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Private Ordering Is Ubiquitous in Health Care, but Why?

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2.1 INTRODUCTION

Twenty years ago, Lester Salamon noted "the extent to which actual public problem solving has come to embrace the collaborative actions of government . . . and private organizations – both for-profit and nonprofit."[1] He traced these "alternative instruments of public action," which engage private actors in the work of governance, back "at least two decades,"[2] corresponding to about 1980. At that time, there was growing disenchantment with top-down governmental command-and-control rule-setting amid energy shortages, environmental degradation, and concern that regulated industries sometimes capture their regulators.[3] Research overseen by the US Public Health Service had, by the early 1970s, produced shocking revelations about the Tuskegee Syphilis Study, undermining people's faith that the government is any better at protecting individual rights than private-sector Institutional Review Boards (IRBs) would be.[4] An expansion of social programs in the mid-twentieth century stretched the role of the state far beyond its traditional governmental functions,[5] making it plausible that lessons from the private sector might be relevant to public governance.

All these factors fueled the rise of private ordering, which Steven Schwarcz defines as a "broad spectrum" of alternatives to having "rules of law originated and

[1] Lester M. Salamon, The Tools of Government: A Guide to the New Governance vii (Lester M. Salamon ed., 2002).

[2] Id.

[3] José A. Gómez-Ibáñez, Regulating Infrastructure: Monopoly, Contracts, and Discretion 41–48 (2003).

[4] Kayte Spector-Bagdady, Governing Secondary Research Use of Health Data and Specimens: The Inequitable Distribution of Regulatory Burden between Federally Funded and Industry Research, 8 J.L. & Biosciences 2–3, 6–8 (Jan.–June 2021).

[5] See, e.g., 49 U.S.C. § 40125(a)(2) (defining "governmental functions" as including activities such as national defense, intelligence gathering, law enforcement, and firefighting).

put into force by sovereign governments."[6] Health care, as a heavily regulated industry, offers fertile soil for privately ordered alternatives to governmental regulation, and William Sage observes that "'private law' in its many forms plays an outsized role in American health governance."[7] This raises a question: Why? Does private ordering in US health care simply mirror a trend that swept many economic sectors after 1980, or is the trend uniquely amplified in health care? Does it reflect, as Professor Sage suggests, a "cognitive dissonance" between health care's lusty appetite for public financing and its deep distaste for public control?[8] Is it a charade that helps politicians conceal vast "public spending on health care behind a curtain of ostensibly private conduct"?[9] Is it, perhaps, required by constitutional constraints on what government actors can do?

This chapter explores this last possibility but discounts the role federalism plays in forcing private ordering. Courts have generally proved unreceptive to arguments that the federal government lacks power to regulate the practice of medicine.[10] Even if courts were receptive to such arguments, federalism merely divides responsibilities between federal public ordering and state public ordering; it is agnostic on whether private ordering is superior to both those alternatives. Federalism thus cannot explain the outsized role private ordering plays in health care. This chapter focuses instead on constitutional speech protections, which bind the federal and state governments alike and which leave room for private actors to oversee medical speech and information flows in ways public agencies cannot do.

2.2 THE PREVALENCE AND VARIETY OF PRIVATE ORDERING SOLUTIONS IN HEALTH CARE

Health care displays a striking diversity of private ordering solutions that engage private actors in the work of governance. Some of the variants seen in health care predate the post-1980 rise of private ordering, making health care one of the early proving grounds for private ordering models. This section samples health care's breathtaking array of private ordering solutions as a prelude to Section 2.3, which explores sector-specific considerations that favor private ordering.

It is useful to state what private ordering is *not*. As conceived in this chapter, private ordering is not the same thing as decisional privacy, which connotes "a realm of personal liberty which the government may not enter,"[11] wherein individuals are

[6] Steven L. Schwarcz, Private Ordering, 97 Nw. U. L. Rev. 319, 325 (2002).
[7] Chapter 1 in this volume, at 7.
[8] Id. at 9.
[9] Id. at 15.
[10] David G. Adams, The Food and Drug Administration's Regulation of Health Care Professionals, in 2 Fundamentals of Law and Regulation: An In-Depth Look at Therapeutic Products 423, 424–25 (David G. Adams et al. eds., 1999).
[11] Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 847 (1992).

free to make decisions in line with their own consciences and without governmental interference. Decisional privacy is a regime without externally imposed rules, leaving individuals to make whatever decisions they prefer (e.g., to consent or not to consent to share their data, to pierce or not to pierce their navels, or to seek or not to seek an abortion) in a cherished realm of private disorder. Private ordering, in contrast, is a framework for creating binding rules that at times may constrain individual choice. It differs from traditional governmental rule-setting by enlisting private actors to help set those rules. Once established, privately made rules sometimes call on individuals to do things they would prefer not to do, or demand that they refrain from actions they view as desirable – as also happens with government-set rules. Private ordering gives private actors a voice in setting the rules but does not leave them free to do whatever they please.

A well-known instance of private ordering is the role private accreditation bodies play in determining whether health care facilities qualify to receive payments under the Medicare and Medicaid programs.[12] The Centers for Medicare and Medicaid Services (CMS), which administers these programs, allows hospitals and other health care facilities to establish eligibility to participate in them by undergoing accreditation by private bodies that CMS approves.[13] Accredited health care facilities do not need to undergo formal governmental regulatory inspections.[14] When challenged in court, this arrangement was held not to be an improper delegation of governmental authority to private actors, because the Secretary of the US Department of Human and Health Services (HHS) retains ultimate authority over decisions to certify or decertify participation in the Medicare and Medicaid programs.[15] In practice, however, the Secretary rarely, if ever, asserts this theoretical authority to override private accreditors' decisions. Timothy Stoltzfus Jost traces this reliance on private accreditation bodies back to the early years of the Medicare program, when heavy resistance from health care providers threatened to derail the program.[16] Private accreditation, as a form of industry self-regulation, seemed less intrusive than direct federal control of Medicare-eligible facilities and elicited their buy-in. It was, in Professor Sage's phrase, a "political settlement."[17]

[12] Schwarcz, supra note 6, at 320–21; Clark C. Havighurst, Foreword: The Place of Private Accrediting among the Instruments of Government, 57 Law & Contemp. Probs. 647 (Autumn 1994).

[13] See Karen S. Rieger, Medical Staff Fundamentals, in 1 Health Law Practice Guide §§ 2:5–2:10 (Alice G. Gosfield et al. eds., 2d ed. 2021).

[14] Id. § 2:6.

[15] Cospito v. Heckler, 742 F.2d 72, 87–88 (3rd Cir. 1984), 471 U.S. 1131 (1985) (cert. denied).

[16] Timothy Stoltzfus Jost, Medicare and the Joint Commission on Accreditation of Healthcare Organizations: A Healthy Relationship?, 57 Law & Contemp. Probs. 15, 23–24 (Autumn 1994).

[17] Chapter 1 in this volume, at 10.

CMS also administers the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[18] regulations,[19] which govern clinical laboratories that perform diagnostic tests used in clinical health care. CLIA is intriguing because it lets regulated entities choose how much public or private ordering they prefer. Nonexempt[20] laboratories conducting moderate- and high-complexity tests can, at their discretion, elect to pursue either a certificate of compliance or a certificate of accreditation.[21] Those choosing a certificate of compliance follow government-set standards and undergo periodic inspections by state agencies to which CMS delegates local inspection responsibilities.[22] Those choosing a certificate of accreditation follow standards set by various CMS-approved private accreditors, which carry out inspections to ensure compliance.[23]

It is wrong to assume private regulation is laxer than its governmental counterpart. At times, private ordering is more stringent. For example, CLIA's concept of high-complexity testing arguably understates the true complexity of genetic and genomic tests. In 1997, a federal advisory body urged the Clinical Laboratory Improvement Advisory Committee (CLIAC), which advises CMS on CLIA matters, to consider creating specialty requirements for genetic testing,[24] and CMS received citizens' petitions supporting this idea.[25] CMS rejected these calls, leaving this superlatively complex type of testing under the same general rules that govern other high-complexity tests. Private accreditation bodies such as the College of American Pathologists have worked to fill this gap in public regulation by developing private standards specifically addressing genetic and genomic testing.[26] Unfortunately, some

[18] Pub. L. No. 100-578, 102 Stat. 2903 (codified as amended at 42 U.S.C. § 263a).

[19] 42 C.F.R. § 493.

[20] See List of Exempt States under the Clinical Laboratory Improvement Amendments (CLIA), Ctrs. for Medicare & Medicaid Servs. (May 30, 2022), https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/exemptstateslist.pdf (exempting clinical laboratories in Washington and New York from CLIA because CMS deems their state laboratory regulations to satisfy CLIA's requirements).

[21] Types of CLIA Certificates, Ctrs. for Medicare & Medicaid Servs. (May 29, 2005), https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/types_of_clia_certificates.pdf.

[22] Clinical Laboratory Improvement Amendments (CLIA) State Agency Contacts, Ctrs. for Medicare & Medicaid Servs. (Dec. 18, 2023), https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/cliasa.pdf.

[23] List of Approved Accreditation Organizations under the Clinical Laboratory Improvement Amendments (CLIA), Ctrs. for Medicare & Medicaid Servs. (May 30, 2022), https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/aolist.pdf.

[24] National Institutes of Health-Department of Energy Working Group on Ethical, Legal & Social Implications of Human Genome Research, Task Force on Genetic Testing, Promoting Safe and Effective Genetic Testing in the United States 30 (N. A. Holtzman & M. S. Watson eds., 1997).

[25] Kathy L. Hudson, Petition Requesting a Genetic Testing Specialty and Standards for Proficiency Testing, Public Citizen (Sept. 26, 2006), https://www.citizen.org/article/petition-requesting-a-genetic-testing-specialty-and-standards-for-proficiency-testing.

[26] Nazneen Aziz et al., College of American Pathologists' Laboratory Standards for Next-Generation Sequencing Clinical Tests, 139 Archives of Pathology & Lab'y Med. 481–93 (2015).

laboratories conduct genomic tests under a CLIA certificate of compliance and are governed by less rigorous public standards.[27]

Private ordering spans a spectrum of approaches. At the more formal end of the spectrum are examples, including those just given, that Steven Schwarcz describes as rules "put into force by private actors pursuant to governmental delegation."[28] Professor Schwarcz recognizes a second, somewhat less formal type of private ordering where the rules are "originated by private actors but put into force by sovereign governments."[29] Health care offers many examples. For example, hospitals and vendors negotiate private contracts but look to courts (public bodies) to enforce them. Courts look to medical experts (private actors) to establish the standard of care that courts (public bodies) enforce in medical malpractice actions.

An instructive example is the US Food and Drug Administration's (FDA) reliance on independent advisory committees, created by statute or at the discretion of the Secretary of HHS and staffed with individual experts, to prepare recommendations on scientific, technical, and policy matters.[30] These committees allow the agency to tap a breadth of sector-specific expertise that may not exist among civil servants. While their advice is not binding on the agency, a recent study of prescription drug decisions found that the agency follows advisory committee votes 88 percent of the time.[31] The 88 percent of advisory committee recommendations that the FDA chooses to implement become privately ordered rules "originated by private actors and put into force by"[32] the FDA, but the agency retains discretion to reject recommendations and does so 12 percent of the time. Not all private recommendations become rules in this private ordering scheme.

In the same way, not all private contracts are enforceable in health care – for example, you cannot sell your newborn or your kidney, even if you are a willing seller and find a willing buyer. Private contracts play a major role in governance of health care just as they do in all industries, but health care exhibits a constant tug-of-war between freedom of contract and welfare-enhancing public constraints on that freedom. Thus, the states limit physicians' freedom to ask patients to waive their right to bring malpractice suits, either through restrictions that state medical practice acts impose on the use of medical liability waivers or through judicial determinations that waivers are coercive and void as against public policy.[33] The Health

[27] Barbara J. Evans et al., How Can Law and Policy Advance Quality in Genomic Analysis and Interpretation for Clinical Care?, 48 J.L. Med. & Ethics 44, 53 (2020).
[28] Schwarcz, supra note 6, at 325.
[29] Id.
[30] Advisory Committees, U.S. Food & Drug Admin., https://www.fda.gov/advisory-committees.
[31] C. Joseph Ross Daval et al., Association of Advisory Committee Votes with US Food and Drug Administration Decision-Making on Prescription Drugs, 2010–2021, 4 JAMA Health Forum e231718 (July 2023).
[32] Schwarcz, supra note 6, at 325.
[33] See, e.g., Tunkl v. Regents of the University of California, 60 Cal.2d 92, 383 P.2d 441 (1963).

Insurance Portability and Accountability Act[34] (HIPAA) Privacy Rule[35] requires health care providers to sign Business Associate Agreements and Data Use Agreements providing contractual privacy protections for data they share with certain data users, but it leaves the specific terms of those agreements largely open to private negotiations between the provider and the data recipient.[36] Federal laws addressing Medicare fraud limit health care providers' ability to enter various contractual arrangements (such as agreeing to give and receive discounts on services provided) that would be perfectly normal and uncontroversial in other business settings.[37] Health care's ambivalence about contractual ordering reflects the reality that individuals operating in the health care sector, however autonomous they may be, are engaged in activities that may leave some of the parties vulnerable or implicate broader public interests (such as keeping Medicare expenditures within reasonable bounds).

At the least formal extreme of private ordering, Professor Schwarcz recognizes rules that are "adopted by private actors without governmental sanction or enforcement."[38] These call to mind Robert Ellickson's work on sources of control, other than governments, that can create rules and incentives to comply with them.[39] Professor Ellickson's "controllers" include (1) ethical principles that foster internal self-control (e.g., voluntary codes, such as the American Medical Association's Code of Medical Ethics,[40] to which members of a professional community bind themselves); (2) contractual rules formed through interpersonal negotiations (e.g., a Data Use Agreement requiring special privacy protections and restricting how a researcher can use health data supplied by a hospital),[41] (3) norms that emerge from social forces (e.g., standard practices, customs, and professional etiquette in clinical care settings); and (4) organizational rules (e.g., institutional policies that hospitals voluntarily adopt to protect patients and research participants in ways that go beyond what law requires).[42] All of these sources of nongovernmental control are at work in health care.

Depending on the type of private ordering scheme, compliance may be more or less of a problem. When, as in Professor Schwarcz's first two private ordering schemes, the private rules are "put into force by" governments or "made pursuant

[34] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).
[35] 45 C.F.R. pts. 160, 164.
[36] Barbara J. Evans, The HIPAA Privacy Rule at Age 25: Privacy for Equitable AI, 50 FSU L. Rev. 741, 802 (2023).
[37] Medicare Fraud and Abuse (Anti-kickback) Statute, 42 U.S.C. § 1320a-7b; Physician Self-referral Law (Stark Law), 42 U.S.C. § 1395nn.
[38] Schwarcz, supra note 6, at 325.
[39] Robert G. Ellickson, Order without Law: How Neighbors Settle Disputes 126 (1991).
[40] AMA, Code of Medical Ethics, https://code-medical-ethics.ama-assn.org/.
[41] See 45 C.F.R. § 164.514(e)(3)(i), (e)(4).
[42] Ellickson, supra note 39, at 126–27.

to" a formal governmental delegation,[43] the state's "monopoly on official use of force"[44] lurks in the background to help ensure compliance with the privately made rules. However, when private rules are made "without governmental sanction or enforcement,"[45] there is a crucial institutional challenge to craft private decision-making structures with sufficient authority and legitimacy to induce compliance with norms that at times may go against individual preferences. Despite this, private rules that arise spontaneously without any governmental involvement often work better than one would expect, possibly because such rules tend to be welfare-enhancing (otherwise, people would not have spontaneously embraced them in the first place).[46] This is not always the case, however.

One final example hints that private ordering schemes struggle for legitimacy in situations where competing interests force private decision-makers to make difficult trade-offs. The HIPAA Privacy Rule regulates permissible flows of clinical health data and sets rules governing when personal data can be shared for various purposes. It respects decisional privacy, but in an asymmetric manner: Individuals can *authorize* the sharing of their data however they wish,[47] but they cannot *refuse* to share their data for certain uses that serve broader public interests.[48] The regulation identifies twenty-three "national priority"[49] data uses that offer sufficient benefit to society that access to personal data may be justified even without individual authorization – for example, to track epidemics, regulate medical product safety, detect domestic violence, acquit accused suspects whose defense turns on medical evidence, and promote health care quality and equity.[50]

For each of these twenty-three data uses, the regulation specifies who, precisely, is empowered to authorize unconsented data sharing in a particular instance.

[43] Schwarcz, supra note 6, at 325.

[44] Jonathan R. Macey, Public and Private Ordering and the Production of Legitimate and Illegitimate Legal Rules, 82 Cornell L. Rev. 1123, 1133 (1997) (citing Robert D. Cooter, Law from Order, in A Not-So Dismal Science: A Broader and Brighter Approach to Economies and Societies (J. Mancur Olson & S. Kahkonen eds., 1998)).

[45] Schwarcz, supra note 6, at 325.

[46] Macey, supra note 44, at 1132–33.

[47] 45 C.F.R. §§ 164.502(a)(1)(iv), 164.508.

[48] The Privacy Rule only requires individual authorization, in the sense of treating it as a precondition of data sharing, in a few instances where the balance of public and private interests tips in favor of the individual, either because the individual's interest in privacy is unusually high (e.g., psychotherapy notes, see 45 C.F.R. § 164.508(a)(2)) or because the data use provides low benefits to society (e.g., selling data or using it for marketing). See id. §§ 502(a)(5)(ii)(B)(1), 164.508(a)(4)(i) (data sales), 164.508(a)(3) (marketing).

[49] Off. of the Assistant Sec'y for Plan. & Evaluation, Confidentiality of Individually Identifiable Health Information: Recommendations of the Secretary of Health and Human Services, Pursuant to Section 264 of the Health Insurance Portability and Accountability Act of 1996, U.S. Dep't Health & Hum. Servs. § I.I (Sept. 10, 1997).

[50] Evans, supra note 36, at 749–51 tbl. 1 (listing twenty-seven norms allowing patients health data to be shared under the HIPAA Privacy Rule, of which twenty-three allow unconsented access to support specific data uses deemed to offer large benefits to society).

For example, legislatures, by enacting laws, can decide that your data can be accessed, even against your wishes, for various public health uses (public ordering).[51] Courts and administrative law judges can decide that your data can be shared without consent for judicial and regulatory uses (another type of public ordering).[52] Licensed medical professionals can decide to share your data with other licensed professionals to inform the treatment of patients with similar illnesses[53] or if they believe, in good faith and consistent with medical ethical standards, that data sharing will avert serious threats to the public or to other individuals – the so-called *Tarasoff* exception (private ordering).[54] Institutional Review Boards or HIPAA Privacy Boards (together, "IRBs") can authorize unconsented research use of your data by approving a waiver (again, private ordering).[55]

Certain things can be inferred from the way the HIPAA Privacy Rule allocates authority to approve each type of unconsented data use. When a data use is especially important to society (such as tracking epidemics or ensuring accurate administration of justice), HIPAA generally favors public ordering and lets legislatures and courts decide whether an unconsented data use serves the public's interests. Individuals "consent" to the rules these bodies set in a Blackstonian sense, by consenting to be governed by the rule of law.[56] Unfortunately, public ordering is not very nimble and cannot accommodate the thousands (millions?) of granular, day-to-day decisions about specific data uses in a modern health care system. Codifying fixed legal rules to resolve all possible trade-offs in all possible circumstances is probably impossible. This reality creates a need to delegate some day-to-day decisions to local – and often private – actors such as IRBs and licensed medical professionals. The HIPAA Privacy Rule constrains the private decision-making power it grants, either by setting its own standards (such as the criteria IRBs must follow when authorizing research pursuant to a waiver)[57] or by reference to external standards (such as state laws and ethical standards that place physicians under strong fiduciary duties to handle patients' data carefully).[58]

The drafters of the HIPAA Privacy Rule undoubtedly worked hard to strike an appropriate balance between public and private ordering of these fraught data access

[51] 45 C.F.R. §§ 164.512(a)–(c).
[52] 45 C.F.R. § 164.512(e).
[53] 45 C.F.R. § 164.502(a)(1)(ii); see also 512 – May a provider disclose information about an individual to another provider, U.S. Dep't Health & Hum. Servs. (Jan. 13, 2009), https://www.hhs.gov/hipaa/for-professionals/faq/512/under-hipaa-may-a-health-care-provider-disclose-information-requested-for-treatment/index.html (clarifying that, except for psychotherapy notes, a HIPAA-covered doctor may disclose a patient's information to another doctor without individual authorization for use in treating "another patient" – not necessarily a family member of the patient whose data are shared).
[54] 45 C.F.R. § 164.512(j); Tarasoff v. Regents of the University of California, 551 P.2d 334 (1976).
[55] 45 C.F.R. § 164.512(i).
[56] Barbara J. Evans, Much Ado about Data Ownership, 25 Harv. J.L. & Tech. 69, 126 (2011).
[57] 45 C.F.R. §§ 164.512(i)(2)(ii)(A)–(C).
[58] See Barry R. Furrow et al., Health Law 117 (8th ed. 2018).

decisions. Even so, the HIPAA Privacy Rule is the poster child for the perils of private ordering in situations where governance requires tough trade-offs between individual rights and public interests. Privacy advocates abhor the power IRBs and other private actors wield to approve unconsented data access,[59] while there are ongoing complaints that IRBs block important research and public health data uses that would benefit society.[60] There may be strong pragmatic reasons to rely on private ordering, but there is ongoing discomfort with it. Why, in spite of this discomfort, is private ordering so prevalent in health care?

2.3 THE ROOTS OF PRIVATE ORDERING IN HEALTH CARE

The sheer variety of private ordering schemes in health care thwarts easy generalizations about why they are so prevalent. Each instance of private ordering is a response to different concerns about regulatory efficiency, buy-in from regulated entities, or the benefits of private-sector expertise to help with specific tasks. No single principle explains them all. Some instances, no doubt, reflect political compromises or follow the post-1980s fad of private ordering in all regulated industries. However, others are responses to a special problem that confronts all health care regulators, state and federal: Regulating health care easily crosses the line into regulating scientific and medical speech.

Centuries before the term "informational medicine" entered the modern lexicon, the practice of medicine has always been mainly an informational service. It involves a few activities that constitute conduct – notably, surgery, inserting catheters, and so forth – but most of the practice of medicine consists of communication: gathering and curating information relevant to a patient's case, rendering a diagnosis, recommending a treatment plan, writing prescriptions, counseling patients and their families. The practice of medicine, at its core, is a physician analyzing relevant parts of the general medical knowledge base (all the knowledge and experience gained through centuries of clinical health care and biomedical research) along with patient-specific medical information and knowledge about a patient's "predicaments, rights, and preferences"[61] to develop tailored communications customized for each particular patient.

[59] Inst. of Med., Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research 66 (Sharyl J. Nass et al. eds., 2009), http://www.nap.edu/catalog/12458.html.

[60] William Burman & Robert Daum, Grinding to a Halt: The Effects of the Increasing Regulatory Burden on Research and Quality Improvement Efforts, 49 Clinical Infectious Diseases 328, 328 (2009) (arguing that the role of IRBs has slowed research); Sarah L. Cutrona et al., Validation of Acute Myocardial Infarction in the Food and Drug Administration's Mini-Sentinel Program, 22 Pharmacoepidemiol Drug Safety 40, 44 (2013) (describing IRB interference with public health data uses).

[61] David L. Sackett et al., Evidence Based Medicine: What It Is and What It Isn't, 312 BMJ 71, 71–72 (1996).

As the Supreme Court confirmed in the 2018 case, *National Institute of Family and Life Advocates, dba NIFLA v. Becerra*,[62] the First Amendment affords strong protection to physicians' professional speech – the recommendations and advice licensed medical professionals utter to patients during clinical treatment encounters. The case did not resolve how strong – strict versus intermediate scrutiny – because the court felt the challenged regulation failed under either standard.[63]

Private ordering circumvents impermissible speech regulation by state actors. Moreover, it upholds a 175-year-old cultural tradition dating back to the 1847 Code of Ethics of the American Medical Association (AMA).[64] The 1847 Code conceived medicine as a knowledge-based profession, distinct from the ill-trained quacks holding themselves out as doctors in that day.[65] Claudia Haupt defines a profession as a self-governing "knowledge community" sharing "common knowledge and experience as a result of training and practice," with "shared notions of validity and a common way of knowing and reasoning."[66] From 1850 through the end of the Progressive Era, the AMA entered an uneasy collaboration with legislatures and supported state regulation of medical practice as a necessary tool to oust ill-trained healers.[67] The resulting state regulatory scheme "is commonly described as a system of self-regulation because the entities, often called 'boards,' which implement the applicable statutes are generally dominated by members of the licensed profession and often rely on customary practice of the profession for standards."[68] Since the 1850s, a self-governing medical staff has remained a central principle of US health law, featured in numerous state and federal statutes.[69] This is not just a cultural tradition or a political compromise, however. It is at times a constitutional necessity, because medical professionals can regulate medical speech, information flows, and evidentiary standards in ways government agencies cannot do.[70]

First Amendment concerns also shaped modern biomedical research oversight. In 1944, President Roosevelt sought to extend wartime research funding into

[62] Nat'l Inst. of Family and Life Advoc., dba NIFLA v. Becerra, 138 S.Ct. 2361 (2018).
[63] Id. at 2375.
[64] See Jeffrey F. Chase-Lubitz, The Corporate Practice of Medicine Doctrine: An Anachronism in the Modern Health Care Industry, 40 Vand. L. Rev. 445, 448 n.14 (1987); James G. Burrow, Organized Medicine in the Progressive Era: The Move Toward Monopoly (1977).
[65] See supra note 64.
[66] Claudia E. Haupt, Professional Speech, 125 Yale L.J. 1238, 1250–51 (2016).
[67] Chase-Lubitz, supra note 64, at 448; see generally Burrow, supra note 64 (describing the AMA's work with state legislatures).
[68] Furrow, supra note 58, at 33; Sylvia R. Cruess & Richard L. Cruess, The Medical Profession and Self-Regulation: A Current Challenge, 7(4) Virtual Mentor: Ethics J. of the Am. Med. Ass'n 1, 1–5 (2005), https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2018-06/oped1-0504.pdf.
[69] 1 Health Law Practice Guide, Ch. 2 (Medical Staff Fundamentals) (2022).
[70] See NIFLA, supra note 62.

ongoing federal financing of medical and other scientific research.[71] To allay concerns that federal funding would undermine constitutionally protected freedom of scientific inquiry, the National Institutes of Health embraced its privately ordered scheme of peer-review "study sections" to select projects for funding.[72] When the Tuskegee Syphilis Study came to light in 1973, it sparked calls for greater research regulation amid concerns that regulators might infringe scientific freedom.[73] In 1974, Congress empowered a National Commission to design the research regulations now known as the Common Rule,[74] and its 1978 report recommended a significant oversight role for private IRBs.[75] While courts had not previously found a "First Amendment 'right to research,'" the Commission felt that the freedom of scientific inquiry would be likely to receive constitutional protection "if a case arose."[76] The Commission noted that "an institution may empower the IRB to apply both content and manner restrictions" on its employees as a condition of employment or receipt of research funds, "whether or not such a system would be constitutional if directly imposed by the state on nonfunded research."[77]

In the medical products area, the FDA has repeatedly faced First Amendment constraints on its power to protect patients from unsafe medical products.[78] While manufacturers cannot actively promote off-label uses of their products, FDA allows them to respond to unsolicited queries from health care professionals by sending peer-reviewed literature about off-label uses.[79] This policy appoints private actors (medical journals and their peer reviewers) to police the boundaries of acceptable speech. In the US legal system, private actors can do things that governments are not allowed to do – and these are, at times, important things that need to be done by

[71] Donald S. Fredrickson, Asilomar and Recombinant DNA: The End of the Beginning, in Committee to Study Decision Making, Inst. of Medicine, Biomedical Politics 258, 259–60 (K. E. Hanna ed., 1991).

[72] Id. at 260; see Nat'l Inst. of Health, Ctr. for Scientific Review, Study Sections (Apr. 4, 2022), https://public.csr.nih.gov/StudySections; see Lori B. Andrews, Is There a Right to Clone? Constitutional Challenges to Bans on Human Cloning, 11 Harv. J.L. & Tech. 643, 661 (1998) (grounding freedom of scientific inquiry in the First and Fourteenth Amendments); Natalie Ram, Science as Speech, 102 Iowa L. Rev. 1187, 1198 (2017) (arguing that research produces knowledge that is the basis for speech, warranting First Amendment protection).

[73] John D. Edsall, Scientific Freedom and Responsibility (1975).

[74] 45 C.F.R. pt. 46, subpt. A.

[75] U.S. Dep't of Health, Educ., & Welfare, Protection of Human Subjects: Institutional Review Boards: Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 43 Fed. Reg. 56,174, 56,192 (Nov. 30, 1978).

[76] Id.

[77] Id.

[78] See Nathan Cortez, Can Speech by FDA-Regulated Firms Ever Be Non-Commercial?, 37 Am. J.L. & Med. 388 (2011) (summarizing a body of twenty-four cases in which FDA-regulated firms claimed First Amendment protection, often successfully).

[79] Michelle M. Mello et al., Shifting Terrain in the Regulation of Off-label Promotion of Pharmaceuticals, 360 New Engl. J. Med.1557–66 (2009).

someone in order to ensure a well-functioning health care system. When public regulation hits constitutional limits, private ordering helps fill regulatory gaps.

2.4 CONCLUSION

Private ordering has been baked into the fabric of US health laws dating back to their origins in the nineteenth century. This is not an aberration but a central fact of US health care oversight. Constitutional constraints on the government's power to regulate some aspects of health care make private ordering a practical necessity in certain contexts. This reality does not alter our sense of unease that health care is a vitally important economic sector posing delicate trade-offs between individual rights and competing interests. Private ordering will always make us a little uncomfortable, even if we acknowledge that it can be effective, efficient, and – at times – legally necessary. This book aims to clarify the opportunities and concerns that accompany private ordering in its many manifestations in the modern health care system.