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Open Pharma: Collective Action to Common Pharmaceutical Knowledge

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Open Pharma: Collective Action to Common Pharmaceutical Knowledge

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ABSTRACT

Open Pharma: Collective Action to Common Pharmaceutical Knowledge

Nicole Foti

Access to medicines is a critical ongoing challenge to advancing goals of health equity. Recent changes in the political economic and technoscientific domains of pharmaceuticals beg a reexamination of shifting processes in this space, especially emergent forms of collective action to address structural conditions for making new and old drugs. In particular, two trends in science—open science and community biology—have created the social and technical conditions through which new alternative imaginaries have emerged to research, develop, and make medicines. This dissertation offers an ethnographic account of these actions to common pharmaceutical knowledge through open science and lay participation in drug research. I examine two sites: the first site is a diffuse network of academic and nonprofit initiatives applying open science to drug research and development; the second site is a citizen science initiative, Open Insulin, leveraging a direct social action approach to make insulin in a community lab.

Drawing on 29 in-depth interviews, over 300 hours of observations of citizen scientists' organizational and research activities, and content analysis of journal articles and university and nonprofit organizations' policies and websites, I trace a burgeoning movement to apply "open" principles and practices to the research and making of pharmaceuticals, an area I refer to as *open pharma*. I begin with an analysis of this open pharma movement by examining three key characteristics. First, I identify the major narratives discursively employed by actors to frame the movement and provide rationales to mobilize others, often drawing on market logics. Next, I trace the active build*ing* and institutionaliz*ing* of open pharma through the establishment of

organizations and open sharing policies. Then I reveal sites of resistance actors experienced in university settings related to publishing and commercialization imperatives—which often translated to patent imperatives. My next set of findings focus on Open Insulin and the connections between their organizational structure and goals for creating more egalitarian alternatives to corporatized science practices and logics. I surface how membership and decision-making authority acted as key nodes of tension and change within the group, and I illustrate the project's mission as continuously constructed in relation to these nodes. Finally, I further explore the discursive production of Open Insulin's mission through two competing visions for making affordable insulin: an unprecedented but more transformative approach for "community manufacturing" through medicine cooperatives, and a more common and socially legitimized approach through a contract manufacturer partnership. As group members organized toward these visions, I unpack specific challenges groups face in looking to resist processes of capitalization in highly technical and regulated domains such as pharmaceuticals.

Through my tracing of movement practices and aims, I illuminate important entanglements between divergent approaches to social change, markets, regulatory regimes, and technoscientific infrastructure that construct and value openness in pharmaceuticals. This research articulates alternative imaginaries for how to organize biomedical knowledge production, and how they variously shape projects to intervene in inequities perpetuated by the political economy of health and illness.

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CHAPTER 1: Introduction

In 2020, the World Health Organization designated expanding access to medicines as one of the urgent health challenges for the next decade. Globally, an estimated one third of people lack access to essential medicines (Quick 2003). The drug research pipeline disproportionately targets diseases affecting people in high-income countries over those most impacting low-income countries (Fisher, Cottingham, and Kalbaugh 2015). In the United States, even medicines that have been around for decades, such as insulin, have seen major price increases, leading to rationing and, in turn, hospitalizations and deaths. Despite concerted legal and advocacy efforts to address this issue, people remain deeply troubled by an industry that brings in billions in profits each year and yet fails to deliver affordable drugs, new or old.

Meanwhile, open science approaches are being increasingly embraced as means to organize biomedical research and scientific knowledge production more broadly. The US Office of Science and Technology Policy named 2023 "The year of open science." Concurrently, the National Institutes of Health (NIH) – the largest public funder of biomedical research globally – launched a new Data Management and Sharing Policy, in which they compel NIH-funded biomedical researchers to plan for how they will widely share data and research resources to better improve our collective understanding of health and advance treatments (NIH 2022).

Against this backdrop, this dissertation offers a sociological analysis of the emergent movement to apply open science principles to the research and making of pharmaceuticals, an area of biomedicine particularly known for entrenched intellectual property regimes. I investigate processes of commoning pharmaceutical knowledge through collective action to develop medicines without patents as well as lay participation in the making of drugs. In particular, I trace a global network of university- and nonprofit-based initiatives using open science in drug

research and development (R&D). I also provide a more detailed examination of a citizen-driven open science initiative to produce insulin in a community biology lab. Through my tracing of movement practices and aims, I illuminate important entanglements between divergent approaches to social change, markets, regulatory regimes, and technoscientific infrastructure that shape and value openness in pharmaceuticals. This research articulates alternative imaginaries for how to organize biomedical knowledge production, and how they variously shape projects to intervene in inequities perpetuated by the political economy of health and illness.

Background

Activity and research focused on different forms of commons has seen a notable expansion in recent decades. A commons can be broadly defined as resources which a community or public has shared and equal rights over. Scholars have noted this burgeoning re-attention to the concept in global efforts to reclaim and establish durable, functioning commons arrangements for the management of varied natural and social resources (e.g., knowledge), such as seeds (Montenegro de Wit 2019), urban space (Jiménez and Estalella 2014: 5), citizenship (Papadopoulos and Tsianos 2013), repair knowledge (Iles 2019), and health and medical care (Gochfeld, Burger, and Goldstein 2001; Hiatt 1975). Some have even described this new and diverse set of approaches as "new commons," which have been inspired in reaction to the enclosure[1] of resources and linked to neoliberalism's dominance and the accelerating

[1] I use the term "enclosure" following other scholars writing on commons approaches and who tend to view its meaning as more expansive than the enclosure of land, for instance. Hess (2008: 6) describes this well, stating: "enclosure in new commons is the gradual or sudden decrease of accessibility of a particular resource. The reasons for enclosure are many: privatization, commercialization, new legislation, increased scarcity through overconsumption, which can be brought about from new populations, natural disaster, neglect, etc. Enclosure is particularly visible where new technologies have created the ability to capture recently uncapturable public goods. This has been the case with outer space, deep seas, Antarctica, the human genome, and indigenous arts. Information technologies combined with new legislation expanding copyright and the definition of what is patentable enable the enclosure of previously openly accessible areas of information—just as barbed wire made the open range

privatization of knowledge and other resources (Hess 2008; McCarthy 2005). Moreover, recent commons scholarship recognizes the commons as a dynamic and evolving social activity (Bollier 2014; De Angelis 2004; Federici 2018; Linebaugh 2014), with newer terms circulating such as "commoning," "commonfare," and "common of the commons" (Casas-Cortés, Cobarrubias, and Pickles 2014). Montenegro de Wit (2019: 45) conveys the commons as "a living, dynamic field of practice – not simply a resource divided amongst people, but a social transformation developed in and through the practices of *commoning*," and that by moving from noun to verb this "helps us appreciate that commons do not just exist; they must be produced and reproduced, negotiated and renegotiated, learned about and labored over." Science and technology, in particular, is an area marked by the enclosure of knowledge, tools, and data through intellectual property protections and privatization, leading some to ask whether such exclusivity regimes have given way to a "tragedy of the anticommons" in biomedical research (Heller and Eisenberg 1998) – where scarce resources are underused due to too many exclusive owners.

As individuals and groups in science react to increasing privatization, there have been concerted efforts to "open" science. This includes an assortment of practices such as open access publishing, open peer review, uninhibited sharing of data and research tools, and agreements that limit or bar patents. Some have underscored the significant overlap, even convergence, of different "open" movements in science and technology, including open source, open access, and open science (Willinsky 2005). Mirowski (2018: 173) suggests that proponents of the open science movement regularly toggle between "wildly different phenomena" in their conceptualization. Indeed, despite the seemingly ubiquitous use of the term "open science" these days, there is a lack of broad consensus over its meaning and enactment (Grubb and Easterbrook

enclosable." That is, new commons vary substantially and do not always operate through formalized processes; rather, many are being conceived and established in reaction to different forms of enclosure.

2011). Scholars have argued that openness in science is anything but singular or fixed in meaning and that openness in research is "a dynamic practice of opening and closing" (Levin and Leonelli 2017). Dichotomies of "open" versus "closed" even appear overly simplistic, considering that both openness and closedness are an inherent part of science historically: the sharing and concealment of technoscientific knowledge have always been selective (Hilgartner 2012; Kelty 2012). Importantly, open science has been formed in close connection with political economic structures, including through its usage of intellectual property forms (Calvert 2012; Parry 2020; Rai and Boyle 2007) and co-existence with academic commercialism (Murray 2010). Many actions to "open" or share biomedical research fall under what Sunder Rajan (2006: 46) calls "strategic decommodification," where acts of placing knowledge in the public domain are calculated, often benefiting big pharmaceutical companies, and are part and parcel of market logics. Moreover, some have argued that in its current incarnation, open science falls readily within the catchment of neoliberalism (Hayden 2010; Kansa 2014; Mirowski 2018).

Citizen science and community biology present another approach through which to "open" science through wider participation, offering yet another dimension to commoning scientific knowledge. Within biology, such terms as "biohacking" and "do-it-yourself biology" (DIYbio) are used to describe efforts that utilize the tools of molecular biology and biotechnology by those either without formal training and/or undertaken outside of "official" spaces, that is, scientific institutions or professional laboratories (Bolton and Thomas 2014; Katz 1990; Kelty 2010). The phenomenon of community biology encompasses these terms and adds a component of people utilizing a community biology lab – a space with wet lab equipment that anyone from the public can access. Such spaces are often not-for-profit and require that users of the space pass a lab safety quiz and, in many labs, pay a fee. According to DIYbiosphere (n.d.), a

network set up to connect DIYbio initiatives, there are around 45 active community labs around the world, on every continent; however, the majority reside in economically wealthier regions. Projects undertaken range across many domains of biology, from botany to fermentation to biomedical research. Other references used to describe this type of space and/or work include maker's space, citizen science, and garage science.[2] Community labs are viewed as attempts to democratize science, enabling people with little or no scientific background to participate in science (Delfanti 2013; Kera 2014; Meyer 2013). However, other scholars debate the extent to which these efforts truly differ from "big bio," arguing that the participants, activities, and ethos of DIYbio tend to reflect, rather than depart from, mainstream biotech (Ikemoto 2017; Wilbanks 2017).

Scholars have also documented a rise in health and biomedical citizen science projects in recent years (Guerrini et al. 2022; Trejo et al. 2021; Wiggins and Wilbanks 2019). These initiatives range from individuals in their homes or kitchens, to groups in home- or garage-based labs, to projects in community biology labs (Talbot 2020). Projects include hacked medical devices and diagnostics, self-experimentation, and patient-led health data collection, often related to rare medical conditions (Pauwels and Denton 2018). For instance, the Open Artificial Pancreas System (OpenAPS) project is a community of amateur coders who built a closed-loop automated insulin delivery system (an artificial pancreas) using open source code to be used in conjunction with a person's smartphone, old out-of-warranty insulin pumps, and continuous glucose monitors. By hacking these medical devices, the initiative aims to make "safe and

[2] Throughout my fieldwork, the terms "biohacker" and "community bio" were both used by participants. However, there was a concerted effort to shift away from the term "biohacking" and toward "community bio," as the former is often negatively sensationalized in the media. Yet, the term "biohacker" offers a tether to the hacker ethic that much of this work emanates from and that gestures to structural critiques of science and knowledge production emphasized by individuals in the community.

effective APS technology available more quickly, to more people, rather than just waiting for current APS efforts to complete clinical trials and be FDA approved and commercialized through traditional processes" (OpenAPS, n.d.). During the COVID-19 pandemic, several DIY and open source biomedical projects surfaced including open source polymerase chain reaction (PCR) equipment to test swabbed surfaces, DIY ventilators, and viral tests for use on humans (Kenny 2020; Weinberger 2020). There are also DIY medicines, in which patients treat themselves outside of professional clinic settings, often with unregulated or experimental treatments (Wexler 2022). Greene (2016) argues that DIY medical technologies are not necessarily a novel phenomenon, as evidenced by a DIY electrocardiogram in the 1950s, among other hacked devices throughout history; however, today it is more common to see lay individuals taking up and distributing DIY knowledge. Some applaud these efforts as encouraging more inclusive approaches to healthcare and biomedical innovation (Fragnito 2020). Others have raised questions about the numerous ethical issues surrounding these projects (Fiske et al. 2019; Trejo et al. 2021).

In 2019, I presented an early set of findings from this dissertation at the annual meeting for the Society for the Social Studies of Science on a panel entitled "Commoning Knowledge: Regeneration Through S&T [Science & Technology]." There we had a lively discussion that brought up important questions: What kinds of similarities and differences can be observed across commoning knowledge projects, such as seeds versus pharmaceuticals? How should technical expertise and safety figure into understandings of what could or should be communally produced and owned? This dissertation offers a continuation of this conversation and seeks to empirically examine the implications of commoning knowledge in pharmaceuticals. It also fills

the lacunae of sociological and science and technology studies literature examining the application of open science to pharmaceuticals.

In this chapter, I first discuss the theoretical frameworks informing this dissertation, noting those that motivated my initial interest in this problem space and offering a preview of literatures that will be covered in greater depth in the chapters that follow. Next, I lay out my research methods. Finally, I offer an overview of the dissertation chapters to follow.

Theoretical Framings

This dissertation draws on several theoretical frameworks that motivate and inform this research on commoning pharmaceuticals. The first is alternative framings for who can and should produce legitimate knowledge in science, including processes of biomedicalization and scholarship on "lay"-"expert" relations and the politics of expertise. Next, I attend to sociological perspectives of health social movements and activism in science. Lastly, I turn to literature on markets and the commodification of the body, health, and medicine.

Scientific Knowledge Production and Lay-Expert Relations

At the center of this dissertation is the production of knowledge. The theoretical inspiration for this research drew, in part, from scholarship that starts with local, community-based knowledge practices as a means to look "up the ladder" of power. Scholars have theorized knowledge production forms that resist, reimagine, and coopt hegemonic practices for the making and ownership of knowledge toward more egalitarian ends (Brown 1992; Epstein 1995; Haraway 1988; Hess 2010; Mohanty 2003; Montenegro de Wit 2019; Navarro 1980). Following these frameworks, which situate knowledge production efforts in relation to larger economic,

legal, and regulatory arenas, this study considers how commoning knowledge processes in pharmaceuticals both reflect and resist hegemonic forms.

Two scholars, Donna Haraway and Vincente Navarro, offer particularly inspiring theorizations of scientific knowledge production "from below." First, Haraway (1988) takes up feminist standpoint theory to argue that with all knowledge producing practices, certain positions reveal some aspects of reality but not others. All knowledge is situated and partial. There is no view from nowhere, no Truth or objectivity, or what she terms the "god trick" that is typically attached to Western scientific knowledge claims. As such, those in subjugated positions within structures of power are better positioned to understand their partiality and produce more critical and accurate notions about the world.

Navarro's (1980) work applies a Marxist perspective of scientific knowledge production and offers the notion of working-class science. He first articulates how claims made by scientists are inherently shaped by the institutions within which they are made, asserting that scientific perspectives uphold hegemonic ideals for the reproduction of the capitalist class. On the subject of scientific knowledge production, Navarro (1980: 538) writes:

> It is the process whereby a perception of reality is transformed into a specific product, i.e. knowledge, a transformation which in science takes place by intellectuals whose primary instruments of work are the theories and methods of science. … Knowledge is being reproduced not in abstract but in specific institutions, subjected to class hegemony, and by scientists whose very specific visions of reality are molded by the ideology of the dominant class (the bourgeoisie), their own social class (the petit bourgeoisie), their race, their sex, their discipline, their political position, among other factors.

Navarro not only considers scientific knowledge as one perspective (among others) of reality but also denounces it as rooted in and reproducing bourgeoisie ideology. He asserts that by focusing solely on biological understandings of medicine and science, it obscures the version of reality that holds the capitalist class and class antagonisms as the actual cause of disease. A scientific (i.e., biological) perspective of disease and illness, then, is a bourgeoisie perspective. The counter to bourgeoisie science, according to Navarro, is working class science, where knowledge production and understanding are rooted in the experiences of the working class.

Finally, the theory of *biomedicalization* provides additional conceptual insights into the ways knowledge is actively being transformed. The theory, generally, is concerned with the ways that "biomedicine broadly conceived is today being transformed from the inside out through old and new social arrangements that implement biomedical, computer, and information sciences and technologies to intervene in health, illness, healing, the organization of medical care, and how we think about and live 'life itself'" (Clarke et al. 2010: 2). One part of this transformation is taking place through processes of the production, consumption, and dissemination of biomedical knowledges. Historically, the producers and gatekeepers of medical knowledge have almost exclusively been physicians; both the attainment and dissemination of medical knowledge were ascribed to the role of medical professionals (Freidson 1970; Starr 1982). That has shifted considerably to a multitude of entities; those involved in the acquisition, distribution and, importantly, the production of biomedical knowledge now include health advocacy and patient groups, healthcare consumers, and other interested "lay" actors. Biomedical citizen science projects and do-it-yourself medicines offer an interesting example of this process as they demonstrate non-expert actors participating in the transmission and production of medical knowledges. Rather than wait on the sidelines for institutions to develop and produce affordable

medicine, lay actors now obtain and produce biomedical knowledge themselves. Moreover, these initiatives beg the empirical question of whether, as the above theorists might suggest, the different types of individuals and communities involved – including those lower within structures of power – then shift the scientific objectives and types of research questions asked toward more egalitarian goals.

The division of "expert" and "lay" scientific knowledge, and the contested space of legitimacy in between, offers an important lens for this dissertation that cuts across expert and non-expert domains. Scholars have shown how expert-produced scientific knowledge shapes people's everyday lives, it figures prominently into life chances, it shapes how resources get brought into existence, such as through technological advances, and how resources are distributed, such as through healthcare access. Expert knowledge is often premised on a particular type of technical, means-end rationality (in the Weberian sense), crowding out other forms of rationality (Habermas 1984), and constructing problems and solutions in terms that make scientific sense, even if it makes less sense in people's messy, everyday interactions and experiences. In our current era, scientific knowledge is truth producing, meaning it is a way of understanding that becomes codified as fact, effectively removing it from the realm of contestation from competing knowledge claims. This begs questions of: *Who* is creating scientific knowledge? *Who* benefits most from this type of knowledge? *Whose* problems are legitimized by science and whose are disregarded? The struggle between lay knowledge versus expert scientific ways of knowing, especially when they are at odds, is a struggle to define what gets constituted as a problem, what kind of problem it is, and how to intervene in it (Frickel et al. 2010; Hess 2009). Thus, who is creating scientific knowledge, with what methods, for the application to which problems, are all implicated in the struggle for social existence and control.

This dissertation examines a community-based project to make insulin that resembles, in some ways, the toxic waste activists studied in Phil Brown's writing on *popular epidemiology*, who saw themselves as "correcting problems not dealt with by the established scientific community" (1992: 273). Popular epidemiology, as Brown (1992: 269) conceptualizes it, is "the process by which laypersons gather scientific data and other information, and also direct and marshal the knowledge and resources of experts in order to understand the epidemiology of disease." It is a phenomenon where citizens, residents, or otherwise "non-experts," pursue scientific knowledge to understand and detect causes of disease related to environmental hazards in their community. In his study of residents in Woburn, Massachusetts, where community members reacted to a sudden rise in childhood leukemia cases and hypothesized a link to chemical plants nearby, Brown observed a series of stages where citizens became involved in the production of scientific knowledge and, in turn, became toxic waste activists. Similar to the stages Brown lays out, concerned individuals in the community lab I examine began to notice the rising cost of insulin and health impacts and attributed it to monopoly control of pharmaceuticals. They hypothesized the connection between health effects and the system behind insulin access, eventually forming a group and engaging with experts, from scientists to lawyers to diabetes patient advocacy groups, and gathered and produced scientific knowledge in their pursuit of remediation to the problem of unaffordable insulin.

Finally, lay activism seeking to intervene in the scientific process can also be traced to Epstein's (1995, 1996) writing on HIV/AIDS activists. Lay activists asserted themselves in biomedical research processes, constructing themselves as credible and thus legitimate participants in the production of biomedical knowledge, and specifically in the conduct of clinical trials. Over time, they were (to varying degrees) able to leverage the needs and concerns

of the community impacted by AIDS by holding a seat at the table in drug regulatory arenas and advancing access to treatment. Epstein argues for the importance of studying social movements that interface with experts to understand both the role of contemporary social movements in influencing biomedicine and science's influence on activism. Scientific expertise is often wielded by those in power, especially in biomedicine and the technical world of pharmaceuticals, to disallow participation and, relatedly, inhibit the democratization of how scientific knowledge and resources get produced and to what ends. As Freese and Lutfey (2011) note, experts within research institutions typically seek the latest "cutting-edge" medical interventions, often to the abandonment of affordable and accessible health interventions, which further reproduces and entrenches health inequality. Considering activists' incursion into the highly technical fields of biomedical and clinical trials research may have implications for understanding whether and how community science can catalyze shifts within the pharmaceutical space. Importantly, in these cases of lay activism in science, they implicate structural factors in their conception of the problem – the causal pathway to harm – and as such, emphasize political and social approaches to remedies.

Health Social Movements and Science Activism

The study of health social movements (HSMs) has by now become a well-established area of scholarship within medical sociology (Britten et al. 2015; Callon and Rabeharisoa 2008; Chamak 2008; Crocetti et al. 2020; Epstein 1995; Klawiter 2008; Nelson 2011). Contemporary HSMs constitute important engines of change in biomedicine (Conrad 2005). Brown and Zavestoski (2004: 685-686) suggest a typology of HSMs: *health access movements*, where movements seek improved access to healthcare provisions; *constituency-based health*

movements, where actors address health inequities along lines of social stratification – race, gender, class, disability, sexuality, and others; and *embodied health movements*, where actors address a specific disease or illness – often a "contested illness" that is unexplained or disputed by medical professionals – by challenging scientific explanations. Embodied health movements can also extend to constituents not currently impacted by the illness but who see themselves as at-risk for a disease, such as breast cancer or type 2 diabetes, for example.

In this framing, the initiatives examined in this dissertation could be viewed as a kind of health access movement, given that access to and the affordability of medicines act as key mobilizing features. There are also aspects of constituency-based movements, in which mobilizing discourses around class and socioeconomic inequities are used in claims for a new model of pharmaceutical production and ownership. In some ways, social action to common pharmaceutical knowledge fuses elements of health access movements with anti-capitalist social movements, with a subset of actors critiquing profit-based medicine. Scholars have unveiled the many issues arising from capitalist-controlled healthcare and pharmaceutical industries, especially in the US where the capitalization of healthcare provisions is particularly acute (Cooper 2008; Lexchin 2018; Light 2004; Navarro 1980; Starr 1982, 2004; Waitzkin 1989). Yet, scholarship on movements to challenge this system has been less abundant (see Murphy 2012 and Nelson 2011 for examples).

Scholars writing at the intersection of medicine, science, and social movements also theorize the influence of patient advocacy organizations. These organizations are formed by patients and their families in order "to connect with each other, serve as a source of information and support, and promote research into their particular diseases" (Panofsky 2011: 32). Panofsky (2011) suggests the potential double-edged nature of advocating for and participating in research.

In one case, two patient advocacy organizations for a rare disease donated money and tissue samples to a lab, leading researchers to identify the underlying genetic cause and then patented the gene and restricted licensure, effectively halting further clinical research. There are also risks for patient advocacy organizations involved in scientific research, as they can lose control over the research direction as scientific experts wield more authority, and patient advocates depend on their expertise to get the research done, an issue I will take up in Chapter 4 of this dissertation. Scholars have further identified how patient advocacy organizations emerge alongside economic markets of science and technology (Callon and Rabeharisoa 2008), even entering into a political economy of hope by donating biomedical resources (blood, tissue, etc.) and "investing" hope in science (Novas 2006). While some patient advocacy organizations fight for structural changes, other groups aim to leverage market-based solutions to address health issues, undermining critiques around access and potentially threatening to reproduce health inequities (Sunder Rajan 2006).

Science activism additionally expands beyond patient advocacy to consider instances in which scientists across varied institutions use the tools of science in their fight for social justice. As science increasingly enters into charged political debates and matters of social equity, scholars have sought to understand how and why scientists engage in social justice work (Benjamin 2013; Bliss 2015; Cordner and Brown 2013; Frickel and Moore 2006). There is a range of subtle ways political action plays out in everyday practices within science, underscoring diverse practices of science activism (Frickel 2004a; Moore 2008; Woodhouse and Breyman 2005). Science activism may unfold in activities that appear to depart from the institutional contexts, such as the military, that they inhabit (Moore 2008). Other forms of science activism follow the social movements they aim to support, such as science to support environmental

movements (Frickel 2004b; McCormick 2009; Ottinger and Cohen 2011). Others, still, seek to intervene in scientific controversies by leveraging their expertise (Krimsky 2000; Oreskes and Conway 2010; Woodhouse and Breyman 2005). While scientists may engage with social causes in order to seek overtly political aims (or mobilize for their field) by wielding their specific forms of expertise and legitimacy, the melding of activist strategies with research frameworks can also lead to watered-down social justice aims and, in the process, reproduce social stratification and hierarchies (Bliss 2015).

Markets and Commodification

A growing body of literature has been devoted to theorizing the commodification of the body, health, and medicine through understandings of markets and capital. Recent research on commodification includes considerations of disabilities (Mallett and Runswick-Cole 2012), science (Toleubayev, Jansen, and van Huis 2010), healthcare (Norman, Russell, and Merli 2016; Timmermans and Almeling 2009), pharmaceuticals (Fishman 2004; Gaudillière and Sunder Rajan 2021; Rodrigues, Lopes, and Hardon 2019; Sunder Rajan 2017), patient experience (Lupton 2014), and markets of body parts (Scheper-Hughes 2001; Sharp 2007) and genetic material (Almeling 2007; Hauskeller and Beltrame 2016). Clarke and colleagues (2010: 22) argue that biomedicine has entered a period of economic transformation, marked by an "emergent biopolitical economy of health, illness, life, death, and medicine." Biomedical institutions have been transformed by corporatization – where private, corporate entities overtake previously social, state-run, or other forms of organizational structure, effectively making them for-profit. Within corporate domains (and increasingly academic), the search for patentable goods flourishes, shifting biomedicine toward processes of commodification. These perceptions

align with other scholars who have underscored the pervasiveness of growing connections between the life sciences and economic markets (Birch and Tyfield 2013; Cooper 2008; Parthasarathy 2017; Rose 2007). Sunder Rajan (2006) proposes that the modern entanglement of the life sciences with market economy represents both a new phase of capitalism as well as evidence that the enterprise of biotechnology cannot be conceptualized outside of contemporary capitalism. In other words, the two phenomena – the life sciences and capitalism – coproduce one another (Jasanoff 2004).

Several events in the latter half of the 20th century catalyzed major shifts in the political economy of pharmaceuticals. Recombinant DNA technology emerged, leading to the formation of the biopharmaceutical industry.[3] Additionally, this period saw new academic commercialization rules established through the 1980 Bayh Dole Act; the rise of venture capital as a viable business model; the bolstering of NIH federal funding in biomedicine through the NIH's war on cancer; and the major US Supreme Court decision in *Diamond v. Chakrabarty* that allowed living modified organisms to be patented and lent to a supportive legal climate for broad intellectual property protections (Sunder Rajan 2006). The Drug Price Competition and Patent Term Restoration Act, commonly known as Hatch-Waxman, was passed in 1984, creating a legal path to expedite the approval of generic drugs and expand the generics industry. Further, the 1995 World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) powerfully reorganized the global circuits of pharmaceuticals, IP, and health by requiring WTO member countries to enforce international IP rules. Prior to the TRIPS

[3] Not only did the entrance of biopharmaceuticals allow for new classes of drugs to be made and the establishment of new markets, but this pharmaceutical area also lent to increases in patents surrounding medicines. A biopharmaceutical might not only use patented bacteria, yeast strains, plasmids, or other patented "BioBricks" (DNA sequences used in synthetic biology) to develop a drug, but clinical trials may include patented mice (Schneider 1988) and other patented transgenic animals (Brown 2000).

Agreement, many low- and middle-income countries exempted pharmaceutical patents to allow for generic copies of drugs (still under patent) to be bought and made as part of public health efforts (Cassier and Corrêa 2013[2009], as quoted in Hayden 2023: 10). In other words, this further shifted the politics of pharmaceuticals from public health to IP and financial markets.

Science and technology studies scholarship on pharmaceuticals tends to focus on different valuation processes that center on the role of capital in the pharmaceutical sector (Biehl 2007; Gaudillière 2013; Petryna, Lakoff, and Kleinman 2006; Sunder Rajan 2017). Scholars have identified how financial markets increasingly hold power over how pharmaceuticals are produced, priced, and valued (Lazonick et al. 2017; Quet 2018; Roy 2023). The "financialization" of the pharmaceutical industry works in tandem with IP regimes (e.g., TRIPS) to increase return on investment and shareholder value, leading to new forms of value (Ecks 2022; Gaudillière 2021) and even new understandings of health (Dumit 2012; Greene 2008). Some have suggested that pharmaceutical patents, which were initially designed to foster and incentivize inventions, have been turned into assets, or "patent-as-asset" (Bourgeron and Geiger 2022). This process of "assetization" – moving from an analysis of technoscientific capitalism that centers not on the commodity but on the asset – occurs when forms of knowledge (including patents), infrastructure, and public goods become assets. In doing so, rationales of investment and return are imposed often with an element of extracting ongoing financial return through forms of "rent" – value that is extracted through ownership and control over a resource (e.g., patent thickets and licensing agreements) (Birch and Muniesa 2020).

Of course, processes of commodification, financialization, and other forms of capitalization in pharmaceuticals, including hegemonic intellectual property regimes, are neither unitary nor seamless. Rather, the political economy of pharmaceuticals constitutes a terrain of

continuous contestation, not only by global pharmaceutical companies, biotech firms, state actors, and powerful international organizations, but also by patients, scientists, and health activists who variously contest, alter, reorient, or "redevise" pharmaceutical markets (Geiger and Gross 2018).[4]

Research Methods

This dissertation employed multi-sited ethnography and situational analysis. Ethnography offers a methodology for describing cultural behavior (Schwandt 2014), emphasizing immersion in the social world and drawing on extensive observational data and other qualitative methods such as formal and informal interviews to explore perspectives and meaning by group members. It is characterized by thick description and heightened attention to the context, detail, and tone of a situation (Juris and Khasnabish 2013). Marcus (1995) elaborated on the methodology to capture the "multi-sited" nature of a social situation, ranging across multiple bounded sites to also include the "context" and collapse distinctions between local sites and global systems. Marcus (1995: 95) states this type of ethnography "moves from its conventional single-site location, contextualized by macro constructions of larger social order... to multi-sites of observation and participation that cross-cut dichotomies such as 'local' and the 'global,' the 'lifeworld' and the 'system.'" The two sites examined in this dissertation are emblematic of this diffuse and multifaceted form.

Further, ethnography operates as more than a set of qualitative techniques, offering a form of "epistemological encounter" (Kelty 2008:18; Marcus and Fischer 1999) where the

[4] The contested area of pharmaceuticals and patents can be seen in the high-profile cases between governments and international IP regimes that centered HIV/AIDS medicine access in South Africa, India, and Brazil in the 1990s. Bourgeron and Geiger (2022) also show how various actors, including patient advocates, contest drug patents and high-priced pharmaceuticals through their analysis of the hepatitis C drug sofosbuvir.

researcher may become personally transformed in attitude or perspective through the research process. In other words, it is a way of engaging with and generating insights from the group, community, movement, social world, and so on being studied, where the process of actively involving oneself in the group or phenomenon offers an epistemological stance and opens empirical possibilities that together create the grounds for conducting politically engaged research (more on this below and in Chapter 5).

I also utilized Clarke's (2005) situational analysis that offers another theory-methods package well suited for multi-sited phenomena. It advocates investigating multiple data sources (e.g., observations, documents, images, and historical and narrative accounts) and allows for greater opportunity to capture social phenomena in their complex, diffuse nature and trace discursive processes at play in a social situation. Following this methodology, I explored and analyzed the messy, multifaceted, and dynamic social processes that discursively shape the commoning of pharmaceutical knowledge, including how discourses and actions are profoundly shaped by political economic structures in the making of drugs as well as social and scientific movements.

Below, I first describe my two fieldsites where I follow open science practices in the research and making of pharmaceuticals. Second, I describe my data collection methods, including in-depth interviews, content analysis, and participant observation, which offered a particularly appropriate approach for the study. Lasty, I describe data analysis techniques used following constructivist grounded theory (Charmaz 2014) and situational analysis (Clarke, Friese, and Washburn 2018). This study was approved by the UCSF Human Research Protection Program's Institutional Review Board (IRB).

Fieldsites

I selected two fieldsites engaged in the commoning of pharmaceutical knowledge. The first site encompasses a broad, diffuse international network of actors and organizations working to apply open science ideas and practices to drug research, development, and/or manufacturing. This site focuses on discourses of "openness" – open source, open science, crowdsource, and others – as they are applied to pharmaceuticals. This site was selected with the aim of tracing this space as an emergent movement of collective action to establish, grow, and institutionalize new logics and practices for sharing knowledge and research tools for drug R&D, often through organizational policies against the filing of patents.

I included in my sample several university-based projects and not-for-profit (non-academic) organizations. There is substantial crossover between many of these initiatives, with several leaders and researchers collaborating on and even leading multiple organizations. This list of university organizations includes Open Source Drug Discovery, The Neuro, Tannenbaum Open Science Institute, Open Source Malaria, Open Source Mycetoma, Open Source Tuberculosis, Open Source Antibiotics, COVID Moonshot, Open Discovery Innovation Network, Viral Interruption Medicines Initiative, Rapidly Emerging Antiviral Drug Development Initiative, AI-driven Structure-enabled Antiviral Platform. Not-for-profit (non-academic) organizations in my sample include the Open Source Pharma Foundation, Medicines 4 Kids, Medicines 4 Neurodegenerative Diseases, Medicines 4 Infectious Diseases, and the Agora Open Science Trust. These initiatives are located in the US, Canada, two European countries, and one in India. Additionally, I analyzed publications about open science in pharmaceuticals generally, that were not connected to any one organization. Data collection methods employed for this site include in-depth interviews and content review (described

below). This fieldsite is the focus of Chapter 2, where further descriptive details are provided along with analysis. (Two of the three chapters that follow are written as standalone empirical chapters; I therefore chose to include more comprehensive details about methods and sampling in those chapters.)

The second site focuses on a single group, Open Insulin. This site was selected to study the application of open source ideas and practices to a pharmaceutical initiative but also to examine lay participation in this space as a possible dimension of commoning pharmaceutical knowledge. Open Insulin, a mostly all-volunteer effort, was founded in 2015 in a San Francisco-Bay Area community biology lab, Counter Culture Labs. The group aims to bioengineer insulin (the molecule) in a community lab, develop a model for manufacturing insulin (the drug)[5] at a small scale through a cooperative structure, and make public their process for making insulin. Volunteers soon joined from nearby community lab BioCurious and slowly the group expanded to others contributing within and outside community labs globally. This expansion was facilitated by meetings being hosted via hybrid virtual/in-person before COVID-19, and then shifting to all virtual meetings when community labs temporarily shut down in 2020. Initial funding for Open Insulin came from a crowdsource campaign that raised over $15,000 and from ongoing individual donations. During my fieldwork, Open Insulin also secured a $25,000 grant and another for $137,000 from private foundations.

Contributors to Open Insulin include individuals from a range of backgrounds and levels of scientific training. A few held scientific PhDs (or were active doctoral students), while others were undergraduate bioscience students, individuals from biotech industry, and some without any professional scientific or pharmaceutical background. The organizational arrangement of

[5] The "molecule" versus "drug" distinction relates to the transition process for turning a molecule that forms the basis for a drug into a safe and legal pharmaceutical for consumption. I discuss this at greater depth in Chapter 4.

Open Insulin began as a small handful of people participating in an unstructured form. Across the three years of fieldwork, the group fluctuated regularly, as many volunteer-based organizations do. The data collection methods used for this site, including multi-year ethnographic observations, were selected to allow for a deep analysis of one initiative. This fieldsite is the focus of Chapters 3 and 4, where I further describe and analyze Open Insulin's organizational structure and aims for community manufacturing, respectively.

Data Collection

In-depth interviews

I conducted 29 in-depth interviews across the two sites, including 11 academic- and nonprofit-based researchers and leaders, and 18 citizen science participants. Academic- and nonprofit-based researchers and leaders included initiatives' founders, directors, a chief operating executive, primary investigators, lawyers, and one legal scholar. I initially identified potential interviewees from an Open Source Pharma conference I attended in 2019 and utilized snowball sampling to recruit additional participants. Citizen science interviewees included participants who were actively involved with Open Insulin, defined as those individuals who attended meetings regularly and contributed to one or more facet of the project. Demographically, interviewees were disproportionately white, educated (Bachelor's degree or higher) men. This reflects community lab demographics and the broader scientific world, with white, educated men, typically middle- to upper-class, largely participating in and leading decisions (Erikainen 2022; Walajahi 2019).

Interviews lasted 1-2 hours, were conducted via video conference or in-person, and followed a semi-structured, open-ended format. I asked questions focused on the history of

initiatives; organizational structure, goals and practices; approaches toward intellectual property and policies toward sharing; barriers and challenges encountered; and personal and organizational conceptions of openness. Interview guides were tailored to individual participants to account for the wide range of projects and institutions examined. Interviewees were given the option to use their real name in publications, which many opted to do. I have decided to use pseudonyms and general descriptors throughout this dissertation; however, for study participants who consented to use their real name, I sometimes use identifiable descriptors, such as their organization's name and position title.

Participant observations

Ethnographic observations were conducted for the second site only, with participants of Open Insulin. I conducted over 300 hours of participant observations over three years between August 2018 to October 2021. This consisted of both in-person and virtual (during COVID-19) observations at Counter Culture Labs. Observations focused on weekly general meetings, where contributors came together to share project updates and discuss organizational needs and priorities. Following the formation of focused working groups, I regularly observed weekly and bi-weekly meetings of several of these, including the Safety and Regulations, Business, and Legal working groups. I also observed key organization-building meetings, including a three-day strategy session in 2019 and nine "vision" meetings in 2021, where participants discussed shifting to a formal organizational structure and determined project directions. Procedurally, fieldnotes included documenting content; the structure of meetings, activities, and decision-making processes; and participant tone, messaging, non-verbal communication (such as reception of ideas by others), and various discourses at play.

I also took an active participant role in Open Insulin for two reasons. First, on a practical level, I found early on that by participating in meetings and volunteering myself in a supportive role, such as by editing documents, I was readily looped into more activities and processes the group engaged in. I shifted from occupying a role where I had to regularly ask for entrée to certain activities, such as requesting access to various communication platforms and meetings, to someone who was included right away. Active participation included voicing my opinion in meetings, taking meeting notes, and helping to coordinate and interact with pro bono legal counsel the group had secured. Decisions regarding the group's organizational structure, questions around intellectual property, and even scientific decisions are all intertwined with legal strategy, and thus my active participation – my position as an "insider" – enabled me access to many key decision-making points around how to collectively act. Second, as a scholar who is deeply interested in research that is politically committed and impactful beyond academia, I followed a particular form of ethnography that draws on concepts of "politically engaged ethnography" found in social movement research (Juris and Khasnabish 2013). This methodology promotes active participation in ethnographic observations and pushes researchers to be accountable to both the academic world and the group of movement actors under study. This methodology functions as a way to attend to power within research, potentially mitigating the objectionable effects of helicopter research – where researchers "fly in" (gain entrée), take data, and "fly out" without concern for or collaboration with the community (Struthers et al. 2005). I further elaborate on this methodological decision and its implications in Chapter 5, including the multiple ways in which I conveyed my position as a researcher and observer to research participants throughout fieldwork to ensure ongoing consent, additional forms of participation, and my use of reflective writing to remain accountable analytically.

In addition, I observed two conferences attended by community biology enthusiasts: Biohack the Planet in 2018 and Global Community Bio Summit in 2020. Detailed fieldnotes were taken during observations. Attending these conferences enabled me to obtain preliminary insights into the concerns and motivations of community biologists and how Open Insulin was situated in this social world.

Content analysis

I also included a broad set of documents and online sources as part of my sample. My analysis of Open Insulin for Chapters 3 and 4 draws on documents including meeting minutes, presentation slides, bylaws, a "Manifesto" the group drafted, grant materials, governance and policy documents, and news articles covering the project. My analysis in Chapter 2 tracing the emergent movement of open science in pharmaceuticals draws on journal and blog articles, websites, organizational policies, presentation materials, and conference brochures posted on Open Source Pharma Foundation's webpage.

These textual materials are an important source of data for this dissertation for a few reasons. Many journal articles and websites reflect and also construct discourses that motivate shifts toward open science in pharmaceuticals. These data provide additional documentation of the ways this emergent movement is being operationalized and established through institutional mechanisms such as policies for sharing research data and tools. For Open Insulin, governance documents provide insights into outcomes of long-term organizing strategies to establish a cooperative organizational structure. This set of documents and web content was comprised as a convenience sample, with many sources provided to me by participants during observations and

interviews. I also searched scholarly databases for articles using varying search terms, such as "open + medicines" and "sharing + pharmaceuticals."

Data Analysis

Data analysis followed constructivist grounded theory (Charmaz 2014) and situational analysis (Clarke et al. 2018) as analytic frameworks. Data were coded using the principles of constructivist grounded theory (Charmaz 2014). Segments of data are assigned "codes" or meaningful labels. Grounded theory encourages the coding of actions to detect processes at work. Initial line-by-line coding, which produced over 100 initial codes, was then organized and clarified through free-writing and analytic memos. I used memoing to draw connections between different points of data, to think carefully about relationships between different codes, and to make decisions that guided further data collection and analysis. This initial coding, which allowed me to stay close to the data, was then adapted into larger classes of codes through focused coding. These focused codes are more meaningful or appear more frequently, and they help to "synthesize, analyze, and conceptualize larger segments of data" (Charmaz 2014:138). I used the qualitative software MAXQDA to code and analyze all interview and observational data.

As this dissertation examines an empirical space that is inherently emerging and evolving, I used situational and social worlds/arenas mapping as "analytic exercises" (Clarke 2018:106) throughout data collection and analysis to better understand the situation at hand. In constructing situational maps, I laid out the human and nonhuman, discursive, historical, cultural, political, and symbolic elements in my research situation. This lends especially well for examining a "messy" social world that is transnationally networked. I also used social

worlds/arenas maps to identify and map out social worlds – "universes of discourse" (Strauss 1978) – and discursive arenas, where various issues are debated and negotiated. This mapping exercise analyzed the organizational and institutional dimensions in interaction, such as funding streams, regulatory and intellectual property agencies, university policies, community biology labs, pharmaceutical and biotech companies, and the organizations in my sample, which all act as social worlds and sub-worlds within the arena of commoning pharmaceuticals. This added an important analytic tool for examining open science in pharma *in relation* to these discursive, and often powerful, arrangements or "ecologies." Mapping exercises were done synchronously with data collection and served as analytic strategies to make clear positions and to articulate the actions, actors, and actants (including non-human) at play.

I used memoing to identify patterns and concepts as they emerged in the data and to move between data collection and coding of data. Both constructivist grounded theory and situational analysis seek to collect and analyze data concurrently, offering a framework for an iterative and inductive approach to data collection and analysis. As analysis takes place alongside data collection, this enabled opportunities for exploring early insights by incorporating and modifying interview questions, observation selection strategies, and participant identification and recruitment.

Chapter Outline

In 2019, I came across a call for attendees of the Open Source Pharma 3 conference, which was the third meeting in five years focused on bridging open source ideas and medicines. I applied to attend on behalf of Open Insulin, and I was selected for one of the limited spots, with conference organizers even sponsoring part of my trip to Paris for the meeting. This conference

introduced me to several thought leaders advancing a program for open science in pharmaceutical R&D and many adjacent projects, such as drug repurposing organizations and open lab platforms to collaborate and share data in real time. This meeting led me to identify a growing network of collective action to apply open science practices to the research and making of drugs. This is the focus of Chapter 2 (written in article form), where I trace and offer a sociological analysis of this emergent space which I refer to as *open pharma*. I show how this social world resembles a scientific/intellectual movement (SIM), which Frickel and Gross (2005: 206) distinguish from other social movement forms in that a central goal of SIMs is "the production and diffusion of ideas and knowledge." Building on this theory, I demonstrate how open pharma actors are indeed organizing to advance a new program of thought. At the same time, unlike other disciplinary fields situated primarily in academia, pharmaceuticals are deeply entwined in, even coproduced by, capitalist political economic structures including regulatory and legal regimes and financial markets. I draw out prominent characterizations of the open pharma movement, including mobilizing narratives (e.g., to reach "market gaps"), processes of institutionalization, and structural barriers actors encounter in universities. My analysis complicates SIM theory's propositions by assessing the limits of typical SIM mobilizing strategies in spaces where movement actors interact (and seek institutional roots) not just within university domains but across varied knowledge terrains including regulatory agencies and commercialization and intellectual property firms.

Chapter 3 narrows in to focus on one project within open pharma, the citizen science group Open Insulin. In this chapter, I examine their internal governance structure. While I did not initially anticipate this as a major analytic focus on its own, the group's organizational structure became an important focal point throughout my fieldwork as project members grappled

with how to engage large numbers of volunteers, how to organize themselves and make decisions, and how to arbitrate and triage among the different and sometimes contradictory goals and priorities project members advocated for. I situate Open Insulin's internal struggles alongside other counter-organizing efforts both within the larger DIY biology movement and other social movements seeking more egalitarian organizational forms. This chapter first introduces Open Insulin's form as an unstructured project, where contributors looked to horizontal approaches to organize themselves, and then traces their shift to a formal organization with a board and membership structure. This new structure sought to bridge organizational forms from cooperatives, open source software companies, and biotechnology nonprofits as a means to create a model for open source, community-based medicines. I examine specific sites of tension and change that emerged around membership, decision-making processes and power, and the mission as a contested and discursive process. This chapter was published in the journal *Citizen Science: Theory and Practice* for a special issue on biomedical citizen science (Foti 2022).

Chapter 4 builds on the previous chapter by further exploring the uncertainty in Open Insulin's mission. I examine two specific but divergent perspectives on the project's objectives and different perceptions of how to enact social change that were embedded. One perspective for how to make affordable insulin was an unprecedented but more transformative vision for "community manufacturing" – a kind of cooperative approach that is used to make and manage other resources (e.g., food coops); the other perspective favored using a contract manufacturing organization, an established and socially legitimized route for making drugs. As group members organized toward these visions, I show how safety and regulatory requirements – and relatedly, material infrastructure – involved in making drugs complicate and constrain alternative imaginaries to produce affordable medicines. Further, I show how actors' viewpoints related to

expertise and "autonomy" shaped their organizing strategies. In unpacking some of the day-to-day activities, challenges, and actors' conceptions around social change, I aim to also comment on a more practical matter: how must counter-organizations looking to resist processes of capitalization in highly technical and regulated domains, such as pharmaceuticals, adapt their organizing strategy in light of these points of friction?

Finally, I conclude with a discussion of the overall findings and implications of the dissertation. I discuss my contributions to three broad areas of literature – social movements, the politics of knowledge and expertise, and markets – and address directions for future research. I also offer reflections on my positionality as a participant observer and my process (and challenges) of employing politically engaged ethnography (Juris and Khasnabish 2013).

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CHAPTER 2: The Open Pharma Movement: Mapping Social Action for a Medicine Commons

Introduction

The open source software movement's remarkable success in transforming computer technology led many to speculate whether such open principles and methods could be applied to other sectors of society. This was particularly true in the case of biotechnology, and especially pharmaceuticals, as patents and other forms of intellectual property (IP) have been criticized for impeding scientific progress in the development and global distribution of medicines (Hope 2008; Jaffe and Lerner 2007; Park, Leahey, and Funk 2023; Parthasarathy 2017). Critics argue that patents stymy research progress by limiting access to important patented materials and methods, as well as negatively impact global health by raising the price of essential medicines (Gold et al. 2010). Additionally, rising costs and increasing complexity of drug development have been cited as serious issues plaguing the current system. A senior executive at Johnson & Johnson recently commented, "The easy diseases have largely been solved. It gets harder and harder as we go after new treatments for ever more challenging diseases" (Kuchler 2019). To many, uninhibited forms of sharing offer great potential to better leverage resources and biomedical knowledge to address emerging and pervasive health problems. While some have advocated for solutions rooted in patent reform and compulsory licensing, a growing contingency have argued for open sharing practices as a fruitful solution.

The push for open science in biomedical research has reached the national level in the United States. The Office of Science and Technology Policy named 2023 "The Year of Open Science" (OSTP 2023). The National Institutes of Health (NIH) launched a new Data Management and Sharing Policy, in which they state: "NIH considers the sharing of such unique [biomedical] research resources (also called research tools) an important means to enhance the

value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research" (NIH 2022a). However, the policy falls short of broad requirements to share data publicly. Moreover, such sharing agreements must also align with objectives of the Bayh-Dole Act and Technology Transfer Commercialization Act of 2000, which promote the transfer of knowledge and technology from federally funded research in universities and other institutions to commercial entities through IP agreements (e.g., patents and licenses). Consequently, the impetus to share knowledge and the impetus to commercialize it sometimes come into tension. Stakeholders are thus actively looking to redraw boundaries between open and closed research environments to reconcile competing objectives.

Early efforts in the application of open source ideas in biomedical research were made in bioinformatics. Programs such as BioPython, Biojava, BioPerl, and others were developed to process biological data and created a basis for open source computational molecular biology. Other major life science projects that are viewed as open source derivatives include the Human Genome Project, the SNP Consortium, and Massachusetts Institute of Technology's BioBricks (Munos 2006). Open access data sharing in genomics and other "big data" sciences is often seen as important for advancements in these fields (Leonelli 2013). Initiatives such as the International Genetically Engineered Machine (iGEM) competition that creates biological knowledge for the public domain and the BrioBrick Foundation's Open Material Transfer Agreement further institutionalized the place of open sharing practices in the biomedical sciences.

One way that open science principles have been explored in drug development is through collaborations known as product development partnerships (also called product development public–private partnerships; De Pinho Campos, Norman, and Jadad 2011). Formed to address

economically neglected diseases that largely impact poor countries and communities, these partnerships bring together industry, universities, foundations, and governments through open data sharing agreements. Prominent examples of product development partnerships include the Drugs for Neglected Diseases Initiative (DNDi), Global Alliance for Tuberculosis Drug Development (TB Alliance), International AIDS Vaccine Initiative, and the Medicines for Malaria Venture (MMV). These organizations are each "dedicated to creating new circuits of exchange among corporate, academic, and governmental organizations," and they share a key feature of "pooling proprietary resources as the key mechanism of enhanced collaboration" (Lezaun and Montgomery 2015: 6). Lezaun and Montgomery (2015) further suggest that economic and institutional insufficiencies to combat neglected tropical diseases offer one of the clearest examples for the imperative to openly share intellectual resources to drive research and development (R&D) in this space, creating a "new moral economy" that has led to these partnerships. Light (2020: 1) similarly argues that DNDi's development of drugs for Hepatitis C offers "an example of markets to maximize public health" and suggests that their organizational model "inverts intellectual property to public health IP to maximize health gain instead of profits." These analyses suggest that product development partnerships may not only leverage open science practices to advance knowledge production, but that they re-orient aspects of the pharmaceutical political economy away from profits and toward public health. Nevertheless, in general, these partnerships do not advance an ideological program for open science as a key characteristic.

However, a movement has emerged with this distinct feature. This paper examines initiatives and other forms of collective action that explicitly invoke discourses of "openness" – open source, open science, crowdsource, and others – to advance a research agenda and, *in*

addition, to build, transmit, and institutionalize new ideologies and logics that variously contest proprietary knowledge in biomedical research and specifically pharmaceuticals. In other words, these actions work to establish a new program of thought, through publications advancing new frameworks for "open" sharing in drug R&D, the emergence of numerous groups and projects that orient their vision around "open" medicines, and the establishment of new institutional mechanisms for advancing open science in drug discovery. I refer to this area of coalescing collective action as *open pharma*,[6] which I borrow partly from the umbrella term "open science" and apply it to those working in and around the research, development, manufacturing, and delivery of pharmaceuticals. The term open pharma is purposefully broad, as the initiatives which characterize themselves as "open" are likewise heterogeneous and mean different things to different people, as I will elucidate in this paper. Examples of open practices include sharing of all data publicly in real time, allowing broad participation without restrictions, and curtailing (or completing restricting) forms of intellectual property. While many forms of data sharing partnerships exist in the biomedical sciences, many of them focus further "upstream" in the stages of drug development (e.g., in basic science and identification of lead compounds). This paper focuses on initiatives looking to push these practices further "downstream," into preclinical and clinical stages and all the way through manufacturing, where intellectual property is cited as increasingly necessary to recover financial resources needed to eventually obtain

[6] To my knowledge, this term has not been used in the scholarly literature. However, there is an organization Open Pharma whose mission bridges the pharmaceutical industry and scientific publishing world "to increase transparency and access to research outputs" through publications (Open Pharma n.d.). Additionally, a policy paper uses a very similar concept "open science drug discovery" (Bountra, Lee, and Lezaun 2017). The authors define this as "initiatives that make raw materials, data and the outputs of scientific research freely available in an effort to avoid duplication of effort and/or re-direct resources to neglected or high-risk areas of pharmaceutical R&D" (2017: 14). This definition is somewhat narrower than mine in that it focuses on specific disease areas and reducing redundancies in science. They further distinguish two overlapping models of open science drug discovery – "pre-competitive R&D consortia" and "open source pharma" – and provide several organizational examples that add to my analysis in tracing this space as a growing area of collective action.

regulatory approval. In this context, my examination of pharma is strategic in order to analyze where and how the biomedical political economy might create the most friction with open science. In analyzing the building of open pharma, I seek to reflect on social and economic processes that shape how drugs are developed and that structure inequities in access to medicines.

Open pharma reflects the type of social action described in Frickel and Gross's (2005) general theory of scientific/intellectual movements (SIMs). Bringing together scholarship from social movements and sociology of ideas, the authors define SIMs as "collective efforts to pursue research programs or projects for thought in the face of resistance from others in the scientific or intellectual community" (Frickel and Gross 2005: 206). They identify four propositions to account for the social conditions under which SIMs emerge, grow, gain influence, and establish varying levels of institutional stability: (1) dissatisfaction with the dominant intellectual practices, in which SIMs actors believe their program of thought offers a course correction; (2) structural conditions, including access to key resources (e.g., funding but also prestige), to coordinate and advance ideas; (3) "micromobilization contexts," or sites where recruitment and sustained interaction exist, including access to settings where influence can occur (e.g., labs, symposia, trainings, departments, and mentorship); and (4) "collective action frames" that focus on how ideas are framed and socialized through shared values and understandings.

Unlike classic examples of SIMs, which focus largely on *academic* institutions as the locus for advancing new fields of thought, pharmaceutical knowledge has deep roots in *industry*.[7] Consequently, any movements to shift intellectual practices in pharma must contend

[7] Frickel and Gross (2005) do identify other contexts that influence the emergence and collective action of SIMs, including industry partnerships; however, academia is their central focus.

with its complex entwinements in capitalist political economic structures, including legal, regulatory, and market structures that organize science and technology. Several important changes over the past 50 years shaped this sociotechnical terrain, including legislation shaping academic commercialization, legal decisions supporting expanded IP protections, and the influx of both federal and venture capital funding into the pharmaceutical sector. Together these all add greater complexity to organizing for change in pharmaceuticals compared to other intellectual fields. Scholars have further identified how financial markets also increasingly hold power over how pharmaceuticals are produced, priced, and valued (Dumit 2012; Roy 2023). It is in this particular political economy that the open pharma movement is situated.

Moreover, different institutional forms – medical facilities, universities, foundations, regulatory agencies, and private biotechnology and pharmaceutical firms – form the social fabric of biomedicine. In his examination of SIMs in biomedicine, Au (2021) notes that movement actors in this field must obtain buy-in across diverse areas of expertise, including researchers but also professionals. Biomedicine functions as an "interstitial" space of knowledge production: "oriented between and towards multiple arenas of knowledge production, consumption, and legitimation" (Stampnitzky 2011: 3). The boundary between academic and commercial science becomes blurred in biomedicine and new, often contradictory, knowledge regimes are formed through the entanglement of university and commercial logics (Vallas and Kleinman 2008). The open pharma movement must therefore attend to these diverse institutions and interests.

Drawing on in-depth interviews and document analysis of journal articles and organizational policies and websites, I examine the building of open pharma. More specifically, I trace a network of individuals and initiatives that are leading efforts to establish, grow, and institutionalize new logics and practices for sharing knowledge and research tools for drug R&D.

Findings are presented in three sections that characterize important dimensions of open pharma. First, I identify movement framings – lenses through which actors understand open pharma's rationales and points of intervention in the status quo and how they convey this to others. Next, I trace the building of institutional infrastructure through policies for open sharing, recruitment mechanisms, and the establishment of larger initiatives to organize people and work. Finally, I describe barriers to the emergent open pharma movement, significantly, in the form of academic norms and structures, including publishing and commercialization imperatives. This analysis seeks to shed light on potential new ways to organize the political economy of pharmaceuticals in order to facilitate access to medicines. At the same time, I question the extent to which these approaches are "radical" departures from the status quo, as some have suggested, or appear more as business as usual. Do open approaches better connect pharmaceuticals to the publics they are supposed to serve? I seek to highlight the nuances of the growing trend to embrace open science, showing the importance of interrogating where, when, and for whom open science is beneficial.

Methods[8]

Data presented here are drawn from a larger qualitative study of open pharma organizations and movement actors. Primary sources of data collected between 2018 and 2022 include: 28 in-depth interviews with organizational leaders, scientists, and advocates in open pharma projects; 300 hours of observations with a citizen science project focused on open source insulin research; and around 45 documents and online sources, including journal articles, websites, presentations, organizational policies, and governance documents pertaining to open pharma. Verbal consent was obtained for all observations and written consent for all interviews.

[8] I have included a Methods section as this chapter was written as a stand-alone empirical article.

Institutional review board approval was obtained from the University of California, San Francisco.

Interviewees included two general groups: 1) citizen science participants and 2) academic- and nonprofit-based researchers and leaders. This paper draws more heavily from the second interview group, although both groups' perspectives are represented in what follows. Interviews followed a semi-structured, open-ended format. Themes explored during interviews principally included: history of initiatives; organizational structure, goals and practices; approaches toward IP and policies toward sharing; barriers and challenges encountered; and personal and organizational conceptions of openness. Interview guides were tailored to individual participants to account for the wide range of projects and institutions examined. As open pharma is still an amorphous network of individuals and organizations, I utilized snowball sampling to recruit participants. Initial interviewees were identified from an Open Source Pharma conference I attended in 2019. Interviewees were located in the US, Canada, two European countries, and one in India.

Interview and observational data were analyzed using principles of constructivist grounded theory (Charmaz 2014) and situational analysis (Clarke, Friese, and Washburn 2018). All interviews were recorded and transcribed verbatim. MAXQDA software was used to manage and code all interview and ethnographic data. Following the grounded theory methodology, codes were applied inductively, and data collection and analysis took place simultaneously. Interviewees were given the consent option to use their real name in publications. While I do not use real names for quotes from study interviews, I do sometimes offer identifiable context (e.g., specific institution and position title) when consent was provided. All quotes used in this article have been edited to remove false starts and filler words for ease of reading.

Documents drawn on for this paper include journal and blog articles, websites, presentation materials, conference brochures posted online, and organizational policies. In these textual materials, I analyzed the discourses authors use, for instance, to argue for different conceptions of openness and rationales for open science in drug development in journal articles and websites. I also examined organizational policies to understand how open pharma initiatives are constructing and operationalizing openness in practice, such as through shared data tools and intellectual property guidelines. This set of document and web content was comprised as a convenience sample. I identified many journal articles by searching scholarly databases using key search terms. Many sources were also suggested by or given to me by participants during and after interviews.

The Open Pharma Movement

Results are presented in three sections that work to trace the open pharma movement in its discourses, practices, and cultural and structural barriers. First, I describe three major narratives open pharma actors employ to frame and package a new program of ideas, organized around grievances with the prevailing system and leveraged to establish logics for "why" open pharma is needed. Second, I describe open pharma in practice – the "what" and also "how" open pharma is being enacted. Data elucidate how movement actors are establishing – actively organiz*ing* and build*ing* – institutional infrastructures (e.g., funding, policies, and employed positions) and micromobilization contexts – spaces where actors can share ideas and recruit others into the movement. The third section identifies norms and structures in university settings that act as barriers to the uptake of open pharma ideas. These include reservations among

scientists to share data before publishing in journals, as well as legal and institutional policies that create imperatives to commercialize knowledge through patents.

(WHY) Movement Framings

In this section, I present three framings that movement actors predominantly utilize as a means to construct and package open pharma as a new, legitimate program of thought. The framings – invoked in interviews, in journal articles, and on organizational websites – articulate three separate yet interrelated grievances actors levied against the status quo in pharmaceutical R&D. Grievances include areas of "market failure," declining innovation, and medicine affordability, with the latter frequently coupled with language around healthcare as a human right. In some instances, actors focused primarily on one grievance narrative. More often, however, two or all three framings were deployed together to challenge prevailing ideas and practices around IP within drug R&D, and to construct a new narrative that advances alternative logics for sharing scientific knowledge.

Neglected diseases and areas of "market failure"

A common framing used by open pharma movement actors focuses on specific disease areas that are understudied and lack therapeutics. The narrative centers on the role of current market-based incentives (e.g., profits) as being inadequate to advance scientific knowledge and drug development in these areas. Characterizations of perceived "market failure," in which economic incentives are believed insufficient to promote investment in R&D, include areas where there is no current pool of users of new medicines, such as research for future pandemics and antibiotic resistance. Additionally, it covers disease areas where potential users are viewed

as too few to motivate investment, such as with rare medical conditions, as well as in categories of disease that predominantly impact the world's poor, including neglected tropical diseases.

Open pharma organizations and individual actors employed this "market failure" framing on websites and in journal articles, and many interviewees articulated their motivation and vision for open pharma through this lens. For example, one participant who founded and leads several open pharma organizations responded to my question about his motivations for open sharing by stating: "It's not because it's a sort of philosophical position that everything should be open, kumbaya peace and love. It's that the current market is structured in a way that there are things one cannot do in the market-based system." To him, the centrality of patents in *market-driven* R&D makes it difficult to advance certain areas of scientific knowledge and develop new pharmaceutical products, underscoring that not only do market structures profoundly shape this area of biomedicine but that these economic structures orient value in particular ways. Markets construct value toward specific disease areas – those that are profitable – by linking value to financial rewards (as opposed to, say, public health benefits). This impacts which types of therapeutics are developed and which are not. He went on to add:

> One cannot invent drugs for diseases that there are very few patients [for]. One cannot invent a drug for a pandemic that may never happen, as we saw. Antibiotics are beginning to fall into the class where, well, the market doesn't work. So in those subsets [of diseases] it's already being appreciated. … [Open sharing] is a business tactic to a problem where there is no other solution. … It's a business tactic to hit a market gap.

This participant deliberately invoked the language and logics of the business world to rationalize open pharma approaches. In this view, open pharma is not a purely "philosophical" position but rather resembles other business ventures looking for "market gaps" and considering

organizational and financial frameworks through which to fill in the gaps. Narratives around market failure and business interventions are also used on organizational websites. Medicines 4 Kids (M4K), for example, a not-for-profit organization formed to develop treatments for rare children's diseases, states in their mission: "By aggregating and aligning the work of global academics, foundations and pharma/biotech researchers, we will advance new cures for childhood diseases not well served by current business models." Similarly, in an announcement by DNDi for a new open science consortium for antivirals, they state the consortium "will target viral families that have been historically neglected by the market" (DNDi 2022). By using a market failure framing, actors employ familiar valuation language around financial investment risks and benefits, leveraging the idea that neglected disease areas are effectively undervalued and thus ripe for new mechanisms to create value out of them.

Importantly, open pharma is characterized as a viable and "complementary" path to traditional pharma, rather than as a substitute for it. As one participant clarified: "The open thing is not meant to be anti-pharma. It's meant to be doing stuff that pharma can't do, so a complementary model. … There's no, it's not binary." Open pharma is seen as part and parcel of the larger pharma industry in terms of collaboration and knowledge sharing to be used by pharma companies, and many actors view the intent as focusing on areas of drug R&D deprioritized by conventional pharma. One interviewee shared: "If you wanna work openly, go for it. But I think it's important just to be aware of what pharma is good at, where the model works, right?" A journal article calling for open source drug R&D similarly stated: "Our model is not a substitute for them, but a way to leverage their capabilities to tackle unmet medical needs, such as the diseases of poverty, orphan diseases and niche markets" (Munos 2006: 7). Another participant focused on specific disease areas as key to open pharma's success, stating:

> [There's] a vague area over here where the pharma industry is doing really well, and a vague area over here where it can't act at all and doesn't get involved. I mean all the kinds of non-glamorous diseases like parasitic infections that affect billions of people where there's no money to be made, because the people can't afford to pay for medicines. And then there's this gray area in the middle, which includes things like malaria and antibiotics and stuff where you think, 'well, it looks at the moment like open has a role to play here,' but we'll have to see how it goes. It depends exactly on the drug and the kind of disease.

Similar to other accounts, this researcher categorizes drug development into areas in which open pharma offers a logical alternative, or "has a role to play," and those in which current market structures adequately serve. He describes disease areas that predominantly impact the global poor, suggesting this as a gap for open pharma to move into, and others (e.g., antimalarial and antibiotic drugs) as additional potential markets. Similar language was used in several journal articles as well (Balasegaram et al. 2017; Todd 2019). One of the earliest articles that explicitly argues for open sharing practices in pharma was published in 2004 and focuses on tropical diseases (e.g., African sleeping sickness, dengue fever, and leishmaniasis), stating:

> While patent incentives and commercial pharmaceutical houses have made Western health care the envy of the world, the commercial model only works if companies can sell enough patented products to cover their research and development (R&D) costs. The model fails in the developing world, where few patients can afford to pay patented prices for drugs (Maurer, Rai, and Sali 2004).

Explicit and implicit in many of these accounts is the view that the market-based system is "working," and working well, for many areas of health that require therapeutics: drugs are

successfully discovered and developed, and reach people. Acutely cognizant of the power of the industry-driven pharmaceutical sector, and wary of making claims perceived to be "ideological," open pharma proponents strategically craft arguments that center the economic opportunities and business case to be made for open pharma approaches for a select set of neglected disease areas. One scientist reflected: "If you wanna make an ideological point, saying that drugs should be inexpensive … that's also a good argument. It's just that *you are up against quite a big machine in terms of resources*" (emphasis added). In this sense, open pharma is meant to be economically strategic, to not compete for resources by focusing on select diseases. Thus, the market failure framing is leveraged as a means to navigate funding challenges by suggesting that open pharma's use of public and philanthropic funds works to fulfill a societal need that private funding cannot, or rather will not, address.

A declining drug innovation ecosystem

A second major narrative within the open pharma movement centers on the so-called "crisis of pharmaceutical innovation" (Gaudillière 2021: 415) and issues of efficiency in drug development. Actors point to the decline in drug innovation – increased R&D costs, reduced efficacy in the research process, and fewer novel products – as a significant issue open pharma is poised to address. Published concerns about decreased innovation have grown among health economists, pharmacists, and industry managers since the early 2000s (Gaudillière 2021). Experts have suggested multiple causes for these trends, including the undertaking of more complex scientific problems that require more as well as different types of expertise and greater collaboration than in previous decades. Also, proponents of open pharma argue that the patent system and market orientations incentivize pharmaceutical companies to avoid financial risks,

consequently producing more 'me too' drugs and 'incremental innovations' over novel therapeutics. Open pharma is accordingly proposed as a means to tip the scales back toward novel drug innovation by better leveraging limited resources through open sharing. These ideas around innovation and speed offer a kind of recognizable frame through which open pharma actors can engage biotech and pharma audiences using familiar terms. As such, this narrative comports with scientific/intellectual movement understandings, where Frickel and Gross (2005) suggest that such movements tend to be more successful and compelling to potential recruits and those with access to needed resources (such as funding agencies) when new ideas are conveyed as a natural outgrowth of current beliefs, values, and assumptions.

Among journal articles that advanced a program for open science in drug development, the issue of falling innovation was common. An early, influential editorial in *Nature* stated: "The low number of novel therapeutics approved by the US FDA in recent years continues to cause great concern about productivity and declining innovation. Can open-source drug research and development, using principles pioneered by the highly successful open-source software movement, help revive the industry?" (Munos 2006: 1). Munos and others authored additional articles, all invoking the decline in drug innovation as a key issue with the status quo and offering up forms of open sharing as the solution (Gold 2021; Munos and Chin 2009).

The issue of efficacy in the research process was also leveraged as a key issue in both publications I analyzed and interviews I conducted. For example, Balasegaram and colleagues (2017: 2) invoke market failure (the previous framing) and efficacy as the two key drivers for their support of open pharma: "We propose that [open source] OS methods are a promising, yet largely untested, way to (1) increase the efficiency of the research process and (2) realign R&D to address the most pressing public health problems as opposed to the most promising market

opportunities." One interviewee – a prominent voice in the movement – responded to a question about motivations for open pharma, commenting: "Oh, purely to do better science. That, that was the only reason." He elaborated sharing that he was fed up with knowing scientific research was often duplicated by different groups due to data and results being kept secret. In industry, for instance, results from experiments and clinical trials are usually concealed through nondisclosure agreements and trade secrets. In academic research, institutional barriers (e.g., technology transfer policies, which I discuss below) keep knowledge confined to individual universities as commercializable assets. Additionally, there is a lack of incentives and opportunities to share certain types of results, including negative findings that are typically not considered 'publishable' in many journals but nonetheless contain valuable knowledge about unsuccessful experiments and tested hypotheses. Many open pharma actors view these as contributors to wasted time and financial resources with labs unknowingly duplicating research, ultimately impeding the efficient advancement of knowledge toward therapeutics.

> Another interviewee who helped found an open science institute summed it up this way: I was very frustrated by the slowness of drug development in the field of neuroscience. We're doing a pretty lousy job treating patients, relative to new treatments compared to cardiology or cancer or other things. … So then, the idea became how can we make this go faster? … Open sharing, we thought, would accelerate the discovery, the understanding of the nervous system that would allow rational, targeted development of treatments.

Here, we see a mix of framings used, between a specific disease area ripe for intervention and a lagging innovation ecosystem; however, this participant's narrative was principally shaped by a concern over the efficacy of knowledge production that underpins drug development. Strikingly,

this language parallels the Silicon Valley philosophy of "failing fast," which advocates for new ideas to be tested quickly – to fail and adapt quickly – in order to advance technological breakthroughs and innovations at a faster pace. Again, we see the use of familiar language in pharma and biotech spheres to frame the issue and solution.

Affordability and access to medicines as political

A final movement framework constructs open pharma as a solution to the problem of affordable medicines globally. For many, this meant better leveraging limited resources and reducing the cost of the process of developing medicines by freely sharing knowledge. That is, if an academic lab or company spent less on R&D by crowdsourcing and building on public repositories of knowledge, then ideally, these savings would be passed down the innovation chain to patients. Others, however, had a more critical view of market mechanisms that shaped healthcare access and looked to open frameworks as a kind of political move to address access to medicines by building a more equitable pharmaceutical system.

Corporate greed within the pharmaceutical industry and the associated politics of medicines as profitable assets was viewed by some as a central concern. Openness was consequently invoked as a means to create more equitable access to medicines. One interviewee made these connections between access and the political economy of pharmaceuticals, articulating his motivation for open science as: "I realized that the priority is not to make a bunch of stockholders more wealthy, but rather it's to get medicine to people that need it to save their lives. That's what's important. … Open source can do that. And it's a much better model than the capitalist model." For him, open pharma was a means to intervene in the economic system

undergirding pharma, which he saw as prioritizing profits over access. Another participant echoed similar points, questioning the role of market logics in the making of medicines:

> The system as we've constructed it, around the north star medicine is an asset [and] companies should maximize profits. You put those two together, you get the system we have. … But if you question the very assumption that medicine should be an asset, that the corporate world should maximize profits, then you come to a different ecosystem, and you imagine a different way. … What happens if we imagine a world where medicine is a human right? How would one develop that medicine? I can't think of any other way other than open science.

Whereas the section above on market failure suggests that the pharma industry works well for some markets and needs and not others, this framing suggests that the industry is not working well in that it produces unequal access to medicines and unequal health outcomes for marginalized groups. In this view, where the market itself is the issue, open pharma is seen not as a complementary model but as a means to supplant the privatized model.

Overall, themes of access and affordability were mobilized in nearly all individual and organizational conceptions of open pharma. However, the extent to which this narrative was placed front and center varied, as did the rationales and mechanisms for how to reach these goals. The Open Source Pharma Foundation (OSPF), for example, organizes around the tagline "medicines for all," and articulates their mission as "Using open source principles, and by nurturing a movement, we seek to create affordable new medicines in areas of great health need" (OSPF n.d.a). In an interview with one of the founders, he also focused on affordable access to medicines as the key injustice and driver for open pharma, noting that in early conversations with collaborators "The big idea [was] creating an open source innovation model for the global poor."

He went on to state: “One of our principles is really coming up with a therapy or a medicine or a vaccine that is accessible to all people.” For him, justifications around access, equity, and justice played a larger role in how he conceived of and legitimized open pharma.

Similarly, for the community project Open Insulin, open principles are proposed as a means to combat the monopolization and high price of insulin in the US, in which openness translates to participation by anyone and goals of publishing instructions for how to make insulin in community labs. Under the headline “Healthcare is a human right,” Open Insulin’s website states: “No one should be deprived of access to life-saving medicine. Access to insulin must be guaranteed, not obtained conditionally from corporate manufacturers for outrageous prices.” Rallying around the egregious price of insulin in the US, Open Insulin views an open science program as a means to “democratize the production of insulin” in order to make it affordable (Open Insulin n.d.).[9] These actors are mobilized primarily by the narrative of access and affordability, with corporate greed being central to their conception of the problem, and because corporate pharma could not then be trusted to fix the issue, open frameworks became essential to their articulations of the solution. For them, openness extends beyond sharing and into participation, where broader participation in the process of research and making drugs – including by individuals not trained in traditional scientific institutions with ties to industry (e.g., lay actors) – offered a means to create more equitable biomedical research and products. In other words, group members sought to address insulin access by intervening in where biomedical research was done and by whom.

While many interviewees hoped open sharing practices would ultimately lead to access to medicines in the process, one participant was skeptical: “There's no guarantee that doing things

[9] Open Insulin also spent considerable effort creating a governance framework derived from open source software organizations (Foti 2022).

in the open makes it more accessible. What it does is it reduces the costs of doing the research. So you can do open access and everything else and still have barriers to access." He explained that the way to ensure access and affordability is through different mechanisms such as governance structure, regulatory data protections, and agreements on price caps.

(HOW) Open Pharma in Practice: Building Infrastructure

This section offers an analysis of open pharma in practice. While I trace the open pharma movement as emerging from a string of largely speculative articles starting in the mid-2000s, in recent years, there has been a rise in formal organizations and institutional mechanisms to operationalize open pharma ideas and practices. I describe how open pharma actors are implementing open science policies, creating institutional supports to train and recruit others in open pharma, obtaining grants and funding, and developing their own funding mechanisms. These efforts to build new infrastructure, as well as leverage already established forms, constitute collective action to advance a program of open pharma. Through this, I show the building of an ecosystem to support different parts of drug R&D using open science and mechanisms for further advancing open pharma discourses.

Policies for open sharing

Central to the institutionalization of open pharma are policies for sharing knowledge, data, and materials. The common policy approach among many open pharma initiatives I examined focused on two elements: to make research outputs (e.g., data, materials, and other scientific knowledge) public, and to not file for patents. For example, the Open Science Policy for the Agora Open Science Trust (described in greater depth later in this section) requires that:

> All scientific outputs – including research-related results (both positive and negative), data, models, methodologies, reagents, and other tools – arising from collaborative research projects in which Agora or its wholly-subsidiaries provide funding or participate must be made publicly available as promptly as possible for research use by others (Agora Open Science Trust n.d.a).

Openness is operationalized through 1) "open access publications;" 2) "open data practices," in which contributors share data according to "FAIR data principles (findable, accessible, interoperable, and reusable);" and 3) by "facilitating access to research tools" by limiting costs of shared research tools and requiring that further sharing by third parties be done on the same basis. Two other major open pharma initiatives, one at McGill University and one at Aarhus University, adopted similar policy approaches that refuse to file patents and mandate sharing research publicly.

Open sharing policies were formulated and adopted with consideration to where the project fell along the R&D process. Many patented biomedical products are built on public scientific knowledge. Open source software follows a similar route, in which companies take open source code, build or 'innovate' on it, and produce proprietary products. In fact, several participants were supportive of this idea for open pharma. One participant shared: "In developing cancer medications or something else, you can imagine taking something which is already public domain, messing around with it a little bit and coming up with something which is improved, and patenting, … and everyone's free to do that." Another interviewee indicated that their initiative was specifically organized with this in mind:

> We started actually visiting companies and asking the question… 'When do you need the patent and the protection and exclusive access to research results, the patent or licensing

> agreement offers you? Is it always at the very beginning of the research value chain, or can it be postponed a little bit and form that public knowledge foundation?' And in most cases in pharma, they said, 'Well, no, we can actually postpone it. We don't really want to take on the expenses of having a patent in the earlier stages when we don't have any commercial use for it.' But having the option to do pre-competitive research openly and then draw a line and say, 'beyond this point, things will get competitive and commercial... [and] we'll need to do it in standard closed and contracted research projects with IP negotiation.' That was sort of the deal from the beginning. And in that way, what we are doing with the open approach isn't undermining traditional proprietary tech transfer mechanisms. It's more like a pipeline for more closed collaboration downstream.

That is, one way to 'do' open pharma involved reconsidering the question of 'when' – or 'where' – along the research pipeline open science exists. "Pre-competitive research" was typically understood as basic and preclinical knowledge production that led to general scientific tools, rather than specific products. This part of the research pipeline companies felt could be shared publicly without compromising their potential to later patent, commercialize, and profit from. "Competitive research" tended to be slightly further downstream toward drug development, where biotech and pharma companies did not wish to invest without being given monopoly protections through IP. This "competitive" line was important for open pharma actors as it was tied to funding. The further downstream, the more private funding traditionally plays a role, as companies usually carry out most commercialization processes that are heavily regulated and expensive. Universities and governments tend not to be equipped – in terms of equipment, funding, and expertise – to do downstream pharmaceutical development. The more private investment funding is involved, the more tethered R&D tends to become to IP. Consequently,

one strategy used to advance open science in R&D was to redefine where that boundary between "pre-competitive" and "competitive" research lay.

For open pharma actors who wished to do away with patents altogether, wanting to see open science practiced throughout the R&D pipeline, they took a different strategy and looked to make larger structural changes to facilitate openness. In particular, actors organized to influence policy changes at national and international levels, to create funding mechanisms, and to adopt changes in regulations to incentivize open sharing practices. Actors met with regulators to advocate for extending market exclusivity protections for rare diseases. Currently, makers of drugs for neglected diseases can apply for patents on the drug, which allows them 20 years of monopoly protection, but they can also apply for an additional seven years of exclusivity for treating rare diseases under the Orphan Drug Act in the US, and similar laws in other countries. One participant with Agora Open Science Trust discussed the making of a policy recommendation and a subsequent meeting with officials to discuss this:

> We're trying to leverage regulatory data protection [and] regulatory market exclusivity, if you're talking about orphan diseases. And there are elements of those regimes that could be made better to encourage open science. … We had made a proposal to the Canadian government, and in talks briefly with some people in the European Union and the United States. … We were suggesting that they extend regulatory data protection for a newly approved drug that would do three things. One is show that they've released all of their preclinical and clinical data into the public domain. [Two] forgo any patents on the product. So if they filed any [patents], then they would have to renounce them. Basically, what that does is it doesn't enable them to use patents to evergreen the exclusivity period.

> … [Three] then also meet a pricing cap requirement. If you could do those three things, then you would get an extension of exclusivity for a period of four years.

The first two proposal items directly attempt to influence the uptake of open science in pharma by publishing all data publicly and by eschewing patents. According to this interviewee, these two policies would effectively bar an all-too-common practice where companies file a patent, make small modifications to the product, and file for additional patents that extend their monopoly protections on the original technology in the process, a tactic called "evergreening" (Hitchings, Baker, and Khong 2012). Finally, the proposal also attempts to place a limit on the price of open pharma drugs made and regulated through this process by building in a "pricing cap." Notably, the proposal draws on legal infrastructure already in place – laws but also previously established government positions and processes. For instance, market exclusivity for drugs for rare diseases is already an established government mechanism, and Canada also has the Patented Medicine Prices Review Board, which caps prices on certain medicines.

The participant went on to explain "The whole idea there was just, it made a clinical asset that we had developed openly, that we were trying to license to a commercial partner, look a little more attractive, because they'd have a longer period on the market where they could have exclusivity, albeit with a pricing cap." Here, he is speaking to the issue of commercialization and, relatedly, funding. Companies may be hesitant to use their resources to develop a drug without assurances that they will recover their costs. The exclusivity protections, then, allow for companies to monopolize the market – in this case, for an extra four years on top of the original seven already legally allowed – to sell the drug without competition. This open pharma leader also suggested to health regulators that they "create a repository where preclinical and clinical data can be submitted along the pathway of drug discovery, as trials are completed and then

released. But once it's released through that mechanism it is protected from competitive use before marketing authorization." He argued this would enable more research and "strengthen that regime to make it more, even more attractive for open science and still make sure all the data is in the public domain for secondary use."

On their website, Agora Open Science Trust suggests that these discussions led to some influence toward establishing more institutional support for open pharma at the national level, saying: "Our testimony before the Canadian Parliamentary Standing Committee on Health in October 2018 led the Committee to issue a report calling on the Canadian Institutes of Health Research to provide funding for open science models of drug discovery and on Health Canada to develop regulatory incentives for pharmaceutical companies that share research data openly and implement affordable prices for their products" (Agora Open Science Trust n.d.-b).

Leveraging current micromobilization contexts and forming new ones

The successful institutionalization of movement ideas also demands settings for sustained interactions where open pharma actors can recruit, explicitly or implicitly, others to adopt their views. That is, movements need "micromobilization contexts" – sites where movement actors can influence others and recruitment can take place (Frickel and Gross 2005; see also McAdam, McCarthy, and Zald 1988). For scientific/intellectual movements, these types of contexts tend to occur at conferences and symposia, as well as within departments and other university settings. Presentations and publications offer a mechanism through which to share ideas but also persuade others as audiences engage with presenters and authors. Training settings, whether in classrooms or laboratories or through informal mentorship, offer additional sites for influence and

recruitment. The advent of virtual conferences and meetings adds another layer of possibilities as movement actors can engage with potential recruits across greater geographical distances.

Actors took advantage of already established spaces to advance arguments about the value of open pharma and recruit new supporters. The most prolific space for developing and growing the discourse of open pharma appeared through written articles, as evidenced in the section above on movement framings. The OSPF website also offers a long list of journal articles, blogs, editorials, and reports on their "Resources" page (OSPF n.d.b). Universities – e.g., laboratories, departments, classrooms, and seminars – also offer environments for open pharma leaders to interact with potential recruits. As much of open pharma's intervention centers on intellectual property and policies, training a new cadre of experts to recommend and draft policies for open pharma projects was important. An IP law professor and open pharma thought leader shared with me:

> One of the things we're trying to create or spur are experts – consultants who could provide the advice. So we're trying to educate lawyers. I'm trying to get my students involved, so when they think about IP, they're not just thinking about patents, but maybe data protection or other types of incentives. Now you go see a patent lawyer, everything looks like a patent. You need them to think more broadly, and then you need business consultants who have experience enough that they can credibly assess and assist firms to develop a plan forward. … As we develop that expertise, we try to package it, [and] get these people available to provide expert advice.

For this participant and other movement actors, legal and business trainees were an important pool of potential recruits that could be mobilized through already established micromobilization

contexts, such as the classroom and mentor-mentee relationships built into the university structure.

Beginning in the mid-2010s, more collective action emerged to build new micromobilization spaces, including the organizing of three international conferences dedicated to open pharma. The first conference, "Open Source Pharma 1," was convened in 2014. The idea for a conference began with a human rights lawyer and scholar who interacted with Open Source Drug Discovery (OSDD) and was impressed by their effort. He received funding for a convening with the Rockefeller Foundation Bellagio Center. Working with a few others who had written about open pharma and led related projects, they selected individuals for the 23 available spots. As the organizer shared with me:

> We had eight plus countries, all different parts of the pharma pipeline, all different sectors – universities, big pharma, small pharma, academics, NGOs. And we sort of conceptualized there at that meeting … does an open source approach to pharma R&D make any sense? And, shall we try to bring it into being? … One of the groups at that meeting was the Tata Trusts who had already been supporting OSDD in India. They got very interested and backed the formation of a nonprofit.

Here, we see how recruitment spaces can translate to institutionalization mechanisms such as funding: the Tata Trusts funding helped launch the Open Source Pharma Foundation, who then organized subsequent conferences. The second Open Source Pharma conference was hosted in 2015 in Germany with around 35 in attendance. The third one, which I also attended, was convened in 2019 in Paris with around 50 attendees. At this meeting, all attendees provided a two-minute "flash talk" to introduce their work and were encouraged to build connections through several networking breaks. The three-day conference was full of presentations that

detailed issues plaguing drug development, posed possible solutions through open science, and offered space to explore specific topics within breakout sessions. In the breakout session I attended, I recall a lively discussion about the possibility of creating a certification system for open pharma projects, akin to the Fair Trade model. For instance, a project that shares all data publicly and refuses patents might receive the highest certification mark, while a project that accepts patenting but agrees to license liberally might receive a lower marking. Ultimately, the conference worked to propagate ideas around open pharma, build and grow a network of movement actors by forging new relationships and collaborations, and train new leaders who could return to their respective networks in universities, companies, governments, and nonprofits and further advance the program of thought.

New micromobilization spaces have also been created through funding positions, full- and part-time, to advance open science ideas. The strongest example of this was a new position for an Open Science Alliance Officer at the Tannenbaum Open Science Institute (TOSI) at McGill (described further below). According to the officer:

> Basically, my role is to go out to other institutes at whatever level, whether it's trainees, leadership [or] anywhere in between, and convince them that designing a set of aligned open science principles, and then committing to it on the part of the entire institute, is really the best way, not only to do neuroscience, but for all of us to work together towards creating cures, or even before that, just basic discovery.

While he participated in other work, including the development of open science policies, a major part of his role involved socializing a new program of thought and recruiting individual researchers and institutional leaders to adopt movement ideas.

Institutional infrastructure

Finally, the building of open pharma infrastructure goes beyond the influencing of ideas and recruitment to actively establishing larger initiatives both within universities and outside of them. These serve as nexuses to receive and distribute funds, bring people together, and organize work, and as such, they often serve to operationalize what open pharma *looks like* on the ground, what is implemented and how in their pursuit of the goal of making of drugs through open sharing practices. As can be seen below, actors leverage both open science and team science approaches, and are piecing together institutional supports for collaboration and non-traditional funding mechanisms (i.e., government and philanthropic funds rather than venture capital and private funding) to form new infrastructure for open pharma.

Several small, open pharma projects exist that are anchored in university laboratories (e.g., Open Source Malaria), but their operations and scope of work tend to be highly subject to the ebb and flow of academic funding. These smaller projects utilize consortium-style approaches with multiple formal partnerships as well as informal contributors. For instance, most open pharma leaders I spoke to indicated they worked formally with other university and government scientists, such as through shared funding, as well as informally, including through scientific and technical support from industry researchers. As one university-based researcher described:

> I got a grant from [government agency] for about 50,000 pounds to keep the lights on basically, which helps us this year to make sure we can keep doing things while we build a case for a bigger proposal, make sure that the core of the project's funded. So it's very much the case that we are going after charity and government funding to keep things moving, with lots of in-kind support from whoever is able to contribute. So the big

> contribution from [disease foundation] over the years for the project has been in helping with the project management, honestly brokership of connecting us with people, access to platforms that they run for antigen testing, things like that, rather than cash.

These projects collaborate with other researchers through an online lab book. Crowdsourced lab notebook platforms (e.g., Just One Giant Lab) also offer a type of institutionalization of open science, generally, and were mentioned in interviews as important tools for open pharma.

Larger initiatives have also been established in universities to institutionalize open science in drug discovery. First, the Montreal Neurological Institute-Hospital at McGill University, often referred to as "The Neuro" for short, offers a prominent example of open pharma infrastructure through its establishment of the Tanenbaum Open Science Institute (TOSI), created through a $20 million dollar donation by the Tanenbaum family. The Neuro treats patients with neurological disorders and has laboratory and clinical research arms, including the Early Drug Discovery Unit that aims to bridge upstream research with downstream development of therapeutics. According to a published interview with the Director, "Open Science at The Neuro will be driven along five key axes: Open Access, Open Data, Open Intellectual Property (IP), Open Biobank, and Open Commercialization." Like other open pharma initiatives, their intervention is to expedite the scientific process by removing barriers formed by IP and technology transfer negotiations. Notably, TOSI constructed an "Open Science Support and Partnership Framework" that "supports and guides other institutes in adopting Open Science practices" (TOSI n.d.) and provides funding to this end. TOSI also supports personnel, such as the Open Science Alliance Officer described above, to help facilitate the uptake of open science at McGill and other universities.

A second major university-based initiative is the Open Discovery Innovation Network (ODIN) at Auhaus University in Denmark. Funded by 54.5 million DKK (around USD $7.8 million) through the Novo Nordisk Foundation – the charitable foundation arm of the Novo Nordisk pharmaceutical company and wealthiest philanthropic fund globally – ODIN distributes funds to projects; the early stages of drug development (e.g., biomarker and target validation research) is one area they fund. ODIN has built collaborative infrastructure to help academic researchers and companies work together using a standard, no-IP contract. One interviewee suggested ODIN's main intervention was to "create a legal framework," developed with the university's technology transfer office, to allow university researchers and companies to work together through "a no IP collaboration model." Their approach to openness translates to public data sharing on the research platform, Zenodo.

Another noteworthy hub that serves as a conduit for funding open pharma and organizing is the Agora Open Science Trust ecosystem. The Canadian charitable nonprofit is set up to hold subsidiary companies focused on specific disease areas. Emblematic of the growing trend toward team science – where large groups of researchers and specialists come together across many institutions to solve complex scientific problems – the trust works to build partnerships among "governments, foundations, patient groups, academic research institutions, and businesses to drive the discovery and development of affordable new medicines" (Agora Open Science Trust n.d.). One subsidiary company is Medicines 4 Kids Pharma (M4K) that focuses on rare childhood diseases. Formed in 2018, M4K grew out of the highly successful Structural Genomics Consortium (SGC), which uses open science to research chemical probes and other upstream tools used in drug development. Building on knowledge from the SGC, M4K received $2 million CAD (around USD $2 million) from the Ontario Institute for Cancer Research to

move toward a potential therapy for the childhood cancer Diffuse Intrinsic Pontine Glioma, for which there is a small patient population and little market incentive to identify drugs for. M4K led a "hit to lead program" to crowdsource the scientific process and then placed results in the public domain. As one M4K leader described, "It's like a very traditional drug discovery program. It's just, instead of patenting the compounds, you just share them." Notably, the Agora Open Science Trust operates as a governance mechanism for M4K, with the trust "governed by an independent board of directors and whose mandate is to use any proceeds from M4K to support open science and the public good" (Morgan, Roberts, and Edwards 2018).

Other "virtual companies" under the Agora Open Science Trust – as one interviewee referred to these subsidiary units – have also formed, including Medicines 4 Neurological Diseases (M4ND) and Medicines 4 Infectious Diseases (M4ID). Leaders of the trust are involved in other new open pharma initiatives as well, including the Viral Interruption Medicines Initiative (VIMI) and the Rapidly Emerging Antiviral Drug Development Initiative (READDI). These organizations are "modeled after, and have been endorsed by DNDi," the major international product development partnership Drugs for Neglected Diseases (VIMI n.d.). This shows that the boundary between product development partnerships and open pharma is not only blurry, but that parts of the open pharma ecosystem are being actively organized in ways that resemble what Light (2020) calls "entrepreneurial collaboration" rather than market-driven competition.

Lastly, new consortia were spurred by the COVID-19 pandemic to bridge open science and drug development. COVID Moonshot received $11 million dollars from the Wellcome Trust to fund preclinical development of an antiviral against SARS-CoV-2. One interviewee described this effort as "possibly the furthest along" in crowdsourced drug discovery. More recently, the

open science consortium AI-driven Structure-enabled Antiviral Platform (ASAP) was formed, funded by a $69 million dollar grant from NIH, and "built on principles of open science and rapid dissemination" (NIH 2022b). The project will work to discover and develop antivirals for COVID-19 but also for future pandemics, an area of perceived "market failure."

Collectively, these initiatives highlight the building of an open pharma ecosystem by organizing institutional mechanisms (e.g., through funding and governance) to enact open science in drug development. But it is also worth noting that a drug has yet to successfully make it through this open science system. Many actors voiced concern about how to fund later phases of drug development without IP and private capital (all initiatives described above are in the preclinical phase or earlier). One interviewee suggested that the generics industry offers an obvious answer: "The distribution systems are in place. The manufacturing is cheap. It's a market-based mechanism. There are pharmacies and government. So all you have to do is really make a new medicine, and then you can take advantage of all that infrastructure."

Barriers to Opening Pharma: Cultures and Structures of (Non)sharing

One striking theme that appeared across nearly all interviews was the belief that entrenched norms and ways of thinking – or "culture," as many participants referred to it – was among the most significant barriers to advancing a program of open science in drug R&D and, often, in biomedical research more broadly. Upon deeper inquiry, the tensions open pharma actors encountered were often tied to structural conditions that directly and indirectly impacted individuals' as well as institutions' motivations and willingness to share biomedical knowledge in open ways. In this section, I examine how academic norms around publishing and institutional policies around commercialization worked against efforts to adopt open pharma ideas.

Academic norms: Publishing and ownership over ideas

A few open pharma movement actors surfaced challenges related to academic norms around publishing and ownership. Some voiced concern over career advancement through publications and receiving credit for ideas, both of which caused friction when considering participation in open forms of data sharing. One researcher focused on this point in particular, saying:

> There is still a lot of suspicion in academia in particular about putting work in the public domain, and whether that screws up being able to publish it in high impact journals. The metric in academia is the paper and the impact factor still. So, I talk with open science people who are involved in doing open science, who still don't want to put data in the public domain, because they fear that that will stop them publishing it later.

Here, he surfaces competing objectives happening in science: the pull to embrace open science and the fear that doing so will jeopardize academic scientists' careers. This participant went on to note that he regularly encountered "great reluctance to share data early," even though his project offered proof one could share data publicly and publish in high impact journals. He speculated that part of this was a fear of "being scooped," or having one's idea taken by someone else who then publishes first and receives credit. Another interviewee shared similar concerns: "So that's kind of what's stopping academia from being open: incentives. We reward first to publish. Right? If you don't wanna get scooped, you keep things secret." Such fears likely become exacerbated by career level, with those in junior positions and those without tenure more vulnerable to unforeseen consequences of sharing data openly. There are also equity concerns scientists may have when weighing whether to share data openly. For instance, researchers in the Global South

may be skeptical to contribute biomedical data that leads to a therapeutic that is then inaccessible to low-income countries and communities. Utility is often prioritized over equity when it comes to data sharing for public health emergencies, as seen during epidemics and pandemics (Pratt and Bull 2021).

Relatedly, the issue of "ownership" was also flagged as a barrier in working with academic researchers. The reward system in academic science tends to compensate, financially and through accolades, leaders of ideas. That is, academic researchers gain recognition and promotion by *leading* papers, grants, and research projects, as opposed to *contributing* to a collective project without attributions to individual contributors. Ownership levels are commonly distinguished by authorship placement in publications, for instance, as well as designations such as Principal Investigator versus Co-Investigator. One interviewee described a situation where he tried to encourage colleagues to let go of the idea that it was "*our* project," and instead to view themselves as temporary leaders, not owners: "We're starting it, and we're leading it because we're busy with it, but one day we'll be done. And then it belongs to whomever wants to progress it." He added that "It's clarifying ownership that's an issue in academia." This account reflects arguments made in the editorial "Six laws of open source pharma drug discovery" (Todd 2019). The sixth "law" states, "An open project is bigger than, and is not owned by, any given lab," and emphasizes that a project should be able to shift and grow in whatever direction anyone wishes (as long as it abides by the project policies for sharing), much like the original ethos of open source software as a community of "contributors." The law continues to say that "if one wishes people to get together to work on something voluntarily then one needs to minimize ownership. It is not about the person, but the project." From this perspective, open pharma demands a cultural shift in order to be successful.

Another interviewee described a related barrier to advancing a program of open science in pharma: "I see one challenge in that, basically, what is now happening is competition. Changing the mindset of [a] competitive spirit into collaborators, this is very difficult. … So [the] open source drug movement is, in my definition, changing the mindset of people from competition to collaboration." To him, the lack of motivation to share scientific data, results, and technologies in open ways was tied to norms within pharma, and society more broadly, that favored competition over collaboration.

Academic structures: Commercialization imperatives

Another barrier participants grappled with was university mandates to commercialize knowledge. In particular, the Bayh-Dole Act (and similar laws in other countries) and university technology transfer offices were cited by multiple interviewees as sites of contention, as patents and lucrative licensure agreements were viewed by universities as not only valuable but legally mandated.

Many open pharma proponents were frustrated by "red tape" put up by technology transfer offices, a problem they not only encountered personally but also implicated in slowing down drug development more broadly. As one open pharma leader explained:

> I'm a professor at [university name] that owns my IP. And it's my responsibility to tell them if anything I have that's potentially commercializable. So now, I invent something in my lab, and I want to give it to my friend at another university. Most of us just send it. But if we follow proper channels, I have to tell my university. … Then the university signs a contract called a material transfer agreement that allows me to do that. And this sort of is just *mud in the system*, cuz it slows everything down. So the more you get

> where someone perceives this to have value – and the university perceives everything to have value, cuz they don't wanna be the sucker that gave something away that made this university a lot of money – then they encumber everything. And you have non-experts looking at something, "Oh, it might be viable!" … Universities wanna be the first to invent and transfer their knowledge. So they keep things secret. … The more you get into drugs, where it's big money, the more secretive they get. It's really distressing. (emphasis added)

For this participant, university policies that mandated researchers disclose knowledge and materials before sharing led to slow and inefficient scientific advancement. In particular, he highlights processes of capitalization (Gaudillière and Sunder Rajan 2021; see also Birch and Muniesa 2020), in which universities approach all knowledge production as potential assets. This capitalization process becomes particularly heightened in areas of biomedicine where there is perceived high financial value, as is the case in pharmaceuticals. He suggests that in such areas of "big money," the more difficult open science practices become. Another open pharma scientist shared similar feelings: "It's been a difficult conversation with tech transfer offices to give away their rights to profit for these [research tools]. I think this is perhaps one of the biggest problems." Nevertheless, participants also acknowledged that, in practice, scientists often shared research tools without involving their tech transfer office, begging the question of how much impact commercialization mandates hold over the day-to-day scientific practices of researchers.[10]

[10] All academic researchers I spoke to were more senior in their career, and I suspect that had an effect on their perception of how much sharing of knowledge and materials was happening outside official university channels. More junior scientists may be less likely to share without obtaining permission from their university first.

Another leader of an open pharma consortium spoke to the struggles of trying to work with new, federally funded partners that were tied to commercialization imperatives:

> I would say that's a significant impediment in the United States where institutions receive federal funds. Bayh-Dole says basically that they have to patent inventions or assign them to the government. I don't think that in practice they [always] are. Scientists are publishing stuff that could have been patented and just doing it. ... But when you get into negotiations with institutions, they don't want to sign something that they perceive as inconsistent with their Bayh-Dole obligations.

He went on to share two specific examples where negotiations with new partners stalled, one that remains in limbo, and another where they were able to find a "creative solution" to work together. The solution involved careful language stating they would not block the institution from patenting but also that the consortium could release data immediately. For the consortium, this compromise allowed them to "take off the table all the harmful effects that those institutions' patenting could have" – namely, data would not be kept secret in order to apply for a patent – while also not explicitly violating legal and institutional policies. But this compromise required concerted and imaginative work to craft.

One university leader echoed similar frustrations; however, his initiative was able to influence his university to eventually adopt open science policies:

> So we are a unit in the university. And if you look at the rules and regulations for professors, there's all kinds of things about patenting and protecting and commercializing and all of these kinds of things. Universities are measured. They get brownie points for every patent they get. So there's a lot of pressure to do a lot of IP and protection and patenting. … It was a very hostile environment at the university. So the university

> president was against it [open science]. The VP of research was against it. When we were doing our open science, our 18 months of education, we would get spies from the Office of Technology Transfer coming to see what we were doing.

Interestingly, this participant recounted the process through which they were able to get university leaders on board, by convincing a committee of business leaders:

> The university has this external committee of advisors, an advisory committee on commercialization, and all these things. These are venture capitalists, and these are CEOs of companies and all that. This is all businesspeople. And so we presented the notion of open science. … The university was sure that these people would say, "This is horrible, and avoid this like the plague." But we presented it to this committee, this group, they loved it. They thought it was great. Get rid of all these problems, all these barriers, make it open, share, we'll find our targets more quickly. It's all good. So in the end, they strongly recommended adopting it. And so the whole university was stuck because they had said that this committee would make the decision, and they did. We were lucky. So it's businesspeople who saved open science at [the institute], which is an interesting notion.

Another open pharma consortium leader compared the challenges of working with universities to their experiences with industry, saying: "We've partnered with commercial entities, [and] there hasn't been the same problem, cuz I think they have a more nuanced view of intellectual property maybe than tech transfer offices."

As I described in a previous section, one university-based initiative outside the US was able to make inroads with their technology transfer offices by emphasizing that patents could still be secured at a later point, that the research was "pre-competitive." After convincing their

technology transfer office that "the open approach isn't undermining traditional proprietary tech transfer mechanism; it's more like a pipeline for more closed collaboration downstream," this participant noted, "I think the tech transfer [office] really has become our strongest advocate, even though they were not happy about the way of working to begin with." Similar to other interviewees, this leader's view was that "it's all about cultural change."

These fascinating accounts highlight the nuances and complexities associated with academic and industry norms. Overall, technology transfer laws stood out as an important factor in shaping how open pharma is being built and implemented. Rather than embracing the idea of freely sharing knowledge and research tools for public use (outside of the limited scope of open access journals), university leaders pushed back. Objectives of the university are supposedly oriented toward education and knowledge production for societal good, not profit. Yet, academic leaders' actions – influenced by legal structures such as Bayh-Dole – seem to contradict these priorities. Meanwhile, capitalist business logics orient objectives toward profits, which are often secured through IP protections that allow companies to monopolize markets, suggesting that industry actors might be anti-open science. As interviewees illuminate, however, industry leaders seem to be more 'open' to open science than academic leaders. These actions appear to reflect observations made by science and technology studies scholars who articulate the dual, seemingly paradoxical, trends of the "industrialization" of the academy and the "collegialization" of industry research (Kleinman and Vallas 2001).

These findings harken back to the important point that biomedicine, and especially pharmaceuticals, is situated in a particular political economy that bears on its construction as an intellectual field. Capitalist political economic structures – including legal, regulatory, and market structures – are deeply integral to biomedicine's development and shape how it is carried

out. In this case, technology transfer laws impact university policies, orienting them further toward financial markets, and this impacts where and how open science is being implemented.

Conclusion

In Janet Hope's (2008) book *Biobazaar,* she examines if biotechnology is being, or could be, revolutionized by open source in the same way software was. She argues that several major initiatives equated to "nucleation sites" for open source biotechnology but not mature working examples. This is because they do not incorporate three key features of the open source software revolution: "successful collaborative technology development, open source licensing, and nonproprietary commercialization" (2008: 321). Although the "revolutionary" tipping point has yet to happen, Hope views these efforts as still being able to improve institutional arrangements to better meet the healthcare needs of people.

Similar to this argument, findings from this paper draw parallel conclusions in that currently open pharma is still emergent. I show how actors are still in the process of formulating ideas, definitions, and practices, and in so doing, determining boundaries about what open pharma is and what it is not. Importantly, this ambiguity is productive in certain ways. "Open" means different things to different people, and this helps to facilitate recruitment to the open pharma movement by allowing actors to invoke multiple narratives and cultural motifs – such as hegemonic ideas that couple scientific innovation (and efficient innovation, in particular) as inherently good for society – that resonate with a wide swath of potential stakeholders. The emergent and unsettled nature of open pharma also facilitates legitimation when deployed in different communities. On the one hand, in biomedical citizen science communities, language around open source leans towards anarchist concepts that critique systems of power and control,

offering an ethos and framework through which to envision community-produced and -owned medicines. On the other hand, in biotech and pharma industry spaces, open source and open science language can be invoked as a business framework with established IP licenses and revenue models.

Open pharma is beginning to formulate new pharma imaginaries and build alternative infrastructures. The production of scientific knowledge that is immediately placed in the public domain is one mechanism, while the creation and implementation of policies that avoid patents is another. Patents offer a key path through which monopoly capitalism is enacted in pharma, so this movement seems to be making inroads in challenging the mutual imbrications of pharma with capitalism, even if in small and bounded ways. However, I also suggest that these imaginaries are not "radical" departures from the usual sociotechnical politics that make up drug development, as my informants sometimes suggest. Rather, regulatory regimes, material infrastructure, and valuation processes such as marketization continue to shape and constrain what is possible in this open pharma space, much as they do for conventional drug development, leading to important tradeoffs in how, why, and for whom open pharma is being constructed.

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CHAPTER 3: A 'Tyranny of Structurelessness'? The Benefits and Burdens of Power Sharing and Governance Models in Citizen Science

Preamble to Chapter 3

The following chapter was published in *Citizen Science: Theory and Practice* as part of the journal's special issue on the topic of biomedical citizen science (Foti 2022). For this article, I draw on my ethnographic data with Open Insulin, focusing on the group's internal governance. The topic of organizational structure and governance as its own empirical focus was not an original aim of this dissertation. However, throughout my fieldwork with Open Insulin, the challenges associated with power sharing and organizational structure were focal points for participants and, consequently, became an area where there was substantial social action. Here, I describe and analyze those actions, illuminating the complex and sometimes unexpected challenges actors face in seeking to build and organize alternative pharmaceutical imaginaries.

Introduction

> *Any group of people of whatever nature coming together for any length of time, for any purpose, will inevitably structure itself in some fashion… We cannot decide whether to have a structured or structureless group; only whether or not to have a formally structured one.*
> -Jo Freeman 1972

Many citizen scientist groups recognize how mainstream scientific institutions – academic, corporate, and government – have structured the scientific enterprise in ways that are harmful to both scientists and society. The publish or perish system, for example, induces immense stress among academic scientists, while the increasing entwinement between science and capital exacerbates inequities through unequal access to the products and benefits of science (Clarke et al. 2010; Sunder Rajan 2006). Many scientists are burdened by bureaucratic responsibilities required by institutional structures, often at the expense of advancing their

research. Weber (1930) famously wrote about the perils of structure in the form of technocratic decision-making, depicting bureaucracy's inevitability as an "iron cage." Overly structured ways of operating can also feel antagonistic to small, community projects positioned as "fun," as many citizen science projects are self-described.

Yet, there are limits to eschewing formalized structures altogether. Jo Freeman (1972), in her essay "The Tyranny of Structurelessness," exposed hidden power dynamics that pervade so-called "leaderless" groups. Examining the women's liberation movement, she argued that the widespread and uncritiqued use of structureless groups as the primary organizational form weakened the movement. Freeman noted that structurelessness may work for certain goals, for example, consciousness-raising groups to increase women's understanding of gendered oppression. However, when groups sought more specific actions, such as change beyond the local and toward national and regional levels, the limits of structurelessness became apparent.

In this paper, I adapt Freeman's argument to the case of citizen science groups who have specific goals of developing practices and infrastructure that resist and reimagine dominant ways of doing biomedical science. Drawing on three years of ethnographic research with the Open Insulin Foundation, I argue biomedical citizen science projects that seek more emancipatory practices (e.g., shifting from neoliberal biomedicine to collectivist goals) must develop and implement governance thoughtfully. Biomedicine is entrenched in multiple overlapping structures of power, or as Murray (2020) aptly describes in his case study of Open Insulin, "trickiness all around." To reimagine this system, or aspects of this system, requires specific actions and intentionality that may benefit from structured decision-making. That is, governance offers mechanisms of accountability to align fundamental values, such as power sharing, to the

mission and decision-making authority. Without this, projects risk reproducing problematic structures and norms many biomedical citizen scientists seek to avoid.

Open Insulin offers an ideal case study for examining organizational governance as it seeks specific actions for social change: to intervene on multiple points within the pharmaceutical industrial complex – including patents, profit, complex supply chains, and power sharing – by putting people with diabetes in control over the production and distribution of insulin (Open Insulin n.d., see also Foti 2020). Open Insulin began as a project under the nonprofit community biology lab Counter Cultures Labs in Oakland, California. The project is largely volunteer-based and is led by members of the public with and without scientific training, as opposed to "establishment" (i.e., institution-based) scientists (Rasmussen et al. 2020). Importantly, the project was founded in 2015 during a period when the price of insulin rose dramatically in the United States (US). Insulin tripled in price between 2002 and 2013 (and has since increased further), leading an estimated 7.4 million individuals who depend on insulin to ration and underuse their medication (Herkert et al. 2019; Hua et al. 2016). Three pharmaceutical manufacturers control the US insulin market and raised their prices concurrently (Cefalu et al. 2018; Robbins 2016). This resulted in numerous deaths and drew substantial attention from the media and legislators (Pear 2019; Sable-Smith 2018).

This paper examines internal governance practices of Open Insulin between 2018 to 2021. I describe their initial informal structure based on horizontal frameworks and trace their shift to a formal organization with membership and board structures. I then describe mutually constitutive themes that acted as sites of tension and change for how internal governance was enacted. These include membership and mechanisms of inclusion and exclusion; leadership and decision-making authority; and the mission as a social process that was regularly debated and

constructed. Findings describe benefits of an open and non-bureaucratic structure, such as appealing to new participants to easily join and drive aspects of the project, as well as challenges participants grappled with, including hidden power dynamics that emerged. The final section discusses and underscores the importance of governance decisions in biomedical citizen science projects that seek to reconstitute biomedicine's relationship with society.

Background

There has been a rise in health and biomedical citizen science projects in recent years (Wiggins and Wilbanks 2019). These initiatives vary from people in their individual homes or kitchens, to groups in home- or garage-based labs, to projects seeded in community biology labs (Talbot 2020). Projects have included, for instance, hacked medical devices, self-experimentation, and patient-led health data collection for often rare medical conditions (Pauwels and Denton 2018). Some praise these efforts as promoting more inclusive approaches to healthcare and biomedical innovation (Fragnito 2020). Others have raised questions about the ethical contours and ambivalences of these projects (Fiske et al. 2019; Trejo et al. 2021). As biomedical citizen science expands, questions about internal and external governance are pertinent. First, this section covers mechanisms of external governance for these groups. Then, I move to scholarship on internal governance and its implications for social change, which many biomedical citizen science projects formed to carry out.

Scholarship on governance, both within and beyond citizen science, suggests a wide breadth of practices and organizational forms to structure relations and collective social action. Scholars have defined governance as "various institutionalized modes of social coordination to produce and implement collectively binding rules, or to provide collective goods" (Börzel and

Risse 2010: 114; see also Levi-Faur 2012). Research on governance among citizen science communities similarly reflects a wide range of relational structures and varied degrees of participation and authority (Göbel et al. 2019). Shirk and colleagues (2012) account for power relations among citizen science projects and suggest that all public participation in scientific research is influenced by the degree and quality of participation.

Within do-it-yourself biology (DIYbio)[11], there have been a variety of efforts to address governance concerns across the budding community. In 2011, a code of ethics was drafted by both the North American and European DIYbio Congresses that includes principles of open access, transparency, and the creation of biotechnology for "peaceful purposes" (DIYBio 2011). The Global Community Biosummit – an annual conference for DIYbio enthusiasts – expanded these principles in 2019 to include accountability, autonomy, and diversity and inclusion (GCBS 2019). There has also been considerable attention to safety oversight, including the implementation of an "Ask a Biosafety Officer" program, collaboration with the US Federal Bureau of Investigation, and the development of a biosafety handbook for community labs (Rasmussen et al. 2020). Similar to Open Insulin, many of these initiatives were spurred to balance desires for inclusivity and openness that are central to the DIYbio movement with concerns about safety and mal intent.

Most biomedical citizen science initiatives are directed informally by individuals or groups, while a handful operate in community biology labs, or public laboratory spaces, with formalized governance structures. For example, The Baltimore Underground Science Space established a board of directors for long-term planning and an executive board for day-to-day

[11] I follow Keulartz and van den Belt's (2016) description of the do-it-yourself biology (DIYbio) movement that underscores its development as influenced by four related movements and applying threads of each to genes, cells, etc.: do-it-yourself (also, do-it-together), citizen science, free software and computer hacking, and the maker movements. Community biology labs also tend to be characterized under the DIYbio umbrella movement.

operations, citing a common issue in all-volunteer groups concerning stability through shifts in leadership (Scheifele and Burkett 2016). Others have also cited risks community labs face by relying on volunteers, where access is limited to those with the financial means to contribute time (de Lange et al. 2021), a known problem in other fields such as conservation biology that leads to issues of representation and inequalities (Vercammen et al. 2020). Counter Culture Labs also has a board of directors, offering a mechanism for fiscal oversight and a body in which serious issues – for example, safety and bullying – could be addressed for projects within the lab and, additionally, requires a membership agreement for new members (CCL n.d.). However, the mission of community biology labs is largely educational – to increase access to biotechnology – and does not necessarily comport to project missions borne in these labs. Thus, groups like Open Insulin are driven to formulate their own organizational structure and mission.

This article focuses on internal governance (while acknowledging broader forms of governance inevitably shape internal processes) and examines power dynamics, both explicit and inadvertent, within a biomedical community science project. To this end, scholars have illuminated the ways in which internal power relations and organizational forms carry implications for organizing for social change. The organizational approach "do-ocracy" that champions self-motivated participation – to "do" something rather than wait to be directed – is found in hacker circles (including Open Insulin) and has been described by Worden (2012: 219) as a "practical anarchy that works well for getting things done. However, it doesn't work well for resolving conflicts between people who want different things to happen; it doesn't protect people who have less ability to do things because of unequal access to time, or to resources, or unequal physical ability; and it is no help to people who believe that certain things just shouldn't be done at all."

Pleyers (2010: 212) specifically identifies frictions between "more informal and horizontal logic" and that of "efficiency and delegation," while Teivainen (2012) argues that unstructured governance can generate ambiguity in political aims and values, leading to undemocratic leadership. Relatedly, della Porta (2013) distinguishes between democratic leadership selection and participatory deliberative models, contending that the former relies on pre-existing identities of members, while the latter results in a process of identity formation through shared decision-making. There are associated debates about tensions between spontaneity versus bureaucratization and the impacts of this for social change (Rigon 2015). The push- and-pull between institutionalization and structurelessness is particularly germane in biomedical citizen science as biomedical regulations demand standardized practices for quality and safety, thus creating strain against anti-structure tendencies.

Many biomedical citizen science projects organize against bureaucratic and neoliberal norms in biomedicine, without always having a clear and detailed picture of what they are for. Importantly, such ambiguity can generate tension between "aspirations and practices (vision and methods)" (Caruso 2013: 81). For example, (Rigon 2015: 76) assessment of the World Social Forum as being defined by what they stood against – neoliberalism – left it vulnerable to ambiguity and "issues of power implicit and unclearly defined." Similarly, Open Insulin formed in reaction to corporatization that deprioritizes affordable medicines, without always having clear consensus on what it was for and how to get there.

Tensions between broad consensus building and representation in decision-making become more acute as initiatives for social change grow in scale (Caruso and Teivainen 2014). As Bacon (2012) suggests, smaller groups (e.g., ten people) may not require governance, whereas it becomes more pressing in larger groups. Despite growing interest in biomedical

citizen science, there is little understanding of internal governance and how this impacts participation, objectives, and values. This paper seeks to fill this gap by examining a bottom-up project between open, horizontal logics and more traditional hierarchical forms of representation.

Methods

Data reported are drawn from a multi-year ethnographic study exploring open source and organizational practices of the community project Open Insulin. This paper draws on 18 in-depth interviews with Open Insulin participants and more than 300 hours of fieldwork in the laboratory and online from August 2018 to October 2021. Observations focused on working group meetings, with emphasis on Safety and Regulations, Business, and Legal working groups, as well as general and ad hoc meetings; a three-day strategy session in 2019 and nine "vision" meetings in 2021; and two conferences, Biohack the Planet in 2018 and Global Community Bio Summit in 2020. Detailed fieldnotes were taken during observations.

In-depth interviews, lasting 1-2 hours, were conducted with Open Insulin volunteers, paid members, and board members. Interviews were conducted via Zoom or in person, and followed a semi-structured, open-ended format. Interview topics explored included participant motivations, on-the-ground practices, group structure and goals, and comparisons of institutions versus community labs, in addition to how members navigated intellectual property and operationalized open source principles. Community lab demographics tend to reflect the broader scientific world, with white, educated men, typically middle to upper class, largely participating in and leading decisions (Erikainen 2022; Walajahi 2019). This is similarly reflected in Open Insulin (although to greater and lesser extents at different points in the project) and in the interview sample. The

data set also comprises documents such as newsletters and media articles about Open Insulin and documents shared in meetings such as grant proposals and governance documents.

Grounded theory (Charmaz 2014) was employed to analyze all data, using initial line-by-line coding and analytic memos to identify relationships between codes and emergent findings. Qualitative software MAXQDA was used to analyze all data. Institutional review board approval was obtained from University of California San Francisco. I use pseudonyms to allow for anonymity except when consent was obtained to allow the use of real names.

Author Positionality

I followed a particular form of ethnography that draws on concepts of politically engaged ethnography found in social movement research (Juris and Khasnabish 2013). This methodology promotes active participation in ethnographic observations and pushes researchers to be accountable to both the academic world and the group of movement actors under study. Following this method, I actively participated in governance discussions. My role in these activities was primarily supportive; I helped review and organize governance documents (including bylaws, organizational structure, and membership criteria) and provided limited feedback in meetings. I also joined informational talks with two outside organizations influential in the drafting of the formal documents. Although I, along with all participants, was invited to provide written comments on the final set of governance documents, I did not, nor did I vote on their adoption.

The participant-observer role comes with challenges that include navigating a precarious position of providing feedback, and potentially dissent, that puts the researcher at risk of losing access to their research site and participants. Of course, there are additional risks to the research

itself, including shaping the social situation in a way that makes the research not "objective," and thus less legitimate. Many scholars have dismissed this objectivist view of ethnographic research as an illusion, yet there remain real concerns about researcher involvement, especially as it relates to power and positionality. I navigated these tensions by limiting my scope of involvement to gentle suggestions that governance be prioritized and that a formal structure be considered that attends to power. Because of this, I believe my participation played a limited role in influencing the outcomes of governance decisions.

Findings

Below, I identify and describe three mutually constructed issues Open Insulin grappled with while negotiating structurelessness versus structured approaches to internal governance: membership and the demarcation of inclusion and exclusion; leadership and decision-making authority; and social processes that shaped the mission, including objectives and underlying values. Sometimes these questions were articulated explicitly during discussions about governance and were visible to members who wrestled with when, why, and how to invoke frameworks for decision-making and power sharing. Other times, these issues surfaced unintentionally while confronting seemingly unrelated challenges. For example, day-to-day operations discussions frequently led to, as one member put it, "heavy meetings," where ostensibly technical conversations morphed into tense discussions about the project's scope, strategies, and purpose.

The Open Insulin Foundation and its Organizational (Re)structuring

First, I provide an overview of Open Insulin's structure chronologically, beginning with their informal organizational approach and then tracing the formation of a formal structure. From their inception in 2015 until 2021, Open Insulin organized themselves informally under horizontal governance frameworks, relinquishing titles and formal hierarchy to delineate tasks and decisions. A horizontal structure was adopted largely in opposition to bureaucratic forms found in corporate and academic science, characterized by centralized and hierarchical decision-making, with an emphasis on qualifications and rules, and a disregard for non-expert knowledge. In the absence of a formal hierarchy, Open Insulin took a "do-ocratic" approach to manage and execute tasks and cited the P2P Foundation in onboarding materials: "'Do-ocracy' is a notion that encourages open participation. It is based on the self-allocation of tasks, and it allows those who carry out these tasks to be recognised and become more influential in order to make decisions" (P2PF n.d.). In practice, this frequently led to ad hoc decision-making. Sometimes participants weighed in to obtain "rough consensus" (Russell 2006); other times participants were silent, effectively making decisions through presumed consensus or lack of dissent. This approach also resulted in eight organically formed working groups in Open Insulin, in which participants engaged in work that most appealed to them.

Many interviewees flagged the lack of organizational structure and management as one of the biggest issues Open Insulin faced. As one participant put it, "It's just kind of like chaotic. … I think we'd get more done if everybody knew what they were going to do, like 'this is your task.'" He points to a tradeoff between self-directedness on the one hand, versus efficiency and clarity of tasks on the other. Relatedly, another member reflected on a time when numerous sub-groups were working on different things that were difficult to balance simultaneously: "People

are going in a bunch of different directions, … hundreds of people showing up to the onboarding meetings over the course of a few months. … At the same time, there was this internship project going on." He identifies a challenge of do-ocratic governance as leading members in too many directions and resulting in people feeling "stretched too thin."

There was a push to formalize the organization in 2021 that was catalyzed by multiple events. The informal structure posed more challenges as participation grew from a small, local group of people to dozens networked around the world. For instance, following a high-profile media article about Open Insulin (Berning 2021), nearly a hundred interested volunteers attended the next onboarding meeting. This prompted practical challenges for organizing volunteers and integrating diverse skills and interests. The push to formalize was furthered after a volunteer used fake credentials to provide legal advice, including an attempt to illegally file fiscal paperwork. This incident brought to the fore a tension that participants regularly grappled with: how to keep a project open and inclusive, while also effectively vetting bad actors. In these instances, Open Insulin confronted similar issues that have pervaded the wider DIYbio movement, including questions about inclusion and exclusion and how to execute decisions (e.g., Just One Giant Lab's developed a "community review" process for distributed projects with hundreds of participants).

In 2021, Open Insulin moved to implement a new, formal organizational structure. They filed for their own nonprofit status with a board of directors, bylaws, and a new membership structure. The structure blended cooperative and open source governance models. It created two forms of participation: an "individual capacity," drawing on concepts from a worker self-directed nonprofit model (or, cooperative) from the Sustainable Economies Law Center, and an "organizational capacity," drawing on Wikimedia Foundation's affiliate framework. The former

functions to maintain power among workers and people with diabetes in the organization; the latter attends to intellectual property concerns for open source technology.

While there were numerous levels and sub-levels of participation that created the overall organizational framework, two features stood out: definitions of work that structured membership and, relatedly, qualifications for becoming a "Member"[12] with voting power. Definitions of work included four priority areas identified as "mission-centric" activities: (1) "backend research and development," which included bioengineering insulin and open hardware activities; (2) "production and distribution," focusing on "how medicines get made and into people's hands" (e.g., manufacturing, regulation, and distribution); (3) "work coordination and infrastructure" that sought to harmonize different aspects of the project; and (4) "recruiting, onboarding, and staffing" (Fieldnotes, September 2021).

Importantly, mission-centric activities helped to structure and define membership. To become a Member, the only status with voting power, an individual had to contribute in one of these areas. All previous informal working groups were reflected in these defined work areas except one, "Open Insulin in Society," a mixed group of academic social scientists (the author included) and community members who met "to contextualize, theorize, and analyze Open Insulin's place in contemporary society" (Fieldnotes, November 2019). This group was categorized without voting power. Additional requirements to apply as a Member included five volunteer hours per week (or 20 hours paid), a peer to vouch for you, and approval by the board. The board of directors' seats were split among people with diabetes and workers, defined as

[12] Uppercase "Member" is used to indicate a participant's membership in this specific defined role in the formal nonprofit structure. Lowercase "member" is used elsewhere as a participant, volunteer, or paid contributor in the informal structure.

"active contributors to the project" in the four priority areas (i.e., Members) (Fieldnotes, September 2021).

Throughout my observations, participants grappled broadly with three areas of governance concerns, including membership, leadership, and the mission. The sections below illustrate both the three sets of concerns, as well as their substantial overlap and the ways in which they mutually intertwined.

Membership

Questions about membership, including inclusion and exclusion, emerged as a central element informing discussions of governance. In order to make and vet decisions for the project, there needed to be shared understanding about who was part of the group, and thus party to those decisions, and who was not. As participants grappled with where to draw the line, they emphasized the benefits and challenges of both open and restricted forms of membership.

A few participants noted the appeal of an organization in which anyone could participate in and shape decisions, potentially benefitting the project by attracting volunteers: "One of the things that's super attractive to me is I can join the organization and within a few months have a pretty good understanding of who everyone is and what everyone is doing… Having worked in biotech… you quickly lose [sight of] the business decision drivers." This participant juxtaposes her experience in industry where she felt removed from organizational decisions to that of Open Insulin, where being able to see and understand everyone's roles acted as an incentive to join the project. Another member recognized the appeal of joining a "very open" group but suggests a disadvantage:

> When you want to have a structure that is very open, [where] people are independent, they can choose what they want to work on and not just assign stuff to people, ... the problem is that you will tend to attract people who are very confident in themselves, and with skills already recognized as experience by society in general.

The participant draws a connection between the open and self-directed nature of the project to the types of people this tends to attract – those with recognized skills and expertise. In other words, she suggests the structure is less conducive to individuals without socially legitimized forms of expertise. She goes onto say "I don't think this is a problem," but she does believe that the group composition needs to be "monitored" by project members to ensure inclusion and "collaboration." Another member echoed a similar cautionary sentiment: "I don't want a bunch of Elon Musk dudes around. … That is not a type of lab that I would want to be in." She cited the "proto-libertarian" mentality as characteristically being at odds with centering social inequality, which she placed a high value on and wanted to see reflected in the project.

The open nature of membership also created tension when a subset of members began pushing the project toward contract manufacturing. As one participant shared about this activity: "That spread us thin and kind of resulted in a whole different side of the organization, with a whole different set of backgrounds and interests, popping up." He goes onto note a shift in organizational activities and priorities that reflected the "status quo" and that this was a result of who was 'in the room': "A lot of people coming from commercial pharma economy who were just kind of like in the mindset of, 'well, this is just how it works.' … So all kinds of gaps just started getting filled in with presumptions around how things work in the status quo." The concomitant open and do-ocratic approach both allowed for industry experts to join and also

drive activities, including in controversial directions, by prioritizing the views of those most active.

The new formalized governance was designed to address many of these concerns. While the long-term effects are yet to be recognized, there were immediate implications. One participant shared her hesitation to apply through the new membership process because it required a peer to attest to her contributions to the project. As much of her time had been spent working with a member who left, she felt she would not qualify, despite clearly meeting the required hours. Multiple women who previously held influential roles in the project did not apply for membership and lost their informal leadership status in the new structure. It is unclear why exactly. Yet, it begs an examination of hidden mechanisms of inclusion and exclusion.

Leadership and Decision-making Authority

The horizontal structure was formed in reaction to mainstream biomedical institutions that prioritize top-down decision-making and incentivize patents and profits over affordable medicines. Numerous interviewees articulated this problem as something that community-based science addresses by offering different organizational forms and incentives. As one participant stated:

> Bureaucratic organizations that operate on a large scale and [that] are very closed in who they let in to work on things and what they let people work on, both of those things are very much determined in a top-down fashion. … Here, if someone thinks something is worth doing, they can just try to do it. So the lack of access to insulin has been a huge problem for a long time, … but within those institutional structures, nothing could be done about it, because it's not really that profitable to address.

He connects characteristics of large bureaucratic institutions, including restrictions around membership and objectives (e.g., prioritization of profits), to the problem of insulin access. This is juxtaposed to the open and self-directed structure of Open Insulin, which he suggests fosters potentially different outcomes.

Participants were attentive to both pros and cons of the open, horizontal structure. Some conveyed enthusiasm toward a "bottom-up" approach to decision-making, including multiple participants who praised it as facilitating goals of "democratizing science" by allowing volunteers to participate in and drive scientific decisions. Others, however, grappled with deeper issues that surfaced in the horizontal structure, where some members had their voices heard over others, potentially reproducing power dynamics the group sought to avoid:

> Claiming to be a collaborative, cooperative space without really thinking through how to make that happen and just defaulting to more or less the problematic things, with men just saying "I'm going to do this. I'm going to do this; you're going to do this." That kind of thing, … it's the same structural similarity but just hidden or unarticulated.

This participant described a key problem emanating from the lack of intentionality around power sharing: similar structures of hierarchical decision-making and authority arise regardless but are "hidden or unarticulated" and thus unable to be reconciled. This happens when people, often men he notes, make decisions for themselves and others with no mechanism for accountability to ensure organizational values of horizontal decision-making are put into practice.

Another participant reflected on the stated goals of shared decision-making versus on-the-ground practices:

> The idea of collective decision [making]… this idea that it is not just experts deciding, that we all decide together [and] we all are experts, not because you have a degree or

> whatever. … I think we are not feeling like a nonprofit … [since] we don't have the board and all of this [organizational hierarchy] in place.

But as she noted, "this isn't really true. It's always like a few people deciding," and that some members "have more power … decision power over other people." She emphasizes the disconnect between the reality in-practice of a handful of people making decisions versus the objective of "collective" decision-making, and suggests this discrepancy or illusion can be sustained because of the absence of a formal organizational structure.

Project members recognized that individuals did indeed hold more influence in shaping organizational priorities and practices. This small handful of people were referred to by different titles, including "core members" or "key people," and were sought out for all consequential decisions. The scientist directing much of the laboratory work was referred to as the "scientific lead," and other "project leads" emerged to help organize and direct working groups. The founder also recognized himself as the "de facto leader," often serving as an obligatory point in which many decisions passed.

Those in authoritative roles likewise recognized themselves in this hidden structure, sometimes critiquing it: "I don't want to be the only one making decisions," one participant voiced in a meeting while discussing project long-term plans. The scientific leader shared similar cautionary observations:

> The whole power dynamic, how people interact, the thing sometimes I think about is how it could be that somebody took over too much on a project… when they are speaking with authority for everybody. *And this kind of stuff can happen even if you don't necessarily understand it's happening.* … When I speak, because I have this title of PhD and it seems that I know what I'm talking about, people say you should know what he's

> talking about. But then, the issue with that for me, the fact that *there is no balance, and I am the only one doing stuff and I am not challenged*. (emphasis added)

Here he reflects on both his own position of influence in the project and points out an important driver of this: the fact that he holds a PhD and people imbue this credential with social and scientific legitimacy. While group members began to unveil the not-so-hidden structure and critique it, they also wrestled with how to organize differently and the complexity of doing so. He goes on to note "I have no idea how I can fix that and if it can be fixed. … It's complicated." The formation of a formal governance structure, including parameters around which decisions could be made by whom, offered the potential to alleviate these issues; however, new challenges also surfaced. First, the new board composition reflected much of the hidden structure of those in positions of authority and even exacerbated inequalities in leadership: The new board reflected wider scientific and societal hierarchies with all white, highly educated men filling positions of power; none of the women who previously held informal leadership roles were on the new board. A special meeting was planned to select additional board members, but no qualified candidates applied.

Second, there was limited engagement to do the arduous work of thinking through power sharing mechanisms and ways to structure decision-making authority, leaving it almost exclusively to the founder. Participants attended focused meetings on and supported the idea of governance, especially to enact the goal for diabetic and worker control. However, there was little action to translate complex ideas into bylaws and collaborative agreements. As the founder expressed to me: "I've actually gotten very little feedback. … I posted these documents in the group and they're all there, but I don't think a lot of people have really read them carefully." Additionally, there was a dearth of governance precedents to bring together traditionally distinct

aims – co-operative owned, open source, and biomedical nonprofit – resulting in an especially time-intensive process to create documents. Finally, a key goal of the new structure allotted a proportion of board seats for people who use insulin, offering a mechanism to confer control by constituents most impacted. To my knowledge, there has been no recruitment to fulfill this objective, and only one person with diabetes, the founder and board president, is represented.

Mission

My analysis identified the mission as a social process that was regularly debated and constructed. Participants grappled with the project's objectives and strategies for how to reach their stated goals. Embedded in these negotiations about what the mission was, and was not, were values (e.g., individualism versus collectivism). The organizational approaches structured who was 'in the room' and who was 'at the table,' granting those in decision-making positions influence over tasks and the direction of the organization, effectively allowing them to express their values.

A key concern among project members was that of mission creep, when objectives change or expand beyond the organization's original scope. Several participants voiced concern that Open Insulin would fall back into practices of corporatization (e.g., proprietary- and profit-driven) or be coopted by corporate interests. As one interviewee stated bluntly: "The biggest problem will be to become too corporate. And we have seen a lot of diabetic organizations starting as very grassroots and just moving towards a lot of centralized structure, or just being bought out… So for me that's the main preoccupation, to keep the mission straight." She goes on to identify "open source" and "keeping the patient at the center" as key elements of the mission. Another participant expressed frustration that venture capitalist (VC) funding continued to be

suggested during meetings: “We don’t say to somebody who is new, this is the value we carry, and we don’t really challenge, necessarily, what people are suggesting… [Like] when people say, ‘should we take money from VCs,’ [it’s like] let’s just put it under a rug and not talk about it.” For him, VC money did not align with the values of Open Insulin, yet he found the informal decision-making approach led to indecisiveness and was inadequate to enforce this view.

The ambiguity in objectives manifested tensions as the project confronted how to move from the laboratory to manufacturing. In 2020, a working group dedicated to regulations and safety arose, primarily driven by professionals with biotech and pharmaceutical industry backgrounds. The group identified contract manufacturing organizations (CMOs) as “the most feasible” way to interact with federal regulations and to safely produce insulin (Fieldnotes 2020 and 2021). Open Insulin successfully secured an initial partnership with a CMO, and volunteers spent countless hours wading through challenging technical details to move forward. Many participants viewed this work as falling within the mission, citing this as a “promising option;” however, one interviewee questioned this logic:

> We weren’t really ready to pursue anything like manufacturing. … Without the organization in place and without the consistent labor and resources and all that behind it, it’s just difficult to do. And so we were able to make a connection with a CMO and start to think about manufacturing, but *manufacturing itself, at that time, informally at least, was outside of the scope of the organization*. (emphasis added)

This statement highlights both incongruent understandings of what was in and out of the project’s scope, and also elastic interpretations based on formal and informal articulations.

Another longtime member commented during a meeting on the sudden shift toward CMOs, saying “we’ve only been talking about this [CMOs], really, for about six months.” This,

along with the rapidly expanding volunteer-base, prompted her to suggest they consider whether to be "mission-driven," and prioritize making and distributing insulin by focusing resources toward this end, or "remain educational." In other words, she surfaced two objectives that she viewed in conflict: making insulin, which prioritized expertise and efficacy, and open science, which prioritized time for training and collaboration. Participants pushed back suggesting they could do both; however, limited resources were recognized as a major barrier. Another interviewee and biotech professional suggested such a mission shift was imperative if they were to become more than "a group of disrupters." While others viewed pharma experts in leadership roles more critically, fearing they would (re)shape the mission in compromising ways, she saw this as essential to achieve the aim of making safe insulin. Embedded in these negotiations were issues about the mission but also implications for membership and decision-making authority (e.g., through the prioritization of industry experts over other groups).

Discussion

This paper examines the internal governance practices of the biomedical citizen science project Open Insulin between 2018 to 2021. It describes their initial informal structure derived from horizontal frameworks and traces the shift to a formal organization with a board of directors. I identify mutually constitutive themes that emerged, which acted as sites of change and shaped how internal governance was enacted. These include membership and mechanisms of inclusion and exclusion; leadership and decision-making structures; and the mission as a social process, where objectives and strategies were regularly negotiated. Findings illustrate benefits of an informal and open structure, such as facilitating participation in science through low barriers

to entry, as well as present challenges participants grappled with, including questions of when, how, and by whom decisions were made and the resulting implications.

Participants perceived advantages and disadvantages of different forms of internal governance. On the one hand, horizontal, self-directed approaches facilitated goals of attracting volunteers and expanding membership, thus broadening access to science. On the other hand, a hidden structure of members with more authority and influence emerged that threatened the goals of power sharing inherent in the horizontal model. Those that held scientific degrees (e.g., PhD) tended to have more power, much like broader society, as participants imported logics of legitimacy and deferred scientific and other decisions to these members. Results also revealed that as pharmaceutical and biotech industry experts assumed a larger role, they ultimately directed the project toward prevailing ways of producing medicines through contract manufacturers, which some viewed as misaligned with earlier interpretations of the mission. Nearly all consequential decisions were, in practice, made by a small group of people. This was veiled under the pretense of horizontal decision-making and thus unable to be reconciled. In other words, there was no mechanism through which to ensure this form of power sharing was enacted. Additionally, lack of clarity around when and how a decision was made, and when it was binding, led to floundered attempts to implement changes in the informal structure.

It was hoped that the formation of a formal governance structure would alleviate many issues. There are promising elements such as designated board seats for people with diabetes to ensure constituent-based power by those who use insulin. Still, new challenges surfaced. First, during the process of developing a new approach, a dearth of governance precedents to carry out simultaneous aims for a co-operative owned, open source, biomedical nonprofit resulted in a time-intensive process for formulating governance that balanced these. Attempts by the founder

to establish more egalitarian processes were stymied by a lack of involvement and feedback from others on how to translate complex mechanisms for power sharing into documented procedures. The process for developing governance thus lacked deep collaboration, potentially undermining its impact through lack of buy-in. Second, following the implementation of the new structure, women who previously occupied informal authoritative roles were not retained in leadership positions. It is unclear why, although one female member shared that the shift away from meetings and toward online communication played a role.

Finally, the new structure runs the risk of prioritizing scientific and expert authority over other forms of knowledge expertise through definitional constructions of "mission-centric" activities that are tied to membership and power. Technical scientific work offers a clear path to membership with decision-making authority. Certain other forms of contribution, however, were conceived as less legitimate (important, maybe, but not so important to confer decision-making power) – for example, the careful and challenging work to attend to the social, moral, economic, and political ecosystem surrounding technology and innovation. Thus, the way decision-making authority was delineated did not inherently support a mechanism that centers critical values, for example, critiques of neoliberalism and re-evaluation of practices to counter harmful norms in biomedicine. In reacting to the issue of mission creep and corporate capture, the project stands vulnerable to another trap: prioritization of expert authority.

Ikemoto (2017) contends that DIYbio reflects norms of institutional science, in part because they have not clarified their position on values and norms, and thus fall back into a similar ethos and practices. I argue one mechanism to address this is through increased attention to internal governance, including interrelated aspects of membership, decision-making authority, and mission. Not being intentional about creating a different way of doing science, including the

organizational infrastructure to structure decisions and relations, poses a threat to the mission to reimagine the process of scientific knowledge production. Invoking a horizontal structure suggests the project values power sharing. Yet, as findings underscore, unequal power and decision-making inadvertently happened but were obfuscated and concealed.

Additionally, I suggest that biomedical citizen science projects are more at risk of falling back into similar problematic practices found in scientific institutions because they inherently rely on expertise. Expertise is needed not only to bioengineer insulin but also to navigate complex regulatory systems and patent regimes. Expert knowledge potentially undermines the creation of new norms and practices by importing particular logics from biomedical intuitions that reflect the status quo. There is also the risk of reflecting the larger scientific order through this prioritization – all white men leading and making decisions, as is the case currently – and consequently importing logics that emanate from positions of privilege in society.

Biomedical citizen projects that seek to challenge and reconstitute the biopolitical economy through more emancipatory practices must attend to and construct infrastructure that will allow them to do this. This extends beyond the physical space and laboratory equipment to carry out the scientific aspects and into organizational infrastructure, including explicating values and how to operationalize those values. Thoughtful governance to actualize values such as power sharing can be tricky to construct, negotiate, and put into practice. Yet, failing to do so risks reproducing problematic structures and norms many biomedical citizen scientists strive to avoid.

Limitations

There are many citizen science projects seeded in community labs that do not define themselves outside typical scientific organizational structures (Erikainen 2022). In fact, many

position themselves as champions of and places for start-ups to get their start. The extent to which Open Insulin reflects other groups in the biomedical citizen science space is unclear, and thus may affect governance approaches.

CHAPTER 3 REFERENCES

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CHAPTER 4: "Making Insulin is the Easy Part": Obstacles in the Making of a Community-based Drug

"Making insulin [in the lab] is the easy part. It's everything that comes after that's hard."
– NIH Assistant Director visiting Counter Culture Labs in 2019

Introduction

The high cost of prescription drugs is a persistent problem in modern society. This reality is particularly acute in the United States where pharmaceutical companies wield enormous political power that enables them vast control over the price of drugs. Despite ongoing efforts to rein in and reform this system, medicine access remains a significant issue. One of the challenges facing collective action to reimagine the pharmaceutical system is the technical complexity involved in making drugs. This is not to say that a complex system necessitates high drug prices, as pharmaceutical companies sometimes argue to rationalize blatant corporate greed; nonetheless, there is a real challenge to the layperson wanting to make a safe and legal drug. A layperson could make a chemical or biological molecule that is the basis for a drug with the right equipment and instructions. Yet, to make this into a safe and legal drug, the molecule must be transformed through a sociotechnical process regulated by the state. In the US, the Food and Drugs Administration (FDA) defines what makes a "safe and effective" drug, acting as powerful gatekeepers in balancing the protection of pharmaceutical users and facilitating access to medicines (Carpenter 2010). Thus, while the molecule insulin could be, and now has been, produced in a community biology lab, that insulin has yet to undergo the sociotechnical transformation into a "safe and legal," and thereby distributable and usable, drug.

In the previous chapter, I showed how Open Insulin's mission and goals were sometimes ambiguous and open to interpretation. Here, I examine specific but divergent takes on the project's objectives, including different perceptions of how to enact social change embedded

within them. In this chapter, I ask: Why don't we have pharmaceutical cooperatives or other community-based organizations, like we have for other resources or goods? What are the barriers impeding such a collective from successfully producing and bringing a drug like insulin to people? In other words, what is it *specifically* that makes this otherwise appealing idea for the equitable distribution of goods a major – and seemingly insurmountable – challenge for medicines? Through an examination of an organization seeking to do just that, I identify three interrelated barriers: regulatory regimes that govern drugs, infrastructure (including facilities, equipment, and experts to operate these), and internal contestation about the vision for how to make affordable insulin in an industry rooted in contemporary capitalist logics (Quet 2018).

Open Insulin and the broader community biology lab movement emerged during a period marked by a rise in the corporatization of science and biomedicine, what some have called "academic capitalism," in which the boundaries between private companies and academic science have blurred (Clark, Pergamon, and Clark 2001; Hoffman 2017). Market orientations increasingly shape research agendas, academic partnerships with industry are viewed favorably, and academic scientists are encouraged to commercialize scientific innovations through patents and start-up companies (Hoffman 2021; Jeske 2022; Kleinman 2003; Popp Berman 2012). Scholars have raised concerns over the influence of corporate interests in the goals and direction of scientific research, exploitation of scientists and loss of autonomy, financial conflicts of interest, and the loss of scientific credibility that rests ostensibly on impartiality (Eisenberg 1987; Fox 1981; Johnson 2017; Kleinman and Vallas 2001). Biomedical institutions have also been transformed by corporatization, in which private, profit-based entities overtake previously social, state-run, or other organizational forms (Clarke et al. 2003). For instance, healthcare centers such as community clinics give way to HMOs, and medical research increasingly channels public

research funds toward discoveries that are then privatized. Some have argued that processes of privatization, especially as they merge with processes of capitalization, skew biomedical research toward addressing health problems in wealthy countries (Silverstein 1999; see also Chapter 2 of this dissertation). In one study, researchers compared drugs in the pharmaceutical pipeline and found that the number of drugs targeting diseases in high-income countries was 3.46 times that of drugs for diseases in predominantly low-income countries (Fisher, Cottingham, and Kalbaugh 2015). Others have made similar claims that financial markets are redefining and *revaluing* health, particularly in the area of pharmaceuticals (Dumit 2012; Gaudillière 2021; Roy 2023).

In his study of Open Insulin, Murray (Murray 2020: 32) describes the project's effort as "anti-biocapitalist," defined as "an opposition to the capitalization of health and medicine." On the one hand, this concept is practical in that it reflects select Open Insulin members' own discourse around wanting to organize in an "anti-capitalist" manner. The concept is also useful in attempting to situate the aims of Open Insulin in contradistinction to literature that theorizes the expanding, changing, and threatening phenomenon in which biotechnology and capitalism are becoming further entwined (Clarke et al. 2010; Cooper 2008; Jasanoff 2004; Sunder Rajan 2006).[13] Indeed, biotechnology and particularly pharmaceuticals are often situated in hegemonic corporate governance regimes that enable capitalization processes in health.

But on the other hand, "anti-biocapitalist" supposes a kind of unidimensional process – one is either advancing the capitalization of biotechnologies or going against it. This approach

[13] Other scholars have offered thought-provoking examples of collective action to counter the capitalization of health. Michelle Murphy (2012) in *Seizing the Means of Reproduction* describes the women's health movement as an example of technoscientific counter conduct, in which women critically took up health technologies and created alternative feminist practices. Alondra Nelson's (2011) writing on the Black Panther Party's sickle cell screening and free community health clinics also offers evidence of grassroots sociotechnical interventions in capitalist healthcare.

supposes one viewpoint of capitalism: that it is a tightly integrated system with powerful internal logics. In this view, if countermovements fail to contest those logics systematically, they are doomed to end up making small incremental reforms that have no impact on the system as a whole. However, processes of capitalization – as well as efforts to organize against capitalization – are both enabled and constrained within different contexts, often happening simultaneously, and significantly shaped by regulatory regimes which also change across locations and time (Aglietta 2001; Gaudillière and Sunder Rajan 2021). In this view, capitalism can be seen as an internally contradictory system that is patched together with various fixes that can be effectively challenged, or at least tempered, with broad enough support. Wright (2019) suggests that combining efforts that variously seek to tame, escape, resist, or dismantle capitalism could ultimately create a different order. Implicit in Wright's account is that all efforts to build counter-organizations will involve compromises with capitalism. Cooperative enterprises, for instance, still have to sell their products. Unions have to enforce the contracts they negotiate. However, the argument is that if the territory of capitalist profit-making can be shrunk, movement actors can weaken the system and have more space for building alternatives.[14]

These two views of capitalism and approaches to counter-organizing offer a point of departure for this chapter. Drawing on ethnographic observations and interviews with Open Insulin members, I reveal and unpack competing ideas about the vision and organizational approach to make affordable insulin – that is, how to organize alternatives in response to monopoly capitalism underpinning the insulin crisis in the US. I first provide a brief overview of "typical" drug development and manufacturing, focusing on regulations. This offers insights into how Open Insulin constructed alternative imaginaries for making insulin. Second, I focus on two

[14] I thank Fred Block for helping me understand these different views of capitalism and, consequently, how to think about different approaches to "anti-capitalist" practices.

imaginaries actors organized around, one that utilized pre-established infrastructure for making drugs and another that envisioned new forms of infrastructure and oversight. Finally, I surface participant values and attitudes toward working with scientific institutions, and particularly pharmaceutical industry actors, with some wanting to act in more "independent" ways and others who viewed working with industry experts as inextricably linked to producing a safe medicine. I suggest that the tensions and tradeoffs observed in Open Insulin not only offer important insights into the barriers that stymie organizing egalitarian alternatives to monopoly capitalism in pharma, but they also help us to think about different orientations to social change, such as the merits of experts versus non-experts in leading these alternatives.

Much of the data presented here draws from observations over the course of several years. Because of this, I have opted to present this chapter as a traditional dissertation chapter, rather than a standalone empirical article, using more narrative and chronological form to highlight the messy, often uncertain nature of organizing for social change in this initiative. During my fieldwork, Open Insulin remained at the stage of making a molecule, not yet reaching the point of interacting with state regulators. As such, findings below tack back and forth between Open Insulin's speculative vision for an alternative, more egalitarian way to produce medicines, and their on-the-ground realities of working to meet material needs, moving through organizational changes, and acting to produce the necessary scientific knowledge to make insulin but also the regulatory and legal knowledge involved in making medicines.

The Regulated Making of Pharmaceuticals

"You have to build the whole system around quality. You can't have the Open Insulin name associated with a renegade that goes awry and harms or kills someone."
– Open Insulin volunteer

In order to analyze collective action to reimagine the making and distributing of drugs, it is useful to have a basic foundation of how drugs are "typically" developed and approved for manufacturing. Briefly, the drug development and approval process involves: identification of a drug compound (e.g., insulin glargine); preclinical in vitro lab tests and animal testing; three phases of clinical trials that build from 20-80 research subjects to hundreds or thousands; drug labeling reviews; a comprehensive review of all nonclinical and clinical data and analyses through a drug application process; facility inspections; and ongoing "post-marketing" monitoring that ensures drugs that are approved and on the market continue to meet safety standards. Figures 4.1 and 4.2 provide additional details on the major components of drug approval and safety regulations.

Generics – or in the case of insulin, biosimilars (the generic equivalent for biologic drugs) – may go through an abbreviated regulatory pathway, still requiring preclinical testing and approved facilities to assess the drug's safety and efficacy. Importantly, oversight is constructed through rigorous standards and procedures. For instance, "good laboratory practices" govern preclinical laboratory studies and set measurable requirements for facilities, equipment, personnel, operating procedures, written protocols, and reports. Meanwhile, "good manufacturing practices" (GMP) act as another set of quality standards that govern manufacturing practices. This includes "strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories" (FDA 2021).

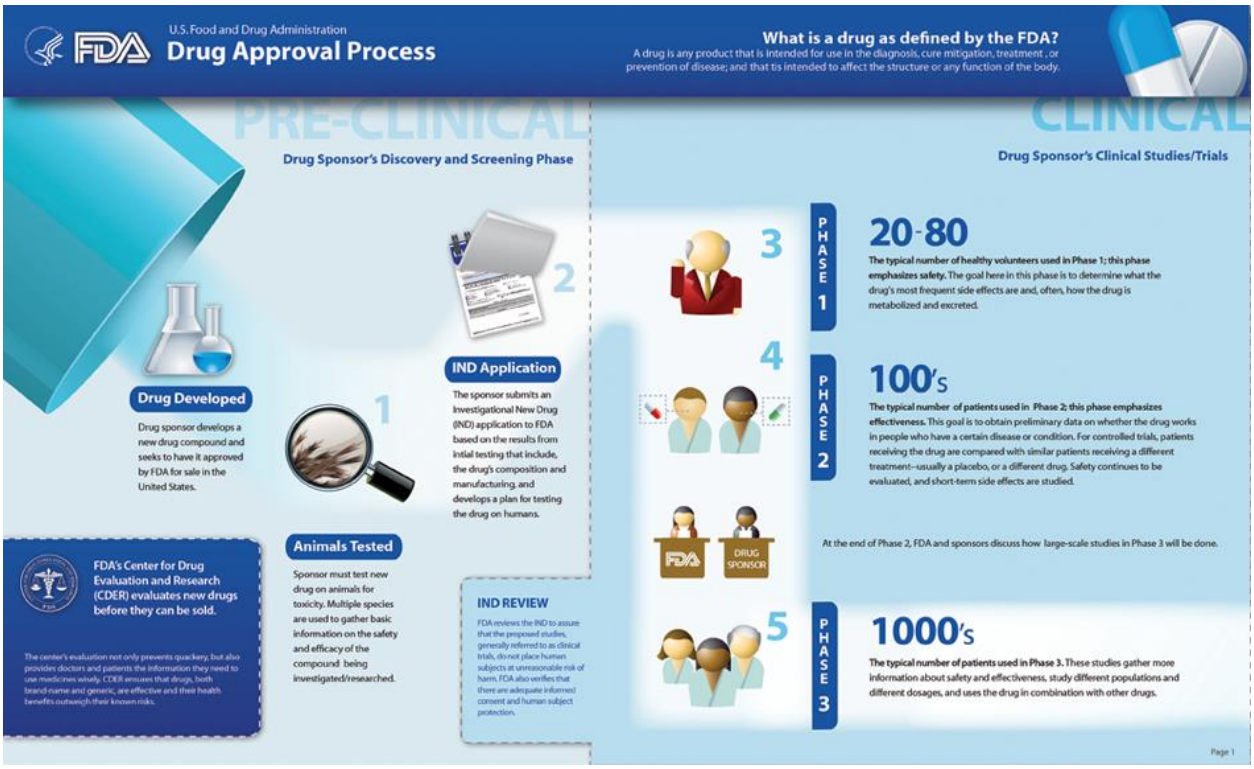

Figure 4.1. Overview of the FDA's drug approval process (1 of 2).

FDA. 2019. "FDA Drug Approval Process Infographic." *FDA*. (https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fda-drug-approval-process-infographic-horizontal).

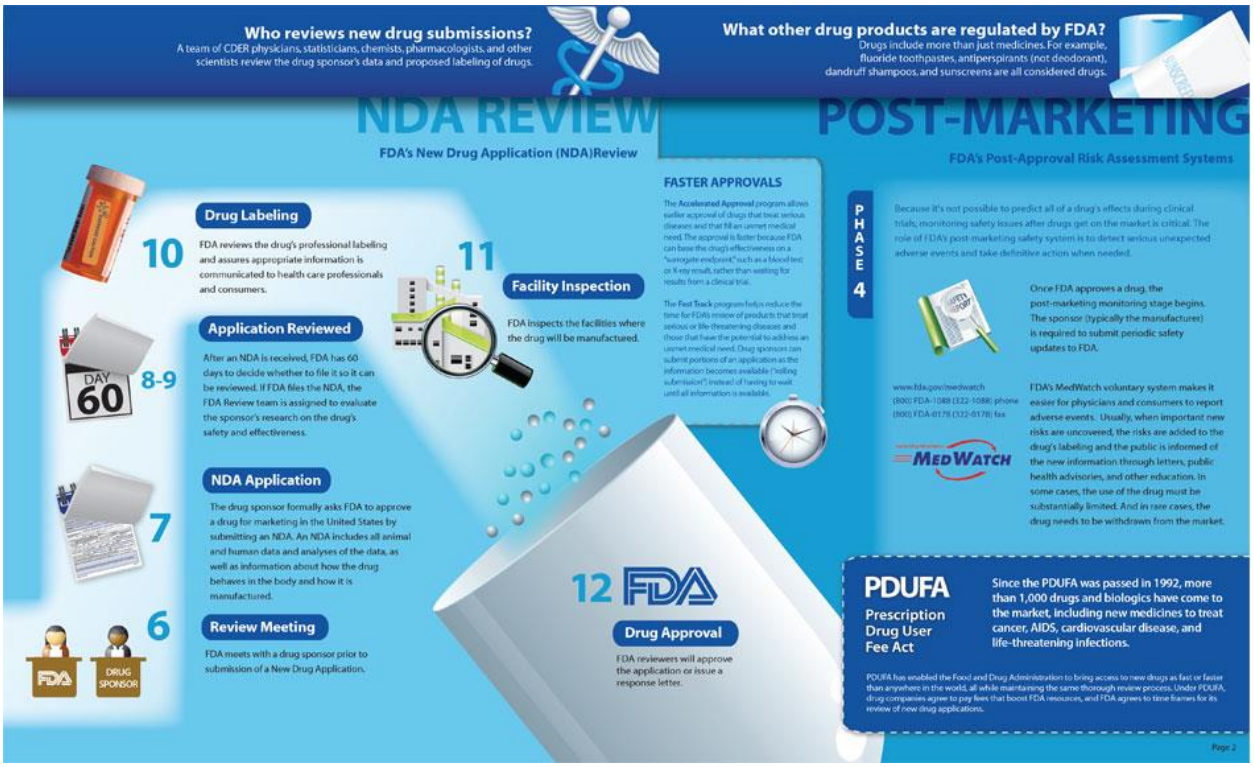

Figure 4.2: Overview of the FDA's drug approval process (2 of 2).

In short, FDA regulations necessitate infrastructure – material equipment and facilities as well as specific expertise and systemized ways of operating. Larger pharmaceutical companies may organize all of this in-house; for smaller pharma and biotechnology companies, it is common to contract out one or more segments to companies with these specific infrastructures (Fisher 2008). For instance, contract research organizations run preclinical research and clinical trials; contract manufacturing organizations (CMO) have FDA-approved manufacturing facilities to make a drug; and contract development and manufacturing organizations (CDMO) offer a full range of services from research through manufacturing.

Of course, the construction of the FDA itself should be approached critically. Scholars have demonstrated the enormous regulatory power the FDA worked to secure over several decades (Carpenter 2010). Problems in oversight over pharmaceuticals' quality have led to numerous harmful drugs. At the same time, the gatekeeping of novel therapies can also result in patient suffering and death, an issue brought to the fore with the COVID-19 pandemic. Scholars have further shown how the FDA embeds social, cultural, and political values into decisions around granting or restricting access to medicines, despite supposing that the drug vetting process is otherwise a technical and objective one (Layne 1984; Wynn and Trussell 2006). With that said, the collective action examined in this chapter does not include advocating for changes to the institution itself nor specific rules and regulations created by the FDA. Rather, Open Insulin actors worked to understand the FDA's processes and build a strategy for how to progress through them (or circumvent them), which I turn to next.

Technical Complexities: Contract Manufacturing Versus "Community Manufacturing"

Open Insulin was founded on the broad vision to make affordable insulin. But more than that, founding members envisioned creating an alternative model for the manufacture and distribution of insulin at a small-scale, through cooperatives that could be owned and operated by people with diabetes and workers of the facility. For instance, a local diabetes advocacy organization might also have the means to produce and provide insulin to its constituents.

This "community manufacturing" vision led members to then contemplate and propose strategies around what this community alternative would actually look like – how could this be done? Much of this speculation centered on safety and regulations. For instance, members explored working within an established FDA process for compounded drugs, in which some hospitals, clinics, and pharmacies are allowed to make select drugs for patients on site. Open Insulin determined this path would not cover an already approved medicine like insulin. Another route members considered was to follow precedents laid by the marijuana industry, which effectively formed patient cooperatives to sell medical marijuana despite its questionable legal status. This route, however, did not address concerns around facilities and quality assurance measures, a concern potentially more serious for insulin as an injectable drug than for marijuana. Finally, there was speculation about advocating for the creation of a state counterpart to the FDA that would oversee the localized production of insulin, and potentially other drugs, using intrastate materials. This would circumvent the FDA's oversight which is limited to interstate food and drug commerce. Participants reasoned that such state regulators might provide more narrow oversight – and potentially be more accessible for community-based organizations – to ensure the safety of the drug. Zettler (2017) describes a recent surge in interest by states to regulate pharmaceuticals at the state level; however, these efforts have been limited, with some

being struck down in court, and none extending to the categories of drugs like insulin that have been long regulated by the FDA.

My goal in describing these speculative imaginaries is not to assess their viability; rather, it is to show that "community manufacturing" was an alternative vision to a corporatized commercialization path, and it was this vision that many Open Insulin members viewed as their core organizing mission and the appropriate focus of their time and resources. Yet, community labs did not offer the sterile environment that drugs are typically made in, that is, an FDA-approved facility that followed good manufacturing practice (GMP) standards mandated by the FDA. In fact, the community biology lab, as one participant put it bluntly, "was about the furthest thing from a GMP facility." FDA regulations and GMP require expertise through the construction of standards for policies, protocols, nomenclature, and equipment to measure and enforce the quality and safety of pharmaceuticals – and Open Insulin's inability to demonstrate meeting these standards in their current laboratory space became a widely shared matter of concern. For example, in a 2019 article in *Medium* that profiled Open Insulin, a University of Washington diabetes expert was quoted saying, "Given the fact that companies that do this for a living have trouble meeting the bar for the FDA, I find it hard to believe that someone can do this in their garage or their bathtub. … It's concerning that someone would inject this into their body" (Smith 2019). His concerns reflected others who similarly constructed the project's narrative as "bathtub insulin," – insulin made in environments not conducive to sanitary standards for making pharmaceuticals, such as in do-it-yourself (DIY) labs. As a result, discourses of safety, risk, and infrastructure were often an area of focus for members of the project.

In order to attend to safety concerns and build out a longer-term strategy, members perceived the creation of a focused group to identify and understand regulations as a priority. The COVID-19 pandemic led to the creation of a summer internship program in 2020 to help students who had lost internship opportunities elsewhere. Four high school and college student interns created the "Safety and Regulations" working group, led by a volunteer with biotech industry experience who had recently joined to assist with laboratory experiments before pivoting when the lab temporarily closed under COVID. Their self-defined charge was to understand how to comply with complex and regularly changing safety and regulatory standards. As the group lead told me:

> Making pharmaceutical drugs is really expensive and really hard. … I think that people had a very naive sense that it would be like, 'Oh, once we have the strains, it'll be easy.' And I'm like, 'Oh man, you guys have no idea.' I had the interns basically find a lot of laws and regulations that we would have to apply to.

At the end of their summer program, the interns crafted a detailed presentation describing regulatory requirements drawing from the Biologics Price Competition and Innovation Act of 2009 – the law that created an FDA pathway for biosimilars. Despite actively searching for parts of the regulatory process that could be "circumvented" (e.g., comparative clinical immunogenicity data), as well as "unconventional" and "affordable" approaches to potentially take to gain safety approval, in the end, they recommended looking to contract manufacturing organizations (CMOs) to develop insulin into a medical-grade drug that could be safely injected into people.

The working group continued after the internship program ended, eventually producing a detailed strategy for working with a CMO which subsequently was used as a key component of a

grant application, and in so doing, the CMO came to take on greater significance as a competing imaginary for what Open Insulin's overall objective should be. In 2020, Open Insulin worked to apply for a grant through a private foundation (I will refer to them as "the Foundation"). This was the largest and one of only a few grants Open Insulin had sought, as previously, the majority of their funds came from crowdsourcing campaigns and private donations. The Foundation funds nonprofits and businesses that offer social and economic benefits for a US-based city in which the Foundation resides and includes an area of emphasis in health and human services, making Open Insulin a good fit. The grant would fund a partnership between Open Insulin and the local community lab to purchase needed laboratory equipment and provide a stipend for the lead scientist to continue making headway toward bioengineering insulin. While the project may have survived without this grant, the lack of funding was a major barrier to making progress. For instance, individual pipetting by a handful of part-time volunteers was less efficient than an automated pipetting machine found in many well-resourced labs, while broken laboratory equipment slowed, and at times stopped, key experiments from being carried out. The grant application was driven by a particularly ambitious volunteer who spearheaded the grant writing effort and was able to organize and motivate others to contribute many hours to the grant application's development.

The original grant application focused on the upstream research strategy for bioengineering insulin in the lab, including needed equipment and paid scientists to support the work, and requested funds toward that end. However, during the review process, grant reviewers requested documentation of Open Insulin's downstream strategy for FDA approval and the manufacturing of insulin. Open Insulin had numerous calls with grant reviewers over the ensuing months. As the Foundation does not typically fund pharmaceutical work, they sought outside

regulatory experts to review the application for feasibility and also requested Open Insulin consult with these experts. The Foundation was expected to make a determination at their September board meeting but delayed the decision to "do more due diligence." The following observational fieldnotes of an Open Insulin internal meeting describe this process:

> The weekly meeting begins with Blain reading from an email from the Foundation: "They [the staff reviewers] are concerned with whether you can make safe and effective insulin and the cost of getting FDA approval. That is why we have solicited the opinion of two experts." Group members decide to use today's meeting to prepare for another call, this time with an FDA consultant who the Foundation has requested Open Insulin meet with. Blain states "We need a cohesive, high-conviction proposal for how we're going to pursue this pathway," referring to the FDA's new process for approving biosimilar drugs. Another member, Jaz, suggests they can submit documentation that the pathway does in fact exist but notes "The second part, how to make safe and effective insulin, is harder to prove. We can say we'll follow GMP and FDA [standards], but to the extent that we can actually prove that?" A new member suggests steering away from the end result of biosimiliarity, because it's a "huge beast." Ellis, a founding member, responds they did in fact avoid this in the original application and focused on the lab work, leaving out anything about "medical grade insulin or distributing to patients." He notes, however, that reviewers "immediately" began asking what the end goal looked like, including an estimated timeline showing significant milestones (e.g., Phase 1 and 2 clinical trials) and expenses for gaining FDA approval. Open Insulin then put together an appendix to address this, which Ellis states "they've been single-mindedly focused on."

Reviewers pressed them to revise their application and narrate a "feasible" strategy to make "safe and effective" insulin, placing more emphasis on the speculative future of manufacturing to fill in perceived "gaps" in the application. This meant articulating a recognizable narrative for moving beyond upstream processes of research toward downstream regulatory requirements, manufacturing, and associated costs. Open Insulin used and refined the Safety and Regulatory working group's research on CMOs. They offered two paths: the unprecedented and still vague "community manufacturing" path, and the CMO path, which was indicated as an "alternative" and "less ideal" approach. The following month, after speaking with the two industry and regulatory experts identified by the funders, Open Insulin received feedback that their timeline and funding "projections were off," which sparked concerns by the funding agency about "credibility." Open Insulin members worked to draft a response. In January, six months after submitting the application and expending substantial effort on the application and review process, the Foundation requested they submit evidence of an example CMO they would partner with. Thus, to be competitive for the grant, and for their application to be legitimized as "credible" from the granters' and accompanying outside experts' perspective, Open Insulin had to articulate their work in terms recognizable to reviewers. This translated to working within current infrastructures for making medicines through the traditional manufacturing mechanism of CMOs.

Conflicting Visions for Social Change

In this section, I further unpack the two paths for making insulin described above by discussing two critical perspectives that animated and drove actors toward particular organizing strategies for affordable insulin. One perspective focused on relations with experts: some viewed

the participation of experts as potentially undermining more transformative goals for diabetic- and worker-owned cooperatives; others viewed experts' participation and leadership as central to successfully producing insulin. Relatedly, the second perspective drew on ideas around "autonomy," in which select actors viewed separation from the entanglements of scientific institutions and capitalist structures and logics as an important place to organize from.

Perceptions of Pharmaceutical Experts' Participation and the Benefits and Limitations

In the months leading up to and following the Foundation grant, the organizational makeup of the Open Insulin shifted with more industry experts with backgrounds in biotech and pharma regulation, safety, and quality assurance volunteering. These new members joined the newly established Safety and Regulatory working group and helped fill the need for researching and documenting the requirements and protocols of traditional drug development, manufacturing, and oversight. Open Insulin wanted to understand these processes in order to determine their own strategy for making safe insulin, yet up to this point, this research had mostly been done by lay volunteers, which was slow and challenging in terms of uncertainty about regulations that may and may not apply to them.

Some Open Insulin members saw the grant as a means for working toward a "true north star," as one participant articulated, reducing the future uncertainty that loomed over the project and being able to organize around concrete tasks with previously laid precedents they could look to. For these members, the involvement of industry professionals was a welcome change. As one member, Ash, described with enthusiasm:

> We've been lucky to attract a lot of now quality and regulatory people into the organization who can then actually speak with authority on these things. The people who are showing up and sticking around are now becoming more regulatory professionals and

> less, you know, biohackers. … One of the things that's fascinating to me about this project is how do you get a bunch of basically anarchist, counterculture revolutionaries to go through FDA, right? How do you get them to comply with FDA regulations? I think it's going to become even more apparent that a lot of the people who joined in the very beginning might start to feel really alienated as we become a much more *structured, rule-bound kind of way of operating*. … We're already in a sea change, as we're transitioning from a very open community-based project to, as Elba calls it, a "mission-driven organization." … But *if we actually want to make a drug and get it to people, I don't think there's any way we can continue in the same way we are and expect to be successful*. … We kind of went through a bit of a shift and started attracting people who I think were super useful, industry experts, some of these people who show up and say, "No, I'm a professional at this. Here's how we can do this." (emphasis added)

Prior to the grant, it was not unusual for industry folks to drop into meetings, but importantly, because the project's objectives were increasingly articulated in terms reflective of typical industry processes through CMOs, more of these folks were "sticking around." This in turn drove research and knowledge production efforts on regulation and manufacturing that furthered the CMO path. For instance, industry experts with the help of other volunteers identified potential CMOs and CDMOs to work with and recommended one to pursue; they drafted and edited a document to facilitate communication with the identified CMO; and finally, they participated in conversations and partnership planning with the CMO.

Other members, in contrast, believed this shift was too much of a compromise on what their vision of Open Insulin ought to be about. As one participant reflected:

> Whenever we look to get resources from these outside sources, they all have their own agendas and their own ways of doing things. And often it *involves not focusing on what we need to focus on to get access to those resources*. Like the Foundation was a fairly minor instance of this. … We were really fortunate that there just happened to be one [a CMO] in the area. … But even having to do enough research on how that might look in the future to constitute a good faith effort, that spread us thin. (emphasis added)

To respond adequately to funders' requests, project members spent considerable effort and time (a key resource for the almost fully volunteer-based group) to understand and articulate traditional industry standards and practices. The same member goes on to describe the particular challenge the project faced: "We didn't have the resources to really develop our own core position in a strong, rigorous way. So all kinds of gaps just started getting filled in with presumptions around how things work in the status quo."

A founding member of Open Insulin viewed the shift in the organizational makeup in a similarly critical way:

> A lot of people coming from the commercial pharma economy who were just kind of like in the mindset of, "Well, this is just how it works. And this is what I spent my career doing. And this is what you're gonna have to do." And like immediately we kind of lost a lot of this more radical spirit of saying like, "Well, no, the people who are using the medicine are going to decide how things are going to be done and what the tradeoffs are." … A large point of this is to just challenge and reevaluate all of the conventional wisdom and see if it really serves the interests of the people using the medicine. That's really at the core of the project, and it was already starting to get seriously diluted by this idea that we just had to get to production in whatever seemed to be the most expedient way.

In these views, "the core position" and "spirit" of Open Insulin should be a "radical" commitment to community manufacturing, whereas "the presumptions" being inserted that distorted that vision assumed that this could not be done without the involvement of CMOs. Moreover, the founding member quoted above surfaces tensions around self-governance, including questioning who was driving decisions (i.e. industry folks rather than diabetics) and the implications on the organization's directions and goals. I turn to examine these themes of independence and autonomy next.

Perceptions of "Autonomy" as an Organizing Value

Social movement actors have regularly contended with whether to take reformist or non-reformist reforms. Non-reformist reforms offer a means to advance a logic of "what should be" rather than comporting with "capitalist needs, criteria, and rationales," and center on the "modification of the relations of power," and in particular "the creation of new centers of democratic power" (Gorz 1967: 7-8). (Ben-Moshe 2018: 348) aptly describes this distinction: "Reformist reforms are situated in the status quo, so that any changes are made within or against this existing framework. Non-reformist reforms imagine a different horizon and are not limited by a discussion of what is possible at present." Recent abolitionist movements against the prison industrial complex and criminalization offer a notable example of non-reformist reforms. Embedded in abolitionist frameworks are efforts at "reducing the scale, power, tools, and legitimacy" of a major epicenter of power, the carceral state, and "to build grassroots power … to fight criminalization and privatization as we organize for collective self-determination" (Akbar 2020: 101, 94). The complexity, which comes through in Open Insulin's context and their wanting to reorder power relations in the pharmaceutical industrial complex, is that the line

between reformist and non-reformist reform is not always clear, as well as there being substantial uncertainty around which reforms can be coopted by the system and which ones open up space for more contestation.

Indeed, a major theme that came up throughout my fieldwork with Open Insulin was participant desires to be "autonomous" or "independent" from mainstream scientific institutions (academic, private, and government labs). Of course, complete agency and self-governance from existing systems and conventional practices of science is impossible. Yet, in the spirit of non-reformist reform strategies to forge new centers of democratic power, one strategy some social movements undertake is "direct social action," not by making claims on the state or others in power, but through actions that "focus upon directly transforming some specific aspects of society by means of the very action itself" (Bosi and Zamponi 2015: 369). Scholars have shown a proliferation in direct social action through food cooperatives, repair cafes, DIY initiatives, alternative housing projects, and platforms for giving and borrowing goods (e.g., mutual aid organizations that became popularized during the COVID-19 pandemic) (Butzlaff and Deflorian 2021). For Open Insulin, this looked like producing a drug in a community biology lab and pursuing a route for community manufacturing.[15]

Open Insulin participants used discourses of autonomy as a kind of heuristic device to both critique aspects of scientific and economic systems undergirding access to medicines, and also to identify alternative imaginaries. In particular, participants viewed the community biology lab as playing a role in building more just alternatives for scientific knowledge production

[15] I have placed Open Insulin's work and aspirations alongside social movement literatures of grassroots organizing and direct social action. However, another important (and not mutually exclusive) placement of their work is within technolibertarian ideals. For Open Insulin, a group formed in the heart of Silicon Valley, the idea of envisioning social change through self-activated and self-governed forms, including less encroachment by the state, comports with the kind of technolibertarian culture common there.

compared to corporatized forms noted earlier. For many participants, these spaces offered a kind of buffer from particular incentive structures and logics (e.g., publishing or profit motives) found in mainstream institutions, and to potentially "think differently," as one participant put it, about the knowledge production goals and directions of science. One participant compared mainstream scientific institutions with the community lab, saying:

> What are the things that make a researcher or a research institution prestigious? It's usually because of some sort of award, accolade, something of merit usually that's related to money. And so what ends up happening is there's this idea that people are operating under the assumption of scarcity because there is something to be had. And so when that happens there is much less collaboration. Why would you share this award money or this recognition with somebody else? You want to be the first to discover, you want to be that person or the institution that is most cutting edge. So the difference is that ideally independent labs or in places like this, community labs, that's not our MO. I mean, granted, we're a non-profit and so there is a level of funding that we need to find to be sustainable. But at the same time, it doesn't have to be the most cutting edge. It could be a repeat of a method that we used 40 years ago, that is no longer in vogue because we have some other newfangled method to take its place. … Our aims are different; we're trying to democratize science, so we're not trying to provide the most prize winners. With that sort of out of the equation, you can just do science. … So, maintaining some level of independence is important to us.

Another member of Open Insulin stated: "The core of what makes this place different is the autonomy of the people who work here, and the autonomy of the organization. That is something that we are really committed to preserving." He further explained that profit motives

found in industry and universities were a key issue in addressing access to insulin. He and others in the group were particularly critical of monopoly capitalism that was at the core of unaffordable insulin in the US, and there was a skeptical sense that by interacting and partnering with individuals in industry, they might import harmful ideas from this system, potentially shifting or diluting their goals.

In these accounts, participants look to distinguish the community lab from conventional research institutions, focusing on perceived structural and cultural differences. This includes hierarchical award systems in mainstream institutions that tend to reward competition over collectivism (a point echoed in Chapter 2 among academic open pharma interviewees) and which are often connected to financial value. The concern over prestige as a scarce resource can also be extended to areas of publishing, with scientists competing for limited publication spots and authorship positions. Scholars have similarly identified this technoscientific orientation toward groundbreaking innovations as often sidestepping issues of access and equity (Parthasarathy 2022). For these participants, having some level of "independence" from these innovation logics allows them to explore other alternatives. In this case, Open Insulin looked to older methods and technologies to produce insulin with the goal of identifying a simple and affordable process for synthesizing insulin, as opposed to the most advanced method. Finally, these participants assert that one aim of community labs is to democratize science, reflecting Santos's (2021) claim that community biology labs offer spaces to redefine ideas about who can be a scientific actor, who can access scientific resources, and who can contribute to knowledge production in the development of biotechnologies. For many participants, there was a perception that by expanding access to technology to individuals outside of mainstream scientific spaces, this would lead to alternative end results – in this case, affordable insulin. Through this account, we see two central

aims: wanting autonomy *from* normative goals and logics of scientific institutions and wanting autonomy *for* alternative goals and values.

And yet, the perceived benefits of operating in community lab spaces were simultaneously met with their limitations. One member suggested an "overwhelming" sense of complexity, "so many layers," in moving from the community lab to safe, injectable insulin. This "transition point," as she described it, entails the implementation of GMP which includes "a rigorous set of requirements that everything from your facility design to your personnel training to how you keep your record." She went on to note that, beyond encountering sophisticated (and ongoing) regulations that require qualified personnel, there are also litigation risks by pharmaceutical companies, as well as the need for distribution strategies to ensure insulin actually reaches the populations they hoped to serve. In another meeting, one participant commented "I don't think people are going to hear 'community-made insulin' and come running to get some. Maybe some will, but a lot of people will be skeptical." As one industry expert stated in a meeting: "You have to build the whole system around quality. You can't have the Open Insulin name associated with a renegade that goes awry and harms or kills someone."

These excerpts illuminate a fundamental tension between Open Insulin as an unstructured community biology project that prioritized DIY work and education, and the pharmaceutical manufacturing and regulatory world that is "highly structured." Participants connected "mission-driven" work, meaning to produce insulin and get it to people, to the need for people with associated know-how – that is, industry professionals – who can help guide the group through this process. The transition to making insulin for human consumption also necessitates a shift toward more "rule-bound" practices to comply with regulations, where the same institutions that the project is critical of also make the rules. Of course, all of this takes *infrastructure* – facilities,

equipment, trained professionals with credentials and expertise, and so on – begging the question of how this will comport with aspirations around self-governance and "autonomy."

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Ultimately, the Foundation did award the grant to Open Insulin, supporting the upstream laboratory research that many desired and that initially motivated the application process. Additionally, Open Insulin had a series of meetings with the CMO they identified on the grant, leading to an initial partnership agreement. However, to my knowledge, this did not advance further than these discussions and agreement. By way of a recap, I share here a slide that was presented to the Open Insulin members, following external pressure to address plans for safety:

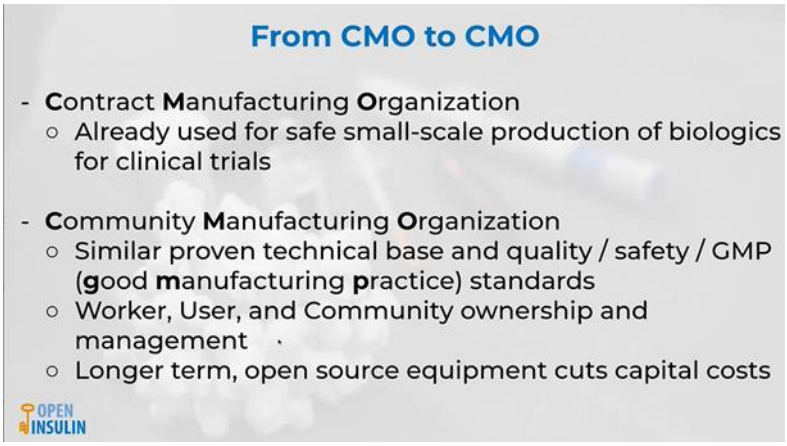

Figure 4.3: Open Insulin presentation slide showing two proposed manufacturing pathways.

The slide shows two manufacturing paths. The first is the pre-existing, commonly used route for making medicines through contract manufacturers. The second is the hypothetical but more transformative alternative model Open Insulin envisioned for "community manufacturing." In the events I described above, of course, the title of the slide did not (yet) come to pass: while one imaginary for alternative drug production envisioned a transition from contract to community

manufacturing, Open Insulin's activities related to the Foundation grant and increased involvement by industry experts added another shift, provisionally anyway, from community back to contract manufacturing. This, therefore, captures in a nutshell the divergent visions for social change that emerged in Open Insulin, and illustrates the twinned concerns about the appropriate role of expertise and differing desires for autonomy embedded within them.

Conclusion

This chapter examined tensions between Open Insulin's goals of producing and distributing insulin outside of traditional mechanisms for making, owning, and stewarding pharmaceuticals and their unavoidable position within political economic structures of science and pharmaceuticals. By tracing how Open Insulin navigated competing visions for social change – including by funders, industry experts, and project members – I show how drug safety and regulations, as a key juncture within the political economy of pharmaceuticals, create considerable friction for counter-organizations looking to resist processes of capitalization in drugs. For some members, the transformative aim to form pharmaceutical cooperatives was the priority; for others, organizing toward seemingly more achievable goals for producing safe insulin was prioritized and meant using a precedented route through contract manufacturers as a means to comply with complex regulatory protocols and technical infrastructure requirements.

In many ways, these observations reflect struggles that social movements and counter-organizing efforts regularly encounter. In the face of limited resources, do actors construct an alternative vision for more near-reach goals in hopes of having a greater chance at succeeding, often in the realm of reformist reforms? Or, do actors organize toward more "revolutionary" imaginaries and non-reformist reforms? For groups that were conceived in the latter, as Open

Insulin was, Doug McAdam (1999) describes a key tension: if a movement is to be sustained, a shift to more formal organizational forms needs to happen (e.g., sustained funding and nodes in which to organize people and the work); however, such a shift threatens the revolutionary core of a movement. Moving from revolutionary goals to reformist aims may reduce opposition, but McAdam also suggests that it will diminish the overall impact. Finding a middle ground is hard but failing to do so will kill the movement. This begs the question of whether such imperatives to shift are heightened in technoscientific spaces. Open Insulin lacks the technical know-how and material capabilities to move beyond biochemistry lab work and into downstream pharmaceutical processes, necessitating interactions with, and ostensibly reliance on, individuals and groups in the corporate pharmaceutical space. Negotiating with contract manufacturers, for example, may enable them to sustain their work by addressing major barriers around facilities, expertise, and resources, but in doing so, this may diminish their revolutionary impact for creating a community-based model for making and distributing drugs.

As society increasingly shifts toward scientific and technical ways of knowing and acting, a phenomenon coproduced with contemporary capitalism, what are the implications for movements and organizations looking to create more equitable and just futures? In spaces that rely on high levels of expertise and infrastructure, how do opportunity structures present challenges for insurgent practices? Does insurgent knowledge production become more difficult, or even impossible? Notably, forms of direct social action have generally been in the realm of everyday expertise, for example, growing seeds and forming an agricultural cooperative. However these require vastly different forms of knowledge and expertise, that may be more easily accessed by lay actors, compared to the making of insulin. Thus, goals for autonomy from corporatized scientific institutions – and by extension experts in these institutions – trigger a real

tension with goals for making safe and legal medicines. This chapter offers insights into some of the unique challenges counter-organizing efforts encountered in the sociotechnical space of pharmaceuticals and the associated role of state regulations in shaping alternative imaginaries.

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CHAPTER 5: Conclusion

Access to medicines continues to be a significant barrier in advancing goals of health equity. A series of changes in the political economic and technoscientific domains of pharmaceuticals in the late 20th century begs a re-examination of this space, especially newer emergent forms of collective action to address structural conditions of making drugs. In particular, there have been concerns over increasing technical complexity in developing new medicines and the slowness of understanding and treating diseases, particularly for many economically neglected diseases that impact the most socioeconomically vulnerable. Concurrently, shifts in the political economy of biomedical research – conducive legal conditions for more patents, influxes of private capital investing, and legal imperatives for universities to commercialize knowledge – have contributed to increasing privatization of pharmaceuticals and, further, their interlinkage with financial markets. Meanwhile, two trends in science – open science and community biology – have created the social and technical conditions through which new alternative imaginaries to research, develop, and make medicines have emerged.

This dissertation provided an investigation of the process of commoning pharmaceutical knowledge through open science and lay participation in the research and making of pharmaceuticals. I sought to understand this phenomenon by bringing together science and technology studies (STS) and social movement lenses to examine alternative imaginaries for the making of drugs, collective action to formulate and institutionalize new ideas and practices of "openness," and structural and technical barriers in the enactment of creating a more equitable pharmaceutical system. In this study, I ask fundamental sociological questions including where, why, and how the open pharma movement arose; how groups reproduce and also resist the enactment of capitalization and other forms of power; processes of shared meaning making in

forming alternative practices and organizations; and external and internal conditions for success, including how groups mobilize resources and recruit actors into the movement. In this final chapter, I first provide an overview of key findings, offering a summary of the three empirical chapters. I then describe specific contributions to the scholarly literature, focusing on three domains: social movements, the politics of knowledge and expertise, and marketization processes where markets construct value. I also reflect on politically engaged ethnography – the methodological approach I followed – providing specific instances of my enactment of participatory research as well as the associated challenges. Finally, I identify important directions for future research.

Summary of Dissertation Findings

In the first empirical chapter, Chapter 2, I traced and analyzed an emergent area of collective action, in which actors are applying open science principles and practices to pharmaceutical research and working to advance a new program of thought. I term this growing movement *open pharma*. This movement was borne of discontent with prevailing practices in drug research and development (R&D) and a desire to adopt new logics and practices. Movement actors were motivated to action due to their dissatisfaction with several trends: prolonged, tedious intellectual property contract negotiations between universities and companies; academic publishing structures that are slow and often fail to publish negative results that help reduce unwanted duplicated research; trade secrets and non-disclosure agreements in industry that impact collective knowledge advancement to treat diseases; and limited funding resources, especially for neglected disease areas, that were spread out and siloed. For many

proponents of open pharma, unencumbered approaches for sharing scientific research quickly and publicly offered a clear solution.

This chapter examined three key characteristics of this open pharma movement. I first discuss major narratives discursively employed by actors to frame the movement and provide rationales to mobilize others. These include an emphasis on neglected disease areas and economic market gaps, inefficiencies in drug innovation, and equitable access to medicines, with the latter most muted compared to strong marketization discourses that actors tended to forefront. Second, I illustrated the active building and institutionalizing of open pharma through several mechanisms, including open sharing policies, both currently in practice at the organizational level and being proposed at the national level, and the establishment of large organizations that act as funding conduits and drive and organize the work (i.e., the extant open science research being done). I also identify points of resistance open pharma actors encountered in universities with commercialization imperatives – which often translates to patent imperatives – and academic researchers' cultural dispositions toward sharing ideas and data before publishing in journals.

Chapter 3 transitioned to focus on one group within the open pharma movement, the citizen science initiative Open Insulin. The group's internal governance structure became a focal point throughout my fieldwork and ultimately underscored several important challenges facing biomedical counter-organizations seeking to construct more egalitarian approaches to scientific knowledge production. Specifically, the project formed using unstructured, horizontal organizational approaches, reacting to bureaucratic structures and hierarchies in mainstream science. However, as the group sought more specific goals to create an alternative model for the production of a pharmaceutical, the push-pull between "structurelessness" and institutionalized

forms became particularly acute as pharmaceutical regulations demand standardized practices for quality and safety, thus creating strain against anti-structure tendencies.

I described Open Insulin's shift from the initial informal structure to a formal organization with a board and membership requirements. I then analyzed how their dual approaches to governance – unstructured and structured – centered on three interrelated social processes that acted as key sites of tension and change. First, the construction of membership became essential as project contributors increasingly struggled to make and vet decisions without clarity on who was part of the group, and thus party to those decisions, and who was not. Second, a lack of shared understanding around decision-making authority led to concealed power dynamics in the unstructured approach; meanwhile, in the formal organization, decision-making roles were tied to technical aspects of the project, leading to hierarchies reflective of the broader scientific world, with all white, educated men in leadership positions. Third, the formation of the project's mission and strategy was an ongoing, discursive process, co-constructed with both membership and leadership processes. The two organizational approaches structured who was 'in the room' and who was 'at the table,' granting some actors more influence over tasks and the direction of the organization. Overall, this chapter offered insights into processes for power sharing – both in theory and in practice – and specific challenges encountered in highly technical and regulated spaces such as pharmaceuticals. That is, structured legal and regulatory arenas pharmaceuticals are situated in shape and constrain alternative imaginaries and organizational approaches.

Finally, in Chapter 4, I further examined structural and technical aspects of making drugs that impact community-based pharmaceutical alternatives. Building on my findings from the previous chapter, where I underscore Open Insulin's mission as a continuous, discursive process,

I describe two visions the organization grappled with: "community manufacturing" and contract manufacturing. The former was an idealized vision for forming insulin cooperatives, where insulin users and workers of the facility would control the means of producing insulin. As actors sought to organize toward this vision, the complexity of safety and regulations, and the associated infrastructure needed to attend to these, became more visible and challenging. The latter vision – working with a pre-established manufacturing organization – offered a common and widely recognized route for making drugs. Yet, this path was also viewed by some as diluting more transformative political goals. As actors grappled with safety, regulations, and infrastructure, differing conceptions around social change became more visible. More "radical" group members viewed this path as compromising their goal of autonomy from mainstream pharmaceutical institutions and actors, and associated logics that reproduce a system of expensive drugs. Meanwhile, others viewed these ties as necessary to produce a safe and legal drug. In this chapter, I sought to ask important sociological questions about the values of social movement participants and the management and consequences of divergent approaches to social change. At the same time, in elucidating the day-to-day struggles of this organization, I also attend to the more specific challenges counter-organizations face in highly technical and regulated domains such as pharmaceuticals.

Contributions to the Literature

This dissertation is situated across several broad areas of scholarship that I bring together. Through a sociological study of Open Insulin and the broader open pharma movement, this research contributes to scholarly understandings of social movements and counter-organizations, particularly those that are situated in technoscientific and resource-intensive fields such as

pharmaceuticals; the politics of knowledge and expertise; and marketization processes, elucidating how open science in pharma is being operationalized as a type of valuation process to address economic market gaps.

First, I focus on three domains within social movements literature: health social movements that critique capitalist health and biomedical institutions (Epstein 1995; Nelson 2011); scientific/intellectual movements (SIMs) theory (Frickel and Gross 2005); and scholarship on grassroots efforts to challenge the commodification and privatization of resources and knowledge. Within the latter domain, I engage with frameworks of open source (Kelty 2008) and the commons (Casas-Cortés, Cobarrubias, and Pickles 2014). I first contribute to these literatures through my tracing of the open pharma movement. In drawing out different characteristics of this movement – narratives, infrastructure building, and structural barriers in universities – I suggest that mobilization efforts within the biomedical sciences and particularly pharmaceuticals are impacted by the spaces and structures within which these fields are situated. Whereas SIMs are typically located in university settings, where actors predominantly interact with and mobilize others in academic spaces, pharmaceuticals are positioned differently vis-à-vis capitalist political economic structures, particularly regulatory domains, industry, and financial markets. As such, movement actors must attend to different mobilization contexts and resource flows as well as interact with multiple diverse individuals, communities, and institutions. Actors' mobilization of resources is acutely key, but also such movements require actors to interact with and mobilize others across diverse fields of expertise, including knowledge fields atypical of the academic settings most SIMs are situated in, such as safety regulations, intellectual property, and financial markets knowledge. Thus, this dissertation calls for elaborating and extending SIMs theory to understand how the interaction of academic with political and economic contexts that

some movements, such as open pharma, must span affect how they emerge, grow, and sustain themselves.

Further, I engage with conceptual framings from the commons (or communally-owned resources) and open source literature by examining the application of open source principles to pharmaceuticals. The open source software movement grew out of critiques of technology ownership, which early proponents claimed should be freely available to all, viewing software technology as public goods and challenging aspects of privatization. I show how there are similar political orientations among some open pharma movement actors and organizations. However, unlike computer technology, pharmaceuticals are surrounded by significant regulatory hurdles to ensure safety and require expensive equipment and infrastructure, including numerous experts. These distinctions significantly impact and shape organizing strategies. As I show in this dissertation, such unique challenges led to a wide range of viewpoints for how best to de-privatize pharmaceutical knowledge, with some viewing small reforms as key to success, while others argued for more fundamental and transformative changes.

Relatedly, I contribute to social movements literature on direct social action by examining an organization leveraging this type of organizing approach to make a pharmaceutical, a highly technical and regulated resource. Through this, I suggest these types of counter-organizations encounter specific challenges that impact resistance to processes of capitalization. Actors require advanced (and also diverse) forms of expertise and substantial resources to operate. Aspirations to emulate other forms of direct social action that draw on ideals of forming autonomous organizations outside of state-based reforms – such as farming cooperatives or mutual aid organizations – were met with significant resistance through regulatory requirements and associated infrastructure. Consequently, theoretical and practical

understandings of commoning knowledge and resources, as well as direct social action, must take seriously the technical and regulatory dimensions of a resource.

Second, this dissertation attends to alternate framings for who can and should produce legitimate knowledge, indicative of processes of biomedicalization (Clarke et al. 2010) and scholarship on the politics of knowledge and expertise. Such scholarship encompasses knowledge production "from below" (Haraway 1988; Navarro 1980), including "lay" and citizen science (Benjamin 2013; Brown 1992; Epstein 1996). My research contributes to this scholarship through an examination of a biomedical citizen science project in which actors take the production of scientific knowledge outside of mainstream scientific institutions. The project attempts to counter the idea that "experts" and well-funded laboratories are the only legitimate producers of scientific knowledge. By operating in community biology labs rather than mainstream laboratories, their organizational home facilitates wider participation, offering an alternative to the normative route where accreditation and institutional affiliation are requisite to access many of the tools of bioscience. Community biology also looks to different incentive systems, notably with regard to profits, publications, and competitive funding terms. On the one hand, this research suggests that these shifts potentially enable community-based scientists to seek different scientific questions (e.g., what is the simplest way to make insulin for community labs, as opposed to what are the most cutting-edge methods) and more egalitarian aims for the production of affordable medicine. On the other hand, regulatory, technical, and infrastructure components to the making of medicines considerably shaped and limited the contributions of lay actors. Thus, scholarship on lay/expert knowledge must attend to specific contexts in which knowledge is produced and who can participate, and in what ways.

Third and finally, I contribute to scholarship on market processes. Open science has been championed as a mechanism through which to facilitate broader access to and benefit from scientific tools and resources. At first glance, this might suggest a kind of transformative approach in how biomedical products are researched, developed, and commercialized, potentially offering fundamental shifts in the political economy of medicines to facilitate equitable access to resources such as medicines. Without patents, for instance, a key legal mechanism through which monopoly capitalism gets enacted and resources priced high is effectively unusable. Upon further scrutiny, this dissertation shows how discourses of financial markets, patents, and other exclusivity protections remain an integral part of open science in pharma. In other words, open pharma, like the broader pharmaceutical industry, is engaging in processes of marketization, in which the market is used to construct value and assert logics, cultures, and institutions that quash, or at least weaken, other values and forms of social exchange.

Generally, the emergent open pharma movement is looking to address the unequal distribution of disease and treatments by focusing on neglected disease areas that disproportionately impact much of the global poor. At the same time, however, movement actors are doing so through market terms. Some are advocating for longer regulatory exclusivity protections in lieu of patents, still incentivizing commercial investors through exclusive market protections. Others are keen on keeping patent protections comfortably in place, focusing on moving the "pre-competitive" line slightly further downstream, thus placing more research knowledge and tools in the public domain for companies to then take and use for patentable commercial products. Actors also employ marketization language to mobilize others, suggesting open science as a kind of business venture to fill "market gaps" and invoking financial value

orientations around investment, risks, and benefits. Neglected disease areas are effectively undervalued in financial markets and thus ripe for new mechanisms to create value out of them. Under this framing, patents are viewed not as an ethical problem, but as a hindrance to the extraction of value from these markets.

Methodological Reflections on Participation and Politically Engaged Ethnography

I noted in Chapter 1 that participation during ethnographic observations with Open Insulin was deemed appropriate for two reasons. The first was practical: I realized early in my fieldwork that my active participation allowed for easier access to many of the ad hoc activities that took place within the group. I was readily looped into communications rather than needing to continually ask to join – or worse, missing altogether – key strategizing meetings as these were often random and not communicated consistently to all collaborators. My position as an "insider" enabled me to be seamlessly included in the daily activities of the project throughout much of my fieldwork (I discuss ethical issues embedded in this and how I addressed them below).

The second reason for participation was political. As a scholar who is deeply interested in research that is politically committed and impactful beyond academia, I sought to undertake a specific type of ethnographic research that is socially engaged and utilizes participation as a way to contribute to the group or movement under study. This functions as a way to attend to power within research, thus mitigating or avoiding the undesirable effects of helicopter research (Struthers et al. 2005). A key edited volume (Juris and Khasnabish 2013) that brings together politically engaged ethnographies describes and demonstrates how ethnographic study of transnational social movements can bridge the researcher-activist divide, in which engaged

ethnography represents "a form of critical social research that can contribute in multiple ways to social change as opposed to simply archiving, commenting on, or dissecting the efforts of grassroots social movements" (2013: 8). It aims to generate knowledge that may be useful for the movement itself and also operates as a form of activism. In other words, it does not simply offer research "of" a social movement but can also be deployed "for" and "in" a movement, while simultaneously acknowledging that social movement networks are already self-reflexive and producers and distributors of knowledge.[16] This form of research also heeds calls for shifting toward more public social science research rooted in social justice. Such activist research is marked by explicit political solidarity with the movement and research that must justify itself in terms of the standards and criteria of the academy (Hale 2008), while simultaneously generating analytic and theoretical insights regarding movement practices, cultures, and forms; internal relations of power and inequality; organizing strategies and tactics; and the nature of wider social, cultural, political, and economic contexts – that are useful to activists (Juris and Khasnabish 2013; Osterweil 2013).

One approach under the umbrella of politically engaged ethnography is *militant ethnography*, which requires the researcher's direct involvement in the activities and actions of the movement, such as by helping to organize activities, identifying and conveying a position during discussions, facilitating meetings, and being an active participant and contributor in events and actions (Juris 2007). This allows for embodied emotions and deeper or more complex

[16] Another methodology that seeks to actively contribute to the community or group being studied is participatory action research (PAR). This method operates through formal collaboration in all parts of research – study design, implementation, analysis, and so forth. Juris and Khasnabish (2013: 375-376) note the importance of this type of research but state that is better suited for formalized, structured groups. As transnational activist networks are often more diffuse, this type of research design is less apt. Additionally, due to certain limitations of this research (namely time and the individual nature of a dissertation), I did not use PAR as a research method. However, I did seek input from Open Insulin members on several occasions, seeking input on research questions, aims, and interview questions, with the idea of constructing a project that may provide useful insights for the group.

understandings of activist activities. As such, my participation was also an epistemological move, where active participation in the researched social world offers a perspective that may differ from merely observing others who engage in resistance practices and activities. This resembles what João Costa Vargas (2006, 2008) calls "observant participation," where participation acts as the primary method by which to interpret and translate the social world.

I utilized this methodology through direct participation in Open Insulin activities, such as by providing my opinion in meetings, taking meeting notes, and helping to develop onboarding materials. I contributed to the project's legal working group for two years, where I coordinated discussions with legal scholars, legislative staffers, and attorneys. I represented Open Insulin's work at two conferences, on a panel discussion on community biology and open source science at the community lab in Oakland in 2018, and at the Open Source Pharma 3 conference in Paris in 2019. In 2019, I also adapted a class lecture on social movements where I reflected on how Open Insulin might draw on this scholarship to inform their goals and strategies. I presented this twice to approximately 30 Open Insulin members across two consecutive weekends, and it was recorded for further dissemination. This presentation functioned, to me, as a bridging of academia and activism emblematic of politically engaged research. Shortly after, I co-founded a working group called "Open Insulin and Society" which met bimonthly and offered a space for Open Insulin members to discuss social science scholarship and to collaborate on writing projects. Additionally, I authored a policy brief published in November 2020 by the Othering and Belonging Institute at the University of California Berkeley. In this brief, I laid out three issues underpinning the insulin crisis in the US and juxtaposed these with Open Insulin's proposed interventions to make affordable insulin. This brief has been used by Open Insulin in a crowdfunding campaign, to introduce and onboard new members, and it offers a resource for

further advocacy they might engage in with politicians, patient advocacy organizations, and funders.

The participant-observer role comes with several challenges. This includes navigating a precarious position of providing feedback, and potentially dissent, that puts the researcher at risk of losing access to their research site and participants. The insider nature of this methodology raises certain ethical issues, such as participants forgetting they are partaking in research and being observed. To address this, as I noted in Chapter 3, myself and two other social scientists who were studying Open Insulin at the time created a set of best practices (referred to in the excerpt below as an "information packet") that was kept on file at the community lab and in the shared project drive along with our consent forms. We also created a statement to read at the beginning of each Open Insulin meeting clearly stating our relation to the project as researchers taking ethnographic notes. The following paragraph was read aloud at meetings where new people were present:

> "I am one of several social scientists who work with the Open Insulin Project. We want to make it clear that this is considered a public meeting and that we may be taking notes. Unless you have given informed consent separately, we will not disseminate any identifying information. If you do not wish for your contributions to be included in our studies, you can approach any one of us [identify who we are] after the meeting. If you want to know more about our research or are interested in participating further, you can approach any of us after the meeting or refer to our information packet."

Another challenge involves risks to the research itself, including shaping the social situation in a way that makes the research not "objective," and thus less legitimate. Many scholars have dismissed this "objectivist" view of ethnographic research as an illusion, yet there

remain real concerns about researcher involvement, especially as it relates to power and positionality. To mitigate any negative impacts of my participation skewing my analytic conclusions, I regularly wrote reflexive memos alongside analytic memos. Reflexive writing offers a pathway through which to implicate and examine one's embodied and tacit understandings of a situation. It provides a key mechanism to unpack one's actions, role, and position within a group and excavate that epistemological knowledge, including troubling the insider-outsider nature associated with this methodology. Such an approach builds on decades of politically committed feminist research that blends epistemological insights with politically committed writing against forms of oppression. The reflexive nature of the method also readily aligns with situational analysis and critical social theory, both of which underscore ongoing reflexivity as a vital aspect of research. As Clarke and colleagues (2018: 107) note, "Researchers should use their own experiences of the phenomenon under study and of doing research as one among many data sources."

Future Directions

This research leads to a few areas of future research related to health equity and the political economy of pharmaceuticals and other biomedical innovations. First, a natural extension of this research would be to further examine the open pharma movement as it evolves and trace whether and how it becomes further institutionalized. An important direction to take such research includes examining how and where pharmaceutical companies are becoming involved – as they actively and increasingly are, per my conversations with open pharma actors – and analyzing not only their motivations but also the implications of corporate involvement for this nascent scientific/intellectual movement. Much like the open source software movement transformed to

co-exist with major software corporations, a move that led to the sustained success of the movement but altered some of the original radical politics from which it was borne, the open pharma movement may also make such a move. Thus, asking questions about who benefits, and how, from such a pivot would be fruitful. In particular, I believe a further examination of the marketization of open science in biomedicine, and relatedly the coproduction of markets and open science, is a particularly important direction for future research.

Second, my dissertation investigates one entry point – that of citizen science and open science – through which to study shifts in the political economy of medicines. A second, potentially more far-reaching, site to examine this includes state actions toward this end. In fact, the United States government responded to two health crises in the last decade with policies to intervene in the US market to drive access to affordable medicines. The COVID-19 pandemic and lack of insulin access in the US made visible questions about the utility, value, and constitution of privatization in the development and delivery of therapeutics. In response to these health crises, government officials sought to restructure the political economy of medicines by displacing the role of private capital and patents through public funding.

Notably, this restructuring addressed two interrelated ends of pharmaceutical innovation: upstream R&D and downstream manufacturing and distribution. Future research could examine these government responses to COVID and insulin access as two sites to analyze state interventions on both ends of pharmaceutical innovation for public benefit. To facilitate upstream R&D during COVID, the US government exercised statutory authority and mobilized billions of dollars to develop therapeutics quickly. This included unprecedented waivers on patent rights for pharma companies (Knowledge Ecology International 2022) and public-private research partnerships that intend to forgo patents and instead produce "direct-to-generics."(Palca

2022; The COVID Moonshot Consortium et al. 2020). These official actions signal a shift in logics that link innovation, intellectual property, and public benefit. To facilitate downstream manufacturing and distribution in response to the insulin crisis, California state lawmakers passed legislation to enable state-manufactured pharmaceuticals and allocated $100 million to make generic insulin (Bella 2022). This law offers a novel effort by the state to challenge capitalist pharmaceutical innovation in the US. These crises and state interventions provide the empirical grounds for pursuing such interrelated questions as: Where and when do legal actions for open innovation form and to what ends? How do economic models and organizational infrastructures (e.g., manufacturing facilities and funding mechanisms) for pharmaceutical innovation emerge, and how do policymakers and stakeholders negotiate and implement them? And what are the potential impacts and limitations of these interventions for health equity? This research would further advance our understanding of new biomedical imaginaries emerging in the US in response to the monopolization of health products.

Coda

In closing, I offer my thoughts about the implications of this research for thinking about social change within the political economy of pharmaceuticals. On the one hand, personally, I identify with and feel a great deal of solidarity towards the aspirations of Open Insulin for community-driven solutions to the monopolization of drugs by corporate pharma. In line with non-reformist reforms (Gorz 1967), I believe envisioning and organizing toward goals that are transformational, and not limited to what is possible in the status quo, is a worthy endeavor.

On the other hand, this dissertation surfaces some of the key challenges in applying ideas from the commons and open source software to pharmaceuticals. For many contemporary

initiatives engaged in commoning goods and knowledge, there is a lower threshold of technical expertise related to safety that is needed. In applying ideas from open source software to pharmaceuticals, there are several relevant ways that biotechnology and the making of drugs is different from computer technology. This includes the need for expensive equipment, slow systematized experimentation that often goes wrong, and perhaps most significantly, pharmaceuticals are surrounded by major regulatory hurdles that do not exist with software. The risk with poor-quality open source software is that nobody will use it; poor-quality pharmaceuticals can cause harm or death.

I suggest that there is ultimately a place for open pharma, but it may be beyond the capacity of small bottom-up, grassroots initiatives in the current technical and regulatory terrain. Thus, working to reform some of these barriers seems worthwhile, for instance, by creating a more conducive regulatory system that still ensures safety but is more amenable to small nonprofit manufacturers and community-based organizations. That is, rather than taking the system as is and working within it, system reforms should open up more space for alternative pharma initiatives. To address access and affordability in the meantime, for example, some combination of large medical centers, state and federal governments, and foundations need to provide the funding for open, nonprofit drug development firms that would both develop new drugs and provide competition for generics that are not produced in sufficient quantity or at prices that are too high. This also fits with the idea of increasing competition in an era of corporate monopolies by creating a public option that is not profit-maximizing. These kinds of reformist reforms – which sit between smaller incremental changes and more transformative approaches – would align with Wright's (2019) model of eroding capitalism to make space for

alternatives. That is, such reforms may help pave the way for further changes to the political economy of drugs to promote equitable access to medicines.

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