The Commercial Speech Doctrine in Health Regulation: The Clash Between the Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm

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The Commercial Speech Doctrine in Health Regulation: The Clash Between the Public Interest in a Robust First Amendment and the Public Interest in Effective Protection from Harm

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I. INTRODUCTION

Historically, government has been given more leeway when invoking its interests in safeguarding the public health than when asserting other state interests. Thus, for example, when considering a constitutional challenge to mandatory smallpox immunization in *Jacobson v. Massachusetts*, the Supreme Court employed its highly deferential, rational basis review rather than the stricter level of scrutiny that it normally employs when individuals assert interests in bodily integrity.† Similarly, Congress and the Food and Drug Administration (FDA) have imposed greater restrictions on the speech of pharmaceutical companies than have been considered acceptable for speech in other commercial settings.

In recent years, however, it appears that a trend is developing toward applying the same level of constitutional scrutiny to health regulation. In *Abigail Alliance*, a three-judge panel in the U.S. Court of Appeals for the D.C. Circuit overrode FDA regulations to recognize a constitutional right of access for patients to experimental chemotherapy.‡ In *Western States*, the U.S. Supreme Court struck down advertising restrictions imposed on pharmacies by Congress.§

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§ *Abigail Alliance for Better Access to Dev. Drugs v. von Eschenbach (Abigail II)*, 445 F.3d 470, 486 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007). To be sure, the en banc D.C. Circuit reversed the panel's decision fifteen months later.
To some extent, it makes sense to treat health regulation more like other kinds of regulation. Government may be too quick to sacrifice individual liberty when threats to health loom. However, courts may be overcompensating in their efforts to right the balance between individual liberties and the public's interest in good health.

In this article, I consider the balance between liberty and health in the context of the right to speak. More specifically, I examine the commercial speech doctrine and suggest how courts should draw the balance between state interests in public health and corporate interests in promotional speech. I argue that there are two important doctrines for retaining some special treatment of public health concerns. First, rather than following the Jacobson principle of deference to legislative judgment, courts should follow the principle of deference to the judgment of public health officials that was enunciated in School Board of Nassau County v. Arline. Second, courts should invoke the principle of trust and its concomitant duty of loyalty to adequately recognize the interests of individuals in not having their relationships with physicians, pharmacists, and other health care providers exploited for the providers' personal gain.

II. THE PRIVILEGED STATUS OF HEALTH CARE

For much of the twentieth century, the Supreme Court treated health care matters differently than issues arising in other industries or settings. When private or public actors invoked health concerns to justify their conduct, the Court often expressed less skepticism than when other reasons were invoked for public or private conduct. Thus, for example, for many years the Court did not apply antitrust law against health care providers as aggressively as it did against individuals or companies in other businesses, until it changed course in the 1970s.

While the special status of health care has influenced doctrine in a number of legal fields, including tort and contracts law, this article focuses on its special status in constitutional law. More specifically, this article focuses on the special status of public health justifications in constitutional law. After describing the Supreme Court's historic principle of deference when governments invoked health concerns, the article describes a current trend toward treating health concerns like other state interests.

A. PUBLIC HEALTH INTERVENTIONS AND THE CONSTITUTION

The Supreme Court's jurisprudence in matters of public health dates back to its 1905 opinion in Jacobson v. Commonwealth of Massachusetts. In that case, Henning Jacobson objected to a local regulation that required him to

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* See Mark A. Hall, Mary Anne Bobinski & David Orentlicher, Health Care Law and Ethics 1296 (7th ed. 2007).
* See id. at 1171, 1296.
receive a smallpox vaccination. The regulation was authorized under a state statute, and the Court considered the constitutionality of the statute. What is striking about the Court's opinion is its broad deference to the judgment of the state legislature. According to the Court, the Constitution was not offended by the statute because it did not represent an "unusual, . . . unreasonable or arbitrary requirement." It did not go "far beyond what was reasonably required for the safety of the public," nor did it lack a "real" relationship with the public health interests at stake.

Of course, the Court rarely strikes down a statute when it requires only that the law not be unreasonable or arbitrary. This is the language of rational basis review, language that the Court invokes when it is not receptive to an individual's interest in escaping the reach of a law. Indeed, while the Court referred to Mr. Jacobson's interests in exercising free will, caring for his body, and controlling his body, the Court did not suggest that the interests had special importance. This oversight cannot be explained by the fact that the case was decided well before the Supreme Court began to develop its fundamental rights doctrine in the 1960s and 1970s. Just fourteen years before Jacobson, in Union Pacific Railway Co. v. Botsford, the Court wrote that "[n]o right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person."

Jacobson's principle of deference to government officials on matters of public health lived on for decades. Thus, in the 1992 Adams case, when prostitutes challenged a state statute that required them to be tested for HIV-infection, the Illinois Supreme Court cited Jacobson for the proposition that "the States have been allowed broad discretion in the formulation of measures designed to protect and promote public health." The Illinois court saw no fundamental rights being implicated by the forced testing and required only that the statute bear "a rational relationship" to the state's public health goals. Because the court employed rational basis review, it could uphold the statute even though medical experts testified that the testing policy was ineffective and possibly counterproductive to the protection of the public's health. In short, the Justices in Jacobson and Adams allowed legislative officials broad discretion in shaping public health policy.

Or consider the U.S. Supreme Court's decision in Whalen v. Roe. In that case, the Court reviewed a challenge to a New York law that provided for a

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8 Id. at 22.
9 Id. at 24.
10 Id. at 27.
11 Id. at 28.
12 Id. at 31.
13 Id. at 26, 29.
14 See id. at 26 ("There are manifold restraints to which every person is necessarily subject for the common good . . . . This court has more than once recognized . . . . that 'persons' . . . . are subjected to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the state . . . .").
17 Id. at 586.
18 Id. at 577.
computerized database to track drug prescriptions for controlled substances.\textsuperscript{20}

In deciding whether the state’s interest in limiting problems with drug abuse could justify the invasion of patient privacy, the Court observed that “States have broad latitude in experimenting with possible solutions” and that the statute was the “product of an orderly and rational legislative decision.”\textsuperscript{21}

III. THE EROSION OF HEALTH CARE’S PRIVILEGED STATUS

In recent years, however, the Supreme Court and lower federal courts have demonstrated a greater willingness to challenge the public health justifications that governments advance to justify their limitations on individual liberties.

A. \textit{Abigail Alliance}

\textit{Abigail Alliance} involved a claim that terminally ill adult patients should be able to purchase experimental drugs that had not yet been approved for sale by the FDA, once the patients had exhausted all other FDA-approved treatment options.\textsuperscript{22}

Under long-standing FDA policy, pharmaceutical companies need to test new drugs in successive research trials and submit the data from the studies to the FDA for approval of the drugs.\textsuperscript{23} In the absence of FDA-approval, the companies are prohibited from marketing a new drug. They can make it available only for limited purposes—to patients who participate in one of the research trials or to a small number of patients whose use of the drug is approved by the FDA under its “compassionate use” program.\textsuperscript{24}

Because the process for conducting the research trials and receiving FDA approval can take many years, terminally ill patients may die while waiting for a drug that might prolong their lives.\textsuperscript{25} The plaintiffs in \textit{Abigail Alliance} therefore asked the court to require a revision of FDA restrictions on access to experimental drugs for terminally ill patients.\textsuperscript{26} More specifically, the plaintiffs asked the court to allow the sale of experimental drugs once they passed through the first stage of testing for safety but before they passed through the later stages of testing for both safety and effectiveness.\textsuperscript{27}

The FDA opposed the plaintiffs’ request on the grounds that making cancer chemotherapy available before completion of the drug testing process would fail to recognize the “importance of marketing drugs with reasonable

\textsuperscript{20} \textit{Id.} at 591.
\textsuperscript{21} \textit{Id.} at 597.
\textsuperscript{22} \textit{Abigail II}, 445 F.3d 470, 472 (D.C. Cir. 2006), \textit{rev’d en banc}, 495 F.3d 695 (D.C. Cir. 2007).
\textsuperscript{23} 21 C.F.R. §§ 312.21(a)-(c) (2010); \textit{see also Abigail II}, 445 F.3d at 473 (“The FDA has promulgated regulations that require three phases of government testing on humans before investigational new drugs can receive FDA approval.”).
\textsuperscript{24} 21 C.F.R. § 312.34 (2010); \textit{see also Abigail II}, 445 F.3d at 474 (internal citation omitted) (“Although the FDA may permit ‘treatment use’ of unapproved new drugs, the FDA has refused as a general matter to allow terminally ill patients to have access to investigational new drugs that have successfully completed Phase I trials.”).
\textsuperscript{25} \textit{See Abigail II}, 445 F.3d at 473-74.
\textsuperscript{26} \textit{Id.} at 471.
\textsuperscript{27} \textit{Id.}
knowledge for patients and physicians of their likely clinical benefit and their toxicity.\textsuperscript{28} Most cancer drugs "have potentially lethal toxicity" as well as the likelihood of substantial compromise of "a patient's remaining quality of life."\textsuperscript{29} Accordingly, it would not serve patients' interests "to make drugs too widely available before there is a reasonable assessment of such risks."\textsuperscript{30}

In a surprising decision, a three-judge panel of the U.S. Court of Appeals for the D.C. Circuit recognized a constitutional right for terminally ill patients. Specifically, the court held that "where there are no alternative government-approved treatment options, a terminally ill, mentally competent adult patient" has a fundamental interest in "access to potentially life-saving" experimental drugs that have successfully completed the first phase of testing.\textsuperscript{31} The court then sent the case back to the trial court to determine whether the FDA could justify its policy under the most demanding constitutional standard of demonstrating that the policy was "narrowly tailored to serve a compelling governmental interest."\textsuperscript{32}

After review by the full court (i.e., \textit{en banc} review), the D.C. Circuit reversed the decision fifteen months later,\textsuperscript{33} but the willingness of the initial panel to subject the FDA's judgment to a strict standard of review represented a sharp departure from the traditional deference of courts to government regulation on behalf of the public's health.

B. \textit{Western States}

While \textit{Abigail Alliance} saw a federal appellate court invoke substantive due process to cabin FDA regulation, \textit{Western States} saw the U.S. Supreme Court invoke the First Amendment to limit the regulatory power of Congress and the FDA.

In \textit{Western States}, the Supreme Court considered the constitutionality of a federal statute that regulated the practice of prescription drug "compounding" by pharmacists.\textsuperscript{34} For most patients, pharmacists dispense pills that have been manufactured by a pharmaceutical company.\textsuperscript{35} But for some patients, the pharmacist actually creates a medication that is tailored to the needs of that patient.\textsuperscript{36} As the Court wrote, "compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product."\textsuperscript{37} Compounding also can be used to provide drugs in forms that are more palatable for children (e.g., as a pleasantly-flavored syrup rather than a medicinal-tasting tablet).\textsuperscript{38}

\begin{footnotes}
\item[28] Abigail Alliance for Better Access to Dev. Drugs \textit{v.} von Eschenbach (\textit{Abigail III}), 495 F.3d 695, 700 (D.C. Cir. 2007) (en banc).
\item[29] \textit{Id.}
\item[30] \textit{Id.}
\item[31] \textit{Abigail II}, 445 F.3d at 486.
\item[32] \textit{Id.}
\item[33] \textit{Abigail III}, 495 F.3d at 728.
\item[34] \textit{Western States}, 535 U.S. 357, 360 (2002).
\item[35] \textit{See id.} at 360-63.
\item[36] \textit{Id.} at 360.
\item[37] \textit{Id.} at 361.
\item[38] \textit{Id.} at 377.
\end{footnotes}
Ordinarily, as indicated in the Abigail Alliance discussion, new drugs may not be marketed without FDA approval. However, the FDA had left regulation of drug compounding to the states.

Because of concerns that some pharmacists were using their compounding authority to manufacture and sell new drugs without satisfying FDA requirements, the FDA imposed new regulations in 1992, and Congress passed a regulatory statute in 1997. Among the statutory rules were provisions that raised First Amendment concerns. Congress had required that prescriptions for compounded drugs not be solicited by pharmacists and that pharmacies could only advertise the fact that they provided compounding services without being able to advertise the fact that they could compound a “particular drug, class of drug, or type of drug.”

The Court struck down the restrictions on solicitation and advertising on the ground that Congress could achieve its public health goals without limiting speech. If Congress was concerned that some pharmacists were using their compounding authority to become manufacturers of new drugs, Congress could address the problem directly by limiting the amount of compounding that pharmacists could do or by restricting the circumstances under which pharmacists could provide compounding services. In striking down the solicitation and advertising provisions, the Court applied its standard First Amendment analysis for regulations of “commercial speech,” without giving any special consideration to the fact that health-based regulations were at issue.

Thus, while the Supreme Court in Jacobson began the twentieth century by establishing special deference to governmental regulations designed to protect the public's health, it began the twenty-first century by suggesting in Western States that health regulations would be analyzed in the same way as other governmental regulations designed to promote the public's general welfare.

Although the Court was too willing to recognize claims based on the public health in the past, it may be too skeptical of public health claims currently. By considering public health regulation in the context of the First Amendment, we can identify important principles for drawing an appropriate balance between liberty and health.

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39 See supra note 24 and accompanying text.
40 Western States, 535 U.S. at 362.
41 Id. at 362-64.
42 Id. at 364-65.
43 Id. at 372.
44 Id.
45 Id. at 367-68.
IV. CURRENT FIRST AMENDMENT CHALLENGES TO HEALTH REGULATION

Two kinds of health care regulations have prompted First Amendment challenges in recent years. As in *Western States*, litigants have challenged direct restrictions on speech promoting the sale of prescription drugs. In addition, plaintiffs have sued over a kind of indirect regulation of pharmaceutical promotion—the use of prescription drug data that can be assembled from pharmacy records to better target a company's marketing efforts. The Supreme Court granted certiorari in January 2011 in a case involving regulation of prescription drug information.47

A. DIRECT RESTRICTION OF PROMOTIONAL SPEECH

The challenges to the direct restriction of promotional speech target an FDA policy that prohibits employees or other agents of pharmaceutical companies from promoting the “off-label” use of prescription drugs.48 When a drug manufacturer seeks approval for a new drug, the manufacturer does so for a specific use or uses.49 Thus, for example, a company may request approval of a new drug for the treatment of diabetes. In support of its request, the company would present data from its research trials demonstrating the safety and effectiveness of the drug in treating diabetes.50 If the FDA approves the drug, it will approve the drug for the treatment of diabetes.51 Accordingly, the drug company may include information only about that use when it prints its labeling information for the drug (as, for example, in the package insert that pharmacists provide when filling a prescription for the drug), and the drug company may market the drug only for the approved purpose.52 When it advertises the drug, when its sales representatives speak to physicians or pharmacists, or when the company contracts with non-employee physicians to present talks about the new drug, the company's spokespersons may only discuss the use of the drug for diabetes.53

Of course, many drugs are useful for treating more than one disease, and physicians may discover that when using a drug for an approved purpose, it provides other benefits to patients. The FDA permits physicians to prescribe drugs for purposes other than an approved purpose, and it permits physicians and others who are not agents of the manufacturer of the drug to discuss unapproved uses.54 However, if a company wants to promote the drug for additional uses, it must present data to the FDA demonstrating the safety and effectiveness of the drug for the additional uses.55 In short, the FDA does not

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47 IMS Health Inc. v. Sorrell, 630 F.3d 263 (2d Cir. 2010), cert. granted, 131 S. Ct. 857 (2011) (No. 10-779).
49 Id. at 4-5.
50 Id. at 4.
51 Id.
52 Id. at 6.
53 Id.
54 Id. at 6-8.
55 Id. at 5-6.
restrict all speech promoting unapproved uses of a drug; it only restricts promotional speech by the drug company.

Why does the FDA distinguish between promotional speech by the company and promotional speech by other persons about an unapproved use? The FDA wants to ensure that drug companies have a sufficient incentive to undertake rigorous research trials to test the drug for the unapproved uses. There are many examples of physicians using drugs that they thought were safe and effective for new uses, but that turned out not to be so. Without careful testing of a drug, many patients may be harmed. Even judicial critics of the FDA restrictions recognize the legitimacy of the FDA’s interest in encouraging pharmaceutical companies to seek approval for new uses of their drugs.

In response to the litigation over the marketing of off-label uses, the FDA has modified its policies for off-label drug promotion, allowing some forms of promotional activity that it once prohibited and that drew the most criticism. In particular, drug companies are no longer prohibited from disseminating articles from medical journals that discuss off-label uses of their drugs, nor are they prohibited from suggesting to an independent sponsor of continuing medical education programs that off-label uses of their drugs be discussed in one of the sponsor’s educational programs. Nevertheless, the FDA retains its general authority to restrict the promotion of unapproved uses of drugs by pharmaceutical companies.

How should courts assess the constitutional questions when Congress or the FDA regulates the promotional speech of drug companies? In some cases, we might question whether First Amendment concerns are implicated at all. In the case of pharmaceutical companies promoting off-label uses of their drugs, the ban on promotional speech constitutes the functional equivalent of a ban on the widespread sale of the drugs for off-label uses (i.e., a ban on conduct). Some off-label use of a drug makes sense as a way to identify potentially valuable new uses of a drug, but widespread use would be premature in the absence of studies to judge the safety and effectiveness of the new use. If the FDA prohibited the substantial selling of drugs for off-label uses, there would not be a First Amendment problem. However, it would be difficult to implement such a prohibition. Pharmaceutical companies sell to wholesalers and pharmacies, but physicians decide when and for which

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56 See Wash. Legal Found. v. Friedman, 13 F. Supp. 2d 51, 71-72 (D.D.C. 1998) (noting that after a drug approved for a particular use is in interstate commerce, “one of the few mechanisms available to FDA to compel manufacturer behavior is to constrain their marketing options”), vacated as moot sub nom. Wash. Legal Found. v. Henney, 202 F.3d 331 (D.C. Cir. 2000).
57 Id. at 56-57.
58 Id.
59 See, e.g., id. at 72.
60 See Wash. Legal Found. v. Henney, 202 F.3d 331, 335-36 (D.C. Cir. 2000) (“In response to questioning at oral argument, the government definitively stated that it subscribed to the ‘safe harbor’ interpretation and further explained that, in its view, neither the FDAMA nor the CME Guidance independently authorizes the FDA to prohibit or to sanction speech.”).
61 Id. at 335-36.
62 Id. at 336.
63 This would be akin to a limitation on the amount of compounding that pharmacists could undertake. See supra text accompanying note 44.
reasons to prescribe a drug. How would FDA officials know whether a pharmaceutical company was selling a drug for on-label or off-label uses? The FDA can pursue its goal of preventing substantial sales of a drug for off-label uses only by banning the promotion of a drug for off-label uses—it will be more difficult for a company to generate substantial sales for off-label uses if it does not promote the off-label uses.

If we reject this functional argument, then the direct regulation of promotional speech by drug companies fits comfortably within the Supreme Court's framework for analyzing other cases involving commercial speech. The commercial speech cases typically revolve around restrictions on advertising or other methods by which individuals or companies propose transactions with potential customers. Thus, the Court has considered restrictions on the advertising of tobacco products, alcoholic beverages, and legal services under its commercial speech doctrine. Likewise, the Court used the commercial speech doctrine to address restrictions on advertising by pharmacists in Western States, and lower courts have employed the doctrine to address restrictions on advertising by pharmaceutical companies in the off-label cases.

Does it make sense for courts to apply the usual Central Hudson framework for advertising when it considers advertising by drug companies or other providers of health care services rather than by providers of non-health care services? The framework itself makes sense. Under Central Hudson, courts consider four factors. If the "commercial speech concerns unlawful activity or is misleading," it does not receive protection under the First Amendment. If the speech is about lawful activity and is not misleading, then the regulation must satisfy three requirements: the regulation must promote a substantial governmental interest, it must directly advance the governmental interest, and it must not be more extensive than is necessary to serve the interest.

These factors are generally appropriate when applied to regulations of health care-related promotional speech. Protecting the public health is a substantial governmental interest, and it is reasonable to require government to implement regulations in a way that serves its public health interests without unnecessarily restricting speech.

That said, one important modification of the Central Hudson standard would ensure a proper balance between the government's need to protect patients from the harms that drugs or other health care services can cause and the First Amendment interests of those who wish to advertise their health care services. In School Board of Nassau County v. Arline, the Supreme Court

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70 Id.
faced a similar question regarding the balance between individual rights and governmental concerns about public health. *Arlene* involved a school system's decision to fire an elementary school teacher when she suffered a third relapse of tuberculosis. The teacher claimed that her firing constituted unlawful discrimination on the basis of disability, and the Court had to draw a balance between the individual right to be free of discrimination and the governmental interest in protecting the public's health. The Court held that the government is entitled to limit the activities of persons with communicable diseases when those persons pose a significant health risk to others. The Court further instructed lower courts that when deciding whether a person poses a significant risk to the health of others and therefore could be subject to restrictions of individual liberty, the courts should defer to the medical judgment of public health officials.

Determining when measures are appropriate for protecting the health of the public is a difficult question, and courts are more likely to draw the right balance when they defer to medical experts than when they defer to legislators or try to make their own judgments. A principle of deference to public health officials would have generated reasonable outcomes in past cases. Take *Jacobson*, for example. While the Supreme Court employed a standard of deference to legislative judgment in rejecting Henning Jacobson's challenge to mandatory smallpox immunization, the holding would have been the same under a standard of deference to public health officials. When the Massachusetts legislature authorized mandatory vaccination, it did so "only when, in the opinion of the board of health, [immunization] was necessary for the public health or the public safety." In other words, the statute itself incorporated a principle of deference to the judgment of public health officials.

Or consider *Western States*. In that case, the Supreme Court applied the *Central Hudson* standard and rejected, by a 5-4 vote, a total ban on the advertising of compounding for particular drugs, classes of drug, or types of drug. As mentioned, the ban had been passed by Congress in a 1997 statute. However, in its 1992 regulatory guidance, the FDA did not adopt a total ban on such advertising. Rather, it identified advertising of compounding for particular drugs, classes of drugs or

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72 Id. at 276.
73 Id.
74 Id. at 287 n.16. Since the case was decided under the Rehabilitation Act, its holding applies to private recipients of federal funding. And since the case's reasoning was incorporated into the Americans with Disabilities Act, it applies as well to all private operators of public accommodations. Ann Hubbard, *Understanding and Implementing the ADA's Direct Threat Defense*, 95 Nw. U. L. Rev. 1279, 1297-1305 (2001).
75 *Arlene*, 480 U.S. at 287-88.
78 Id. at 27 (quoting MASS. REV. LAWS ch. 75, § 137 (1902)).
79 See id.
81 Id. at 360; see also *Food and Drug Administration Modernization Act of 1997* § 127(a), 21 U.S.C. § 353a (2006).
82 See *Western States* at 362-63.
types of drugs as one of several factors that could trigger an FDA investigation. Making the advertising a factor to be taken into account in deciding whether a violation of promotional regulations occurred, rather than making the advertising an automatic violation, is more sensitive to First Amendment concerns, and it was the policy adopted by the public health officials rather than the legislators.

In applying a principle of judicial deference to the judgment of officials with special expertise, the Supreme Court has not limited that principle to health care matters, nor has it limited the principle to non-constitutional matters. When the Court issued its most recent decisions on affirmative action in higher education, it held that courts should defer to the judgment of university officers in deciding whether affirmative action policies meet the constitutional standard of being narrowly tailored to serve a compelling governmental interest.84

In short, judicial deference can serve an important role in cases involving constitutional rights. When the judgment of people with special expertise is involved, the Court has recognized the value of relying on their judgment.

B. INDIRECT REGULATION OF PROMOTIONAL SPEECH

In the indirect regulation line of cases, it also makes sense for courts to give special consideration to the medical nature of the regulations.

These cases involve regulations of "data mining" by health information companies. The companies compile information from pharmacies about their drug prescriptions, analyze the data, and sell their analyses to pharmaceutical companies so the companies' sales representatives can better target their marketing activities.85 For example, the sales representative would know whether a doctor prefers the company's drug for high blood pressure, or whether the doctor prefers a competitor's drug.86 The representative also would know if the doctor recently switched from using one drug to using another drug for one patient or many patients.87 While data mining companies provide analyses that allow a drug company to discover the prescribing practices of a particular physician, the names of patients have been stripped from the data to preserve their anonymity.88

Critics of data mining have observed that it can aggravate problems associated with the promotional activities of drug companies.89 Pharmaceutical company marketing can result in the prescribing of a drug that provides less benefit, causes more side effects, or comes with a higher price tag than an alternative drug.90 In addition, the marketing can result in the prescribing of a drug when no drug was actually needed. Thus,

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85 David Orentlicher, Prescription Data Mining and the Protection of Patients' Interests, 38 J. L. MED. &ETHICS 74, 74 (2010).
86 See id. at 74-75.
87 See id. at 75.
88 Id.
89 Id.
90 See id. at 75-76.
prescription drug data can contribute to both physical harm and financial harm for patients.91

In response to concerns about data mining, three states have passed laws regulating the use of prescription data by drug companies to promote their products. In New Hampshire, drug companies may use data that has been aggregated, but they cannot examine the prescribing practices of a particular physician.92 In Vermont, drug companies can use physician-specific prescribing information only if the physician gives consent (an "opt-in" approach),93 while in Maine, drug companies can use physician-specific prescribing information unless a physician objects by registering with the state (an "opt-out" approach).94

Thus far, all three statutes have been challenged in court, and the legal cases have generated a split between the U.S. Court of Appeals for the First Circuit and the U.S. Court of Appeals for the Second Circuit. The First Circuit upheld both New Hampshire's ban95 and Maine's opt-out approach,96 while the Second Circuit invalidated the Vermont opt-in strategy.97 The Supreme Court accepted certiorari in the Vermont case on January 7, 2011.98

As many writers have observed, it is not clear that these regulations should trigger First Amendment protection at all. While the contours of the First Amendment are not clear, its protection has extended not to the mere use of words or information but to some form of expression, whether it be the advocacy of political or religious views, the reporting of news, the writing of a novel, the painting of a picture or the advertising of a commercial product.99 The data mining laws regulate economic transactions between data mining companies and their customers, not the content of their expression.100 Thus, for example, drug company sales representatives are free to deliver the same messages to physicians and pharmacists in Maine, New Hampshire, and Vermont that they deliver in other states.101 Following this line of thinking, the First Circuit concluded that the sale of prescription data constitutes commercial conduct rather than commercial speech and therefore it does not raise First Amendment concerns.102

91 See id. at 75.
93 18 VT. STAT. ANN. § 4631(d) (2010).
94 Orentlicher, supra note 85, at 78; see also ME. REV. STAT. tit. 22, §§ 1711-E(2) to (2-A) (2010).
95 See IMS Health Inc. v. Ayotte, 550 F.3d 42, 64 (1st Cir. 2008).
96 See IMS Health Inc. v. Mills, 616 F.3d 7, 32 (1st Cir. 2010).
97 See IMS Health Inc. v. Sorrell, 630 F.3d 263, 282 (2d Cir. 2010), cert. granted, 131 S. Ct. 857 (2011) (No. 10-779).
99 And of course, not all expression is protected. States may prohibit the publication of obscenity or speech that is likely to incite imminent violence. See generally Brandenburg v. Ohio, 395 U.S. 444, 448 (1969).
100 See Orentlicher, supra note 85, at 80.
101 See id.
102 See IMS Health Inc. v. Ayotte, 550 F.3d 42, 52-53 (1st Cir. 2008).
Other scholars have pointed to the many constitutionally uncontroversial statutes that protect the privacy of personal information. Federal laws restrict the use of customer data by credit card companies, video rental stores, and health care providers. To be sure, the data mining companies try to protect patient privacy by stripping patient names from their data, but confidentiality may not be adequately protected that way. Moreover, there is more to the privacy concern than anonymity, as exemplified by principles of professional responsibility in medicine and principles of agency in law.

The relationship between patients and their physicians, pharmacists, and other health care providers depend very much on considerations of trust. For patients, their health—and indeed their lives—may be at stake, their sickness may leave them vulnerable and unable to help themselves, and they lack the expertise to make their own assessments about their medical needs. Consequently, principles of medical ethics impose a number of duties on physicians to promote and preserve patient trust. Doctors must maintain patient confidentiality, they must obtain the patient’s informed consent to treatment, and they must minimize conflicts of interest.

The duty to minimize conflicts of interest reflects a key element of the duty to maintain trust—physicians, pharmacists, and other health care providers may use the information they gain from their relationships with patients to serve the patient’s interests, but they may not exploit the relationship for personal gain. If patients must wonder whether medical personnel are pursuing their own interests, then patient trust will diminish, and the ability of physicians and other providers to treat illness will be impaired. Thus, while health care providers may charge for their services—for they otherwise would not be able to afford to provide the services—they should not try to extract additional financial rewards from their relationships with patients. For example, physicians should not refer patients to laboratories or radiologic facilities in which the physicians invest.

In the context of data mining, when pharmacies sell information about prescriptions for their own profit and that of pharmaceutical companies, patients can easily worry about the trustworthiness of their pharmacists. If pharmacies cut ethical corners with their use of patient information for personal gain, will their desire for personal gain also lead them to cut corners with their measures to protect patient confidentiality or with their standards for ensuring the safety of the drugs they dispense? If patients are uncertain about the trustworthiness of pharmacists, then patients may be less willing to fill their prescriptions after receiving them from their doctors.

104 Id. at *14, *18-20, *32-33.
105 See Orentlicher, supra note 85, at 75-76.
108 Id.
109 Id.
110 Id.
111 And in fact, federal law prohibits most such "self-referrals" by physicians. HALL, BOBINSKI & ORENTLICHER, supra note 5, at 1372-73.
Even strong advocates of First Amendment protection for companies that collect and use personal data for commercial purposes recognize a distinction between health care information and other kinds of information. In his argument on behalf of the free flow of information, Eugene Volokh does not object to laws that protect the privacy of health care information on the ground that such laws simply reinforce the implicit promise of health care providers to maintain the privacy of that information.\footnote{112} Principles of agency law also support the ability of legislatures to enact statutes restricting the use of prescription data for commercial purposes. The agent's duty of loyalty precludes agents from exploiting their relationship with principals for personal enrichment.\footnote{113} Accordingly, when agents use confidential information that they acquire in the course of their relationship with the principal, the principal has the right to capture any profits made from the use of the information.\footnote{114} Similarly, in addition to prohibiting lawyers from disclosing confidential information they gain while representing their clients, the Model Code of Professional Responsibility prohibits lawyers from using the information to the disadvantage of the client.\footnote{115} Prescription data laws simply reinforce the duty of loyalty that pharmacists owe their patients.

As the agent's duty of loyalty suggests, it would not be a problem for pharmacies to make prescription data available to public health officials or researchers who use the data to better understand how to improve health and health care. And in fact, the state statutes distinguish between using prescription data for drug company promotion and using it for health care research.\footnote{116} But why should we distinguish between a pharmacist charging a patient to fill a prescription and a pharmacist selling prescription drug information to a data mining company? Why does the duty of loyalty treat the pharmacist's profit from selling prescription data differently than the pharmacist's profit from filling a prescription? In both cases, not only does the pharmacist personally profit, but the patient also benefits. When a pharmacy sells prescription drug information, its operating costs are lower, and it can afford to lower the prices it charges to patients.

There are two responses to this argument. First, while pharmacists profit when they fill prescriptions, they do not write the prescriptions. Thus, even though pharmacists have an economic incentive to encourage patients to fill prescriptions, they cannot exploit that incentive by issuing unnecessary prescriptions—they have to wait for patients to come to the pharmacy with a prescription written by a physician. Second, patients recognize that

\footnote{115} MODEL RULES OF PROF'L CONDUCT R. 1.18(b) (2011).
pharmacies profit by filling prescriptions. When patients bring their prescriptions to a pharmacy, they are tacitly consenting to the pharmacist's profit. However, patients are not aware that their prescription data is sold to data mining companies, so the pharmacist's profit is not sanctioned by patient consent.

In sum, the special nature of health care information suggests that the Maine, New Hampshire, and Vermont laws should not trigger First Amendment concerns, and the Supreme Court should uphold them. Or as Neil Richards has argued, these kinds of regulations should be subject to the highly deferential rational basis level of review that the Court employs when constitutional rights are not threatened.

Even if the Supreme Court were to characterize trade in prescription data as commercial speech, it still should uphold the data mining laws under the same approach as suggested for laws that directly regulate the speech of drug companies. As discussed above, courts should defer to the judgment of public health officials in applying the Central Hudson standard to regulations of health care-based commercial speech.

How would such deference play out in the context of data mining regulations? Recall that under Central Hudson, courts will uphold regulations of commercial speech (a) that promote a substantial governmental interest, (b) that directly advance the governmental interest, and (c) that are not more extensive than is necessary to serve the interest. The states with data mining statutes cite their interests in protecting public health and containing health care costs, and these readily qualify as substantial state interests. Indeed, even the courts that have found data mining statutes unconstitutional recognized that the state's interests satisfied the substantial interest prong of Central Hudson. Judicial disagreement has centered on the next two prongs of Central Hudson. Courts have questioned whether the states have established a sufficient connection between data mining and harm to patient health or between data mining and high health care costs. Courts also have questioned whether restrictions of speech are necessary to address the problems that data mining raises. Under this article's proposed approach, courts should defer to the judgment of public health officials in deciding

See Mark A. Hall & Carl E. Schneider, Patients as Consumers: Courts, Contracts, and the New Medical Marketplace, 106 Mich. L. Rev. 643, 682 (2008) (footnotes omitted) ("[D]rug companies are not fiduciaries but sell wares like any merchant. Second, drug prices are readily stated and readily disclosed before purchase, so that, unlike hospital prices, pharmaceutical prices reflect what many informed purchasers will pay in arm's length transactions.").

See Orentlicher, supra note 85, at 76-77.

I am grateful to Professor Kevin Outterson for this point. See also Hall, Bobinski & Orentlicher, supra note 5, at 1373.


See, e.g., id. at 568; IMS Health Inc. v. Sorrell, 630 F.3d 263, 266 (2d Cir. 2010), cert. granted, 131 S. Ct. 857 (2011) (No. 10-779).


See, e.g., Sorrell, 630 F.3d at 275-76; Ayotte, 490 F. Supp. 2d at 180-82.

See, e.g., Sorrell, 630 F.3d at 279-82; Ayotte, 490 F. Supp. 2d, at 181-83.
whether data mining statutes meet the Central Hudson requirements that regulations of speech directly advance the state's interests and that the restrictions of speech are not more extensive than necessary.

It may seem to make more sense for courts to defer to public health officials on the question whether data mining statutes directly advance the state's interests than on whether the statutory restrictions on speech are not more extensive than necessary. Public health officials are in a better position than judges to decide whether a data mining statute will promote patient health or contain health care costs. But are they in a better position than judges to decide whether a data mining statute infringes too much on freedom of speech? Yes. Another way to ask this question is to ask whether there are other public health measures that infringe less on speech and that are effective ways to protect patients from the harms of data mining. And public health officials are better positioned than judges to assess the effectiveness of alternative regulations. Consider again the analogy to judicial deference to university officers on affirmative action. The Supreme Court adopted a policy of deference even though one could argue that judges are better able than education officers to decide whether an affirmative action policy violates principles of equal protection.

V. CONCLUSION

In the past, courts showed too much deference to government officials when deciding the constitutionality of health care regulations. Broad deference to legislatures does not give adequate weight to the individual interests at stake. On the other hand, there is important value in showing deference to the judgment of public health officials, whose expertise makes them much better able than legislators or judges to decide when health regulations are needed.

In addition, when health regulations are designed to protect the integrity of the relationship between patients and their health care providers by enforcing the provider's duty of loyalty, courts should make space in the Constitution for such regulations.