

Against Fiduciary Utopianism: The Regulation of Physician Conflicts of Interest and Standards of Care

Sam F. Halabi*

This Article critically examines calls by scholars, legislators, and regulators advocating the imposition of fiduciary duties upon a broad range of actors including judges, jurors, agencies, parents, friends, and even entire countries. The Article examines the physician-patient relationship—an archetypal and frequently cited relationship in which fiduciary duties, administered by courts, are asserted to work well. It argues that some of the most significant problems fiduciary duties are used to address like asymmetry of information, conflicts of interest, and professional conduct have not only been handled badly by courts, but have actually found more effective resolution through legislative fact-finding, acknowledgment of the complexity of medical practice, and ultimately regulatory solutions aimed at sources of conflicts of interest and specific circumstances in which claims for medical malpractice arise. Behind many of these initiatives are physicians themselves—who experience the sources of potential conflicts and endeavor to create self-regulatory and legislative solutions to them. In contrast, court-administered fiduciary duties are often marginalized as judicially manageable claims related to the duties of loyalty and the duty of care converge, litigants focus on settlement, and the high expectations held for fiduciaries are rarely enforced. The Article concludes that not only may imposing more fiduciary duties on more relationships not generate the benefits many scholars suggest, but that doing so will stymie more targeted and effective solutions to problems that occur in trust relationships.

* Visiting Professor, The University of Iowa College of Law; Manley O. Hudson Professor of Law at the University of Missouri–Columbia; Scholar, O’Neill Institute for National and Global Health Law, Georgetown University. J.D. Harvard, MPhil Oxford (St. Antony’s College), B.A., B.S., Kansas State University. The author thanks Royce Barondes, Frank Bowman, Larry Dessem, Martha Dragich, Susan Saab Fortney, Wilson Freyermuth, Michael Green, Brian Holland, Bob Jerry, Thom Lambert, Erika Lietzan, Paul Litton, Fran Miller, Tim Mulvaney, Richard Reuben, Christopher Robertson, Richard Saver, Ben Trachtenberg, and Saurabh Vishnubhakat for helpful comments and suggestions. The author also thanks the participants at the American Society of Law, Medicine, and Ethics Health Law Professors Conference, Texas A&M School of Law, as well as faculty and students at the University of Ottawa’s Centre for Health Law, Policy, and Ethics. Finally, the author thanks Alison Matusofsky, Lauren Smith, Larissa Tiller, and Benjamin Zinkel for excellent research assistance.

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INTRODUCTION

Legal scholars, legislators, and regulators have in recent years undertaken an expansive effort to make agencies, judges, jurors, Medicare billers, friends, and even entire countries into fiduciaries to one or more constituencies, replete with duties of care, deliberation, good faith, and loyalty enforceable by judicial means.¹

1. See, e.g., 29 C.F.R. § 2510.3-21(j) (2017) (requiring retirement plan advisors be fiduciaries); Isaac D. Buck, *Furthering the Fiduciary Metaphor: The Duty of Providers to the Payers of Medicare*, 104

Traditionally reserved for relationships in the nominally private sphere that nevertheless impacted public or quasi-public interests—e.g., attorneys and clients, directors and shareholders, guardians and wards—purported fiduciary duties now abound. This effort to stretch the fiduciary analogy promises more robust virtue, exercised by more of society’s actors, for the benefit of those locked out or marginalized by prevailing economic and political structures.

These fiduciary duties, it is theorized, will make decision-makers more conscientious of stakeholders who trust them to act justly, add a stratum of judicially imposed oversight to ensure that those decision-makers do so, and promote transparency through the responsibility of fiduciaries to articulate reasons for their action or inaction, justify those reasons, and keep adequate records so that justifications may be subject to judicial or public scrutiny.² These benefits will flow from the structure of the fiduciary relationship, especially its empowerment of the quintessentially informed, deliberative, beneficent fiduciary empowered by law to decide what is right. Fiduciaries’ discretion—the flexibility to decide—is inherently virtuous, as it is exercised with “superior information, experience, or expertise,” and done so for the welfare of their beneficiaries.³

To be sure, scholarly inquiry encourages areas of law to be studied and then loaned or applied elsewhere, often beneficially so. Comparative constitutional law has played a substantial role in promoting the expansion of due process and right-to-life norms into constitutional frameworks drawn from heterogeneous traditions.⁴ Judges in common law countries routinely apply concepts developed in contract, employment, and corporate law to questions involving wills and trusts, divorce, and negligence.⁵ The notion of “duty” plays a prominent role in many of these contexts, as it does in the current movement encouraging the expansion of fiduciary duties outside their conventional private law domains.⁶

Yet it is argued here that the expansion of the fiduciary metaphor has exceeded the limit of its beneficial application. It has become utopian—in the satirical sense

CALIF. L. REV. 1043 (2016) (discussing how medical providers who bill Medicare are now fiduciaries); Ethan J. Leib & Stephen R. Galoob, *Fiduciary Political Theory: A Critique*, 125 YALE L.J. 1820 (2016) (covering literature on public authorities theorized to be subject to fiduciary constraints including judges, regulators, and states in the international system); Ethan J. Leib, *Friends as Fiduciaries*, 86 WASH. U. L. REV. 665 (2009) (friends); Evan J. Criddle, *Fiduciary Administration: Rethinking Popular Representation in Agency Rulemaking*, 88 TEX. L. REV. 441 (2010); Evan J. Criddle & Evan Fox-Decent, *A Fiduciary Theory of Jus Cogens*, 34 YALE J. INT’L L. 331 (2009).

2. Criddle, *supra* note 1, at 469.

3. *Id.* at 471.

4. Sam F. Halabi, *Constitutional Borrowing as Jurisprudential and Political Doctrine in Shri D.K. Basu v. State of West Bengal*, 3 NOTRE DAME J. INT’L & COMPAR. L. 73 (2013); *see also* David Schleicher, *City Unplanning*, 122 YALE L.J. 1670 (2013).

5. *See, e.g.*, Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463 (2002); Donald C. Langevoort, *Half-Truths: Protecting Mistaken Inferences by Investors and Others*, 52 STAN. L. REV. 87 (1999); Robert J. Rhee, *The Tort Foundation of Duty of Care and Business Judgment*, 88 NOTRE DAME L. REV. 1139 (2013).

6. Rhee, *supra* note 5.

intended by Sir Thomas More—a place literally too good to be true.⁷ Like Plato’s *Republic*, the world of fiduciaries empowers a multitude of benign oligarchs, “philosopher-kings,” whose contemplative, beneficent, and transparent decisions will salvage the world torn asunder by ugly partisan lawmaking, opportunistic contracting behavior, and decreasing judicial oversight of shrinking legal duties between citizens.

If the policies and reforms advocated by fiduciary utopians rendered benign or unimportant inefficiencies, it might not be worth an article-length contribution. But the criticism presented herein goes beyond those leveled by scholars like Seth Davis, who doubts that fiduciary norms may be applied in contexts where there is not a “discrete class of beneficiaries,” or Ethan Leib and Stephen Galoob, who argue that applications of fiduciary theory to public authorities is conceptually ambiguous and undisciplined.⁸

Rather, this Article argues that the application of fiduciary duties to more legal relationships distracts from lawmaking and law-enforcement processes that lead to more effective solutions to the problems that fiduciary duties are asserted to solve. For example, imposing a broad “duty of loyalty” on a class of political authorities undermines the fact-gathering and policy process that leads to targeted solutions where concrete, identifiable problems emerge. The “loyalty” of corporate directors is not under threat by ambiguous, poorly understood sources that require broad duties. It is under threat by the temptation to use corporate assets for personal gain or to exploit opportunities that rightfully belong to the corporation.⁹ Although ERISA-covered employers are fiduciaries with respect to the decisions they make when implementing health and benefit plans for their employees, the actual requirements for their conduct are determined largely through statute and notice-and-comment rulemaking.¹⁰

7. THOMAS MORE, *UTOPIA* (George M. Logan, Robert M. Adams & Clarence H. Miller eds., 2006).

8. Seth Davis, *The False Promise of Fiduciary Government*, 89 NOTRE DAME L. REV. 1145, 1158 (2014); Leib & Galoob, *supra* note 1, at 1846; *see also* Mark Osiel, *Rights to Do Grave Wrong*, 5 J. LEGAL ANALYSIS 107, 165–67 (2013) (analyzing the distinction between metaphorical and legal invocations of the fiduciary, especially by Jeremy Waldron); Sean P. Sullivan, *Powers, But How Much Power? Game Theory and the Nondelegation Principle*, 104 VA. L. REV. 1229, 1254–55 (2018) (analyzing Congress’s delegation of authority to agencies as representative of the fiduciary relationship between principal and agent).

9. Despite well-developed Delaware case law on director conflicts of interest, most states, including Delaware, adopt a statutory approach to managing them. *See, e.g.*, DEL. CODE ANN. tit. 8, § 144 (2017); CAL. CORP. CODE § 309(a) (West 2020); Gregory H. Shill, *The Golden Leash and the Fiduciary Duty of Loyalty*, 64 UCLA L. REV. 1246, 1256–59, 1261–64 (2017). As Robert Anderson and Derek Muller have argued in the attorney context, gatekeeping the profession itself is a legitimate alternative for ensuring the behavior of fiduciaries. Robert Anderson IV & Derek T. Muller, *The High Cost of Lowering the Bar*, 32 GEO. J. LEGAL ETHICS 307 (2019).

10. EMP. BENEFITS SEC. ADMIN., U.S. DEP’T OF LAB., MEETING YOUR FIDUCIARY RESPONSIBILITIES (2017), <https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/meeting-your-fiduciary-responsibilities.pdf> [https://perma.cc/LW6S-

The evidence in support of this argument is one of the storied fiduciary relationships in law—the doctor-patient relationship. Determined from the time of ancient Athens to be fiduciaries with respect to those they heal, physicians are required by law to use their specialized skills for the benefit of patients without regard to personal gain; to do so according to the degree of skill and care that would ordinarily be exercised by a physician in similar circumstances; to keep records that justify the treatment decisions they order; and to maintain the confidences and sensitive information with which they are entrusted. Indeed, physicians are among the most admired and respected professions for precisely these reasons.¹¹

But physicians' adherence to these principles of fiduciary behavior have not resulted from broadly drawn duties of loyalty, care, and confidence enforced by similarly sage judges in federal and state courts. Rather, they have resulted from specific, targeted laws and regulations—the development of which physicians themselves as well as patients have participated and shaped. Transparency in the conduct of medical treatment has resulted from “disclosure” and “sunshine” laws aimed not at physicians, but at those who would tempt them with costly drugs and therapies that may not benefit their patients.¹² Patient confidence has been secured by state and federal laws that understand that just because physicians are expertly trained and care about their patients does not mean that they know all the ways that privacy may be breached.¹³

In short, rather than the learned, discretion-wielding heroes suggested by much of the recent literature on fiduciaries, the behavior of physicians toward their patients has been shaped by legislators, regulators, and physicians themselves who understand that notwithstanding their extensive training, physicians care for patients in a complex world of finance, health, illness, and treatment that conventional lawmaking processes can and should address.¹⁴ The ambitious

TARY]; Ann Laquer Estin, *Sharing Governance: Family Law in Congress and the States*, 18 CORNELL J.L. & PUB. POL'Y 267, 321–23 (2009) (summarizing ERISA's reach).

11. Niall McCarthy, *America's Most and Least Trusted Professions*, FORBES (Jan. 4, 2018, 7:54 AM), <https://www.forbes.com/sites/niallmccarthy/2018/01/04/americas-most-and-least-trusted-professions-infographic/#38b8e1df65b5> [https://perma.cc/7HSY-5L5S]; Dayna Bowen Matthew, *Implementing American Health Care Reform: The Fiduciary Imperative*, 59 BUFF. L. REV. 715, 730 (2011) (“Physicians in Ancient Greece organized themselves into a professional guild, in which members shared professional principles most famously articulated sometime during the fourth century B.C. by the Greek medical philosopher Hippocrates. Hippocrates wrote the oath which required new physicians to swear upon Apollo and a number of healing gods to uphold the ethical principles of their profession: ‘I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous.’” (footnote omitted)).

12. See, e.g., Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119, 689 (2010) (codified as amended at 42 U.S.C. § 1320a-7h); CAL. HEALTH & SAFETY CODE § 24173(c) (West 2006).

13. Julie K. Taitsman, Christi Macrina Grimm & Shantanu Agrawal, *Protecting Patient Privacy and Data Security*, 368 NEW ENG. J. MED. 977 (2013).

14. SHARON P. DOUGLAS, AM. MED. ASS'N, CEJA REP. NO. 1-A-12, REPORTS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS 2 (2012), <https://www.ama-assn.org/sites/ama->

application of more fiduciary duties to more actors in society falsely promises a greater level of “trust” by those actors than even conventional fiduciaries have ever been able to deliver.

Moreover, at least in those contexts in which courts are understood to better police fiduciary principles, there are good reasons to doubt that they will be better positioned to enforce fiduciary principles applied to more relationships. The passive recipients of competitively generated evidence and information, litigation is a poor substitute for the fact-finding and community engagement undertaken in legislative and administrative processes. For both substantive and process reasons, court-administered duties are not likely to generate better social outcomes. To be sure, judicially identified fiduciary duties may be codified by legislatures which may in turn inform later iterations of rules and standards for fiduciaries’ conduct, discretion, and good faith. But doing so frequently depends on a sufficiently aggrieved beneficiary to adequately complain. Given the context in which breaches of fiduciary duty arise, there are good reasons to doubt that level of grievance will be sufficiently frequent, robust, or optimal.

Part I of this Article assesses the existing literature addressing fiduciary duties and promoting their proliferation. Part II explains the history and structure of fiduciary relationships generally and the physician-patient relationship specifically. Part III surveys state and federal laws addressing the physician-patient relationship. Part IV analyzes the policy gains achieved through application of fiduciary duties and through legislative or regulatory approaches. Part V provides a brief conclusion.

I. THE ORIGIN, STRUCTURE, AND EXPANSION OF FIDUCIARY RELATIONSHIPS

A. The Role of Fiduciary Relationships in Law

Fiduciary relationships are favored under law when they promote a special trust between parties that benefits society generally. In those relationships, one party (the entrustor) is dependent upon another party (the fiduciary) for some service that “public policy encourages.”¹⁵ Fiduciary duties are “imposed when public policy encourages specialization in particular services . . . and when the entrustors’ costs of specifying and monitoring the fiduciaries’ functions threaten to

assn.org/files/corp/media-browser/public/about-ama/councils/Council%20Reports/council-on-ethics-and-judicial-affairs/ceja-1a12.pdf [https://perma.cc/P7T5-RYLJ] (“Arguments that physicians should never allow considerations other than the welfare of the patient before them to influence their professional recommendations and treatment do not mesh with the reality of clinical practice. Physicians regularly work with a variety of limits on care: clinical practice guidelines, patient preferences, availability of certain services, the benefits covered by a patient’s insurance plan, and the time physicians and nurses can spend caring for a patient all influence what interventions physicians recommend and what care they provide.”).

15. Tamar Frankel, *Fiduciary Duties*, in 2 THE NEW PALGRAVE DICTIONARY OF ECONOMICS AND THE LAW 127, 127 (Peter Newman ed., 1998); see also Thomas P. Gallanis, *The Contribution of Fiduciary Law*, in THE WORLDS OF THE TRUST 388, 390–94 (Lionel Smith ed., 2013).

undermine the utility of the relationship to entrustors.”¹⁶ In other words, fiduciaries are at their most desirable when entrustors lack the time, resources, or capability to (1) do what fiduciaries can do and/or (2) effectively monitor them when they’re doing it.¹⁷ The duty is supposed to give entrustors “incentives to enter into fiduciary relationships,” which is done by “reducing entrustors’ risks and costs of preventing abuse of entrusted power, and of ensuring quality fiduciary services.”¹⁸ In return for the cost to fiduciaries for carrying out their duties, the law “increases their marketability by endowing them with a reputation for honesty backed by reputation.”¹⁹ However, the main purpose of the relationship is not to “satisfy both parties’ needs, but only those of the entrustor.”²⁰

Fiduciary duties are comprised of broadly applicable standards which courts then complete with more specific rules. According to Robert Sitkoff,

[i]n all fiduciary relationships we find general duties of loyalty and care, typically phrased as standards, which proscribe conflicts of interest and prescribe an objective standard of care. But we also find specific subsidiary fiduciary duties, often phrased as rules, that elaborate on the application of the duties of loyalty and care to commonly recurring circumstances in the particular form of fiduciary relationship.²¹

The duty of loyalty is the “core” fiduciary duty, the obligation to act toward the entrustor or beneficiary without regard to one’s personal interest, to act unselfishly.²² Because fiduciary relationships “trade upon high levels of trust and leave one party in a position of domination, inferiority, or vulnerability,” the “fiduciary is prohibited from engaging in self-interested transactions” and pursues the interests of her beneficiary above her own.²³ The fiduciary must be undivided and undiluted in this fidelity. “The duty of loyalty proscribes misappropriation and regulates conflicts of interest by requiring a fiduciary to act in the ‘best’ or even ‘sole’ interests of the [beneficiary].”²⁴

16. Frankel, *supra* note 15, at 128.

17. See Reid Peyton Chambers, *Judicial Enforcement of the Federal Trust Responsibility to Indians*, 27 STAN. L. REV. 1213 (1975); Joseph L. Sax, *The Public Trust Doctrine in Natural Resource Law: Effective Judicial Intervention*, 68 MICH. L. REV. 471 (1970); Donna M. Nagy, *Insider Trading, Congressional Officials, and Duties of Entrustment*, 91 B.U. L. REV. 1105 (2011); Michael A. Perino, *A Scandalous Perversion of Trust: Modern Lessons from the Early History of Congressional Insider Trading*, 67 RUTGERS U. L. REV. 335 (2015); E. Mabry Rogers & Stephen B. Young, *Public Office as a Public Trust: A Suggestion that Impeachment for High Crimes and Misdemeanors Implies a Fiduciary Standard*, 63 GEO. L.J. 1025 (1975).

18. Frankel, *supra* note 15, at 128.

19. *Id.*

20. Tamar Frankel, *Fiduciary Law*, 71 CALIF. L. REV. 795, 801 (1983).

21. Robert H. Sitkoff, *An Economic Theory of Fiduciary Law*, in PHILOSOPHICAL FOUNDATIONS OF FIDUCIARY LAW 197, 198 (Andrew S. Gold & Paul B. Miller eds., 2014); see also Hall, *supra* note 5, at 491 (“Instead, general principles of fiduciary obligation give rise to various sets of rules in many different settings in which the rules share only broad, familial resemblance.”).

22. *Fiduciary Duty*, BLACK’S LAW DICTIONARY 625 (6th ed. 1990).

23. Leib, *supra* note 1, at 672–74.

24. Sitkoff, *supra* note 21, at 201.

Practically speaking, the duty of loyalty “requires fiduciaries to . . . avoid conflicts of interest, secret profits, and misappropriating benefits that should accrue to the beneficiary.”²⁵ This highest duty applies to a wide range of private law relationships: attorney-client, corporate director-shareholders, trustee-beneficiary, agent-principal, guardian-ward, and physician-patient.²⁶

The second duty that is commonly included as part of a fiduciary relationship is the duty of care.²⁷ This duty is similar to the duty of loyalty in that it requires the fiduciary to act in an unselfish manner, yet, “unlike the duty of loyalty, the party alleging a breach must be able to show that an injury resulted from the fiduciary’s failure to meet the standard of care.”²⁸ The fiduciary duty of care can range widely in content, dependent as it is on the conduct of what courts expect of similarly situated fiduciaries and the factual specificity of decisions they make.²⁹

The third duty is that of utmost candor and disclosure.³⁰ This duty requires fiduciaries to reveal the reasons supporting the actions they take with respect to beneficiaries and, when tied to the duty of loyalty, may further require fiduciaries to disclose influences or interests that may affect the objectivity of their advice or actions.³¹ Physicians, for example, must disclose the risks of the therapies they advise to their patients; corporate directors must “provide stockholders with accurate and complete information material to a transaction or other corporate event that is being presented to them for action.”³²

In many fiduciary relationships, like attorney-client and physician-patient, beneficiaries are also protected by a duty of confidentiality.³³ The fiduciary has the duty not to misappropriate the information for the fiduciary’s own use (the duty of

25. Leib, *supra* note 1, at 674.

26. John H. Langbein, *Questioning the Trust Law Duty of Loyalty: Sole Interest or Best Interest?*, 114 YALE L.J. 929 (2005).

27. Leib, *supra* note 1, at 674.

28. *Id.*

29. See Roy Ryden Anderson & Walter W. Steele, Jr., *Fiduciary Duty, Tort and Contract: A Primer on the Legal Malpractice Puzzle*, 47 SMU L. REV. 235 (1994); William A. Gregory, *The Fiduciary Duty of Care: A Perversion of Words*, 38 AKRON L. REV. 181, 182 (2005) (“It has become commonplace for courts and commentators to refer to the ‘fiduciary duty of care.’ The three most egregious examples of this confusing rhetoric are the Delaware corporate law cases, the Uniform Partnership Act (1997), and the legal malpractice cases that consider the concept of ‘fiduciary breach’ by an attorney.” (footnotes omitted)).

30. John F. Mariani, Christopher W. Kammerer & Nancy Guffey-Landers, *Understanding Fiduciary Duty*, 84 FLA. BAR J. 21 (2010).

31. *Green v. H&R Block, Inc.*, 735 A.2d 1039, 1056 (Md. 1999) (citing RESTATEMENT (SECOND) OF AGENCY § 389 (AM. L. INST. 1958) as authority for an agent’s obligation to her principal to disclose any information the principal would reasonably want to know).

32. Donald C. Langevoort, *Agency Law Inside the Corporation: Problems of Candor and Knowledge*, 71 U. CIN. L. REV. 1187, 1198 (2003) (quoting *Malone v. Brincat*, 722 A.2d 5 (Del. 1998)).

33. See *Hammonds v. Aetna Cas. & Sur. Co.*, 237 F. Supp. 96, 102 (N.D. Ohio 1965) (finding that the physician-patient relation is fiduciary); *Lockett v. Goodill*, 430 P.2d 589, 591 (Wash. 1967); *MacDonald v. Clinger*, 446 N.Y.S.2d 801, 805 (N.Y. App. Div. 1982).

loyalty) but also a separate duty to keep the information itself confidential.³⁴ An attorney, for example, may not use information learned in the course of a representation adversely to the client's interest and also may not communicate confidential information to others.³⁵ Generally, a fiduciary may disclose protected information "only in accordance with certain procedural and substantive safeguards, chief among them full and fair disclosure by the fiduciary."³⁶

Fiduciaries are ultimately bound to their entrustors by a duty of good faith, a duty that contracts or expands depending on the context in which it is applied.³⁷ Against corporate directors, for example, the duty is synonymous with that of loyalty.³⁸ The fiduciary relationship between doctors and patients by contrast "arises from the trust and confidence patients place in physicians."³⁹ Leib asserts the duty of good faith is controversial either because "many have a hard time distinguishing a fiduciary's duty of good faith from a general duty of good faith that pervades all performance of contractual duties," or because "many feel that the duty of good faith is simply a way of expressing duties imposed by other obligations, like the duty of disclosure, the duty of loyalty, or the duty of care."⁴⁰

B. *The Expansion of Fiduciary Relationships*

So described, it is unsurprising that legislators, regulators, and legal scholars have advocated that fiduciary relationships apply to more actors in the legal system. Why wouldn't we want more loyal, competent, discreet, and faithful legal, market, and social actors? As Leib argues, the concept of a fiduciary relationship "is self-consciously open, flexible, and adaptable to new kinds of relationships."⁴¹ So why not do so?⁴²

34. See SUSAN R. MARTYN, BACK TO THE FUTURE: FIDUCIARY DUTY THEN AND NOW 12–13, 21 (Lawrence J. Fox, Susan R. Martyn & Andrew S. Pollis eds., 2009), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2056401 [https://web.archive.org/web/20200326210936/https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2056401].

35. MODEL RULES OF PRO. CONDUCT r. 1.6 (AM. BAR ASS'N 2020); see also *Murfreesboro Med. Clinic v. Udom*, 166 S.W.3d 674, 683 (Tenn. 2005) ("In analyzing this issue, we see no practical difference between the practice of law and the practice of medicine. . . . These relationships are 'consensual, highly fiduciary and peculiarly depend[ent] on the patient's or client's trust and confidence in the physician consulted or attorney retained.'" (quoting *Karlin v. Weinberg*, 390 A.2d 1161, 1171 (1978))), *superseded by statute*, TENN. CODE ANN. § 63-1-148 (2016).

36. Sitkoff, *supra* note 21, at 201.

37. *Gager v. Mathewson*, 107 A. 1, 2–3 (Conn. 1919); see also Robert T. Miller, Lyondell Chemical Co. v. Ryan: *The Duty of Good Faith Comes to Revlon-Land*, 11 ENGAGE 14, 14 (2010) (analyzing the good faith component of the board's duty of loyalty in the corporate context).

38. *Am. Fed. Grp., Ltd. v. Rothenberg*, 136 F.3d 897, 906 (2d Cir. 1998).

39. Matthew, *supra* note 11, at 726.

40. Leib, *supra* note 1, at 676.

41. *Id.* at 672.

42. See *McKnatt v. McKnatt*, 93 A. 367, 370 (Del. Ch. 1915) ("There is no fixed test to establish a fiduciary relationship. It cannot be defined. It embraces the relation of physician and patient, nurse and patient, and generally all persons who are in any relation of trust and confidence.").

Indeed, Leib has answered his own invitation, arguing that fiduciary responsibilities should apply to judges, juries, and even friends.⁴³ Evan Criddle and Evan Fox-Decent have advocated the use of fiduciary principles to identify rules in international relations that all states must obey like prohibitions on slavery, genocide, and aggressive war. They anchor their analysis in the “state’s fiduciary obligation to govern in accordance with principles of integrity, fairness, and solicitude.”⁴⁴ Evan Criddle has separately argued for the adoption of a “fiduciary model” for agency rulemaking, one that requires regulators to honor the moral dignity of the individuals subject to their rules, do so with the integrity and fairness thought of as applying to fiduciaries, and to take action fairly, reasonably, and transparently. The fiduciary model Criddle advocates also expands the scope—as fiduciary duties do—for judicial review of agency action or inaction.⁴⁵

In an important paper aimed at addressing the problem of medical providers’ overbilling of Medicare, Isaac Buck has argued for a fiduciary duty between physicians and, effectively, taxpayers, so that Medicare may seek judicial remedies for physicians’ breach of the duty of loyalty to payers.⁴⁶ According to Buck, the typical fiduciary duty that applies to physicians may be easily extended to other entrustors:

After all, physicians occupy a position of trust, unlike the role one would ascribe to sellers in other industries. . . . [I]n a professional medical practice, trust between patient and physician is essential and . . . the government as insurer depends upon the honesty of the doctor and is easily taken advantage of if the doctor is not honest.⁴⁷

In 2016, the Department of Labor advocated the application of a fiduciary rule to investment advisers making recommendations pursuant to qualified retirement plans and individual retirement accounts.⁴⁸ That rule redefined the term investment advice within pension and retirement plans. Under the Employee Retirement Income Security Act of 1974 (ERISA; Pub. L. No. 93-406), a person who provides investment advice has a fiduciary obligation, which means that the person must provide the advice in the sole interest of plan participants.⁴⁹ Under the prior regulation, securities brokers and dealers who provided services to retirement

43. Leib, *supra* note 1; Ethan J. Leib, David L. Ponet & Michael Serota, *A Fiduciary Theory of Judging*, 101 CALIF. L. REV. 699 (2013); Ethan J. Leib, Michael Serota & David L. Ponet, *Fiduciary Principles and the Jury*, 55 WM. & MARY L. REV. 1109 (2014) (jurors and juries).

44. Criddle & Fox-Decent, *supra* note 1, at 333.

45. Criddle, *supra* note 1.

46. Buck, *supra* note 1, at 1055.

47. *Id.* at 1089 (citing *United States v. Rutgard*, 116 F.3d 1270, 1294 (9th Cir. 1997)).

48. *Chamber of Com. v. U.S. Dep’t of Lab.*, No. 17-10238, 2018 WL 3301737 (5th Cir. June 21, 2018), *rev’g* 231 F. Supp. 3d 152 (N.D. Tex. 2017); *Mkt. Synergy Grp., Inc. v. U.S. Dep’t of Lab.*, No. 16-CV-4083-DDC-KGS, 2017 WL 661592 (D. Kan. Feb. 17, 2017).

49. See Definition of the Term “Fiduciary”; Conflict of Interest Rule—Retirement Investment Advice, 81 Fed. Reg. 20,946 (Apr. 8, 2016) (to be codified at 29 C.F.R. pts. 2509, 2510, 2550), <https://www.federalregister.gov/documents/2016/04/08/2016-07924/definition-of-the-term-fiduciary-conflict-of-interest-rule-retirement-investment-advice> [<https://perma.cc/3P6N-8DQX>].

plans and who were not fiduciaries were not required to act in the sole interests of plan participants by, for example, disclosing conflicts of interest.⁵⁰ Rather, their recommendations had to meet a suitability standard, which requires that recommendations be suitable for the plan participant, given factors such as an individual's income, risk tolerance, and investment objectives. The suitability standard is a lower standard than a fiduciary standard.⁵¹ Although the rule is now effectively dead, it represents a policy manifestation of the academic trends described above.

The possibilities (and in some cases realities) are endless. Professors may be fiduciaries with respect to their students.⁵² Parents may be fiduciaries to their children.⁵³ Employees are already fiduciaries in many respects for their employers when an agency relationship forms, but what about to each other? Physicians owe fiduciary duties to their patients, but what about pharmacists to their customers?⁵⁴ Joshua Margolis has argued that publicly traded healthcare firms owe fiduciary duties to both shareholders and patients.⁵⁵ Internet and digital device users worldwide vest a certain and sometimes large amount of trust in online platforms, social media, and Internet service providers, so what about a fiduciary duty to ensure that privacy is maintained, breaches are protected against, and equal access to all web content (which now rescinded net neutrality rules were intended to address)?⁵⁶ Tamar Frankel, one of the most important voices in the law of fiduciaries, has broadly “challenged lawmakers, lawyers, and judges to put trust and fiduciary duty at the heart of modern law.”⁵⁷

II. PHYSICIANS AS FIDUCIARIES

Advocates of the expansion of fiduciary duties to more relationships frequently identify the physician-patient relationship as representative of the core features of what might be gained should the analogy be extended.⁵⁸ The physician

50. See 15 U.S.C. § 78c(a)(4).

51. 29 C.F.R. § 2510.3–21(j) (2017).

52. Melissa Astala, Comment, *Wronged by a Professor? Breach of Fiduciary Duty as a Remedy in Intellectual Property Infringement Cases*, 3 HOUS. BUS. & TAX L.J. 31 (2003); Hazel Glenn Beh, *Student Versus University: The University's Implied Obligations of Good Faith and Fair Dealing*, 59 MD. L. REV. 183, 202–03 (2000); Robert Faulkner, *Judicial Deference to University Decisions Not to Grant Degrees, Certificates, and Credit—The Fiduciary Alternative*, 40 SYRACUSE L. REV. 837, 855–66 (1989); Alvin L. Goldman, *The University and the Liberty of Its Students—A Fiduciary Theory*, 54 KY. L.J. 643 (1966).

53. Elizabeth S. Scott & Robert E. Scott, *Parents as Fiduciaries*, 81 VA. L. REV. 2401 (1995); *K.M. v. H.M.*, [1992] S.C.R. 3 (Can.).

54. *Anonymous v. CVS Corp.*, 728 N.Y.S.2d 333 (Sup. Ct. 2001).

55. Joshua D. Margolis, *Professionalism, Fiduciary Duty, and Health-Related Business Leadership*, 313 JAMA 1819 (2015).

56. Jack M. Balkin, *Information Fiduciaries and the First Amendment*, 49 U.C. DAVIS L. REV. 1183 (2016).

57. David J. Seipp, *Trust and Fiduciary Duty in the Early Common Law*, 91 B.U. L. REV. 1011, 1012 (2011).

58. See *infra* notes 61–65.

is the learned, competent, and compassionate professional exercising her expertise with the sole end of healing her patient (who knows little or nothing about disease and pharmacology), alleviating her pain, or advising her on different aspects of nutrition and wellness.⁵⁹ This physician discloses all material risks of procedures and therapies, scrupulously guards confidences entrusted to her by her patient, and keeps detailed records that justify her decisions and advice.⁶⁰ She treats her patient to the standard of care that other physicians would agree would meet professional expectations and does so free of financial or romantic interests that might cloud her judgment.⁶¹ Often described as the “gatekeepers” to medical services, physicians are in the position that makes patients reliant on them for access to medical aid, thus creating a relationship of dependency.⁶² Advocates argue their fiduciary duties “attach” at the beginning of the relationship—which is from the time the physician agrees to treat the patient—and carry on throughout the time a patient is under the physician’s care.⁶³

According to Tamar Frankel, the patient’s entrustment of power over his or her body to the physician—the essential trust of something vital—suffices to create a fiduciary relationship between the two.⁶⁴ Evan Criddle and Evan Fox-Decent argue that the physician is a fiduciary because “[the patient] is peculiarly vulnerable to the [physician]’s power in the sense that she is unable, either as a matter of fact or law, to exercise the entrusted power.”⁶⁵ Health law scholars and professional organizations concur. Dayna Matthew argues that “[c]urrent applications of fiduciary law are pervasive in the medical context and are firmly based on the well-established ethical responsibilities that providers historically owed to their patients.”⁶⁶ The American Medical Association (AMA) has recognized that the physician-patient relationship is “based on trust,” and thus the physician has an obligation to place patients’ welfare above her own self-interest.⁶⁷ In a comprehensive analysis of physicians’ fiduciary duties under state law, Max

59. *M.A. v. United States*, 951 P.2d 851, 854 (Alaska 1998) (“[W]e have recognized that the unique nature of the physician-patient relationship confers upon physicians a fiduciary responsibility toward their patients.”).

60. See Thomas L. Hafemeister & Selina Spinos, *Lean on Me: A Physician’s Fiduciary Duty to Disclose an Emergent Medical Risk to the Patient*, 86 WASH. U. L. REV. 1167, 1187 (2009).

61. See *Wohlgemuth v. Meyer*, 293 P.2d 816, 820 (Cal. Ct. App. 1956); *Witherell v. Weimer*, 421 N.E.2d 869 (Ill. 1981), *superseded by statute*, 735 ILL. COMP. STAT. 5 / 13-215 (2019).

62. Hafemeister & Spinos, *supra* note 60, at 1186.

63. Thomas H. Boyd, *Cost Containment and the Physician’s Fiduciary Duty to the Patient*, 39 DEPAUL L. REV. 131, 137 (1989).

64. TAMAR FRANKEL, *FIDUCIARY LAW* 17 (2011).

65. Criddle & Fox-Decent, *supra* note 1, at 349.

66. Matthew, *supra* note 11, at 730.

67. AM. MED. ASS’N, *Chapter 1: Opinions on Patient-Physician Relationships*, in CODE OF MEDICAL ETHICS, at Op. 1.1.1 (2016), <https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-overview> [<https://perma.cc/UG3L-ZKP8>].

Mehlman has argued that “regarding physicians as fiduciaries for their patients is essential not only for patients but for physicians.”⁶⁸

All of this more or less reflects reality, so far as it goes.⁶⁹ Physicians, especially in the United States, are among the most robustly trained and vetted professionals worldwide.⁷⁰ They are indeed in a relationship of immense trust from frequently ill and vulnerable patients, and the potential conflicts of interest that might taint their decision-making are generally disclosed and transparent for patients to see and understand.⁷¹ Physicians and their supporting medical provider networks keep detailed records as to almost every step in the treatment process.⁷² The only part that is wrong is that it is the fiduciary relationship, legally enforced by courts, that has gotten us here.

The following analysis examines what courts have stated physicians’ fiduciary duties include, whether or not those courts ever held physicians accountable for those duties.

A. Physicians’ Duty of Loyalty

For nearly all fiduciary relationships, the core duty is that of loyalty, to avoid conflicts of interest that may jeopardize the obligation of the fiduciary to act on behalf of the trustee alone.⁷³ In the *Republic*, Plato wrote that “[N]o physician, in so far as he is a physician, considers his own good in what he prescribes, but the good of his patient; for the true physician is . . . not a mere money-maker.”⁷⁴ In 1760, fiduciary law was first adopted in colonial America to “protect patients in relationships with physician providers.”⁷⁵

As with many fiduciaries, the possible conflicts of interest are manifold, pervasive, and, for physicians, operate at both primary (payment to physicians for services) and secondary (profit for recommending drugs or devices in which the

68. Maxwell J. Mehlman, *Why Physicians Are Fiduciaries for Their Patients*, 12 IND. HEALTH L. REV. 1, 57 (2015).

69. See Jessica Mantel, *A Defense of Physicians’ Gatekeeping Role: Balancing Patients’ Needs with Society’s Interests*, 42 PEPP. L. REV. 633, 643–44 (2015).

70. See Ezekiel J. Emanuel & Victor R. Fuchs, *Shortening Medical Training by 30%*, 307 JAMA 1143, 1144 (2012).

71. Mehlman, *supra* note 68.

72. Christine Sinsky, Lacey Colligan, Ling Li, Mirela Prgomet, Sam Reynolds, Lindsey Goeders, Johanna Westbrook, Michael Tutty & George Blike, *Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties*, 165 ANNALS INTERNAL MED. 753, 753–60 (2016), <http://annals.org/aim/fullarticle/2546704/allocation-physician-time-ambulatory-practice-time-motion-study-4-specialties> [<https://perma.cc/6AQU-7H6E>].

73. *State ex rel. McCloud v. Seier*, 567 S.W.2d 127, 128 (Mo. 1978) (en banc) (“Moreover, as this [fiduciary] duty contemplates the physician’s undivided loyalty to his patient, such duty necessarily runs contrary to the dual allegiance that would result if the physician were employed and paid by his patient’s adversary.”).

74. PLATO, *THE REPUBLIC* 17 (Benjamin Jowett trans., Cosimo Classics 2008) (1888).

75. Matthew, *supra* note 11, at 719.

physician has a financial stake) levels. Frances Miller detailed the potential conflicts of interest that face physicians in modern practice:

At a fundamental level a patient's best interests will not always coincide with what seems to be the physician's most advantageous financial or professional position. Physicians are uniquely situated to persuade patients to purchase medical services, for patients rarely possess the sophisticated diagnostic skills that would prompt them to second guess physician advice. Moreover, when physicians are paid on a fee-for-service basis, their income increases the more services they provide, regardless of whether the patient actually needs them. If the physician works for a profit-sharing independent practice association (IPA) or health maintenance organization (HMO), the fewer services he or she provides the more money the physician makes at the end of the year The . . . possibility of conflict of interest at this primary level is inevitable because of one or another of these economic incentives.

A different kind of conflict of interest . . . is involved when physicians derive secondary income from the care they order for their patients. This happens whenever physicians own substantial equity interests in medical service organizations to which they refer patients.⁷⁶

In their review of the evidence regarding physician conflicts of interest, Christopher Robertson, Susannah Rose, and Aaron Kesselheim found that across specialties and therapies, physicians tended to order more diagnostics, tests, and procedures when they held a financial interest in the firms or facilities conducting those services.⁷⁷ In some circumstances, these self-referrals were also associated with adverse patient outcomes.⁷⁸

Arguing for a fiduciary duty applicable between physicians and Medicare, Buck cites the preference for physicians to prescribe Lucentis, a drug used to treat age-related macular degeneration, to Avastin, a far cheaper drug that has been shown to be equally effective but which has not been equally prescribed.⁷⁹ The reason for this is the incentive Medicare Part B creates by reimbursing the prescribing-physicians for the average price of the drug plus six percent every time they use it on a patient.⁸⁰ Federal and state courts have acknowledged that “gifts or compensation from drug companies influence medical professionals’ treatment

76. Frances H. Miller, *Secondary Income from Recommended Treatment: Should Fiduciary Principles Constrain Physician Behavior?*, in *THE NEW HEALTH CARE FOR PROFIT: DOCTORS AND HOSPITALS IN A COMPETITIVE ENVIRONMENT* 153, 154–55 (Bradford H. Gray ed., 1983), <https://www.ncbi.nlm.nih.gov/books/NBK216764/> [<https://perma.cc/N9EQ-TMM7>].

77. See Christopher Robertson, Susannah Rose & Aaron S. Kesselheim, *Effect of Financial Relationships on the Behaviors of Health Care Professionals: A Review of the Evidence*, 40 *J.L. MED. & ETHICS* 452, 463 (2012).

78. See *id.* at 462–63.

79. See Buck, *supra* note 1, at 1055.

80. *Id.* at 1056 (noting that Lucentis gains the doctors \$120 per dose versus Avastin at \$3 per dose).

decisions” in ways that implicate physicians’ fiduciary duty of loyalty.⁸¹ Yet courts have “resisted efforts” to allow patients to challenge physician conduct based on breach of that duty.⁸²

B. Physicians’ Duty of Candor

Physicians’ duty of candor or disclosure is broad and includes not only revealing personal interests that may affect the objectivity of advice given or treatment recommended, but also material risks related to those prescriptions and informed consent more broadly.⁸³ Originally involving nonconsensual touching of the body by a physician, informed consent was made actionable under the tort theory of battery, anchored as it is in the dignity that comes with bodily autonomy.⁸⁴ Battery theory emphasized that “every human being of adult years and sound mind has a right to determine what shall be done with his own body.”⁸⁵

Since its first official appearance in 1957, informed consent has been significantly expanded.⁸⁶ Now situated in medical negligence, a physician has a duty to disclose to a patient the material risks associated with a proposed procedure when a reasonable patient would need to hear that information to make an informed decision.⁸⁷

Indeed, patients have been far more successful at challenging physicians’ fiduciary duty of candor than the duty of loyalty because courts extend such deference to physicians’ treatment decisions and confuse fiduciary duty and

81. *Murthy v. Abbott Lab’s*, 847 F. Supp. 2d 958, 971, 972 (S.D. Tex. 2012); see *Garcia v. Coffman*, 946 P.2d 216, 219, 221, 226 (N.M. Ct. App. 1997).

82. *Hall*, *supra* note 5, at 493.

83. *Hales v. Pittman*, 576 P.2d 493, 497 (Ariz. 1978) (“However, because of the fiduciary relationship between physician and patient, the scope of the disclosure required can be expanded by the patient’s instructions to the physician.”); *Natanson v. Kline*, 350 P.2d 1093, 1101–02 (Kan. 1960) (“The courts frequently state that the relation between the physician and his patient is a fiduciary one, and therefore the physician has an obligation to make a full and frank disclosure to the patient of all pertinent facts related to his illness.”); *Jacobs v. Painter*, 530 A.2d 231, 239 (Me. 1987) (“Dr. Painter’s duty to disclose arose, as it always has, from the fiduciary character of the physician-patient relationship.”); *Cooper v. Roberts*, 286 A.2d 647, 650 (Pa. Super. Ct. 1971) (“[A] physician’s duty to disclose is . . . imposed by law which governs his conduct in the same manner as others in a similar fiduciary relationship.”). In the context of fiduciary duties more generally, Professor Thomas Gallanis has observed that “[a]cademic writing has concentrated on the other fiduciary duties, such as loyalty, prudence, and impartiality. The duty to inform is due for scholarly treatment.” T.P. Gallanis, *The Trustee’s Duty to Inform*, 85 N.C. L. REV. 1595, 1596 (2007).

84. See Jay Katz, *Informed Consent—Must It Remain A Fairy Tale?*, 10 J. CONTEMP. HEALTH L. & POL’Y 69, 73, 77–78 (1994); Krista J. Sterken, Michael B. Van Sicklen & Norman Fost, *Mandatory Informed Consent Disclosures in the Diagnostic Context: Sometimes Less Is More*, 17 N.Y.U. J. LEGIS. & PUB. POL’Y 103, 107 (2013).

85. *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1912). See generally Sharon Nan Perley, *From Control over One’s Body to Control over One’s Body Parts: Extending the Doctrine of Informed Consent*, 67 N.Y.U. L. REV. 335 (1992).

86. See *Salgo v. Leland Stanford Jr. Univ. Bd. of Trs.*, 317 P.2d 170, 181 (Cal. Ct. App. 1957).

87. *Canterbury v. Spence*, 464 F.2d 772, 781 (D.C. Cir. 1972) (establishing the first objective standard in informed consent cases).

malpractice inquiries (a point further developed in Part III).⁸⁸ In the well-known case of *Moore v. The Regents of the University of California*, the patient sued the doctor who treated him for hairy cell leukemia, challenging the physician's orders to remove his spleen as well as "blood, bone marrow aspirate, and other bodily substances" as conflicted with the physician's intent to use those substances in potentially lucrative clinical research.⁸⁹ The Supreme Court of California in *Moore* determined that the physician had breached his fiduciary duty, not of loyalty, but of disclosure, since the economic interest of a physician may be material to a patient's decision.⁹⁰ "[A] physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."⁹¹

In that decision, the court adopted the "reasonable patient" standard when determining materiality.⁹² Most courts have in fact adopted a "reasonable physician" inquiry that operates much like a standard of care analysis privileging physicians' opinions of one another, not the trust relationship they share with the patient.⁹³

Several courts have held that physicians have an affirmative duty to disclose information that will affect a patient's care.⁹⁴ For instance, not only do physicians have an affirmative duty to disclose to patients any financial interest in clinical research,⁹⁵ some have "imposed a duty on physicians to reveal financial incentives received in a Health Maintenance Organization ("HMO") contract to hold down costs by refusing to order additional tests or by making referrals to specialists."⁹⁶ In

88. *Billings v. Sisters of Mercy*, 389 P.2d 224, 228 (Idaho 1964) ("[I]t is now generally held that the fiduciary relationship between physician and patient imposes a duty of disclosure, breach of which constitutes fraudulent concealment."); *McCormick v. England*, 494 S.E.2d 431, 436–37 (S.C. Ct. App. 1997) ("The jurisdictions that recognize the duty of confidentiality have relied on various theories for the cause of action, including invasion of privacy, breach of implied contract, medical malpractice, and breach of a fiduciary duty or a duty of confidentiality.").

89. *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 485 n.10 (Cal. 1990).

90. *Id.* at 485.

91. *Id.*

92. Nadia N. Sawicki, *The Abortion Informed Consent Debate: More Light, Less Heat*, 21 CORNELL J.L. & PUB. POL'Y 1, 19 (2011); *Nixdorf v. Hicken*, 612 P.2d 348, 354 (Utah 1980) ("The relationship between a doctor and his patient creates a duty in the physician to disclose to his patient any material information concerning the patient's physical condition. This duty to inform stems from the fiduciary nature of the relationship . . .").

93. 4 LEONARD J. NELSON III, *MEDICAL MALPRACTICE* § 22.05 (2020) (reporting that the reasonable patient standard "remains the minority position"). In states using the reasonable physician standard, a physician would only be required to disclose "an interest extraneous to the patient's health" if other physicians customarily did so. *Moore*, 793 P.2d at 484.

94. *Emmett v. E. Dispensary & Cas. Hosp.*, 396 F.2d 931, 935 (D.C. Cir. 1967) ("We find in the fiducial qualities of that relationship [between physician and patient] the physician's duty to reveal to the patient that which in his best interests it is important that he should know.").

95. See Marc A. Rodwin, *Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System*, 21 AM. J.L. & MED. 242, 248 (2005).

96. Richard W. Bourne, *Medical Malpractice: Should Courts Force Doctors to Confess Their Own Negligence to Their Patients?*, 61 ARK. L. REV. 621, 641 (citing *Shea v. Esensten*, 208 F.3d 712, 717 (8th Cir. 2000)).

addition to holding HIV-infected physicians liable under an “informed-consent theory,” for treating patients without disclosing their HIV status, some courts have held that the “refusal of a physician to reveal financial or other interests is a breach of fiduciary duty.”⁹⁷ Furthermore, physicians are required to disclose “emergent medical risks” to patients that they are either the cause of through medical error, or that they discover during the course of treatment of something unrelated to the emergent medical risk.⁹⁸ The duty of candor is so strong, under the fiduciary relationship, that a few courts have concluded that failure to disclose is tantamount to active concealment.⁹⁹

C. Physicians’ Duty of Care

Once the doctor-patient relationship is established, physicians, like attorneys, corporate directors, and other fiduciaries are under an obligation to perform their professional activities carefully and competently, generally as judged by the prevailing standards of professional competence in the relevant field of medicine.¹⁰⁰ While typically adjudicated as malpractice actions, courts have confirmed the duty of care as one of physicians’ fiduciary duties.¹⁰¹

The distinction between deviation of the standard of care as a fiduciary and that of any other ordinary actor owing someone else a duty (ordinary negligence) is significant.¹⁰² Corporate directors and general partners, for example, must be guilty of “gross negligence” before courts will impose liability for violation of the fiduciary

97. *Id.* at 641 (citing Moore, 793 P.2d at 485); Faya v. Almaraz, 620 A.2d 327, 339 (Md. 1993); Estate of Behringer v. Med. Ctr. at Princeton, 592 A.2d 1251, 1283 (N.J. Super. Ct. Law Div. 1991) (holding that disclosure of HIV-positive status was required under hospital’s informed-consent doctrine)).

98. AM. MED. ASS’N, *Chapter 8: Ethics for Physicians & the Health of the Community*, in CODE OF MEDICAL ETHICS, *supra* note 67, at Op. 8.12.

99. Guy v. Schuldt, 138 N.E.2d 891, 895 (Ind. 1956) (“Usually, there must be some active effort on the part of one to be guilty of concealment but where a fiduciary or confidential relationship exists, such as physician-patient, there exists a duty to disclose material information between the parties and a failure to do so results in concealment.”); Daniel Sperling, *(Re)disclosing Physician Financial Interests: Rebuilding Trust or Making Unreasonable Burdens on Physicians?*, 20 MED. HEALTH CARE & PHILOS. 179, 181–82 (2017).

100. Nestorowich v. Ricotta, 767 N.E.2d 125, 128 (N.Y. 2002).

101. Toman v. Creighton Mem’l St. Josephs Hosp., Inc., 217 N.W.2d 484, 489 (Neb. 1974) (“‘Malpractice’ has been defined by the court as the treatment of a case by a surgeon or physician in a manner contrary to the accepted rules and with injurious results to the patient; hence, any professional misconduct or any unreasonable lack of skill or fidelity in the performance of professional or fiduciary duties.”); Georgetown Realty v. Home Ins. Co., 831 P.2d 7, 14 n.7 (Or. 1991) (“The form of action for a claim against a fiduciary for breaching a duty of care arising from the relationship is not materially different from a claim against a physician, a lawyer, or an engineer for breaching a duty of care arising from such a relationship.”).

102. See, e.g., Christopher K. Odinet, *The Unfinished Business of Dodd-Frank: Reforming the Mortgage Contract*, 69 SMU L. REV. 653, 675–76 (2016) (analyzing the relevance of the absence of such a duty on lenders).

duty of care.¹⁰³ For attorneys, physicians, and many other fiduciaries, courts have equated breaches of the fiduciary duty of care with malpractice, imposing ordinary negligence and preponderance of the evidence standards when adjudicating claims by beneficiaries.¹⁰⁴

After the physician relationship is established, the patient must prove the applicable standard of care and then establish the physician's deviation from that standard to the patient's detriment.¹⁰⁵ Generally, the standard of care is the "degree of skill and care that would ordinarily be exercised by an average physician in similar circumstance."¹⁰⁶ Specialists are required to exercise a higher degree of skill and care in their area of expertise.¹⁰⁷ Due to the complex nature of medical malpractice litigation, physicians are almost always retained to be expert witnesses.¹⁰⁸

The physician's duty of care includes numerous related obligations.¹⁰⁹ Those obligations include retention of a competent support staff, making and keeping adequate records, keeping current with diagnostic and treatment advances, and maintaining privileges with necessary healthcare facilities.¹¹⁰ These obligations clarify that physicians must minimize any potential interference with their ability to treat patients once the physician-patient relationship has been established. Doctors are also held to the duty of "technical competence,"¹¹¹ which includes completing

103. Julian Velasco, *A Defense of the Corporate Law Duty of Care*, 40 J. CORP. L. 647, 653–54 (2015); Joseph W. Yockey, *Does Social Enterprise Law Matter?*, 66 ALA. L. REV. 767 (analyzing the adaptation of fiduciary duties in the benefit corporation context).

104. *Schieffer v. Cath. Archdiocese of Omaha*, 508 N.W.2d 907, 912 (Neb. 1993) (holding that parishioner's breach of fiduciary duty claim against priest was not actionable as it was "merely another way of alleging that the defendant grossly abused his pastoral role, that is, he engaged in malpractice"); *Navajo Tribe of Indians v. United States*, 9 Cl. Ct. 227, 258 (1985) (holding that trustee's standard of care is determined by the circumstances of time and place that surrounded the trustee when he took or failed to take the action in question); *Himel v. Cont'l Ill. Nat'l Bank & Tr. Co.*, 596 F.2d 205, 209 n.4 (7th Cir. 1979) (finding that under Illinois law, breach of fiduciary duty will result from violations of obligations of a trustee in carrying out the trust according to its terms of care and diligence in protecting and investing trust property and of exercising good faith); *Wright v. Nimmons*, 641 F. Supp. 1391, 1402 (S.D. Tex. 1986) (holding that a trustee must exercise at least that degree of care that a reasonably prudent person would devote to his own affairs under like circumstances).

105. Meghan C. O'Connor, *The Physician-Patient Relationship and the Professional Standard of Care: Reevaluating Medical Negligence Principles to Achieve the Goals of Tort Reform*, 46 TORT TRIAL & INS. PRAC. L.J. 109, 117 (2010).

106. John W. Ely, Arthur J. Hartz, Paul A. James & Cynda A. Johnson, *Determining the Standard of Care in Medical Malpractice: The Physician's Perspective*, 37 WAKE FOREST L. REV. 861, 862 (2002).

107. Cara E. Davies & Randi Zlotnik Shaul, *Physician's Legal Duty of Care and Legal Right to Refuse to Work During a Pandemic*, 18 CANADIAN MED. ASS'N J. 167, 167 (2010).

108. Chris Taylor, *The Use of Clinical Practice Guidelines in Determining Standard of Care*, 35 J. LEGAL MED. 273, 273 (2014).

109. *Stigliano v. Connaught Lab'ys, Inc.*, 658 A.2d 715, 720 (N.J. 1995) ("The relationship between treating physicians and their patients, sometimes described as fiduciary in nature, gives rise to a duty to testify in judicial proceedings about treatment rendered to the patient.").

110. Boyd, *supra* note 63, at 139.

111. Rodwin, *supra* note 95, at 249.

continuing education courses and consulting outside medical professions “when indicated.”¹¹²

D. Physicians’ Duty of Confidentiality

The fiduciary relationship between doctors and patients “arises from the trust and confidence patients place in physicians to operate in good faith, remain loyal to their patients, and subordinate their own self-interest and the interests of others.”¹¹³ While professional canons also speak to the duty of confidentiality, courts have also read that obligation to be part of the broader fiduciary duties that physicians owe patients.¹¹⁴ Because trust is essential to the functioning of the fiduciary relationship, confidence provides an important assurance to the entrustor seeking advice.¹¹⁵ Throughout treatment, the physician is bound to “ensure the confidentiality of the relationship, and, most significantly, to provide a level of care that meets accepted standards in the profession.”¹¹⁶ Unauthorized disclosures of patient information are actionable for damages precisely to ensure the integrity of physician-patient communications.¹¹⁷

As with duties of loyalty and candor, courts have developed exceptions. Marc Rodwin has noted that while “[p]sychiatrists owe loyalty to their patients” they are also expected to abrogate that loyalty under certain circumstances that pose risks to the safety of others.¹¹⁸ In *Tarasoff v. Regents of the University of California*, the Supreme Court of California determined that mental health physicians must protect third parties threatened with bodily harm by their patients, including through disclosure.¹¹⁹ In addition, physicians are required to report certain contagious diseases, and physicians whose patients have HIV are “ethically obligated to divulge

112. AM. MED. ASS’N, *AMA Principles of Medical Ethics*, in CODE OF MEDICAL ETHICS, *supra* note 67, <https://www.ama-assn.org/sites/default/files/media-browser/principles-of-medical-ethics.pdf> [<https://perma.cc/PEQ6-RJNF>].

113. Matthew, *supra* note 11, at 726.

114. *McCormick v. England*, 494 S.E.2d 431, 435 (S.C. Ct. App. 1997) (“A majority of the jurisdictions faced with the issue have recognized a cause of action against a physician for the unauthorized disclosure of confidential information unless the disclosure is compelled by law or is in the patient’s interest or the public interest.”).

115. Maxwell J. Mehlman, *The Patient-Physician Relationship in an Era of Scarce Resources: Is There a Duty to Treat?*, 25 CONN. L. REV. 349, 369 (1993); *Gracey v. Eaker*, 837 So. 2d 348, 354 (Fla. 2002) (“These cases are also persuasive authority and support our conclusion that a psychotherapist who has created a fiduciary relationship with his client owes that client a duty of confidentiality, and that a breach of such duty is actionable in tort.”); *Domako v. Rowe*, 475 N.W.2d 30, 34 (Mich. 1991); *Parris v. Limes*, 277 P.3d 1259, 1265 n.3 (Okla. 2012) (“Oklahoma has long recognized that the relationship between a physician and patient is a fiduciary and confidential relationship.”).

116. Boyd, *supra* note 63, at 137.

117. *Tehven v. Job Serv.* N.D., 488 N.W.2d 48, 51 (N.D. 1992) (“Courts have generally recognized a patient’s right to recover damages from a physician for unauthorized disclosure of medical information as . . . [a] breach of the fiduciary relationship between a physician and a patient.”).

118. Rodwin, *supra* note 95, at 251–52.

119. *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334, 345–46 (Cal. 1976).

a patient's confidences and warn sexual partners known to be at risk of contagion."¹²⁰

E. Physicians' Duty of Good Faith

Broadly, courts have encompassed physicians' fiduciary duties with an ultimate obligation to act in good faith.¹²¹ Courts have admonished physicians not only "to act in their patients' best interest [as part of their fiduciary duty]," but to also "deal fairly with their patients, while eschewing kickbacks, excessive services, and improper referrals."¹²² The latter breaches of good faith, as in the corporate context, overlap significantly with the duty of loyalty. As Dayna Bowen Matthew notes, the good faith and fair dealing aspect of physicians' fiduciary duties have been given central importance by courts:

Some courts have a long-established history of acknowledging the fiduciary nature of the physician-patient relationship in medical malpractice cases, holding that the provider's fiduciary duty arises from the trust and confidence patients place in physicians to operate in good faith, remain loyal to their patients, and subordinate their own self-interest and the interests of others.¹²³

III. THE LIMITATIONS AND STRUCTURAL INCAPACITY OF COURTS TO REMEDY BREACHES OF PHYSICIANS' FIDUCIARY DUTIES

Despite the lofty rhetoric courts attach to the fiduciary relationship between physicians and patients, they have been largely reluctant to enforce fiduciary duties, per se, against physicians. Indeed, prominent scholars of the physician-patient relationship have noted the actual application of a physician's fiduciary duty is "sparse"¹²⁴ and rarely applied in such a way as to vindicate the relationship as a truly fiduciary one.¹²⁵ Numerous structural factors explain why courts hesitate to fully

120. Rodwin, *supra* note 95, at 252; Ad Hoc Comm. on Med. Ethics, *American College of Physicians Ethics Manual. Part I: History of Medical Ethics, The Physician and the Patient, The Physician's Relationship to Other Physicians, The Physician and Society*, 101 ANNALS INTERNAL MED. 129, 134 (1984), *cited in* Mehlman, *supra* note 68, at 9 n.8.

121. *Black v. Littlejohn*, 325 S.E.2d 469, 482 (N.C. 1985) ("The relationship of patient and physician is generally considered a fiduciary one, imposing upon the physician the duty of good faith and fair dealing."); *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 879 (Ohio 1991) ("The physician-patient relationship is a fiduciary one based on trust and confidence and obligating the physician to exercise good faith.").

122. Matthew, *supra* note 11, at 728–29.

123. *Id.* at 726.

124. Hafemeister & Spinos, *supra* note 60, at 1167.

125. Rodwin, *supra* note 95, at 255; Michelle Oberman, *Mothers and Doctors' Orders: Unmasking the Doctor's Fiduciary Role in Maternal-Fetal Conflicts*, 94 NW. U. L. REV. 451, 459–68 (2000) (describing challenges to physicians' loyalty); *see also* Mehlman, *supra* note 68, at 10 n.9 (noting that in three states—Alabama, Delaware, and Minnesota—courts have rejected the fiduciary metaphor for the physician-patient relationship).

execute the relationship, factors that would apply with equal force to the proliferating regimes advocates of more fiduciary duties now propose.

A. The Rules of Civil Procedure Confound Fiduciary Duties

Under both federal and state rules of civil procedure, plaintiffs must bring all their claims arising out of the same transactional nucleus of facts in the same civil action.¹²⁶ Judicial efficiency and *res judicata* favor disposition of cases comprehensively so that litigation ends once the rights of the parties have been determined.¹²⁷ In the case of patients with claims against physicians, they will by these principles be required to bring common law claims in contract and other torts, as they do, in addition to claims for breach of fiduciary duty.¹²⁸ These former claims often have advantageous features from the perspective of trial judges—more questions are clearly factual and reserved for the jury; fewer equitable remedies that require judicial intervention; and clearer law, especially binding judicial precedent.

Remedies for breaches of fiduciary duties require far more extensive involvement of courts in private law relationships than remedies available in common law actions sounding in contract or other tort claims.¹²⁹ Disgorgement, for example, would require the court to undertake a thorough examination of the profits made by a disloyal physician, whereas compensatory damages in a malpractice action require only an assessment of the evidence a patient-plaintiff would submit through the normal discovery and trial process.¹³⁰ As Einer Elhauge concluded in the antitrust context, “the rare usage of disgorgement actions thus seems to have been based mainly on a general premise that private actions already

126. William A. Fletcher, “*Common Nucleus of Operative Fact*” and *Defensive Set-Off: Beyond the Gibbs Test*, 74 IND. L.J. 171, 171 (1998) (“Under the influence of modern procedural rules encouraging liberal joinder of parties and claims, the size of a permissible unit of litigation has substantially increased in this century. In both state and federal courts the goal of these joinder rules has been to foster procedural fairness and judicial efficiency, ‘to secure the just, speedy, and inexpensive determination of every action.’” (quoting FED. R. CIV. P. 1)).

127. Albrecht Zeuner & Harald Koch, *Effects of Judgments (Res Judicata)*, in 16 INTERNATIONAL ENCYCLOPEDIA OF COMPARATIVE LAW ONLINE ¶ 25 (Mauro Cappelletti ed., 2014), http://dx.doi.org/10.1163/2589-4021_IECO_COM_160903 [<https://perma.cc/6NXP-LGK6>] (“The main purpose inherent in the concept of *res judicata* is to ensure that once a matter has been decided further controversy or uncertainty about it is eliminated. This implies on the procedural level that the rendering of an inconsistent decision concerning the same subject matter must be prevented. For as long as the possibility remains that a different judgment may be rendered in a new proceeding, legal certainty has not yet been achieved and the litigation is not yet finally concluded.”).

128. See, e.g., Stephen R. Feldman & Thomas M. Ward, *Psychotherapeutic Injury: Reshaping the Implied Contract as an Alternative to Malpractice*, 58 N.C. L. REV. 63, 77 (1979).

129. Mary C. Burdette & Scott D. Weber, Remedies for Breach of Fiduciary Duty 1 (June 26–28, 2013) (unpublished manuscript), <https://www.dallasprobatelawfirm.com/documents/Remedies-For-Breach-Of-Fiduciary-Duty.pdf> [<https://perma.cc/J3BW-GJHF>].

130. ERI Consulting Eng’rs, Inc. v. Swinnea, 318 S.W.3d 867, 873 (Tex. 2010) (“[C]ourts may fashion equitable remedies such as profit disgorgement and fee forfeiture to remedy a breach of fiduciary duty.”).

provide adequate monetary relief, so that disgorgement claims would not provide an additional benefit.”¹³¹

B. Courts Reject Patients’ Fiduciary Duty Claims

Courts routinely reject attempts by patients to vindicate fiduciary duties owed to them by physicians in favor of medical malpractice suits that feature adversarial discovery, jury determinations, and passive involvement of judges. This is true for all the duties identified above. In *Hales v. Pittman*, the Arizona Supreme Court was explicit in its preference for medical malpractice rather than breach of fiduciary duty actions for breach of the duty of candor:

Additionally, if an undisclosed risk occurs, a patient may pursue a malpractice action premised on a negligence theory. We do not believe that the law in Arizona should be extended to recognize a new cause of action based on breach of trust when an adequate remedy for this case already exists. To do otherwise would ignore the underlying premise that the patient controls his own destiny.¹³²

Interpreting Kansas law, a federal district court declared that all physician fiduciary duties were subsumed by medical malpractice actions based on the same acts or omissions:

Under Kansas law, a plaintiff who brings a claim against a doctor or hospital for failure to perform the legal duty to exercise reasonable care, skill and diligence in the treatment of a patient may not also maintain other claims against the doctor or hospital for actions that arise from the same series of events as the underlying malpractice claim. . . . Kansas courts will not permit a plaintiff to “creatively classify” a claim as something other than one for medical malpractice if the substance of the claim concerns the physician-patient relationship.¹³³

The Nebraska Supreme Court declared that “any professional misconduct or any unreasonable lack of skill or fidelity in the performance of professional or fiduciary duties is ‘malpractice’ and comes within the professional or malpractice statute of limitations.”¹³⁴ Similarly, in New Mexico, “it is this affirmative duty of full and fair disclosure that is at the heart . . . of fiduciary duty. However, the failure of a physician to disclose the factors that might influence a patient in his decision is a negligence cause of action that is triable by jury.”¹³⁵ In Minnesota (one of three jurisdictions to broadly reject fiduciary duties for physicians) an appellate court determined that such an action might be plausible where the underlying facts are independent of medical diagnosis, treatment, and care.¹³⁶ Ohio, Texas, and

131. Einer Elhauge, *Disgorgement as an Antitrust Remedy*, 76 ANTITRUST L.J. 79, 83 (2009).

132. *Hales v. Pittman*, 576 P.2d 493, 497 (Ariz. 1978).

133. *Kernke v. Menninger Clinic, Inc.*, 172 F. Supp. 2d 1347, 1354 (D. Kan. 2001).

134. *Colton v. Dewey*, 321 N.W.2d 913, 917 (Neb. 1982).

135. *Garcia v. Coffman*, 946 P.2d 216, 223 (N.M. Ct. App. 1997).

136. *D.A.B. v. Brown*, 570 N.W.2d 168, 171–72 (Minn. Ct. App. 1997).

Washington courts have similarly wrapped fiduciary duty claims up with malpractice claims. In Delaware, fiduciary duties for physicians were rejected altogether because the Delaware Supreme Court reserved its courts of chancery for the core responsibility of adjudicating disputes involving corporate fiduciaries.¹³⁷

Indeed, Anna Laakmann has observed:

[D]espite frequent incantations of fiduciary principles, courts have enforced physicians' fiduciary duties in a haphazard, ad hoc manner. While medical ethical codes and case law routinely pronounce physicians as fiduciaries, the legal substance behind this label remains elusive. Courts' vague characterization of physicians' fiduciary duties offers woefully little guidance on the legally permissible bounds of physician behavior under conditions of endogenous uncertainty.¹³⁸

C. Courts De-Trust the Duty of Care

The physician's duty of care, as a fiduciary matter, should ensure that her practice matches her level of competence, deficiencies in knowledge or ability, and efforts to obtain help when needed. In terms of individual patient care, physicians should provide medical care based on objective evidence whenever possible. This includes demonstrating a sense of inquiry and taking a scientific approach to solving clinical issues for the benefit of the patient.¹³⁹

As a historical matter, courts rarely analyzed the duty of care as a function of the fiduciary relationship with patients. Rather, courts focused on physician-patient disputes as a matter of evidence, with which they were structurally better suited to assess. As Mark Hall has surmised, courts have found that "evidence of financial incentives would tend to unfairly inflame jurors, and they have resisted efforts to craft legal theories based on fiduciary law that would circumvent conventional medical malpractice standards."¹⁴⁰

In claims by patients against physicians, the standard of care must almost always be established through expert testimony.¹⁴¹ Expert witnesses typically formulate their opinions on the standard of care "by combining their own personal experience and knowledge of customary practices with their knowledge of the

137. Mehlman, *supra* note 68, at 22.

138. Anna B. Laakmann, *When Should Physicians Be Liable for Innovation?*, 36 CARDOZO L. REV. 913, 955–56 (2015).

139. Alfredo D. Espinosa-Brito, *Rapid Response: The Clinical Method Is the Scientific Method Applied to the Care of a Patient*, Response to *Doctors Are Not Scientists*, BMJ (June 27, 2004), <https://www.bmj.com/rapid-response/2011/10/30/clinical-method-scientific-method-applied-care-patient> [<https://perma.cc/5CRK-WWG3>].

140. Hall, *supra* note 5, at 493.

141. *Carney-Hayes v. Nw. Wis. Home Care, Inc.*, 699 N.W. 2d 524, 537 (Wis. 2005).

medical literature.”¹⁴² Courts have historically given great weight to customary practices among physicians.¹⁴³

The use of physician custom gave rise to judicially crafted rules that made actions challenging physician competence difficult. “Locality” rules, for example, required patients to find an expert in the community to testify on their behalf as to the applicable standard of care, even though doing so forced even sympathetic physicians to choose between their local reputation (a core objective of the fiduciary relationship) and testifying on behalf of injured patients.¹⁴⁴ In *Small v. Howard*, the Massachusetts Supreme Judicial Court determined that the defendant-surgeon “was bound to possess that skill only which physicians and surgeons of ordinary ability and skill, practi[cing] in similar localities.”¹⁴⁵ Many states adopted and expanded this rule. Expert testimony by physicians who were not familiar with the local practices were inadmissible.¹⁴⁶ Finding an expert within the defendant’s community was rare as many physicians refused to testify, thus leaving the plaintiff to outsource to “national” witnesses.¹⁴⁷

Technological advances and persistent “conspiracy of silence” did result in some abandonment of locality rules in favor of national standards of care.¹⁴⁸ The majority of states have now adopted a “national standard of care” based on the expansion of healthcare resources and the nationalization of medical school curriculum. The national standard of care requires physicians to act with the degree of skill and care ordinarily possessed by a reasonable and prudent physician in the same medical specialty acting under the same or similar circumstances.¹⁴⁹

Yet the evolution of national standards of care has been gradual, and large jurisdictions with national medical schools retain locality rules. “Of 2007, 21 states maintained a version of the locality rule and 29 states followed a national standard.¹⁵⁰ Of the 21 states that followed a version of the locality rule, 3 followed a statewide standard, 2 the same-community standard, 11 the same- or

142. Glenn E. Bradford, *The “Respectable Minority” Doctrine in Missouri Medical Negligence Law*, 56 J. MO. BAR 326, 327 (2000); see also Fred L. Cohen, *The Expert Medical Witness in Legal Perspective*, 25 J. LEGAL MED. 185, 191 (2004).

143. Peter Moffett & Gregory Moore, *The Standard of Care: Legal History and Definitions: The Bad and Good News*, 12 W. J. EMERGENCY MED. 109, 110 (2011).

144. John M. Tyson, Comment, *Statutory Standard of Care for North Carolina Health Care Providers*, 1 CAMPBELL L. REV. 111, 115–16 (2012); Cristina Carmody Tilley, *Tort Law Inside Out*, 126 YALE L.J. 1320, 1345 (2017) (“The *Restatement’s* discussion of negligence refers to ‘community’ more than a dozen times, always as a source of liability standards. First, the *Restatement* squarely indicates that the duty a defendant owes a plaintiff is contingent on the community in which the dispute takes place.”).

145. O’Connor, *supra* note 105, at 118; *Small v. Howard*, 128 Mass. 131, 136 (1880), *overruled by* *Brune v. Belinkoff*, 235 N.E.2d 793, 798 (Mass. 1968).

146. *Walls v. Boyett*, 226 S.W.2d 552, 556 (Ark. 1950) (modifying locality rule to include same general neighborhood).

147. Tyson, *supra* note 144, at 118.

148. O’Connor, *supra* note 105, at 120.

149. See generally *Munro v. Regents of Univ. of Cal.*, 263 Cal. Rptr. 878, 882 (Ct. App. 1989).

150. Brian K. Cooke, Elizabeth Worsham & Gary M. Reisfield, *The Elusive Standard of Care*, 45 J. AM. ACAD. PSYCHIATRY & L. 358, 361 (2017).

similar-community standard, and 5 the similar-community standard for general practitioners and a national standard for specialists.”¹⁵¹

Even within states following national standards of care, rules of evidence regarding scientific support for expert testimony vary significantly. For example, even where there is a majority standard, courts permit physicians to enter evidence as to a “respectable minority” judgment by a physician.¹⁵² The respectable minority doctrine allows physicians choice in an alternative medicine approach to treatment to not be seen as a deviation from the standard of care.¹⁵³

With respect to other sources of evidence, clinical practice guidelines originated as a means of improving the quality of care by attempting to create uniformity across regional differences in clinical practice, balance overuse and underuse of certain medical services, and provide a means for communicating outcomes-based and cost-effective clinical practices to physicians.¹⁵⁴ Clinical practice guidelines are “a systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”¹⁵⁵ The introduction of clinical practice guidelines into medical malpractice litigation was intended to establish standards of care with more certainty and less subjectivity.¹⁵⁶

While the promise of the clinical practice guidelines was probably always overestimated because of idiosyncratic patient needs, courts have nevertheless turned them into another evidentiary complication, rarely using them to identify a physician’s fiduciary duty of care to a patient.¹⁵⁷ In many cases where guidelines are admitted into evidence, they do not supply a source of conclusive evidence.¹⁵⁸ In *Frakes v. Cardiology Consultants, P.C.*, for example, a physician presented a printed table by the American Heart Associations to establish the standard of care for interpreting exercise stress tests.¹⁵⁹ The court allowed the chart into evidence not to determine the standard of care, but because doing so would “organize the expert testimony to assist the trier of fact to more easily understand a highly technical

151. *Id.*

152. Bradford, *supra* note 142, at 329.

153. Joseph H. King, Jr., *Reconciling the Exercise of Judgment and the Objective Standard of Care in Medical Malpractice*, 52 OKLA. L. REV. 49, 57 (1999); *Hall v. Hillbun*, 466 So. 2d 856, 871 (Miss. 1985); *McCourt v. Abernathy*, 457 S.E.2d 603, 607 (S.C. 1995) (quoting jury instruction which stated that “[s]uch differences [due] to preference . . . do not amount to malpractice”).

154. Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 649 (2001).

155. Taylor, *supra* note 108, at 278 (quoting INST. OF MED. COMM. TO ADVISE THE PUB. HEALTH SERVS. ON CLINIC PRACT. GUIDELINES, CLINICAL PRACTICE GUIDELINES: DIRECTION FOR A NEW PROGRAM 1, 38 (Marilyn J. Field & Kathleen N. Lohr eds., 1990)).

156. Sam A. McConkey, IV, Note, *Simplifying the Law in Medical Malpractice: The Use of Practice Guidelines as the Standard of Care in Medical Malpractice Litigation*, 97 W. VA. L. REV. 491, 506 (1995).

157. Taylor, *supra* note 108, at 281; Mello, *supra* note 154, at 663–65.

158. *Frakes v. Cardiology Consultants, P.C.*, No. 01-A-01-9702-CV-00069, 1997 WL 536949 (Tenn. Ct. App. Aug. 29, 1997); *Hinlicky v. Dreyfuss*, 848 N.E.2d 1285 (N.Y. 2006).

159. *Frakes*, 1997 WL 536949, at *2.

subject.”¹⁶⁰ In *Hinlicky v. Dreyfuss*, after a flowchart depicting clinical guidelines was submitted, the court admitted it over a hearsay objection on the basis that it illustrated the physician’s thought process, rather than as evidence of the standard of care—a distinction it acknowledged might not matter to jurors.¹⁶¹

However, courts have also rejected clinical practice guidelines on the basis of hearsay. In *Greathouse v. Rhodes*, the plaintiff attempted to introduce clinical practice guidelines as evidence of the standard of care for the management of unstable angina.¹⁶² The trial court refused (and the appellate court held it was not an abuse of discretion to do so) because the guidelines were hearsay and not used for purposes of impeachment.¹⁶³ As one study concluded, courts have generally not relied on clinical practice guidelines, “and when they have, they were used conservatively.”¹⁶⁴

The unpredictability of standards of care works haphazardly against both patients and physicians.¹⁶⁵ Courts have been known to jettison an accepted standard and impose their own.¹⁶⁶ In *Helling v. Carey*, a thirty-two-year-old woman suffered severe damage to her eye after a physician failed to administer a glaucoma test.¹⁶⁷ The Court ruled for the plaintiff even though the customary standard was for the test to be administered to those over forty years old.¹⁶⁸ The court applied, in essence, the Hand Formula, determining that a low-cost measure with a high probability of benefiting patients sufficed to establish the applicable standard of care.¹⁶⁹

D. Implications for Current Proposals

These structural judicial limitations would almost certainly confront the regimes now being advocated by fiduciary proponents. Consider the fiduciary duty Buck proposes for medical providers who bill Medicare. Under the regime he envisages, Medicare would be able to pursue breach of fiduciary duty claims against

160. *Id.* at *4.

161. *Hinlicky*, 848 N.E.2d at 1291.

162. *Greathouse v. Rhodes*, 618 N.W.2d 106 (Mich. Ct. App. 2000) (discussing plaintiff’s allegation that defendant failed to properly diagnose and treat an unstable angina that caused a heart attack and death), *rev’d on other grounds*, 636 N.W.2d 138 (Mich. 2001).

163. *Id.* at 115.

164. Douglas S. Ruhl & Gil Siegal, *Medical Malpractice Implications of Clinical Practice Guidelines*, 157 OTOLARYNGOLOGY–HEAD & NECK SURGERY 175, 176 (2017).

165. *Harris v. Groth*, 663 P.2d 113, 120 (Wash. 1983) (“Our holding today may be summarized as follows. The standard of care against which a health care provider’s conduct is to be measured is that of a reasonably prudent practitioner possessing the degree of skill, care, and learning possessed by other members of the same profession in the state of Washington. The degree of care actually practiced by members of the profession is only some evidence of what is reasonably prudent—it is not dispositive.”).

166. Philip G. Peters, Jr., *The Quiet Demise of Deference to Custom: Malpractice Law at the Millennium*, 57 WASH. & LEE L. REV. 163, 164 (2000).

167. *Helling v. Carey*, 519 P.2d 981, 982 (Wash. 1974); O’Connor, *supra* note 105, at 123–25.

168. *Helling*, 519 P.2d at 985.

169. *See generally* The T.J. Hooper, 60 F.2d 737 (2d Cir.), *cert. denied*, 287 U.S. 662 (1932); *Helling*, 519 P.2d 981.

individual providers which would be tailored to their excessive treatments.¹⁷⁰ But claims that Medicare has been wrongly billed are almost *always* accompanied by claims of common law fraud, payment by mistake, and unjust enrichment, each of which the Department of Justice (which represents Medicare in wrongful payment cases) must and does bring as an advocate aiming for the best chance for recovery for its client. Given that a court may give Medicare effectively the same remedy—the amount it was overcharged—through a contract claim determined by a jury, it is likely that the fiduciary duty claim Buck proposes, which would require court-managed disgorgement or a constructive trust, would be disfavored, despite its compelling and urgent rationale.

Similarly, Evan Criddle’s recommendation for Congress to amend the Administrative Procedures Act to incorporate fiduciary principles of purposefulness, integrity, solicitude, fairness, reasonableness, and transparency, and to expand judicial review over some aspects of their implementation, may not lead to more faithful behavior. In a careful and methodical analysis, Criddle advocates loosening (1) the doctrine of nonreviewability, which limits the types of claims that may be raised against agency inaction, and (2) the doctrine of standing, which limits the types of parties who may bring claims based on agency inaction.¹⁷¹ He also advocates inclusion of White House communications as part of the reviewable record judges may consider.¹⁷² But as Criddle himself acknowledges, his proposals multiply the grounds upon which courts may reach “arbitrary and capricious” conclusions.¹⁷³ As David Zaring has persuasively argued about judicial review of agency action generally, “courts do not, in the end, discern the differences among these various [agency review] doctrines, frequently do not distinguish among the doctrines in application, and probably do not really care which standard of review they apply most of the time.”¹⁷⁴

Ethan Leib advocates the adoption of principles to guide a judicial finding of “friendship” with accompanying rules as to the screening of minor conflicts, threshold presumptions, and limitations on remedies like disgorgement.¹⁷⁵ Yet as with fiduciary duties for Medicare providers and agency rule-makers, the hope that expansion of judicial review will strengthen rather than weaken the fiduciary duties is in doubt. Indeed, Leib’s argument focuses on friendships that involve routine legal disputes over business opportunities, gifts, and property. Remedies for breaches of fiduciary duty are often *equitable*—by their nature judges seek to *avoid* applying them if adequate alternative legal remedies exist.¹⁷⁶

170. Buck, *supra* note 1, at 1074–75.

171. Criddle, *supra* note 1, at 483.

172. *Id.* at 484–85.

173. *Id.* at 486.

174. David Zaring, *Reasonable Agencies*, 96 VA. L. REV. 135, 138 (2010).

175. Leib, *supra* note 1.

176. DOUG RENDLEMAN & CAPRICE L. ROBERTS, REMEDIES: CASES & MATERIALS 346 (8th ed. 2011) (“There is constant pressure to utilize the remedies test for the parties’ right to a jury trial. That test is more practical and easier to apply.”); E. Allan Farnsworth, *Your Loss or My Gain? The*

IV. STATE AND FEDERAL LEGISLATIVE APPROACHES TO CONFLICTS OF INTEREST

As detailed above, much of the literature on expanding fiduciary obligations depends on utopian accounts of fiduciary heroes whose conduct is monitored by equally utopian judges.¹⁷⁷ But in actual operation, the fiduciary construct is not only costly, it may overemphasize the conduct of the fiduciary actor and underemphasize the context in which a purported breach occurs. In other words, instead of blaming a fiduciary for a conflict of interest, it may be more efficient to target the source of the conflict. The practice of medicine, like the practice of law, or the management of a corporation, as well as parenthood and friendship, occurs in a complex social marketplace.¹⁷⁸ Studying the resource constraints that physicians face in modern practice, the AMA contextualized the physician's fiduciary duty:

Physicians' primary ethical obligation is to promote the well-being of individual patients. Physicians also have a long-recognized obligation to patients in general to promote public health and access to care. This obligation requires physicians to be prudent stewards of the shared societal resources with which they are entrusted. Managing health care resources responsibly for the benefit of all patients is compatible with physicians' primary obligation to serve the interests of individual patients Arguments that physicians should never allow considerations other than the welfare of the patient before them to influence their professional recommendations and treatment do not mesh with the reality of clinical practice. Physicians regularly work with a variety of limits on care: clinical practice guidelines, patient preferences, availability of certain services, the benefits covered by a patient's insurance plan, and the time physicians and nurses can spend caring for a patient all influence what interventions physicians recommend and what care they provide.¹⁷⁹

Given the complex universe in which fiduciary duties are actually applied, broadly worded and executed duties are less, not more, likely to lead to clear expectations by fiduciaries or entrustors.

Dilemma of the Disgorgement Principle in Breach of Contract, 94 YALE L.J. 1339, 1368 (1985); James Steven Rogers, *Restitution for Wrongs and the Restatement (Third) of the Law of Restitution and Unjust Enrichment*, 42 WAKE FOREST L. REV. 55, 85–86 (2007); Doug Rendleman, *Measurement of Restitution: Coordinating Restitution with Compensatory Damages and Punitive Damages*, 68 WASH. & LEE L. REV. 973 (2011).

177. Todd E. Pettys, *The Myth of the Written Constitution*, 84 NOTRE DAME L. REV. 991, 1039 (2009) (“By obscuring judges’ physicality . . . robes promote the public’s image of judges as a select class of people blessed with an almost superhuman capacity to deduce case-specific answers from the nation’s fundamental legal precepts.”).

178. F. Patrick Maloney, *The Industrialization of Medicine*, 24 PHYSICIAN EXEC. 34 (1998); Joanne Reeve, Tom Blakeman, George K. Freeman, Larry A. Green, Paul A. James, Peter Lucassen, Carmel M. Martin, Joachim P. Sturmberg & Chris van Weel, *Generalist Solutions to Complex Problems: Generating Practice-Based Evidence - The Example of Managing Multi-Morbidity*, 14 BMC FAM. PRAC. 112 (2013).

179. DOUGLAS, *supra* note 14, at 2, 5.

Physician conflicts of interest in federal and state law demonstrate how little was obtained through judicially enforced fiduciary duties.¹⁸⁰ Rather, the costs of healthcare, the financial integrity of publicly funded healthcare systems, and the statutory and regulatory targeting of *sources* of conflicts of interest—pharmaceutical firms, self-referrals, device manufacturers—allowed legislators to shape the practice of medicine in ways that achieved most if not all of the aims of fiduciary duties without the structural and resource barriers courts face.

A. Prohibited Conflicts of Interest

The core fiduciary obligation—that of loyalty—generally admonishes fiduciaries to put the interests of their entrustors above their own. The duty to avoid conflicts of interest is then another aspect of the physician’s fiduciary duties, such as avoiding conflicts “between their commitment to heal patients and their economic self-interest.”¹⁸¹ Rodwin has defined conflict of interest as “[a]nything that compromises the fiduciary’s loyalty to the fiducie or the fiduciary’s exercise of independent judgment on the fiducie’s behalf,” and has identified two main kinds of conflicts: “(1) conflicts stemming from financial and other personal interests; and (2) conflicts stemming from divided loyalties of an actor performing competing roles.”¹⁸²

However, if a conflict does arise, that does not automatically disqualify the fiduciary from acting in his or her role.¹⁸³ Under this principle, fiduciaries are not necessarily prohibited from entering into transactions that are or appear conflicted; in many cases, they may still take advantage of opportunities as long as they disclose their interest to their entrustors.¹⁸⁴ Robertson, Rose, and Kesselheim write that there “are reasons to doubt whether conflicts of interest impact the behaviors of physicians” because of professional codes of conduct and the norms of evidence-based medicine.¹⁸⁵ In the corporate context, directors may, by way of

180. See *supra* Section III and accompanying footnotes.

181. Karine Morin, Herbert Rakatansky, Frank A. Riddick, Jr., Leonard J. Morse, John M. O’Bannon III, Michael S. Goldrich, Priscilla Ray, Matthew Weiss, Robert M. Sade & Monique A. Spillman, *Managing Conflicts of Interest in the Conduct of Clinical Trials*, 287 JAMA 78, 80 (2002).

182. Rodwin, *supra* note 95, at 244.

183. Boyd, *supra* 63, at 137; see also *Incentives to Physicians: Wise Policy or Risky Temptation?*, RELIAS MEDIA (Nov. 1, 2004), <https://www.reliasmedia.com/articles/8327-incentives-to-physicians-wise-policy-or-risky-temptation> [<https://perma.cc/XSU3-3FDW>] (“Under no circumstances may physicians place their own financial interests above the welfare of their patients If a conflict develops between the physician’s financial interest and the physician’s responsibilities to the patient, the conflict must be resolved to the patient’s benefit.” (citations omitted)).

184. Claire Hill & Richard Painter, *Compromised Fiduciaries: Conflicts of Interest in Government and Business*, 95 MINN. L. REV. 1637, 1643 (2011); Wulf A. Kaal & Richard W. Painter, *Initial Reflections on an Evolving Standard: Constraints on Risk Taking by Directors and Officers in Germany and the United States*, 40 SETON HALL L. REV. 1433, 1452–53 (2010).

185. Robertson et al., *supra* note 77, at 452.

comparison, take advantage of opportunities that might belong to the corporation after proper disclosure and approval by other directors.¹⁸⁶

Physicians operate under similar fiduciary obligations. A prescribed drug or therapy may be provided by a firm that has paid a physician to speak or consult or might be delivered in a facility in which the physician has a financial stake.¹⁸⁷ In some circumstances, disclosure may provide an adequate safeguard for the patient's interests.¹⁸⁸ In others, the transaction may pose such a significant risk to patient welfare that they are prohibited entirely.¹⁸⁹ As detailed above, courts enforcing physicians' fiduciary duties with respect to these conflicts tended to conflate duties of loyalty and candor with routine medical malpractice actions. Fiduciary duties themselves played a negligible role in patient protection. As Marc Rodwin famously quipped, "although doctors perform fiduciary-like roles and hold themselves out as fiduciaries in their ethical codes, the law holds doctors accountable as fiduciaries only in restricted situations."¹⁹⁰

State and federal legislators, on the other hand, have regulated physician conflicts of interest in multifaceted and nuanced ways. Under some regulatory schemes, physicians are regulated directly—they are prohibited from entering into certain transactions that pose risks for patient primacy, allowed to enter into those transactions if they meet constraining criteria, or mandated to disclose potential conflicts.¹⁹¹ Under other regulatory schemes, it is the *sources* of financial conflicts—pharmaceutical and medical device firms, for example—that are

186. See generally MODEL BUS. CORP. ACT §§ 8.60–63, 8.70 (AM. BAR ASS'N 2010); FRANKLIN A. GEVURTZ, CORPORATION LAW 382–407 (2d ed. 2010).

187. Moe Litman, *Self-Referral and Kickbacks: Fiduciary Law and the Regulation of Trafficking in Patients*, 170 CANADIAN MED. ASS'N J. 1119 (2004); Sujit Choudhry, Niteesh K. Choudhry & Adalsteinn D. Brown, *Unregulated Private Markets for Health Care in Canada? Rules of Professional Misconduct, Physician Kickbacks and Physician Self-referral*, 170 CANADIAN MED. ASS'N J. 1115, 1115 (2004) ("The term *kickback* refers to the financial compensation of physicians for patient referrals. Compensation can flow from IHFs to referring physicians, or from specialists to primary care physicians (*fee-splitting*). Compensation can consist of cash payments for each referral, discounted office space or leases for medical equipment, or business loans at below-market rates. Compensation for referrals is unobjectionable in most markets, but is problematic in health care in view of the potential conflict between physicians' financial self-interest and their duty to advise patients solely on the basis of health needs.").

188. Robert Steinbrook, *Online Disclosure of Physician-Industry Relationships*, 360 NEW ENG. J. MED. 325, 325–27 (2009).

189. MARC A. RODWIN, CONFLICTS OF INTEREST AND THE FUTURE OF MEDICINE: THE UNITED STATES, FRANCE, AND JAPAN 209 (2011).

190. Rodwin, *supra* note 95, at 242; Nan D. Hunter, *Risk Governance and Deliberative Democracy in Health Care*, 97 GEO. L.J. 1, 23 n.109 (2008) ("Marc Rodwin has argued that the concept of doctors as fiduciaries for their patients is 'a dominant metaphor' in health law, but that courts enforce it in only limited circumstances.").

191. See, e.g., FLA. STAT. § 456.054(2) (2020) (establishing that it is a violation of a state criminal statute for a "health care provider" to "offer, pay, solicit, or receive a kickback, directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients").

targeted.¹⁹² Below we detail legal and regulatory regimes that more effectively address physician conflicts of interest.

1. *Anti-Kickback Statutes*

In 1972, Congress adopted the federal Anti-Kickback Statute, imposing criminal penalties for exchanging (or offering to exchange) anything of value, in an effort to induce (or reward) the referral of healthcare products or services reimbursed by federal health programs like Medicaid and Medicare.¹⁹³ The Anti-Kickback Statute is broadly drafted and establishes penalties for individuals and entities on both sides of prohibited transactions so that both physicians and those who would attempt to induce them to prescribe drugs or treatment are covered. The statute is also cognizant that medical practice occurs in a complex environment so that certain types of payments are excluded from consideration by statute.¹⁹⁴ Congress further gave HHS the authority to create more safe harbors and authorized the HHS Office of Inspector General (OIG) to issue binding advisory opinions, which function like case-by-case safe harbors.¹⁹⁵ Together, these safe harbors protect specifically identified business and financial practices from criminal and civil prosecution including space rental, equipment rental, personal services and management contracts, health maintenance organizations, preferred provider organizations, and sales of medical practices.¹⁹⁶ Congress was explicit in its effort to codify existing professional ethical canons regarding physician loyalty.¹⁹⁷

The federal Anti-Kickback Statute encouraged states to adopt laws tailored for medical practice within their jurisdiction. While Minnesota's Anti-Kickback Statute provides that its rules must be "compatible with, and no less restrictive than" the federal Anti-Kickback Statute, New Mexico's Anti-Kickback Statute reaches

192. See generally 42 C.F.R. §§ 402–403 (2019). The government has good reasons for doing so. Healthcare-related fraud, almost all of which is white-collar crime or civil fraud, costs the government billions of dollars. Mihailis E. Diamantis, *White-Collar Showdown*, 103 IOWA L. REV. ONLINE 320, 320–21 (2017) ("The FBI estimates that the annual cost of white-collar crime in the United States is around half a trillion dollars, roughly thirty times the cost for every other crime combined.")

193. 42 U.S.C. § 1320a-7b.

194. *Id.* § 1320a-7b(b)(3).

195. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, 2000–02.

196. 42 C.F.R. § 1001.952 (2019); David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust "Reposed in the Workmen,"* 30 J. LEGAL STUD. 531, 534–35 (2001).

197. The legislative report accompanying the enactment of the statute states that the purpose of the statute was to:

[P]rovide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and which contribute appreciably to the cost of the Medicare and Medicaid programs. Thus . . . the criminal penalty provision would include such practices as the soliciting, offering or accepting of kickbacks or bribes . . . involving providers of health care services.

H.R. REP. NO. 92-231, at 1 (1972), as reprinted in 1972 U.S.C.C.A.N. 4989, 5093. It was understood at the time (and thereafter) that although the legislative history and the statute itself spoke in broader terms, the overriding purpose of the statute was to "ensure that medical decisions are not influenced by financial rewards from third parties." H.R. REP. NO. 104-276, pt. 1, at 497 (1995).

further, “providing that any person who knowingly solicits, receives, offers, or pays remuneration directly, indirectly, overtly, covertly, in return for referrals or purchasing, leasing, ordering or arranging goods, facilities, or services for which payment is made in whole or in part with public money shall be guilty of a felony.”¹⁹⁸ “The state statute does not apply to properly disclosed discounts or to a bona fide employee-employer relationship.”¹⁹⁹ States have tailored their anti-kickback statutes for the unique aspects of medical practice in their territories.²⁰⁰ For example, state anti-kickback laws usually apply to all payers while the federal law applies only to federal healthcare program payments.

2. *Stark Laws*

As more patients became Medicare eligible after 1965, Congress adopted the Ethics in Patient Referral Act of 1989 (Stark Law), which prohibited physicians, or their immediate family members, who had a financial relationship with the providers of designated health services entities from referring Medicare patients to those entities.²⁰¹ Physicians with interests in companies that provided clinical laboratory services, physical therapy services, occupational therapy services, outpatient speech-language pathology services, radiology and certain other imaging services, radiation therapy services and supplies, and durable medical equipment and supplies were prohibited from referring patients to those companies.²⁰² Revised in 2008 and again under the Affordable Care Act, Stark “greatly limit[s] a physician’s ability to hold financial interests in [providers that create conflicts of interest].”²⁰³ Financial interests under the law include ownership and investment interests, as well as compensation arrangements.²⁰⁴

The Stark Law is not only tailored to specific services where physician conflicts are common, but also makes physicians referring to conflicted entities strictly liable.²⁰⁵ Disclosure may not cure the conflict (although it may reduce the penalty) and it is irrelevant whether a physician intended to refer a patient for

198. Kathryn Leaman, *State Anti-Kickback Statutes: Where the Action Is*, 2 HEALTH L. & POL’Y BRIEF 22, 23 (2008).

199. *Id.*

200. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP’T OF HEALTH & HUM. SERVS., LAWS AGAINST HEALTH CARE FRAUD RESOURCE GUIDE (2014), <http://www.healthsmartmso.com/downloadfile/FWA/Care1stFWA/11%20-%20FWA-Law%20Against%20Health%20Care%20Fraud.pdf> [<https://perma.cc/4HZB-QNH2>].

201. STAFF OF S. COMM. ON FIN., 114TH CONG., WHY STARK, WHY NOW? SUGGESTIONS TO IMPROVE THE STARK LAW TO ENCOURAGE INNOVATIVE PAYMENTS MODELS 4 (2016), <https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf> [<https://perma.cc/RW4K-YWY8>].

202. *Physician Self-Referral*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/> [<https://perma.cc/EHE8-V5CJ>] (Jan. 5, 2015, 5:59 AM).

203. Matt Frederiksen & Emily Egan Weaver, *Understanding the Federal Physician Self-Referral Statute: “Stark Law,”* 17 J. HEALTH CARE COMPLIANCE 47, 48 (2015).

204. 42 C.F.R. § 411.354 (2019).

205. Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS HEALTH L. 15 (2011).

financial gain or not.²⁰⁶ Congress’s purpose in enacting the Stark Law was to “limit the influence of financial relationships on physician referrals.”²⁰⁷ Congress’s intention was to create a “bright line rule, which would encourage hospitals and other providers to self-police their arrangements with physicians.”²⁰⁸

As with the Anti-Kickback Statute, Congress gave HHS “the authority to except certain relationships from the general referral prohibition.”²⁰⁹ With that authority, HHS established through regulations exceptions to ensure that the referral prohibition of the Stark Law “was not overly broad.”²¹⁰ For example, physicians may consult with one another about the best treatment options for a patient and evade violation of the law as long as the “‘request and need for the consultation are documented in the patient’s medical record After the consultation is provided,’ the [referred physician] must prepare ‘a written report of his or her findings, which is provided to the physician who requested the consultation.’”²¹¹ The referred physician “must communicate ‘with the referring physician on a regular basis about the patient’s course of treatment and progress.’”²¹²

Congress shaped judicial management of physician conflicts under Stark by authorizing a burden shifting framework under which the physician would be presumed to have violated the prohibition on self-referrals but could raise an exception as an affirmative defense. Those exceptions include referrals within the same group practice, office space, equipment, bona fide employment relationships, and several exceptions for physician recruitment and compensation arrangements.²¹³ “[M]any of the exceptions require that the arrangement be (1) in writing, (2) signed by the parties, (3) commercially reasonable without regard to referrals, and (4) fair market value.”²¹⁴ The Affordable Care Act also gave the HHS the authority to “decrease the penalty of the Stark Law violation if the violation has been self-disclosed.”²¹⁵

As with the Anti-Kickback Statute, states have adopted their own versions of self-referral prohibitions.²¹⁶ Thirty-four states have laws regarding referrals by healthcare providers to entities in which they have a financial interest (e.g., a

206. STAFF OF S. COMM. ON FIN., *supra* note 201, at 2, 5, 6.

207. *Id.* at 2.

208. *Id.* at 5.

209. Stacey A. Tovino, *Gone Too Far: Federal Regulation of Health Care Attorneys*, 91 OR. L. REV. 813, 863 (2013).

210. *Id.*

211. United States *ex rel.* Barker v. Tidwell, No. 4:12-CV-108 (CDL), 2015 WL 3505554, at *4 (M.D. Ga. June 3, 2015) (quoting 42 C.F.R. § 411.351 (2019)).

212. *Id.*

213. Rick Rifenburg, Paul A. Gomez, Travis Jackson & Ryan M. McAteer, *What You Don’t Know Can Hurt You: Best Practices and Key Legal Issues in Health Care Due Diligence*, 19 J. HEALTH CARE COMPLIANCE 15, 19 (2017).

214. *Id.*

215. Frederiksen & Weaver, *supra* note 203, at 64.

216. CAL. BUS. & PROF. CODE §§ 650.01–.02 (West 2020); OR. REV. STAT. § 441.098 (2020).

physician referring a patient to a surgical center in which he or she is an investor).²¹⁷ Some state laws mirror federal law. Others prohibit all self-referrals and ban physicians from any ownership interest in hospitals or other facilities to which they refer patients. Several simply require disclosure of financial interests to patients. Most states also prohibit fee splitting or giving rebates for referrals, which might also apply to some transactions between referral sources. For example, many states' laws prohibit paying or accepting payment from others to refer claimants to healthcare providers, or to provide services to a person knowing that the person has been referred in exchange for payment of a fee.²¹⁸

The rationale behind these state statutes “regarding a physician’s receiving compensation for the referral of patients or the prescription of drugs is to protect consumers from economic arrangements in the medical disciplines that will increase the cost of health care, restrict the patient’s access to medical goods and services, or otherwise harm patients as consumers.”²¹⁹ Indeed, regulations of physician referrals overlap with the physician’s duty of loyalty and candor to patients.²²⁰ State legislatures have “accepted the rationale that patients should receive their medical opinions about their own treatment, and about referrals to other physicians or specialists, that are not the product of a conflict of interest on the part of the referring physician.”²²¹ These statutes all relate to the physician’s obligation to provide patient care free from conflicts of interest and to fully inform patients about the care they receive.²²²

3. *Anti-Detailing Laws*

In addition to Congress and state legislatures adopting measures to address physician conflicts of interest including prohibitions, safe harbors, and disclosures, state legislatures have also attempted to address specific sources of conflicts like incentives extended by drug and device firms. Prescription drug marketing is a large part of the success of the pharmaceutical industry, which grossed over \$800 billion in 2011.²²³ Eighty percent of marketing efforts to influence physicians are through industry gifts and detailing, the activity of pharmaceutical sales representatives (reps) when they make calls to physicians and provide them with “details”—scientific

217. ASTRO, STATE SELF-REFERRAL LAW CITATIONS, <https://www.astro.org/uploadedfiles/content/advocacy/state%20self-referral%20laws.pdf> [https://perma.cc/N249-EWKU] (last visited Nov. 7, 2020).

218. IDAHO CODE § 41-348 (2020); FLA. STAT. § 456.054 (2020).

219. 61 AM. JUR. PROOF OF FACTS 3D 245 § 8 (2018).

220. Compare Julie E. Kass & John S. Linehan, *Fostering Healthcare Reform Through a Bifurcated Model of Fraud and Abuse Regulation*, 5 J. HEALTH & LIFE SCIS. L. 75, 97 (2012), with Greg Radinsky, *Defining a Group Practice: An Analysis of the Stark I Final Rule*, 41 ST. LOUIS U. L.J. 1119, 1122 (1997).

221. 61 AM. JUR. PROOF OF FACTS 3D, *supra* note 219.

222. *Id.*

223. Melissa N. Hoffman, *Pharmaceutical Detailing Is Not for Everyone: Side Effects May Include Sub-Optimal Prescribing Decisions, Compromised Patient Health, and Increased Prescription Drug Spending*, 33 J. LEGAL MED. 381, 382 (2012).

information, benefits, side effects, or adverse events—related to a drug.²²⁴ Detailing activity includes both innocuous gifts like free samples for patients as well as inducements for physicians themselves.

Detailing is partnered with data mining—understanding how and why physicians prescribe the drugs they do then adopting a range of tactics to encourage them to prescribe more of a certain, inevitably more expensive, drug.²²⁵ Data mining involves large third-party firms that assemble information about physicians' prescribing practices and sell it to drug companies for marketing and sales purposes.²²⁶ The data gathered includes the physician's name and address; the patient's gender and age; the name, dosage and quantity of the medication; and the date and location where the prescription was filled.²²⁷

Detailing is a “massive and expensive” venture for pharmaceutical manufacturers, with the sole purpose of marketing brand-name drugs.²²⁸ “On average, 28 detailers visit a single prescriber in a week, and 14 detailers contact a single specialist each week.”²²⁹ Firms spend an average of \$8,290 per physician.²³⁰ Studies have shown visiting physicians increases drugs sales, and even small gifts or free samples have been shown to have an effect.²³¹ Pharmaceutical manufacturers provide more than \$15 billion worth of free samples to ninety percent of U.S. physicians each year.²³²

The adverse effects on physicians and patients are well established. Physicians' prescribing behavior may be compromised. Detailers try to promote their drug for use in the widest population of patients without any thought to the specific patient at the moment's well-being.²³³ “If they see that I'm prescribing more of Drug X than their Drug Y, they might show me their data that points to the problems of

224. David Grande, *Limiting the Influence of Pharmaceutical Industry Gifts on Physicians: Self-Regulation or Government Intervention?*, 25 J. GEN. INTERNAL MED. 79, 79 (2009).

225. Hoffman, *supra* note 223.

226. JOHN KASPRAK, FEDERAL APPELLATE COURT DECISION — NEW HAMPSHIRE PRESCRIPTION DRUG INFORMATION LAW (2008), <https://www.cga.ct.gov/2008/rpt/2008-r-0680.htm> [<https://perma.cc/AKD3-G76Y>].

227. Hoffman, *supra* note 223.

228. *Id.*

229. *Id.*

230. *Id.* at 383.

231. Richard Saver, *Deciphering the Sunshine Act: Transparency Regulation and Financial Conflicts in Health Care*, 43 AM. J.L. & MED. 303, 315 (2017).

232. Hoffman, *supra* note 223, at 389.

233. *See id.* at 341.

Drug X.”²³⁴ The patient may receive care affected by detailers’ representations, rather than individual needs, potentially causing adverse outcomes.²³⁵

As early as 1991, the AMA issued ethical guidelines that allowed gifts less than \$100, if they primarily entailed a benefit to patients.²³⁶ The Pharmaceutical Research and Manufacturers of America (PhRMA), the industry’s main lobby, followed with voluntary guidelines, similar to AMA’s, to declare its commitment “to ensure their medicines are marketed in a manner that benefits patients and enhances the practice of medicine.”²³⁷ The AMA also created the Physician Data Restriction Program (PDRP) allowing physicians to protect their individual prescribing data from detailers while still being available for medical research.²³⁸

Several states, encouraged by their physicians, viewed pharmaceutical detailing as a threat to the integrity of their practices and to patient welfare. In 2006, New Hampshire adopted the Prescription Information Confidentiality Act which declared that prescription information shall not be “used, transferred, licensed, or sold for any commercial purpose except for limited purposes.”²³⁹ Specifically, it served to safeguard the privacy of both patients and physicians by preventing the sale of prescription information for use by pharmacies and drug companies to promote specific medications or monitor sales.²⁴⁰ The Prescription Information Confidentiality Act was carefully drafted to not interfere with legitimate use of identifiable data (e.g., utilization review, compliance, academic research, or insurance company reimbursement to pharmacies).²⁴¹

Vermont adopted a similar measure in an effort to promote “physician confidentiality, avoidance of harassment, and the integrity of the doctor-patient relationship.”²⁴² Vermont had three objectives with this law: (1) avoiding harm to

234. *Hearing on H.B. 1346 Before the House Comm. on Exec. Dep’ts & Admin.*, 159th Gen. Ct., 2006 Sess. (N.H. 2006) (statement of Dr. Marc Sadowsky, President of N.H. Medical Soc’y); see also Memorandum or Amicus Curiae Coalition for Healthcare Communications in Support of Plaintiff’s Prayer for Permanent Injunction at 16, *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008) (No. 06-280-PB) (citing and quoting Dr. Sadowsky’s testimony on H.B. 1346).

235. Hoffman, *supra* note 223, at 386; Tamara R. Piety, “A Necessary Cost of Freedom”? *The Incoherence of Sorrell v. IMS*, 64 ALA. L. REV. 1, 11 (2012).

236. See Hoffman, *supra* note 223, at 388; see also AM. MED. ASS’N, *Chapter 9: Ethics of Professional Self-Regulation*, in CODE OF MEDICAL ETHICS, *supra* note 67, at Op. 9.6.2.

237. Grande, *supra* note 224, at 79; see also AM. MED. ASS’N, *Chapter 9: Ethics of Professional Self-Regulation*, in CODE OF MEDICAL ETHICS, *supra* note 67, at Op. 9.6.2; PhRMA, CODE ON INTERACTIONS WITH HEALTH CARE PROFESSIONALS (2009), https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/Code-of-Interaction_FINAL21.pdf [<https://perma.cc/WJ4N-9ZSX>].

238. Hoffman, *supra* note 223, at 391; see also Douglas S. Kaplan & Wayne H. Fujita, Am. Med. Ass’n, *Physicians Discuss Use of Prescribing Data*, 105 W. VA. MED. J. 52 (2011).

239. N.H. REV. STAT. § 318:47(f) (2006).

240. *Id.*

241. *Id.*

242. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 572 (2011); see S. 115, 2007–2008 Leg., Reg. Sess. (Vt. 2008).

public health, (2) controlling costs, and (3) protecting physician's privacy.²⁴³ The law aimed to give physicians control over how information about prescribing practices could be used with respect to marketing through its "opt-in" provision.²⁴⁴ Vermont's law barred the use of data unless a physician "opts-in."²⁴⁵

Third-party data miners brought suit against both laws, arguing that they represented viewpoint discrimination in violation of the First Amendment.²⁴⁶ The First Circuit upheld New Hampshire's law while the Second Circuit invalidated Vermont's.²⁴⁷ The Second Circuit determined that Vermont's law constituted an "unconstitutional regulation of commercial speech."²⁴⁸ In 2011, Vermont appealed to the United States Supreme Court, which granted certiorari.²⁴⁹ In a 6-3 vote, the Court held in *IMS v. Sorrell* that a statute prohibiting the sale of prescriber-identifying information is unconstitutional under the First Amendment.²⁵⁰ The Supreme Court was relatively indifferent to the fiduciary relationship between physicians and patients adversely affected by the measures adopted by New Hampshire and Vermont. In the Court's view, the damage to the relationship was a "necessary cost of freedom" for the data miners.²⁵¹

B. Candor and Disclosure

While anti-detailing laws failed, states achieved greater success using mechanisms of transparency to reveal industry tactics that created conflicts of interest for physicians.²⁵² State legislatures led in the regulation of the content of

243. Michelle M. Mello & Noah A. Messing, *Restrictions on the Use of Prescribing Data for Drug Promotion*, 365 NEW ENG. J. MED. 1248, 1248 (2011).

244. *Id.*

245. *Id.*

246. *Id.* at 1249; see *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434 (D. Vt. 2009), *rev'd*, 630 F.3d 263 (2d Cir. 2010), *aff'd*, 564 U.S. 552; *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 557 U.S. 936 (2009), and *abrogated by Sorrell*, 564 U.S. 552; *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007) (holding the statute was subject to the First Amendment, prescription information was commercial speech, and the statute did not advance the state's interest in promoting public health), *rev'd in part and vacated in part*, 550 F.3d 42 (1st Cir. 2008); see also Kasprak, *supra* note 226.

247. *Ayotte*, 550 F.3d 42; see also Stephanie Saul, *Federal Court Upholds Drug Privacy Law*, N.Y. TIMES (Nov. 18, 2008), <https://www.nytimes.com/2008/11/19/business/19drug.html> [<https://perma.cc/U8VC-MD9Z>].

248. *Sorrell*, 630 F.3d at 282; see *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980) (providing that the test requires the government show that regulations restricting commercial speech meet two requirements: (1) the regulation serves a substantial state interest, and (2) the governmental interest could not be adequately served by a more limited expression on the commercial speech).

249. *Sorrell*, 564 U.S. 552; see also Robert Corn-Revere & Ronald G. London, *Supreme Court Invalidates Vermont Law Limiting Data Mining for Pharmaceutical "Detailing,"* DAVIS WRIGHT TREMAINE LLP (June 23, 2011), https://www.dwt.com/advisories/Supreme_Court_Invalidates_Vermont_Law_Limiting_Data_Mining_for_Pharmaceutical_Detailing_06_23_2011/ [<https://perma.cc/3EG2-HDNA>].

250. Corn-Revere & Ronald G. London, *supra* note 249.

251. Piety, *supra* note 235, at 1.

252. JENNIFER STAMAN, CONG. RSCH. SERV., R40790, *REQUIRING DISCLOSURE OF GIFTS AND PAYMENTS TO HEALTH CARE PROFESSIONALS: A LEGAL OVERVIEW 1* (2009).

physician disclosures to patients, although Congress followed with the Physician Payments Sunshine Act in 2010.

1. *Conflicts of Interest*

Before the Physician Payments Sunshine Act was adopted as part of the Affordable Care Act in 2010, California, the District of Columbia, Maine, Massachusetts, Minnesota, Vermont, and West Virginia had adopted laws requiring disclosure of pharmaceutical firm and medical device companies' payments to physicians for a range of activities including consulting, speaking, and leading continuing medical education seminars, in addition to outright gifts.²⁵³

Dr. Peter Lurie, deputy director of Public Citizen's Health Research Group, outlined the effects of these practices:

Physicians typically claim that they are unaffected by such interactions (although they are willing to acknowledge that their colleagues might be influenced). But pharmaceutical companies would not be catering to the culinary and travel preferences of physicians if they thought their efforts were for naught. The evidence strongly suggests that the companies are right. For instance, contact with pharmaceutical company representatives is associated with changes in the prescribing practices of residents and physicians and more rapid adoption of new drugs by prescribers. Sponsorship of continuing medical education programs by a pharmaceutical company and all-expenses-paid travel to conferences are associated with increases in the prescribing rate of the sponsors' drugs. Finally, interactions with a pharmaceutical company representative are associated with an increased likelihood of requesting that the representative's company's drug be added to the hospital formulary. Thus, as companies with a clear conflict of interest in promoting a specific product continue to influence physicians, the result can be prescribing based on marketing, rather than science.²⁵⁴

A report from the Institute of Medicine found that the drug company practice of giving doctors gifts and meals, along with other financial incentives, may influence physicians to prescribe a specific drug when another drug might be more beneficial to the patient.²⁵⁵ The American Medical Association acknowledged these

253. Joseph S. Ross, Josh E. Lackner, Peter Lurie, Cary P. Gross, Sidney Wolfe & Harlan M. Krumholz, *Pharmaceutical Company Payments to Physicians: Early Experiences with Disclosure Laws in Vermont and Minnesota*, 297 JAMA 1216, 1216–17 (2007).

254. *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry: Hearing Before the Special S. Comm. on Aging*, 110th Cong. 23–24 (2007) (statement of Dr. Peter Lurie, Deputy Director, Public Citizen's Health Research Group).

255. Chris Hendel, *Vermont Passes Sunshine Law Limiting Drug Company Gifts to Doctors*, CONSUMER REPS. (June 10, 2009, 5:11 PM), <https://www.consumerreports.org/cro/news/2009/06/vermont-passes-sunshine-law-limiting-drug-company-gifts-to-doctors/index.htm> [https://perma.cc/B26U-P37Q].

risks to the duties physicians owed to patients.²⁵⁶ The AMA advised physicians that only small gifts and “modest meals” might be allowed and, even then, must “entail a benefit to patients,” not be “of substantial value,” or must “serve a genuine educational function” to be permitted.²⁵⁷ Even those small promotional items, however, had been shown to affect physician behavior.²⁵⁸

a. State Disclosure Laws

In 1993, Minnesota adopted the country’s first physician payment sunshine law.²⁵⁹ It not only banned gifts to practitioners, it required that firms report payments and other compensation paid to practitioners under the law.²⁶⁰ In 2004, California introduced SB 1765 “to place limits on promotional gifts pharmaceutical companies may give to physicians and other health care professionals that are consistent with established guidelines,” out of concern that the gifts were affecting “both the utilization and types of drugs prescribed.”²⁶¹ The bill was specifically aimed at easing public concerns about conflicts of interest between doctors and drug company sales representatives.²⁶² The bill required pharmaceutical companies to comply with PhRMA and OIG guidelines, set limits on giving gifts to medical or healthcare professionals, except for drug samples, educational materials, and related materials, and mandated that the companies develop and maintain a policy that complies with these guidelines.²⁶³ Lawmakers noted the ineffectiveness of voluntary guidelines on their own as too “permissive” and “a number of troublesome practices became commonplace after the guidelines were adopted.”²⁶⁴ The legislation attempted to remedy the situation by enforcing the guidelines on a governmental level, where failure to comply could result in civil enforcement action or prosecutors could “file complaints seeking injunctive relief and restitution” and “could also seek civil penalties.”²⁶⁵

256. *Marketing and Advertising of Pharmaceuticals*, NAT’L CONF. OF ST. LEGISLATURES (Nov. 5, 2018), <http://www.ncsl.org/research/health/marketing-and-advertising-of-pharmaceuticals.aspx> [<https://perma.cc/95RA-R58N>]; AM. MED. ASS’N, *Chapter 8: Ethics for Physicians & the Health of the Community*, in CODE OF MEDICAL ETHICS, *supra* note 67, at Op. 8.061.

257. AM. MED. ASS’N, *Chapter 9: Ethics of Professional Self-Regulation*, in CODE OF MEDICAL ETHICS, *supra* note 67, at Op. 9.6.2.

258. David Grande, Dominick L. Frosch, Andrew W. Perkins & Barbara E. Kahn, *Effect of Exposure to Small Pharmaceutical Promotional Items on Treatment Preferences*, 169 ARCHIVES INTERNAL MED. 887 (2009), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/773513> [<https://perma.cc/7G65-LX6H>].

259. MINN. STAT. § 151.461 (2020); *id.* § 151.252, subdiv. 3 (2019).

260. § 151.252, subdiv. 3.

261. S. HEALTH & HUM. SERVS. COMM., BILL ANALYSIS, S. 1765, 2003–2004 Leg., Reg. Sess., at 4 (Cal. 2004).

262. *Id.* at 3.

263. *Id.* at 1.

264. *Id.* at 3–4.

265. *Id.* at 7.

Even after SB 1765, California physicians and medical professionals led the nation in the number of gifts taken, over \$1.4 billion in 2014.²⁶⁶ SB 790, an update to the law, aims to curb financial payments, gifts, and incentives to physicians. Massachusetts adopted a similar strategy through its Pharmaceutical and Medical Device Manufacturer Code of Conduct, which incorporated the requirements from two medical trade associations' codes, PhRMA and AdvaMed; however, the state's code also included several of its own requirements and prohibitions that were not later preempted by federal Physician Payments Sunshine Act.²⁶⁷

Vermont adopted one of the first laws requiring payment disclosure from the medical industry to physicians and research hospitals or universities.²⁶⁸ The state's law revealed that "[t]he median payment [to a physician] was \$177, and the largest payment was \$20,000. Sixty-eight percent of these payments were in the form of food, which clearly provides no patient benefit and, therefore, in our view, is likely to violate the AMA and the PhRMA guidelines."²⁶⁹

After adoption of the federal Physician Payments Sunshine Act as part of the Affordable Care Act, detailed below, many states have adopted laws that extend disclosure requirements to medical providers not covered like physician assistants and nurse practitioners.²⁷⁰

b. The Federal Physician Payments Sunshine Act

Well after Minnesota's 1993 law, but in parallel with state efforts, Congress explored legislative efforts at requiring disclosure of payments by firms to physicians.²⁷¹ The federal Physician Payments Sunshine Act was first introduced as a stand-alone bill by Senators Charles "Chuck" Grassley and Herbert "Herb" Kohl in 2007.²⁷² After it initially failed to pass, the bill was included in an amended form in the Affordable Care Act as section 6002.²⁷³ The Act requires that all manufacturers of drugs or medical devices that are covered by Medicare, Medicaid, or Children's Health Insurance Program (CHIP) report "[p]ayments [and] transfers

266. Geneva Peppers, *Senate Passes Bill Restricting Gifts from Pharma Companies to Doctors*, KRCTV (May 18, 2017), <https://krctv.com/archive/senate-passes-bill-restricting-gifts-from-pharma-companies-to-doctors> [<https://web.archive.org/web/20201009022516/https://krctv.com/archive/senate-passes-bill-restricting-gifts-from-pharma-companies-to-doctors>].

267. MASS. GEN. LAWS ch. 111N, § 6(1) (2012).

268. VT. STAT. ANN. tit. 18, § 4632 (2019).

269. *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry: Hearing Before the Special S. Comm. on Aging*, *supra* note 254, at 23–24.

270. Meena Datta, *States May Be Moving to Expand the Federal Sunshine Law*, LAW 360 (July 11, 2014, 10:42 AM), <https://www.law360.com/articles/550642/print?section=california> [<https://perma.cc/AY2K-WY3J>].

271. Elizabeth Richardson, *Health Policy Brief: The Physician Payment Sunshine Act*, HEALTH AFFS. (Oct. 2, 2014), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=127 [<https://perma.cc/6Q3N-J6TM>]; *see also* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, sec. 6002, § 1128G(a)(1)(A), 124 Stat. 119 (2010).

272. *See* Richardson, *supra* note 271, at 2.

273. *Id.*

of value” made to physicians or teaching hospitals that are \$100 or more.²⁷⁴ Drug samples that are not meant for sale and are distributed to physicians for patients to use are excepted from reporting.²⁷⁵ In addition, the Act does not require that the doctors or hospitals themselves report such information, but it does permit them to contest the data should they feel it is inaccurate.²⁷⁶ All reports must be made in a timely manner and must be reported in full or risk fines up to \$1,000,000.²⁷⁷

The Act lists both the types of recipients the companies must report, as well as what types of transfers that must be reported. It requires that those gifts be reported, along with any other “transfer of value,” which includes “honoraria, consulting fees, food, travel, education, research, charitable contribution,” as well as investments doctors make in the companies, such as stocks or shares.²⁷⁸ The Secretary of Health and Human Services aggregates and posts that information on a website available to the public.²⁷⁹ Patients may search the site to see if their physicians or hospitals have received transfers of value and in what amount.²⁸⁰

The Act is aimed at protecting the patient’s right to be informed about their healthcare. Conflicts of interest preoccupied Congress in the years leading to adoption of the Sunshine Act. Senator Grassley, long concerned about integrity in various sectors of the healthcare system, became concerned with the relationship between doctors and the pharmaceutical industry after learning that medical research was being conducted that was funded by pharmaceutical companies that manufactured the drugs being researched.²⁸¹ Grassley investigated industry activities in the research process and discovered a significant lack of disclosure about industry ties.²⁸² Contemporaneously, the *New York Times* reported in a series of articles that the largest pharmaceutical companies were paying hundreds of millions of dollars through rebates to doctors across the nation every year in return for them prescribing certain classes of medications instead of their competitors’ versions.²⁸³ By giving the doctors rebates for the amount of drugs they prescribed, the doctors were incentivized to prescribe more expensive drugs in higher doses, sometimes to

274. Patient Protection and Affordable Care Act § 1128G(d)(1)(B)(i).

275. *Id.* at § 1128G(d)(1)(B)(ii).

276. *Id.* at § 1128G(c)(1)(C)(ix).

277. *Id.* at § 1128G(b)(2).

278. *Id.* at § 1128G(a)(1) (A)(iv).

279. *Id.* at § 1128G(c)(1)(C).

280. *Id.* at § 1128G(d)(3)(A), (B).

281. *Let the Sunshine In: Implementing the Physician Payments Sunshine Act: Roundtable Before the Special S. Comm. on Aging*, 112th Cong 1, 2 (2012) (statement of Sen. Charles Grassley).

282. *Grassley Q & A: Disclosing Drug Industry Dollars to Doctors*, CHUCK GRASSLEY (Sept. 10, 2011), <https://www.grassley.senate.gov/news/news-releases/grassley-q-disclosing-drug-industry-dollars-doctors> [<https://perma.cc/QK8V-G6V8>].

283. Alex Berenson & Andrew Pollack, *Doctors Reap Millions for Anemia Drugs*, N.Y. TIMES (May 9, 2007), <https://www.nytimes.com/2007/05/09/business/09anemia.html> [<https://perma.cc/L69F-962Z>]; Gardiner Harris & Janet Roberts, *Doctors’ Ties to Drug Makers Are Put on Close View*, N.Y. TIMES, (Mar. 21, 2007), <https://www.nytimes.com/2007/03/21/us/21drug.html> [<https://perma.cc/NHC8-C6DT>].

unsafe levels.²⁸⁴ After the Act failed to pass on its own in 2008, it was reintroduced by Grassley and Kohl in 2009 as a part of the Affordable Care Act, which passed in 2010.²⁸⁵

The disclosure regime is structured so as to require firms to report payments, instead of imposing burdens on physicians. Indeed, the information required to be disclosed was already being collected by drug and device firms.²⁸⁶ The law is therefore a less burdensome way to get at a source of physician conflicts of interest than a duty-of-loyalty inquiry undertaken by a court.

c. System Effects of Federal and State Sunshine Laws

Transparency laws have not only benefited patients, who now have access to information on sources of payments to physicians, but also law enforcement ensuring the healthcare sector's financial integrity.²⁸⁷ The database is cautious in its communications to patients. Shantanu Agrawal, the former deputy administrator for the Centers for Medicare & Medicaid Services (CMS), stated that the government would not “draw conclusions about the disclosed payments,” and “cautioned” the public not to do so either because “[f]inancial ties and relationships between medical manufacturers and health care providers do not necessarily signal wrongdoing.”²⁸⁸ In addition, the “Open Payments program does not identify which financial relationships are beneficial and which could cause conflicts of interest.”²⁸⁹ Patients themselves are allowed to draw their own conclusions.²⁹⁰ In one study conducted in the medical research context, this comports with patient

284. Berenson & Pollack, *supra* note 283; 153 CONG. REC. S11,215, S11,217–18 (daily ed. Sept. 6, 2007) (statement of Sen. Grassley).

285. *Paid to Prescribe? Exploring the Relationship Between Doctors and the Drug Industry: Hearing Before the Special S. Comm. on Aging*, *supra* note 254, at 1 (statement of Sen. Herbert Kohl, Chairman of the Comm.).

286. Press Release, Chuck Grassley, U.S. Sen., Grassley, Kohl Say Public Should Know When Pharmaceutical Makers Give Money to Doctors (Sept. 6, 2007), <https://www.grassley.senate.gov/news/news-releases/grassley-kohl-say-public-should-know-when-pharmaceutical-makers-give-money> [<https://perma.cc/U3EW-NW5R>].

287. James Rickert, *If Obamacare Is Dismantled, Keep the Sunshine Act to Illuminate Physician Conflict of Interest*, STAT (Jan. 25, 2017), <https://www.statnews.com/2017/01/25/sunshine-act-physicians-conflict-of-interest/> [<https://perma.cc/7QZR-H8ZL>].

288. Peter Frost, Alex Richards, Cynthia Dizikes & Ellen Jean Hirst, *Obamacare Sunshine Act Sheds Light on \$3.5B Paid to Doctors*, CHI TRIB. (Oct. 1, 2014, 2:00 AM), <http://www.chicagotribune.com/business/ct-sunshine-act-1001-biz-20141001-story.html> [<https://perma.cc/3K7T-ND7G>].

289. Robert Lowes, *Open Payments Data Release Has Big Gaps*, MEDSCAPE (Sept. 30, 2014), <https://www.medscape.com/viewarticle/832614> [<https://perma.cc/QGV5-RBRB>]; Jeanne Whalen, Joseph Walker & Jonathan D. Rockoff, *Payments Reveal Range of Doctors' Ties with Industry*, WALL ST. J. (Oct. 1, 2014), <https://www.wsj.com/articles/payments-show-range-of-doctors-ties-with-industry-1412208328> [<https://perma.cc/4DG4-S2DN>].

290. *See Open Payments Data in Context*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/OpenPayments/About/Open-Payments-Data-in-Context.html> [<https://perma.cc/A2WG-YZWF>] (Nov. 1, 2019, 8:25 AM).

interests—they want to know about potential conflicts, even if it might not ultimately change their mind about seeing a particular physician.²⁹¹

Not only patients, but governmental entities also use the data for purposes of ensuring the integrity of the quality and financing of the health system. The information has been used to help investigate providers and firms for violating anti-kickback statutes.²⁹² Disclosure supports “enforcement of the healthcare fraud and abuse laws by identifying financial relationships that may warrant further scrutiny for association with problematic referrals or false claims.”²⁹³ In 2017, the HHS Office of the Inspector General specified that it would “analyze 2015 data extracted from the Open Payments website” for purposes of commencing investigations.²⁹⁴

In a class action suit filed against Insys Therapeutics, Inc. in 2014, four months after the release of the first Open Payments data, the plaintiffs used Insys’s own data against them.²⁹⁵ The plaintiffs alleged that the payments the company made to physicians who promoted the company’s drug Subsys through speeches “essentially were kickbacks to induce prescriptions.”²⁹⁶ The case was settled in 2015 for \$6.1 million, but the same data was used to launch investigations of improper financial incentives by authorities in Oregon, Massachusetts, and four other states, as well as the HHS Office of Inspector General.²⁹⁷ On May 14, 2018, the U.S. government officially intervened as a plaintiff.²⁹⁸

Since the adoption of the Act, physicians, hospitals, and healthcare systems have altered their relationship with pharmaceutical representatives by either limiting their interactions with them or completely denying them access to their offices.²⁹⁹

291. Christine Grady, Elizabeth Horstmann, Jeffrey S. Sussman & Sara Chandros Hull, *The Limits of Disclosure: What Research Subjects Want to Know About Investigator Financial Interests*, 34 J.L. MED. & ETHICS 592, 594, 596–97 (2006).

292. Richard S. Saver, *Shadows amid Sunshine: Regulating Financial Conflicts in Medical Research*, 145 CHEST 379, 383 (2014).

293. *Id.*

294. OFF. OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUM. SERVS., OIG WORK PLAN 16 (2017), <https://oig.hhs.gov/reports-and-publications/archives/workplan/2017/hhs%20oig%20work%20plan%202017.pdf> [<https://perma.cc/CW6W-SP6W>].

295. James Swann, *Litigation, Risk to Reputation May Come from Scrutiny of Doctors’ Payment Data*, BLOOMBERG BNA (Oct. 2, 2014), <http://www.bna.com/litigation-risk-reputation-n17179895627/> [<https://web.archive.org/web/20160910122004/http://www.bna.com/litigation-risk-reputation-n17179895627/>].

296. Brian A. Dahl, *Mining Open Payments Spend Data*, CORP. COMPLIANCE INSIGHTS (Mar. 15, 2016), <http://www.corporatecomplianceinsights.com/mining-open-payments-spend-data-managing-risk-transparency/> [<https://perma.cc/S8FZ-Q74Y>].

297. *Id.*

298. Nate Raymond & Jonathan Stempel, *U.S. Joins Whistleblower Case Against Insys over Kickbacks*, REUTERS (May 14, 2018, 3:18 PM), <https://www.reuters.com/article/us-insys-opioids/u-s-joins-whistleblower-case-against-insys-over-kickbacks-idUSKCN1IF31M> [<https://web.archive.org/web/20200810001944/https://www.reuters.com/article/us-insys-opioids/u-s-joins-whistleblower-case-against-insys-over-kickbacks-idUSKCN1IF31M>].

299. Pharmaceutical companies have also reduced the amount of certain types of transfers, as payments for honoraria declined by about fifty percent and by more than thirty percent for gifts in

A study released by SK&A, a healthcare database, in 2016 suggests that this change stems in part directly from the disclosures required by the Act. For instance, the “no-access rate” to physicians and hospitals for reps “jumped from 27.8% in December 2013 to 36.5% in June 2016.”³⁰⁰ Furthermore, some health systems actually cited the Act as the reason for its altered stance on admitting reps, such as ThedaCare in Wisconsin, which barred reps from its clinics in 2013 because “[p]atients want and deserve complete confidence that their interests are the only interests when prescribing decisions are made, and by making this change, we can provide that confidence.”³⁰¹

Some evidence suggests that the Act may have reduced the number of prescriptions all together. After observing that there was a reduction in the overall number of branded drugs being prescribed since the Act, a team of researchers at the University of Michigan compared three states, Connecticut, Massachusetts, and New York, post-disclosure law:

Overall, these results consistently suggest that the disclosure law was effective in reducing the total number of prescriptions and *possibly* in driving physicians to substitute away from branded drugs to generics. These results are among the first to provide empirical evidence that disclosure laws had an impact on physician prescription behavior, both in a statistical and economic sense.³⁰²

The results of the researchers’ study revealed that by comparing “physicians’ prescriptions with the prescriptions written by physicians in the control group(s),” there was a “48-59 percent decrease for name-brand statins, a 46-54 percent decrease for branded antidepressants and a 40-45 percent decrease for branded antipsychotics.”³⁰³ As Professor Manchada, one of the lead researchers, stated, “[t]here was a much larger relative decrease in name-brand drug prescriptions,

2015. Thomas Sullivan, *Open Payments 2015 Data Released*, POLY & MED., <https://www.policymed.com/2016/07/open-payments-2015-data-released.html> [https://perma.cc/24ET-G2MY] (May 5, 2018).

300. Robert Lowes, *More Physicians Saying ‘No Drug Reps Allowed,’* MEDSCAPE (Sept. 13, 2016), <http://www.medscape.com/viewarticle/868748> [https://perma.cc/27HR-9N5S].

301. *Id.*; see also Diana Swift, *Industry Incentives May Drive Pricier Anti-VEGF Drug Use*, MEDSCAPE (June 23, 2016), <https://www.medscape.com/viewarticle/865279> [https://perma.cc/8BBS-W2ML] (citing a study where industry incentive payments or reimbursements, of even one to twenty-five dollars, were linked to a greater likelihood of a physician injecting patients with the payer’s drugs, even when the cheaper brand was just as effective).

302. Tong Guo, S. Sriram & Puneet Manchanda, “*Let the Sun Shine In*”: *The Impact of Industry Payment Disclosure on Physician Prescription Behavior* 3 (Feb. 25, 2019) (unpublished manuscript), <https://ssrn.com/abstract=2953399> [https://web.archive.org/web/20180603204010/https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2953399].

303. *Id.*; Greta Guest, *Doctors Write Fewer Prescriptions After Sunshine Laws Reveal Drug Company Payments*, MICH. NEWS (June 21, 2017), <http://ns.umich.edu/new/releases/24922-doctors-write-fewer-prescriptions-after-sunshine-laws-reveal-drug-company-payments> [https://perma.cc/CD4W-46NU].

which means some doctors shifted toward generics as a result of the disclosure and that fits with the intent of the law.”³⁰⁴

Even where fiduciary duties have led courts to conclude that physicians should disclose financial arrangements, and most have concluded otherwise, the benefit to the broader healthcare sector has been limited. Indeed, the nature of judicially enforced fiduciary duties works against the broader system effects accomplished by the Physician Payments Sunshine Act. As Richard Saver has argued, “[a]s with provider quality reporting, the real benefits of financial conflicts transparency more likely accrue over the long term and through secondary audiences beyond patients.”³⁰⁵

2. Informed Consent

a. Federal and State Sunshine Laws

While the federal law aimed at addressing conflicts of interest in the practice of medicine, legislators also believed that disclosure was a material part of the informed consent process. As with the Anti-Kickback Statute, Stark laws, and equivalent state statutory approaches, transparency laws were based upon ethical and legal frameworks designed to enhance and protect patient informed consent principles.³⁰⁶ “The Sunshine Act ensures the openness and transparency of the financial ties between doctors and the drug and medical device industries. These financial relationships are valuable and lead to new therapies and technologies, but the public has a right to know about these financial ties.”³⁰⁷

[T]his legislation does not regulate the business of drug and device companies. Let the people in industry do their business since they have the training and the skills to get the job done. But keep the American people apprised of the business you are doing and how you are doing it. After all, what is at risk isn’t merely private interest but the health and well-being of all Americans who depend upon the drugs and medical devices to sustain and to improve their lives.³⁰⁸

The purpose of the law was to effectively reach the same result as a fiduciary duty of candor, although far more effectively so. “By requiring drug companies and medical device manufacturers to report on their gifts to doctors we are empowering patients to talk with their doctors about the drugs they are prescribed and to learn

304. Guest, *supra* note 303.

305. Saver, *supra* note 231, at 343.

306. RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 3, 114 (1986).

307. *Let the Sunshine In: Implementing the Physician Payments Sunshine Act: Roundtable Before the Special S. Comm. on Aging*, *supra* note 281, at 1 (statement of Sen. Kohl, Chairman, Special Comm. on Aging).

308. 155 CONG. REC. S788 (daily ed. Jan. 22, 2009) (statement of Sen. Charles Grassley).

more about the influence of the pharmaceutical industry on the practice of medicine.”³⁰⁹

b. State Statutory Protections for Informed Consent

As detailed in Section III.B, *supra*, courts addressing claims by patients for violations of informed consent turned them into a species of medical malpractice with accompanying evidentiary complexities including expert testimony.³¹⁰ Common law disclosure requirements were inconsistent and evolved unpredictably since inquiries into the doctrine are so factually idiosyncratic.³¹¹ Without clear guidelines to follow, physicians did not know if their disclosure complied with judicially crafted requirements.

Physicians turned to state legislatures to clarify the law of informed consent.³¹² In response, state legislatures established procedures for disclosure, adopted consent forms as evidence of compliance with disclosure requirements, and authorized administrative processes to specifically list the risks the provider is expected to disclose.³¹³ In the codification process, state statutes selected the standard under which informed consent liability was to be analyzed, many adopting patient-centered standards.³¹⁴

In 1996, Pennsylvania’s General Assembly codified its state’s common law doctrine of informed consent.³¹⁵ The Act expanded its informed consent doctrine, established a standard that emphasized the patient’s perspective (“receiving information of the procedure, risks, and alternatives would have been a substantial factor in the patient’s decision”) and set forth the content of that consent.³¹⁶ That informed consent must be obtained by the physician directly, and not through any agent or assistant.³¹⁷

309. Press Release, Special Comm. on Aging, U.S. Senate, Grassley, Kohl Say Public Should Know When Pharmaceutical Makers Give Money to Doctors (Sept. 7, 2007), <https://www.aging.senate.gov/press-releases/grassley-kohl-say-public-should-know-when-pharmaceutical-makers-give-money-to-doctors> [<https://perma.cc/Z4X8-ER8F>].

310. Leonard J. Nelson, III, Michael A. Morrisey & Meredith L. Kilgore, *Medical Malpractice Reform in Three Southern States*, 4 J. HEALTH & BIOMEDICAL L. 69, 71 (2008); Sheldon F. Kurtz, *The Law of Informed Consent: From “Doctor Is Right” to “Patient Has Rights,”* 50 SYRACUSE L. REV. 1243, 1245 (2000) (“Today, the right of a patient to participate to some extent in medical decision making affecting the patient is universally dictated by the ‘informed consent’ laws of all states.”).

311. Sterken et al., *supra* note 84, at 115.

312. *Id.* at 117.

313. Anthony Szczygiel, *Beyond Informed Consent*, 21 OHIO N.U. L. REV. 171, 193 (1994).

314. *Id.* Jurisdictions were evenly split on whether to apply the reasonable patient or reasonable physician standard.

315. Daniel A. Durst, *Cutting Through Pennsylvania’s Medical Informed Consent Statute: A Reasonable Interpretation Abolishing the Surgical Requirement*, 104 DICK. L. REV. 197, 202 (1999); Act of Nov. 26, 1996, No. 135, § 10(811-A), 1996 Pa. Laws 776, 789, *repealed by* Act of Mar. 20, 2002, No. 13, § 5104(a)(2), 2002 Pa. Laws 154, 197.

316. Durst, *supra* note 315, at 218 n.164.

317. *Shinal v. Toms*, 162 A.3d 429, 433 (Pa. 2017).

Enacted in 1971, the Georgia Medical Consent Law provided a broadly worded obligation upon physicians to disclose the “treatment or course of treatment” and, having done so, only claims of fraud could be asserted by patients.³¹⁸ When the Georgia Court of Appeals interpreted this statute in 1975, it ruled that the common law doctrine of informed consent simply did not apply in the state of Georgia.³¹⁹ As a result, patients were left with one option: to recover under the theory that consent was obtained through fraud.³²⁰ The court’s strict interpretation of no informed consent in Georgia led the legislature to adopt the limited informed consent statute in 1988.³²¹ The statute promoted patient autonomy through the adoption of the prudent patient standard.³²² However, the statute “does not impose a general requirement of disclosure”³²³ upon physicians, but rather it requires disclosure that falls within six statutory categories for a specific list of surgical procedures.³²⁴ The statutory requirements include statute of limitations requirements, allows cause of action cases to be rooted in both malpractice and battery for failure to obtain basic consent, and imposes an affidavit requirement.³²⁵

Informed consent statutes consistently have detailed disclosure requirements to ensure patient autonomy and physician responsibility. These statutes are influenced by the AMA’s lengthy guidelines addressing informed consent.³²⁶ For

318. J. Harold Richards, *Informed Confusion: The Doctrine of Informed Consent in Georgia*, 37 GA. L. REV. 1129, 1141 (2003); GA. CODE ANN. § 31-9-6.1(b)(2) (1991).

319. Richards, *supra* note 318, at 1130; Young v. Yarn, 222 S.E.2d 113, 114 (Ga. Ct. App. 1975), *overruled by* Ketchup v. Howard, 543 S.E.2d 371 (Ga. Ct. App. 2000).

320. Richards, *supra* note 318, at 1142–43; *see* Spikes v. Health, 332 S.E.2d 889, 892 (Ga. Ct. App. 1985).

321. Richards, *supra* note 318, at 1144; GA. CODE ANN. § 31-9-6.1 (2001).

322. § 31-9-6.1(a)(3) (2001).

323. Albany Urology Clinic, P.C. v. Cleveland, 528 S.E.2d 777, 780 (Ga. 2000) (holding that the physician did not have a duty to disclose cocaine abuse habit since it did not fall within six statutory categories).

324. GA. CODE ANN. § 31-9-6.1(a)(1) to (6) includes the six statutory factors listed below:

- (1) A diagnosis of the patient’s condition requiring such proposed surgical or diagnostic procedure;
- (2) The nature and purpose of such proposed surgical or diagnostic procedure;
- (3) The material risks generally recognized and accepted by reasonably prudent physicians of infection, allergic reaction, severe loss of blood, loss or loss of function of any limb or organ, paralysis or partial paralysis, paraplegia or quadriplegia, disfiguring scar, brain damage, cardiac arrest, or death involved in such proposed surgical or diagnostic procedure which, if disclosed to a reasonably prudent person in the patient’s position, could reasonably be expected to cause such prudent person to decline such proposed surgical or diagnostic procedure on the basis of the material risk of injury that could result from such proposed surgical or diagnostic procedure;
- (4) The likelihood of success of such proposed surgical or diagnostic procedure;
- (5) The practical alternatives to such proposed surgical or diagnostic procedure which are generally recognized and accepted by reasonably prudent physicians; and
- (6) The prognosis of the patient’s condition if such proposed surgical or diagnostic procedure is rejected.

325. Richards, *supra* note 318, at 1145; Simpson v. Dickson, 306 S.E.2d 404, 406 (Ga. Ct. App. 1983).

326. AM. MED. ASS’N, *Chapter 2: Ethics of Consent, Communication & Decision Making*, in CODE OF MEDICAL ETHICS, *supra* note 67, at Op. 2.1.1.

example, Oregon statute section 677.097 states a physician or physician's assistant obtains informed consent by explaining: "(1) in general terms the procedure or treatment to be undertaken; (2) that there may be alternative procedures or methods of treatment, if any; and (3) that there are risks, if any, to the procedure or treatment."³²⁷

C. Competence and the Professional Standard of Care

State legislatures have also been active in shaping the course of patients' claims based on physicians' duty of care, but in many respects, it is fundamentally tied to the nature of the role courts play in law.³²⁸ Under a fiduciary theory, the duty of care would require physicians to be educated and informed about the procedures, conditions, and surgeries they are administering.³²⁹ In reality, the inquiries are less objective and more subjected to competing expert witness testimony.

Because courts have determined that claims against physicians are broadly negligence claims, there are constitutional (state and federal) and statutory limits as to the extent state legislatures and governors may intrude.³³⁰ Indeed, many legislative efforts aimed at shaping negligence claims against physicians have been struck down by state supreme courts.³³¹ With an estimated seven to seventeen medical malpractice claims filed per 100 physicians every year, and those claims characterized as negligence claims, courts feel an understandable obligation to protect access to courts for those damaged through contractual breach or tortious injury.³³²

State legislatures have endeavored to establish standards of care for physicians and to influence some evidentiary matters like qualification of expert witnesses. Nevertheless, the level of physician care gives rise to frequent seesaw conflicts between state legislatures and state courts. In the informed consent context, for example, in 1975, the Supreme Court of Wisconsin established a framework for patient claims and physician exculpation in *Scaria v. St. Paul Fire & Marine*

327. OR. REV. STAT. § 677.097(1)(a)–(c) (2019).

328. See generally RESTATEMENT (SECOND) OF TORTS § 283 (AM. L. INST. 1965) (stating that a defendant's conduct is measured by the reasonable person standard, and comparing their conduct to that of a reasonable person in similar circumstances).

329. Fred L. Cohen, *The Expert Medical Witness in Legal Perspective*, 25 J. LEGAL MED. 185, 191 (2004); Moffett & Moore, *supra* note 143, at 109.

330. Amy Jurevic Sokol & Christopher J. Molzen, *The Changing Standard of Care in Medicine: E-Health, Medical Errors, and Technology Add New Obstacles*, 23 J. LEGAL MED. 449, 470 (2002).

331. *Watts ex rel. Watts v. Lester E. Cox Med. Ctrs.*, 376 S.W.3d 633 (Mo. 2012) (striking down damages caps); *John v. Saint Francis Hosp., Inc.*, 405 P.3d 681 (Okla. 2017) (striking down affidavit requirement); *N. Broward Hosp. Dist. v. Kalitan*, 219 So. 3d 49 (Fla. 2017) (striking down damages cap); Mark A. Behrens & Andrew W. Crouse, *The Evolving Civil Justice Reform Movement: Procedural Reforms Have Gained Steam, but Critics Still Focus on Arguments of the Past*, 31 U. DAYTON L. REV. 173, 180–81 (2006) (surveying major movements in tort reform).

332. Moffett & Moore, *supra* note 143, at 109.

*Ins. Co.*³³³ In 1982, the Wisconsin legislature codified that framework for Wisconsin's informed consent statute.³³⁴ Enacted in 1982, Wisconsin Statute section 448.30 provided that "a physician's duty to inform 'is driven by what is reasonably necessary for a reasonable person to make an intelligent decision with respect to the choices of treatment or diagnosis.'"³³⁵ In addition to supporting patients through the reasonable standard approach, codification of the listed exceptions originally stated in *Scaria* served to protect physicians from certain liability.³³⁶ In *Jandre v. Wisconsin Injured Patients & Families Compensation Fund*, the Wisconsin Supreme Court expanded a physician's duty by requiring physicians to disclose all diagnostic approaches.³³⁷ The Wisconsin legislature responded to *Jandre* with 2013 Wisconsin Act 111,³³⁸ which did not require the disclosure of information about alternative medical modes of treatments for any condition the physician has not included in his or her diagnosis at the time the physician informs the patient.³³⁹ It also adopted a physician-centered standard.

After *Helling*, the case discussed in Part III.C, *supra*, in which the Washington Supreme Court rejected custom as decisive of the standard of care, a number of state legislatures responded and proactively drafted legislation that defined the standard of care.³⁴⁰ In 1977, North Carolina enacted a statute with the specific intent of reflecting the common law practices of the state.³⁴¹ Section 90-21.12 requires expert witnesses for the plaintiff to (1) testify on the standard of care that the defendant-physician is held to and whether the defendant-physician violated that standard; and (2) show whether the defendant was the proximate cause of the

333. *Scaria v. St. Paul Fire & Marine Ins. Co.*, 227 N.W.2d 647, 652–53 (Wis. 1975) (establishing the legal standard and five exceptions that limited physician liability).

334. WIS. STAT. § 448.30 (2018); Michael Rohde, *Information Overload: How the Wisconsin Supreme Court Expanded the Doctrine of Informed Consent*, 46 J. MARSHALL L. REV. 1097, 1103–04 (2013).

335. *Jandre v. Wis. Injured Patients & Fams. Comp. Fund*, 813 N.W.2d 627, 647 (Wis. 2012) (quoting *Martin v. Richards*, 531 N.W.2d 70, 78 (Wis. 1995)).

336. *Scaria*, 227 N.W.2d at 653; WIS. STAT. ANN. § 448.30 (West 2018) ("[P]hysician's duty to inform the patient under this section does not require disclosure of: (2) Detailed technical information that in all probability a patient would not understand. (3) Risks apparent or known to the patient. (4) Extremely remote possibilities that might falsely or detrimentally alarm the patient. (5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment. (6) Information in cases where the patient is incapable of consenting.").

337. *Sterken et al.*, *supra* note 84, at 104–05; *Jandre*, 813 N.W.2d 627.

338. Assemb. B. 111, 101st Leg., 2003 Sess. (Wis. 2013).

339. § 448.30(7).

340. *Id.*; WASH. REV. CODE § 4.24.290 (2019) (stating that a physician is only liable if the defendant failed to act as a reasonable medical professional in the circumstances).

341. Tyson, *supra* note 144, at 112–13; see Casey Hyman, *Setting the "Bar" in North Carolina Medical Malpractice Litigation: Working with the Standard of Care that Everyone Loves to Hate*, 89 N.C. L. REV. 234 (2010); see also N.C. GEN. STAT. § 90-21.12 (2011) (establishing relevant standard of care for medical malpractice actions).

plaintiff's injuries.³⁴² In Connecticut, the state legislature enacted section 52-184c.³⁴³ Section 52-184c defines the standard of care and the qualification of expert witnesses.³⁴⁴ Additionally, section 52-184 strictly requires that a specialist can only testify for defendants who are specialists.³⁴⁵ Overall, thirty-two states have provisions regarding minimum qualifications for expert witnesses who testify in medical malpractice/liability cases.³⁴⁶

State legislatures have also attempted to limit judicial oversight of the standard of care determination. Twenty-seven states, the District of Columbia, and Puerto Rico have specific provisions providing for alternative dispute resolution (arbitration, mediation, or settlement conferences) in medical liability or malpractice cases. Seventeen jurisdictions—Alaska, Delaware, Hawaii, Idaho, Indiana, Kansas, Louisiana, Maine, Massachusetts, Montana, Nebraska, New Hampshire, New Mexico, Utah, Virginia, the Virgin Islands, and Wyoming—have requirements that medical liability or malpractice cases be heard by a screening panel before trial.³⁴⁷ Twenty-eight states have requirements for filing an affidavit or certificate of merit in order for a medical liability/malpractice claim to move forward.³⁴⁸

D. Statutory Protection of Physician-Patient Confidentiality

Physician-patient confidentiality protects information shared between a patient and her physician. Physician-patient confidentiality exists to protect those required to consult with physicians from disclosure of secrets, to prevent physicians from disclosing humiliating or embarrassing information about a patient, and to encourage patients to give full disclosure to their physicians.³⁴⁹ “The doctor-patient relationship requires confidentiality and privacy to work effectively.”³⁵⁰

While the protection of patient information has a long history in medicine generally, formal legal protection of physician-patient communications is entirely statutory; it did not exist at common law before legislatures enacted physician-patient privilege statutes.³⁵¹ Although some courts have upheld

342. Hyman, *supra* note 341, at 240. *See generally* § 90-21.12.

343. CHRISTOPHER REINHART, STANDARD OF CARE IN MEDICAL MALPRACTICE CASES (2003), <https://www.cga.ct.gov/2003/olrdata/jud/rpt/2003-R-0486.htm> [<https://perma.cc/S9GA-75AA>]; Jennifer S.R. Lynn, *Connecticut Medical Malpractice*, 12 BRIDGEPORT L. REV. 381, 392 (1992); CONN. GEN. STAT. § 52-184c(a) (1991).

344. CONN. GEN. STAT. § 52-184c(a).

345. *Id.* § 52-184c(b) (nonspecialists); *id.* § 52-184c(c) (specialists).

346. *Medical Liability/Medical Malpractice Laws*, NAT'L CONF. OF ST. LEGISLATURES, <http://www.ncsl.org/research/financial-services-and-commerce/medical-liability-medical-malpractice-laws.aspx> [<https://perma.cc/2GP7-HUDK>] (Aug. 15, 2011).

347. *Id.*

348. *Id.*

349. *See Perry v. Fiumano*, 403 N.Y.S.2d 382 (App. Div. 1978); BURR W. JONES, THE LAW OF EVIDENCE: CIVIL AND CRIMINAL (6th ed. 2006).

350. Brief Amici Curiae of the New England Journal of Med. et al. in Support of Petitioners at 7, *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011) (No. 10-779), 2011 WL 771329.

351. Gerald L. Higgins, *The History of Confidentiality in Medicine: The Physician-Patient Relationship*, 35 CANADIAN FAM. PHYSICIAN 921 (1989); *see Tucson Med. Ctr., Inc. v. Rowles*, 520

physician-patient confidentiality as a physician's fiduciary duty, legislatures have done a better job at protecting patient communications.³⁵² New York was the first state to enact a physician-patient privilege statute in 1828, and currently, statutes have been enacted by the majority of U.S. states.³⁵³ Protections covered under physician-patient confidentiality differ state to state, but most statutes have common features.³⁵⁴ Generally, the privilege belongs to the patient and the patient has the right to expressly or impliedly waive the privilege.³⁵⁵ Most statutes maintain exceptions for certain public health reporting requirements, child abuse, injuries sustained by a lethal weapon, and other specific concerns, although these exceptions vary state to state.³⁵⁶

Although there is no federal physician-patient *evidentiary* privilege in judicial proceedings, physician-patient confidentiality is addressed by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).³⁵⁷ HIPAA's Privacy Rule protects any electronic communication concerning a patient's protected health information made by covered healthcare providers.³⁵⁸ Unauthorized disclosure of confidential patient information is prohibited.³⁵⁹

Federal and state courts of varying jurisdictions have not recognized claims for breach of confidentiality outside of statutorily defined causes of action. For example, in *Humphers v. First Interstate Bank of Oregon*, a mother who gave her daughter up for adoption sued the physician who delivered her daughter for revealing the mother's identity to the daughter.³⁶⁰ The mother brought the lawsuit under a broad theory of breach of information obtained in a confidential or privileged relationship.³⁶¹ The court refused to recognize a special cause of action, anchoring its analysis instead on the Oregon statute providing for discipline or disqualification of a physician who "wilfully or negligently divulge[d] a professional secret."³⁶²

Geisberger v. Willuhn, an Illinois case, reached a similar conclusion, stating that breach of confidential relationship, breach of contract, and breach of privacy were

P.2d 518 (Ariz. Ct. App. 1974); *United States v. Meagher*, 531 F.2d 752 (5th Cir.), *cert. denied*, 429 U.S. 853 (1976).

352. See, e.g., OHIO REV. CODE ANN. § 2317.02 (West 2017); GA. CODE ANN. § 24-12-21 (2016); see also *Horne v. Patton*, 287 So. 2d 824 (Ala. 1973).

353. Daniel W. Shuman, *The Origins of the Physician-Patient Privilege and Professional Secret*, 39 SMU L. REV. 661, 676 (1985), <https://scholar.smu.edu/smulr/vol39/iss2/3> [<https://perma.cc/XQF6-B8QJ>].

354. See *Hobbs v. Lopez*, 645 N.E.2d 1261 (Ohio Ct. App. 1994).

355. *Id.*

356. *Id.*

357. U.S. DEP'T OF HEALTH & HUM. SERVS., SUMMARY OF THE HIPAA PRIVACY RULE (2013), <https://www.hhs.gov/sites/default/files/privacysummary.pdf> [<https://perma.cc/83AY-8WTY>].

358. *Id.*

359. 42 U.S.C. § 1320d-6 (1996).

360. *Humphers v. First Interstate Bank of Or.*, 696 P.2d 527, 527 (Or. 1985).

361. *Id.*

362. *Id.* at 535.

not valid causes of action by a patient for a physician's unauthorized disclosure of confidential information.³⁶³ The court in *Geisberger* also narrowly construed the statute protecting patient confidential information, stating that privileged communication only exists if the communication was necessary for the performance of a professional duty on the part of the physician, and communications must relate to the private, rather than the public, life of the patient.³⁶⁴

Various courts have taken similar positions as the courts in *Humphers* and *Geisberger*.³⁶⁵ Furthermore, while some statutes establish a cause of action for breach of physician-patient confidentiality, some courts have only recognized physician-patient privilege as rule of evidence.³⁶⁶ Additionally, even when courts recognize a cause of action for breach of a physician's fiduciary duty, they still reach outcomes adverse to the patient's interest in confidentiality.³⁶⁷ By strictly construing statutes and not recognizing causes of action for breach of duty of confidentiality, courts have not protected patient confidentiality as well as legislatures.

Several states have enacted legislation dealing with HIV/AIDS patients' confidentiality.³⁶⁸ The legislative intent of HIV/AIDS statutes is twofold: to protect the general public from an incurable disease and do so without infringing HIV/AIDS patients' confidentiality rights.³⁶⁹ Most HIV/AIDS legislation created new rights for HIV/AIDS patients who wish to remain confidential in legal proceedings and who wish to receive confidential HIV testing.³⁷⁰ On the other hand, legislatures sought to protect healthcare providers who give care to HIV-infected patients from being infected themselves.³⁷¹ As a result, HIV/AIDS statutes not only provide confidentiality protection to patients, but they also allow exceptions for disclosure of confidential information.³⁷² The twofold purpose of HIV/AIDS statutes was intended by legislatures to strike a balance between patient confidentiality and public health, and these statutes were intended to protect one without compromising the other.

Courts, on the other hand, have ruled against protecting HIV/AIDS patients' confidentiality in favor of public health. Regarding the seemingly simple notion of whether an HIV/AIDS patient could use a pseudonym during litigation, the court

363. *Geisberger v. Willuhn*, 390 N.E.2d 945, 946–48 (Ill. App. Ct. 1979).

364. *Id.* at 947–48.

365. *See, e.g., Quarles v. Sutherland*, 389 S.W.2d 249 (Tenn. 1965); *Ruzzier v. Nw. Lake Forest Hosp.*, No. 1-16-1300, 2017 WL 2124349 (Ill. App. Ct. May 10, 2017); *May v. N. Health Facilities, Inc.*, No. 2008-P-0054, 2009 WL 806927 (Ohio Ct. App. Mar. 27, 2009).

366. *See Quarles*, 389 S.W.2d at 251–52; *Davis v. Earls*, No. W2000-00280-COA-R3-CV, 2001 WL 589138 (Tenn. Ct. App. May 30, 2001).

367. *See Quarles*, 389 S.W.2d at 251–52.

368. FLA. STAT. § 381.004 (2018) (outlining informed consent procedures and confidentiality for HIV/AIDS patients); OHIO REV. CODE ANN. § 3701.242 (West 2018); 410 ILL. COMP. STAT. 305 / 9 (2018).

369. *See Waddell v. Bhat*, 571 S.E.2d 565, 566 (Ga. Ct. App. 2002).

370. *See* 410 ILL. COMP. STAT. 305 / 2, 305/9.

371. *Waddell*, 571 S.E.2d at 566.

372. *See* GA. CODE ANN. § 24-12-21 (West 2016).

in *Doe v. Hall* ruled that use of a pseudonym is not protected by statute and the decision is at the trial court's discretion.³⁷³

In *Smith v. Datla*, the court ruled that the statute of limitations regarding HIV/AIDS patient confidentiality had run out, and the patient had no other remedy at common law or otherwise.³⁷⁴ The *Smith* case shows how unwilling courts are to construe statutes liberally or provide common law protections for patient confidentiality.

At the federal level, not only do federal courts not recognize an evidentiary privilege arising from the fiduciary nature of the doctor-patient relationship, U.S. Supreme Court rulings have limited the reach of federal statutes that might support such a privilege. While HIPAA acknowledged that patient medical information is sensitive and must be kept private, federal courts have not allowed it to serve as the basis of an evidentiary privilege.³⁷⁵ In *IMS v. Sorrell*, the case striking down Vermont's law protecting physician prescribing information, the ruling acknowledged the risk of exposing a patient's prescription history because of increasingly sophisticated ways of identifying patients from otherwise deidentified sources, especially with access to physicians' names and locations.³⁷⁶ Protections for genetic privacy, similarly, have been far more expansive in state and federal legislatures than in courts.³⁷⁷

E. Good Faith

As suggested in Parts I.A and II.E, the fiduciary duty of good faith generally and the physician's duty specifically lack coherent or consistent meaning as courts have fashioned that duty.³⁷⁸ Courts have stated generally that because the relationship is based on trust and confidence, the utmost good faith must be exercised.³⁷⁹

373. *Doe v. Hall*, 579 S.E.2d 838, 840 (Ga. Ct. App. 2003).

374. *Smith v. Datla*, 164 A.3d 1110, 1124 (N.J. Super. Ct. App. Div. 2017).

375. *Whalen v. Roe*, 429 U.S. 589, 602 n.28 (1977) (“The physician-patient evidentiary privilege is unknown to the common law.”); *United States v. Witt*, 542 F. Supp. 696, 698–99 (S.D.N.Y.) (holding that there is no generally recognized physician-patient privilege), *aff'd*, 697 F.2d 301 (2d Cir. 1982); *United States v. Burzynski Cancer Rsch. Inst.*, 819 F.2d 1301, 1311 (5th Cir. 1987) (“In the context of federal criminal proceedings, no physician-patient privilege exists.”); *Nw. Mem'l Hosp. v. Ashcroft*, 362 F.3d 923, 926 (7th Cir. 2004) (“We do not think HIPAA is rightly understood as an Act of Congress that creates a privilege.”).

376. Brief Amici Curiae of the New England Journal of Med. et al. in Support of Petitioners, *supra* note 350, at 8.

377. See generally Anya E.R. Prince, *Comprehensive Protection of Genetic Information: One Size Privacy or Property Models May Not Fit All*, 79 BROOK. L. REV. 175 (2013).

378. AM. MED. ASS'N, *supra* note 67 (stating that physicians have an obligation to “place patient's welfare above the physician's own self-interest”).

379. *Cates v. Wilson*, 350 S.E.2d 898, 905 (N.C. Ct. App. 1986), *modified*, 361 S.E.2d 734 (N.C. 1987); see also Thomas L. Hafemeister & Richard M. Gulbrandsen, Jr., *The Fiduciary Obligation of Physicians to “Just Say No” if an “Informed” Patient Demands Services that Are Not Medically Indicated*, 39 SETON HALL L. REV. 335, 370 (2009).

Under common law, a physician must exercise the utmost good faith.³⁸⁰ This doctrine's requirements are self explanatory when it is easily recognizable that the physician is acting in bad faith.³⁸¹ The generality of the good faith obligation provides a great framework for a physician's career; however, the lack of enumerated steps to ensure physicians' actions are made in good faith creates confusion. This lack of guidance and clarity makes physicians more susceptible to disciplinary or malpractice action.

As a statutory matter, good faith has been used broadly to preserve the integrity of the physician-patient relationship against specific pressures like the provision of emergency treatment, the prescription of pain medications, and the special duties that accompany the protection of children.³⁸²

A majority of state statutes have either explicitly defined "good faith" and/or have listed specific requirements for physician practices. For example, when prescribing a controlled substance which is a narcotic, the Illinois Controlled Substance Act clearly defines good faith to mean

the prescribing or dispensing of a controlled substance by a practitioner in the regular course of professional treatment to or for any person who is under his or her treatment for a pathology or condition other than that individual's physical or psychological dependence upon or addiction to a controlled substance³⁸³

In addition, the Act specifically requires a physician in good faith to meet requirements for multiple prescriptions and to keep a record of all controlled substances received, administered, dispensed, or professionally used otherwise than by prescription.³⁸⁴ A physician also acts in good faith when prescribing or distributing a controlled substance or any other drug in the course of professional practice to relieve pain and suffering or diseases for a duration that is medically necessary.³⁸⁵ Delaware has similarly provided for the specific administration of naloxone, a drug used to treat opioid overdoses that may have significant side effects, requiring physicians to use it in good faith.³⁸⁶

Equally important, state statutes actively limit a physician's fear of future liability by providing a greater incentive to engage in emergency practices that could

380. See, e.g., *Black v. Littlejohn*, 325 S.E.2d 469, 482 (N.C. 1985); *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 879 (Ohio 1991); *Hummel v. State*, 196 S.W.2d 594, 595 (Ark. 1946) (quoting ALFRED W. HERZOG, *MEDICAL JURISPRUDENCE* § 96 (1931)).

381. See generally *Hoopes v. Hammargren*, 725 P.2d 238, 242 (1986) (finding that physician's sexual relations with patient could violate duty of utmost good faith); N.Y. EDUC. LAW § 6509 (McKinney 2008) (defining professional misconduct).

382. See Gail B. Agrawal, *Resuscitating Professionalism: Self-Regulation in the Medical Marketplace*, 66 MO. L. REV. 341, 384–85 (2001).

383. 720 ILL. COMP. STAT. ANN. 570 / 102(u) (1971).

384. *Id.* at 570 / 312(a), (a-5), (c), (d); see also 42 PA. CONS. STAT. § 8331 (1978) (defining good faith in rendering emergency when a reason).

385. See TENN. CODE ANN. § 63-6-214(b)(12) (2016); CAL. BUS. & PROF. CODE § 2242 (West 2007).

386. See generally DEL. CODE tit. 16, § 3001G (2020).

potentially save lives.³⁸⁷ At common law, any emergency aid provided by a physician resulted in the creation of a physician-patient relationship where there was duty of reasonable care owed.³⁸⁸ “To encourage physicians to stop at the scene of an emergency, usually a roadside accident, and to render assistance to injured parties without fear of malpractice litigation,” states granted varying degrees of immunity from civil liability for physicians.³⁸⁹ Generally, these laws require (1) an emergency; (2) the absence of a legal duty to act; and (3) care provided in good faith.³⁹⁰

Similarly, states offer the immunity for physicians who in good faith report or assist in investigations of an alleged child abuse or neglect.³⁹¹ Pennsylvania law, like many states, provides a presumption of good faith for physicians reporting or participating in investigations related to child abuse.³⁹²

CONCLUSION

This Article has argued that the extension of fiduciary duties to more actors in society, while appealing to the hope for more people acting in the interest of others, may in fact not work in practice. Because fiduciaries are attributed to possess knowledge, skill, deliberation, discretion, and, generally, power and virtue, it is understandable to wish for more people to look and act as fiduciaries are theorized to do. Indeed, physicians play a central role in fiduciary narratives because they are fairly described by all of the panegyric attributes extended to attorneys, trustees, guardians, and other regulated professionals.

Yet the attributes and the reality of the fiduciary relationship are different, critically so when it comes to holding fiduciaries to account for the virtues they are supposed to possess. The practice of medicine, like the practice of law, accounting, the stewardship of resources for others, and the protection of minors or incapacitated persons, occurs against a complex backdrop that implicates not only the entrustor’s relationship with the fiduciary but the fiduciary’s relationship with society more broadly. In the physician-patient context, this has led professional bodies, legislators, and regulators to draft complex, certainly imperfect systems to address pressures on fiduciaries’ loyalty, candor, competence, discretion, and even good faith. As this Article demonstrates, those systems accomplish more for greater

387. Stewart R. Reuter, *Physicians as Good Samaritans: Should They Receive Immunity for Their Negligence When Responding to Hospital Emergencies?*, 20 J. LEGAL MED. 157 (1999).

388. *Colby v. Schwartz*, 144 Cal. Rptr. 624, 627 (Ct. App. 1978).

389. Reuter, *supra* note 387; *Pemberton v. Dharmani*, 469 N.W.2d 74, 76 (Mich. Ct. App. 1991) (quoting H.B. 4326, 78th Leg., 1975–1976 Sess. (Mich. 1975)) (“[T]he bill would *encourage* health care personnel to render emergency care in hospitals and other health care facilities.”).

390. See MICH. COMP. LAWS § 691.1501 (2016) (defining the scope of immunity eligibility); 23 PA. CONS. STAT. § 6318 (2014).

391. See TEX. FAM. CODE ANN. § 261.106 (West 1995); *id.* at § 261.104 (mandating that the content of a report include: “(1) the name and address of the child; (2) the name and address of the person responsible for the care, custody, or welfare of the child; and (3) any other pertinent information concerning the alleged or suspected abuse or neglect.”).

392. 23 PA. CONS. STAT. § 6318 (2014).

numbers of patients, physicians, and those with whom they work and live than judicially enforced duties are likely to achieve.