



FDA REGULATION OF PHYSICIANS’ PROFESSIONAL SPEECH

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INTRODUCTION

On September 28, 2022, after six years of effort and two draft guidance documents, the U.S. Food and Drug Administration (FDA) finalized its Guidance on Clinical Decision Support Software¹ (CDS Guidance). Clinical Decision Support (CDS) tools are an important category of medical software designed to assist health

¹ See U.S. FOOD & DRUG ADMIN., FDA-2017-D-6569, CLINICAL DECISION SUPPORT SOFTWARE: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2022) [hereinafter CDS GUIDANCE], <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software> (finalizing two earlier draft guidances, CLINICAL DECISION SUPPORT SOFTWARE: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019) and CLINICAL AND PATIENT DECISION SUPPORT SOFTWARE: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2017), and discussing FDA’s authority to regulate CDS software).

care professionals.² CDS tools process patient-specific health information along with various other sources of medical knowledge—such as clinical practice guidelines, drug labeling information, insights from published medical literature, or fresh insights derived by an artificial intelligence/machine learning (AI/ML) algorithm imbedded in the CDS tool itself—to offer a health care professional a set of patient-specific diagnostic or treatment recommendations for use in clinical health care.³

The clinical care context distinguishes CDS tools from consumer-facing home health applications and other health-related software designed for use by medical laypeople. CDS tools have a trained medical professional in the loop to consider outputs from the software and formulate the final advice conveyed to patients. This context also positions CDS tools as the latest skirmish in a longstanding boundary dispute between the states' authority to regulate the practice of medicine and FDA's authority to regulate medical products such as the drugs and medical devices widely employed in modern medical practice.

The federal power to regulate medical practice—historically a focus of state regulation—was a fraught topic in the legislative debate preceding passage of the 1938 Food, Drug, and Cosmetic Act⁴ and flared up recently in connection with the Affordable Care Act.⁵ The states, through their medical practice acts, other statutes, and common law, define the scope of medical practice and regulate it.⁶ Arguments

² See, e.g., *Clinical Decision Support*, HEALTHIT.GOV (Apr. 10, 2018), <https://www.healthit.gov/topic/safety/clinical-decision-support> [<https://perma.cc/JWV8-YUGQ>] (describing a range of CDS tools providing decisional support to health care professionals).

³ See JULIA ADLER-MILSTEIN ET AL., MEETING THE MOMENT: ADDRESSING BARRIERS AND FACILITATING CLINICAL ADOPTION OF ARTIFICIAL INTELLIGENCE IN MEDICAL DIAGNOSIS 15 (2022), <https://nam.edu/wp-content/uploads/2022/09/Meeting-the-Moment-Addressing-Barriers-and-Facilitating-Clinical-Adoption.pdf> (defining and discussing CDS tools).

⁴ Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 1–2252); see Joel E. Hoffman, *Administrative Procedures of the Food and Drug Administration*, in 2 FUNDAMENTALS OF LAW AND REGULATION: AN IN-DEPTH LOOK AT THERAPEUTIC PRODUCTS 13, 17–23 (David G. Adams et al. eds., 1999) (discussing the legislative debate in the late 1930s).

⁵ Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 42 U.S.C.).

⁶ 46 AM. JUR. 2D *Existence of Physician and Patient Relationship* §§ 3, 5, 6, 9 (2019); see also Patrick D. Blake, Note, *Redefining Physicians' Duties: An Argument for Eliminating the Physician-Patient Relationship Requirement in Actions for Medical Malpractice*, 40 GA. L. REV. 573, 601 (2006).

that FDA should not regulate the practice of medicine often invoke principles of federalism or the Tenth Amendment reservation of powers to the states.⁷ Courts have been unreceptive to those arguments, however.⁸

The modern view is that the Constitution does not bar the federal government from touching medical practice issues—at least not as a matter of federalism—although Congress and federal agencies, as a policy matter, make efforts to respect the states’ primacy in regulating the practice of medicine.⁹ Under this view, FDA’s authority to regulate the practice of medicine is ultimately set by Congress subject to no real constitutional constraint, and FDA can expand this authority by petitioning Congress to amend FDA’s enabling statutes.

This dynamic was seen in FDA’s recent success in expanding its authority to regulate physicians’ off-label uses of medical devices. The agency has long described its role as controlling which medical products are commercially available and ensuring that labeling accurately describes the uses for which the products have been shown safe and effective.¹⁰ However, “labeling is not intended to preclude the physician from using [his/her/their] best judgment in the interest of the patient, or to impose liability if [he/she/they] does not follow the package insert”—physicians,

⁷ See, e.g., EPSTEIN, BECKER & GREEN, P.C., CLINICAL DECISION SUPPORT COALITION, CITIZEN PETITION 2, 11–12 (Feb. 6, 2023) (ascribing the limitation of FDA’s authority to regulate the practice of medicine to constitutional principles of federalism and to the Tenth Amendment), <https://perma.cc/RX5B-BAME>; see also *infra* note 249 and accompanying text (discussing federalism arguments offered by a state Attorney General questioning FDA’s legal authority to regulate physician disclosures about LASIK eye surgery).

⁸ See David G. Adams, *The Food and Drug Administration’s Regulation of Health Care Professionals*, in 2 FUNDAMENTALS OF LAW AND REGULATION 423, 424–25 (David G. Adams et al. eds., 2011) (discussing federalism concerns and noting that, “while agreeing that the FDA does not or should not regulate the practice of medicine, the courts have not fashioned a general exemption to shield physicians from the adulteration, misbranding, and new drug provisions of the [Food, Drug, and Cosmetic Act]. Nor have the courts found constitutional limitations on FDA’s authority to regulate physicians.”).

⁹ *Id.*; see also Legal Status of Approved Labeling for Prescription Drugs, 37 Fed. Reg. 16503, 16504 (Aug. 15, 1972) (discussing, in the preamble to a proposed rulemaking, Congress’s legislative intent in passing the Food, Drug, and Cosmetic Act and characterizing FDA’s non-interference with physicians’ off-label prescribing of drugs as more of a policy choice than a legal restriction on the agency’s authority).

¹⁰ Legal Status of Approved Labeling for Prescription Drugs, 37 Fed. Reg. at 16503.

not FDA, set the standard of care.¹¹ Congress codified this principle when expanding FDA's oversight of medical devices in 1976.¹² Largely unnoticed in medical circles, President Biden signed legislation on December 29, 2022 repealing this pillar of physician autonomy in medical device regulation.¹³

FDA sought this change after a federal court held, in 2021, that FDA interfered with the practice of medicine by selectively banning a particular off-label use while otherwise leaving a device on the market.¹⁴ The court held that FDA can ban a device altogether but cannot micromanage how physicians use devices it has not banned.¹⁵ The use in question was already receiving extensive state-level oversight requiring multiple physicians to certify, case-by-case, that no other treatment had worked and that the off-label use was in the patient's best interests.¹⁶ After losing this case, FDA pressed Congress in June 2022 to amend the medical device statutes to let the agency do what the court said it could not do.¹⁷ Congress declined, but the desired amendment reappeared deep in the 1,653-page December appropriations bill and was quietly enacted.¹⁸ Legal professionals with subject-matter expertise view this as opening the door to FDA oversight of medical practice.¹⁸ This change potentially affects CDS tools, which are subject to FDA regulation as medical devices.

¹¹ *Id.* at 16504.

¹² 21 U.S.C. § 396.

¹³ Food and Drug Omnibus Reform Act, § 3306, 136 Stat. 4459, 5834 (2022) (enacted as part of the Consolidated Appropriations Act, Pub. L. No. 117-328, 136 Stat. 4459 (2022)). This law is approximately 1,653 pages in length. See *117th Congress—Second Session*, NAT'L ARCHIVES, <https://www.archives.gov/federal-register/laws/117-second-session>.

¹⁴ *Judge Rotenburg Educ. Ctr., Inc. v. United States Food & Drug Admin.*, 3 F.4th 390 (D.C. Cir. 2021).

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ Jeffrey N. Gibbs & Sara W. Koblitz, *Doctoring the Law: Congress May Let FDA Regulate the Practice of Medicine*, HYMAN, PHELPS & MCNAMARA PC FDA LAW BLOG (Dec. 22, 2022), <https://www.thefdalawblog.com/2022/12/doctoring-the-law-congress-may-let-fda-regulate-the-practice-of-medicine/>.

¹⁸ *Id.*; see also Richard Samp, *Proposed Legislation Would Ban Vital Procedure*, NEW CIV. LIB. ALLIANCE BLOG (May 13, 2022), <https://nclalegal.org/2022/05/proposed-legislation-would-ban-vital-procedure/>.

This article challenges the modern view that there is no real constitutional constraint on FDA's authority to regulate the practice of medicine. The CDS Guidance is an intriguing counterexample where there is a meaningful constitutional constraint on FDA's power to regulate the practice of medicine, flowing not from principles of federalism but from the First Amendment.

FDA's September 2022 publication of the CDS Guidance sparked a flurry of adverse commentary alleging—with sound basis—that the guidance materially deviates from the statute it purports to interpret, Section 3060 of the 21st Century Cures Act¹⁹ (the Cures Act).²⁰ In mapping a path forward, an important point for FDA to consider is that Congress has no power to grant FDA jurisdiction beyond what the U.S. Constitution allows. The constraint on FDA's authority to regulate CDS software is not merely a statutory constraint created by the Cures Act. Rather, it is a constitutional constraint imposed by the First Amendment. In the Cures Act, it appears Congress has already granted FDA as much jurisdiction to regulate CDS software as the First Amendment will allow. If FDA is displeased with that grant of jurisdiction, pressing Congress to grant FDA more jurisdiction is unlikely to be availing, because, in this case, Congress—like FDA—is up against a genuine constitutional constraint.

Part I discusses First Amendment protection of physicians' professional speech, while also noting the strong framework of non-constitutional speech protections physicians long enjoyed under general health laws predating the emergence of modern First Amendment doctrine. These strong statutory protections may help explain the sparsity of First Amendment cases squarely addressing physicians' rights of access to the informational inputs of professional speech and their rights, as a profession, to exercise epistemic control of the medical evidence base in the sense of determining which sources of evidence are appropriate for a doctor to consider when advising a patient.²¹ Strongly protected by general health laws, these rights rarely are transgressed in ways that spark constitutional disputes. However, new medical technologies (and the government's attempts to regulate them) can exert new pressures that earlier health laws did not contemplate, leaving the First

¹⁹ See 21st Century Cures Act, Pub. L. No. 114-255, sec. 3060(a), 130 Stat. 1033, 1130 (2016) (codified at 21 U.S.C. § 360j(o)).

²⁰ See *infra* notes 159–160 (citing this commentary).

²¹ See discussion *infra* Part I.B.

Amendment as physicians' only line of defense.²² CDS tools, I argue, have brought such a moment.

Part II describes the statutory basis for FDA's regulation of CDS tools and explains how the Cures Act limits FDA's jurisdiction and requires procedural protections to avoid unjustified intrusions on physicians' free speech rights. Part III explains that the CDS Guidance deviates from the statute it purports to interpret in ways that impose a scheme of content-based regulation of physicians' professional speech.²³ Part IV explains why ostensibly non-binding guidance documents, such as FDA's CDS Guidance, can nevertheless threaten immediate injuries to the rights of physicians and patients in their care. CDS tools offer great promise to improve health care, but they pose risks that call for careful oversight. The medical profession has a crucial role to play in that oversight, and the First Amendment keeps us safer by ensuring governmental agencies cannot oust them from that role.

I. FIRST AMENDMENT PROTECTION OF PHYSICIANS' PROFESSIONAL SPEECH

Scholars debate the breadth of speech activity that is "regulable,"²⁴ but it has always seemed at least plausible that the government should be able to regulate physicians' speech, subject only to rational-basis review, to protect vulnerable patients. The health care sector is pervasively regulated, and—with a few exceptions such as surgery, which is obviously conduct—the vast majority of health care "transpires

²² See discussion *infra* Part I.C.

²³ See discussion *infra* Part III.

²⁴ See, e.g., James Weinstein, *Participatory Democracy as the Central Value of American Free Speech Doctrine*, 97 VA. L. REV. 491, 492 (2011) ("[H]ighly protected speech is the exception, with most other speech being regulable because of its content with no discernible First Amendment constraint . . ."). But see Barry P. McDonald, *Government Regulation or Other "Abridgements" of Scientific Research: The Proper Scope of Judicial Review Under the First Amendment*, 54 EMORY L.J. 979, 1009 (2005) ("The Court has generally taken an 'all-inclusive' approach . . . asserting that all speech receives First Amendment protection unless it falls with[in] certain narrow categories of expression . . ."); see also, e.g., Eugene Volokh, *The Trouble with "Public Discourse" as a Limitation on Free Speech Rights*, 97 VA. L. REV. 567, 584, 591 (2011) (noting that the "all-inclusive approach"—or, more precisely, the "presumptive all-inclusive approach"—is the approach the Court has generally set forth, though with some exceptions, and noting that, at times, the exceptions are overcounted by separately counting various legal scenarios that all share a common feature, e.g., that there is no constitutional protection of false statements of fact).

through the medium of speech”²⁵ (e.g., rendering diagnoses, writing prescriptions, and advising patients). A decade ago, some circuits, in some cases, subjected restrictions on medical professional speech to rational-basis review²⁶ even as others applied intermediate scrutiny²⁷ or other variations.²⁸

A 2018 compelled speech case, *National Institute of Family and Life Advocates v. Becerra*²⁹ (“the *NIFLA* case” or “*NIFLA*”), held that at least intermediate, and possibly strict, scrutiny should apply.³⁰ The Supreme Court was skeptical that professional speech, as a category, is “exempt from ordinary First Amendment principles.”³¹ Professional speech is the advice a licensed health care provider gives to a patient within the confines of the medical treatment relationship, based on the provider’s “expert knowledge and judgment.”³² The *NIFLA* case addressed the constitutionality of a California law requiring pro-life “crisis pregnancy centers” that support alternatives to abortion to make certain mandatory disclosures.³³ If the crisis pregnancy centers were state-licensed clinics, they were forced to post a government-drafted notice that “California has public programs that provide immediate free or low-cost access to . . . abortion for eligible women.”³⁴ In the Court’s view,

²⁵ Robert Post, *Informed Consent to Abortion: A First Amendment Analysis of Compelled Physician Speech*, 2007 U. ILL. L. REV. 939, 950 (2007) (describing the practice of law).

²⁶ See, e.g., *Pickup v. Brown*, 740 F.3d 1208, 1231 (9th Cir. 2014) (applying rational basis review in a First Amendment challenge to a state law prohibiting licensed mental health care providers from providing sexual orientation change efforts (SOCE) therapy to children under 18), *abrogated by Nat’l Inst. of Fam. & Life Advoc. v. Becerra (NIFLA)*, 138 S. Ct. 2361 (2018).

²⁷ See, e.g., *King v. Governor of N.J.*, 767 F.3d 216, 234 (3d Cir. 2014) (applying intermediate scrutiny to a state law prohibiting SOCE therapy for children under 18), *abrogated by NIFLA*.

²⁸ *Id.* at 235 (noting that other circuits had applied “a more deferential standard of review or, possibly, no review at all” to regulations of professional speech).

²⁹ *NIFLA*, 138 S. Ct. 2361.

³⁰ *Id.* at 2375.

³¹ *Id.* (declining to “foreclose the possibility” that there might be a reason to exempt professional speech from ordinary First Amendment principles, while not persuaded to do so in *NIFLA*).

³² *King*, 767 F.3d at 232.

³³ *NIFLA*, 138 S. Ct. at 2368.

³⁴ *Id.* at 2369.

this notice impermissibly altered the content of the clinics' speech by forcing them to promote the "very practice [they were] devoted to opposing."³⁵

The five-justice majority in *NIFLA* concluded that the challenged state law could not withstand even intermediate scrutiny and thus did not address whether strict scrutiny should apply.³⁶ Justice Kennedy, in a concurrence joined by three members of the majority, felt the challenged California law raised "a real possibility" that anti-abortion clinics "were targeted because of their beliefs" and forced to "express a message contrary to their deepest convictions,"³⁷ suggesting there may have been four votes favoring strict scrutiny.

Professor Daniel Halberstam notes that physician speech about contraception and abortion sparked the Supreme Court's most sustained discussion of First Amendment protections within the physician-patient relationship.³⁸ This fact was masked by the focus, in contraception and abortion cases, on whether the *patient's* rights were fundamental: State interference with physician speech was analyzed as a burden on the patient's right to receive care, rather than as a First Amendment problem.³⁹

Abortion cases like *Thornburgh v. American College of Obstetricians and Gynecologists*⁴⁰ and *City of Akron v. Akron Center for Reproductive Health, Inc.*⁴¹ rejected state-compelled physician speech requirements as undue burdens on the patient's rights, rather than on First Amendment grounds. With only a passing nod to the First Amendment, *Planned Parenthood of Southeastern Pennsylvania v. Casey*

³⁵ *Id.* at 2371.

³⁶ *Id.* at 2375.

³⁷ *Id.* at 2378 (Kennedy, J., concurring, joined by Roberts, C.J., Alito, J., and Gorsuch, J.).

³⁸ Daniel Halberstam, *Commercial Speech, Professional Speech, and the Constitutional Status of Social Institutions*, 147 U. PA. L. REV. 771, 835 (1999).

³⁹ *Id.* at 835; see also Paula Berg, *Toward a First Amendment Theory of Doctor-Patient Discourse and the Right to Receive Unbiased Medical Advice*, 74 B.U. L. REV. 201, 205–06 (1994) (noting the Burger Court's tendency to invalidate viewpoint-based restrictions on physician speech on grounds that they violated patients' privacy rights, and the Rehnquist Court's tendency to uphold viewpoint-based restrictions on physician speech in abortion cases "with little or no First Amendment analysis").

⁴⁰ 476 U.S. 747 (1986), *overruled in part by* *Planned Parenthood v. Casey*, 505 U.S. 833, 884 (1992).

⁴¹ 462 U.S. 416 (1983), *overruled in part by* *Planned Parenthood v. Casey*, 505 U.S. at 884.

overruled those two cases,⁴² as if striking a compromise in which the states could resume interfering with physician speech as a *quid pro quo* for the Court's decision to sustain patients' fundamental right to an abortion.⁴³ A subsequent erosion of patients' reproductive rights culminated in *Dobbs v. Jackson Women's Health Organization*,⁴⁴ which rejected the fundamental right to an abortion. This erosion of reproductive rights has had grave impacts on women's power of self-determination and on the quality of care for patients facing difficult or unwanted pregnancies. It has, however, had a clarifying side effect on law. It has forced courts to describe laws compelling abortion-related speech more squarely as what they actually are: a First Amendment problem.

Reproductive rights controversies of the past sixty years, while failing to produce durable reproductive rights, have fueled an ongoing judicial dialogue about the First Amendment limits of governmental interference with the practice of medicine and with the physician-patient relationship. These limits, once established, have impacts beyond reproductive care and will shape the future of the physician-patient relationship in AI-enabled health care. The precise impact, however, remains somewhat unclear. *NIFLA* and earlier abortion cases on compelled speech did not squarely address the scope of the government's power to regulate the speech that physicians desire to convey to their patients. The major concern with the CDS Guidance, as discussed below,⁴⁵ is that it interferes with physicians' freedom to speak, as opposed to forcing them to convey unwanted state-sponsored messages.

A. Values Served by Protecting Physicians' Freedom to Formulate and Express Expert Clinical Opinions

Since the 1960s, the "complex and difficult relationship between the First Amendment and the regulation of professional speech" has remained somewhat

⁴² *Planned Parenthood*, 505 U.S. at 884 ("To be sure, the physician's First Amendment rights are implicated . . . We see no constitutional infirmity in the requirement that the physician provide the information mandated by the State here."); *see id.* at 882 (overruling *Akron* and *Thornburgh* to the extent they found a constitutional violation in state-compelled physician speech about "the nature of the procedure, the attendant health risks and those of childbirth, and the 'probable gestational age' of the fetus").

⁴³ *Id.* at 882.

⁴⁴ 597 U.S. 215 (2022).

⁴⁵ *See* discussion *infra* Part III.

“obscure and controversial.”⁴⁶ Cases often addressed professional advertising as opposed to the professional speech physicians utter to patients during medical treatment encounters.⁴⁷ Some scholars maintained that the state’s power to regulate the practice of medicine encompasses a power to regulate what physicians say to patients during medical practice.⁴⁸ In apparent support of this view, state medical licensing bodies impose disciplinary sanctions on providers whose advice deviates from standards of competency recognized within the professional community, and state courts can hold such providers accountable in malpractice suits.⁴⁹ Physicians have no First Amendment defense when sued for giving wayward medical advice,⁵⁰ and state medical practice regulations generally receive only a rational basis review.⁵¹

In the run-up to *NIFLA*, some circuit courts of appeal “recognized ‘professional speech’ as a separate category of speech that is subject to different rules” allowing content-based regulation by the states as part of a “a generally applicable licensing and regulatory regime.”⁵² *NIFLA* rejected this view. In doing so, it evoked First Amendment arguments raised in dissents to the 1960s contraception cases *Poe v. Ullman*⁵³ and *Griswold v. Connecticut*.⁵⁴ After *NIFLA*, the law is aligned with these dissents.

Poe and *Griswold* both involved a Connecticut law that sought to banish contraception from the scope of care that can be discussed or obtained within a

⁴⁶ See Post, *supra* note 25, at 944.

⁴⁷ *Id.*

⁴⁸ *Id.* (citing Katharine McCarthy, Conant v. Walters, *A Misapplication of Free Speech Rights in the Doctor-Patient Relationship*, 56 ME. L. REV. 447, 464–65 (2004), for the view that “the state retains the power to regulate the conduct of physicians, even when speech may be used to carry the conduct out”).

⁴⁹ See Post *supra* note 25, at 947, 950–51 (citing cases).

⁵⁰ See Claudia E. Haupt, *Professional Speech*, 125 YALE L.J. 1238, 1242 (2016) (“Imposing professional malpractice liability has never been found to offend the First Amendment.”).

⁵¹ See Post, *supra* note 25, at 952.

⁵² Nat’l Inst. of Fam. & Life Advoc. v. Becerra (*NIFLA*), 138 S. Ct. 2361, 2371 (2018); see also *supra* notes 26–28 and accompanying text.

⁵³ 367 U.S. 497 (1961).

⁵⁴ 381 U.S. 479 (1965).

physician-patient relationship.⁵⁵ *Poe* left the law standing without reaching the merits of the constitutional claim, because the plaintiffs had not shown the law was likely to be enforced against them.⁵⁶ Several years later, *Griswold* reached the merits and struck the law down as intruding on a constitutionally protected right of marital privacy.⁵⁷ This started the trend of framing professional speech problems as a patient-rights concern.

In their *Griswold* dissents, Justices Black and Stewart acknowledged that the Connecticut law might be “offensive,”⁵⁸ “uncommonly silly,”⁵⁹ and “asinine”⁶⁰ but could not persuade themselves it was forbidden by the Constitution.⁶¹ Both dissenters mused that the First Amendment protects a physician’s right to give advice about contraceptives within a physician-patient relationship.⁶² “But speech is one thing; conduct and physical activities are quite another”⁶³ and the Due Process Clause did not, in their view, bar the state from limiting the permissible scope of medical conduct.⁶⁴ Justice Douglas, who wrote for the majority in *Griswold*, was even more supportive of physicians’ First Amendment rights in his 1961 dissent to *Poe v. Ullman*: “The right of the doctor to advise his patients according to his best

⁵⁵ *Poe*, 367 U.S. at 498 (describing the law as “prohibit[ing] the use of contraceptive devices and the giving of medical advice in the use of such devices”).

⁵⁶ *Id.* at 507–08.

⁵⁷ 381 U.S. at 485–86 (Douglas, J.).

⁵⁸ *Id.* at 507 (Black, J., joined by Stewart, J., dissenting).

⁵⁹ *Id.* at 527 (Stewart, J., joined by Black, J., dissenting).

⁶⁰ *Id.*

⁶¹ *Id.* at 527 (Black, J., joined by Stewart, J., dissenting).

⁶² *See id.* at 507 (Black, J., joined by Stewart, J., dissenting) (“Had the doctor defendant here . . . been convicted for doing nothing more than expressing opinions to persons coming to the clinic that certain contraceptive devices, medicines, or practices would do them good and would be desirable, or for telling people how devices could be used, I can think of no reasons at this time why their expressions of views would not be protected by the First and Fourteenth Amendments, which guarantee freedom of speech.”); *id.* at 529 n.3 (Stewart, J., joined by Black, J., dissenting) (“If all the appellants had done was to advise people that they thought the use of contraceptives was desirable, or even to counsel their use, the appellants would, of course, have a substantial First Amendment claim.”).

⁶³ *Id.* at 508 (Black, J., joined by Stewart, J., dissenting).

⁶⁴ *Id.* at 511.

lights seems so obviously within First Amendment rights as to need no extended discussion.”⁶⁵

In fact, First Amendment protection of physician's professional speech was not so obvious as Justice Douglas suggested. Scholars struggle to theorize physicians' free speech rights in a clinical health care environment that is otherwise under heavy state regulation. Professor Eugene Volokh notes that the conduct/speech distinction “is likely to be more misleading than helpful” in professional speech cases, foreclosing First Amendment analysis by calling speech “conduct” instead of holding the government to its burden to justify speech regulation with evidence that the speech causes real harms.⁶⁶ Professor Paula Berg explores the government's imposition of ideology-based restrictions on physician speech about reproductive health care and advances a First Amendment theory of physician-patient communications focused on the patient's interest in receiving complete, unbiased medical information and advice.⁶⁷

Professor Robert Post crucially recognizes that regulation of physicians' speech raises First Amendment concerns not just when it forces doctors to convey state-approved ideological messages, but more broadly whenever “the state either requires physicians to communicate information that the medical profession regards as false, or prohibits physicians from communicating information the medical profession regards as true.”⁶⁸

Government regulation that constrains physicians' ability to consider and convey information that the medical profession regards as true “does not merely compromise the ability of individual members of the public to receive accurate information; it also undermines public trust that professional physician speech will reflect the expertise of the ‘medical community.’”⁶⁹ Such regulation “jeopardizes the

⁶⁵ *Id.* at 513 (Douglas, J., dissenting); *see also id.* at 514–15 (“We witness in this case the sealing of the lips of a doctor because he desires to observe the law, as obnoxious as the law may be. The State has no power to put any sanctions of any kind on him for any views or beliefs that he has or for any advice he renders. These are his professional domains into which the State may not intrude.”).

⁶⁶ Eugene Volokh, *Speech as Conduct: Generally Applicable Laws, Illegal Courses of Conduct, “Situation-Altering Utterances,” and the Uncharted Zones*, 90 CORNELL L. REV. 1277, 1346 (2005).

⁶⁷ *See Berg, supra* note 39, at 202, 206, 251–57.

⁶⁸ *See Post, supra* note 25, at 939.

⁶⁹ *Id.* at 979.

capacity of the medical profession to serve as a reservoir of expert knowledge that can reliably be communicated to the public through physician-patient disclosures.”⁷⁰ First Amendment protection serves to “preserve the independence of physician communications designed to enlighten patient decision making.”⁷¹

Yet physician independence is not an end in itself; it exists to serve other values. Those values include the creation and dissemination of medical knowledge. Professor 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” and with a “shared reservoir of knowledge” which its members “help define and to which they contribute.”⁷² Professor Joseph Blocher portrays the First Amendment as a bulwark against “epistemic harm” that might flow from governmental interference “with the disciplinarity and social practices” through which a profession determines its accepted truths.⁷³

If the medical profession reliably induces true beliefs in patients (that vaccines prevent certain diseases, for example), it may be particularly important that the messages coming from that profession be unedited by others. Conversely, as Justice Breyer has put it, when “speech is subject to independent regulation by canons of the profession[,] . . . [which] obligat[e] speech[,] . . . the government’s own interest in forbidding that speech is diminished.” The creation of knowledge, in other words, depends on a kind of nongovernmental regulation, which in turn shields that knowledge from unnecessary governmental regulation.⁷⁴

Twenty-five years ago, Professor Halberstam expressed an idea that neatly encapsulates the central concern with FDA regulation of CDS tools: “The State may ensure professionals’ faithfulness to the public aspects of their calling, but it may not usurp their role or determine independently the bodies of knowledge that may be accessed or the individual judgments that may be rendered in a given case.”⁷⁵

⁷⁰ *Id.* at 980.

⁷¹ *Id.* at 989.

⁷² See Haupt, *supra* note 50, at 1250–51.

⁷³ Joseph Blocher, *Free Speech and Justified True Belief*, 133 HARV. L. REV. 439, 491 (2019).

⁷⁴ *Id.* (citing *Garcetti v. Ceballos*, 547 U.S. 410, 446 (2006) (Breyer, J., dissenting)).

⁷⁵ See Halberstam, *supra* note 38, at 773.

Professor Halberstam's concept of "bounded speech practices" frames professional communications not as "abstract exchanges of views and ideas between persons about whom nothing is known" but rather as "context-dependent interactions with purposes" that are largely pre-defined (such as trying to help a sick person get well).⁷⁶ There is a boundary within which governments grant the professions autonomy to set their own internal standards of evidence—that is, to decide for themselves which bodies of knowledge are appropriate to consider in that context and relevant to the purpose being served. If a doctor's advice to patients strays outside these professional evidentiary standards (for example, by advising patients that a vaccine causes autism when there is an evidence-backed professional consensus to the contrary), the government can apply disciplinary sanctions and can subject the doctor to tort liability to patients who prove they were injured as a result.⁷⁷ Governmental regulation serves a boundary-policing function; it is a form of private ordering with "rules originated by private actors but put into force by sovereign governments," to borrow Professor Steven Schwarcz's terminology.⁷⁸ However, if the government invades that boundary and dictates specific bodies of knowledge the profession can and cannot consider when forming its professional judgments, heightened scrutiny would be warranted.⁷⁹

Whether that scrutiny is intermediate or strict is not critical to this article's later analysis of the CDS Guidance.⁸⁰ In First Amendment cases, FDA's asserted governmental interest generally involves patient safety. This is a weighty interest that lends itself to portrayal as either substantial or compelling as needed, especially when "the Supreme Court has frequently adopted an astonishingly casual approach to identifying compelling interests."⁸¹ The difference between strict and intermediate scrutiny then turns on the tailoring requirements. Under strict scrutiny, regulation

⁷⁶ *Id.* at 828.

⁷⁷ *Id.* (noting that "[T]he Court welcomes governmental regulation as partly constitutive of the communicative interaction [between doctor and patient], that is, as assuring that communications that are dependent on predefined communicative goals remain within the boundaries of that discourse.").

⁷⁸ Steven L. Schwarcz, *Private Ordering*, 97 NW. U. L. REV. 319, 324 (2002).

⁷⁹ *See id.* at 850–60 (exploring the intermediate scrutiny of commercial speech doctrine as an alternative to rational-basis review of content-based professional speech regulations).

⁸⁰ *See* discussion *infra* Part III.

⁸¹ Richard H. Fallon, Jr., *Strict Judicial Scrutiny*, 54 UCLA L. REV. 1267, 1321 (2007).

of physicians' professional speech is "justified only if the government proves that they are narrowly tailored to serve compelling state interests."⁸² Under intermediate scrutiny, the burden to justify content-based speech regulations still falls on the government.⁸³ Since 1990, FDA has faced numerous First Amendment challenges, with most resolved under the commercial speech doctrine.⁸⁴ Observers note, however, that intermediate scrutiny in FDA First Amendment cases has evolved into "de facto strict scrutiny under the *Central Hudson* name," with courts requiring narrow tailoring and giving little deference to the legislature/agency.⁸⁵ The Court has brushed over the strict/intermediate distinction in recent health-sector cases.⁸⁶ As Part III explains, the CDS Guidance appears problematic under either standard.

B. *Non-Constitutional Protections for Physicians' Professional Speech*

If the First Amendment protects professionals from the "epistemic harm"⁸⁷ of having the State "usurp"⁸⁸ their role in setting standards of evidence for professional decision-making, why is there so little case law confirming this fact? A possible explanation is that, in clinical health care settings, this epistemic problem is so

⁸² Nat'l Inst. of Fam. & Life Advocs. v. Becerra (*NIFLA*), 138 S. Ct. 2361, 2371 (2018) (internal citations omitted).

⁸³ Sorrell v. IMS Health, Inc., 564 U.S. 552, 571–72 (2011) ("Under a commercial speech inquiry, it is the State's burden to justify its content-based law" and "the State must show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest").

⁸⁴ See Nathan Cortez, *Can Speech by FDA-Regulated Firms Ever be Non-Commercial?*, 37 AM. J.L. & MED. 388 (2011) (summarizing a body of 24 cases in which FDA-regulated firms claimed First Amendment protection, with courts applying the commercial speech doctrine in 17 of the cases).

⁸⁵ Carl Wiersum, *No Longer Business as Usual: FDA Exceptionalism, Commercial Speech, and the First Amendment*, 73 FOOD & DRUG L.J. 486, 486, 511–12 (2018); see, e.g., Thompson v. Western States Med. Ctr., 535 U.S. 357, 371–73 (2002) (applying the commercial speech doctrine as allowing speech regulation only "as a last—not first—resort" and stating "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so").

⁸⁶ *NIFLA*, 138 S. Ct. at 2375; see also Sorrell, 564 U.S. at 571 ("As in previous cases, however, the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied.").

⁸⁷ See Blocher, *supra* note 73, at 491.

⁸⁸ See Halberstam, *supra* note 38, at 773.

crucial that general health laws had already addressed it before modern First Amendment law emerged.

Professor David Rabban traces the emergence of modern First Amendment doctrine to Justice Holmes' 1919 *Abrams* dissent⁸⁹ and a series of dissenting and concurring opinions⁹⁰ from Justice Brandeis between 1920–27.⁹¹ This places it just after the end of a long legislative struggle from 1847–1920 that laid the foundations of modern health law.⁹² Norms of physician autonomy, free speech, freedom of scientific inquiry, and freedom of association—things we describe today as First Amendment matters—pervaded the American Medical Association's (AMA) 1847 Code of Ethics, which framed medicine not as a mere occupation but as a knowledge-based profession distinct from the “irregulars”—quacks, healing sectarians, and peddlers of patent medicine and miracles who thrived on the scantily regulated U.S. health care landscape.⁹³ The 1847 Code asserted that “[n]o one can be considered a regular practitioner, or a fit associate in consultation, where practice is based on an exclusive dogma to the rejection of the accumulated experience of the profession, and of the aids actually furnished by [current scientific and medical knowledge].”⁹⁴

From 1850–1920, the AMA worked tirelessly with legislatures to craft state medical practice laws to protect the public from ill-trained irregulars while preserving significant professional autonomy for licensed medical professionals.⁹⁵ Courts,

⁸⁹ *Abrams v. United States*, 250 U.S. 616, 627 (1919) (Holmes, J., dissenting).

⁹⁰ *Shaefer v. United States*, 251 U.S. 466, 482 (1920) (Brandeis, J., dissenting); *Pierce v. United States*, 252 U.S. 239, 253 (1920) (Brandeis, J., dissenting); *Gilbert v. Minnesota*, 254 U.S. 325, 334 (1920) (Brandeis, J., dissenting); *United States ex rel. Milwaukee Soc. Democratic Publ'g Co. v. Burlison*, 255 U.S. 407, 417 (1921) (Brandeis, J., dissenting); *Whitney v. California*, 274 U.S. 357, 372 (1927) (Brandeis, J., concurring).

⁹¹ See generally David M. Rabban, *The Emergence of Modern First Amendment Doctrine*, 50 U. CHI. L. REV. 1205 (1983).

⁹² See JAMES G. BURROW, *ORGANIZED MEDICINE IN THE PROGRESSIVE ERA: THE MOVE TOWARD MONOPOLY* (1977) (recounting the development of health care regulations in this period).

⁹³ 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) (citing American Medical Association, Code of Ethics (adopted 1847), in *Proceedings of the National Medical Conventions Held in New York, May 1846, and in Philadelphia, May 1847*, at 100 (Am. Med. Ass'n ed., 1847)).

⁹⁴ *Id.*

⁹⁵ See generally BURROW, *supra* note 92 (tracing the history of these efforts).

legislatures, and state medical boards look to members of the medical profession to set their own standards of care, evidentiary standards, ethics codes, and qualifications for entry to the profession.⁹⁶ An authoritative treatise on health law observes that “[h]ealth professional licensure in the United States 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.”⁹⁷ State medical practice regulation is not a scheme of public ordering in the traditional sense of providing “rules of law originated and put into force by sovereign governments.”⁹⁸ Instead, it relies heavily on private ordering, with some rules “originated by private actors [the medical profession] but put into force by sovereign governments” while others are “put into force by private actors pursuant to governmental delegation.”⁹⁹ A self-governing medical staff is a bedrock principle of U.S. health law, required by diverse state and federal statutes.¹⁰⁰

Before modern First Amendment doctrine emerged, the laws governing clinical health care already incorporated many features to prevent epistemic harms by securing medical professional control over the medical knowledge base. These old laws, though not informed by a modern understanding of the First Amendment, nevertheless are consistent with it and serve values now described as First Amendment values. Only later, after 1940, does one find instances where new health laws are consciously designed to avoid First Amendment problems.¹⁰¹ Examples include

⁹⁶ See Haupt, *supra* note 50, at 1250–51; see also BARRY R. FURROW ET. AL, HEALTH LAW: CASES, MATERIALS, AND PROBLEMS 33 (8th ed. 2018) (noting the medical profession’s role in setting its own regulatory standards).

⁹⁷ FURROW ET AL., *supra* note 96, at 33; see also S.R. Cruess & R.M. Cruess, *The Medical Profession and Self-Regulation: A Current Challenge*, VIRTUAL MENTOR, ETHICS J. OF THE AM. MED. ASS’N, Apr. 2005, at 1–5 (characterizing state medical regulatory structures as heavily reliant on professional self-regulation).

⁹⁸ See Schwarcz, *supra* note 78, at 325.

⁹⁹ *Id.*

¹⁰⁰ See 1 AM. HEALTH L. ASS’N, HEALTH L. PRAC. GUIDE, ch. 2 (2022).

¹⁰¹ See Barbara J. Evans, *Private Ordering Is Ubiquitous in Health Care, but Why?*, in HEALTH LAW AS PRIVATE LAW: PATHOLOGY OR PATHWAY? (I. Glenn Cohen, Christopher T. Robertson, Wendy Epstein & Susannah Baruch eds., forthcoming 2024) (providing examples).

the National Institutes of Health's (NIH) reliance on "study sections"¹⁰² (peer-review groups of private biomedical scientists) to rank proposed biomedical research projects for NIH funding. President Roosevelt's 1944 push to extend wartime research funding into ongoing public support for scientific research sparked concern about governmental interference with freedom of scientific inquiry; private scientific peer review eased this concern.¹⁰³ In the 1970s, a congressionally appointed commission designing the biomedical research regulation known as the Common Rule¹⁰⁴ eschewed direct governmental regulation, instead delegating key oversight responsibilities to private Institutional Review Boards (IRBs).¹⁰⁵ The Commission expressed concern that "if a case arose," courts would be likely to hold that the First Amendment protects freedom of scientific inquiry.¹⁰⁶ In contrast, a private "institution may empower the IRB to apply both content and manner restrictions" on its employees as a condition of employment or for receiving research funds "whether or not such a system would be constitutional if directly imposed by the state on nonfunded research."¹⁰⁷

Modern health law makes heavy use of these and many other private ordering solutions, engaging the medical profession, private accreditation bodies, and other non-governmental actors in oversight roles that might raise First Amendment concerns if performed by state and federal agencies.¹⁰⁸ This approach reduces, but does

¹⁰² Donald S. Fredrickson, *Asilomar and Recombinant DNA: The End of the Beginning*, in COMM. TO STUDY DECISION MAKING, INST. OF MED., BIOMEDICAL POLITICS 258, 260 (K.E. Hanna ed., 1991); 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); see also *Study Sections*, NAT'L INST. OF HEALTH, CTR. FOR SCI. REV. (Apr. 4, 2022), <https://public.csr.nih.gov/StudySections> (describing NIH study sections).

¹⁰³ See Fredrickson, *supra* note 102, at 259–60.

¹⁰⁴ 45 C.F.R. pt. 46(A).

¹⁰⁵ 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. 56174, 56192 (Nov. 30, 1978).

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ See generally Evans, *supra* note 101 (providing examples of various types of private ordering solutions in health care regulation).

not fully eliminate,¹⁰⁹ concerns about governmental interference with the sources of knowledge physicians can consult when formulating their professional speech. Health care is governed by sector-specific statutes and regulations that already afford strong basic protections to physician autonomy, free speech rights, and freedom of scientific inquiry; this fact helps explain why there are not more First Amendment cases clarifying the appropriate standard of review when health care regulations inflict epistemic harms.

C. *The Challenge of New Medical Technologies*

Regulation of new medical technologies can pose new threats to physician autonomy and free speech rights that earlier health laws may not have contemplated. When this occurs, the speech protections incorporated in existing health care statutes and regulations may not suffice, and the First Amendment may be physicians' only line of defense. FDA's efforts to regulate CDS tools take place in a clinical care data ecosystem with well-established norms governing physicians' access to and use of information.

In treatment relationships, licensed physicians serve as conduits through which laypeople tap into the body of knowledge the professionals possess.¹¹⁰ Physicians, "through their education and training, have access to a corpus of specialized knowledge"¹¹¹—that is, the vast reservoir of all the diverse types of medical information that the profession regards as appropriate for a doctor to consider when making clinical decisions. This medical knowledge base includes some information—e.g., evidence from multiple, well-controlled clinical trials—that the profession views as high-quality.¹¹² It also includes lower-quality evidence—e.g.,

¹⁰⁹ See, e.g., Philip Hamburger, *Getting Permission*, 101 NW. U. L. REV. 405 (2007) (discussing First Amendment concerns with IRB oversight of human-subjects research under the Common Rule); see also *In re R.M.J.*, 455 U.S. 191, 193–96 (1982) (challenging government enforcement of professional standards of legal ethics restricting the words attorneys could use to describe their qualifications and practice areas); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 353 (1977) (challenging government enforcement of professional ethical rules restricting advertising by attorneys).

¹¹⁰ See Haupt, *supra* note 50, at 1250 (noting that "the professional-client relationship is asymmetric: the professional has knowledge the client does not have, which leads the client to seek out her advice").

¹¹¹ *King v. Governor of N.J.*, 767 F.3d 216, 232 (3d Cir. 2014).

¹¹² See, e.g., Alice K. Jacobs et al., *ACCF/AHA Clinical Practice Guideline Methodology Summit Report: A Report of the American College of Cardiology Foundation/American Heart Association*

individual case reports or physicians' past experience treating patients with similar symptoms—that is still admissible and relevant for a professional to consider.

“The value of the professional's services stems largely from her ability to apply this specialized knowledge to a client's individual circumstances.”¹¹³ At the very core of the practice of medicine lies a thought process in which physicians tailor their communications to the individual patient's circumstances, drawing on sources of general and patient-specific medical information the profession deems relevant to clinical decision-making.

Recent meta-analyses suggest that only 10–18% of health care decisions have high-quality, well-validated evidence to support them.¹¹⁴ The remaining 82–90% of day-to-day medical practice involves physicians intelligently filtering lower-quality and contested sources of medical evidence—and, at times, the lack of any evidence at all—to offer patients the best expert recommendations the physicians, in their professional judgment, can make. Law confides this task to licensed medical professionals precisely because their education, training, and experience equip them to navigate high-stakes evidentiary ambiguities.

When formulating professional speech, a physician analyzes patient-specific medical information and information from the general medical knowledge base of accrued medical discoveries and experience, also taking the patient's “predicaments, rights, and preferences”¹¹⁵ into account. The result is a tailored set of recommendations to prevent, diagnose, or treat the patient's disease. First Amendment protection of professional speech includes protecting against inappropriate government interference with information flows physicians depend on when

Task Force on Practice Guidelines, J. AM. COLL. CARDIOLOGY, Jan. 2013, at 213–65; OXFORD CTR. FOR EVIDENCE-BASED MED., CEBM LEVELS OF EVIDENCE TABLE (2011), <https://www.cebm.net/wp-content/uploads/2014/06/CEBM-Levels-of-Evidence-2.1.pdf>.

¹¹³ *King*, 767 F.3d at 232.

¹¹⁴ See, e.g., Mark H. Ebell et al., *How Good Is the Evidence to Support Primary Care Practice?*, 22 BMJ EVIDENCE BASED MED. 88, 88–92 (2017) (finding that 18% of primary care decisions had high-quality research-based evidence to support them); Jeremy Howick et al., *The Quality of Evidence for Medical Interventions Does Not Improve or Worsen: A Metaepidemiological Study of Cochrane Reviews*, 126 J. CLINICAL EPIDEMIOLOGY 154, 154–59 (2020) (finding 9.9% had high-quality evidence).

¹¹⁵ David L. Sackett et al., *Evidence Based Medicine: What It Is and What It Isn't*, 312 BMJ 71, 71–72 (1996).

tailoring their speech to the needs of the audience—in this case, the individual patient.¹¹⁶ In the 21st century, those information flows increasingly include insights gleaned by digital analytical tools processing real-world clinical data for large patient populations at scale and in real time (or close to it), to inform physicians’ care of individual patients. Those analytical tools include AI/ML CDS tools.

Physicians’ right to receive this information is the free speech right of concern in this article. The question here is not whether CDS tool developers have a right to “speak” through their software; they may, but that is not the focus here.¹¹⁷ Nor do I suggest that AI/ML agents have legal personhood and free speech rights of their own, although others have explored this as a future possibility.¹¹⁸

The United Nations’ 1948 Universal Declaration of Human Rights lists “freedom of opinion and expression” as a “fundamental human right” and explains that “this right includes freedom . . . to seek, *receive*, and impart information and ideas through any media”¹¹⁹ The First Amendment protects not just speakers, but listeners and users of information, as the Supreme Court has recognized in both expressive and commercial speech contexts.¹²⁰ Professor Helen Norton observes that a “‘listener-centered’ approach understands the First Amendment to permit

¹¹⁶ See generally Daniel E. Rauch, *Customized Speech and the First Amendment*, 35 HARV. J.L. & TECH. 405 (2022) (reviewing the body of First Amendment cases protecting speakers’ access to information flows they need to target and tailor their speech to the needs of specific audiences).

¹¹⁷ See *Sorrell v. IMS Health*, 564 U.S. 552, 570 (2011) (noting that “the creation and dissemination of information are speech within the meaning of the First Amendment”).

¹¹⁸ See, e.g., Toni M. Massaro, Helen Norton & Margaret E. Kaminski, *Siri-ously 2.0: What Artificial Intelligence Reveals About the First Amendment*, 101 MINN. L. REV. 2481, 2523 (2017) (concluding that “foundational free speech theory and doctrine present surprisingly few barriers to First Amendment coverage” of speech by “strong” AI tools, but pointing out important drawbacks to such coverage); Helen Norton, *Robotic Speakers and Human Listeners*, 41 SEATTLE U. L. REV. 1145 (2018) (reviewing RON COLLINS & DAVID SKOVER, *ROBOTICA: SPEECH RIGHTS AND ARTIFICIAL INTELLIGENCE* (2018)).

¹¹⁹ G.A. Res. 217 (III) A, Universal Declaration of Human Rights, art. 19 (Dec. 10, 1948) (emphasis added), <https://www.un.org/en/about-us/universal-declaration-of-human-rights>.

¹²⁰ See, e.g., *Stanley v. Georgia*, 394 U.S. 557, 564 (1969) (noting, in an expressive speech context, “[i]t is now well established that the Constitution protects the right to receive information and ideas”); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 756 (1976) (noting, in a commercial speech context, “the protection afforded is to the communication, to its source and its recipients both”).

the government to regulate the speech of comparatively knowledgeable speakers” to protect vulnerable listeners.¹²¹ Yet the Supreme Court has a history of viewing physicians as “‘sophisticated and experienced’ consumers” of medical information, diminishing the state’s interest in regulating information flows to protect recipients who are licensed health care professionals.¹²² Physicians are the audience for the class of software tools FDA’s CDS Guidance proposes to regulate.¹²³

Restricting a speaker’s access to the informational inputs of speech “necessarily alters the speech’s content” and amounts to “content-based regulation of speech.”¹²⁴ Regulations targeting the speech of a licensed health care provider “based on its communicative content” are “presumptively unconstitutional.”¹²⁵ *NIFLA* notes that, absent a clear, evidence-backed justification, content-based speech regulations are particularly dangerous “in the fields of medicine and public health, where information can save lives.”¹²⁶

The First Amendment protects individual autonomy—including the autonomy of physicians and their patients—by “enabling common citizens to become aware of the issues before them and arguments on all sides and thus to pursue their ends fully and freely.”¹²⁷ The state wrongs physicians if it starves them of information flows they wish to consider as they decide what “their ‘reason’ tells them”¹²⁸ they should or should not say to an individual patient during a clinical treatment

¹²¹ Helen Norton, *Powerful Speakers and Their Listeners*, 90 U. COLO. L. REV. 441 (2019).

¹²² *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 577 (2011) (concluding that the audience of physicians “consists of ‘sophisticated and experienced’ consumers” of information, warranting special skepticism of “regulations that seek to keep people in the dark for what the government perceives to be their own good”).

¹²³ *See supra* notes 1–2 and accompanying text.

¹²⁴ *Riley v. Nat’l Fed’n of the Blind*, 487 U.S. 781, 795 (1988).

¹²⁵ *Nat’l Inst. of Fam. & Life Advocs. v. Becerra (NIFLA)*, 138 S. Ct. 2361, 2371 (2018) (internal citations omitted).

¹²⁶ *Id.* at 2374 (internal citations omitted).

¹²⁷ OWEN M. FISS, *THE IRONY OF FREE SPEECH* 3 (1976).

¹²⁸ *Miami Herald Publ’g Co. v. Tornillo*, 418 U.S. 241, 254 (1974) (quoting *Associated Press v. United States*, 326 U.S. 1, 20 n.18 (1945)).

encounter.¹²⁹ The state likewise harms patients by interfering with physician access to potentially relevant information flows on which the provider, exercising skilled professional judgment, may wish to rely. The long tradition of respect for physician autonomy in U.S. law rests on the belief that members of the medical profession—rather than the government—are in the best position to decide which parts of the vast medical knowledge base are admissible and relevant when diagnosing and treating an individual patient.

The next two Parts discuss, first, the statutory basis for FDA regulation of CDS tools and, second, the CDS Guidance, which purports to interpret that statute. Considerable detail is necessary in order to highlight how the CDS Guidance deviates from the statute and why these deviations raise concerns about content-based regulation of physicians' professional speech.

II. THE CURES ACT TRACED A CONSTITUTIONALLY SOUND LINE BETWEEN MEDICAL PRACTICE SOFTWARE AND FDA-REGULABLE DEVICE SOFTWARE

Historically, the tailoring of professional speech took place in the minds of “our family doctors—who kept hand-written records about us sealed away in big file cabinets” and held the shared medical knowledge base in memory.¹³⁰ Today, CDS tools assist physicians in this same tailoring process, which is integral to the practice of medicine. Are such tools part of the practice of medicine, or are they medical devices that FDA can regulate? The First Amendment constrains how Congress and FDA can answer this question.

In 2013, FDA unveiled its concept of “software as a medical device (SaMD)”: stand-alone medical software, designed to run on various platforms such as personal computers, hand-held devices, or in the cloud, that constitutes a medical device in its own right.¹³¹ The agency for many years—and without controversy—

¹²⁹ See CHARLES FRIED, *MODERN LIBERTY AND THE LIMITS OF GOVERNMENT* 101 (2007) (“Governments violate these constitutionally protected liberties . . . by making it harder to send or hear certain messages just because government does not like the message.”).

¹³⁰ U.S. DEP'T HEALTH & HUM. SERVS., *CONFIDENTIALITY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: RECOMMENDATIONS OF THE SECRETARY OF HEALTH & HUM. SERVS. PURSUANT TO SECTION 264 OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996* (Sept. 10, 1997) [hereinafter *HHS, 1997 Recommendations*], <https://perma.cc/M9TK-YZQW>.

¹³¹ INT'L MED. DEVICE REGULATOR'S FORUM, *SOFTWARE AS A MEDICAL DEVICE (SAMd): KEY DEFINITIONS* (2013), <https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf>.

had regulated software that runs on a specific hardware device (e.g., a pacemaker or imaging device) and affects the device's overall safety and effectiveness.¹³² In contrast, the 2013 policy proposed to extend FDA's regulation to software that is not directly moored to specific device hardware, such as stand-alone software processing information already residing in patients' medical records.

Law scholars promptly expressed concern that FDA's 2013 plan to regulate stand-alone medical software posed serious First Amendment problems.¹³³ In 2016, Congress stepped in to clarify the scope of FDA's jurisdiction to regulate medical software. The result was Section 3060 of the Cures Act,¹³⁴ which expressly removes certain categories of medical software from the definition of a "device"¹³⁵ that FDA can regulate. When Congress enacted Section 3060, the 2018 *NIFLA* case was still two years in the future and the level of First Amendment protection for professional speech was somewhat unclear. Despite this, the jurisdictional line Congress drew in Section 3060 is robust even after *NIFLA*. The discussion below explains why this is so.

As seen on the left side of Figure 1, the Cures Act presumes that a CDS tool is part of the practice of medicine, and not a medical device that FDA can regulate, if it meets the three criteria numbered (i)—(iii). The first two criteria ask whether the software analyzes patient-specific medical information along with other (i.e., non-patient specific) medical information, to develop diagnostic, treatment, or predictive recommendations to communicate to a health care professional. Software that meets these first two criteria is simply replicating the same thought process that

¹³² *Id.*; see also *What are Examples of Software as a Medical Device?*, U.S. FOOD & DRUG ADMIN. (Dec. 6, 2017), <https://www.fda.gov/medical-devices/software-medical-device-samd/what-are-examples-software-medical-device>.

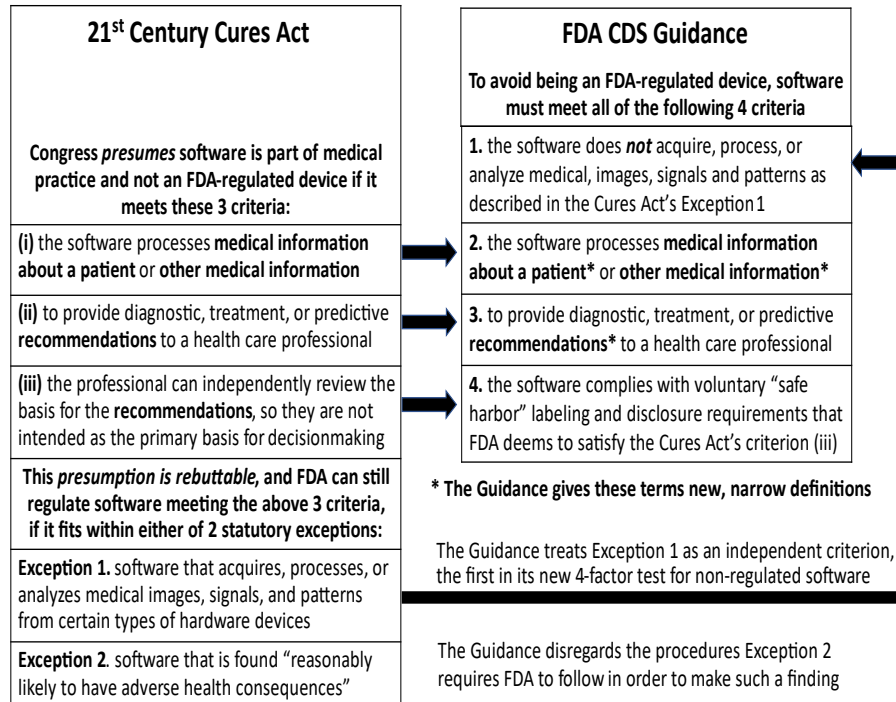
¹³³ See, e.g., Adam Candeub, *Digital Medicine, the FDA, and the First Amendment*, 49 GA. L. REV. 933, 939, 953–65 (2015) (arguing that "FDA stands on firm legal ground regulating medical devices that invasively measure bodily functions or take actual physical specimens" but its exercise over tools "that simply process information . . . or use approved medical devices to provide medical information raises serious legal concerns").

¹³⁴ See 21st Century Cures Act, Pub. L. No. 114-255, § 3060(a), 130 Stat. 1033, 1130 (2016) (codified at 21 U.S.C. § 360j(o)).

¹³⁵ See 21 U.S.C. § 321(h)(1) (defining "device" and excluding "medical and certain decisions support software" as described in 21 U.S.C. § 360j(o)).

physicians have historically used to tailor medical advice to the needs of individual patients.

Figure 1. Regulation of CDS Software Under the 21st Century Cures Act



However, there is a third criterion: Can the physician using the software independently review the basis for its recommendations? If so, the physician remains in charge of the CDS tool, and Congress views it as part of the practice of medicine, best left for oversight by the medical profession and state medical practice regulators.¹³⁶ If this third criterion is not met, the software is an incomprehensible “black box”¹³⁷ evading physician oversight and control, and Congress subjects it to FDA regulation as a medical device. “This distinction is a workable and sensible one,” according to a recent National Academy of Medicine discussion paper.¹³⁸

Still focusing on the left side of Figure 1, Congress made two exceptions. Software meeting all three of the criteria numbered (i)–(iii) is *presumed* to be part of

¹³⁶ See ADLER-MILSTEIN ET AL., *supra* note 3, at 14.

¹³⁷ See W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421 (2017) (discussing difficulties with comprehensibility of AI medical software).

¹³⁸ See ADLER-MILSTEIN ET AL., *supra* note 3, at 14.

medical practice, but FDA can overcome that presumption—and still regulate a CDS tool as a device—if it fits in either exception. These exceptions are numbered 1 and 2 on the lower left side of Figure 1.

Two factors suggest that Section 3060 is constitutionally sound and could withstand a First Amendment challenge if one arose.

A. Section 3060 Does Not Itself Impose Content-Based Regulation of Professional Speech

The Cures Act supplies no special meanings for the terms “medical information about a patient,” “other medical information,” and “recommendations.” Under well-settled rules for construing legal texts,¹³⁹ those terms—as used in the statute—have their ordinary, common-sense meanings. In everyday usage, in many state and federal statutes,¹⁴⁰ and even elsewhere in the Food, Drug, and Cosmetic Act,¹⁴¹ the phrase “medical information” about a patient is broadly understood. It includes—along with clinical observations and many other things—a patient’s medical images, diagnostic test results (including, at times, gene sequence information) that originated as signals from *in vitro* diagnostic tests,¹⁴² and patterns

¹³⁹ ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 69 (2012) (discussing the Ordinary Meaning Canon of statutory construction); see also LARRY M. EIG, CONG. RSCH. SERV., 97-589, *STATUTORY INTERPRETATION: GENERAL PRINCIPLES AND RECENT TRENDS* 8 (2014), <https://sgp.fas.org/crs/misc/97-589.pdf> (same).

¹⁴⁰ See, e.g., CAL. CIV. CODE § 56.05(i) (“‘Medical information’ means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient’s medical history, mental or physical condition, or treatment.”); 15 U.S.C. § 1681a(i) (“The term ‘medical information’ (1) means information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to (A) the past, present, or future physical, mental, or behavioral health or condition of an individual; (B) the provision of health care to an individual; or (C) the payment for the provision of health care to an individual.”).

¹⁴¹ See, e.g., 21 U.S.C. §§ 379aa(c)(2), 379aa-1(c)(2) (requiring reporting to FDA of new “medical information” concerning serious adverse events with nonprescription drugs and dietary supplements, with the term presumably understood broadly to include all forms of information bearing on the patients’ condition rather than in the narrowly restricted sense used in CDS GUIDANCE, *supra* note 1).

¹⁴² See *In Vitro Diagnostics*, U.S. FOOD & DRUG ADMIN. (Feb. 23, 2023), <https://www.fda.gov/medical-devices/products-and-medical-procedures/in-vitro-diagnostics> (“In vitro diagnostics (IVD) are tests done on samples such as blood or tissue that have been taken from the human body”

and signals from signal acquisition systems such as Holter monitors, electroencephalograms, and continuous glucose monitors.¹⁴³

Thus, the terms “medical information about a patient” and “other medical information,” as used in the Cures Act, encompass all the patient-specific and other (non-patient-specific) information flows that the medical profession considers relevant when developing diagnostic, prognostic, and treatment advice for a patient. CDS tools can draw on the full range of inputs that physicians customarily use when making medical decisions, yet still qualify as non-FDA-regulated medical practice software, assuming all three of the criteria (i)–(iii) are met.

The Cures Act does not restrict or limit the medical information flows physicians can receive—whether directly from the patient’s medical record or from medical practice CDS software processing these same inputs—when making clinical decisions about their patients. It thus imposes no content-based restriction on physicians’ use of medical information when tailoring their professional speech. It envisions that the medical profession, rather than FDA, should determine which

such as a strep throat test that examines secretions from a person’s throat or a genetic test that examines a blood or tissue specimen); *cf. In Vivo Testing Methods*, DRUG DEV. & DIAGNOSTICS, <https://drugdevelopment.fi/diagnostics/in-vivo/> (explaining that *in vivo* diagnostics are “more invasive” testing tools for “monitoring and imaging targets within the body as opposed to *in vitro* tests which are performed outside the body on samples taken from the subjects. *In vivo* tests vary from simple skin tests for determining antigens that cause allergic diseases to highly technical Positron Emission Tomography (PET) imaging” as well as X-rays, MRI scans, and ultrasound imaging technology).

¹⁴³ See, e.g., 45 C.F.R. § 160.103 (defining “protected health information,” which refers to the medical information the HIPAA Privacy Rule protects in clinical health care settings where that regulation applies); 42 U.S.C. § 1320d(4) (providing the 1996 HIPAA statute’s definition of “health information” as “any information, whether oral or recorded in any form or medium, that: (A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual”); 42 U.S.C. § 1320d-9(b)(1) (stating, in a new section introduced by GINA, that Congress deems “genetic information,” as broadly defined by GINA at 42 U.S.C. § 300gg-91, to be health information, for purposes of making it subject to HIPAA’s privacy protections); see also Genetic Information Nondiscrimination Act § 105(a), 122 Stat. 881 (2008) (codified at 42 U.S.C. § 1320d-9(a)) (expanding the definition of “health information” that HIPAA protects to include genetic information). Note that in medical privacy law and in most other health regulatory contexts, the term “health information” is the preferred term for referring to “medical information” created and used in clinical health care settings, although the two terms are used interchangeably.

types of medical information are admissible and relevant to clinical decision-making.

B. Section 3060 Correctly Places the Burden on the Government to Justify Content-Based Regulations of Physicians' Professional Speech

Exception 2, shown at the lower left in Figure 1, does important work that is constitutionally required. This exception allows FDA to regulate any CDS tool—even if it meets the three criteria (i)–(iii) and is presumptively medical practice software—if the Secretary of Health and Human Services first makes a finding that the software “would be reasonably likely to have serious adverse health consequences.”¹⁴⁴ To make such a finding, the Secretary must issue a final order after notice in the Federal Register and at least 30 days for public comment; the notice must explain the rationale for the finding and identify evidence supporting it.¹⁴⁵ Thus, the Secretary (acting through FDA) bears the burden to show that the risks are real and not mere speculation or conjecture. This procedure complies with the constitutional requirement that the government must bear the burden of justifying content-based regulation of physicians' professional speech.¹⁴⁶

Once a CDS tool has met Congress's three criteria to qualify (presumptively) as part of medical practice, this second exception, in effect, flips the FDA's usual regulatory burden of proof. Under the FDA's medical device premarket clearance and approval processes, a device manufacturer must provide evidence to convince the agency to let the device move into clinical use.¹⁴⁷ This evidence must show the device has a “reasonable assurance of safety and effectiveness” (for premarket approval) or that it is at least “substantially equivalent” to another device already allowed onto the market (for premarket clearance).¹⁴⁸ Either way, the manufacturer

¹⁴⁴ 21 U.S.C. § 360j(o)(3)(A).

¹⁴⁵ *Id.* § 360j(o)(3)(A)–(B).

¹⁴⁶ See *supra* notes 82–83 and accompanying text.

¹⁴⁷ See 21 U.S.C. § 360(k) (premarket notification requirements for FDA-cleared devices); *id.* § 360e(c) (stating requirements for an FDA device premarket approval application).

¹⁴⁸ See INST. OF MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 5–6 (2011) (noting that devices moving through FDA's premarket approval process require evidence showing a “reasonable assurance of safety and effectiveness,” but new Class II (moderate risk) devices moving through FDA's clearance process do not actually require such evidence and only have to show the device is “as safe and effective as” (i.e., not worse than) a predicate (earlier) device already allowed onto the market).

must produce at least some evidence bearing on whether the device is likely to provide safe and effective performance *before* it can enter the market.

However, a CDS tool that meets criteria (i)–(iii) is presumed *not* to be an FDA-regulated device and does not automatically fall under these requirements. Instead, FDA must provide a “rationale and identification of the evidence” supporting its finding that the CDS tool is “reasonably likely to have serious adverse health consequences”—i.e., that it is *unsafe*—in order to have grounds to regulate it.¹⁴⁹ The burden is on FDA to provide such evidence. If there is no evidence one way or the other, the party who bears this burden—in this case, FDA—will lose,¹⁵⁰ and the CDS tool will remain under the oversight of the medical profession and medical practice regulators who, as noted earlier, rely heavily on the medical profession to set standards that the regulators enforce.¹⁵¹

This is not just a statutory requirement; it is required by the First Amendment. *NIFLA* did not decide whether content-based restrictions on physicians’ professional speech should receive strict or intermediate scrutiny under the First Amendment, because the restriction in that case was unconstitutional either way.¹⁵² Even under the more government-friendly intermediate standard of scrutiny, the government still bears the “burden to demonstrate that the harms it recites are real” and that its proposed regulations “will in fact alleviate them to a material degree.”¹⁵³ “This burden is not satisfied by mere speculation or conjecture.”¹⁵⁴ Courts typically show great deference to an agency’s assessment of scientific data within its area of expertise, but in First Amendment cases courts are less deferential and display a greater willingness to decide for themselves where the “weight of the evidence” lies.¹⁵⁵

¹⁴⁹ 21 U.S.C. §§ 360j(o)(3)(A)(i), (B)(ii).

¹⁵⁰ *Int’l Dairy Foods Ass’n v. Boggs*, 622 F.3d 628, 637–38 (6th Cir. 2010).

¹⁵¹ *See, e.g., FURROW ET AL., supra* note 96; *see also Cruess & Cruess, supra* note 97.

¹⁵² *Nat’l Inst. of Fam. & Life Advocs. v. Becerra (NIFLA)*, 138 S. Ct. 2361, 2375 (2018).

¹⁵³ *Pearson v. Shalala (Pearson I)*, 164 F.3d 650, 659 (D.C. Cir. 1999) (internal quotation marks omitted) (quoting *Ibanez v. Fla. Dep’t of Bus. & Prof. Reg.*, 512 U.S. 136, 146 (1994)).

¹⁵⁴ *Edenfield v. Fane*, 507 U.S. 761, 770–71 (1993).

¹⁵⁵ *Pearson v. Shalala (Pearson II)*, 130 F. Supp. 2d 105 (D.D.C. 2001); *see also Brown v. Ent. Merchs. Ass’n*, 564 U.S. 786, 799–800 (2011) (critiquing evidence the State of California cited as justifying a content-based speech regulation and determining that the evidence was insufficient to meet the government’s burden in a free speech case).

The Cures Act envisions that the medical profession will control the medical knowledge base that can be used to inform patient care. This control extends to new types of inferential knowledge gleaned by 21st-century CDS tools, unless FDA produces solid evidence that a specific CDS software function is “reasonably likely to have serious adverse health consequences” and follows legislatively prescribed procedures to place that software function back under FDA oversight.

When the House of Representatives voted to concur in Senate amendments to the Cures Act, House members expressed their clear understanding that Section 3060 significantly narrows FDA’s authority to regulate medical software.¹⁵⁶ One House member noted that Section 3060 “makes it difficult for FDA, in the future, to bring software that is used to support or sustain human life back under FDA’s jurisdiction.”¹⁵⁷ That is quite true, because the First Amendment *requires* that it be difficult for FDA to impose content-based restrictions on physicians’ professional speech.

III. THE CDS GUIDANCE DEVIATES FROM THE CURES ACT

The right side of Figure 1 summarizes FDA’s September 28, 2022 CDS Guidance.¹⁵⁸ A meta-analysis of client alerts and podcasts subsequently published by major law firms active in the life science, digital health, and device regulatory areas found a high level of consensus among seasoned attorneys with subject-matter expertise that the CDS Guidance is out of conformity with the Cures Act.¹⁵⁹ The CDS

¹⁵⁶ 162 CONG. REC. H6994 (daily ed. Nov. 30, 2016) (remarks of Rep. Frank Pallone) (“I am . . . concerned that the bill removes certain categories of medical software from FDA oversight.”); *see id.* at H6996 (remarks of Rep. Marsha Blackburn) (“[S]ection 3060 is there addressing medical technology and software. This is so important that we get the FDA on the right track and move components of this away so that it does not face FDA approval processes that will slow down access to the marketplace for patients.”).

¹⁵⁷ *Id.* at H6994 (remarks of Rep. Pallone).

¹⁵⁸ *See* CDS guidance, *supra* note 1.

¹⁵⁹ *See* Nick Paul Taylor, *FDA Finalizes Guidance on How Clinical Decision Support Software is Regulated*, *MedTech Dive* (Sept. 28, 2022) (quoting Bradley Merrill Thompson, Attorney & Chief Data Scientist, Epstein, Becker & Green, P.C.), <https://www.medtechdive.com/news/fda-final-guidance-clinical-decision-support/632824/>; Stacy Cline Amin et al., *FDA Releases Foundational Digital Health Guidance*, MORRISON & FOERSTER LLP (Sept. 28, 2022), <https://www.mofo.com/resources/insights/220928-additional-clarifications-for-clinical-decision>; Dan Kagan et al., *Your Clinical Decision Support Software May Now Be Regulated by FDA as A Medical Device*, DLA PIPER LLP (Sept. 29, 2022), <https://www.dlapiper.com/en/insights/publications/2022/09/your-clinical-decision->

Guidance purports to interpret the statute, but attorneys voiced doubt “whether some of this interpretation squares with the statute”¹⁶⁰ amid a prevailing sense that

support-software-may-now-be-regulated-by-fda-as-a-medical-device; Vernessa T. Pollard & Anisa Mohanty, *FDA Issues Long-Awaited Final Clinical Decision Support Guidance*, MCDERMOTT, WILL & EMERY LLP (Sept. 30, 2022), <https://www.mwe.com/insights/fda-issues-long-awaited-final-clinical-decision-support-software-guidance>; Gregory H. Levine et al., *Is Your Clinical Decision Support Software A Medical Device? Final Guidance Details FDA’s Latest Thinking*, ROPES & GRAY LLP (Oct. 3, 2022), <https://www.ropesgray.com/en/insights/alerts/2022/10/is-your-clinical-decision-support-software-a-medical-device>; 5 *Key Takeaways from FDA’s Final Guidance on Regulation of Clinical Decision Support Software: FDA Outlines Significant Changes for CDS*, COVINGTON & BURLING, LLC (Oct. 3, 2022), <https://www.cov.com/en/news-and-insights/insights/2022/10/5-key-takeaways-from-fdas-final-guidance-on-regulation-of-clinical-decision-support-software-fda-outlines-significant-changes-for-cds>; Wade Ackerman et al., *Unpacking FDA’s Final Clinical Decision Support Guidance*, LAW 360 (Oct. 7, 2022), <https://www.cov.com/-/media/files/corporate/publications/2022/10/unpacking-fdas-final-clinical-decision-support-guidance.pdf>; Lisa M. Baumhardt et al., *The Incredible Shrinking Exemption: FDA Final CDS Guidance Would Significantly Narrow the Scope of Exempt Clinical Decision Support Software Under the Cures Act*, HYMAN, PHELPS & MCNAMARA PC FDA LAW BLOG (Oct. 10, 2022), <https://www.thefdalawblog.com/2022/10/the-incredible-shrinking-exemption-fda-final-cds-guidance-would-significantly-narrow-the-scope-of-exempt-clinical-decision-support-software-under-the-cures-act/>; Jodi Daniel et al., *FDA Issues Final Guidance on Clinical Decision Support Software*, CROWELL & MORING LLP (Oct. 10, 2022), <https://www.cmhealthlaw.com/2022/10/fda-issues-final-guidance-on-clinical-decision-support-software/>; *FDA’s Final Clinical Decision Support Guidance: The Good News and the (Really) Bad News*, KING & SPALDING LLP (Oct. 12, 2022), <https://www.kslaw.com/news-and-insights/fdas-final-clinical-decision-support-guidance-the-good-news-and-the-really-bad-news/>; Mahnu V. Davar et al., *FDA Releases Significantly Revised Final Clinical Decision Support Software Guidance and Related Changes*, ARNOLD & PORTER KAYE SCHOLER LLP (Oct. 17, 2023), <https://www.arnoldporter.com/en/perspectives/advisories/2022/10/fda-releases-significantly-revised-final-clinical>; *FDA Issues Final Guidance on Clinical Decision Support Software*, DUANE MORRIS LLP (Oct. 21, 2022), https://www.duanemorris.com/alerts/fda_issues_final_guidance_clinical_decision_support_software_1022.html; *FDA Finalizes Clinical Decision Support (CDS) Software Guidance*, WILSON SONSINI GOODRICH & ROSATI (Oct. 21, 2022), <https://www.wsgr.com/en/insights/fda-finalizes-clinical-decision-support-cds-software-guidance.html>; *FDA’s Latest Twist on Digital Health Oversight Brings Big Shift*, COOLEY LLP (Jan. 3, 2023), <https://www.cooley.com/news/insight/2023/2023-01-03-fda-latest-twist-on-digital-health-oversight-brings-big-shift>.

¹⁶⁰ See *Non-Binding Guidance: Key Takeaways from FDA’s Final Guidance on Clinical Decision Support Software*, ROPES & GRAY (Nov. 11, 2022), <https://www.ropesgray.com/en/insights/podcasts/2022/11/podcast-non-binding-guidance-key-takeaways-from-fdas-final-guidance-on-clinical-decision-support> (remarks of Greg Levine).

“FDA clearly intends to regulate software that Congress explicitly removed from FDA’s jurisdiction.”¹⁶¹

The discussion below is not an exhaustive compendium of the various ways the CDS Guidance deviates from the statute, which have been discussed elsewhere.¹⁶² It focuses instead on three specific deviations that offend the First Amendment, while also noting a fourth aspect of the guidance that further diminishes physician autonomy even though it does not appear to raise constitutional concerns.

A. *The CDS Guidance Seeks to Expand FDA’s Jurisdiction to Regulate CDS Software Without Following Procedures Required by the Constitution and the Cures Act*

The CDS Guidance ignores the Cures Act’s second exception,¹⁶³ which allows FDA to reclaim jurisdiction the Cures Act took away but requires various procedural and substantive safeguards.¹⁶⁴ Publishing a guidance document was not the right procedure, nor did the CDS Guidance supply the required evidence supporting FDA’s contention that specific or time-sensitive recommendations from CDS tools are “reasonably likely to have serious adverse health consequences.”¹⁶⁵ The CDS Guidance treats the Cures Act’s procedural requirements as mere “surplusage” that is “idle and nugatory” with no legal effect.¹⁶⁶

Instead, the Guidance offers vague speculations about “automation bias” which is “the propensity of humans to over-rely on a suggestion from an automated

¹⁶¹ See FDA’s *Final Clinical Decision Support Guidance: The Good News and the (Really) Bad News*, KING & SPALDING, LLP, *supra* note 159; see also Ackerman et al., *supra* note 159 (“The FDA has meaningfully narrowed the scope of recommendations that could qualify as nondevice clinical decision support . . . revealing that the FDA intends to actively regulate more clinical decision support functions as software as a medical device.”).

¹⁶² See EPSTEIN, BECKER & GREEN, P.C., *supra* note 7 (describing these deviations); see also *supra* note 159 (citing various other sources discussing these deviations).

¹⁶³ 21 U.S.C. § 360j(o)(3).

¹⁶⁴ *Id.* § 360j(o)(3)(A)–(C).

¹⁶⁵ *Id.* § 360j(o)(3)(A).

¹⁶⁶ See SCALIA & GARNER, *supra* note 139, at 174–79 (describing the Surplusage Canon of statutory construction, which “leans in favor of a construction which will render every word operative, rather than one which will make some idle and nugatory” (internal citations omitted)); see EIG, *supra* note 139, at 14 (same).

system,”¹⁶⁷ but supplies no evidence that these conjectures are real with respect to any medical software functions the agency has examined. The Guidance, in effect, speculates that automation bias will regularly diminish the autonomy of most or all physicians in most settings when they work with any type of CDS tool, such that a tool’s recommendations would override their own expert medical judgment. As evidentiary support, the Guidance cites a single six-page scholarly article, published in an *aeronautics and astronautics* journal in 2004 (well before the advent of modern CDS tools).¹⁶⁸ That article defined “automation bias” in the context of *Critical* (not *Clinical*) Decision Support systems.¹⁶⁹ On this basis, the CDS Guidance speculates that “[a]utomation bias *may be* more likely to occur” and what sort of risks it “*may* carry.”¹⁷⁰ This is pure conjecture, and the Guidance fails to identify any solid evidence from clinical studies quantifying the frequency, extent, and impact of automation bias when real physicians use various types of CDS tools in actual clinical care settings.

The CDS Guidance thus fails to satisfy the statutory requirement for the agency to identify evidence to support a finding that CDS tools are “reasonably likely to have serious adverse health consequences” because of automation bias.¹⁷¹ This aspect of the CDS Guidance fits a pattern Professor Lars Noah has described, in which FDA sidesteps legislatively required procedural and substantive safeguards to do things a statute would allow the agency to do, but only “after expending greater effort.”¹⁷² The CDS Guidance declined to expend the required effort. In this instance, however, that effort is constitutionally required.¹⁷³

¹⁶⁷ See CDS GUIDANCE, *supra* note 1, at 11.

¹⁶⁸ *Id.* (citing M.L. Cummings, *Automation Bias in Intelligent Time Critical Decision Support Systems*, in 2 AM. INST. OF AERONAUTICS AND ASTRONAUTICS 1ST INTELLIGENT SYSTEMS TECHNICAL CONFERENCE 557–62 (2004)).

¹⁶⁹ *Id.*

¹⁷⁰ *Id.* (emphasis added).

¹⁷¹ 21 U.S.C. § 360j(o)(3)(A).

¹⁷² Lars Noah, *Governance by the Backdoor: Administrative Law(lessness) at the FDA*, 93 NEB. L. REV. 89, 90, 136 (2014).

¹⁷³ See *supra* notes 82–83 and accompanying text.

B. The CDS Guidance Alters the Statute's Structure in Order to Support Its Broad Reading of a Narrow Saving Clause

The meaning of clauses in a statute is shaped by their placement in the statute's overall structure.¹⁷⁴ A second notable aspect of the CDS Guidance is that it alters the very structure of the Cures Act. The text in question is Exception 1 shown at the lower left in Figure 1. Software meeting the three statutory criteria¹⁷⁵ (i)–(iii) for medical practice software is excluded from FDA oversight “unless the function is intended to acquire, process, or analyze a medical image or a signal from an *in vitro* diagnostic device or a pattern or signal from a signal acquisition system.”¹⁷⁶ The word “unless” marks this clause as an exception: The plain meaning of “unless” is “except if.”¹⁷⁷ Exception 1 is, in fact, a saving clause: It saves FDA's jurisdiction to regulate some software that otherwise would be excluded from FDA oversight because the software technically meets the criteria (i)–(iii).

In the Guidance, this “unless” clause is no longer a mere exception, as it is in the statute. Instead, the Guidance elevates it to an independent criterion, co-equal with the three criteria Congress specified for excluding software from FDA's jurisdiction¹⁷⁸ and first among them. The exception—or rather, its negation¹⁷⁹—takes pride of place as Criterion 1 in the Guidance's new four-factor test to decide whether a CDS tool is part of medical practice and hence excluded from FDA regulation. The statutory criteria (i)–(iii) are demoted to the Guidance's criteria 2–4.

Does this matter? If the statute states three criteria to be met, plus one exception to be eluded, does not $3 + 1 = 4$? None of the attorney commentary cited earlier has focused on this aspect of the Guidance, which works a fundamental restructuring

¹⁷⁴ See EIG, *supra* note 139, at 4.

¹⁷⁵ 21 U.S.C. § 360j(o)(1)(E)(i)–(iii).

¹⁷⁶ *Id.* § 360j(o)(1)(E) (opening clause).

¹⁷⁷ See *Unless*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/unless> (last visited Apr. 14, 2024) (“except on the condition that : under any other circumstance than”); *Unless*, WORDREFERENCE.COM, <https://www.wordreference.com/synonyms/unless> (last visited Apr. 14, 2024) (noting that “unless” is understood in the sense of “except if”); SCALIA & GARNER, *supra* note 139, at 69.

¹⁷⁸ 21 U.S.C. § 360j(o)(1)(E)(i)–(iii).

¹⁷⁹ See CDS GUIDANCE, *supra* note 1, at 7 (stating, as Criterion 1 of a four-part test, that the software is “*not* intended to acquire, process, or analyze a medical image or a signal from an *in vitro* diagnostic device or a pattern or signal from a signal acquisition system” (emphasis added)).

of the statute. This restructuring does matter, and for an important reason. Converting the “unless” clause into a co-equal criterion liberates it from the natural limit that befalls all exceptions: An exception cannot logically be broader than the basic rule it is nuancing. This logical principle has guided judges, in other legal contexts, to interpret exceptions modestly when doing otherwise would undermine the overall purpose of a statute.¹⁸⁰ This is especially true when the exception is a saving clause: “If there is a conflict, the savings clause gives way. Courts will attempt to give the savings language some effect, but may have to narrow that effect to avoid eviscerating the new law.”¹⁸¹

The CDS Guidance interprets the saving clause (its new Criterion 1) very broadly and, in doing so, eviscerates the Cures Act. The large circle in Figure 2 portrays the universe of “medical information about a patient” that physicians routinely refer to when formulating their professional speech, and which might be used as inputs to a CDS tool.¹⁸² Will such tools fit in the saving clause for software whose “function is intended to acquire, process, or analyze a medical image or a signal from an *in vitro* diagnostic device or a pattern or signal from a signal acquisition system”?¹⁸³ It depends how broad the saving clause actually is.

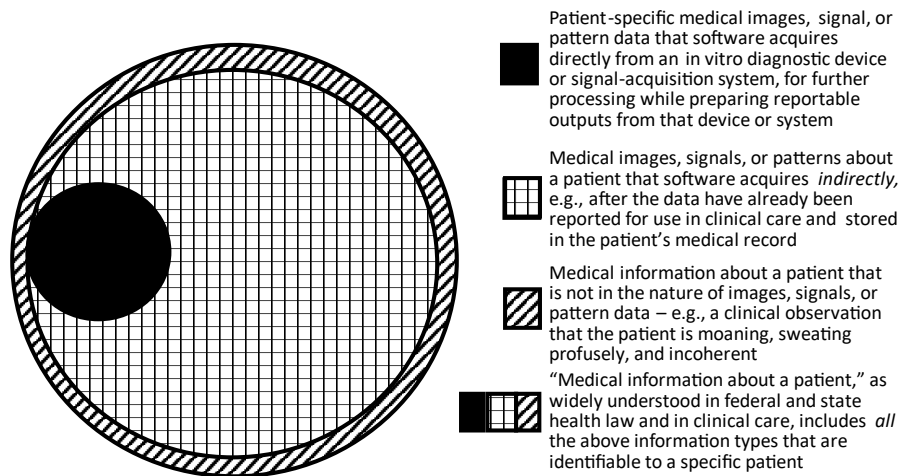
¹⁸⁰ See, e.g., *Berkovitz v. United States*, 486 U.S. 531 (1988), *United States v. Gaubert*, 499 U.S. 315 (1991), and *Cope v. Scott*, 45 F.3d 445 (D.C. Cir. 1995) (construing the “discretionary function” exception to the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2402, 2671 et seq.). The overall purpose of the Federal Tort Claims Act was to make it possible to sue the federal government for certain torts. However, its “discretionary function” exception at 28 U.S.C. § 2680(a) excludes suits “based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of a federal agency or an employee of the Government.” If read broadly, this exception seemingly would rule out most tort suits against the federal government, because “government policies will almost always leave some room for individual choice” and thus might be characterized as discretionary functions. *Cope*, 45 F.3d at 448. Courts apply a two-part test that recognizes “not all actions that require choice—actions that are, in one sense ‘discretionary’—are protected as ‘discretionary functions’ under the FTCA.” *Id.* The two-part test narrows the exception to prevent it from overwhelming the statute’s overall purpose, which was to restrict sovereign immunity and allow many tort claims against the federal government to move forward.

¹⁸¹ See EIG, *supra* note 139, at 38 (internal citations omitted).

¹⁸² See *infra* Part III.C (discussing types of patient-specific medical information physicians use in clinical care).

¹⁸³ 21 U.S.C. § 360j(o)(1)(E) (emphasis added).

**Figure 2. Types of Patient-Specific Health Data
Used as Inputs to Medical Software**



Under a narrow interpretation, the saving clause allows FDA to regulate software that directly acquires images, signals, or patterns from the *in vitro* diagnostic device or signal acquisition system that generated them. This interpretation would save FDA's power to regulate the solid black area in Figure 2. An example would be a software tool that enhances diagnostic images, such as mammograms or dental X-rays, to highlight areas suspicious for disease in outputs from the imaging device.¹⁸⁴ FDA had long been regulating AI/ML software of this type, and the narrow exception would let it continue doing so.

Under a broad interpretation, the saving clause allows FDA to regulate software that processes *any* data that *ever at any point in its history* came from an *in vitro* device or signal acquisition system. "Many types of CDS software utilize information acquired second- or third-hand (for example, data originally from an IVD or other device that has now been recorded in a patient's electronic patient record)."¹⁸⁵ This broad interpretation would let FDA continue regulating software in

¹⁸⁴ Bradley Merrill Thompson, *Learning from Experience: FDA's Treatment of Machine Learning*, MOBILE HEALTH NEWS (Aug. 23, 2017), <http://www.mobihealthnews.com/content/learning-experience-fda%E2%80%99s-treatment-machine-learning> [https://perma.cc/Q95C-9R22].

¹⁸⁵ Christina Kuhn, Wade Ackerman, Scott Danzis et al., *FDA Outlines Updated Approach to Regulating Digital Health Technologies*, COVINGTON (Dec. 20, 2017), <https://www.cov.com/>

the black area but also expand FDA's jurisdiction to regulate the gridded area of Figure 2. In contrast to the black area, the gridded area includes stand-alone software that FDA traditionally has not regulated in the past. "If broadly interpreted," it is unclear how CDS tools "that incorporate patient data from these various sources could ever fall outside of FDA device regulation."¹⁸⁶ Much or most advanced CDS software does incorporate at least some data in the gridded area that, after leaving the device that originally generated it, now resides in patients' medical records.

Attorneys¹⁸⁷ and the Government Accountability Office/National Academy of Medicine were skeptical of the broad interpretation: Would the mere fact that a tool processes a few bits of gene variant data (perhaps decades after that data emerged from a sequencing analyzer) mean that it is "processing a signal from an *in vitro* diagnostic device" and thus FDA-regulated?¹⁸⁸ If so, the exception swallows most or all of the statute's basic rule, violating the Presumption Against Ineffectiveness—a rule of statutory construction that favors interpretations that further rather than obstruct a statute's overall purpose.¹⁸⁹ It also violates the rule that saving clauses should be construed narrowly to avoid "eviscerating the new law" in which Congress inserted the saving clause.¹⁹⁰ This statute's purpose was to reduce FDA's authority to regulate CDS tools, and a broad interpretation would obstruct that purpose.

The House of Representatives understood the scope of the saving clause to be narrow. H.R. 6, the 21st Century Cures bill that the House passed 344-77 on July 10, 2015, contained an exception letting FDA continue to regulate "software that does not, *through the use of an in vitro* diagnostic device or signal acquisition

media/files/corporate/publications/2017/12/fda_outlines_updated_approach_to_regulating_digital_health_technologies.pdf.

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ See ADLER-MILSTEIN ET AL., *supra* note 3, at 17; see also U.S. GOV'T ACCOUNTABILITY OFF., GAO-22-104629, ARTIFICIAL INTELLIGENCE IN HEALTH CARE: BENEFITS AND CHALLENGES OF MACHINE LEARNING TECHNOLOGIES FOR MEDICAL DIAGNOSTICS 56, 59–61, 68 (2022).

¹⁸⁹ See SCALIA & GARNER, *supra* note 139, at 63.

¹⁹⁰ See EIG, *supra* note 139, at 38.

system, acquire, process, or analyze an image or physiological signal.”¹⁹¹ “Through the use of” envisions direct data acquisition, corresponding to a narrow saving clause.

The Senate dallied over the Cures Act until after the 2016 election, but then moved quickly to pass legislation in time for President Obama to sign it. A diligent search of the legislative history¹⁹² finds no record of how the House’s “through the use of” became “from” in the Senate Bill (“unless the function is intended to acquire, process, or analyze a medical image or a signal *from* an *in vitro* diagnostic device or a pattern or signal *from* a signal acquisition system”¹⁹³). When the House voted to concur in the Senate amendments to the Cures Act on November 30, 2016, there is no sign that the House saw this minor text edit as materially changing the narrow exception it had approved in 2015.¹⁹⁴

Members of the House expressed their clear understanding that Section 3060 substantially narrows the scope of FDA’s authority to regulate CDS software.¹⁹⁵ It defies reason that Congress would pass a statute removing many CDS tools from FDA’s jurisdiction, only to insert a broad saving clause putting the vast majority of them right back in. The CDS Guidance portrays the Cures Act as a vain and pointless exercise of the legislative power that did precisely that

C. *The CDS Guidance Would Restrict Physicians’ Freedom to Use, Process, and Analyze Certain Types of Clinical Data that Physicians Regard as Appropriate Inputs to Inform Their Professional Speech*

Much has been written about the CDS Guidance’s highly unorthodox definitions of “medical information about a patient” and “other medical information” that a CDS tool can use as inputs without falling under FDA’s device regulations.¹⁹⁶

¹⁹¹ H.R. 6, 114th Cong. § 2241 (2015) (emphasis added) (as passed by House, July 13, 2015).

¹⁹² See H.R. 34, 114th Cong. (2015) (enacted) (describing the legislative history of the Cures Act, which was renumbered from H.R. 6 to H.R. 34 after consolidation with another piece of legislation).

¹⁹³ 21 U.S.C. § 360j(o)(1)(E) (emphasis added).

¹⁹⁴ 162 CONG. REC. H6874–H7006 (daily ed. Nov. 30, 2016) (debating and voting to concur in Senate Amendments to H.R. 34, the bill including, among other things, the Cures Act).

¹⁹⁵ *Id.* at H6994 (quoting remarks of Rep. Frank Pallone and Rep. Marsha Blackburn).

¹⁹⁶ See EPSTEIN, BECKER & GREEN, P.C., *supra* note 7 (discussing these definitions); see also *supra* notes 159–161 (citing various other sources critiquing definitions provided in CDS GUIDANCE, *supra* note 1).

In the statute, these terms take their ordinary meanings and encompass the full range of patient-specific and non-patient-specific information that the medical profession regards as clinical-quality information suitable for use in clinical decision-making.¹⁹⁷ In the CDS Guidance, these terms have cramped definitions that have the effect of imposing a prior restraint—FDA premarket review—on physicians’ freedom to use CDS tools to help them process much of this same clinical-quality information.¹⁹⁸ For example, the medical profession considers patient-identifiable medical images, signals, and pattern data gathered using FDA-regulated devices and stored in a patient’s medical record to be clinical-quality data, and they regularly use such data to inform their professional speech to patients. Under the CDS Guidance, however, physicians would not be able, without FDA’s permission, to use a CDS tool to help them analyze those same data types.

To summarize the remainder of this section, the CDS Guidance bases FDA’s jurisdiction to regulate CDS tools on the *types of information* the tool uses as its inputs, even when all of the inputs in question are clinical-quality data. This approach, even if it did not violate the statute, misses a key point: The level of risk a CDS tool poses—and the need for regulatory oversight—depends not just on the types of inputs it uses, but on what it does with those inputs. Even if a CDS tool uses only the simplest clinical data as inputs, it could still harm patients if its algorithm asserts that $2 + 2 = 5$ and is so non-transparent that physicians would be unable to detect the error. Under the CDS Guidance, such software would escape FDA regulation, whereas the statute would subject it to FDA oversight.¹⁹⁹

Medical information about a patient. In the Cures Act, and in real-life health care settings, a patient’s medical information includes everything included in the entire large circle in Figure 2, so long as the data are identifiable to the particular

¹⁹⁷ See *supra* notes 140–143 and accompanying text (discussing these definitions); see also Chintan Patel & Chunhau Weng, *Clinical Data Quality and Validation*, in *ENCYCLOPEDIA OF DATABASE SYSTEMS* 349–50 (2009) (“Clinical data quality is defined as the accuracy and completeness of the clinical data for the purposes of clinical care, health services and other secondary uses such as decision support and clinical research.”).

¹⁹⁸ See discussion *infra* Part III.C (sections entitled “Medical information about a patient” and “Other medical information”).

¹⁹⁹ See 21 U.S.C. § 360j(o)(1)(E)(iii) (allowing FDA to regulate a CDS tool if it is a non-transparent black box that would not enable a “health care professional to independently review the basis for” its recommendations); see also *supra* fig. 1, criterion (iii) (portraying this provision).

patient.²⁰⁰ In the CDS Guidance, the concept of “medical information about a patient” is reduced to a mere shell of itself: the diagonally hashed ring in Figure 2. The diagonally hashed ring includes physicians’ clinical observations about a patient—for example, whether the patient had fever or reported pain or had a palpable lump in their abdomen. However, it excludes the patient’s image, signal, and pattern data generated using imaging devices (such as MRI machines), *in vitro* diagnostic devices (such as gene sequencing analyzers), and signal acquisition systems (such as an electrocardiogram or a continuous glucose monitor that tracks blood sugar levels over time). It excludes them, even if they long ago left the hardware medical device that generated them and are now stored in patients’ medical records, to which physicians already have access. These latter types of information, according to the CDS Guidance, are not “medical information about a patient” even though, in reality, all these types of information are regularly stored in patients’ medical records, and physicians routinely refer to image, signal, and pattern data when formulating diagnoses and treatment plans they communicate to patients every day.²⁰¹

The CDS Guidance defines “medical information about a patient” as “the type of information that normally is, and generally can be, communicated between [health care providers] and patients in the context of a clinical decision, meaning that the relevance of the information to the clinical decision being made is well understood and accepted.”²⁰² Patient-identifiable medical images, signals, and patterns (such as a patient’s genome sequencing data, waveforms, or continuous glucose monitor readings that may be stored in the patient’s medical record) are *not* “patient-specific medical information” under the CDS Guidance’s cramped definition.

A frequently cited statistic is that 70% of clinical decisions rest on laboratory test results and 70% of the information in a patient’s medical record consists of such data and—while the precise statistics are debated and could be either lower or higher²⁰³—it seems clear that the definition in the CDS Guidance would exclude

²⁰⁰ See *supra* notes 140–143 (citing several typical legal definitions of “medical information”).

²⁰¹ See CDS GUIDANCE, *supra* note 1, at 9–10.

²⁰² *Id.* at 9.

²⁰³ See Michael J. Hiltunen, *Dispelling the 70% Claim with Laboratory’s True Value*, MED. LAB MGMT., Oct. 2017 (comparing the 70% figure with various higher and lower figures from several studies).

much or most of the patient-specific medical information that physicians routinely use in clinical practice today. The CDS Guidance deems it unsafe for physicians, without FDA’s supervision, to use software to help them analyze roughly 70% of the patient-specific data that physicians already analyze on a regular basis in their own minds today.

The Guidance considers “a single, discrete test or measurement result” such as a “blood glucose lab test result” to be “medical information,” but “a more continuous sampling of the same information (e.g., continuous glucose monitor readings)” is not “medical information” but instead is a “pattern/signal.”²⁰⁴ “FDA recognizes that there is a continuum between a single sample and a continuous sample”²⁰⁵ but struggled painfully, in its October 18, 2022 Webinar, to enunciate a principle governing how many discrete samples it takes for “medical information” to turn into a “pattern/signal.”²⁰⁶ There can never be a coherent principle for this, because the Guidance’s definition is radically indeterminate. A physician might well discuss waveform data or a pattern of continuous glucose readings with a patient who is intelligent, engaged, and curious how a disease is progressing. A core aspect of physician autonomy is that the physician can tailor the information communicated during clinical encounters to the needs and capacities of the specific patient.

The CDS Guidance posits that there is a determinate amount of simple information, known to FDA, that clinicians communicate to their patients, who the Guidance presumes are uniformly disengaged and medically illiterate. Patients, in FDA’s view, are capable of understanding “a blood glucose lab test result” but incapable of discussing “continuous glucose monitor readings” with their physician.²⁰⁷ Yet physicians need autonomy to tailor their professional speech precisely because some patients are capable of understanding (and want to discuss) trends in their continuous glucose monitor readings, whereas others might say, “Just get to the point, Doc. How was my blood sugar last Thursday at 3:00 p.m. when I had it tested at the lab?” Physicians, not FDA, are present in the room with each unique

²⁰⁴ See CDS GUIDANCE, *supra* note 1, at 9–10.

²⁰⁵ *Id.* at 10.

²⁰⁶ Transcript of Webinar at 13–14, *Clinical Decision Support Software—Final Guidance*, U.S. FOOD & DRUG ADMIN. (Oct. 18, 2022), <https://www.fda.gov/media/162880/download>.

²⁰⁷ See CDS GUIDANCE, *supra* note 1, at 9–10.

patient and are best positioned to decide which informational inputs are admissible and relevant when preparing expert advice for that patient.

In the Cures Act as in real life, patient-identifiable images, signals, and patterns are a *subset* of a patient's medical information.²⁰⁸ In contrast, the CDS Guidance conceives these as two entirely non-overlapping, disjoint sets: Patient-identifiable image, signal, and pattern data *are not* medical information about a patient. "Taken together, Criterion 1 and Criterion 2 describe the types of data inputs used in devices (Criterion 1) and the types of data inputs used in Non-Device CDS (Criterion 2)."²⁰⁹ This disjunction was necessary, apparently, to justify FDA's decision to treat the statute's saving clause as a self-standing criterion in its own right, and to allow the saving clause to swallow most of the statute's basic rule. The CDS Guidance offers a novel take on set theory, in which an FDA-regulated *subset* can somehow be greater than the *entire set of which it is a part*, if Congress has—to FDA's dismay—delegated most of that set elsewhere.

Other medical information. The CDS Guidance offers a similarly cramped definition of "other medical information"²¹⁰—the broader medical knowledge base supplying the context when health care providers assess "medical information about a patient" who is standing in front of them. The CDS Guidance "interprets other medical information to include information such as peer-reviewed clinical studies, clinical practice guidelines, and information that is similarly independently verified and validated as accurate, reliable, not omitting material information, and supported by evidence."²¹¹

As already noted, recent meta-analyses indicate that 82–90% of clinical decisions made in health care today rest on evidence that would not meet this standard.²¹² The "other medical information" that informs day-to-day clinical decision-making is far more expansive than the CDS Guidance's cramped definition. It includes, for example, all the types of medical evidence listed in the U.S. Preventive

²⁰⁸ See *supra* notes 139–143 and accompanying text (displaying the breadth of what is included in common legal definitions of "medical information").

²⁰⁹ See CDS GUIDANCE, *supra* note 1, at 7.

²¹⁰ 21 U.S.C. § 360j(o)(1)(E)(i).

²¹¹ See CDS GUIDANCE, *supra* note 1, at 9.

²¹² See Ebell et al., *supra* note 114 (providing a meta-analysis of the quality of medical evidence that informs real-world clinical decisions); Howick et al., *supra* note 114 (same).

Services Task Force’s Grade Definitions²¹³ and in the Journal of the American College of Cardiology’s Classification of Recommendations and Level of Evidence scheme.²¹⁴ These sources have varying evidentiary quality, and not all would satisfy the CDS Guidance’s standard of being “independently verified and validated as accurate, reliable, not omitting material information, and supported by evidence.”²¹⁵ *Yet all are used to inform the professional speech of licensed physicians delivering clinical health care today.*

Beyond the publicly disseminated sources—such as clinical practice guidelines, information in FDA-approved labeling, and published case reports or clinical trial results—other medical information also includes insights physicians glean in real time, in the privacy of their own reasoning minds, based on experiences with past patients who were either similar to, or different from, the patient at hand. Unprocessed data about past patients is now, and has always been, a crucial part of the medical knowledge base physicians consider in real time when making clinical decisions. “Only for the simplest maladies (such as when a patient’s finger has a splinter in it that obviously should not be there) can health care providers treat one patient in informational isolation from others.”²¹⁶ Rare disease communities struggle to obtain effective clinical care for “‘n of 1’ single-instance medical mysteries” precisely because the base of “other medical information” lacks any information about past patients with the same malady to serve as comparators.²¹⁷

The constitutional harm in the CDS Guidance’s definitions is that they conceive “the practice of medicine” to be the 10–18% of clinical health care encounters in which physicians have the luxury of relying on information that is “independently verified and validated as accurate, reliable, not omitting material

²¹³ *Grade Definitions*, U.S. PREVENTIVE SERVS. TASK FORCE, <https://perma.cc/G2LD-RQTK>.

²¹⁴ See Jacobs et al., *supra* note 112, at 234 tbl. 4.3.

²¹⁵ See CDS GUIDANCE, *supra* note 1, at 9.

²¹⁶ Barbara J. Evans, *The HIPAA Privacy Rule at Age 25: Privacy for Equitable AI*, 50 FLA. ST. U. L. REV. 741, 758 (2023).

²¹⁷ *Id.*; see also Edward Hancock & Matt Might, *Genetic Testing and ‘Crowdscreening’ Enabling Precision Medicine, Faster Research*, SEVENBRIDGES BLOG (Dec. 14, 2015), <https://www.sevenbridges.com/matt-might-genetic-testing-crowdscreening-phenotypes-changing-medical-research-better> (discussing Matt Might’s quest for diagnosis and treatment of his son who had the first recorded case of a novel N-glycanase (NGLY1) deficiency, a congenital disorder of glycosylation).

information, and supported by evidence.”²¹⁸ Software processing high-quality information of this sort is, in FDA’s view, non-device medical practice software that physicians can appropriately manage without FDA oversight. Software processing any additional, lower-quality medical information is a device that FDA should regulate.

This position denies the reality that medical professionals are already navigating these lower-quality sources of other medical information in 82–90% of the decisions they make in current medical practice.²¹⁹ CDS tools processing such information could help physicians filter the available information and more accurately assess its relevance to the patients they are treating. The CDS Guidance presumes it is more dangerous to equip physicians with CDS tools to help filter, manage, and screen the relevance of such data than to leave physicians navigating the same data by hand. The CDS Guidance asserts that it is presumptively unsafe for physicians to use CDS tools that incorporate the full range of other medical information that physicians routinely work with today. FDA proposes to place prior constraints on physicians’ access to information derived using those tools, imposing a scheme of content-based regulation on their professional speech.

To borrow words from a federal judge hearing a First Amendment challenge to FDA’s policies in a different context: By deeming medical professionals incompetent to use such tools “until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe.”²²⁰ The role of the medical profession is to determine which parts of an uncertain medical knowledge base—including inferences drawn from preexisting, clinical-quality health data—are pertinent and sufficiently reliable to support clinical inferences about a specific patient. That has never been FDA’s role.

In *NIFLA*, the Supreme Court criticized speech regulations that are “under-inclusive”—that is, those that restrict some information flows that the government deems harmful while letting other, similar information flows continue.²²¹ The CDS Guidance hypothesizes that it is harmful for licensed physicians to process medical

²¹⁸ See CDS GUIDANCE, *supra* note 1, at 9.

²¹⁹ See *supra* note 114 and accompanying text.

²²⁰ Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 67 (D.D.C. 1998).

²²¹ Nat’l Inst. of Fam. & Life Advocs. v. Becerra (*NIFLA*), 138 S. Ct. 2361, 2375 (2018) (internal citations omitted).

information that is not “independently verified and validated as accurate, reliable, not omitting material information, and supported by evidence” without oversight by FDA.²²² To address this concern, the CDS Guidance proposes that FDA should regulate whether physicians can process such information *with the aid of a CDS tool*. Yet physicians already process such information every day *in their own reasoning minds*, and FDA has no jurisdiction to halt this latter form of information processing. If the hypothesized harm is as real as the CDS Guidance asserts, the regulatory measure it proposes is woefully incomplete and under-inclusive.

Fortunately, the hypothesized harm does not appear to be real: Licensed medical professionals, because of their training and expertise, routinely apply information of varying evidentiary quality in their clinical practice of medicine while maintaining high overall standards of patient safety and bearing the weight of malpractice liability if they fail to do so. If FDA seeks to restrict physicians’ access to CDS tools that process that same information, FDA first must bear its constitutional burden of showing that those tools are “reasonably likely to have serious adverse health consequences.”²²³ The CDS Guidance has not done so.

D. The CDS Guidance Sidesteps Congress’s Mandate to Oversee the Understandability of CDS Tools, a Key Provision of the Cures Act to Enhance Physician Autonomy

This final feature of the Guidance, unlike the previous three, does not necessarily raise constitutional concerns. It reflects a reasonable exercise of a regulator’s discretion, but one that could further diminish physician autonomy.

In the Cures Act, Congress left FDA with a limited residual role to backstop the medical profession’s oversight of software that analyzes “medical information about a patient” and “other medical information” to offer “recommendations” to a health care professional.²²⁴ Congress did not define those three terms in the Cures Act, which means they are to be construed as having their ordinary broad meanings, rather than the narrow meanings the CDS Guidance gives them. For software that meets these first two statutory criteria,²²⁵ the Cures Act envisions only three circumstances where FDA can regulate CDS tools:

²²² See CDS GUIDANCE, *supra* note 1, at 9.

²²³ 21 U.S.C. § 360j(o)(3)(A)–(C).

²²⁴ *Id.* § 360j(o)(1)(E)(i)–(ii).

²²⁵ *Id.*

- First, FDA can step in if it produces evidence that a software function is “reasonably likely to have adverse health consequences” and subjects that evidence to a 30-day public comment period.²²⁶
- Second, FDA can continue regulating software that acquires, processes, or analyzes medical images, signals from *in vitro* diagnostic devices, and patterns and signals from signal acquisition systems.²²⁷ The rules of statutory construction, as well as legislative history, strongly indicate that Congress understood this exception to be narrow and to refer to software that acquires images, signals, and results *directly* from an *in vitro* device or signal acquisition system.²²⁸
- Third, FDA can regulate CDS tools that fail to meet the final statutory criterion: that is, tools that are so inscrutable and incomprehensible that a health care professional using the software would be unable to understand or critique the basis of its recommendations.²²⁹

This third statutory criterion enhances physician autonomy in two ways. First, it strongly incentivizes software developers to invest in making CDS tools as transparent and explainable to physicians as possible. Doing so would help developers avoid the costs and burdens of falling under FDA regulation. Second, it ensures that if CDS tools are too incomprehensible for physicians to manage and control, FDA will vet the tools to ensure they are reasonably safe and effective for clinical use by physicians who may not be able to act as learned intermediaries standing between the software and the patient.

Rather than interpret the final statutory criterion and enunciate principles for applying it, the CDS Guidance offers a voluntary safe harbor. Developers will be deemed to satisfy this criterion if a CDS tool provides various labeling disclosures and software outputs.²³⁰ Unfortunately, these safe harbor provisions will not ensure that CDS tools measure up to the statutory standard, which requires that a health care provider be able to “independently review the basis for [the software’s]

²²⁶ *Id.* § 360j(o)(3).

²²⁷ *Id.* § 360j(o)(1).

²²⁸ See *supra* Part III.B (describing textual analysis and legislative history that support a narrow interpretation).

²²⁹ 21 U.S.C. § 360j(o)(1)(E)(iii).

²³⁰ See CDS GUIDANCE, *supra* note 1, at 14.

recommendations.”²³¹ The gap between the Guidance and the statute may be particular severe, for example, with deep learning neural networks.²³² The CDS Guidance’s safe harbor calls for sponsors to summarize “the logic or methods” the software relies on to make its recommendations and offers, as examples, disclosing that the software uses “statistical modeling” or “AI/ML techniques.”²³³ Simply disclosing that a deep neural network (which may internally represent data in a manner that has no “direct physical meaning”²³⁴) uses “AI/ML techniques” does little to ensure physicians will actually be able to understand the basis for its recommendations.

For this last criterion, the CDS Guidance sets a standard that is considerably more lenient than the statute. This lenient standard could allow black-box software, which Congress wanted FDA to regulate, to escape FDA oversight. The existence of the safe harbor undercuts incentives for software developers to invest in making their CDS tools more explainable. FDA’s approach to this final statutory criterion thus serves to erode physician control over the CDS tools they use.

The CDS Guidance invested major effort in construing the statute’s first two criteria in narrow ways that would, if followed, place most CDS tools under FDA regulation. With most CDS tools already consigned to FDA regulation under the CDS Guidance’s other criteria, the Guidance apparently used the safe harbor as a means of encouraging voluntarily compliance with various burdensome labeling requirements.

This approach relieved the agency of having to explain how it intends to enforce the statute’s final criterion. Enforcing this criterion seemingly would require the agency to enunciate standards and procedures for assessing whether CDS software is explainable to the user—an admittedly daunting challenge that the agency has

²³¹ 21 U.S.C. § 360j(o)(1)(E)(iii).

²³² See, e.g., Rich Caruana et al., *Intelligible Models for Healthcare: Predicting Pneumonia Risk and Hospital 30-Day Readmission*, ASS’N FOR COMPUTING MACH. KDD, Aug. 2015; Andreas Fischer, *How to Determine the Unique Contributions of Input-Variables to the Nonlinear Regression Function of a Multilayer Perceptron*, 309–10 *ECOLOGICAL MODELLING* 60, 63 (2015).

²³³ See CDS GUIDANCE, *supra* note 1, at 14.

²³⁴ Tim Albrecht et al., *Deep Learning for Single-Molecule Science*, 28 *NANOTECHNOLOGY* 1, 9 (2017).

consistently declined to face up to in the two drafts and in the final CDS Guidance.²³⁵

E. How the CDS Guidance Goes Beyond FDA's Past Attempts to Regulate Physicians' Speech

The CDS Guidance is not the first time FDA has sought to regulate the content of physicians' professional speech, but it differs fundamentally from past examples. Many of FDA's past efforts sought to control physician speech about FDA-regulated products.²³⁶ Yet recommendations flowing from a CDS tool are not claims *about the software*. Those recommendations are flows of processed (or reprocessed) medical information intended for a sophisticated audience: a licensed health care professional. Inputs to a CDS tool include various types of clinical-quality data already present in patients' medical records: for example, patient-specific images, signals, and pattern data collected using FDA-regulated medical devices, and real-world clinical outcomes data from the medical records of similarly situated past patients. The medical profession considers this information appropriate to use (and regularly uses it) in clinical decision-making. The recommendations from a CDS tool are themselves information. As the Supreme Court confirmed in 2011, "the creation and dissemination of information are speech within the meaning of the First Amendment."²³⁷

This section argues that the CDS Guidance marks a troubling expansion of FDA's past regulation of professional speech. It considers, first, the agency's past efforts to regulate what physicians can say about FDA-regulated products. It then discusses FDA's regulation of *in vitro* and *in vivo* diagnostic devices—diagnostic tests and imaging devices that, like CDS tools, also supply informational inputs to

²³⁵ See ADLER-MILSTEIN ET AL., *supra* note 3, at 17 (noting that "it is still not clear how the FDA plans to assess whether the third condition, bearing on the concept of explainability, has been met" and stressing that, "[w]ithout greater clarity on these matters, clinicians lack a sense of whether a given type of [CDS tool] usually is, or usually is not, subject to FDA oversight or what FDA's oversight process entails").

²³⁶ See discussion below in this subpart, providing examples of FDA's earlier efforts to regulate physicians' speech about FDA-regulated products.

²³⁷ *Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 570 (2011) (rejecting an argument advanced in an earlier case, *IMS Health v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), that informational outputs from data processing services are "a mere 'commodity' with no greater entitlement to First Amendment protection than 'beef jerky'").

physicians' professional speech.²³⁸ This section distinguishes both these types of speech regulation from the scheme proposed under the CDS Guidance.

Regulation of speech about FDA-regulated products. FDA's efforts in this area have centered on problematic devices such as Essure, a permanent birth control device for implantation in the Fallopian tubes that was approved in 2002 and withdrawn by its manufacturer in 2018 after a history of adverse events;²³⁹ breast implant devices, which carry meaningful risks including ruptures, follow-up surgeries, autoimmune disorders, and certain types of cancer;²⁴⁰ and Laser-Assisted In Situ Keratomileusis (LASIK) lasers used in popular outpatient surgeries that reshape the cornea to reduce dependency on eyeglasses but which, when things go wrong, can leave patients with visual loss, debilitating visual impairments, or severe dry eye syndrome.²⁴¹ FDA-regulated labeling for such products is directed at the physicians who implant or use the devices during surgeries. This makes the surgeon a critical link in conveying device warnings and risk information to patients. FDA has used various strategies to cajole, frighten, or force physicians to act as its mouthpiece.

For breast implants, FDA issued a non-binding guidance document in 2020 calling for physicians and patients, before surgery, to review and both sign a "Patient Decision Checklist" with FDA-recommended disclosures.²⁴² The following year, FDA issued an order "restrict[ing] the sale and distribution of breast implants to only health care providers and facilities that provide information to patients utilizing [FDA's] 'Patient Decision Checklist.'"²⁴³ Physicians wishing to perform

²³⁸ See *supra* note 142 (defining *in vivo* and *in vitro* diagnostic devices).

²³⁹ *FDA Activities Related to Essure*, U.S. FOOD & DRUG ADMIN. (Mar. 31, 2023), <https://www.fda.gov/medical-devices/essure-permanent-birth-control/fda-activities-related-essure>.

²⁴⁰ *Risks and Complications of Breast Implants*, U.S. FOOD & DRUG ADMIN. (Mar. 8, 2023), <https://www.fda.gov/medical-devices/breast-implants/risks-and-complications-breast-implants>.

²⁴¹ *What Are the Risks and How Can I Find the Right Doctor for Me?*, U.S. FOOD & DRUG ADMIN. (Aug. 18, 2018), <https://www.fda.gov/medical-devices/lasik/what-are-risks-and-how-can-i-find-right-doctor-me>.

²⁴² U.S. FOOD & DRUG ADMIN., *BREAST IMPLANTS – CERTAIN LABELING RECOMMENDATIONS TO IMPROVE PATIENT COMMUNICATION: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 5–6, 10–16* (2020), <https://www.fda.gov/media/131885/download>.

²⁴³ *FDA News Release: FDA Strengthens Safety Requirements and Updates Study Results for Breast Implants*, U.S. FOOD & DRUG ADMIN. (Oct. 28, 2021), <https://www.fda.gov/news-events/>

breast implant surgeries—and to have access to the supplies those surgeries require—are thus required to follow FDA's script during their informed consent process.

For LASIK procedures, FDA sent a series of letters to eye care professionals and professional societies starting in 2009. The agency expressed concern that “eye care professionals’ advertisements for LASIK procedures and FDA-approved lasers used for the LASIK procedures failed to inform consumers of the indications, limitations, and risks associated with LASIK procedures and the approved lasers.”²⁴⁴ FDA might have grounds under some circumstances to intervene if physicians mischaracterize *FDA-regulated devices*, but the agency has no basis to regulate what doctors can say about the *medical procedures* doctors perform. FDA's second letter threatened that “any person, including an eye care professional” could be subject to FDA enforcement action.²⁴⁵

In 2022, FDA published a draft guidance calling for a LASIK “Patient Decision Checklist” reminiscent of FDA's breast implant checklist.²⁴⁶ The draft LASIK guidance elicited over 700 public comments.²⁴⁷ Various surgeons, medical professional societies, and medical device manufacturers criticized FDA's proposed intrusion on the practice of medicine.²⁴⁸ A state Attorney General—after reciting how FDA's sales restrictions had transformed its non-binding breast cancer guidance

press-announcements/fda-strengthens-safety-requirements-and-updates-study-results-breast-implants.

²⁴⁴ *FDA Letter to Eye Care Professionals*, U.S. FOOD & DRUG ADMIN. (May 22, 2009), <https://www.fda.gov/medical-devices/lasik/fda-letter-eye-care-professionals-may-22-2009>; see also *FDA Letter to Eye Care Professionals*, U.S. FOOD & DRUG ADMIN. (Sept. 23, 2011), <https://www.fda.gov/medical-devices/lasik/fda-letter-eye-care-professionals-september-23-2011>; *FDA Letter to the American Society of Cataract and Refractive Surgery*, U.S. FOOD & DRUG ADMIN. (Mar. 20, 2012), <https://www.fda.gov/medical-devices/lasik/fda-letter-american-society-cataract-and-refractive-surgery-march-20-2012>.

²⁴⁵ *FDA Letter to Eye Care Professionals* (Sept. 23, 2011), *supra* note 244.

²⁴⁶ U.S. FOOD & DRUG ADMIN., *LASER-ASSISTED IN SITU KERATOMILEUSIS (LASIK) LASERS—PATIENT LABELING RECOMMENDATIONS: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF* (2022), <https://www.fda.gov/media/160239/download>.

²⁴⁷ See Docket No. FDA-2022-D-1253, REGULATIONS.GOV, <https://www.regulations.gov/docket/FDA-2022-D-1253> (last visited Apr. 14, 2024) (showing 749 public comments filed).

²⁴⁸ Roni Caryn Rabin, *Lasik Patients Should Be Warned of Complications, FDA Draft Says*, N.Y. TIMES, Dec. 7, 2022.

into a practically binding informed consent regulation—argued that “[r]egulating how doctors seek informed consent is a role reserved to the states” and noted that FDA has no authority to preempt states’ informed consent laws (especially not with a guidance document).²⁴⁹ Under this view, federalism is the key constraint on FDA’s authority to regulate physicians’ professional speech. That same comment did, however, note that FDA lacks authority “to regulate the information doctors give to their patients.”²⁵⁰ That edges closer to the nub of the matter: FDA’s attempts to regulate physician speech trigger First Amendment concerns.

Regulation of diagnostic products. A second major area where FDA arguably regulates professional speech is through its oversight of *in vitro* and *in vivo* diagnostic devices.²⁵¹ When FDA subjects diagnostic devices to premarket review, it is placing a prior restraint on physicians’ access to, and use of, the information such devices provide. Yet it is well established that FDA can regulate such devices—such as a diagnostic test kit or an X-ray machine—to ensure the device is reasonably safe and effective for use in clinical care.²⁵² FDA also can regulate software that receives inputs directly from that device as part of the workflow of producing and presenting the device’s informational output at the time testing is performed.²⁵³ Subject to constitutional limits imposed by the commercial speech doctrine,²⁵⁴ FDA can regulate labeling and promotional claims the product sponsor makes *about* these devices.

Professor Adam Candeub highlights a crucial distinction that helps explain why FDA can regulate hardware *in vitro* and *in vivo* diagnostic devices (which produce informational inputs to physicians’ speech, such as diagnostic test results and medical images), while facing First Amendment constraints on its regulation of

²⁴⁹ Comment from Daniel Cameron, Att’y Gen. of Ky., to U.S. Food & Drug Admin. 2, 4 (Nov. 24, 2022), <https://www.regulations.gov/search/comment?filter=FDA-2022-D-1253-0520>.

²⁵⁰ *Id.* at 3.

²⁵¹ See *supra* note 142 (defining *in vitro* and *in vivo* diagnostic devices).

²⁵² See generally Candeub, *supra* note 133, at 953–65 (arguing that “FDA stands on firm legal ground regulating medical devices that invasively measure bodily functions or take actual physical specimens” but its exercise over tools “that simply process information . . . or use approved medical devices to provide medical information raises serious legal concerns”).

²⁵³ See *supra* fig. 1, exception 1.

²⁵⁴ See generally Wiersum, *supra* note 85 (discussing application of the commercial speech doctrine in FDA-related cases).

CDS tools (which also produce informational inputs to physicians' speech).²⁵⁵ Under his analysis, *in vivo* and *in vitro* devices interact with physical reality (e.g., a biospecimen taken from a patient's body or a condition existing within the patient's body), and FDA's oversight ensures that the information they extract from physical reality bears a reasonable relationship to that reality.²⁵⁶ In contrast, CDS tools process patient-specific and other medical information that already has been extracted from physical reality and deemed suitable for use in clinical health care (and is, in many cases, already recorded in patients' medical records). Whereas *in vitro* and *in vivo* diagnostics convert physical reality into information, CDS tools turn information into new insights and information, according to this argument.

Readers skeptical that this distinction is constitutionally significant might try the following alternative argument: The Court in *NIFLA* maintained that government agencies cannot impose content-based restrictions on speech without "'persuasive evidence . . . of a long (if heretofore unrecognized) tradition' to that effect."²⁵⁷ There is a long, well recognized tradition allowing FDA to regulate hardware *in vitro* and *in vivo* diagnostic devices and software that is a component of, or accessory to, such devices. There is no similar tradition for CDS tools. Yet it is deeply unsatisfying to advance this as the crucial distinction. Under this view, FDA's regulation of *in vitro* and *in vivo* diagnostics under the Medical Device Amendments of 1976 "slipped in under the wire" before a flood of post-1990 commercial speech cases highlighted First Amendment problems with FDA oversight, whereas CDS tools arrived too late to establish a similarly long tradition.²⁵⁸ Nobody wants First Amendment protection to be so arbitrary.

Below, I argue that Professor Candeub's view is correct, but explaining why this is so requires further detail about how regulatory oversight of diagnostic products works. FDA considers three factors when assessing whether a diagnostic device is

²⁵⁵ See Candeub, *supra* note 133, at 958–63 (explaining how a nexus with physical reality is integral to Congress's definition of a device that FDA can regulate and that the terms Congress chose in the device definition all "point to items that have physical effects in the world").

²⁵⁶ *Id.*

²⁵⁷ Nat'l Inst. of Fam. & Life Advocs. v. Becerra (*NIFLA*), 138 S. Ct. 2361, 2372 (2018) (internal citations omitted).

²⁵⁸ See generally Cortez, *supra* note 84 (surveying important post-1990 FDA commercial speech cases).

reasonably safe and effective. The first factor is physical risks of the testing modality itself, and the second and third factors address informational risks of the test results.

This first factor, the physical risk of testing, is minimal for *in vitro* diagnostic tests that only require a blood draw or urine specimen but potentially serious for *in vitro* tests requiring specimens retrieved through invasive surgical biopsies. There also can be significant risks for *in vivo* imaging tests that expose patients to toxic chemicals or radiation, as was the case when CT brain perfusion scans left patients with a “freakish band” of baldness circling horizontally around their heads, leaving tufts of hair on top of the head and below a wide bald stripe.²⁵⁹ Regulating diagnostic devices to ensure they do not over-irradiate patients raises no speech concerns.

Next, FDA assesses whether the test *results* are safe and effective by reviewing evidence of two additional factors: analytic and clinical validity.²⁶⁰ Analytic validity refers to how accurately and reliably a diagnostic device detects the presence or absence of the “analyte”—the characteristic of reality, such as a genetic variant, disease-causing pathogen such as streptococcus, or a fractured bone—that the test purports to detect.²⁶¹ Clinical validity refers to whether the presence or absence of the analyte provides clinically meaningful information about a person’s state of health, and it depends on the evolving state of scientific knowledge about the role the analyte plays in causing or preventing disease.²⁶²

²⁵⁹ See Walt Bogdanich, *After Stroke Scans, Patients Face Serious Health Risks*, N.Y. TIMES, July 31, 2010 (providing photographs of patient injuries).

²⁶⁰ See INST. OF MED., POLICY ISSUES IN THE DEVELOPMENT OF PERSONALIZED MEDICINE IN ONCOLOGY 27 (2010) (statement of Dr. Alberto Gutierrez, U.S. Food & Drug Admin., Off. of In Vitro Diagnostic Devices) (stating that FDA bases its review of *in vitro* diagnostics on a review of analytic and clinical validity); see also U.S. SEC’Y’S ADVISORY COMM. ON GENETIC TESTING, ENHANCING THE OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT 15 nn.10–11 (2000) (defining analytic/analytical and clinical validity of test results). *But see* U.S. FOOD & DRUG ADMIN., DEVELOPING ANALYTICAL STANDARDS FOR NGS TESTING (2015) (discussion paper from an FDA public workshop presenting a standards-based approach to evaluating the performance of Next Generation Sequencing *in vitro* diagnostic tests, using the closely related but slightly different concepts of “analytical performance” and “clinical performance” instead).

²⁶¹ See U.S. SEC’Y’S ADVISORY COMM. ON GENETIC TESTING, *supra* note 260, at 15 n.10 (defining analytic validity as how well a test detects, identifies, calculates, or analyzes the presence or absence of the particular physical characteristic it is designed to detect).

²⁶² See *id.* at 15 n.11 (defining clinical validity as how strongly the measured characteristic is correlated with the presence, absence, or risk of a specific disease or other health condition).

The difference between analytic and clinical validity was on display during the COVID pandemic, as analytically valid tests became available to detect COVID antibodies. At first, scientists hoped that the presence of antibodies in a person's blood meant that the person could no longer catch COVID, but it later turned out that people with antibodies could still be reinfected.²⁶³ The tests had analytic validity for detecting the antibodies, but not clinical validity for predicting future immunity, and scientists' understanding of the tests' clinical validity evolved over time as people with antibodies got sick.

FDA's premarket review of *in vitro* diagnostic test kits and *in vivo* diagnostic devices clearly imposes a prior restraint on professional speech: Physicians cannot receive diagnostic information from these devices until FDA clears or approves them for clinical use.²⁶⁴ This is speech regulation, but it does not violate the First Amendment, I argue, because FDA nuances the scope of its premarket review in ways that would survive scrutiny even under a strict or intermediate standard.²⁶⁵ Claims of analytic validity and claims of clinical validity are different types of speech and raise different concerns about the scope of permissible regulation, and FDA nuances its oversight of hardware medical devices accordingly.

Claims of analytic validity are statements of fact, susceptible to objective proof one way or the other: Does the patient have, or not have, the analyte this test is designed to detect?²⁶⁶ Analytic validity addresses Professor Candeub's concern about whether the information tests extract from physical reality bears a reasonable relationship to that reality.²⁶⁷ For many tests, analytic validity is easily verified by running the test on "well-characterized" biospecimens in which the analyte is already known to be present or absent through prior use of independent testing methods. Proving analytic validity continues to be challenging for genomic tests (where a test's accuracy can vary across different regions of the genome and for

²⁶³ *Based on Science: Having Antibodies to the Novel Coronavirus Is Not the Same Thing as Having Immunity to COVID-19*, NAT'L ACADS. SCI., ENG'G & MED. (Oct. 4, 2022), <https://www.nationalacademies.org/based-on-science/having-antibodies-to-the-novel-coronavirus-is-not-the-same-thing-as-having-immunity-to-covid-19>.

²⁶⁴ See generally INST. OF MED., MEDICAL DEVICES AND THE PUBLIC'S HEALTH, *supra* note 148 (discussing FDA's 510(k) and premarket approval processes for medical devices).

²⁶⁵ See discussion *infra* this subsection.

²⁶⁶ See *supra* note 261.

²⁶⁷ See *supra* notes 255–256 and accompanying text.

different gene variant types) and for tests that detect novel or rare analytes for which well-characterized specimens are unavailable.²⁶⁸

False statements of fact receive First Amendment protection in some settings where falsehoods would cause little harm or where excessive fact-checking might chill speech that is true.²⁶⁹ However, propagating factually incorrect information about a patients' analytes is not an example where "[f]alse factual statements can serve useful human objectives."²⁷⁰ Regulatory oversight of analytic validity raises few First Amendment concerns and is a common feature both in FDA's oversight of diagnostic test kits and in the regulation of clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988.²⁷¹

Claims of clinical validity are in the nature of expert medical opinion or scientific speech: Does the fact that a patient has a specific analyte support valid scientific inferences about their state of health? Here, FDA's oversight is more nuanced. Manufacturers are not required to make clinical claims and have the option of marketing a diagnostic test kit with analytical claims only: for example, simply claiming that the test kit accurately and reliably detects COVID antibodies, without suggesting that this information supports inferences that the patient is immune to future COVID infections. It is then left up to physicians to determine, in their expert judgment, whether and how to make use of the analytically valid test result. The same is true of many *in vivo* devices. If an X-ray machine produces analytically accurate images of bones, its manufacturer may not need to add a clinical claim that this information is "useful for diagnosing bone fractures." The doctor viewing such an

²⁶⁸ See Barbara J. Evans et al., *How Can Law and Policy Advance Genomic Analysis and Interpretation for Clinical Care?*, 48 J.L. MED. & ETHICS 44, 48 (2020) (discussing the challenges of assessing analytic validity for genomic tests); see Bin Chen et al., *Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases and Conditions*, MORBIDITY & MORTALITY WKLY. REP., June 12, 2009, at 1, 5 (discussing problems with availability of well-characterized specimens to use to verify the analytic validity of certain types of tests).

²⁶⁹ See, e.g., *United States v. Alvarez*, 567 U.S. 709 (2012) (striking down a statute that made it a crime to lie about having received military decorations or medals); see generally Helen Norton, *Lies and the Constitution*, 2012 SUP. CT. REV. 161 (2012) (surveying theories for affording First Amendment protection to at least some types of factually incorrect speech).

²⁷⁰ *Alvarez*, 567 U.S. at 733 (Breyer, J., concurring).

²⁷¹ Act of Oct. 31, 1988, Pub. L. No. 100-578, 102 Stat. 2903 (codified as amended at 42 U.S.C. § 263a).

image in the clinical setting can determine whether the image supports such a diagnosis for the patient at hand.

If a manufacturer elects to make clinical claims in its device labeling, FDA requires the manufacturer to supply evidence supporting that the claim is true, on average, for the population of patients for whom the manufacturer intends the device to be used. For example, the prostate-specific antigen (PSA) test was intended for surveillance and prognostic use in men already diagnosed with prostate cancer, and FDA reviewed evidence of clinical validity for that use.²⁷² The PSA test labeling does not claim the test has clinical validity for use in screening healthy men to detect possible new cases of prostate cancer.²⁷³ Physicians widely use the test for this latter purpose, but its clinical validity is unconfirmed.²⁷⁴ FDA only requires evidence of analytic and clinical validity for the manufacturer's intended use. Physicians are free to use the analytically valid information the test provides when formulating expert advice for patients both within and outside of the intended user population.²⁷⁵

Returning to Professor Candeub's analysis: Why is FDA's regulation of *in vitro* diagnostic test kits constitutionally acceptable, while FDA regulation of medical software raises concerns? FDA's premarket review of diagnostic hardware devices provides a reasonable assurance that their analytic validity has received at least some form of evidence-based regulatory review before devices can move into clinical use. This review helps ensure a device faithfully portrays the underlying reality—the analyte—that it tests and helps prevent provably false information from entering a setting (clinical care) where it could cause serious harm. FDA's oversight of diagnostic testing hardware does not, however, include an evidence-based premarket review of clinical validity in every instance. Clinical validity is a matter of scientific opinion, evolving over time and entitled to strong First Amendment protection to avoid chilling the professional "disciplinarity and social practices"

²⁷² NAT'L CANCER POLICY FORUM, INST. OF MED., DEVELOPING BIOMARKER-BASED TOOLS FOR CANCER SCREENING, DIAGNOSIS, AND TREATMENT: WORKSHOP SUMMARY 70 (Margie Patlak & Sharyl Nass rapporteurs, 2006) (reporting presentation of Dr. Scott Ramsey).

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ 21 U.S.C. § 396.

through which it evolves.²⁷⁶ Accordingly, FDA limits the scope of its premarket review of the clinical validity of hardware diagnostic devices to claims the manufacturer asserts to be true, on average, for the test's intended user population. Assessing whether an analytically valid test result supports clinically valid inferences about the state of an individual patient's health would require additional patient-specific information—available to the treating physician—that FDA does not have.

FDA's proposed regulation of CDS tools is distinguishable. When CDS tools process data from patient medical records, they are processing data that the medical profession already regards as clinical-quality data, including images, signals, and pattern data from FDA-regulated *in vitro* diagnostic devices and signal acquisition systems. The analytic validity of this information is not in question. Thus, the principal justification for FDA's regulation of diagnostic hardware devices is absent for CDS tools that process clinical-quality health information from patients' medical records.

Beyond that, all of the reasons why FDA takes a light-handed approach to regulating the clinical validity of diagnostic hardware apply with equal force here. If a software developer makes claims that the software's recommendations are clinically valid, on average, for the software's intended patient population, then FDA certainly would be justified in requiring evidence to support those claims. However, assessing whether the software produces valid inferences for a specific patient requires information that only the treating physician—rather than FDA—possesses. The Cures Act envisions that such determinations should be confided to the medical profession, and not to FDA, as long as the software enables the “health care professional to independently review the basis for” its recommendations “so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.”²⁷⁷

As long as the physician using a CDS tool would be able to understand and critique the basis of its recommendations, Congress confides the task of assessing the clinical validity of its recommendations to the medical profession rather than to FDA. The Cures Act does not deny that the clinical validity of CDS tools is an important concern; it merely specifies who is responsible for assessing it. If, on the

²⁷⁶ See Blocher, *supra* note 73, at 491.

²⁷⁷ 21 U.S.C. § 360j(o)(1)(E)(iii).

other hand, a CDS tool is an inscrutable black box providing recommendations whose basis physicians would be unable to review, then Congress assigns this responsibility to FDA.²⁷⁸

Under the CDS Guidance, as now written, FDA's decision to impose a prior restraint—FDA premarket review—on a CDS tool depends on the *types of information* the tool uses as its inputs. The medical profession considers patient-identifiable medical images, signals, and pattern data stored in a patient's medical record to be admissible and relevant to inform their professional speech to patients. Under the Guidance, however, physicians would not be able, without FDA's permission, to use a CDS tool to help them process those data types. The same is true of real-world outcomes data from past patients: Physicians throughout history have relied on such data to inform their expert advice to current patients, but the CDS Guidance would place a prior restraint on their freedom to use a CDS tool to help them sift through these same data.

The CDS Guidance would restrict physicians' access to an important source of information to inform their professional speech. Unlike FDA's past regulation of what physicians can say *about FDA-regulated devices*, this amounts to regulating what physicians can say *about their patients' health and health care*.

Inferential knowledge gleaned by CDS tools is an increasingly important part of the medical knowledge base. Modern health laws enacted after the 1847 AMA Code of Ethics have long treated medical professionals, rather than the government, as the best judge of which sources of medical information are admissible and relevant to clinical decision-making.²⁷⁹ There is no “‘persuasive evidence . . . of a long (if heretofore unrecognized) tradition’”²⁸⁰ allowing FDA to impose content-based regulations on physicians' access to desired informational inputs. “The citizen [including a physician] is entitled to seek out or reject certain ideas and influences without Government interference or control.”²⁸¹

Justice Kennedy's remark in an earlier First Amendment case aptly summarizes the position medical professionals face in today's AI-enabled health care system: “Technology expands the capacity to choose, and it denies the potential of this

²⁷⁸ *Id.*

²⁷⁹ See BURROW, *supra* note 92; Chase-Lubitz, *supra* note 93.

²⁸⁰ Nat'l Inst. of Fam. & Life Advocs. v. Becerra (*NIFLA*), 138 S. Ct. 2361, 2372 (2018).

²⁸¹ United States v. Playboy Ent. Grp., Inc., 529 U.S. 803, 817–18 (2000).

revolution if we assume the Government is best positioned to make these choices for us.”²⁸² Once clinical-quality, analytically valid data have been created and reported—for example, into a patient’s medical record—they are simply a form of medical information. FDA’s power to restrict further use and processing of that information is subject to First Amendment constraints.

IV. THE PRACTICAL BINDING EFFECT OF FDA’S NON-BINDING CDS GUIDANCE

It is axiomatic that federal agencies like FDA only have as much regulatory authority as Congress gives them through statutes like the Cures Act. An agency cannot expand its authority beyond what Congress gave it, and this is true regardless of whether the agency acts through a regulation or through a guidance, because neither of those instruments can rewrite a statute. FDA officials acknowledged as much in an October 18, 2022 Webinar about the CDS Guidance, reassuring listeners that “there’s no product that was previously not a device that becomes a device as a result of finalization of this guidance.”²⁸³ That states the obvious: A guidance cannot make a product be a device unless the statute says it is a device. Left unsaid was that a guidance can cause people to *believe* a product is a device and voluntarily submit to device regulation even when the statute does not require them to do so.

Voluntary compliance is key to the art of regulating by means of guidance. Guidances are non-binding, which means FDA cannot punish people for disobeying its CDS Guidance unless the agency can also prove they disobeyed the Cures Act itself.²⁸⁴ When a guidance misstates a statute, an agency seemingly would be unable to prove that ignoring the guidance amounts to a statutory violation. The guidance would be unenforceable: No court would force you to obey it. Even so, a non-binding guidance often induces “grudging compliance, ‘even when the doubts as to the lawfulness of the [guidance] are substantial.’”²⁸⁵ The practical reality is that even a flawed guidance document “still establishes the law for all those unwilling to

²⁸² *Id.* at 818.

²⁸³ See *Clinical Decision Support Software—Final Guidance*, *supra* note 206, at 19 (remarks of Brendan O’Leary, Deputy Director, Digital Health Center of Excellence at FDA).

²⁸⁴ Mark Seidenfeld, *Substituting Substantive for Procedural Review of Guidance Documents*, 90 TEX. L. REV. 331, 347 (2011).

²⁸⁵ Sean Croston, *The Petition is Mightier Than the Sword: Rediscovering an Old Weapon in the Battles Over “Regulation Through Guidance,”* 63 ADMIN. L. REV. 381, 387 (2011) (alteration in original) (quoting William Funk, *A Primer on Nonlegislative Rules*, 53 ADMIN. L. REV. 1321, 1340 (2001)).

pay the expense, or suffer the ill-will of challenging the agency in court.”²⁸⁶ If nobody has the courage, patience, or resources to challenge it, a guidance is said to be “practically binding.”²⁸⁷

Guidances are especially hard to challenge in court. Regulations that misstate a statute can be challenged right away in court and set aside before the agency even tries to enforce them. With rare exceptions,²⁸⁸ courts hesitate to hear challenges to guidances before the agency actually enforces them. “Even assuming standing to sue can be shown, a guidance document may not be considered final agency action or ripe for review.”²⁸⁹ In a number of past cases, even after the agency sent warning letters based on a questionable guidance, “the FDA invariably argued that the controversy was not ripe for review. If a company voluntarily corrected the violations of federal law alleged in a warning letter . . . then it lost any chance to challenge the legal basis for FDA’s objections.”²⁹⁰

To obtain judicial review of the CDS Guidance, an FDA-regulated company seemingly “would have to wait until it’s in the throes of an enforcement action requiring compliance.”²⁹¹ Courts can protect you from unlawful governmental coercion but, short of that, courts cannot protect you from your own choice to take a path you perceive as safer amid uncertainty. In the October 18 Webinar, FDA

²⁸⁶ Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 167 (2000).

²⁸⁷ See Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like: Should Agencies Use them to Bind the Public?*, 41 DUKE L.J. 1311, 1315 (1992).

²⁸⁸ See *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000) (“[A]n agency’s [guidance document] can as a practical matter, have a binding effect. If an agency acts as if a document issued at headquarters is controlling in the field, if it treats the document in the same manner as it treats a legislative rule . . . [and] if it leads private parties . . . to believe that [the agency] will [apply the policy expressed in the document], then the agency’s document is for all practical purposes ‘binding.’”).

²⁸⁹ Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 420 (2007).

²⁹⁰ See Noah, *supra* note 172, at 126–27.

²⁹¹ Bradley Merrill Thompson, *FDA’s Final Guidance on Clinical Decision Support Violates the Law*, LINKEDIN (Sept. 27, 2022), <https://www.linkedin.com/pulse/fdas-final-guidance-clinical-decision-support-law-thompson-rac>.

officials invited software developers “to reach out to us”²⁹²—suggesting a strategy of “encouraging ‘voluntary’ compliance with a request that the agency could not impose directly on a regulated entity.”²⁹³

Physicians, though not directly regulated by the CDS Guidance, will incur an immediate First Amendment injury if regulated companies voluntarily comply with the Guidance. The CDS Guidance is not merely deciding whether a hardware device should be made available for physicians to use in their best judgment. Rather, it seeks to regulate flows of information medical professionals need in order to *form* their best judgments. Courts display a reluctance to view information itself as an FDA-regulable “product” because of its intangibility, out of reluctance to hinder free flows of information in society, and because of First Amendment/free speech concerns.²⁹⁴

Courts have, however, displayed willingness to allow pre-enforcement challenges to FDA guidance documents and unofficial policies when First Amendment rights are at stake. An example of this phenomenon was *Washington Legal Foundation v. Kessler*, a First Amendment challenge to an FDA policy restricting product manufacturers’ ability to send copies of medical textbook chapters and published articles describing off-label uses of their products to physicians.²⁹⁵

The case is cited here simply for the fact that it withstood the initial barriers that so often stymie pre-enforcement challenges to non-binding agency policies and guidance documents. FDA argued the case was not ripe for review because the agency was still developing a final policy and further argued that the physician plaintiffs lacked standing to challenge the policy, which targeted drug and device manufacturers. Nevertheless, the D.C. Circuit court allowed the challenge to move forward, noting that FDA’s actions, though aimed at manufacturers, “have resulted in a significant curtailment of this source of information to doctors” and “there

²⁹² See *Clinical Decision Support Software—Final Guidance*, *supra* note 206, at 19; see also *id.* at 15 (making a similar call for software developers to “reach out to the digital health inbox” at FDA).

²⁹³ Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901, 906 (2008).

²⁹⁴ Joseph L. Reutiman, *Defective Information: Should Information Be a Product Subject to Products Liability Claims*, 22 CORNELL J.L. & PUB. POL’Y 181, 188–90 (2012).

²⁹⁵ 880 F. Supp. 26 (D.D.C. 1995).

exists an enforceable First Amendment right to receive information.”²⁹⁶ The court also noted the “gravity” of the allegation that FDA was impairing physicians’ First Amendment rights and that “access to the courts is essential to the decision of such questions.”²⁹⁷ The agency argued that product manufacturers were free to disregard the “advice” in its policy, but the court noted the immense pressures favoring voluntary compliance and concluded that the challenge was ripe for review.²⁹⁸

FDA’s CDS Guidance presents similar concerns. “The law is clear that where a law or other official act has resulted in the silencing of an otherwise willing speaker, those who wished to receive information from that speaker may challenge the constitutionality of the law or act.”²⁹⁹ The practical binding effect of FDA’s CDS Guidance threatens immediate injury to the free speech rights and the autonomy not just of physicians but of their listeners: patients seeking the best-informed professional advice they can receive as they grapple with difficult and potentially life-altering medical decisions. Physicians and patients have cause to challenge the CDS Guidance now.

CONCLUSION

In a 1997 report to Congress, the U.S. Department of Health & Human Services (HHS) described the strains information technology has placed on the traditional medical information ecosystem.³⁰⁰ FDA’s six-year struggle to issue its final CDS Guidance exemplifies those strains.

Traditionally, clinical inferences—the inferences physicians draw about what is wrong with a patient and how best to treat it—took place within the minds of “our family doctors.”³⁰¹ Insights physicians gained while treating past patients have always informed their clinical inferences about current patients. When CDS tools assist that same reasoning process that previously took place inside the family doctor’s brain, there is a risk that policymakers may overreact and fail to recognize that drawing patient-specific inferences—whether with software or with gray matter—

²⁹⁶ *Id.* at 31.

²⁹⁷ *Id.* at 33.

²⁹⁸ *Id.* at 36–37.

²⁹⁹ *Id.* (citing *Va. State Bd. of Pharmacy v. Va. Citizens’ Consumer Council*, 425 U.S. 748, 756–57 (1976)).

³⁰⁰ HHS, 1997 RECOMMENDATIONS, *supra* note 130.

³⁰¹ *Id.* at pt. I.

is the very core of the practice of medicine and lies outside FDA's regulatory mandate.

In that same 1997 Report to Congress, HHS framed the challenge as being to preserve longstanding norms of medicine on an altered landscape of massively decentralized health care mediated by large-scale electronic information flows.³⁰² At the outset, HHS studied the informational norms and data flows that traditionally supported clinical health care and “carefully examined the many uses that the health professions, related industries, and the government make of health information.”³⁰³ The challenge that lay ahead, in HHS's view, would be to protect those traditional medical informational norms and data uses on a vastly altered modern health care landscape where vast “networks of insurers and health care professionals” are linked by automated systems making electronic transfers of “secrets . . . from doctors to hospitals to insurance companies.”³⁰⁴ The goal of federal policy, HHS concluded, should be to protect patients while preserving essential information flows on which the practice of medicine has always relied.

FDA is an HHS agency and, as such, should embrace that goal. The goal is not for FDA to supplant the role medical professionals have traditionally played in the medical information ecosystem. Physicians' role requires managing a vast medical knowledge base, which includes diverse sources of information of varied evidentiary quality and also includes vast stores of as-yet-unprocessed medical records that may be pregnant with untapped insights about how to diagnose and treat future patients.

As Congress recognized in the Cures Act, and as the U.S. framework of health law has recognized for 175 years, that knowledge base is best managed by trained medical professionals rather than by government officials. Automated systems processing information from that knowledge base produce new insights that, in turn, become part of that knowledge base. These systems should in the first instance be governed by the medical profession.

³⁰² *Id.* § I.I.

³⁰³ *Id.* at pt. I.

³⁰⁴ *Id.*