taking a firm position on the side of stringent labeling "irrespective of the detectability" and in line with "the demands expressed in numerous surveys by a large majority of consumers." These are both claims to have a high access to information necessary to

[827] A finding that is by no means surprising in the intellectually rigorous capture literature, see (Carpenter and Moss 2014b), particularly (Carpenter and Moss 2014a, 2-5,13-16; 2014c; Novak 2014; Posner 2014)

make and enforce this decision. While this evidence is only weakly consistent with Beneficial Constraints, it would be an exceptionally shocking neutral convener indeed who brought stakeholders together to declare to them the proper course of action. Thus, we represent this extremely shocking nature with our highest non-anathema rating of 60 dB for Beneficial Constraints over State as Venue.

$WoE_{Recitals\ 21+22}$, Beneficial Constraints vs. Folk Economic Model = 90 dB

Just as with $E_{ANNEX\ I}$, the concept of a precautionary principal which explicitly animated this law as well as the specific exercise of authority to require labeling simply would not appear in a world where regulators did not believe it was possible for them to properly manage the introduction of a new technology. A fundamental feature of the Precuationary Principle case this earth-shatteringly anathema to the Folk Economic World can only be represented but the exceptionally high distinction we defined in $E_{ANNEX\ I}$ for similar reasons: 90 dB.

$WoE_{Recitals\ 21+22}$, Beneficial Constraints vs. Market Ideological = 90 dB

To see this evidence in a Market Ideological world, we would have to make the intellectual leaps to define consumer interest as the sole and ultimate voice of the market **and** then believe the contradictory tenant that this voice should be enforced not through market forces but through direct action of the state. While the first leap is plausible in a market ideological world, the second is definitionally anathema. We thus assign our contradiction capturing, anathema-level distinction of 90 dB here as we did in the previous section on the Folk Economic Model.

A summary of the explicit Bayesian type validation of $E_{Recitals\ 21+22}$ for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 60. The significance of this analysis is discussed in the following section on the weight of evidence $E_{Recitals\ 21+22}$.

The Weight of Evidence Recitals 21+22

As seen by the weights of evidence in the last column of Table 60, the piece of evidence presented above ($E_{Recitals\ 21+22}$) increases our confidence that Beneficial Constraints is the most plausible state of the world against all rivals except Capture. At 90 dB for each, this piece of evidence speaks overwhelmingly against the two models which see regulators as simply an incompetent (Folk Economic Model) or undesirable (Market Ideological) impediments to the market. The neutral moderator role of the State as Venue model is also extremely incongruent with this piece of evidence given the firm position the EU takes on the side of stringent labeling for GMO products "irrespective of the detectability" and in line with "the demands expressed in numerous surveys by a large majority of consumers." The placing of impediments to adoption makes also makes it extremely unlikely (90 dB) to see this evidence in an Adoption Catalyst world.

The real stakes of the Beneficial Constraints model, however, lies in the placing of constraints as well as the intention for those constraints to be beneficial to both industry and society. It is thus not surprising that this piece of evidence speaks less loudly against Technology Based Regulation (6 dB) models and in favor of Capture (-3 dB) as each of these models also see the regulator as a constrainer. With regard to Technology-based Regulation, this piece of evidence contains specifications which are primarily about principles (e.g. "ethical and religious") rather than specific measures which is more in line with Beneficial Constraints

Table 60: BayesTV Constitutive Variable Comparison Summary for $E_{Recitals\ 21+22}$*

(Independent Variables)					Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Beneficial Constraints	*No specific relevance*	EU forgoes claims to expertise in favor of consumer surveys but not firm advocacy	*No specific relevance*	While labeling can be flexible, this labeling regime is very stringent and comprehensive[828]	Constraint was actual a repeal of prior de facto ban[829]	
Adoption Catalyst	*No distinguishing relevance*	*No distinguishing relevance*	Market is the driver, labeling scheme	*No distinguishing relevance*	Clearly constraining not catalyzing adoption	90 dB
Capture	*No distinguishing relevance*	Regulators claim higher information but from consumers, possibility of cultural capture but better understood as FEM or Market Ideological[830]	*No distinguishing relevance*	While labeling can be flexible, this labeling regime is very stringent and comprehensive	Constraints demanded by consumers, not by regulated industry, but possibility of "cultural capture"[831]	-3 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Strict specification of protocols but primarily principle rather than technical	Constraints are principle not technology based	6 dB
State as Venue	*No distinguishing relevance*	EU claims knowledge of consumer needs and expertise to evaluate compliance with them	*No distinguishing relevance*	*No distinguishing relevance*	Not simply moderating, constraining from a clear precautionary perspective	60 dB
Folk Economic Model	Precautionary Principle creates stakeholder relations	EU claims knowledge of consumer needs and expertise to evaluate compliance with them	*No distinguishing relevance*	*No distinguishing relevance*	Constraints on GE to repeal a de facto ban (removed impediment)	90 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Consumer interest supersedes firm interest AND the state should make this adjudication; contradicts supremacy of the market.	Constraints on GE to repeal a de facto ban (removed impediment)	90 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{Recitals\ 21+22\ vs.}$ Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 53 for further explanation and Chapter 1 for complete methodological specification.

[828] (D. Vogel 2012, 79)

[829] (D. Vogel 2012, 78–79)

[830] Some evidence of Green-Green coalitions between consumers and producers (Kurzer and Cooper 2007b), but this is better understood as a "plausible reading of the public interest" (Kwak 2014, 79) and better examined through Folk Economic Model or Market Ideological imaginaries.

[831] (Carpenter and Moss 2014a, 19–20; Kwak 2014)

although other parts of EC No 1829/2003 and EC No 1830/2003 do include specific measures, narrowing the distinction to only a clearly noticeable difference (6 dB).

As explained at length in the Appendix, while the technoscientifically arbitrary line between recombinant DNA and "traditional methods" of gene editing are congruent with capture by traditional agricultural producers, the background information on the case makes clear that consumers pressed for this line, not incumbent industry as specified in capture theory. In essence, for this piece of evidence to be highly likely to be seen in a world where Capture is the true state and where we do *not* see *deliberate* action by agricultural firms[832] to divert regulation toward their private interest at the expense of the public interest, we must define capture as cultural capture: how non-material factors such as identity, status, and relationships can lead to regulatory outcomes which favor the interests of regulated firms at the expense of the public interest.[833] However, cultural capture is often indistinguishable from plausible contestation of the public interest.[834] Thus, while we would be likely to see this evidence in a Capture world, it raises at least as many questions about the nature of capture than it answers about the true state of the world.[835] To that end, while this evidence is more likely to be observed in a Capture world than a Beneficial Constraints world, the difference is not as extreme as it may appear because the reliance on a very weak form of cultural capture means that this evidence can reasonably be seen as a legitimate contestation of what is beneficial to the public interest (and thus might be a Beneficial Constraint rather than capture) meaning we can go no higher than the smallest meaningful difference in the weight of evidence (-3 dB).[836]

BLACK SWAN EVIDENCE AND THE COUNTERFACTUAL

Before adjudicating the final type classification and sensitivity to priors, due diligence requires us to consider what evidence would be consistent with the extreme opposite of the suggested type classification being the most probable state of the world; the so-called "black swan" evidence. As Beneficial Constraints is the most likely type for the gene editing cases and the nearest rivals are Adoption Catalyst and Capture, the extreme opposites (from Table 1) are either the Folk Economic Model or Market Ideological because they reject the competence and/or legitimacy of regulation (lower access to information, one or zero desirable outcomes).[837] In a Folk Economic or Market Ideological world, we would expect to see regulators acting lost due to lower access to information than market participants and either recusing themselves from regulation in order to stay out of the way until the market has innovated[838] or implementing harsh

[832] See (D. Vogel 2012, 80–81) for the discussion of the dominance of "consumer interest" and "public support" over agricultural industry lobbying in the GM debate around Directive 2001/18/EC and Regulations EC No 1829/2003 and EC No 1830/2003.
[833] (Kwak 2014, 79–80)
[834] (Kwak 2014, 79)
[835] A finding that is by no means surprising in the intellectually rigorous capture literature, see (Carpenter and Moss 2014b), particularly (Carpenter and Moss 2014a, 2-5,13-16; 2014c; Novak 2014; Posner 2014)
[836] Recall that negative WoE means that the evidence speaks more loudly for the challenger imaginary (in this case Capture) than the comparator imaginary (in this chapter, Beneficial Constraints)
[837] Note that the black swan imaginaries are selected conceptually rather than empirically but the extremely high decibel scores for the Folk Economic Model and Market Ideological on all four pieces of evidence highlighted with explicit BayesTV increases our confidence that these two imaginaries are extremely unlikely to be the true state of the world.
[838] While this may seem fanciful, this "wait and see" attitude was exactly how the US Federal Reserve approached mobile payment apps for years. (Lowry 2016, 384)

and inappropriate anti-innovative regulations. While no evidence has been found that carries this information,[839] a skeptical reader should contact the author with such evidence so that it may be incorporated into analysis and allow us to radically update our priors.

FINAL TYPE CLASSIFICATION AND SENSITIVITY TO PRIORS

For final classification based on updating our beliefs in which regulatory imaginary is the most probably animating the regulatory framework around gene editing, we add the decibel comparisons between the Beneficial Constraints imaginary and each of the alternative models from each piece of evidence and then add those to the priors discussed at the beginning of this section. These comparisons are presented in Table 61.

Consistent with the design and intent of Bayesian type validation, the evidence can tell several disciplined and clear stories depending on how it is combined with priors and across cases. If we combine all of the evidence for both the US and EU cases, we find overwhelming reason to believe that GE technology is regulated from the Beneficial Constraints imaginary (from a rock concert to more than twice the shockwave threshold). If we look just at the US case (Table 61, column a "US Post"), we find decisive evidence [840] (80+ dB) for Beneficial Constraints over the Folk Economic Model and Market Ideological imaginaries. We also see evidence which is above the threshold of a very well established theory (50-70 dB) for Beneficial Constraints over Capture, State as Venue, and Technology-based Regulation. For Adoption Catalyst in the US case, we find a meaningful difference (4 dB) in favor of Beneficial Constraints. If we look at just the EU case (Table 61, column a "EU Post"), we find decisive evidence (80+ dB) for Beneficial Constraints over all alternative imaginaries except Capture where we find merely meaningful evidence (3 dB) and Technology-based Regulation where we find moderately strong evidence (16 dB). These overall weights of evidence should then each be considered against the reader's priors to update our belief in what the most probable state of the world is.

If the reader adopted naïve priors with equal weights (0 dB in favor of or against Beneficial Constraints) for the combined case of GE in the US and EU (Table 61, column a "combo posterior"), then the evidence presented above would create well-established (50-70 dB) or decisive (80+ dB) in favor of Beneficial Constraints over alternative regulatory imaginaries. While there are fair reasons to disaggregate the data to a per-case level as that is where the

[839] See Appendix section on $WoE_{OSTP1986}$ Beneficial Constraints vs. Market Ideological) for discussion of why the "substantially equivalent" standard in the Coordinated Framework is not an example of this hands off attitude.

[840] Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival. Fairfield and Charman (2022, 162–63) proceed to explain that a more stringent threshold of 50-70 decibels equates to the thresholds of confidence used by quantitative Bayesian statisticians in the physical and biological sciences; they note that 62 dB is roughly equivalent to the 5 sigma threshold for discovering a new particle in Physics and 67 dB the chance that any given commercial airplane flight will crash vs. land safely. While Fairfield and Charman (2022, 162, footnote 34) also caution us that you cannot truly mathematically convert Bayesian odds to frequentist p-values because they are different ontological statements, most quantitative social scientists are happy with $p<0.1$ (~27 dB) and $p<0.05$ (~30 dB) for publication and are ebullient about $p<0.01$ (~37 dB). Fairfield and Charman ultimately recommend a threshold of 80-100 dB to consider a qualitative research question "settled" both to guard against potential unaccounted for bias as well as to deal with the reality that quantitative social scientists often show higher skepticism toward qualitative evidence than they do towards their own thresholds of significance.

Table 61: BayesTV Prior and Posterior Weights of Evidence for the GE Cases, US Coordinated Framework and EU Precautionary Principle evidence (in dB)

	a				b				c			
Weight of Evidence (WoE)*	**Naïve**				**Background Info**				**Skeptical**			
	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior
$\frac{Beneficial\ Constraints}{Adoption\ Catalyst}$	0	4	150	154	-10	-6	140	144	-50	-46	100	104
$\frac{Beneficial\ Constraints}{Capture}$	0	70	3	73	-10	60	-7	63	-50	20	-47	23
$\frac{Beneficial\ Constraints}{Technology\ Based\ Regulation}$	0	50	16	66	-10	40	6	56	-50	0	-34	16
$\frac{Beneficial\ Constraints}{State\ as\ Venue}$	0	50	110	160	-10	40	100	150	-50	0	60	110
$\frac{Beneficial\ Constraints}{Folk\ Economic\ Model}$	0	110	180	290	0	110	180	290	-50	60	130	130
$\frac{Beneficial\ Constraints}{Market\ Ideological}$	0	114	130	244	0	114	130	244	-50	64	80	80

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

regulation actually occurred (at the US/EU levels), this combined weight of evidence is useful for us to understand how GE is imagined to be regulated cross-nationally. The evidence thus aggregated tells us that GE is regulated from the Beneficial Constraints imaginary regardless of priors (Naïve, Background Information, or Skeptical). Indeed, it would take a prior roughly equivalent to the likelihood of any commercial airplane flight crashing (~67 dB) in favor of Technology-based Regulation (the nearest cross-case rival) in order to break even with Beneficial Constraints at this level of aggregation.

However, as the actual Coordinated Framework and Precautionary Principle approaches to GE regulation were decided through separate processes, it is also useful to disaggregate down to the US/EU level and compare against priors. In the US Coordinated Framework case, we see that the evidence remains very very strong (40+ dB), well-established (50-70 dB) or decisive (80+ dB) against all models except Adoption Catalyst across Background Info priors (Table 61, column b "US Post"). With skeptical priors (Table 61, column c "US Post"), the US case has only well-established evidence for Beneficial Constraints over Folk Economic and Market Ideological imaginaries while Capture has merely strong evidence (20 dB) against it and Technology-based Regulation and State-as-Venue are indistinguishable from Beneficial Constraints. With these skeptical priors, Adoption catalyst remains very very strongly favored (46 dB) not due to the evidence but due to the priors.

In the US case, the Adoption Catalyst result for background information and Skeptical priors is not surprising and consistent with the common understanding of the Coordinated Framework as encouraging the adoption of GE technology. It was identified as the nearest rival model after the initial piece of evidence and thus used as the selection criteria for the second piece of evidence which suggests that it may be "spoken for" a bit too loudly by design. However, were the BayesTV process to continue for additional evidence selected to specifically adjudicate between the two models, Beneficial Constraints would ultimately be more likely based on the case narrative above because the Coordinated Framework did not cross from encouraging GE technology into catalyzing adoption through incentives or proactive programs.[841]

In the EU Precautionary Principle case, we see that the evidence remains decisive (80+ dB) against all models except Capture and Technology-based Regulation for Background Info priors (Table 61, column b "EU Post") and either very well established (50-70 dB) or decisive against all models except Capture and Technology-based Regulation for Skeptical priors (Table 61, column c "EU Post"). In the EU case, the classification of the case is less clear given the strong appearance of capture given the anti-GE and "pro-traditional" content of Directive 2001/18/EC and Regulations EC No 1829/2003 and EC No 1830/2003. However, the strength of the evidence in favor of Capture relies on the concept of cultural capture which ultimately reduces down to contested definitions of the public good.[842] As discussed above in the description of GE technology and its regulation, these sorts of contests over what is "beneficial" are better understood and analyzed as definitions of desired goals than as inherent features of a particular regulatory approach. To remain transparent, the BayesTV process scores the ambiguity of

[841] How this background information figures into the evidence presented is discussed at length in the Appendix where the BayesTV is explicitly carried out for each piece of evidence. See the discussion in the Appendix section $P(E_{OSTP1986} | T_{Adoption\ Catalyst} I)$.

[842] See the discussion above in What is a "Beneficially Constraining" Regulator? as well as the far more detailed discussion of cultural capture in the Appendix section $WoE_{Recitals\ 21+22}$ Beneficial Constraints vs. Capture.

support for Capture into the analysis. However, it is up to the reader to consider when and why cultural capture is a more useful lens to understand what is happening with EU GE regulation than Beneficial Constraints where the benefit is defined as pro-"traditional" (non-GMO) products. For the author, separating out regulatory method from regulatory goal is more analytically useful because it allows us to recognize interesting similarities in method (Beneficial Constraints) which would be obscured by purely a focus on outcomes (pro vs. anti-GMO).

Based on these four pieces of evidence, we see that how clearly GE can be considered a case of Beneficial Constraints depends on the priors you adopt and the aggregation you are interested in. In isolation for any set of priors, these four pieces of evidence (OSTP 1986, Annex I, Blue Book Reproduction, and Recitals 21+22) are overwhelmingly convincing in favor of Beneficial Constraints over all alternative models for the general approach to GE regulation across the US and EU.

However, at the individual regulatory domain level, we see divergent conclusions based on priors that nevertheless may be undermined by additional case information. In the US, the Adoption Catalyst model becomes noticeably (6 dB) and very very strongly (46 dB) more likely than Beneficial Constraints for Background Info and Skeptical priors respectively, although it is likely that this would disappear if further evidence were highlighted in the explicit analysis analysis based on the narrative analysis in the case background. In the EU, the Capture model stands out as noticeably (7 dB) and very very strongly (47 dB) more likely than Beneficial Constraints based on the "cultural capture" understanding of capture although I argue that this is analytically misleading here as it confuses regulatory goal with regulatory method.

All told, though, we can decisively reject the negative imaginaries of the Folk Economic Model and Market Ideological with decisive (80+ dB) evidence no matter which priors or level of aggregation one chooses (see the bottom two rows of Table 61). We also have very very strong (40 dB) to decisive (80+ dB) against the neutral imaginary of State-as-Venue in all except the skeptical prior US case (Table 61, column c "US Post"), although this US exception is again driven not by the evidence but by the extremely strong (likely unrealistic) prior. This allows us to focus our consideration on the proactive state models of Adoption Catalyst and Beneficial Constraints as well as drawing out attention to analytically complex and empirically interesting refinements of the Capture imaginary.

APPENDIX D: SUPPLEMENT TO CHAPTER 7 – EXPLICIT BAYESIAN TYPE VALIDATION (BAYESTV) OF HOW CONFIDENT WE CAN BE THAT HITECH (US) AND DIRECTIVE 2011/24/EU REPRESENT AN ADOPTION CATALYST IMAGINARY FOR ELECTRONIC HEALTH RECORDS REGULATION

As the illustrative case for adoption catalyst, EHR is subjected in this section to a Bayesian Type Validation (BayesTV) in order to demonstrate how confident we can be that it does, indeed, represent a distinctive regulatory imaginary of disruptive innovation. In the main manuscript, only a summary of the BayesTV was presented along with an overview of the method. In this appendix, we first repeat this review of what BayesTV, how it is applied, and then proceed to apply it explicitly to EHR in the US (HITECH Act of 2009) and the EU (Directive 2011/24/EU). It concludes by explaining that, for any reasonable set of priors, we can be reasonably to overwhelmingly confident that EHR is indeed a case of adoption catalyst.

BAYESIAN TYPE VALIDATION (BAYESTV): AN OVERVIEW

As explained in chapter 4, this project employs a new method called Bayesian Type Validation (BayesTV). BayesTV combines two gold-standard pillars of qualitative methodology, process tracing and typological theory, to produce a completely qualitative method of theory development and testing. While excellent qualitative work has always included theory development and theory testing, the logic of how qualitative theory building works has often been the target of incredulous skeptics. BayesTV uses the deductive logic of typological theory to complement the inductive logic of Bayesian process tracing (BayesPT)[843] to produce a disciplined and clear method of analyzing evidence and communicating results. This section briefly reviews how BayesTV operates in practice before it is applied to the evidence in this case.

To efficiently classify cases and refine the deductive typology, BayesTV incorporates a search process that focuses on the most informative pieces of evidence. The first piece of evidence explicitly[844] analyzed for a case should be the strongest piece of support for the most likely type based on background knowledge of the case.[845] The second piece of evidence should

[843] (Fairfield and Charman 2017; 2022)

[844] Explicit Bayesian analysis (whether process tracing of hypotheses or validation of types) refers to the use of mathematical likelihood ratios as developed in (Fairfield and Charman 2017) and refined in (Fairfield and Charman 2022). Implicitly, all process tracing and most qualitative research can be described as a Bayesian method of reasoning.(Fairfield and Charman 2017, 1–2) The choice of 'how explicit to get' is a tradeoff between exhaustive transparency and laboriousness which should be decided on how informative additional explicit analysis would be as opposed to an implicit summary of the weight of evidence.

[845] Since BayesTV is concerned with type validation, cases are selected using background information to be representative of a particular type. This is *not* a form of confirmation bias as the disciplined consideration of the likelihood of observing this evidence under *all* alternative types clearly and transparently presents the judgements made by the analyst. While a skeptic could certainly disagree with such judgment, the goal of a logical Bayesian approach is to clearly identify the "locus of contention" (Fairfield and Charman 2017, 16) rather than claim to be beyond contention or to set up an "entirely agree vs. entirely disagree" dichotomy. Where a transparent frequentist would rely upon preregistration of hypotheses and appeal to stochastic analysis to reject or fail to reject a null hypothesis, a Bayesian approach instead seeks to transparently state priors and indicate how evidence is used to update those priors.(Fairfield and Charman 2017, 1,6) The author and reader may ultimately disagree with the conclusions of a logical Bayesian analysis but both should be able to clearly state precisely where they disagree (evidence selection, likelihood ratios, missing hypotheses/theories in the set, etc.) rather than rely on less precise statements of agreement or disagreement based on sum total statements or reverse-engineering of an argument.

be selected as the strongest piece of support for the nearest rival to the most likely type based on background knowledge of the case *and* analysis of the first piece of evidence. Once the first two pieces of evidence have been explicitly analyzed, BayesTV considers whether additional evidence needs to be analyzed based on the possible priors (naïve, skeptical, etc.) and how loudly the first two pieces of evidence have adjudicated between the possible types. The extreme counterfactual state of the world is also considered and evidence for such a "black swan" event is described and sought. Once the analyst is satisfied that sufficient explicit evidence has been analyzed to build a type validation case, the weight of the evidence is placed against defined sets of priors in order to identify the sensitivity of the classification to a reader's prior beliefs about the world.

As a process of search built on highlighting the most informative pieces of evidence, BayesTV (and all logical Bayesianism) relies on the *information value* of evidence rather than the idiosyncrasies of a specific piece of evidence. While specific pieces of evidence are presented below, they are analyzed as a representative of all "informationally equivalent"[846] evidence which provides insight into the relative likelihood of which type is the true state of the world. Thus, what may appear to be a selective reification of evidence is actually a carefully considered process of which evidence to highlight in the explicit analysis in order to distinguish between possible states of the world in a clear and disciplined manner.

In metaphorical terms, the goal of BayesTV is not to cut a node out of its web of interconnections and carefully study its nodal properties under a microscope but rather to carefully consider which node to lift from a web in order to trace the interconnections. The goal is always to pull on the node which reveals the most information about the web rather than to find the most perfect individual node.

This focus on information value may appear unsettling to traditional qualitative scholars who emphasize the richness of evidence presented in their case narrative built upon deep case knowledge[847] to judge the effectiveness of an argument. Indeed, it may seem like cherry picking only one or two pieces of self-justificatory evidence!

However, as qualitativists have long pointed out to quantitativists when accused of selecting on the dependent variable or having too many variables for too few cases, one cannot naïvely apply frequentist statistical intuition to qualitative work.[848] While other qualitative methods such as analytical narratives and comparative historical analysis place their empirical richness directly into the text of their research reports to demonstrate analytic rigor, BayesTV uses deep case knowledge to rigorously highlight the most informative evidence in their research reports. Akin to Charles Proteus Steinmetz, who was hired by Henry Ford to fix a generator and invoiced $10,000 for a single chalk X and two lines of instructions, only a small bit of evidence may appear in the final writeup ('$0.01 of chalk') but the expertise and deep case knowledge lies in

[846] (Fairfield and Charman 2017, 5 in Online Appendix)
[847] C.f. (Johnston 2012, 70) and "the importance of local or area knowledge for general theory."
[848] Compare the logic of (Brady and Collier 2010) to that in (Gary King, Keohane, and Verba 1994). A concise review of the struggles of quantitativists to grapple with qualitative evidentiary standards appears in (Fairfield and Charman 2022, 124–26).

knowing which piece to highlight to maximize information value ('$9,999.99 for knowing where to place the X').[849]

Building on deductive typological theory and the inductive logic of logical Bayesian process tracing, Bayesian Type Validation (BayesTV) employs a disciplined process of search for informative evidence in order to provide transparently produced degrees of belief in whether a particular case is most plausibly operating under a particular type rather than the rival types. In this project, this translates into degrees of belief about whether regulators are truly operating under one type of regulatory imaginary (e.g. folk economic constrainer) or another (e.g. beneficial constraint, adoption catalyst, etc.). As the goal of this project is to inductively refine the deductive typology developed in Chapter 3, BayesTV is well suited to demonstrating how confident we can be that real empirical examples exist of the variety of ways that regulators, entrepreneur, and innovators co-create disruptive technological innovation.

POSSIBLE TYPES AND PRIORS

The possible regulatory imaginaries which the EHR case could assume are detailed in the deductive typology developed in Chapter 3 and presented in Table 5 from that chapter (reproduced below as Table 62). From the deductive typology and the reasoning in chapter two, we have seven distinct types which are plausible: the Folk Economic Model, Market Ideological Model, State-as-Venue, Capture, Technology-Based Regulation, Beneficial Constrainer, and Adoption Catalyst. These seven imaginaries present the rival worlds under which the BayesTV must evaluate the evidence in order to conclude which imaginary the evidence speaks most strongly for.[850]

Based on the title of this chapter and discussion so far, it should not surprise the reader that my prior is that EHR is a characteristic Adoption Catalyst case. To state this precisely, it should be noted that each row in Table 5 can be read as a sentence[851] and thus the Adoption Catalyst would read as follows: the adoption catalyst conceives of a regulator with higher access to knowledge about the regulated domain who is the primary adoption catalyst of an innovation while being agnostic about whether that regulator is viewed as a rulemaker or stakeholder or whether there are one or many perceived ideal outcomes. The presentation of evidence below in the execution of BayesTV is meant to give the reader, whatever their priors, an updated belief in whether or not the prior sentence is the true state of the world in the EHR case.

While priors are a vital part of Bayesian reasoning, the most important analysis in BayesTV is the *sensitivity*[852] of the results to the priors rather than choosing precise priors before the analysis. For type validation, we are interested in how confident we can be that a particular case fits a particular type rather than weighing between plausible hypotheses. For that reason, while the author is likely to have a strong prior for one type (the type being verified) and the reader may have indifferent or strongly contrarian priors, what matters is how loudly the evidence needs to speak to convince different types of readers. Thus, we will return to the discussion of priors in

[849] (Gilbert King 2011)
[850] (Fairfield and Charman 2017, 1,10)
[851] This is a result of the consistency of a deductive typology, discussed at greater length in Chapter 2. Note that in that discussion the grammar of the sentence is exactly consistent for all 24 lines in Table 1 while in this chapter I have simplified the grammar to highlight the defining features of the driver of adoption type.
[852] (Fairfield and Charman 2017)

Table 62: Complete Typological Property Space of Regulatory Imaginaries

		Constitutive Variables (Independent Variables)				Dependent
Model Name	**#**	**Relationship**	**Info**	**Driver**	**Outcomes**	**Effect**
Folk Economic Model (Christensen 1997)	1	Rulemaker	Lower	Market	Zero	Impediment
	2	Rulemaker	Lower	Market	One	Impediment
Market Ideological*	3	Rulemaker	Higher	Market	Zero	Impediment
	4	Stakeholder	Higher	Market	Zero	Impediment
State-as-Venue (Skocpol 1985)	5	Rulemaker	Lower	Regulator	Many	Moderator
	6	Stakeholder	Lower	Market	Many	Moderator
	7	Stakeholder	Lower	Regulator	Many	Moderator
Capture (Stigler 1971)	8	Stakeholder	Lower	Market	One	Constrainer
	9	Stakeholder	Lower	Regulator	One	Constrainer
Technology-Based Regulation "Conventional Command and Control" (Malloy 2010)	10	Rulemaker	Higher	Market	One	Constrainer
	11	Rulemaker	Lower	Regulator	One	Constrainer
	12	Stakeholder	Higher	Market	One	Constrainer
Beneficial Constrainer (Streeck 1997)	13	Rulemaker	Higher	Market	Many	Constrainer
	14	Stakeholder	Higher	Market	Many	Constrainer
Adoption Catalyst	15	Rulemaker	Higher	Regulator	Many	Driver
	16	Stakeholder	Higher	Regulator	Many	Driver
	17	Rulemaker	Higher	Regulator	One	Driver
	18	Stakeholder	Higher	Regulator	One	Driver
Trivial	19	*Rulemaker*	*Lower*	*Regulator*	*Zero*	*Impediment*
	20	*Stakeholder*	*Lower*	*Regulator*	*Zero*	*Impediment*
	21	*Rulemaker*	*Lower*	*Market*	*Many*	*Impediment*
	22	*Stakeholder*	*Lower*	*Market*	*Zero*	*Impediment*
Logically Inconsistent	23	~~Rulemaker~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~
	24	~~Stakeholder~~	~~Higher~~	~~Regulator~~	~~Zero~~	~~n/a~~

* (Henderson and Appelbaum 1992) completed Chalmers Johnson's (1982) 2x2 of market|plan x rational|ideological by defining the idea of "market ideological" which privileges market structures for organizing social and economic interaction beyond efficient cost-benefit tradeoffs due to an ideological preference for market structures over planning. More modern ears are more familiar with the term "market fundamentalism" as popularized by George Soros (1998) although the concept is as old as capitalism itself with well-reasoned critique of it at least as old as Polanyi ([1944] 1957). The modern usage is well explained in (Block and Somers 2014).

the conclusion of this section ("Final Type Classification and Sensitivity to Priors"). For now, the reader should consider what regulatory imaginary she thinks best fits the EHR case.

We can assign several possible prior probabilities to the case being of a particular type.[853] If we are to adopt a naïve assumption, we would weight all of the imaginaries equally (~14.3% each). If, instead, we use background information about the EHR cases, we might be led to believe that either the Technology-Based Regulation, Beneficial Constraints, or Adoption Catalyst imaginaries are more likely given the proactive actions of the state in the US and EU. Finally, we may adopt a strong skeptic's approach which would put a strong disadvantage to the

[853] Following the advice of (Fairfield and Charman 2017, 3-4 in online appendix). This paragraph presents extremes and a paradigmatic midpoint. The reader could adopt whatever priors she sees fit, but it is most instructive to think in classes of priors rather than a continuum because we can then concentrate on tipping points.

Adoption Catalyst imaginary because it is the focus of this chapter and then equally weight each of the other imaginaries.

EMPIRICAL CASE SELECTION: UBIQUITOUS ADOPTION

Since a key defining characteristic of EHR is interoperability leading to health information portability,[854] the empirical cases were selected for being the first attempts to create political economy-wide adoption of EHR. The US HITECH Act of 2009 and Directive 2011/24/EU were not the first moments when parts of their respective political economies adopted electronic health records. However, they were the first explicit drives to take pockets of adoption and make them widespread throughout the healthcare industry. They were both explicitly targeted at shifting the normal operating procedure from paper-based charting to electronic health records throughout their entire national medical system.

BAYESTV OF EHR IN HITECH AND DIRECTIVE 2011/24/EU

In verifying that EHR is an example of the Adoption Catalyst regulatory imaginary, the key constituent variables are information and driver. An Adoption Catalyst conception of innovation regulation is defined by a regulator who is conceived as having higher access to information about a regulated domain and a belief that the regulator is the adoption catalyst rather than (or due to the failure of) the market. The two following sections on each of the empirical EHR cases will present evidence to update our belief in whether that is the true conception of regulators within each case. The evidence will focus on statements within the legislation or made by the regulators who implemented the regulations and how likely they are to be observed in rival states of the world (see Table 1).

Following the advice of Fairfield and Charman (2022, 124–70), the weights of evidence are determined qualitatively but consistently through six paired comparisons of types (most likely vs. each of the six rivals) with the evidence evaluated in the order most logically coherent to the analyst. Note that because it *mathematically* does not matter in what order we incorporate evidence, we can choose the order most logical to the *substantive* comparisons at hand.[855] We can also reduce the number of comparisons by recognizing that *mathematically* a paired comparison of the six rival types against the same type is equivalent to comparing each of the rival types to each other.[856] Thus, we need only six total comparisons in order to consider all possible pairs and we are free to pick which type will be the comparator for all six rivals based on the *substance* of the case.

In their application of logical Bayesianism to social inquiry, Fairfield and Charman (2022, 129–36, esp. p.134) recommend that paired comparisons of types should be assigned weights of evidence (WoEs) in decibels (dB) based on a plain language description of relative differences. While earlier approaches relied on an auditory metaphor of "how loudly the data is speaking,"[857] the final specification recommends a generalized use of the logarithmic decibel (dB) scale to match the logarithmic nature of human sense perception without a reliance on a particular sense

[854] See section "Technological Innovation: " above.
[855] We can also redo our analysis with the evidence in a different order as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 139–40)
[856] We can also redo our analysis with different comparator type as a consistency check if we are concerned that some arbitrariness may have slipped into our subjectivity, see (Fairfield and Charman 2022, 140–42)
[857] (Fairfield and Charman 2017, esp. p.6 in online appendix)

Table 63: Qualitative-to-Quantitative Reference Levels for the decibel (dB) Comparison Scale

dB	Acoustic Perception	Plain Language Description	Equivalent Odds or Likelihood Ratio (approx.)
3	Smallest meaningful difference	Very weak	2:1
6	Clearly noticeable difference	Weak	4:1
10	Twice as loud	Moderate	10:1
20	Four times louder	Strong	100:1
30	Eight times louder	Very Strong	1000:1

Based on (Fairfield and Charman 2022, 133, Table 4.1), Note: Some digital audio files that illustrate these different decibel levels are available at: https://tashafairfield.wixsite.com/home/bayes-book

Table 64: Weights of Evidence for HITECH and Directive 2011/24/EU (in dB)

Odds Ratio*	Initial Evidence		Near Rival Evidence	
	US E_{NCHIT}	EU E_{ART14}	US $E_{Meaningful\ Use}$	EU E_{INFSO_PC}
$\frac{Adoption\ Catalyst}{Beneficial\ Constraints}$	6 dB	10 dB	3 dB	10 dB
$\frac{Adoption\ Catalyst}{Capture}$	54 dB	30 dB	40 dB	10 dB
$\frac{Adoption\ Catalyst}{Technology\ Based\ Regulation}$	10 dB	20 dB	20 dB	30 dB
$\frac{Adoption\ Catalyst}{State\ as\ Venue}$	40 dB	3 dB	60 dB	-3 dB
$\frac{Adoption\ Catalyst}{Folk\ Economic\ Model}$	90 dB	50 dB	60 dB	60 dB
$\frac{Adoption\ Catalyst}{Market\ Ideological}$	90 dB	50 dB	60 dB	50 dB

* Note that the comparisons are properly labeled as odds ratios since they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WOE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically $(-\infty,\infty)$ although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WOE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WOE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

metaphor.[858] In keeping with the intuitive human sense perception metaphor, the lower bound for discernable differences is set at 3 dB ("smallest meaningful difference," "very weak," 2:1) while the upper bound is set at 30 dB ("eight times louder," "very strong," 1000:1). A set of qualitative-to-quantitative reference levels, their perceptual references, a natural language description of the relationship, as well as the corresponding odds or likelihood ratios is reproduced from (Fairfield and Charman 2022, 133) in Table 63.

Table 64 provides a summary of the weight of each of the pieces of evidence. The reasoning behind these weights of evidence is summarized in the sections which follow while the full explicit BayesTV analysis may be found in the Appendix. The possibility of counterfactual evidence is explicitly defined after analysis of the evidence. The final interpretation and comparison with priors occurs in Table 69 on page 342.

INITIAL EVIDENCE: STATUTORY INTENT

The first piece of evidence for each case is selected based on the highest likelihood to correspond with the adoption catalyst imaginary. As the EHR cases were selected in order to verify the adoption catalyst imaginary, their overarching statements of statutory intent shall be used to make the initial case for adoption catalyst over rival types as the true state of the world. In the US case, this evidence comes from the introduction to the first of a series of articles where the National Coordinator for Health Information Technology (NCHIT) David Blumental laid out case for the statutory authority given to regulators under the HITECH Act. In the EU case, this evidence comes from Article 14 of Directive 2011/24/EU which directs the European Commission to adopt EHR which interoperates between the member states.

HITECH Act in the United States (2009-2015)

In launching the HITECH act, a series of articles were published in the New England Journal of Medicine by David Blumenthal, the National Coordinator for Health Information Technology (NCHIT).[859] In these articles, Blumenthal explicitly laid out the origin and intent of the HITECH Act of 2009 to the medical profession. In the first of the series, he made clear claims about how regulators perceived their actions:

> *"The HIT components of the stimulus package — collectively labeled HITECH in the law — reflect a shared conviction among the fledgling Obama administration, the Congress, and many health care experts that electronic information systems are essential to improving the health and health care of Americans. However, proponents of HIT expansion face substantial problems. Few U.S. doctors or hospitals — perhaps 17% and 10%, respectively — have even basic EHRs, and there are significant barriers to their adoption and use: their substantial cost, the perceived lack of financial return from investing in them, the technical and logistic challenges involved in installing, maintaining, and updating them, and consumers' and physicians' concerns about the privacy and security of electronic health information. HITECH addresses these obstacles head on, but huge challenges await efforts to implement the law and fulfill President Barack Obama's promise that every American will have the benefit of an EHR by 2014." (Blumenthal 2009, 1477)*

The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be to see this evidence under the assumption that each potential regulatory imaginary was true.

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[858] Both the senses of sight and sound, for example, evolved logarithmically in humans; a tenfold increase in absolute light power or sound intensity is perceived as a doubling in "brightness" or "loudness" by human senses. See (Fairfield and Charman 2022, 129–30) for further explanation of the appropriateness of the logarithmic scale across the physical, biological, and social sciences.

[859] (Blumenthal 2009; 2010; Blumenthal and Tavenner 2010; Blumenthal 2011a; 2011b)

Justification for E_{NCHIT} as Evidence for the Most Likely Type (Adoption Catalyst)

In the world in which the regulator imagines themselves to be the driver of adoption for EHR, this statement is extremely likely. In reporting a "shared conviction among the fledgling Obama administration, the Congress, and many health care experts that electronic information systems are essential," Blumenthal is claiming higher access to knowledge about the regulated domain than the "[f]ew doctors or hospitals…[that] have even basic EHRs." This piece of evidence also demonstrates a clear perception of HITECH as the driver of innovation adoption in recognizing "significant barriers to [EHR] adoption" which "HITECH addresses…head on." Noting a low level adoption, declaring a conviction that higher adoption is needed, and establishing that the HITECH regulation intents to increase adoption by addressing obstacles head on is clearly most likely in a world where the regulator sees themselves as the Adoption Catalyst.

WOE_{NCHIT}, Adoption Catalyst vs. Beneficial Constraints = 6 dB

With the emphasis on economic barriers to adoption (cost, perceived lack of return), this evidence may also appear in a world where the regulator sees themselves as a Beneficial Constrainer. However, in such a world, the language about HITECH "address[ing] these obstacles head on" is inconsistent with an imaginary that instead sees the market as the primary driver of adoption and prefers to simply set an additional obstacle which encourages beneficial innovation. We can represent this different with a clearly noticeable weight of evidence (6 dB) in favor of Adoption Catalyst

WoE_{NCHIT}, Adoption Catalyst vs. Capture = 54 dB

In a world where the regulator had been captured by the regulated entity (medical professionals), the only reason this evidence would be seen is if they were blatantly lying. A premiere journal such as the NEJM would be highly unlikely to publish five articles which perpetuate a falsehood against the preferences of its audience and professional community. Alternatively, we may think that medical software companies have captured regulators in order to force them to purchase a boondoggle technology (EHR) which has no particularly identifiable or measurable economic or social benefit. However, this evidence makes clear that the regulator does see a measurable social benefit "to improving the health and health care of Americans" and other statements in the case narrative make clear the financial and economic benefits of electronic rather than paper-based information storage and retrieval.[860] We could, of course, decide that such claims are spurious and do not truly represent the public interest, but such discussions are better left to debates over contending plausible readings of the public interest rather than accusations of capture subverting the public interest.[861] We begin with an anathema-level weight of evidence (60 dB) against Capture in favor of Beneficial Constraints due to the rejection of strict readings of capture (the regulated entity or boondoggle technology) but we will weaken (6 dB) that slightly in deference to the multiple potential (if implausible) stories which critic may propose.

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[860] See (Hoffman 2016, 9–14) for a discussion of the established benefits of EHR.

[861] In other contexts, this might be an accusation of "cultural capture" where the regulator has been wooed by whizzbang tech that promises much and delivers little. However, EHR has clear and measurable benefits and even in places where cultural capture is taken seriously (e.g. finance), the originator of the analytic term suggests that he has named it only to point out has it is not a particularly fruitful lens for analysis and policymaking (Kwak 2014, 79). See the discussion at great length about cultural capture in Appendix C about the near-rival evidence ($E_{Recitals\ 21+22}$) in the EU Precautionary Principle case.

WOE_{NCHIT}, Adoption Catalyst vs. Technology Based Regulation = 10 dB

In this world, the regulator would mandate the adoption of a specific technology. One might broadly construe this to be consistent with "President Barack Obama's promise that every American will have the benefit of an EHR by 2014." Yet this evidence claims it "addresses these obstacles [to adoption] head on" rather than mandating that a particular solution be adopted. It is possible a technology-based regulator would make this statement, but much more likely that one would instead require medical providers to buy or implement a *specific* EHR rather than encourage adoption of *any* EHR that overcomes the significant barriers. Because the outcomes are principle based (see the near-rival evidence about Meaningful Use) rather than solution based, we can be moderately (10 dB) confident that although a technology is being pushed for adoption, it is a set of technical principles rather than single solution/implementation as might be expected in a Technology Based Regulation world.

WOE_{NCHIT}, Adoption Catalyst vs. State as venue = 40 dB

In the state-as-venue world, it is highly unlikely that a regulator would look to take on obstacles and push for change against the wishes of most stakeholders in a domain. Instead, the regulator would look to convene discussion and would likely yield to the wishes of stakeholders, as such a world sees the regulator as merely a moderator. In addition, the State as Venue imaginary relies on a regulator to profess a low level of access to information to drive this ceding of authority to other stakeholders which is contradicted by the clear statement of sector wide analysis[862] at the core of this evidence ("there are significant barriers to their adoption and use…")[863] We can represent our shock at seeing this evidence in such a world as compared to the extreme consistency of this evidence with the Adoption Catalyst world with a weight of evidence moderately (10 dB) greater than very strong (30 dB), thus 40 dB.

WoE_{NCHIT}, Adoption Catalyst vs. Folk Economic Model = 90 dB

A folk economic regulator would think intervention to encourage innovation is anathema. This evidence would only be observed as a condemnation of a bad plan which is opposite of the context it actually appeared in. In addition, the Folk Economic Model imaginary sees the regulator as lacking access to information while this evidence stakes a clear claim to possess information beyond that perceived by regulated entities.

WoE_{NCHIT}, Adoption Catalyst vs. Market Ideological = 90 dB

The logic of the market ideological world is the same as the folk economic for this evidence. A Market Ideological imaginary would see this sort of intervention beyond the imagination of the market and EHR's clear "perceived lack of financial return from investing in them" as patent blasphemy.

A summary of the explicit Bayesian type validation of E_{NCHIT} for each of the regulatory imaginaries in Table 1 which were narratively explained above is presented below in Table 65. The significance of this analysis is discussed in the following section on the weight of evidence E_{NCHIT}.

[862] See Malloy (2010, 337–43) for further discussion of how exactly this sort of higher sectoral knowledge is the particular value-add of regulatory agencies as compared to the local knowledge of individual regulated entities.
[863] (Blumenthal 2009, 1477)

Table 65: BayesTV Constitutive Variable Comparison Summary for E_{NCHIT}*

Constitutive Variables (Independent Variables)					Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Adoption Catalyst	*No specific relevance*	Regulator provides high level analysis of opportunities and challenges of EHR; beyond that of regulated entities	HITECH clearly pushes for adoption through incentives & punishments	*No specific relevance*	Evidence clearly states that under-adoption is a problem this regulation seeks to solve; catalyze adoption	
Beneficial Constraints	*No distinguishing relevance*	*No distinguishing relevance*	Incentives for adoption of identified tech, not guardrails for innovation	*No distinguishing relevance*	Beyond simply constraints, HITECH pushes for adoption beyond existing barriers	6 dB
Capture	*No distinguishing relevance*	Clear demonstration of knowledge through outreach in highly respected journals	*No distinguishing relevance*	*No distinguishing relevance*	Regulator seeks to push adoption beyond constraints rather than constrain	54 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Although regulator pushes a specific set of technological principles, they do not constrain the implementation to a single tech solution	10 dB
State as Venue	*No distinguishing relevance*	High level analysis of barriers to adoption represents high rather than low level of systemic information	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is pushing far beyond a moderating role to change the perceptions of regulated entities	40 dB
Folk Economic Model	*No distinguishing relevance*	Regulator clearly stakes claim to high level of knowledge beyond that of market actors	HITECH pushes for adoption beyond market desires	*No distinguishing relevance*	Far from creating an impediment, HITECH seeks to remove impediments to adoption and innovation around EHR	90 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	HITECH pushes for adoption beyond market desires	Clearly not laisses faire		90 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled WoE_{NCHIT}, Adoption Catalyst vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 35 for further explanation and Chapter 4 for complete methodological specification.

The Weight of Evidence NCHIT

The piece evidence presented above (E_{NCHIT}) increases our belief that the Adoption Catalyst is the true regulatory imaginary conceived by the HITECH Act. It provides unsurprisingly strong support for the Adoption Catalyst imaginary over the three least proactive regulatory imaginaries (Folk Economic Model (90 dB), Market Ideological (90 dB), Capture (54 dB)) making this evidence a strong bulwark against any claim that regulators are always an impediment to innovation. At 40 dB difference, this evidence provides an exceptionally strong level of evidence against the state as venue imaginary because the regulator is clearly pushing far beyond merely serving as a moderator. At 10 dB difference, this evidence moderately increases our belief that Adoption Catalyst rather than Technology Based Regulation is at work here because although HITECH does seek to catalyze the adoption of EHR technology, that technology is principle based (e.g. Meaningful Use) rather than solution or implementation based.[864] Finally, at 6 dB, this evidence weakly but clearly increases our belief that Adoption Catalyst rather than Beneficial Constraints is the more plausible imaginary because although both imaginaries seek to encourage innovation, only Adoption Catalyst looks to push beyond the imagination of the market with incentives and punishments.

Directive 2011/24/EU in the EU (2011-2021[865])

While several member-states had already implemented a national EHR system prior to EU action, Article 14 of Directive 2011/24/EU directed the Commission to "adopt the necessary measures for the establishment, management and transparent functioning" of an EHR system operating among the nations of the EU and Norway. While Directive 2011/24/EU leaves the language as "voluntary," it does require that the Union shall support and encourage the participation of the member states.[866]

The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be to see this evidence under the assumption that each potential regulatory imaginary was true.

Justification for E_{ART14} as Evidence for the Most Likely Type (Adoption Catalyst)

In an Adoption Catalyst world, Article 14 of Directive 2011/24/EU is a consistent piece of evidence, but the voluntary nature does not provide a strong declaration of purpose. However, in directing the Commission to facilitate adoption, this evidence would reflect a driver variable which sees the regulator as driving adoption. This Directive by the European Parliament and the Council in and of itself also suggests an information variable where these regulators see themselves as having greater knowledge of the regulated domain than any one participant in healthcare.

WoE_{ART14}, Adoption Catalyst vs. Beneficial Constraints = 10 dB

This evidence would be rather uninformative in a beneficial constraints world as it works very hard to be voluntary and not to constrain member states. The EU is directed to drive adoption, but it is not directed to constrain bad paths and encourage good ones.

[864] See the discussion below around $E_{Meaningful\ Use}$ for a discussion of this distinction between principles and solution based technological specification.

[865] Projected completion of "gradual implementation" in 22 EU countries is 2021 (European Commission 2019) although it was originally slated for 2020 in (European Commission 2012).

[866] (European Parliament and Council of the European Union 2011, OJ L:88/63)

WoE_{ART14}, Adoption Catalyst vs. Capture = 30 dB

In a world where the regulator has been captured by the regulated entity (member states and their medical systems), this drive for cross-national adoption would be very unlikely to be seen as different member states would have disparate preferences. We can be very confident that this drive for adoption would not be in the interest of a capturing entity.

WoE_{ART14}, Adoption Catalyst vs. Technology Based Regulation = 20 dB

A technology-based regulation regulator would not make compliance voluntary or be so vague in the necessary measures. The specifications included, such as they are, are principles such as interoperability and common types of data rather than specific implementations. 20 dB is a strong indication of this weight.

WoE_{ART14}, Adoption Catalyst vs. State as venue = 3 dB

The state-as-venue type regulator could reasonably make the rather broad and voluntary statement in this piece of evidence. However, this piece of evidence is somewhat more directed than the state-as-venue moderator role which would be less likely to direct towards the adoption of EHR and would instead suggest discussing the benefits and potential costs of adopting EHR.

WoE_{ART14}, Adoption Catalyst vs. Folk Economic Model = 50 dB

In a world where the regulator is merely deadweight upon innovation, this evidence would be highly unlikely as the regulator would not attempt to spur coordination and innovation.

WoE_{ART14}, Adoption Catalyst vs. Market Ideological = 50 dB

In a world where the market demand is privileged for ideological reasons at the expense of policy goals, a directive would be very unlikely to encourage a supranational (non-market) authority to facilitate creation of a non-market transfers of information.

A summary of the explicit Bayesian type validation (BayesTV) of E_{ART14} for each of the regulatory imaginaries in Table 1 is presented below in Table 66. The significance of this analysis is discussed in the following section on the weight of evidence E_{ART14}.

The Weight of Evidence ART14

The evidence provided by Article 14 of Directive 2011/24/EU (E_{ART14}) is most likely in the Adoption Catalyst world, although it speaks only weakly louder than for the State-as-Venue imaginary due to the broad and general principles it seeks to drive the adoption of which could reasonably be read as simply drawing together stakeholders. As there are no constraints given in the very general wording, Adoption Catalyst is a moderately (10 dB) more likely than Beneficial Constraints since there is also not a strong drive for adoption other than a directive to adopt. Finally, the remaining imaginaries would all be rather unlikely to have this piece of evidence and thus provide strong (20 dB) to exceptionally strong (50 dB) weight of evidence against each imaginary.

Table 66: BayesTV Constitutive Variable Comparison Summary for E_{ART14}*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Adoption Catalyst	*No specific relevance*	*No specific relevance*	The EU is driving adoption by directing the Commission to facilitate adoption	*No specific relevance*	Commission is directed to facilitate establishment and functioning	
Beneficial Constraints	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is driving establishment and adoption	*No distinguishing relevance*	No constraints are mentioned or implemented	10 dB
Capture	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	No constraints mentioned, especially not those consistent with medical business interests	30 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Principle-based guidelines (such as they are) not implementation based.	20 dB
State as Venue	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Regulator taking a proactive rather than moderating approach	3 dB
Folk Economic Model	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is driving establishment and adoption	*No distinguishing relevance*	Regulator driving innovation not impeding it	50 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is driving establishment and adoption	Clearly *not* laisses faire	Regulator driving innovation not impeding it	50 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled WoE_{ART14}, Adoption Catalyst vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 35 for further explanation and Chapter 4 for complete methodological specification.

NEAR RIVAL EVIDENCE:

As can be seen from the weight of evidence summary in Table 64, the initial evidence was least decisive about a different alternative type for each of the cases. In the US HITECH case, the nearest rival imaginary is the Beneficial Constrainer imaginary because the prevalence of economic barriers and overcoming perception is compatible with both Adoption Catalyst and Beneficial Constrainer imaginaries. In the EU Directive 2011/24/EU case, the nearest rival imaginary is the State as Venue imaginary due to the broad and voluntary language of the directive.

In this section, we consider a piece of evidence which is most supportive of the respective nearest rival type for each of the two empirical cases. For the US HITECH case, this evidence comes from the core mechanism of the implementation, the Meaningful Use standard, because it represents a constraint which was meant to beneficially incite innovation. For the EU case, this evidence comes from public consultation on the eHealth Action Plan 2012-2020 because it represents the state acting as a venue rather than as an active driver of innovation.

HITECH Act in the United States (2009-2014)

As initially envisioned and introduced to the medical community, the HITECH Act's key goal was to achieve not just adoption of any EHR but the "meaningful use" of "certified EHR."[867] These two key terms were formally defined through the notice and comment procedure leading to a standard of meaningful use which included "a set of core objectives that constitute an essential starting point for meaningful use of EHRs and a separate menu of additional important activities from which providers will choose several to implement."[868] In the words of the regulatory architects reaching out to the regulatees:

> *"The meaningful use rule strikes a balance between acknowledging the urgency of adopting EHRs to improve our health care system and recognizing the challenges that adoption will pose to health care providers. The regulation must be both ambitious and achievable. Like an escalator, HITECH attempts to move the health system upward toward improved quality and effectiveness in health care. But the speed of ascent must be calibrated to reflect both the capacities of providers who face a multitude of real-world challenges and the maturity of the technology itself." (Blumenthal and Tavenner 2010, 504)*

By establishing a constraint meant to drive beneficial challenges, the Meaningful Use regulation is a piece of evidence which would be highly likely under the Beneficial Constrainer imaginary identified as a near rival to the Adoption Catalyst imaginary in the US HITECH case. The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be to see this evidence under the assumption that each potential regulatory imaginary was true.

Reasoning about $E_{Meaningful\ Use}$ under the Comparator Type (Adoption Catalyst)[869]

In the world where the regulator sees themselves as a driver of adoption, the meaningful use standard as defined and justified in this piece of evidence would be very likely to be observed. The stress on balancing the need for adoption with the challenges thereof is a justification which would be made by a regulator looking to drive adoption beyond the imagination of the market.

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[867] (Blumenthal 2009, 1479)

[868] (Blumenthal and Tavenner 2010, 502–3)

[869] To avoid excessive repetition in the paired comparisons which follow, this first section in the explicit BayesTV analysis covers the reasoning for how (un)surprising this piece of evidence is under the most likely type (which will also serve as the comparator type for ease of final tabulation).

Yet, when compared to the mission statement in E_{NCHIT} above, it is slightly less likely that an Adoption Catalyst would concede the challenges rather than evangelize although both are quite likely. On the other hand, the incentives and punishments behind the meaningful use standard (see case narrative) are exactly the actions of the archetypical Adoption Catalyst imaginary.

$WoE_{Meaningful\ Use}$, Adoption Catalyst vs. Beneficial Constraints = 3 dB

As the near rival imaginary from the analysis of the initial evidence, the Beneficial Constrainer imaginary was used to select $E_{Meaningful\ Use}$. Since meaningful use aims to increase use and innovation of EHR technology through a set of specific core objectives and menu of extensions, it is consistent with the logic of the beneficial constrainer who believes themselves to have higher access to information than market participants. However, the emphasis on the urgency of adoption rather than the softer encouragement of market innovation to meet the standard are less consistent with a beneficial constrainer who axiomatically sees themselves as helping the market to drive innovation adoption. As this is a slim distinction, 3 dB represents the smallest meaningful difference.

$WoE_{Meaningful\ Use}$, Adoption Catalyst vs. Capture = 40 dB

In laying out this final meaningful use regulation, CMMS spoke of balancing "the urgency of adopting EHRs" with "the challenges that adoption will pose to health care providers."[870] In a world where the regulator had been captured by industry, we would expect far less pressure to impose challenges on industry. We might think that these challenges are a cover for a handout to preferred firms, but it is clear that the carrots of subsidies came along with the sticks of withholding Medicare payments, a far cry from a simple pork handout.

$WoE_{Meaningful\ Use}$, Adoption Catalyst vs. Technology Based Regulation = 20 dB

With the specification of a standard rather than a particular technology to adopt, meaningful use would be highly unlikely in a world where CMMS saw themselves as a Technology-Based Regulator. The language of the evidence even concedes that technology is not yet "mature" enough to mandate a specific choice.

$WoE_{Meaningful\ Use}$, Adoption Catalyst vs. State as venue = 60 dB

While the meaningful use regulation was generated through the Notice and Comment Procedure of the Administrative Procedures Act of 1947 (the standard regulatory process in the United States), the content of the final rule clearly went beyond simply convening stakeholders to discuss relevant needs. Instead, meaningful use decided what needs were to be prioritized and mandated a list of them. This would be highly unlikely to be observed in a world where CMMS saw themselves as a State-as-venue regulator.

$WoE_{Meaningful\ Use}$, Adoption Catalyst vs. Folk Economic Model = 60 dB

In a world where CMMS saw itself as merely deadweight upon the healthcare industry, we would be highly unlikely to observe a final regulation such as meaningful use which sets a difficult standard for industry to meet. Indeed, they would do exactly the opposite as they would be trying to minimize the harm they cause industry by mandating new practices.

[870] (Blumenthal and Tavenner 2010, 504)

$WoE_{Meaningful\ Use}$, Adoption Catalyst vs. Market Ideological = 60 dB

The same justification as for the Folk Economic Model holds even more strongly here; a market ideological regulator would consider it the height of violation to impose hard external constraints against the wishes of market participants.

A summary of the explicit Bayesian type validation (BayesTV) of $E_{Meaningful\ Use}$ for each of the regulatory imaginaries in Table 1 is presented below in Table 67. The significance of this analysis is discussed in the following section on the weight of evidence $E_{Meaningful\ Use}$.

The Weight of Evidence Meaningful Use

As we can see from the last column of Table 67, the piece evidence presented above ($E_{Meaningful\ Use}$) increases our belief that the Adoption Catalyst is the true regulatory imaginary conceived by the HITECH Act. While it was selected to align most closely with the nearest rival imaginary (Beneficial Constraints), it provides weakly stronger support for the Adoption Catalyst rather than Beneficial Constraints (3dB). Unsurprisingly, it also reinforces support for the Adoption Catalyst imaginary over the two least proactive regulatory imaginaries (Folk Economic Model and Market Ideological) which, at 60 dB difference, makes this evidence an exceptionally strong bulwark against any claim that regulators are always an impediment to innovation. At 40 dB, we also have very very strong evidence against Capture as the Meaningful Use standard is a difficult one for any conceivable capturing entity (medical or IT) to meet. At 60 dB difference, this evidence also provides extremely strong evidence against the state as venue imaginary because despite the use of the notice and comment process to draft meaningful use, the final specification was clearly influenced by the agenda of CMMS rather than simply an aggregate of the stakeholders. Finally, at 20 dB), this evidence strongly increases our belief that adoption catalyst rather than technology based regulation is at work here because the standard in meaningful use is performance and principle based rather than particular implementation or technology based.

Table 67: BayesTV Constitutive Variable Comparison Summary for $E_{\text{Meaningful Use}}$*

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Adoption Catalyst	*No specific relevance*	The principles and standards laid out in the meaningful use standard demonstrate clear claims to high information	The meaningful use standard comes with carrots and sticks to drive adoption	*No specific relevance*	Archetypical catalyst: using incentives and punishments to drive adoption	
Beneficial Constraints	*No distinguishing relevance*	*No distinguishing relevance*	The regulator rather than the market is the driver (incentives)	*No distinguishing relevance*	Meaningful use can be seen as either a constraint or a set of adoption principles	3 dB
Capture	*No distinguishing relevance*	Regulator set a firm and "meaningful" standard that was beyond the wishes of market actors	*No distinguishing relevance*	*No distinguishing relevance*	Drove adoption of an innovation rather than allowing short term economic calculus to constrain it.	40 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	A principle (performance) based standard rather than a solution based one	20 dB
State as Venue	*No distinguishing relevance*	State gathered information from Notice and Comment then adjudicated & prioritized it	*No distinguishing relevance*	*No distinguishing relevance*	Far more than moderating, CMMS regulator clearly set out its own agenda for meaningful use.	60 dB
Folk Economic Model	*No distinguishing relevance*	Principles and standards demonstrate competence	Regulator is driving adoption with carrots and sticks	*No distinguishing relevance*	Regulator catalyzing adoption and innovation, not impeding it	60 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	Regulator is driving adoption with carrots and sticks	Far from standing back, regulator is driving	Regulator catalyzing adoption and innovation, not impeding it	60 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled $WoE_{\text{Meaninful Use}}$, Adoption Catalyst vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 35 for further explanation and Chapter 4 for complete methodological specification.

Directive 2011/24/EU in the EU (2011-2021)

As part of passing any major EU initiative, a public consultation is required. This process involves a 90 day period of soliciting responses to a questionnaire by the directorate-general (DG). Following promulgation of Directive 2011/24/EU, the Information Society and Media Directorate-General (DG INFSO) was tasked with creating the eHealth Action Plan for 2012-2020 (2012). This action plan laid out the steps towards implementing the required eHealth Network as laid out in Directive 2011/24/EU.[871] As part of implementation, DG INFSO undertook a public consultation with the following four proposed objectives:

> *"Objective 1: Increase awareness of the benefits and opportunities of eHealth, and empower citizens, patients and healthcare professionals.*
>
> *Objective 2: Address issues currently impeding eHealth interoperability*
>
> *Objective 3: Improve legal certainty for eHealth*
>
> *Objective 4: Support research and innovation in eHealth and development of a competitive European market." (DG INFSO 2011, 2)*

Leading to the following three summary recommendations from respondents:

> *"1) The need to support systematic evaluation of the benefits and costs, effectiveness/usefulness of eHealth solutions;*
>
> *2) Improving interoperability and strengthening the evidence-based approach; and*
>
> *3) Facilitating cooperation between Member States and regions and, exploring innovative financing and reimbursement schemes." (DG INFSO 2011, 2)*

By focusing on awareness, standard setting, and facilitating cooperation, this framing of both the objectives and the responses is a piece of evidence which would be highly likely under the State-as-Venue imaginary which was identified as a near rival to the Adoption Catalyst imaginary in the Directive 2011/24/EU case. The explicit Bayesian type validation (BayesTV) below analyzes how likely we would be to see this evidence under the assumption that each potential regulatory imaginary was true.

Reasoning about E_{INFSO_PC} under the Comparator Type (Adoption Catalyst)[872]

Consistent with the justification for E_{ART14} discussed above, the focus on "facilitating cooperation," "increase[ing] awareness," and "address[ing]… imped[iments]" is less forceful than would be expected if Adoption Catalyst is the true state of the world. On the other hand, as public consultation is a mandatory procedure for major European Commission policymaking, this softening of language may simply be to cater to the audience of stakeholders while soliciting their opinion.

WoE_{INFSO_PC}, Adoption Catalyst vs. Beneficial Constraints = 10 dB

While most of the objectives and summary responses concern gathering and sharing information, the third objective (to improve legal certainty) as well as the second summary

[871] (European Commission 2012, 3)

[872] To avoid excessive repetition in the paired comparisons which follow, this first section in the explicit BayesTV analysis covers the reasoning for how (un)surprising this piece of evidence is under the most likely type (which will also serve as the comparator type for ease of final tabulation).

response (improve interoperability) could be construed as constraints. Were beneficial constraints to be the true state of the world, we would expect to see this emphasis on setting good rules of the game. However, the non-binding nature of these constraints combined with the "raising awareness" and performing "systematic evaluation" of EHR would be unlikely since they would reduce the ability of the rules to beneficially constrain behavior towards a beneficial end. Thus, the evidence speaks moderately for Adoption Catalyst over Beneficial Constraints because the it is consistent with Adoption Catalyst while surprisingly toothless in a Beneficial Constraints world.

WoE_{INFSO_PC}, Adoption Catalyst vs. Capture = 10 dB

While a captured regulator might seek to clarify laws and reinforce existing professional organizations, the focus on educating the regulatees on the benefits of adopting EHR would be extremely unlikely unless we grant that the regulators have been captured by tech firms pushing a shoddy or unnecessary product. Regulators in the US and EU seem to have a firm technical belief in the promise of EHR, undermining this interpretation. Thus, we have a possible but not plausible story leading to moderate (10 dB) evidence in favor of Adoption Catalyst over Capture.

WoE_{INFSO_PC}, Adoption Catalyst vs. Technology Based Regulation = 30 dB

A technology based regulator would be focused on gathering the technical specifications for adoption rather than proposing general principles and gathering feedback on how to refine those principles. Thus, this evidence very strongly (30 dB) speaks against technology based regulation being the true state of the world.

WoE_{INFSO_PC}, Adoption Catalyst vs. State as venue = -3 dB

As originally laid out in *Bringing the State Back In* (Skocpol 1985), states by definition (and uncontroversially) act as venues because that is, functionally, what states do. Indeed, the distinction in that pathfinding work was to say that venue was not all that states did and that venue is not synonymous with states. Thus, if state-as-venue is the true state of the world, "facilitating cooperation" between stakeholders is paradigmatically what regulators should be doing. Thus, we would be extremely likely to see this evidence in such a world. By the same token, because the state is required to seek public consultation as described in the previous section, this is not particularly informative about the relative likelihood of state-as-venue vs. adoption catalyst. Thus, 3 dB (the smallest meaningful difference), adequately captures the closeness of this comparison but in favor of the State as Venue rather than Adoption Catalyst because it is so axiomatically consistent.

WoE_{INFSO_PC}, Adoption Catalyst vs. Folk Economic Model = 60 dB

Given the proactive approach undertaken by the regulator in not only seeking the mandated public consultation but in doing so with clearly defined objectives meant to spur innovation and adoption, we would be extremely unlikely to observe this evidence in a Folk Economic world. This piece of would be simply anathema.

WoE_{INFSO_PC}, Adoption Catalyst vs. Market Ideological = 50 dB

While there are concessions to setting up a "competitive market," this evidence clearly mentions doing so for rational cost-benefit reason rather than because markets are simply 'the right thing to do.' Thus, the evidence is extremely strongly against the Market Ideological imaginary.

A summary of the explicit Bayesian type validation (BayesTV) of E_{INFSO_PC} for each of the regulatory imaginaries in Table 1 is presented below in Table 68. The significance of this analysis is discussed in the following section on the weight of evidence E_{INFSO_PC}.

The Weight of Evidence INFSO_PC

As we can see from the last column of Table 68, the information provided by INFSO_PC (E_{INFSO_PC}) increases our belief that the Adoption Catalyst is the true regulatory imaginary conceived by the Directive 2011/24/EU. As it was selected to align most closely with the nearest rival imaginary (state-as-venue), it provides weakly stronger support (3dB) for the State-as-Venue imaginary over the Adoption Catalyst imaginary because it derives from a mandated procedure to facilitate stakeholder interaction and feedback. Unsurprisingly, it also reinforces support for the Adoption Catalyst imaginary over two of the three least proactive regulatory imaginaries (Folk Economic Model and Market Ideological) which, at 60 and 50 dB difference, makes this evidence an exceptional strong barrier against any claim that regulators are always an impediment to innovation. Intriguingly, at only 10 dB, this evidence only moderately speaks against the capture imaginary due to concessions it makes to established market actors (professional organizations) and the educating work it does to spread the benefits of EHR. However, this support also shows the analytical limits of Stiglerian capture within corporatist[873] or coordinated[874] market societies as the language emphasizing market stakeholders in such contexts is observationally equivalent between the negative sentiment suggested by Stiglerian capture and the positive sentiment of public consultation. At 10 dB difference, this evidence provides a moderate increase in our belief in favor of Adoption Catalyst over Beneficial constraints as there is no explicit discussion of constraints in the objectives or responses from DG INFSO's public consultation even if we might generously attempt to read them in between the lines. At 30 dB difference, this evidence provides a very strong evidence in favor of Adoption Catalyst over Technology Based Regulation because the discussions are general principle rather than specific implementation based.

[873] (c.f. Esping-Andersen 1990), although he preferred the term Christian Democratic after the parties that often construct such societies and others have described them as continental or conservative welfare capitalist societies.
[874] (c.f. Hall and Soskice 2001a)

Table 68: BayesTV Constitutive Variable Comparison Summary for E_{INFSO_PC} *

	Constitutive Variables (Independent Variables)				Dependent	
Imaginary	**Relationship**	**Information**	**Driver**	**Outcomes**	**Effect**	**WoE w.r.t to MLT†**
Most Likely Type: Adoption Catalyst	*No specific relevance*	Regulator is gathering information but muddy on how much it has	Regulator is increasing awareness and facilitating adoption; driving but weakly	*No specific relevance*	Actions are consistent with catalyst but not strongly indicative of it	
Beneficial Constraints	*No distinguishing relevance*	*No distinguishing relevance*	Not waiting for the market to drive, facilitating	*No distinguishing relevance*	If there are constraints, they are not very constraining	10 dB
Capture	*No distinguishing relevance*	Regulators gather information and spreading it as well	*No distinguishing relevance*	*No distinguishing relevance*	Implausible capturing entity (EHR tech firms) who are in their infancy at this time. Tech more promise than reality	10 dB
Technology-Based Regulation	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	*No distinguishing relevance*	Gathering principles rather than mandating specific implementations	30 dB
State as Venue	*No distinguishing relevance*	Regulator gathering information is axiomatic State as Venue	*No distinguishing relevance*	*No distinguishing relevance*	Although axiomatically consistent, it is also consistent with Adoption Catalyst	- 3 dB
Folk Economic Model	*No distinguishing relevance*	Regulator gathering and spreading info, no low access	Regulator weakly driving adoption	*No distinguishing relevance*	Regulator is proactively educating and spreading the innovation, rather than impeding its development	60 dB
Market Ideological	*No distinguishing relevance*	*No distinguishing relevance*	Regulator weakly driving adoption	Certainly not leaving the outcome up to the market		50 dB

* The full explicit Bayesian type validation including prose explanations for each significant cell summarized in this table can be found in the appendix sections labeled WoE_{INFSO_PC}, Adoption Catalyst vs. Name of Imaginary) for each respective row labeled by the regulatory imaginary in the first column.

† Following the logical Bayesian reasoning in BayesTV, the most likely type (MLT) in the first row is presented to serve as a comparator for the six other types in the rows below. The other imaginary types are expressed as a weight of evidence (WoE) relative to the most likely type in dB where positive dB means that the MLT is more likely than the rival type and negative dB means the MLT is less likely than the rival type. See note on Table 35 for further explanation and Chapter 4 for complete methodological specification.

BLACK SWAN EVIDENCE AND THE COUNTERFACTUAL

Before adjudicating the final type classification and sensitivity to priors, due diligence requires us to consider what evidence would be consistent with the extreme opposite of the suggested type classification being the true state of the world; the so called "black swan" evidence. As adoption catalyst is the most likely type for the EHR case, the extreme opposite (from Table 1) is the Folk Economic Model imaginary because it is at the extreme other end of the effect spectrum. In a folk economic world, we would expect to see regulators acting lost due to lower access to information than market participants and either recusing themselves from regulation in order to stay out of the way until the market has innovated[875] or implementing harsh and inappropriate anti-innovative regulations. While no evidence has been found that carries this information, a skeptical reader should contact the author with such evidence so that it may be incorporated into analysis and allow us to radically update our priors.

FINAL TYPE CLASSIFICATION AND SENSITIVITY TO PRIORS

For final classification based on an update of belief in which imaginary is the true state of the world, we add the decibel comparisons between the Adoption Catalyst imaginary and each of alternative imaginaries from each piece of evidence and then add those to the priors discussed at the beginning of this section. These comparisons are presented in Table 69.

Consistent with the design and intent of Bayesian Type Validation, the evidence can tell several disciplined and clear stories depending on how it is combined with priors and across cases. If we combine all of the evidence for both the US and EU cases, we find decisive evidence[876] to believe that EHR technology is regulated from the Adoption Catalyst imaginary (80+ dB, Combo Posterior Column under a in Table 69) for all rival imaginaries except Beneficial Constraints, where we see very strong (29 dB) evidence. If we look just at the US case (Table 69, column a "US Post"), we find decisive (80+ dB) for Adoption Catalyst over the Capture , State as Venue, Folk Economic Model, and Market Ideological imaginaries, strong (30 dB) evidence over Technology Based Regulation, and moderate (9 dB) evidence over Beneficial Constraints. If we look at just the EU case (Table 69, column a "EU Post"), we find decisive evidence (80+ dB) for Adoption Catalyst over the Folk Economic Model and Market Ideological imaginaries, well-established evidence (50-70 dB) over the Technology Based Regulation imaginary, exceptionally strong (40 dB) evidence against Capture, and strong (20 dB) evidence

[875] While this may seem fanciful, this "wait and see" attitude was exactly how the Federal Reserve approached mobile payment apps for years. (Lowry 2016, 384)

[876] Fairfield and Charman (2017, 11; 2022, 132–33) recommend a threshold of 30 dB for the evidence "speaking clearly" as this is the sound of "talking clearly" in a quiet room. A threshold of 50 dB represents "skeptical" difference between a very well-established theory and a highly implausible rival. Fairfield and Charman (2022, 162–63) proceed to explain that a more stringent threshold of 50-70 decibels equates to the thresholds of confidence used by quantitative Bayesian statisticians in the physical and biological sciences; they note that 62 dB is roughly equivalent to the 5 sigma threshold for discovering a new particle in Physics and 67 dB the chance that any given commercial airplane flight will crash vs. land safely. While Fairfield and Charman (2022, 162, footnote 34) also caution us that you cannot truly mathematically convert Bayesian odds to frequentist p-values because they are different ontological statements, most quantitative social scientists are happy with $p<0.1$ (~27 dB) and $p<0.05$ (~30 dB) for publication and are ebullient about $p<0.01$ (~37 dB). Fairfield and Charman ultimately recommend a threshold of 80-100 dB to consider a qualitative research question "settled" both to guard against potential unaccounted for bias as well as to deal with the reality that quantitative social scientists often show higher skepticism toward qualitative evidence than they do towards their own thresholds of significance.

against Beneficial Constraints. The State as Venue imaginary ends up equally as plausible as the Adoption Catalyst imaginary for the EU Directive 2011/24/EU case. These overall weights of evidence should then each be considered against the reader's priors to update our belief in what the most probable state of the world is.

If the reader adopted naïve priors with equal weights (0 dB for or against Adoption Catalyst) for the combined case of AVs in the US and EU (Table 69, column a "combo posterior"), then the evidence presented above would create decisive (80+ dB) to overwhelming (100+ dB) in favor of Adoption Catalyst over all alternative regulatory imaginaries except Beneficial Constraints where it would be only very strong (29 dB). While there are fair reasons to disaggregate the data to a per-case level as that is where the regulation actually occurred (at the US/EU levels), this combined weight of evidence is useful for us to understand how EHR is imagined to be regulated cross-nationally. The evidence thus aggregated tells us that EHR is regulated from the Adoption Catalyst imaginary for Naïve and Background Information priors while the Skeptical priors are able to tile the scale towards Beneficial Constraints.

Table 69: BayesTV Prior and Posterior Weights of Evidence for the EHR Cases, US HITECH and EU Directive 2011/24/EU (in dB)

	a				b				c			
Weight of Evidence (WoE)*	**Naïve**				**Background Info**				**Skeptical**			
	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior	Prior	US Post	EU Post	Combo Posterior
$\frac{Adoption\ Catalyst}{Beneficial\ Constraints}$	0	9	20	29 dB	-10	-1	10	19 dB	-50	-41	-30	-21 dB
$\frac{Adoption\ Catalyst}{Capture}$	0	94	40	134 dB	0	94	40	40 dB	-50	44	-10	84 dB
$\frac{Adoption\ Catalyst}{Technology\ Based\ Regulation}$	0	30	50	80 dB	-10	20	40	70 dB	-50	-20	0	30 dB
$\frac{Adoption\ Catalyst}{State\ as\ Venue}$	0	100	0	100 dB	0	100	0	100 dB	-50	50	-50	50 dB
$\frac{Adoption\ Catalyst}{Folk\ Economic\ Model}$	0	150	110	260 dB	0	150	110	260 dB	-50	100	60	210 dB
$\frac{Adoption\ Catalyst}{Market\ Ideological}$	0	150	100	250 dB	0	150	100	250 dB	-50	100	50	200 dB

* Note that the comparisons are presented as odds ratios to concisely show that they are comparisons between two possible worlds (numerator and denominator). Each of the cell values, however, is a weight-of-evidence (WoE) expressed in decibels. While odds ratios must be between zero and 100% (aka. [0,1]) decibels may be positive or negative (theoretically (-∞,∞) although practically (-194,194) because above 194 dB sound waves become shock waves). A negative WoE means that the evidence speaks more strongly for the denominator (bottom) than the numerator (top) while a positive WoE means that the evidence speaks more strongly for the numerator (top) than the denominator (bottom).

However, as the actual US HITECH Act and EU Directive 2011/24/EU approaches to EHR regulation were decided through separate processes, it is also useful to disaggregate down to the US/EU level and compare against priors. In the US HITECH Act case, we see that the evidence remains decisive (80+ dB) against all imaginaries except Beneficial Constraints and Technology Based Regulation across Background Info priors (Table 69, column b "US Post"). Technology Based Regulation slips to strong (20 dB) evidence against it while Beneficial Constraints becomes indistinguishable (-1 dB).[877] With skeptical priors (Table 69, column c "US Post"), the US case maintains decisive (80+ dB) evidence against Folk Economic Model and Market Ideological imaginaries, well established (50-70 dB) evidence against State as Venue, and exceptionally strong (44 dB) evidence against Capture. The extreme weight of the skeptical priors (50 dB) allows Beneficial Constraints and Technology Based Regulation to rise above Adoption Catalyst as favored alternatives.

Although the weight in favor of Beneficial Constraints and Technology Based Regulation are primarily driven by overly strong skeptical priors strong priors, we should not be surprised that these two imaginaries are the nearest rivals as both share elements with Adoption Catalyst. Beneficial Constraints shares the proactive nature of the Adoption Catalyst imaginary which seeks to encourage innovation. Technology Based Regulation shares the drive for adoption of a technology with Adoption Catalyst, although Adoption Catalyst is more pro innovation and flexible than the blanket mandate of Technology Based Regulation. Beyond merely the weights of evidence, however, if we dive into the analysis and case narrative of the HITECH act, we see that this regulation lacks the constraining aspects of both Beneficial Constraints and Technology Based Regulation. HITECH uses incentives and punishments rather than constraints or mandates in order to drive the innovation and adoption of EHR beyond the imagination of the market.

In the Directive 2011/24/EU case, we see that the evidence weighted against Background Info priors (Table 69, column b "EU Post") remains decisive (80+ dB) against Folk Economic Model and Market Ideological imaginaries, very strong (40 dB) against Capture and Technology Based Regulation, moderate (10 dB) against Beneficial Constraints, and indecisive (0 dB) between State as Venue and Adoption Catalyst. Weighted against Skeptical priors (Table 69, column c "EU Post"), the EU case maintains well-established evidence (50-70 dB) against the Folk Economic Model and Market Ideological imaginaries but flips to favoring or indifference between all other imaginaries over Adoption Catalyst. This flip against all but the most anathema imaginaries demonstrates that the EU case is at best a weak representation of Adoption Catalyst but is not particularly indicative of which of the rivals may be preferable. From the narrative analysis in Appendix D, it is clear that the coordinated market economy engagement with stakeholders muddies the waters in favor of the State as Venue imaginary.

Based on these four pieces of evidence, we see that how clearly EHR can be considered a case of Adoption Catalyst depends on the priors you adopt and the aggregation you are interested in. In isolation for any set of priors, these four pieces of evidence (NCHIT, ART14, Meaningful Use, INFSO_PC) are overwhelmingly convincing in favor of Adoption Catalyst over all alternative models for the general approach to EHR regulation across the US and EU except for Beneficial Constraints, where the evidence is very strongly in favor of Adoption Catalyst.

However, at the individual regulatory domain level, we see divergent conclusions based on priors that nevertheless may be undermined by additional case information. In the US, the

[877] Recall that 3 dB is the smallest meaningful difference, see Table 63

Beneficial Constraints and Technology Based Regulation imaginaries become increasingly likely relative to Adoption Catalyst as we increase the weight of the prior against Adoption Catalyst, although this relies on a lack of deeper reading of the HITECH act where the consistency with the constraint worlds breaks down due to the lack of constraints in favor of incentives and punishments. In the EU, the Adoption Catalyst is universally less strongly supported except against the extreme opposite imaginaries of Folk Economic Model and Market Ideological because the EU aimed to facilitate adoption through outreach and education which is also highly consistent with a State as Venue imaginary. At the very least, however, EHR in both cases, combined and isolated, allows us to soundly reject the Folk Economic Model and Market Ideological imaginaries in favor of imaginaries which are more proactive and beneficial to innovation.