

# United States Court of Appeals For the First Circuit

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Volume I of II

No. 07-1945

IMS HEALTH INC. AND VERISPAN, LLC,

Plaintiffs, Appellees,

v.

KELLY A. AYOTTE, NEW HAMPSHIRE ATTORNEY GENERAL,

Defendant, Appellant.

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APPEAL FROM THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW HAMPSHIRE

[Hon. Paul J. Barbadoro, U.S. District Judge]

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Before

Lipez, Selya, and Siler,\*  
Circuit Judges.

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Laura E. B. Lombardi, Assistant Attorney General, with whom Richard W. Head, Associate Attorney General, was on brief, for appellant.

Sean M. Fiil-Flynn, with whom Stacy Canan, Bruce Vignery, and Michael Schuster, were on brief, for AARP, Community Catalyst, National Legislative Association on Prescription Drug Prices, National Physicians Alliance, New Hampshire Medical Society, and Prescription Policy Choices, amici curiae.

Mark Rotenberg and Melissa Ngo on brief for Electronic Privacy Information Center and 16 Experts in Privacy Law and Technology, amici curiae.

Thomas R. Julin, with whom Patricia Acosta, Michelle Milberg,

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Bert W. Rein, Andrew M. Miller, Joshua S. Turner, Wiley Rein LLP, and John Kamp on brief for Coalition for Healthcare Communications, amicus curiae.

Stephen J. Judge, Wadleigh, Starr & Peters, Donald B. Ayer, Donald Earl Childress III, and Jones Day on brief for Wolters Kluwer Health, Inc., amicus curiae.

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November 18, 2008

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**SELYA, Circuit Judge.** The spiraling cost of brand-name prescription drugs is a matter of great concern to government at every level. New Hampshire has attempted to curb this escalating problem by enacting innovative legislation. Certain affected companies have challenged New Hampshire's legislative response, and that challenge raises important constitutional questions that lie at the intersection of free speech and cyberspace. The tale follows.

Pharmaceutical sales representatives, known in industry argot as "detailers," earn their livelihood by promoting prescription drugs in one-on-one interactions with physicians. A valuable tool in this endeavor, available through the omnipresence of computerized technology, is knowledge of each individual physician's prescribing history. With that informational asset, detailers are able to target particular physicians and shape their sales pitches accordingly. Convinced that this detailing technique induces physicians to prescribe expensive brand-name drugs in place of equally effective but less costly generic drugs, New Hampshire enacted a law that among other things prohibited certain transfers of physicians' prescribing histories for use in detailing. See 2006 N.H. Laws § 328, codified at N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006) (the Prescription Information Law). A duo of data miners promptly challenged the law as invalid on various grounds. The district court found that it worked an

unconstitutional abridgement of free speech and enjoined its enforcement. See IMS Health Corp. v. Ayotte, 490 F. Supp. 2d 163, 183 (D.N.H. 2007) (D. Ct. Op.). This appeal ensued.

In the pages that follow, we explain why we are not persuaded that the regulated data transfers embody restrictions on protected speech. In our view, the portions of the law at issue here regulate conduct, not speech. Unlike stereotypical commercial speech, new information is not filtered into the marketplace with the possibility of stimulating better informed consumer choices (after all, physicians already know their own prescribing histories) and the societal benefits flowing from the prohibited transactions pale in comparison to the negative externalities produced. This unusual combination of features removes the challenged portions of the statute from the proscriptions of the First Amendment.

There is a second basis for our decision. Even if the Prescription Information Law amounts to a regulation of protected speech – a proposition with which we disagree – it passes constitutional muster. In combating this novel threat to the cost-effective delivery of health care, New Hampshire has acted with as much forethought and precision as the circumstances permit and the Constitution demands.

## I. BACKGROUND

The raw facts are largely undisputed. Modern-day detailing begins when a prescription is filled.<sup>1</sup> At that moment, the pharmacy stores in its computerized database a potpourri of information about the transaction, such as the name of the patient, the identity of the prescribing physician, the drug, its dosage, and the quantity dispensed. Due to the complex relationships that mark the delivery of health care products and services in the twenty-first century, this information quickly finds its way into other databases, including those of insurance carriers and pharmacy benefits managers.

The plaintiffs in this case, IMS Health Inc. and Verispan, LLC, are in the business of data mining. For present purposes, that means that they purchase data of the type and kind described above, aggregate the entries, group them by prescriber, and cross-reference each physician's prescribing history with physician-specific information available through the American Medical Association. The final product enumerates the prescriber's identity and speciality, the drug prescribed, and kindred information. The scope of the enterprise is mind-boggling: these two plaintiffs alone record, group, and organize several billion

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<sup>1</sup> Our description of detailing owes much to the precise accounts provided by two district courts, including the court below. See IMS Health Corp. v. Rowe, 532 F. Supp. 2d 153, 157-65 (D. Me. 2007); D. Ct. Op., 490 F. Supp. 2d at 165-74.

prescriptions each year. To protect patient privacy, prescribers' names are encrypted, effectively eliminating the ability to match particular prescriptions with particular patients.

These massive collections of information have great utility for certain non-profit entities (e.g., educational institutions, public interest groups, and law enforcement agencies). New Hampshire's concern, however, is with a frankly commercial use: the exploitation of the mined data by pharmaceutical companies, whose detailers use it in marketing drugs to physicians.

At this point, the art of detailing warrants further elaboration. Detailing involves tailored one-on-one visits by pharmaceutical sales representatives with physicians and their staffs. This is time-consuming and expensive work, not suited to the marketing of lower-priced bioequivalent generic drugs (drugs that are pharmacologically indistinguishable from their brand-name counterparts save for potential differences in rates of absorption). The higher profit margins associated with brand-name drugs leaves the personal solicitation field open to brand-name drug manufacturers, who in the year 2000 spent roughly \$4,000,000,000 on detailing.<sup>2</sup>

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<sup>2</sup> Because of the ready availability of reliable figures, the parties used the year 2000 as a benchmark year for illustrative purposes. It is clear from the anecdotal evidence that both the incidence of detailing and the gross amounts expended in its service have increased in the intervening years.

Brand-name drug manufacturers engage in detailing in several situations. For instance, detailing is employed where a manufacturer seeks to encourage prescription of a patented brand-name drug as against generic drugs, or as against a competitor's patented brand-name drug, or as a means of maintaining a physician's brand loyalty after its patent on a brand-name drug has expired.

If a physician's prescribing habits present an appropriate opportunity, the detailer attempts to gain access to the physician's office, usually by presenting herself as a helpful purveyor of pharmaceutical information and research. The detailer comes to the physician's office armed with handouts and offers to educate the physician and his staff about the latest pharmacological developments. In other words, detailers open doors by holding out the promise of a convenient and efficient means for receiving practice-related updates.

Withal, a physician's time is precious, and detailers must manage their way around physicians' natural reluctance to make time for promotional presentations. To this end, detailers typically distribute an array of small gifts to physicians and their staffs, host complimentary lunches, and pass out free drug samples. From time to time, a detailer will invite a physician to attend an all-expense-paid conference or to accept a lucrative speaking engagement.

Most of these freebies cut very little ice. The free samples, however, are highly prized. Their sheer volume is astounding: in the year 2000, an estimated \$1,000,000,000 in free drug samples flowed from detailers to physicians. That flood of free medications enables physicians to offer drugs free of charge to selected patients. Many physicians thus tolerate detailing visits in order to reap the harvest of samples that these visits bring.<sup>3</sup>

Once inside a physician's office, detailers are capable of mounting an impressively sophisticated and intense marketing pitch. The detailer works to establish an ongoing relationship with the physician and, in most cases, detailers' visits become a regular occurrence. For example, the average primary care physician interacts with no fewer than twenty-eight detailers each week and the average specialist interacts with fourteen.

Given the frequency of these exchanges, it is not surprising that prescriber-identifiable information can be an invaluable asset to the detailer. That information enables the detailer to zero in on physicians who regularly prescribe competitors' drugs, physicians who are prescribing large quantities of drugs for particular conditions, and "early adopters" (physicians with a demonstrated openness to prescribing drugs that

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<sup>3</sup> Nevertheless, a significant number of physicians flatly refuse detailing visits, convinced that they are either unethical or a waste of time.



have just come onto the market). The information also allows the detailer to tailor her promotional message in light of the physician's prescribing history.

## **II. THE LEGISLATIVE RESPONSE**

In time, the New Hampshire legislature moved to combat what it saw as a pernicious effect of detailing. On January 4, 2006, a bill, which would become the Prescription Information Law, was introduced in the House of Representatives. Hearings before the House and Senate followed. Those hearings made the goals of the proposed statute pellucid: the protection of privacy interests, the safeguarding of patient health, and cost containment. Testimony taken at the hearings indicated that the last of these was the bill's driver.

In due course, the proposed bill passed both chambers, was signed by the governor, and took effect on June 30, 2006. In relevant part it provides:

Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion,

or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

N.H. Rev. Stat. Ann. § 318:47-f.

The statute further provides that nothing contained in this language should be read to prohibit the dispensing of prescription medications to a patient, the transmission of prescription information either between a prescriber and a pharmacy or between pharmacies, the transfer of prescription records evident to a pharmacy's change in ownership, the distribution of care management materials to a patient, or the like. Id. The statute makes explicit that nothing in the above-quoted language should be read to "prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes." Id. Last – but surely not least – it provides both criminal and civil penalties for violations. Id. §§ 318:55, 358-A:6.

### **III. THE LITIGATION**

Within a month of the effective date of the Prescription Information Law, the plaintiffs initiated this constitutional challenge. They filed a civil action in the United States District Court for the District of New Hampshire, naming the Attorney General in her official capacity as the defendant and seeking

declaratory and injunctive relief. Their complaint alleged that the statutory ban on transfer and use of prescriber-identifiable information transgressed the Free Speech Clause of the First Amendment, was void for vagueness, and offended the Commerce Clause.

A period of expedited discovery and a four-day bench trial ensued. The district court took the matter under advisement and subsequently wrote a thoughtful rescript in which it concluded that the Prescription Information Law regulated speech, not conduct. D. Ct. Op., 490 F. Supp. 2d at 174-75. Accordingly, it applied the conventional constitutional test for commercial speech, inquiring whether the law (i) supported a substantial government interest, (ii) directly advanced that interest, and (iii) was more extensive than necessary to serve that interest. Id. at 177 (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980)).

The district court found the governmental interests advanced in support of the law insufficient. Id. at 178-81 & n.13. With specific reference to cost containment, the court maintained that the state had failed to prove that substituting non-bioequivalent generic drugs for brand-name drugs would be generally advantageous to patients' health. Id. at 180-81. The court also said that cost containment could not satisfy the third prong of the Central Hudson test because so many other regulatory options

existed for curtailing detailing – none of which would involve restrictions on speech. See id. at 181-83 (listing continuing medical education, gift bans, and possible revisions of the state's Medicaid program).

In the end, the court declared the relevant portions of the Prescription Information Law unconstitutional and enjoined its enforcement. Id. at 183. The court did not reach the plaintiffs' other constitutional challenges.

This timely appeal followed. The issues raised engender de novo review. See Bose Corp. v. Consumers Union, 466 U.S. 485, 514 (1984); Mandel v. Boston Phoenix, Inc., 456 F.3d 198, 209 (1st Cir. 2006).

#### **IV. STANDING**

"Standing is a threshold issue in every federal case." Berner v. Delahanty, 129 F.3d 20, 23 (1st Cir. 1997). It bears directly upon a court's power to adjudicate a dispute. Id. Consequently, we first address an issue of standing – an issue that touches upon the nature of the conduct that should serve as the focal point of our inquiry.

New Hampshire has sought to improve the quality of interactions between detailers and physicians by regulating upstream transactions of prescriber-identifiable information between data miners and those who would put that information to use in detailing. The state directs our attention to these prohibited

upstream transactions, claiming that they comprise the relevant conduct for present purposes. The plaintiffs demur, positing that the relevant conduct is composed of the downstream interactions between detailers and physicians because it is those interactions that the legislature intended to affect. The district court sided with the plaintiffs on this point. See D. Ct. Op., 490 F. Supp. 2d at 175.

The record reveals that three sets of transactions are interwoven here. These include (i) the data miners' acquisition of prescriber-specific information from pharmacies and others; (ii) the data miners' sale of that information (now processed) to pharmaceutical companies for use in detailing (transfers for other purposes are exempted); and (iii) the use of that information by pharmaceutical company detailers to promote particular products to physicians. New Hampshire chose to regulate the first and second of these transactional subsets, not the third. Given this model, basic principles of standing jurisprudence help us to resolve this preliminary dispute.

"A party ordinarily has no standing to assert the First Amendment rights of third parties." Wine & Spirits Retailers, Inc. v. Rhode Island (Wine & Spirits I), 418 F.3d 36, 49 (1st Cir. 2005); accord Eulitt ex rel. Eulitt v. Me. Dep't of Educ., 386 F.3d 344, 351 (1st Cir. 2004). No pharmaceutical company, detailer, or

physician is a party in this case.<sup>4</sup> It follows that unless they can come within some exception to the general jus tertii principle, the plaintiffs lack standing to assert the First Amendment rights of the participants in the targeted downstream (third-stage) interactions. In other words, they cannot assert the rights of detailers to use prescriber-identifiable information in communicating face-to-face with physicians, nor can they assert the rights of physicians to receive that information during such interactions. Cf. U.S. West, Inc. v. FCC, 182 F.3d 1224, 1232 (10th Cir. 1999) (considering commercial speech rights where the plaintiff directly sought to use the information for its own marketing).

The plaintiffs convinced the district court that the exception laid down in Craig v. Boren, 429 U.S. 190, 194-95 (1976), allowed their assertion of third-party rights. See D. Ct. Op., 490 F. Supp. 2d at 175 n.10 (citing Craig for the proposition that vendors may assert the rights of their customer base). We think that in so concluding the court lost sight of the narrowness of this jus tertii exception. See Wine & Sprints I, 418 F.3d at 49

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<sup>4</sup> To be sure, some of the amici profess to represent such interests. But, absent special circumstances (not present here), issues advanced exclusively by an amicus ought not to be considered on appeal. See, e.g., United States v. Bongiorno, 106 F.3d 1027, 1034 (1st Cir. 1997); United States v. Taylor, 54 F.3d 967, 972 (1st Cir. 1995); Lane v. First Nat'l Bank, 871 F.2d 166, 175 (1st Cir. 1989).

(characterizing the exception as "isthmian" and refusing to allow franchisor to assert First Amendment rights of franchisees).

The exception is rooted in practical considerations. Under it, a litigant will be permitted to raise a third party's rights only when three criteria are met: the third party has suffered a constitutional injury in fact, the litigant enjoys a close relationship with the third party, and an obstacle exists to the third party assertion of his or her own rights. See Powers v. Ohio, 499 U.S. 400, 410-11 (1991) (citing Craig, 429 U.S. at 190).

The inapplicability of the exception is evident. There is no indication in the record that pharmaceutical companies, detailers, or physicians are somehow incapable of or inhibited from vindicating their own rights. In the absence of any such barrier, Craig does not pertain. See Eulitt, 386 F.3d at 352-53; see also Singleton v. Wulff, 428 U.S. 106, 110, 114-16 (1976).

Of course, the Court has indicated some willingness to relax third-party standing in the First Amendment context. See Kowalski v. Tesmer, 543 U.S. 125, 130 (2004). But in practical terms, this relaxation evinces nothing more than a receptiveness to facial attacks on allegedly overbroad laws. See Osediacz v. City of Cranston, 414 F.3d 136, 140 (1st Cir. 2005). Otherwise, hindrance – the existence of an obstacle to the vindication of one's own rights – remains a necessary prerequisite; and no court has exhibited a willingness to write the hindrance element out of

the standing test as a matter of general convenience.<sup>5</sup> See Wine & Spirits I, 418 F.3d at 49; Richard H. Fallon, Jr., As-Applied and Facial Challenges and Third Party Standing, 113 Harv. L. Rev. 1321, 1359-64 (2000); see also Osediacz, 414 F.3d at 140 n.2 (noting that "[e]ven this limited relaxation . . . is controversial"). Thus, the data miners must assert their own rights and explain how those rights are infringed by the operation of the Prescription Information Law.

As we proceed, we restrict our analysis to whether the data miners' activities – the acquisition, aggregation, and sale of prescriber-identifiable data – constitute speech or conduct and whether New Hampshire's legitimate governmental interests are sufficient to counterbalance any speech rights inherent therein. We think it important to note, however, that this restriction on jus tertii rights does not prevent consideration of New Hampshire's interest in combating detailing. Standing rules are at bottom a

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<sup>5</sup> The dissent seems to equate prudential standing rules with precatory guidelines. That is an incorrect assessment. Although the Court has said that prudential standing doctrine derives primarily from pragmatic concerns, that is a far cry from saying that standing rules can be ignored by a district court in the interests of expediency. See Valley Forge Christian Coll. v. Americans United for Sep'n of Church and State, Inc., ("Merely to articulate these principles is to demonstrate their close relationship to the policies reflected in the Art. III requirement of actual or threatened injury amenable to judicial remedy."). For example, the prohibition against adjudicating generalized grievances is a prudential doctrine – but we can find no case in which that barrier has been lifted in the interest of pragmatism. Here, then, detouring around third-party standing rules requires a showing of hindrance. See Kowalski, 543 U.S. at 129-30.



limitation on a court's competence to adjudicate a dispute. See Warth v. Seldin, 422 U.S. 490, 501 (1975). Conversely, consideration of a state's interest addresses the state's power to enact laws and is in no way denigrated by a lack of standing. After all, courts long have recognized that a law may be predicated on criteria broader than those presented by a particular case. See, e.g., Crawford v. Marion Cty Election Bd., 128 S. Ct. 1610, 1623 (2008); Gonzales v. Raich, 545 U.S. 1, 17 (2005).

#### **V. SPEECH OR CONDUCT?**

The next issue requires a determination of whether or not the challenged portions of the Prescription Information Law regulate protected speech. The state offers a simplistic solution to this nuanced problem: it asseverates that the law falls under the exception to First Amendment coverage limned in Bartnicki v. Vopper, 532 U.S. 514 (2001), so that it may prohibit the use of prescriber-identifiable information without further ado. See id. at 526-27 (dictum).

Bartnicki does not take the state very far. The Bartnicki Court confronted a bizarre situation, in which an illegally intercepted wire communication fell fortuitously into the hands of an individual who had neither played a role in its interception nor knew the interceptor. Given that the information bore upon a matter of public concern, the Court opined that Congress could not constitutionally prohibit the disclosure of

that information by the innocent recipient. Id. at 534. In so concluding, it introduced a distinction between "use" and "disclosure" of illegally intercepted communications: the First Amendment allowed absolute prohibition of the former but only allowed prohibition of the latter when the discloser had participated in the interception. Id. at 529. It carefully distinguished the situation at hand from other situations in which valid laws prohibited the use of illegally intercepted wire communications. See id. at 527 n.10.

The state does not explain why Bartnicki should be understood to shed light on the instant case, and we believe that any comparison is inapt. The facts of the two cases are materially distinguishable, and the state's expansive reading of Bartnicki is insupportable on policy grounds. Were the state capable of forbidding every use of information regardless of the specific nature of either the use or the information, the state's power to control the flow of information would be nearly absolute. The First Amendment does not protect the rights of persons to give and receive information only to allow the wholesale prohibition of its use by government fiat. While various uses of transferred information can be barred or restricted for independent reasons (licensing agreements are a prime example), they cannot be prohibited merely because they are "uses."

Rejecting the state's mechanistic reliance on Bartnicki is only the beginning, not the end. Although Bartnicki does not control, we nonetheless believe that what the state seeks to regulate here is conduct, not expression. This case poses the relatively narrow question of whether the Prescription Information Law constitutionally may bar these plaintiffs (data miners) from aggregating, manipulating, and transferring data for one particular purpose only. This brings vividly to mind Chief Justice Roberts's admonition that "it has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." Rumsfeld v. Forum for Acad. & Inst. Rights, Inc. (FAIR), 547 U.S. 47, 62 (2006) (quoting Giboney v. Empire Storage & Ice Co., 336 U.S. 490, 502 (1949)).

We recognize, of course, that pure informational data can qualify for First Amendment protection. See Univ'l City Studios, Inc. v. Corley, 273 F.3d 429, 446-47 (2d Cir. 2001) ("Even dry information, devoid of advocacy, political relevance, or artistic expression, has been accorded First Amendment protection."); see also Va. Bd. of Pharm. v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976) (deeming ordered pairs of drug prices and products commercial speech). But that coin has a flip side. As Justice Holmes famously observed, "the First

Amendment while prohibiting legislation against free speech as such cannot have been, and obviously was not, intended to give immunity for every possible use of language." Frohwerk v. United States, 249 U.S. 204, 206 (1919).

The proof of this pudding is that entire categories of speech receive no protection at all from the First Amendment. Some have been explicitly recognized as lying outside the compass of the Free Speech Clause by virtue of longstanding tradition. See, e.g., Chaplinsky v. New Hampshire, 315 U.S. 568, 571-72 (1942) (listing as examples "the lewd and obscene, the profane, the libelous, and the insulting or 'fighting' words"); see also Thompson v. W. States Med. Ctr., 535 U.S. 357, 367 (2002) (explaining that false or misleading commercial speech may be barred completely without constitutional concern).

There are other species of speech-related regulations that effectively lie beyond the reach of the First Amendment. These include agreements in restraint of trade, see, e.g., Nat'l Soc'y of Prof. Eng'rs v. United States, 435 U.S. 679, 697-98 (1978); communications in furtherance of crimes, see, e.g., Giboney, 336 U.S. at 498; statements or actions creating hostile work environments, see, e.g., O'Rourke v. City of Prov., 235 F.3d 713, 735 (1st Cir. 2001); and promises of benefits made by an employer during a union election, see, e.g., NLRB v. Gissel Packing Co., 395 U.S. 575, 618-20 (1969). The Supreme Court has

recognized that these exceptions exist, see, e.g., Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 515 (1972); see also Richard H. Fallon, Jr., Sexual Harassment, Content Neutrality, and the First Amendment Dog That Didn't Bark, 1994 Sup. Ct. Rev. 1, 8, but for whatever reason, the Justices have never deemed it necessary to address why or how these content-based prohibitions manage to escape First Amendment scrutiny. Thus, these laws loom as tacit but unexplained exceptions to the suzerainty of the First Amendment. See Wine & Spirits I, 418 F.3d at 53.

Scholars have labored to formulate theories about why First Amendment immunity exists in such cases. See, e.g., Neil M. Richards, Reconciling Data Privacy and the First Amendment, 52 U.C.L.A. L. Rev. 1149, 1165-74 (2005); Frederick Schauer, The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Salience, 117 Harv. L. Rev. 1765, 1777-84 (2004). Despite these efforts, the matter remains a doctrinal mystery.

In our view, the most natural explanation for this phenomenon is that this complex of de facto exceptions derives from a felt sense that the underlying laws are inoffensive to the core values of the First Amendment – inoffensive because they principally regulate conduct and, to the extent that they regulate speech at all, that putative speech comprises items of nugatory informational value. It is this unusual combination of features

that distinguishes these laws and places them outside the ambit of the First Amendment. Cf. Chaplinsky, 315 U.S. at 572 (explaining inapplicability of First Amendment to fighting words because these words are "of such slight social value as a step to truth that any benefit that may be derived from them is clearly outweighed by the social interest in order and morality").

We believe that the transfers of prescriber-identifiable information regulated by the Prescription Information Law (transfers that otherwise would flow from pharmacies to data miners to detailers for the purpose of promoting the dispensation of expensive brand-name drugs) fit within this integument. The challenged portions of the statute principally regulate conduct, and to the extent that the challenged portions impinge at all upon speech, that speech is of scant societal value.

We say that the challenged elements of the Prescription Information Law principally regulate conduct because those provisions serve only to restrict the ability of data miners to aggregate, compile, and transfer information destined for narrowly defined commercial ends. In our view, this is a restriction on the conduct, not the speech, of the data miners. Cf. Wine & Spirits I, 418 F.3d at 49 (viewing "provision of advertising services, including designing advertisements, arranging for their placement in various media, and licensing the common use of trade names" as conduct rather than speech). In other words, this is a

situation in which information itself has become a commodity. The plaintiffs, who are in the business of harvesting, refining, and selling this commodity, ask us in essence to rule that because their product is information instead of, say, beef jerky, any regulation constitutes a restriction of speech. We think that such an interpretation stretches the fabric of the First Amendment beyond any rational measure.

The plaintiffs advance two related theories as to why their information processing constitutes speech. First, they analogize their situation to that of a newspaper, noting that they, like a newspaper, collect information of public concern, analyze it, and distribute it for a fee. Second, they liken this case to those in which the Supreme Court has struck down commercial speech restrictions on the ground that the speech contributes to the efficiency of the marketplace. The response to both of these arguments is rooted in the conduct/speech distinction: While the plaintiffs lip-synch the mantra of promoting the free flow of information, the lyrics do not fit the tune.<sup>6</sup> The Prescription Information Law simply does not prevent any information-generating activities. The plaintiffs may still

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<sup>6</sup> Characterizing the Prescription Information Law as a paternalistic ban on the influx of information into the marketplace misses the point. Detailers do not routinely disclose a physician's prescribing history to that physician. Indeed, many physicians who interact with detailers never discover that the detailers possess such information.

gather and analyze this information; and may publish, transfer, and sell this information to whomever they choose so long as that person does not use the information for detailing. Like in FAIR, 547 U.S. at 62, the restriction here is on the conduct (detailing) not on the information with which the conduct is carried out.

The plaintiffs' true complaint, of course, is that in banning this use of their data, we risk drying up the market for their services. To that concern we repeat: "the First amendment does not safeguard against changes in commercial regulation that render previously profitable information valueless." Wine & Spirits I, 418 F.3d at 48. In that case, we offered an example of the closure of a tax loophole rendering tax-shelter information worthless. See id. It is the same here: the seller of information can not be heard to complain that its speech is infringed by a law making the most profitable use of that information illegal. See id. ("The First Amendment's core concern is with the free transmission of a message or idea from speaker to listener, not with the speaker's ability to turn a profit.").

Although speech, protected or not, is implicated by the Prescription Information Law, it consists primarily of communications between detailers and doctors – but no detailer or doctor is a plaintiff here. Therefore, an adjudication of that aspect of the law must await a proper plaintiff.



We add, moreover, that the fact that this information can be freely transferred to anyone for non-detailing purposes renders this case a world apart from statutes that have been struck down in the interest of "provid[ing] a forum where ideas and information flourish." Thompson, 535 U.S. at 367 (quoting Edenfield v. Fane, 507 U.S. 761, 767 (1993)); see also 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 516 (1996) (striking down statute prohibiting advertisement of liquor prices); Edenfield, 507 U.S. at 777 (striking down statute prohibiting in-person solicitation by accountants); Va. Bd. of Pharm., 425 U.S. at 771-73 (striking down statute prohibiting advertisement of price information for drugs).

Pharmaceutical detailing has pushed the art of marketing into uncharted waters. In the service of maximizing drug sales, detailers use prescribing histories as a means of targeting potential customers more precisely and as a tool for tipping the balance of bargaining power in their favor. As such, detailing affects physician behavior and increases the likelihood that physicians will prescribe the detailers' (more expensive) drugs. The New Hampshire legislature found this advantage in bargaining power invidious (chiefly because of its inflationary impact on drug prices) and determined that it compromised the integrity of physician decisionmaking. Consequently, the legislature sought to level the playing field not by eliminating speech but, rather, by

eliminating the detailers' ability to use a particular informational asset – prescribing histories – in a particular way.

To be sure, certain information exchanges are foreclosed by the Prescription Information Law. They are not, however, the sorts of exchanges valued by the Supreme Court's First Amendment jurisprudence but, rather, are exchanges undertaken to increase one party's bargaining power in negotiations. We believe that in moving to combat the novel problems presented by detailing in the information age, New Hampshire has adopted a form of conduct-focused economic regulation that does not come within the First Amendment's scope.

Accordingly, we hold that the challenged portions of the Prescription Information Law fall outside the compass of the First Amendment. They thus engender rational basis review as a species of economic regulation. See, e.g., Nat'l Amusements, Inc. v. Town of Dedham, 43 F.3d 731, 736 (1st Cir. 1995). The plaintiffs concede that the challenged portions of the law survive that modest level of scrutiny. The challenge under the Free Speech Clause must, therefore, fail.

## **VI. FIRST AMENDMENT SCRUTINY**

Although we could end our odyssey here, there is another path open to us that leads to the same distinction. Even if the Prescription Information Law is treated as a restriction on

protected speech, it is nonetheless constitutional. This, then, constitutes an alternative ground for our decision.

Assuming, *arguendo*, that the acquisition, manipulation, and sale of prescriber-identifiable data comes within the compass of the First Amendment, the Prescription Information Law would have to survive intermediate scrutiny as a regulation of commercial speech. See Florida Bar v. Went For It, Inc., 515 U.S. 618, 623 (1995). As we explained above, *see supra* Part IV, the plaintiffs lack standing to assert the rights of the pharmaceutical companies, the detailers, or the physicians. Their challenge must therefore rise or fall based on the curtailment of their own rights (rights emanating from the upstream transactions to which they are privy).

If speech at all, these transactions are commercial speech; that is, they at most embody "expression related solely to the economic interest of the speaker and its audience." Cent. Hudson, 447 U.S. at 561. While the plaintiffs argue for a narrower definition of commercial speech limited to activities "propos[ing] a commercial transaction," Bd. of Trs. of State Univ. of N.Y. v. Fox, 492 U.S. 469, 473-74 (1989), the case law is inhospitable to this argument. See, *e.g.*, Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 309 (1st Cir. 2005); El Día, Inc. v. P.R. Dep't of Consumer Affairs, 413 F.3d 110, 115 (1st Cir. 2005). We therefore reject it and conclude instead that the Prescription

Information Law, if regarded as a restriction on protected speech, must be analyzed under the rubric of commercial speech.

That conclusion brings front and center the familiar Central Hudson test. Under Central Hudson – so long as the speech in question concerns an otherwise lawful activity and is not misleading – statutory regulation of that speech is constitutionally permissible only if the statute is enacted in the service of a substantial governmental interest, directly advances that interest, and restricts speech no more than is necessary to further that interest. See Cent. Hudson, 447 U.S. at 556; Wine & Spirits Retailers, Inc. v. Rhode Island (Wine & Spirits II), 481 F.3d 1, 8 (1st Cir. 2007). In administering this test, we must remain mindful that the party seeking to sustain a restriction on commercial speech bears the burden of justifying that restriction. Thompson, 535 U.S. at 373; Edenfield, 507 U.S. at 770.

On behalf of the Prescription Information Law, New Hampshire cites three governmental interests: maintaining patient and prescriber privacy, protecting citizens' health from the adverse effects of skewed prescribing practices, and cost containment. For simplicity's sake, we restrict our analysis to the third of these interests.

Fiscal problems have caused entire civilizations to crumble, so cost containment is most assuredly a substantial

governmental interest. As such, cost containment suffices to satisfy the first prong of the Central Hudson test.

The next question – whether the law directly advances that interest – is not so cut and dried. To succeed on this prong of the test, the state "must demonstrate that the harms it recites are real and that [the] restriction will in fact alleviate them to a material degree." Edenfield, 507 U.S. at 770-71. Speculation, surmise, or fevered imaginings will not carry the day. Id. at 770.

This does not mean, however, that certitude is required. A state need not go beyond the demands of common sense to show that a statute promises directly to advance an identified governmental interest. See, e.g., Burson v. Freeman, 504 U.S. 191, 211 (1992). While empirical data must plausibly point to a conclusion, that data need not be "accompanied by a surfeit of background information." Florida Bar, 515 U.S. at 628. States are allowed "to justify speech restrictions by reference to studies and anecdotes" or even to justify them "based solely on history, consensus, and simple common sense." Id. (internal quotation marks omitted).

Here, the state's evidence falls into three evidentiary subsets, each of which forges some part of the causal chain leading from transfers of prescribers' histories for use in detailing to higher drug prices.

The first category embodies evidence showing that detailing increases the cost of prescription drugs. The second involves a showing that prescribers' histories enhance the success of detailing. The final category encompasses evidence indicating that, notwithstanding these escalating costs, detailing does not contribute to improved patients' health. Drawing these inferences, the state reasons that stripping detailers of the ability to use prescribers' histories as a marketing tool will decrease the quantities of (relatively expensive) brand-name drugs dispensed, increase the quantities of (relatively inexpensive) generic drugs dispensed, and thus reduce or contain overall costs. The plaintiffs respond with evidence of the positive effects of detailing enhanced by prescribers' histories and by noting that the state has not proven that health care costs will ebb following increased substitution of generic drugs for brand-name drugs.

The state's initial point is unarguable: pharmaceutical companies use detailing to promote the sale of brand-name drugs, and those drugs cost significantly more than their generic counterparts.<sup>7</sup> Detailing works: that it succeeds in inducing physicians to prescribe larger quantities of brand-name drugs

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<sup>7</sup> Of course, targeted detailing is employed not only to promote the sale of brand-name drugs in lieu of generic drugs, but also to encourage prescribers to choose one particular brand-name drug over another. The latter situation is not the state's primary concern because the cost differential between competing brand-name drugs is less likely to be significant.

seems clear (even if the exact magnitude of that effect is not). See, e.g., Puneet Manchanda & Elisabeth Honka, The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An integrative Review, 5 Yale J. Health Pol'y L. & Ethics 785, 809 (2005); Ashley Wazana, Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?, 283 J. Am. Med. Ass'n 373, 378 (2000). The fact that the pharmaceutical industry spends over \$4,000,000,000 annually on detailing bears loud witness to its efficacy.

The testimony adduced at trial reinforced these common-sense conclusions. Dr. Jerome Avorn, a professor at Harvard Medical School specializing in pharmacoepidemiology and pharmacoconomics, described studies showing that detailing substantially increases physicians' rates of prescribing brand-name drugs. This account echoed testimony of the president and president-elect of the New Hampshire Medical Society.

The evidence in support of the second step in the progression – that detailing becomes incrementally more successful when pursued with the aid of physician-specific prescribing histories – is less formidable. Still, Dr. Avorn drew analogies to opine that detailers armed with prescribing histories enjoyed a significant marketing advantage, resulting in greater leverage, increased sales of brand-name drugs, and higher drug costs – all with no corresponding benefit to patients. In addition, a former

detailer, relying on personal experience, testified about various kinds of leverage that prescribing histories afforded detailers (e.g., the ability to target physicians prescribing large quantities of generic drugs, the ability to zero in on a physician's customary prescribing choices, and the ability to punish physicians who fail to display allegiance to particular brand-name drugs). Each of these witnesses emphasized that prescribing histories helped the detailer to become more adversarial in her presentation and to focus on the weakness of the physician's erstwhile drug of choice as opposed to the clinical virtues of the detailed drug. A promotional brochure published by IMS for detailers' use corroborated many of these claims, as did a submitted newspaper article that formed part of the legislative history underlying the Prescription Information Law. See Liz Kowalczyk, Drug Companies' Secret Reports Outrage Doctors, Boston Globe, May 25, 2003, at A1.

The plaintiffs did not deny that prescribing histories made detailing more efficacious. They did, however, try to cast detailing as a helpful and informative activity. In their view, prescribing histories enable detailers both to target the physicians most likely to benefit from an educational interaction and to craft a marketing message tailored to the physician's practice. The plaintiffs offered the testimony of Dr. Thomas Wharton, a distinguished cardiologist, to support this



characterization. Dr. Wharton found detailing to produce highly informative interactions in which "the level of discourse is elevated." Other testimony indicated that the availability of prescribing histories permitted detailers to inform physicians more quickly of negative information. Finally, the plaintiffs adduced evidence anent the purported value of identifying and targeting "early adopters."

The district court determined that the state's asserted cost containment interest failed to satisfy the second prong of the Central Hudson test. The court based this determination on its conclusion that the final link in the chain of reasoning was missing: "[t]he Attorney General appears to assume that any health care cost savings that will result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care." D. Ct. Op., 490 F. Supp. 2d at 180. This assumption was flawed, the court wrote, because brand-name drugs sometimes served patients better than their generic counterparts; thus, it was possible that an increase in generic drug prescriptions might compromise patient care, engender new medical costs, and overwhelm any savings. Id. at 180-81.

Admittedly, the state's showing that health care costs would lessen should prescriber histories be denied to detailers was not overwhelming. But even though there was no direct evidence on that point, the state did present unrebutted testimony

to the effect that detailing tended dramatically to increase the prescription of brand-name drugs (and, thus, the cost of prescription drugs) without conferring any corresponding public health benefit. This was the opinion of Dr. Avorn, and Dr. Wazana's article reached the same conclusion. See Wazana, supra, at 375. The record also contains evidence of widespread incidents – Vioxx and calcium channel blockers are two prominent examples – that pointed in the same direction. Finally, the record contains a study that found that 11% of detailers' statements to physicians were demonstrably inaccurate.<sup>8</sup> See M. G. Ziegler, P. Lew & B.C. Singer, The Accuracy of Drug Information from Pharmaceutical Sales Representatives, 273 J. Am. Med. Ass'n 1296 (1995).

In the face of this highly suggestive evidentiary predicate, the district court's demand that the state prove that the substitution of generic drugs for brand-name drugs would not lead to higher net health care costs subjected the state to a level of scrutiny far more exacting than is required for commercial speech. See City of Renton v. Playtime Theatres, Inc., 475 U.S. 41, 51 (1986) (permitting city to rely on experiences of different localities); Nat'l Amusements, 43 F.3d at 742 (permitting town to rely on residents' complaints, "constabulatory

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<sup>8</sup> The plaintiffs responded to this study by citing the federal Food and Drug Administration regulations prohibiting false medical advertisements. See 21 C.F.R. § 202.1. That response is a non-sequitur. The fact that certain behavior is prohibited by law is not a guarantee that persons will not engage in it.

concern with a pattern of incidents," and common sense). The state provided competent evidence that detailing increases the prescription of brand-name drugs, that brand-name drugs tend to be more expensive, that detailers' possession of prescribing histories heightens this exorbitant effect, that many aggressively detailed drugs provide no benefit vis-à-vis their far cheaper generic counterparts, and that detailing had contributed to pharmaceutical scandals endangering both the public health and the public coffers. Viewed against that background, the fact that some detailed brand-name drugs may produce superior results in some cases is too flimsy a hook on which to hang a conclusion that a decrease in the prescription of brand-name drugs would be unlikely to yield a net diminution in health care costs. While the state's position is not ironclad, the district court's objection to it partakes of a far greater degree of conjecture.

In the last analysis, this is more a matter of policy than of prediction. Just as some brand-name drugs produce superior results when compared to generic drugs, some generic drugs produce superior (or, at least, equal) results when compared to brand-name drugs. The record contains substantial evidence that, in several instances, detailers armed with prescribing histories encouraged the overzealous prescription of more costly brand-name drugs regardless of both the public health consequences and the probable outcome of a sensible cost/benefit analysis. By

way of contrast, the record contains no evidence that in the absence of detailing, physicians have tended to prescribe generic drugs more often than either their patients' health or their patients' pocketbooks warranted. The district court seems to have overlooked this dichotomy.

Perhaps more important, the court appears to have disregarded the constraints under which states operate in formulating public policy on cutting-edge issues. New Hampshire was the first state to deny detailers access to prescribing histories. Had other states been in the vanguard, it might be permissible to take New Hampshire to task for not presenting studies relative to the law's effect on net health care costs. But to demand such evidence from the first state to refuse detailers access to prescribing histories is to demand too much: that evidence simply does not exist. The First Amendment requires states to assess their own interests realistically and to take only reasonable steps in furtherance of these discerned interests; it does not require Augean feats in order to sustain regulations restricting commercial speech.

The short of the matter is that while a state legislature does not have unfettered discretion "to suppress truthful, nonmisleading information for paternalistic purposes," 44 Liquormart, 517 U.S. at 510, there is in this area "some room for the exercise of legislative judgment," id. at 508. We are

duty bound to grant the New Hampshire legislature such elbow room here.

To this we add that, as Justice Brandeis famously observed, "[i]t is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments." New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting). That is the case here – and we must allow the state legislature some leeway to experiment with different methods of combating a social and economic problem of growing magnitude.

At this point, the plaintiffs interpose yet another potential roadblock: they urge us to withhold deference to the legislature's choice of goals and measures in light of the thinness of the legislative record and the relative celerity (four months) with which the legislature acted. They compare New Hampshire's legislative record to the legislative record granted deference by the Supreme Court in Turner Broadcast System v. FCC, 520 U.S. 180, 199 (1997) (noting that the congressional record included "years of testimony and reviewing volumes of documentary evidence and studies offered by both sides" compiled three years of hearings).

This is a red herring. It is fanciful to suggest that the congressional record in Turner represents the threshold for

deference. Furthermore, the plaintiffs' argument converts the issue of deference into a mechanical counting of days and pages. We flatly reject this myopic approach. After all, deference is a matter of degree. Here, we defer to the New Hampshire legislature only on the narrow question of whether it is sensible to conclude (hypothetically) that net medical outlays will decrease as a result of the withdrawal of prescribing histories from detailers. Given the contents of the legislative record, we believe that deference is in order.

We need not probe this point more deeply. In the end, we conclude that the state adequately demonstrated that the Prescription Information Law is reasonably calculated to advance its substantial interest in reducing overall health care costs within New Hampshire.

This leaves the third Central Hudson question: whether the regulation is no more extensive than necessary to serve the state's interest in cost containment. The Supreme Court has explained that this standard requires the restriction to be "in reasonable proportion to the interest served." Edenfield, 507 U.S. at 767. More recently, the Court applied a gloss, stating that "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." Thompson, 535 U.S. at 371.

Invoking Thompson, the district court concluded that New Hampshire's goal of cost containment could have been achieved by three alternative measures, none of which would have restricted speech. D. Ct. Op., 490 F. Supp. 2d at 181-83. On that basis, the court found that the third prong had not been met.

Our starting point is well-marked: "If the First Amendment means anything, it means that regulating speech must be a last – not first – resort." Thompson, 535 U.S. at 373. This does not mean, however, that a state must forgo legitimate regulatory goals merely because an objector can hypothesize alternative measures of doubtful efficacy that would leave speech unencumbered.

In this instance, the district court seems to have overestimated the extent to which the alternatives it described were geared to accomplish the state's objective. The Prescription Information Law was a targeted legislative response to a particular problem that had proven resistant to a number of different regulatory approaches. The three measures embraced by the district court were no improvement on those ineffectual approaches.

The first of the measures comprises a ban on gifts between detailers and physicians. Such a measure would target a harm that the legislature never deemed central to its aims. Some studies do indicate that detailers' gifts influence prescribing

behavior, but the New Hampshire legislature only saw such gift-giving as pernicious when it occurred within the context of a high-intensity sales pitch made possible by a detailer's possession of a physician's prescribing history. Moreover, such a ban would have unintended consequences; it would necessarily cut off the flow of free samples that physicians receive from detailers and often dispense to indigent patients. New Hampshire was constitutionally entitled to attempt to regulate detailing without killing this golden goose.

The second measure comprises an envisioned campaign to educate physicians to prescribe generic drugs whenever possible. This suggested measure fails as a matter of simple economics. Pharmaceutical companies spend over \$4,000,000,000 per year on detailing. Against that marketing juggernaut, the state would need to commit enormous resources to put across a contrary message. It is not a ground for striking down a commercial speech regulation that some counter-informational campaign, regardless of the cost, might restore equilibrium to the marketplace of ideas. See Posadas de P.R. Assocs. v. Tourism Co., 478 U.S. 328, 344 (1986).

The third measure hinges on the thought that it would be workable for New Hampshire to retool its Medicaid program so that non-preferred drugs – such as expensive brand-name drugs for which non-bioequivalent generic substitutes exist – would only be



dispensed upon a physician's consultation with a pharmacist. See D. Ct. Op., 490 F. Supp. 2d at 182. This suggested measure fails for impracticability, for incompleteness, and for coming too late in the prescription process. Implementing it would take extra time out of a doctor's day and, in all events, would make no inroads with respect to privately insured patients. And finally, this third measure represents a crude attempt to remedy the compromised prescribing habits of physicians after the fact. We explain briefly.

Physicians prescribe medications for individuals on the basis of a multitude of factors. A generic drug – whether or not bioequivalent – will rarely be capable of being recommended across the board as a substitute for a brand-name drug because each drug offers subtly different situation-specific advantages. The physician must attend to the patient's individual symptoms, make a diagnosis, and prescribe accordingly. Detailing provably skews physicians toward prescribing more brand-name drugs by highlighting strengths of brand-name drugs unrelated to the patient's individual condition. Inserting one more laborious step into the decisionmaking process may incline physicians to prescribe fewer brand-name drugs and more generic drugs; but it will do nothing to correct for or efface the distorting factors previously introduced into the physician's prescribing habits. The New Hampshire legislature enacted the Prescription Information

Law not only to lower costs but also to prevent detailers from exerting so much influence over physicians' prescribing habits.

In sum, we find that neither the plaintiffs nor the district court has identified an alternative to the Prescription Information Law that promises to achieve the goals of the law without restricting speech. Consequently, we hold that the Prescription Information Law is no more restrictive than necessary to accomplish those goals.

That ends our First Amendment inquiry. For the reasons elucidated above, we hold that the challenged portions of the Prescription Information Law survive the rigors of intermediate scrutiny. Thus, even if one assumes that those provisions to some extent implicate commercial speech, they do not violate the First Amendment.

#### **VII. VOID FOR VAGUENESS**

Terming numerous undefined words and phrases in the Prescription Information Law amorphous or ambiguous, the plaintiffs contend that the statute is unconstitutionally vague.<sup>9</sup> This contention need not detain us.

The pertinent statutory text is set out earlier in this opinion, see supra Part II, and it would serve no useful purpose

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<sup>9</sup> The plaintiffs mention in passing that the Prescription Information Law is overbroad but they do not develop an overbreadth argument. Any such argument is, therefore, waived. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990).

to repastinate that ground. It suffices to say that the plaintiffs question virtually everything from soup to nuts – from the meaning of the adjective "identifiable" to the scope of the phrase "commercial purpose." They allege that this pervasive imprecision chills protected speech (especially since violations of the statute may trigger both criminal and civil penalties). See Reno v. ACLU, 521 U.S. 844, 872 (1997).

We readily acknowledge that the Prescription Information Law is not a model of legislative craftsmanship. But statutes do not need to be precise to the point of pedantry, and the fact that a statute requires some interpretation does not perforce render it unconstitutionally vague. See Ridley v. Mass. Bay Transp. Auth., 390 F.3d 65, 93 (1st Cir. 2004). That is the case here.

A federal court may interpret state law by using the same method and approach that the state's highest court would use. See Nat'l Pharms., Inc. v. Feliciano-de-Melecio, 221 F.3d 235, 241-42 (1st Cir. 2000); see also Planned Parenthood of Idaho, Inc. v. Wasden, 376 F.3d 908, 930 (9th Cir. 2004) ("Ordinarily, in construing a state statute, we follow the state's rules of statutory interpretation.").

Under New Hampshire law, an inquiring court may consider legislative history to aid in clarifying an ambiguous statute. Hughes v. N.H. Div. of Aero., 871 A.2d 18, 26 (N.H. 2005). The objective is to construe a statute "in light of the legislature's

intent in enacting [it], and in light of the policy sought to be advanced by the entire statutory scheme." Carlisle v. Frisbie Mem. Hosp., 888 A.2d 405, 417 (N.H. 2005). Consistent with that approach, an inquiring court should not hesitate to "presume any narrowing construction or practice to which the law is fairly susceptible." City of Lakewood v. Plain Dealer Publ'g Co., 486 U.S. 750, 770 n.11 (1988) (internal quotation marks omitted); see Stenberg v. Carhart, 530 U.S. 914, 944-45 (2000); R.I. Ass'n of Realtors, Inc. v. Whitehouse, 199 F.3d 26, 36 (1st Cir. 1999).

Read in light of the legislature's manifest intent, the Prescription Information Law is sufficiently clear to withstand the plaintiffs' vagueness challenge. The legislature's avowed intent was to curtail in New Hampshire what it viewed as the pernicious practice of targeted detailing by pharmaceutical companies. It sought to do so by prohibiting "for any commercial purpose" the dissemination and use of the data on which targeting had come to depend: prescriber histories. In keeping with this narrow purpose, the statute excludes from its coverage almost every commercial use other than detailing; the listed exemptions include "pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research or as otherwise provided by law." N.H. Rev. Stat. Ann. § 318:47-f.

As we understand the state's position, these categories of exceptions are to be construed broadly to avoid impinging upon uses of prescriber-identifiable data that do not implicate the state's core concern. For example, the Attorney General explicitly acknowledged in the court below that the Prescription Information Law does not bar the plaintiffs from selling prescriber-identifiable data to pharmaceutical companies for research or for recruiting physicians to participate in clinical trials of newly developed drugs. Given that understanding, the fact that data derived from such research or trials later may be used in the companies' general marketing cannot transform the permitted uses into ones that have an impermissible purpose. After all, marketing and sales are the ultimate purposes for virtually all research done by pharmaceutical companies. As long as the companies do not undertake targeted detailing of New Hampshire-based clinical trial participants – whose prescribing data was obtained for research purposes – there is no violation of the Prescription Information Law.

We recognize that this construction of the Prescription Information Law is not inevitable. But this is a facial challenge, and the state's articulated purpose narrows the interpretive lens through which we must view the problem. See Davis v. FEC, 128 S. Ct. 2759, 2770-71 (2008) (noting that in facial challenges courts should "extend[] a measure of deference

to the judgment of the legislative body that enacted the law"); Wash. State Grange v. Wash. State Repub. Party, 128 S. Ct. 1184, 1194 (2008) (explaining that deference requires an inquiring court to ask whether challenged law could possibly be implemented constitutionally). This perspective requires us to give the exceptions their full scope and eliminates any chilling effect. Health care professionals who use prescriber-identifiable data to influence physician prescribing decisions other than through direct marketing need not be concerned that their activity will offend the statute.

This narrow reading of the Prescription Information Law similarly serves to allay concerns that pharmacies and other sources of prescriber data will be subject to prosecution based on some improper downstream use of that data. As long as such entities impose conditions on the transfer of such data that require purchasers to comply with the terms of the law, they are safe. Thus, when data is requested for one of the myriad uses that are permissible under the Prescription Information Law, there should be no chilling effect.<sup>10</sup>

For these reasons, we reject the plaintiffs' contention that the law is void for vagueness.

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<sup>10</sup> Because no pharmaceutical company is a party to this litigation, we decline to address whether an action could be maintained under the Prescription Information Law against a pharmaceutical company that uses data properly acquired for one purpose to target physicians for detailing.

### VIII. DORMANT COMMERCE CLAUSE

Finally, the plaintiffs mount a Commerce Clause challenge to the Prescription Information Law. They maintain that the statute violates the Constitution by regulating conduct wholly outside New Hampshire. This argument is unavailing.

The Commerce Clause, ostensibly an affirmative grant of power to Congress "[t]o regulate Commerce . . . among the several states," U.S. Const. art. I § 8 cl. 3, embodies a negative aspect that "prevents state and local governments from impeding the free flow of goods from one state to another." Alliance of Auto. Mfrs. v. Gwadosky, 430 F.3d 30, 35 (1st Cir. 2005) (quoting Houlton Citizens Coal. v. Town of Houlton, 175 F.3d 178, 184 (1st Cir. 1999)). The proper mode of analysis under this so-called "dormant Commerce Clause" depends upon the scope of the challenged statute. See id. A law that purports to regulate conduct occurring wholly outside the enacting state "outstrips the limits of the enacting state's constitutional authority and, therefore, is per se invalid." Id.; see Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 79 (1st Cir. 2001), aff'd, 538 U.S. 644 (2003). This is the principle that the plaintiffs see as controlling here.

Their argument runs along the following lines. They point out that the New Hampshire law lacks any explicit mention of a geographic limitation. Building on this foundation, they invite us to hold that the N.H. Rev. Stat. Ann. § 318:47-f. prohibits the

licensing, transfer, use, and sale of prescriber-identifiable data everywhere, (including transactions that take place wholly outside New Hampshire). So interpreted, the statute would, among other things, prohibit the transfer of data from a pharmacy benefits manager located in, say, New York to Verispan, a Delaware firm headquartered in Pennsylvania. Such a direct regulation of out-of-state transactions would, the plaintiffs assert, be per se invalid under the dormant Commerce Clause. See Alliance of Auto. Mfrs., 430 F.3d at 35.

For its part, the state urges us to interpret the law as governing only in-state transactions. As we already have explained, a federal court normally should interpret state law using the same method and approach that the highest court of the state would use. See Nat'l Pharms., 221 F.3d at 241-42.

An assertion that the Commerce Clause invalidates a particular statutory scheme presents a facial challenge to that statute. See generally United States v. Nascimento, 491 F.3d 25, 41 (1st Cir. 2007) (distinguishing facial and as-applied Commerce Clause challenges to federal law), cert. denied, 128 S. Ct. 1738 (2008). "[I]n evaluating a facial challenge to a state law, a federal court must . . . consider any limiting construction that a state court or enforcement agency has proffered." McGuire v. Reilly, 386 F.3d 45, 58 (1st Cir. 2004) (quoting Ward v. Rock Against Racism, 491 U.S. 781, 795-96 (1989)). This same deference



obtains in the courts of New Hampshire. See In re Morgan, 742 A.2d 101, 109 (N.H. 1999) (counseling deference to administrative interpretations of statutes unless such an interpretation is "plainly incorrect").

Two additional principles of statutory interpretation figure into the equation. First, state statutes should be presumed to govern only conduct within the borders of the enacting state. See K-S Pharms., Inc. v. Am. Home Prods. Corp., 962 F.2d 728, 730 (7th Cir. 1992); State v. McGlone, 78 A.2d 528, 530 (N.H. 1951). Second, statutes should be given a constitutional as opposed to an arguably unconstitutional interpretation whenever fairly possible. See Arizonans for Official English v. Arizona, 520 U.S. 43, 78 (1997); Nascimento, 491 F.3d at 38; see also Sibson v. State, 259 A.2d 397, 400 (N.H. 1969) (explaining that "a statute will be construed to avoid a conflict with constitutional rights whenever that course is reasonably possible").

Here, the New Hampshire Attorney General – the state official charged with enforcing its laws – has exhorted us to read the Prescription Information Law to "relate only to activity that takes place domestically." Appellant's Reply Br. at 13. This narrowing construction is reasonable and accords with the tenet that laws should not be presumed to have extraterritorial effect. It also avoids any doubt about the law's constitutionality under the dormant Commerce Clause. As the Seventh Circuit wisely

observed when confronted with a similar state statute lacking any built-in geographic restriction, it would make no sense to read the statute to regulate out-of-state transactions when the upshot of doing so would be to annul the statute. See K-S Pharms., 962 F.2d at 730.

There is no need to belabor the point. We are confident that the New Hampshire Supreme Court would interpret the Prescription Information Law to affect only domestic transactions. Seen in this light, the plaintiffs' dormant Commerce Clause challenge necessarily fails. This law may result in a loss of profit to out-of-state data miners due to the closing of one aspect of the New Hampshire market for their wares, but that circumstance amounts neither to regulating conduct outside the state nor to "necessarily requir[ing] out-of-state commerce to be conducted according to in-state terms." Wine & Spirits II, 481 F.3d at 15.

We add a coda. Our dissenting brother concedes that, on its face, the Attorney General's interpretation of the Prescription Information Law obviates any Commerce Clause problem. He nevertheless suggests that that interpretation leaves the Act with "negligible impact" and is, therefore, unreasonable. We fail to see the logic in this suggestion.

To be sure, the Attorney General's plausible interpretation of the Prescription Information Law, which permits

the routine transfer of data to out-of-state facilities where it can then be aggregated and sold legally to others, may not accomplish very much.<sup>11</sup> But that does not make the Attorney General's interpretation unreasonable. See Maquire, 386 at 58; In re Morgan, 742 A.2d at 109. There is no rule that forbids a legislature from enacting prophylactic legislation to prevent disfavored activity before individuals engage in that activity.

#### **IX. CONCLUSION**

We need go no further. For the reasons elucidated above, we reverse the decision of the district court and vacate the injunction against enforcement of the Prescription Information Law.

**Reversed.**

**- Concurring/Dissenting Opinion Follows -**

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<sup>11</sup> The question remains, however, whether the purchasers could subsequently make use of the aggregated data in New Hampshire. That question is not before us.

**LIPEZ, Circuit Judge,** concurring and dissenting.

Although I agree with the majority that the district court's decision cannot stand, I respectfully disagree with the majority's refusal to address the First Amendment issue at the core of this case. The majority focuses on the so-called upstream transactions - the acquisition, aggregation, and sale of prescriber-identifiable data by the plaintiffs - and concludes that such activity is not speech within the purview of the First Amendment. That conclusion is self-evident and beside the point. In enacting the Prescription Information Confidentiality Act ("the Prescription Act" or "the Act"),<sup>12</sup> the New Hampshire Legislature chose to regulate the upstream transactions because it wanted to alter the message used by pharmaceutical detailers in pursuing a downstream transaction with health care professionals. In other words, the Act was designed to limit the speech of those detailers. The majority relies on the prudential doctrine of standing to avoid deciding whether that limitation violates the First Amendment. In my view, that avoidance is wasteful and unwise, unsupported by principles of standing, and analytically flawed.

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<sup>12</sup> The legislation did not include a formal title for the statute; I have adopted a formulation that blends the district court's and the parties' usage.

Consequently, after examining the issue of standing, I address the issue that we should be addressing - whether the Act restricts protected commercial speech between detailers and prescribers and, if so, whether the State can justify that restriction under the commercial speech test of Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557, 566 (1980). I conclude that the Act does restrict commercial speech, and that the State's interest in cost containment justifies that restriction. I also conclude, contrary to the majority, that we should remand the case for consideration of the plaintiffs' Commerce Clause challenge.

**I.**

The majority admits that speech is implicated by the Prescription Act and identifies that speech as "primarily [the] communications between detailers and doctors." It purports to refuse to address the Act's impact on that targeted speech, based on principles of standing, because "no detailer or doctor is a plaintiff here." However, not only do my colleagues misguidedly invoke standing to avoid explicitly resolving the constitutionality of the Act's restriction on communications between detailers and doctors, but they also accept the State's justification for the restriction without allowing the plaintiffs to establish the First Amendment values at stake. The majority's use of standing principles is thus doubly wrong.

### **A. The Prudential Policies of Third Party Standing**

In Craig v. Boren, 429 U.S. 190 (1976), the Supreme Court considered whether a beer vendor could challenge on equal protection grounds an Oklahoma statute that prohibited the sale of "nonintoxicating" 3.2% beer to males under 21 and to females under 18. The question was whether the beer vendor had standing to raise the equal protection objections of 18- to 20-year-old males.

The Court noted that the plaintiff had the requisite "injury in fact" to satisfy the constitutional standing requirement, id. at 194,<sup>13</sup> leaving only a prudential concern about whether the plaintiffs should be allowed to raise third-party constitutional claims.

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<sup>13</sup> The Court stated there:

The legal duties created by the statutory sections under challenge are addressed directly to vendors such as appellant. She is obliged either to heed the statutory discrimination, thereby incurring a direct economic injury through the constriction of her buyers' market, or to disobey the statutory command and suffer, in the words of Oklahoma's Assistant Attorney General, "sanctions and perhaps loss of license." This Court repeatedly has recognized that such injuries establish the threshold requirements of a "case or controversy" mandated by Art. III.

429 U.S. at 194.

In concluding that the vendor's claims could go forward, the Court observed that it is "settled that limitations on a litigant's assertion of jus tertii are not constitutionally mandated, but rather stem from a salutary 'rule of self-restraint' designed to minimize unwarranted intervention into controversies where the applicable constitutional questions are ill-defined and speculative." Id. at 193. However, in the circumstances before the Court in Craig, such "prudential objectives" could not be furthered because "the lower court already ha[d] entertained the relevant constitutional challenge and the parties ha[d] sought or at least ha[d] never resisted an authoritative constitutional determination." The Court continued:

In such circumstances, a decision by us to forgo consideration of the constitutional merits in order to await the initiation of a new challenge to the statute by injured third parties would be impermissibly to foster repetitive and time-consuming litigation under the guise of caution and prudence. Moreover, insofar as the applicable constitutional questions have been and continue to be presented vigorously and "cogently," the denial of jus tertii standing in deference to a direct class suit can serve no functional purpose.

Id. at 193-94 (citation omitted).

There is no debate that the plaintiffs in this case also meet the requirements for Article III standing. Like the beer vendors in Craig, the plaintiffs here are direct targets of the challenged statute. By seeking to prevent pharmaceutical

detailers from using prescriber data in their sales pitches to New Hampshire health care providers, the Act diminishes the market for the prescriber data collected, organized and sold by plaintiffs and thereby inflicts "a direct economic injury through the constriction of [the] buyers' market." 429 U.S. at 194. Thus, as in Craig, only the prudential standing doctrine is at issue, and here, too, pragmatic considerations are paramount. The district court heard evidence from about a dozen witnesses and considered voluminous other materials in preparing its thoughtful and comprehensive decision. Nothing in the extensive record even hints that the plaintiffs were unable or unwilling to aggressively litigate the First Amendment issues at stake in the "downstream" transactions between the detailers and physicians. Such an inability or unwillingness would counsel prudence in resolving the First Amendment issues raised by those transactions without the participation of the pharmaceutical companies or doctors. But here the First Amendment issues raised by the exchanges between detailers and physicians were explored exhaustively.

Moreover, the district court expressly confronted the question of third-party standing before proceeding with the case. The court told the parties that, if the State sought to invoke standing as a barrier to full resolution of the action, it would stay the case for thirty days to allow intervention by a pharmaceutical company. The court explained:



[I]t's very clear you are working closely with the pharmacy companies here. They don't want to be the ones to stand up and fight the doctors. They want you to do it. We all know what's going on here, and the reality is if they have to, they will come out from behind the scenes and get out into the forefront, because they want this information, and they want you to be fighting the battle for them. But if we have to, we'll get them in here. I just don't think it really matters.

So the state should think about that. If you want to fight on that issue, that's what I would do. I would first do an argument on third-party standing. If I think there's any issue with third-party standing, if the plaintiff asked for it, I will give them 30 days to amend to bring in a new plaintiff pharmacy company, in which case it seems to me the third-party standing argument disappears.

I didn't think we were going to be talking about third-party standing today, since it's not really raised in the briefs now. But if you want to press that, I think we'll have to deal with it that way.

(Emphasis added.) The Attorney General then said that "we don't intend to press that at this time." The issue was not addressed by either party on appeal.

In these circumstances, as in Craig, "a decision . . . to forgo consideration of the constitutional merits in order to await the initiation of a new challenge to the statute by injured third parties would be impermissibly to foster repetitive and time-consuming litigation under the guise of caution and prudence." 429 U.S. at 193-94. The prudence invoked by the majority serves no purpose and it ignores the judgment of the district court, based on its immersion in the details of the case,

that the absence of the pharmaceutical companies as parties did not compromise the proper adjudication of the case.

I recognize that the Supreme Court's precedent on third-party standing since Craig, as well as our own precedent, set out a formal three-prong inquiry that could not be satisfied here because, as the majority observes, there is no indication in the record that pharmaceutical companies or health care providers who prescribe medication are unable to assert their own rights. See, e.g., Kowalski v. Tesmer, 543 U.S. 125, 129-30 (2004); Powers v. Ohio, 499 U.S. 400, 410-11 (1991); Wine & Spirits Retailers, Inc. v. Rhode Island (Wine & Spirits I), 418 F.3d 36, 49 (1st Cir. 2005). However, none of those cases suggests that the pragmatic factors emphasized by the Court in Craig no longer have force in comparable circumstances.

The prudential limitations on standing were designed to "add to the constitutional minima a healthy concern that if the claim is brought by someone other than one at whom the constitutional protection is aimed, the claim not be an abstract, generalized grievance that the courts are neither well equipped nor well advised to adjudicate." Sec'y of State of Md. v. Joseph H. Munson Co., 467 U.S. 947, 955 n.5 (1984); see also Miller v. Albright, 523 U.S. 420, 446 (1998) (O'Connor, J., concurring) (stating that the requirement that a litigant assert his own legal rights "arises from the understanding that the third-party

rightholder may not, in fact, wish to assert the claim in question, as well as from the belief that 'third parties themselves usually will be the best proponents of their rights'") (citation omitted). The Supreme Court has recognized that the "lessening" of these limitations may be justified where other concerns, such as the danger of chilling free speech, are more pressing, Munson, 467 U.S. at 956, or where, as in Craig, such limitations do not serve the purpose for which they were designed.

Indeed, the Court in Tesmer conceded that it had been "quite forgiving with the[] criteria [for third-party standing] in certain circumstances," and identified the context of the First Amendment as one in which flexibility may be warranted. Tesmer, 543 U.S. at 130. In Munson, the Court described its conclusion to allow third-party standing in terms also applicable here: "The activity sought to be protected is at the heart of the business relationship between [the plaintiff] and its clients, and [the plaintiff's] interests in challenging the statute are completely consistent with the First Amendment interests of the [third parties] it represents. We see no prudential reason not to allow it to challenge the statute." 467 U.S. at 958. Thus, notwithstanding the Court's more detailed articulation of the third-party standing inquiry since Craig, see Miller, 523 U.S. at 447 (O'Connor, J., concurring), the pragmatic considerations highlighted in that decision remain relevant.

This case illustrates the importance of pragmatism. There is no reason to reject the district court's decision to proceed without a pharmaceutical company as a plaintiff unless that decision would result in a trial of the "generalized grievance that the courts are neither well equipped nor well advised to adjudicate," Munson, 467 U.S. at 955 n.5. The reality is that the court and the parties have expended substantial time, resources and energy to address comprehensively the First Amendment issue at the heart of this case. That issue has been vigorously tried and thoughtfully adjudicated. Given our authority to review the court's entire judgment, it is imprudent to avoid that issue.

#### **B. The Unavoidable Issue**

The majority's analysis reveals yet another reason why its reliance on standing is inappropriate. In the first part of its analysis, the majority finds no constitutional flaw in the Act's restriction on "certain information exchanges" because those transfers "are not . . . the sorts of exchanges valued by the Supreme Court's First Amendment jurisprudence." However, to reach that conclusion, the majority considers the societal benefits of a particular form of detailing - the very speech that it claims is beyond the scope of this appeal.

My colleagues insist that the limited scope of review "does not prevent consideration of New Hampshire's interest in

combating detailing." I do not understand how the majority can have it both ways. If the constitutionality of the Act's impact on the detailers' speech is off limits in this case because a pharmaceutical company is not a party, how can the majority make a judgment about the low value of that speech in deciding that the Act regulates only conduct and not speech? Surely we must consider the plaintiffs' First Amendment contentions before concluding that the upstream information "exchanges" that make the speech possible are not worthy of First Amendment protection.

This inconsistency pervades the majority's decision. After making judgments about the nature of the detailing transaction and how it increases the likelihood that physicians will prescribe more expensive drugs, the majority asserts that "the legislature sought to level the playing field not by eliminating speech but, rather, by eliminating the detailers' ability to use a particular informational asset - prescribing histories - in a particular way." (Emphasis added.) Here the majority is characterizing the speech interest that is supposedly beyond the scope of its opinion, and characterizing it incorrectly. The very elimination of the detailers' ability to use "a particular informational asset" restricts the message they are allowed to disseminate and implicates the free speech concerns of the First Amendment.

Moreover, in discussing its alternative holding, which treats the plaintiffs' upstream transactions as speech subject to the First Amendment rather than conduct,<sup>14</sup> the majority weighs the value of detailing, based on the regulated data, against the Legislature's policy objectives and the harms identified by the government. Again, the majority's conclusion that the Act does not violate the First Amendment rests on a judgment about the speech - i.e., the detailing - that the majority purports to place off limits for analysis. For example, the majority points to "substantial evidence" in the record

that, in several instances, detailers armed with prescribing histories encouraged the overzealous prescription of more costly brand-name drugs regardless of both the public health consequences and the probable outcome of a sensible cost/benefit analysis. By contrast, the record contains no evidence that in the absence of detailing, physicians have tended to prescribe generic drugs more often than either their patients' health or their patients' pocketbooks warranted.

The majority ultimately concludes that "the state adequately demonstrated that the Prescription Information Law is reasonably calculated to advance its substantial interest in reducing overall health care costs within New Hampshire."

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<sup>14</sup> The majority never actually identifies the specific speech component of the acquisition, aggregation and sale of information from pharmacies to data miners and from data miners to pharmaceutical companies.

Thus, the majority does what it says standing doctrine forbids: it evaluates the Act based on the law's impact on the speech between detailers and prescribers. The majority's approach is hardly surprising given that this speech was the Act's target. What is surprising is the majority's failure to appreciate that reliance on standing principles is misplaced where, as here, the issue that the majority seeks to avoid is unavoidable. Although ostensibly limiting its First Amendment inquiry to the upstream transactions - the acquisition, aggregation, and sale of prescriber-identifiable data - and deciding in its primary holding that these transactions involve conduct only, the majority makes judgments about the nature, value, and consequences of the speech that occurs in the downstream transactions between detailers and doctors. As the majority discovered, it is impossible to assess the constitutionality of the Act without factoring in the Legislature's specific objective to limit the speech of the detailers.

Moreover, there is no reason to think that the majority's judgments about the statute would change in a case where a pharmaceutical company was a plaintiff. All of the relevant considerations were explored by the district court. They have similarly been explored in the majority's analysis because the majority could not characterize the upstream transactions as

merely conduct without making judgments about the value of the "downstream" speech between the detailers and the doctors.

Thus, both the practicalities of this litigation and the nature of the First Amendment issue require that the case be analyzed as the parties tried it and the district court decided it. I therefore proceed with that analysis. Although my discussion will at times overlap with the majority's, I have chosen to present my complete view of the record and the governing law. The First Amendment question here is both important and close, and I wish to fully explain why, in the end, I conclude that the district court erred in declaring the Prescription Act unconstitutional.

## II.

In recounting the background of this case, I draw heavily on the comprehensive and thoughtful recitation of the facts set out by the district court. See IMS Health Inc. v. Ayotte, 490 F. Supp. 2d 163, 165-74 (D.N.H. 2007). Those facts are largely undisputed; the parties primarily contest their legal significance.<sup>15</sup>

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<sup>15</sup> The appellees argue that we should apply the deferential clear error standard in reviewing the facts found by the district court, rather than the de novo standard that typically applies in First Amendment cases, see Bose Corp. v. Consumers Union, 466 U.S. 485, 514 (1984), because the court held in favor of the free speech claim. Several circuits have adopted such an approach, see, e.g., Multimedia Publ'g Co. of S.C., Inc. v. Greenville-Spartanburg Airport Dist., 991 F.2d 145, 160 (4th Cir. 1993); Daily Herald Co. v. Munro, 838 F.2d 380, 383 (9th Cir. 1988), while others exercise



## A. Pharmaceutical Sales and Marketing

More than three billion prescriptions are written each year by doctors and other licensed health care professionals, covering approximately 8,000 different pharmaceutical products. These prescriptions are filled by approximately 54,000 retail pharmacies; in 2004, such retail prescription sales totaled \$168 billion.<sup>16</sup> In an effort to increase and protect their share of this vast market, pharmaceutical companies engage in various promotional activities. The public is most familiar with direct-to-consumer advertising, in which the drug companies tout the virtues of their products in television commercials and other media, typically urging consumers to ask their doctors for the advertised drugs. However, the bulk of the drug companies' promotional efforts are aimed directly at physicians and other

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independent review regardless of the outcome in the district court. Our court has not yet spoken on the issue, see United States v. Frabizio, 459 F.3d 80, 97 (1st Cir. 2006) (Torruella, J., concurring), but I need not resolve the question here because my disagreement with the district court stems from a different view of the law rather than the facts. Legal issues, as well as mixed questions dominated by legal issues, are subject to de novo review. See In re PolyMedica Corp. Sec. Litig., 432 F.3d 1, 4 (1st Cir. 2005).

<sup>16</sup> The number of prescriptions per capita averaged 10.6 in the United States overall; New Hampshire was close to that average, with 10.1 prescriptions per capita. Trends and Indicators in the Changing Health Care Marketplace, Kaiser Family Foundation, <http://www.kff.org/insurance/7031/print-secl.cfm>, at 20-21 [hereinafter Trends and Indicators].

prescribers.<sup>17</sup> The primary method for such promotion is detailing, which usually is accompanied by the provision of free drug samples that prescribers can distribute to patients.<sup>18</sup> As inducements to increase their access to physicians who are sometimes reluctant to meet with them, detailers also frequently offer free meals and other gifts to the doctors and their staffs. As I shall explain, these practices are both widely used and widely criticized.

### 1. Detailing

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<sup>17</sup> The record contains varying reports on the amount that pharmaceutical companies spend on promotion, although the figures consistently are in the billions. For example, a declaration by two experts for the Attorney General, Dr. Jerry Avorn and Dr. Aaron Kesselheim, stated that the industry spent about \$4 billion in 2000 on direct-to-physician strategies. Declaration at 4 (citing Susan Okie, AMA criticized for letting drug firms pay for ethics campaign, Wash. Post, Aug. 30, 2001). A 2005 Report by Rep. Henry Waxman to the Democratic Members of the Committee on Government Reform stated that promotions targeting physicians totaled \$5.7 billion in 2003, including advertising in professional journals. Memorandum Re "The Marketing of Vioxx to Physicians," May 5, 2005, at 6 n.15 (citing Pharmaceutical Research and Manufacturers Ass'n). The Kaiser Family Foundation reported that drug manufacturers spent \$7.8 billion in 2004 on advertising directed toward physicians. See Trends and Indicators, supra, at 22. The Foundation is a nonprofit organization that provides information and analysis on health care issues to the government, media, health care community and the general public. Finally, a brief submitted by amici (AARP, et al.) cites a New York Times article reporting that drug companies spent \$13.9 billion promoting their products in 1999, most of which was directed toward doctors and other prescribers. Sheryl Gay Stolberg & Jeff Gerth, High-Tech Stealth Being Used to Sway Doctor Prescriptions, N.Y. Times, Nov. 16, 2000, at A1.

<sup>18</sup> The companies also place advertisements in medical journals and sponsor meetings in which physicians are recruited to speak to their colleagues about medical conditions and therapies.

Detailing is the face-to-face advocacy of a product by sales representatives who visit doctors' offices and hospitals to meet with the prescribing health care professionals. Although the objective of these visits is to make sales, detailers often provide valuable information about the drugs they are selling. Doctors may be alerted by a detailer to tests showing the risk of a drug interaction or a drug's side effects. One survey showed that most physicians meet with pharmaceutical representatives about four times a month. See Ashley Wazana, Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?, 283 J. Am. Med. Ass'n 373, 375 (Jan. 19, 2000). Consumers Union has reported research showing many more encounters: "[T]he average primary care physician interacts with 28 sales representatives each week; the average specialist interacts with 14." Consumers Union, Prescription for Change, <http://www.consumersunion.org/pdf/drugreps.pdf> (March 2006) (quoting research from Health Strategies Group). Whatever the frequency, it is undisputed that pharmaceutical detailing plays a substantial role in the dissemination of information about drugs to physicians.

Detailing focuses primarily on brand-name drugs that are entitled to patent protection. Once a patent expires, competitors may obtain approval to sell generic bioequivalent versions of the drug, which are equally effective for most patients but usually much less expensive than their brand-name counterparts. New

Hampshire law provides that pharmacies may substitute a bioequivalent generic drug for a brand-name drug unless the prescriber specifies that the brand-name drug is "medically necessary." N.H. Rev. Stat. Ann. § 318:47-d (2003). Thus, once bioequivalent generic drugs become available, sales of the related brand-name drug tend to fall and detailing is no longer considered a cost-effective marketing technique.<sup>19</sup> However, non-bioequivalent options also are available for some medical conditions, and the drug companies aggressively market to urge physicians to choose their patented brand-name medications over such alternatives. Thus, it is this choice - between a still-under-patent, branded drug and a similar, but biologically different generic medication - that is at the heart of this case.<sup>20</sup>

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<sup>19</sup> Pharmaceutical manufacturers attempt in various ways to retain the dominance of a brand-name drug. For example, they may create a modified version - such as a new time-release capsule - that will have its own period of patent protection.

<sup>20</sup> Even "bioequivalent" generic drugs are not identical to their branded counterparts. They are required to demonstrate absorption capability between 80 and 125 percent of the branded version, and variations in absorption may trigger different side effects when patients switch from the brand-name drug to a generic version. In addition, because there may be multiple generic options, a patient may experience different reactions depending upon which generic alternative is dispensed. For some patients, these variations could have significant impact, making continued use of the brand-name drug the best approach. However, as I understand the record, a doctor's decision to continue prescribing a brand-name drug after its patent has expired is not at issue here because the prescribing choice in that situation is not typically the focus of pharmaceutical detailing.

As I will discuss below, studies indicate that detailing has "a significant effect on physician prescription behavior." Puneet Manchanda & Elisabeth Honka, Symposium - Pharmaceutical Innovation and Cost: An American Dilemma: The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review, 5 Yale J. Health Pol'y, L. & Ethics 785, 809 (Summer 2005) ("While there seems to be little consensus about the size of the effect, it is clear that the effect is positive and significant in a statistical sense.").

## 2. Samples and Other Perks

Free samples and courtesy gifts are routinely given by detailers as part of their sales visits, and they are important tools in pharmaceutical marketing. Doctors rely on receiving drug samples that they can distribute to patients who are unable to afford the high cost of some medications.<sup>21</sup> Keeping office doors

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<sup>21</sup> During the legislative process leading to adoption of the statute, the president of the New Hampshire Medical Society, Marc Sadowsky, noted the importance of the samples to his psychiatric practice:

Some of the medicines I prescribe are \$8 a pill, \$8-10 a pill. I have patients who are stable on these medicines and then they lose their job, don't qualify for any insurance and I am carrying them to keep them stable. That is, I'm giving them samples. I have to sign for the samples every time I get them. So, when the drug reps come in, I have to talk to them. . . . So, I think it is kind of an important thing because these medicines can cost people thousands of dollars a year and I have a good number of citizens of New Hampshire that I am giving free samples to . . . .

open to detailers ensures that the doctors will have a continued supply of samples, and some physicians are therefore reluctant to restrict detailing. Even when drug cost is not an issue, the free samples are helpful to physicians who want to test new remedies before committing to them. A patient's positive results during a trial period may lead to a long-term prescription - the detailer's desired outcome. En route to that objective, however, the free samples have provided access to helpful treatment that patients otherwise may not have received. The cost of the samples distributed annually by pharmaceutical representatives has been estimated at more than \$11 billion.<sup>22</sup>

It is not only the patients who benefit from the drug companies' largess, however. Physicians and other medical office staff members frequently receive "good will" gifts from detailers, including office supplies, free meals, and conference travel funding - perks that are designed to encourage long-term relationships with, and loyalty toward, the detailers.<sup>23</sup> Studies

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<sup>22</sup> The parties' Second Amended Joint Stipulation of Facts ("Stipulation of Facts") used this figure; the Kaiser Family Foundation reported that the retail value of drug samples provided in 2004 was \$15.9 billion. See Trends and Indicators, supra, at 22.

<sup>23</sup> As an example, a nurse-practitioner who was the director of a hospital-based cholesterol management center testified at a committee hearing on the New Hampshire law that one drug representative offered to bring coffee and bagels to the center every Tuesday in exchange for "'two prescriptions every week.'" Legislative History, at 41 (hereinafter Legis. Hist.) (testimony of Carolyn Finocchiaro).

have shown that these sorts of gifts can have a subtle effect on physicians,<sup>24</sup> and, because they typically are unrelated to the provision of medical care, they have come under particular fire by both consumer advocates and medical professionals themselves. The Pharmaceutical Research and Manufacturers of America ("PhRMA") in 2002 adopted a voluntary code governing interactions with health care professionals that discourages such inducements

unless either the value of what is provided is insubstantial (less than \$100) and the inducement is primarily for the benefit of patients, or the value of the inducement is minimal and the inducement is directly related to the provider's practice. For example, an occasional gift of a stethoscope is acceptable

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A similar anecdote was described in a 2006 New York Times article that also was included in the Legislative History. The article reported that a district manager for a pharmaceutical company sent an e-mail to detailers stating:

"Our goal is 50 or more scripts per week for each territory. If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past [consulting arrangements] that you have provided or paid for and get the business!! You can do it!!"

Gardiner Harris & Robert Pear, Drug Maker's Efforts to Compete in Lucrative Insulin Market are Under Scrutiny, N.Y. Times, Jan. 28, 2006.

<sup>24</sup> Although studies show that physicians have a "mostly negative" attitude toward gifting, the studies also report that such gifts "induce reciprocal feelings among physicians." Manchanda & Honka, 5 Yale J. Health Pol'y, L. & Ethics, at 809; see also Jason Dana & George Loewenstein, A Social Science Perspective on Gifts to Physicians from Industry, 290 J. Am. Med. Ass'n 252, 252-54 (July 9, 2003).

under the Code because it is not deemed to be of substantial value and the gift benefits patients. In contrast, an unrestricted gift certificate to a local bookstore may not be offered under the Code regardless of its value because it does not benefit patients and is unrelated to the health care professional's practice. The Code draws similar distinctions with respect to meals and entertainment.

490 F. Supp. 2d at 168-69 (citations omitted).<sup>25</sup>

### 3. Data Mining and Prescriber Profiles

When detailers enter medical offices to market their products, they are equipped not only with detailed information about the drugs they are attempting to sell but also with considerable knowledge about their audience. Much of that prescriber information is supplied by the plaintiffs and similar companies, who play a crucial behind-the-scenes role in the flirtation between pharmaceutical sales representatives and

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<sup>25</sup> In 2007, a health care consumer advocacy group based in Boston, Community Catalyst, and the Institute on Medicine as a Profession, a research group at Columbia University, announced a national campaign calling for restrictions on the interaction between doctors and pharmaceutical companies. Stephanie Saul, Doctors and Drug Makers: A Move to End Cozy Ties, NY Times, Feb. 12, 2007, at C10. A number of medical centers, including those at Yale, the University of Pennsylvania and Stanford, have announced restrictions on gifts and other interactions between their staff members and the pharmaceutical industry. Some states, including Maine, Vermont and Minnesota, have passed laws either prohibiting gifts to doctors from drug companies or requiring disclosure of the gifts. Id.; see Me. Rev. Stat. Ann. tit. 22, § 2698-A (2004) (disclosure); Minn. Stat. § 151.461 (1994) (prohibition); Vt. Stat. Ann. tit. 18, § 4632 (2007) (disclosure).



prescribers.<sup>26</sup> These so-called "data mining" companies collect and organize information about doctors and their prescribing patterns, converting information gleaned from "thousands of sources" into a commodity for which the pharmaceutical industry pays substantial sums.<sup>27</sup> From retail pharmacies and other entities, such as insurers, that acquire the data as part of the business they conduct, the data miners obtain information on every pharmaceutical sale, including the form, strength and dosage of the drug, the amount dispensed, and the name and address of the prescriber. The information includes an identifying code for each patient, although the patient is not personally identified. From other sources, including the American Medical Association, the plaintiffs obtain information about individual prescribers and their specialities.<sup>28</sup>

The data mining companies weave the information together to produce, among other databases, "prescriber profiles" - individualized reports on the prescriptions being written by

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<sup>26</sup> The Stipulation of Facts states that plaintiffs IMS Health Inc. and Verispan LLC "are the world's leading providers of information, research and analysis to the pharmaceutical and healthcare industries."

<sup>27</sup> According to the Stipulation of Facts, these sources are: pharmaceutical wholesalers, pharmacies, physicians, hospitals and clinics.

<sup>28</sup> The AMA's Physician Masterfile contains demographic, educational, certification, licensing and speciality information for more than 800,000 active U.S. medical doctors and more than ninety percent of practicing osteopathic doctors.

particular doctors. The information is then sold to third parties for various commercial uses, including pharmaceutical marketing, and also is provided at no charge for nonprofit purposes, such as academic and medical research.<sup>29</sup> The data provide a historical view of a physician's prescribing practices, allowing the pharmaceutical companies to identify doctors who have displayed a willingness to try new products (the "early adopters") and to target doctors whose drug choices they seek to change. With knowledge of the physicians' prescribing history, the detailers are able to tailor their messages to those doctors' specific circumstances - for example, emphasizing the potential side effects of a competitor's brand-name product that the detailer knows the doctor has been using, or highlighting the advantages of the detailers' branded drug over the generic alternative the doctor routinely prescribes. The detailer's verbal message in favor of the brand-name drug may be furthered by the provision of free samples of the medication, encouraging what is initially a "no-cost" switch to the more expensive drug. The companies also use reports obtained shortly after detailing visits to assess whether the sales calls had an effect on the targeted prescribers'

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<sup>29</sup> Pharmaceutical companies also have non-marketing uses for the prescriber-identified data, including to "[d]etermine which products to develop and license," to "[i]mplement prescription recall programs," and to accelerate the development of new drugs based on "the needs and habits of those whose health these new drugs are designed to improve." Stipulation of Facts, at 4-5.

drug choices. The detailer's compensation is sometimes tied to the success of his or her efforts.

This use of prescriber-identified data has drawn sharp criticism on many fronts, including among physicians who object both to the disclosure of information they deem confidential and to the hard-sell messages delivered by detailers who may know more about their prescribing habits than do the doctors themselves. In 2006, the AMA responded to the concerns by initiating the Prescribing Data Restriction Program ("PDRP"), which allows physicians to restrict access to their prescribing data by pharmaceutical detailers. The AMA also developed guidelines for the use of prescribing data "to provide ethical guidance to the healthcare industry." The guidelines urge that companies, inter alia, "[c]ontinually reinforce that use of prescribing data to overtly pressure or coerce physicians to prescribe a particular drug is absolutely an inappropriate use." Neither the PDRP nor the guidelines have quelled the concerns. The PDRP has been criticized because prescriber information will be withheld only if doctors affirmatively opt out, and the opt-out choice must be renewed every three years. Voluntary guidelines are seen as insufficient to offset the commercial incentives to use the information. Some states, like New Hampshire, turned to legislation to address the concerns.

#### **B. New Hampshire's Statutory Response**

The Prescription Act prohibits the transmission or use of both patient-identifiable and prescriber-identifiable data for certain commercial purposes.<sup>30</sup> Violators are subject to both criminal and civil penalties. N.H. Rev. Stat. Ann. § 318:55. In pertinent part, the statute provides:

Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose, except for the limited purposes of pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law. Commercial purpose includes, but is not limited to, advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

In effect, the statute prohibits the use of prescriber-identifiable data for all purposes related to detailing, but seeks to preserve access to the data for other uses - including other commercial purposes.<sup>31</sup> I agree with the district court that the

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<sup>30</sup> Plaintiffs have not challenged the restrictions on patient-identifiable data.

<sup>31</sup> The Act also permits the continued use of aggregated prescriber data, categorized by speciality, zip code and geographic

prohibited uses are narrowly defined and that the statute does not, for example, prohibit pharmaceutical companies from using prescriber-identifiable data for their own research. See 490 F. Supp. 2d at 171.<sup>32</sup>

#### 1. Legislative History

In introducing the proposed legislation at a hearing before the Senate Committee on Executive Departments and Administration, Representative Cindy Rosenwald, one of the statute's co-sponsors, explained that it had two goals: "It will protect privacy and it will save money for the state, for consumers and businesses. It will accomplish these goals by prohibiting the sale or use of individual patient or prescriber identity for marketing brand name prescription drugs." A written attachment to her testimony, which included a section entitled "What H.B. 1346 will do," states that the law will, inter alia, "[h]opefully reduce the prescription drug costs for patients, employers & the State Medicaid program."

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region, but without prescriber identification.

<sup>32</sup> Indeed, on the first day of trial, counsel for the Attorney General agreed that pharmaceutical companies could use the prescriber information to recruit physicians to participate in clinical trials.

About sixteen individuals testified at the hearing.<sup>33</sup> A representative of the Department of Health and Human Services, Gregory Moore, emphasized both the privacy and cost reduction purposes of the legislation. He described the prescriber data as the physicians' "trade secrets" and further stated:

The Department also believes that these activities ultimately drive up the cost of prescription drugs and the cost of health care in the aggregate. Since no other state has passed legislation like this, it would be hard for us to quantify what that impact might be, but I find it unlikely the drug companies are sending details into doctors' offices for the purpose of selling doctors cheaper medication. In fact, I'm confident that, if you're a doctor, that one of the best ways to get a detailer into your office would be if you switched to prescribing a generic drug over a brand drug.

Also testifying in favor of the legislation was the president-elect of the New Hampshire Medical Society, Dr. Seddon Savage, who said the law "will deter marketing intended to manipulate the practice of individual physicians that is intended to increase market share for the individual companies, possibly at the expense of appropriate decision making for the patients." He further stated that "[n]umerous studies have shown that . . . [doctors'] decision making can be and sometimes is shaped by marketing efforts."

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<sup>33</sup> An earlier, less comprehensive hearing was held before the House Committee on Health, Human Services and the Environment.

Savage's general testimony was reinforced by comments from Dr. Marc Sadowsky, a psychiatrist and the president of the New Hampshire Medical Society. He reported a phone conversation with a patient who said that her primary care doctor had thought a brand-name medicine might be better for her than the generic she was using. Sadowsky continued:

I said, "Well, you're doing fine on the generic and your co-pay is going to go up \$40 a month, \$500 a year. So, it is not entirely clear to me why we're doing this." . . . I think that that was an example of the primary care physician having been marketed to directly and didn't really have a clinical reason for doing it except that that was the last drug rep who came to see him and said this is a better medicine for anxiety, even though the person was asymptomatic at the time.

In Sadowsky's view, there was "no apparent reason" for the requested switch "except presumably that [the doctor] ha[d] been marketed to effectively."

Among those speaking against the statute was a representative of the New Hampshire Association of Chain Drug Stores, Stuart Trachy, who described the proposed legislation as "too broad" and observed that "the opt out program that the AMA is going to be instituting should take care of the concerns that we have heard in terms of specific doctors being concerned that their prescribing data is out there." A spokesman for plaintiff IMS, Robert Hunkler, stated that restricting prescriber-identifiable information would not lower health care costs because

"pharmaceutical companies will[] in all likelihood continue to send sales reps to all doctors without the ability to more specifically hone in on the right people with the right message. It will likely incur more costs to the system." Hunkler also predicted that the acknowledged beneficial uses of the data, including medical research, would be compromised because the information would no longer be readily available. Responding to complaints from doctors that drug companies "know more about [their] prescribing behavior than [they] know," Hunkler stated that IMS was working toward greater access: "[W]e think that a preferable solution is to provide this information to doctors, to health researchers and others instead of turning out the light and taking it away from everyone." The American Medical Association also expressed opposition to the legislation, commenting in a prepared statement that the PDRP would "provide[] physicians with the tools they need to restrict information that they do not want shared while avoiding legislatively-mandated restrictions that could have unintended consequences."

## 2. Legislative Action and Legal Challenge

The Prescription Act was approved by the Legislature in May 2006, and it took effect on June 30 of that year. Four weeks later, on July 28, 2006, IMS and Verispan filed the complaint in this case, alleging that the Act violated the First Amendment and the Commerce Clause, and that it was void for vagueness and



overbreadth. They sought declaratory and injunctive relief against the statute's enforcement. Meanwhile, in compliance with the Act, Verispan modified its databases so that it could identify and suppress all prescriber-identifiable data from New Hampshire prescriptions before the information was released to third parties. IMS also stopped selling prescriber-identifiable information obtained from New Hampshire sources to third parties.

During a four-day bench trial in January and February 2007, the court heard live testimony from ten witnesses, most of whom were physicians. A former detailer and a representative of each plaintiff also testified. The parties also submitted voluminous written materials, including a number of journal articles describing studies on detailing. The State highlighted the testimony of Dr. Jerry Avorn, a professor at Harvard Medical School whose research focuses on the use of prescription drugs and their outcomes, and who also works at Brigham and Women's Hospital in the Division of Pharmacoepidemiology and Pharmacoeconomics.<sup>34</sup> Through Avorn's testimony on the medical literature and the testimony of practitioners who recounted specific experiences with

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<sup>34</sup> He explained those two fields as follows:

Pharmacoepidemiology is the study of the utilization of drugs in large populations, as well as the consequences of that use, whether a benefit or adverse event; and pharmacoeconomics is the connection between drug use and economics, what the drugs cost[], but also how they fit into the health care system and what their benefits might save the health care system.

detailing, the Attorney General sought to show that detailing in general, and use of prescriber-identifiable data in particular, influences physicians to prescribe brand-name drugs more frequently than would occur with "evidence-based" decision-making that was untainted by the detailers' marketing messages.<sup>35</sup> The Attorney General asserted that the Act advanced the State's substantial interests in prescriber privacy, public health and cost-containment.

On their behalf, the plaintiffs elicited considerable testimony about the beneficial aspects of detailing and the use of prescriber-identifiable data to target physicians. For example, Dr. Thomas Wharton, Jr., director of cardiology at Exeter Hospital, testified that discussions initiated by drug company representatives provide "a very stimulating forum" for discussing the treatment of coronary disease.<sup>36</sup> He also stated that the "level of discourse is elevated" when a drug representative knows his prescribing habits: "[I]f they know that I'm a user of the

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<sup>35</sup> The parties and witnesses at times contrasted prescribing decisions that relied on "evidence-based" data - i.e., decisions resulting solely from consideration of replicable clinical data - with decisions influenced by the "contact and communication" from detailers. See, e.g., Stipulation of Facts, at 12; Avorn and Kesselheim Declaration, at 5; Avorn Testimony, Day 3, PM Session, at 60, 110.

<sup>36</sup> Wharton stated that "there is a lot of good intellectual stimulation, education, cross-fertilization, all in a sense based upon the drug rep initiating discussion, presenting data, presenting papers, some of which we know about and some of which we don't. So it's a very educational, informational experience."

drug, they will direct what they have to say to me toward any brand-new information that might have come out rather than starting with the basics. If they know that I'm a user of a drug, I would think that they are more likely to come to me if a new adverse effect is announced regarding that drug." Plaintiffs also emphasized the lack of evidence showing that restriction of prescriber-identifiable data would lead to a decrease in drug costs and attempted to show that less efficient detailing would result, potentially increasing the pharmaceutical companies' marketing costs and, in turn, increasing the cost of their products.<sup>37</sup>

### **C. The District Court's Decision**

On April 30, 2007, the district court ruled that the Prescription Act impermissibly restricted commercial speech and therefore violated the First Amendment. It rejected the Attorney General's argument that the Act targeted only unprotected factual information rather than constitutionally protected speech and also rejected her contention that the statute regulated only non-speech "uses" of the prescriber-identifiable data. Having concluded that

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<sup>37</sup> Plaintiffs offered two anecdotes on this point through Dr. Wharton. First, he testified that, since passage of the Prescription Act, he had been "visited for the first time ever" by a detailer seeking to sell drugs for diabetes, a condition his practice does not treat. In addition, Wharton stated that he was surprised that it took "months and months and even a request to the company" for him to be detailed on a "purportedly revolutionary" anti-smoking drug, despite the practice's substantial history of prescribing other anti-smoking products.

the Act restricted protected commercial speech, the court examined whether the Attorney General had sufficiently justified the regulation under the three-part inquiry set out in Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557, 566 (1980).

Under Central Hudson, truthful commercial speech that does not promote unlawful activity may be limited only if it "(1) is in support of a substantial government interest, (2) 'directly advances the governmental interest asserted,' and (3) 'is not more extensive than is necessary to serve that interest.'" El Dia, Inc. v. P.R. Dep't of Consumer Affairs, 413 F.3d 110, 113 (1st Cir. 2005) (quoting Central Hudson, 447 U.S. at 566). The district court considered the State's asserted interests in protecting prescriber privacy, promoting public health, and containing health care costs. It concluded that the record did not reveal a distinct privacy interest that was supported by the Act and held that neither the public health interest nor the interest in containing health care costs was directly advanced by the statute.

In addition, the court found a "fundamental flaw" in the Attorney General's argument that the regulation was necessary because "pharmaceutical companies manipulate health care providers by using prescriber-identifiable data to enhance the effectiveness of highly persuasive but truthful commercial speech." 490 F.

Supp. 2d at 181. Instead of restricting such information, the court stated, "if the State is concerned that truthful detailing is causing health care providers to make inadvisable prescribing decisions, 'the remedy to be applied is more speech, not enforced silence.'" Id. (quoting Whitney v. California, 274 U.S. 357, 377 (1927) (Brandeis, J., concurring)).

The court also addressed the third Central Hudson prong and found that the State could advance its health and cost-containment interests, and specifically the unnecessary prescription of brand-name drugs, without restricting protected speech. The court noted that the State could, inter alia, directly limit the samples and gifts given to prescribers and their staffs, educate health care providers about the health and cost implications of their prescribing decisions, require health care providers to participate in continuing education programs offering objective information about the advantages and disadvantages of different drug choices, or adopt a Medicaid pharmacy program that takes cost considerations into account.

Accordingly, the court held that the statute could not be enforced "to the extent that it purports to restrict the transfer or use of prescriber-identifiable data." Id. at 183. It therefore granted the plaintiffs' request for declaratory relief and a permanent injunction. It did not reach their vagueness or Commerce Clause arguments.

### III.

The Attorney General continues to argue on appeal that the Prescription Act restricts only the use of information and that this regulation of non-expressive conduct does not implicate the First Amendment. From the Attorney General's perspective, the statute regulates a commercial transaction and not protected speech. See generally Neil M. Richards, Reconciling Data Privacy and the First Amendment, 52 UCLA L. Rev. 1149, 1194 (2005) (concluding that restrictions on use of consumer data to target advertisements were "not a regulation of speech at all, but rather a regulation of information use - the business activity of deciding to whom to market products"). At trial, the Attorney General contended that the Act did not restrict the content of the pharmaceutical manufacturers' advertising or marketing messages, which she acknowledges would trigger First Amendment scrutiny.<sup>38</sup> Rather, the legislature made the "unusual" - and in the Attorney General's view - permissible choice "to strike at the source of the information," Day 1, AM Session, at 45, thereby regulating the distribution and use of a "commodity" rather than limiting a speaker's message.<sup>39</sup>

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<sup>38</sup> The Attorney General points out that the Act does not regulate the "speakers" (the pharmaceutical companies) at all, but restricts only the entities that sell prescriber-identifiable prescription data to other parties.

<sup>39</sup> The Attorney General wisely no longer contends that the First Amendment is inapplicable to the Prescription Act because it

Like the district court, I think this argument attempts to create a dividing line that does not exist in the factual context of this case. While the statute explicitly prohibits any "use" of prescriber-identifiable data,<sup>40</sup> one of the Legislature's desired outcomes is the modification of the marketing messages communicated by pharmaceutical detailers. See, e.g., Defendant's Memorandum of Law in Support of its Objection to Plaintiff's Motion for Preliminary Injunction, at 30-31 ("By prohibiting the license, transfer, use, or sale of prescriber-identifiable prescription data for commercial purposes, the Act prevents pharmaceutical companies from using that information to pressure physicians into changing their prescriptions from less costly medications to name brand drugs for reasons unrelated to the

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targets only factual information. As the district court held, "the transmission of truthful information concerning the prescribing practices of New Hampshire's health care providers . . . is not exempt from First Amendment review merely because it targets factual information rather than viewpoints, beliefs, emotions, or other types of expression." 490 F. Supp. 2d at 175; see Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 762 (1976) ("Purely factual matter of public interest may claim protection."); Universal City Studios, Inc. v. Corley, 273 F.3d 429, 446-47 (2d Cir. 2001) ("Even dry information, devoid of advocacy, political relevance, or artistic expression, has been accorded First Amendment protection.") (citing Supreme Court precedent). Moreover, while the statute directly regulates the prescriber-identifiable data, the Legislature's objective is to restrict the messages presented by the detailers to their physician customers. As I explain, this objective informs my assessment of the regulation.

<sup>40</sup>In addition to the catch-all prohibition on "use," the statute, as previously noted, prohibits the licensing, transfer or sale of the information.

clinical needs of patients." ). The State has attempted to insulate this expression-based intention from First Amendment scrutiny by directing its legislation to an earlier step in the communicative process. However, it may not skirt the Constitution's requirements in such fashion. Indeed, the Attorney General seeks to minimize the impact of the Act by emphasizing that detailers may continue to use the same face-to-face marketing approach with physicians, notwithstanding the Prescription Act. But if the State acknowledges that the form of marketing conduct remains the same (i.e., face-to-face promotion by detailers), it is difficult to see how the statute may be viewed solely as a regulation of the commercial transaction itself, rather than as a limitation on the content of the expression that may be used to conduct that transaction. See U.S. West, Inc. v. FCC, 182 F.3d 1224, 1232 (10th Cir. 1999) (finding that prohibition of telecommunications companies' use of customer proprietary data for targeted marketing constitutes a restriction on protected commercial speech).

I recognize that there are three separate commercial activities involved here: first, the transfer of the data to data miners, including the plaintiffs, from the entities that acquire prescription information in the ordinary course of their businesses (such as pharmacies and insurance companies); second, the transfer of the data in aggregated form from the plaintiffs to



the pharmaceutical companies; and, third, the marketing of drugs to prescribers by detailers whose sales pitches make use of the data. To serve its interests in protecting privacy, promoting public health and containing health care costs, the Legislature targeted the content of the message communicated in the third transaction. The statute restricts that message indirectly by imposing restrictions on the first two transactions.<sup>41</sup> Because the statute's purposes are linked to the third transaction, I conclude - as did the district court - that the assessment of the statute's impact must be similarly focused.<sup>42</sup> See IMS Health, 490 F. Supp. 2d at 176 ("The law is . . . squarely aimed at speech

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<sup>41</sup> The Prescription Act expressly governs the first type of transaction by restricting the conduct of "any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity." Whether the Legislature viewed the plaintiffs - the "middlemen" in the data transfer process - as "electronic transmission intermediar[ies]" or "other similar entit[ies]" is unclear, but I think they are properly treated as such for purposes of our discussion. To comply with the statute, all parties making this prescriber-identifiable available for sale presumably must condition the sale on an agreement by the purchasers not to use the data in ways prohibited by the Act. By restricting the release of the information into the marketplace, the State limits the content of the message ultimately communicated by the detailers.

<sup>42</sup> The State's interest in patient privacy is implicated as well by the first two transactions, through which prescription data is transferred to entities uninvolved in individual patients' health care. That interest does not play a part in our analysis because, as noted, the plaintiffs do not challenge the statute's restriction on patient-identifiable data. The State's articulated privacy interest in prescriber information is intertwined with its health and cost-containment interests and relates solely to the third transaction. See infra Section IV.A.

that proposes a commercial transaction even though it does not explicitly bar such speech."); Boos v. Barry, 485 U.S. 312, 321 (1988) (noting that "[r]egulations that focus on the direct impact of speech on its audience" must be viewed as speech-based for purposes of First Amendment analysis).

The Attorney General asserts that the Supreme Court drew "a sharp distinction" in Bartnicki v. Vopper, 532 U.S. 514 (2001), between regulating the use of information - which she claims does not implicate the First Amendment - and regulating its disclosure. In Bartnicki, the Court held that the First Amendment protected a reporter's disclosure of the contents of an illegally intercepted communication about a matter of public interest. Id. at 518. In its discussion, the Court described a prohibition against the "use" of the contents of an illegal wiretap as "a regulation of conduct," while holding that a prohibition against the "disclosure" of such material "is fairly characterized as a regulation of pure speech." Id. at 526-27. The Attorney General seizes on this language to argue that the Prescription Act and its prohibition against "use" of prescriber-identifiable data is similarly immune from First Amendment attack. However, the examples of prohibited "uses" listed by the Court in Bartnicki are materially different from the prohibition at issue here. They involve conduct in which the impact on speech is non-existent or, at most, incidental - for example, using unlawfully intercepted

information about a business rival to create a competing product or using illegally recorded information to trade in securities or for extortion. Id. at 527 n.10. Here, by contrast, the prohibited "use" at issue is the dissemination of a commercial message through marketing, advertising or promotion - expressions that unquestionably are entitled to First Amendment protection. See Thompson v. W. States Med. Ctr., 535 U.S. 357, 366-67 (2002) (quoting Va. State Bd. of Pharmacy, 425 U.S. at 763, for the proposition "that a 'particular consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate'").<sup>43</sup>

The multi-step nature of the statutory prohibition - imposing the restraint on the providers of the underlying information rather than directly on the communicator of the message - does not remove that protection. Supreme Court precedent establishes that where the goal of a regulation relates to suppression of expression, even a restriction that indirectly achieves that objective may run afoul of the First Amendment. See

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<sup>43</sup> The Attorney General's analogy to Bartnicki is not entirely inapplicable to the Prescription Act. The prohibited commercial purposes listed by the Act also include "evaluat[ing] the prescribing behavior of an individual health care professional . . . or the effectiveness of a professional pharmaceutical detailing sales force." Such activities do not themselves constitute protected commercial speech and are equivalent to the "uses" identified in Bartnicki. They are not our concern here.

Grosjean v. Am. Press Co., 297 U.S. 233, 249 (1936) (invalidating a license tax on publications with circulations of 20,000 or more that sold advertising "because, in light of its history and of its present setting, it is seen to be a deliberate and calculated device in the guise of a tax to limit the circulation of information to which the public is entitled"); see generally Minneapolis Star & Tribune Co. v. Minnesota Comm'r of Revenue, 460 U.S. 575, 581 (1983) (holding unconstitutional a tax on newsprint and ink used in the production of newspapers).<sup>44</sup>

By contrast, legislation whose purpose is to regulate economic conduct, and which only incidentally affects speech, typically does not raise First Amendment concerns. See generally Rumsfeld v. Forum for Acad. & Inst. Rights, Inc., 547 U.S. 47, 62 (2006) ("FAIR") ("'[I]t has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.'") (quoting Giboney v. Empire Storage & Ice Co., 336 U.S. 490, 502 (1949)). Our circuit considered this principle at some length in two related decisions concerning a Rhode Island statute

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<sup>44</sup> The Court in Minneapolis Star & Tribune Co. made no finding on the State's motive, but observed that "differential treatment, unless justified by some special characteristic of the press, suggests that the goal of the regulation is not unrelated to suppression of expression, and such a goal is presumptively unconstitutional." 460 U.S. at 585.

regulating the retail sale of alcohol. See Wine & Spirits Retailers, Inc. v. Rhode Island, 481 F.3d 1, 6-7 (1st Cir. 2007) ("Wine & Spirits II"); Wine & Spirits Retailers, Inc. v. Rhode Island, 418 F.3d 36, 48-49 (1st Cir. 2005) ("Wine & Spirits I"). Although the State relies on the Wine & Spirits decisions in arguing that the Prescription Act falls outside the First Amendment's scope, those cases support a contrary conclusion.

The regulation at issue in Wine & Spirits originally prohibited any "chain store organization" from holding a Class A retail liquor license, but gave the Department of Business Regulation the discretion to determine whether a business was a "chain store." Some businesses were evading the restriction by adopting chain-store-like features within a different business structure, described as "franchised package stores." The State responded by amending the statute to identify the specific conduct it sought to prohibit; i.e., it defined the term "chain store organization" to include businesses that participated in "a coordinated or common advertisement with one or more liquor licensed business in any advertising media" or that coordinated marketing strategies. At the same time, the State adopted a provision explicitly excluding franchisees from holding Class A liquor licenses.<sup>45</sup> Wine & Spirits had been operating as a

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<sup>45</sup> The statute provides, in part:

To promote the effective and reasonable control and

franchisor of independently owned liquor retailers and, among other activities, provided marketing, advertising and business advice and services. In the first of the two cases, Wine & Spirits claimed that the regulation improperly infringed on its right to communicate with its customers by, for example, designing advertisements and arranging for their placement in various media. Wine & Spirits I, 418 F.3d at 49. In the second case, we also considered a claim by Wine & Spirits' franchisees that the regulation imposed an improper limitation on the content of their advertising. Wine & Spirits II, 481 F.3d at 6.

We found no First Amendment issue in either instance. In the first case, we stated that the regulation did not "prohibit the communication of advice between a franchisor and the holders of Class A liquor licenses," 418 F.3d at 47, but only forbade implementation of Wine & Spirits' business model. We concluded that "[t]he provision of advertising and licensing services is not speech that proposes a commercial transaction and therefore does not constitute commercial speech." Id. at 49. In the later case, we observed that the prohibition on coordinated or common

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regulation of the Rhode Island alcoholic beverage industry and to help the consumer by protecting their choices and ensuring equitable pricing. Class A liquor license[s] authorized by this title shall not be granted, issued, renewed or transferred to or for the use of any liquor franchisor or franchisee.

R.I. Gen. Laws § 3-5-11.1(a).

advertisements "does not target speech; each individual liquor licensee remains at liberty to disseminate information about its prices and products to other retail stores and to the public at large." 481 F.3d at 6. We observed: "The statute at issue here merely proscribes conduct - the launching of advertisements resulting from pre-agreed commercial strategies. Such a ban is not a ban on commercial speech." Id.

Thus, the Wine & Spirits prohibition was against an acting-in-concert business approach - not against the message the liquor stores were seeking to disseminate.<sup>46</sup> To be sure, the statute had an incidental impact on the speech of both the franchisor and franchisees. Wine & Spirits was, in effect, prevented from marketing its services to particular businesses, and the franchisees could not distribute advertisements in coordination with other retail liquor stores. But the statute's objective was to regulate business methods, see supra n.35, and, as we observed in Wine & Spirits I, "the First Amendment does not safeguard against changes in commercial regulation that render previously profitable information valueless." 418 F.3d at 48.

Here, however, the Legislature did not simply prohibit a business model or strategy. Instead, it restricted the

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<sup>46</sup> We observed that "the statute imposes no burden on the communication between the speaker and the intended audience but has the effect of decreasing the audience's demand for a particular kind of business advice." 418 F.3d at 48 n.3.

substance of the messages being communicated by pharmaceutical detailers in their sales pitches by curtailing information previously available to detailers. In other words, the State targeted, albeit indirectly, the speech of the detailers in order to achieve its multiple objectives. Such a regulation is a limitation on commercial speech, and the State consequently must bear the burden of demonstrating that it satisfies the Central Hudson test. See, e.g., 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 499 (1996) (noting that "the State retains less regulatory authority when its commercial speech restrictions strike at 'the substance of the information communicated' rather than the 'commercial aspect of [it]'" (quoting Linmark Assocs., Inc. v. Willingboro, 431 U.S. 85, 96 (1977)); cf. City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 429 (1993) (noting the Court's prior "statements that the test for whether a regulation is content based turns on the 'justification' for the regulation") (citing Ward v. Rock Against Racism, 491 U.S. 781, 791 (1989); Clark v. Cmty. for Creative Non-Violence, 468 U.S. 288, 293 (1984)).<sup>47</sup>

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<sup>47</sup> The plaintiffs argue that the Act should be analyzed as a content-based restriction on speech subject to strict scrutiny rather than as a regulation of commercial speech subject to intermediate scrutiny. Although the statute unquestionably affects content by limiting the information the detailer may communicate, I find no merit in this view of the applicable standard. The targeted speech concerns the promotion of a product - the classic context for commercial speech. Content-based restrictions on commercial speech are subject only to intermediate scrutiny. See



#### IV.

Before delving into the Central Hudson test and its application here, I pause briefly to clarify what this case is not about. We are not considering the State's authority to restrain untruthful, unlawful or otherwise misleading speech. Such communications - e.g., insider information about securities, fraudulent statements, or speech that would violate intellectual property laws - are routinely regulated without First Amendment inquiry.<sup>48</sup> Although the State is concerned about the potentially misleading effect of the information provided by detailers to prescribers, it does not characterize the messages it seeks to restrict as categorically untruthful or deceptive. Thus, my analysis presumes that New Hampshire's prohibition on the use of

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Naser Jewelers, Inc. v. Concord, 513 F.3d 27, 33 (1st Cir. 2008) ("Central Hudson serves as an alternative to the more exacting standards applied to content-based restrictions on non-commercial speech."). Alternatively, the plaintiffs contend that the statute should be subject to strict scrutiny because it has a chilling effect on non-commercial speech. However, I agree with the majority that, properly construed, the terms of the statute are exceedingly narrow and that, so understood, the Act does not impermissibly burden speech outside its scope.

<sup>48</sup>The Supreme Court has treated as a threshold question under the Central Hudson test "whether the commercial speech concerns unlawful activity or is misleading." Thompson v. W. States Med. Ctr., 535 U.S. 357, 367 (2002). "If so, then the speech is not protected by the First Amendment." Id. My references to the three-pronged Central Hudson inquiry do not include this preliminary inquiry.

prescriber-identifiable data affects communications that are truthful and otherwise lawful. As such, they may be limited only with adequate justification.

To justify a commercial speech restriction, the State bears the burden of proving the three elements of the Central Hudson test: (1) the restriction is in support of a substantial government interest; (2) it directly advances the asserted interest; and (3) it is "not more extensive than is necessary to serve that interest." Central Hudson, 447 U.S. at 566; El Dia, 413 F.3d at 113; see also Thompson, 535 U.S. at 367. I consider each prong in turn.

#### **A. Substantial Government Interest**

The Attorney General maintains that the Prescription Act supports the State's substantial interests in protecting patient and prescriber privacy, promoting public health, and containing health care costs. Although the plaintiffs do not challenge the importance of the public health and cost-containment interests, they contend that the evidence in the record fails to prove that either interest is directly advanced by the statute as required by the second prong of Central Hudson. They wholly reject the Attorney General's contention that the Act serves a privacy interest.

I, too, accept as substantial the State's asserted interests in cost-containment and quality health care. However,

I join the district court in rejecting on this record prescriber privacy as a sufficient interest to justify the Prescription Act. The State does not claim an interest in preventing public disclosure of the prescriber-identifiable data, and indeed it could not, as the statute allows the data to be disclosed and used for a myriad of purposes. See Defendant's Trial Memorandum, at 20 n.10 (conceding that the law does not "attempt to keep prescriber-identifiable data secret or entirely private").

Rather, the Attorney General explains in her brief that the State's privacy interest is in the "patient-physician relationship," specifically in New Hampshire patients' "reasonable right to expect that their relationship with the physician is private, and [that] a pharmaceutical detailer is not manipulating the physician's prescribing behavior." The Attorney General contends that detailers have become "an invisible intruder in the physician's examination room."

However, the regulation does not in any cognizable way touch on the privacy of the examination room. Although the statute bars disclosure of patient-identifiable information as well as prescriber data, the plaintiffs do not challenge the prohibition on the use of specific patient data. Thus, no patient identifying information is at issue in this case. Any privacy justification must therefore reside in the prescriber-identifiable data. Rather than arguing that "the [prescriber-identifiable]

data is being exploited to compromise patient privacy," the Attorney General argues that "pharmaceutical companies are using the data to help persuade doctors to make inadvisable prescribing decisions." 490 F. Supp. 2d at 179. The district court properly recognized the flaw in this depiction of a privacy interest:

[W]hat the Attorney General claims as a distinct interest in protecting prescriber privacy is nothing more than a restatement of her contentions that the law can be justified because it prevents pharmaceutical companies from using prescriber-identifiable data in ways that undermine public health and increase health care costs.

Id. Accordingly, I join the district court in rejecting the Attorney General's argument that the Prescription Act is justified by a substantial privacy interest.

I thus turn to consider whether the Prescription Act is a narrowly tailored provision that directly advances the State's substantial interests in quality health care and cost-containment.

#### **B. Advancing the Interest**

The Attorney General asserts that the Prescription Act satisfies the second prong of the Central Hudson test - that it advances the State's interest - because it reduces the likelihood that prescribers will make unnecessarily expensive and unwise drug choices. I borrow the district court's well stated description of the Attorney General's logic:

The chain of reasoning . . . begins with the major premise that prescriber-identifiable data allows pharmaceutical companies to target

health care providers for marketing and tailor marketing messages in ways that make detailing more persuasive. Next, it assumes that because prescriber-identifiable data makes detailing more persuasive, it inevitably leads to more prescriptions for brand-name drugs when compared with generic alternatives because only branded drugs are detailed. Finally, it assumes that any increase in the number of prescriptions written for brand-name drugs when compared to generic alternatives harms the public health and increases health care costs because branded drugs often turn out to be more harmful than generic alternatives and almost always are more expensive. Accordingly, a ban on the use of prescriber-identifiable data for marketing purposes promotes public health and contains health care costs by prohibiting pharmaceutical companies from using prescriber-identifiable data to promote the sale of brand-name drugs.

490 F. Supp. 2d at 180.

The district court accepted the premise that detailing with prescriber-identifiable data is more persuasive, but found that the Attorney General had failed to establish a link between such detailing and any negative impact on public health or drug costs. On the health concern, the court found that it is "counterintuitive and unproven" that, on balance, "brand-name drugs are more injurious to the public health than generic alternatives." Id. In addition, the court was unpersuaded that the State's public health purpose was served by barring the use of prescriber data to target "early adopters" of new drugs because "the record does not establish either that early adopters are more likely to be influenced by detailing than other health care

providers or that new drugs are generally more injurious to the public health than existing medications." Id.

The court found the Attorney General's position on cost-containment similarly deficient. It stated that "[n]on-bioequivalent generic drugs are not always as effective as brand-name alternatives," id., and found that the Attorney General had not proven that any reductions in health care costs stemming from reduced use of newer, more expensive medications "can be achieved without compromising patient care." Id. at 181. It thus found that none of the State's asserted interests was advanced by the Prescription Act. Moreover, to the extent that the Attorney General successfully drew a connection between truthful, non-misleading detailing based on prescriber-identifiable data and "inadvisable prescribing decisions," the district court opined that more speech, not less, was the remedy required by the First Amendment. Id.

I consider the State's showing on each of the two interests in turn.

1. Interest in the Quality of Health Care

To validate the Prescription Act on the basis of its impact on the quality of health care, the Attorney General needed to show that detailing with prescriber-identifiable data influences medical professionals to choose drugs that are less safe or less appropriate to meet patients' needs than the non-

patented alternatives they would otherwise prescribe. I agree with the district court that no evidence in the record supports the proposition that newer, brand-name drugs are generally less safe or effective than older, generic ones.

The record does contain evidence that, at times, physicians are persuaded to prescribe new drugs that are less effective for patients. Dr. Avorn testified that, in the wake of extensive marketing for new hypertension medications, known as calcium-channel blockers, many doctors switched from "better, older, less-marketed products" to new products that gave patients "less benefits in terms of preventing strokes or heart disease." The record did not, however, support a conclusion that such occurrences were the norm; rather, the Attorney General's evidence primarily was directed toward showing that detailing routinely persuades health care professionals to prescribe patented medications when they offer no benefit over cheaper generic alternatives. In other words, the Attorney General's focus was on the unnecessarily high prices paid for functionally equivalent drugs. That circumstance is pertinent to the cost-containment interest I discuss in the next section, rather than to an interest in safe and appropriate health care.

Other evidence relevant to the interest in quality health care showed that detailers use prescriber-identifiable data to target early adopters, who then prescribe promoted new drugs

that sometimes turn out to have harmful side effects. However, the Attorney General's argument is not that a greater number of physicians become early adopters because of targeted detailing; it claims the pharmaceutical companies use the data to identify physicians who already are inclined to adopt new drugs. In other words, the targeted doctors would likely have been among the first users of new drugs in any event. Thus, the possible adverse effect on health care stemming from reliance on the prohibited data would arise only from the possible difference in time between an early adopter's alert from a detailer and the physician's notice from another source. The record provides no basis for concluding that, in the ordinary case, that difference in time would have a significant health effect.<sup>49</sup>

However, the evidence did indicate that access to early adopters was economically advantageous for the pharmaceutical companies. By soliciting the earliest possible use of new medications, the companies can maximize the financial advantage of their exclusive rights while their high-priced drugs are patent-protected. See, e.g., Day 3, PM Session, at 52 (Testimony of Dr.

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<sup>49</sup> It is worth noting that some patients inevitably must be exposed to the risks of trying new drugs because it is through use by patients, after more limited clinical testing, that side effects and other problems are detected. In addition, the risks must be weighed against the benefits of early adoption of drugs that prove to be "breakthrough" developments in treatment. See, e.g., Day 4, AM Session, at 100 (Testimony of Randolph Frankel); AM Session (Part 2), at 15 (recording State counsel's observation that "obviously sometimes a newer drug is better").



Avorn) ("[The drug companies] are very conscious that the patent life is ticking away, and there's a tremendous impetus on the part of the industry to be able to maximize their income as much as possible the minute the drug is released on the market."). While a few weeks or months delay in adoption of a new drug might make a substantial financial difference, the Attorney General has not shown that it would have material health consequences.

It is unsurprising that I find the Attorney General's showing on the State's health care interest to be inadequate - or at least undeveloped - given that justification's limited role in both the legislative process and the trial. Promoting quality health care was not one of the two purposes of the law identified by the Act's sponsor when she introduced the legislation,<sup>50</sup> and the district court noted that the legislative history contained no "substantial support for the view that it was promoted as a public health measure, except to the extent that containing healthcare costs itself has a positive public health benefit." Tr. of Status Conference, April 11, 2006, at 44.<sup>51</sup> In a colloquy with counsel

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<sup>50</sup> In addition to Representative Rosenwald's statement about the purposes of the Act, the co-sponsor, Senator Foster, stated during the Senate Floor Debate that "[t]o me what this legislation is about is dollars and cents."

<sup>51</sup> In reviewing the State's interests during a mid-trial oral hearing, the district court stated: "I didn't see any discussion in the legislative history that . . . targeted detailing was leading to unhealthy prescription practices; that doctors were injuring their patients by denying them therapies that they would benefit from or by giving them drugs that would harm them. . . . This is a

toward the end of the trial, the court observed that it did not see "one shred of evidence in this record, either in the legislative history or in the trial" that prescription of higher-priced drugs instead of generics "produces unhealthy or less healthy outcomes for anybody in New Hampshire." Additionally, the plaintiffs effectively countered the Attorney General's limited showing on adverse health effects with evidence that targeted detailing is just as likely to offer health benefits; it allows drug companies to quickly alert prescribers when new drug side-effects are discovered and provides early notification to specialists of helpful new treatments for their patients.<sup>52</sup> Thus, I agree with the district court that the record fails to show that the Prescription Act directly advances the State's interest in safer or better medical care. See 44 Liquormart, 517 U.S. at 505 ("[A] commercial speech regulation 'may not be sustained if it provides only ineffective or remote support for the government's purpose.'") (quoting Central Hudson, 447 U.S. at 564).

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bill about costs. It's not a bill about safety." Day 4, AM Session (Part 2), at 3-4.

<sup>52</sup> In his declaration, Randolph B. Frankel, vice president of public affairs at IMS, stated that early adopters' delayed awareness of innovative drugs affects patients other than their own because other prescribers deliberately wait for early adopters to test the safety and effectiveness of the drugs. He commented: "When new drugs that have been tested and approved are not adopted or adopted very slowly this generally harms public health and may increase the overall cost of public healthcare." Declaration, at 10.

## 2. Interest in Containing Prescription Drug Costs

To justify the statute as a cost-control measure, the Attorney General has the burden of demonstrating that prescriber-identifiable data plays a significant role in the decisions of health care professionals to choose more expensive brand-name drugs over comparably effective, but less expensive, generic alternatives. See 44 Liquormart, 517 U.S. at 505 ("[T]he State bears the burden of showing not merely that its regulation will advance its interest, but also that it will do so 'to a material degree.'") (quoting Edenfield v. Fane, 507 U.S. 761, 771 (1993)). In other words, the Attorney General must show that (1) detailing generally has a persuasive effect on physicians and that (2) the use of prescriber-identifiable data magnifies that persuasive effect, increasing the physicians' tendency to prescribe unnecessary brand-name drugs.<sup>53</sup>

### a. The evidence

The impact of detailing on prescriber drug choice was amply documented by both empirical and anecdotal evidence. The

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<sup>53</sup> I note that targeted detailing is used not only to promote patented, brand-name drugs over generic medicines, but also to encourage prescribers to choose a particular brand-name drug over a patented competitor. The latter situation is not the State's primary concern because the cost difference between brand-name drugs is less likely to be substantial. The State particularly wants to prevent pharmaceutical sales representatives from unduly influencing physicians and other health care professionals to select more expensive brand-name drugs over considerably cheaper generic options that provide essentially the same benefits.

following is a sampling of the evidence submitted to the legislature or at trial:

●Dr. Savage, president-elect of the New Hampshire Medical Society, testified at the Senate committee hearing that "[n]umerous studies" have shown that doctors' prescribing decisions "can be and sometimes [are] shaped by marketing efforts."

●During the trial, Savage's predecessor as president of the medical association, Dr. Sadowsky, related a particular instance when one of his patients, at the suggestion of her primary care doctor, asked for a brand-name drug that Sadowsky considered no better than a less expensive generic. See supra Section II.B.1. He attributed the request to detailing of the primary care physician. Sadowsky also testified:

I believe that detailing has had an [e]ffect on my prescribing. I think that just looking back I think that when medicines have gone off patent, I don't think that I thought about this consciously, but I think that my rate of prescriptions of those medicines declined in preference to the medicines I was being detailed about.

●The declaration submitted during the trial by Drs. Avorn and Kesselheim reported from their research and others' work that "[p]hysicians use of targeted prescriptions increases substantially after visits with sales representatives," Declaration, at 6, and the same result was reported in an article

reviewing academic research on the effect and role of detailing. The article concluded that, "not only is detailing an important source of information, it affects physician prescription behavior in a positive and significant manner." Manchanda & Honka, supra, at 787. The article cites multiple studies in which doctors acknowledged that detailing affected their prescribing behavior and reported one study showing that family physicians who relied least on sales representatives were most likely to prescribe generic drugs, "while only 12% of those who said they relied 'a great deal' on detailers prescribed generic drugs." Id. at 799.<sup>54</sup>

●In her article reviewing 29 surveys exploring the relationship between physicians and pharmaceutical sales representatives, Ashley Wazana reported that "[t]here was an independent association between meetings with pharmaceutical representatives and formulary addition requests for the drug of

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<sup>54</sup> Manchanda and Honka also noted that many studies report that physicians believe that prescription behavior may be influenced by detailing.

This opinion is supported by virtually all the studies that have investigated the effect of detailing (either in isolation or with other marketing instruments) using behavioral data either at the market or individual physician level. While there seems to be little consensus about the size of the effect, it is clear that the effect is positive and significant in a statistical sense.

Id. at 809.

the representative's company."<sup>55</sup> See Wazana, supra, at 375. Most of the requested drugs, however, "presented little or no therapeutic advantage over existing formulary drugs." Id.

●A CALPIRG "white paper" contained in the Legislative History cited the finding of a Pennsylvania study that 40% of patients in a state assistance program received hypertension drugs different from those recommended by medical guidelines. According to the paper, the study reported that,

[i]f doctors had prescribed according to those guidelines, the state could have saved \$11.6 million, or nearly 24% of the total money it spent on hypertension medicine. The study suggested that pharmaceutical promotion was partly at fault for the variance between the medicines that were recommended versus those that were prescribed.

Emily Clayton, CALPIRG, 'Tis Always the Season for Giving: A white paper on the practice and problems of pharmaceutical detailing (2004), at 4-5.<sup>56</sup>

The Legislature was thus on solid ground in concluding that pharmaceutical detailing influences prescriber drug choices.

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<sup>55</sup> A formulary is a list of drugs approved for use in a particular setting, such as in a hospital or for a Medicaid program.

<sup>56</sup> Drs. Avorn and Kesselheim also noted the extensive campaigns in favor of new hypertension medications, known as calcium-channel blockers, "despite the fact that professional guidelines did not consider them first-choice therapies for the treatment of hypertension. . . . This distortion of practice away from the use of drugs recommended in national guidelines was estimated to have increased health care expenditures by around \$3 billion dollars [sic] in 1996 alone." Declaration, at 7.

The added benefit to pharmaceutical companies of marketing with access to prescriber-identifiable data, although less exhaustively covered, also was the subject of considerable testimony by the Attorney General's witnesses. Their testimony depicted targeted detailing as more aggressive and persuasive, and thus more potent than regular detailing in guiding prescriber behavior toward the detailer's desired outcome - the decision to use the sales representative's patented, brand-name drug. On the specific impact of detailing with prescriber-identifiable information, the evidence included the following:

●Dr. Gary Sobelson, a family practice physician, testified at trial that he was unaware of scientific evidence showing that the sale of prescriber-specific data increases drug costs, but observed that such knowledge "puts me at a disadvantage that I'm not comfortable being at." He told of being persuaded to prescribe a brand-name drug, Zithromax, instead of an equivalent generic Amoxicillin, based on an incorrect assumption that Zithromax, which had the advantage of requiring a shorter course of therapy, was minimally more expensive than the older Amoxicillin. After discovering that Zithromax was five times more expensive, he moved away from Zithromax because "I'm interested in prescribing rationally for my patients in a way that both maximizes their outcome but also helps maintain the lowest

possible cost to both them individually and, frankly, to our society at large."

●Sobelson also described how detailers use prescriber-identifiable information when marketing to a physician who typically prescribes a competitor's equivalent product, citing two cholesterol-lowering medications, Lipitor and Zocor, in his example:<sup>57</sup>

[W]hen a drug representative for Lipitor comes to see me, . . . they are going to know to present data that would focus me to why I should prefer Lipitor over Zocor. It's a very, very specific focus that particularly is fueled if they happen to know that 80 percent of my prescribing is Zocor. And so when the Lipitor rep comes around, they are going to have their targeted information provided by their marketing department. This is how we've learned from our study groups that you get doctors to move from Zocor to Lipitor.

●Sobelson's experience on the receiving end of the marketing dovetailed with the description provided by a former detailer of his strategy when he had prescriber information. Shahram Ahari testified that, when he knew a physician's patterns, "I have a fair idea why, and so it becomes almost a cat and mouse game when I get them to say their objections and for me to shift

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<sup>57</sup> The issue here is detailing aimed at promoting a brand-name option over a non-bioequivalent - cheaper - alternative. However, as noted earlier, detailing also is used to influence the choice among competing brand-name drugs. Sobelson's testimony indicating the influence of detailing in the brand-name setting supports an inference that it is equally effective in the competition between brand-name and generic drugs.



those objections or doubts and downplay or negate them altogether." By contrast, without prescriber-specific information,

it becomes less about the business and more about knowing the science of my drug. . . . [I]t puts the power of the detail more in the physician's hands because I don't truly know what his concerns are or what his perspectives or biases are. . . . [I]t shifts the power of the conversation to a more equal footing.

●A Boston Globe article included in the Legislative History reported similar information; a sales representative told of his understanding that, if he learned that a doctor was prescribing a competitor's product, his presentation should focus on undermining that product. Liz Kowalczyk, Drug Companies' Secret Reports Outrage Doctors, Boston Globe, May 25, 2003, at A1.

●Plaintiff IMS has explained the benefits of data-mining with a focus on prescriber-specific data: "By using a data-mining solution, IMS can pinpoint prescribers who are switching from one medication to another. A sales person can use this model to target doctors who have switched from the drug they are selling and to devise a specific message to counter that switching behavior." Paul Kallukaran & Jerry Kagan, Data Mining at IMS HEALTH: How We Turned a Mountain of Data into a Few Information-rich Molehills, IMS Abstract.

●In both his testimony and declaration, Dr. Avorn stated that detailing becomes less information-focused and a more

powerful tool of persuasion when the sales representative is armed with prescriber-specific information. In his joint declaration with Dr. Kesselheim, he related the "counter-detailing" experience of his research unit at Harvard Medical School, in which he and his colleagues used prescriber-specific data obtained from pharmacy records to choose physicians for educational visits by clinical pharmacists, accompanied by mailed "unadvertisements." He reported that these targeted interventions resulted in a 14 percent reduction in inappropriate prescriptions,<sup>58</sup> Declaration at 9, and he saw significance in these results for commercial detailing:

Our educational programs (known as "academic detailing") focused on improving patient care through reducing excessive use of inappropriate medications. But when these techniques are used by companies whose main goal is simply to increase product sales, the impact on patients and on the health care system are quite different. The studies we have cited indicate that more physician-specific detailing will lead to more prescriptions of brand-name agents, often with no additional patient benefit but at much higher cost to patients and to state-based insurance programs, which will continue to drive up the cost of health care in New Hampshire.

Id. at 10.

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<sup>58</sup> As discussed infra, the plaintiffs cite this success with counter-detailing as evidence that the State could have achieved its objective of cost-containment without suppressing speech. As I explain, counter-detailing is not a comparable alternative.

Avorn echoed these observations at trial, explaining that prescriber-identified data was important to the success of his counter-detailing because "that's how we knew whom to visit, and we also knew what to say to them because we knew what drugs they were prescribing." In the declaration, he stated that restricting access to prescriber-specific information, "[m]aking it more difficult for manufacturers to tailor their marketing strategies to . . . individual physicians[,] would actually encourage detailers to present physicians with a more neutral description of the product that would emphasize presentation of information over promotion." Declaration, at 11; see also Day 3, PM Session, at 140 (Avorn Testimony) ("[I]f the sales rep knows my prescribing history, they will market to me or at me in a way that goes well beyond just providing me with the data. It's not really education at that point. It's not a level playing field.").

●An assumption that prescriber-identifiable detailing impacts drug choice is reflected in the professional guidelines cautioning against using the data aggressively. As noted above, the AMA has adopted suggestive guidelines against the use of "prescribing data to overtly pressure or coerce physicians to prescribe a particular drug." Such indirect evidence supports the State's view that eliminating access to the information will decrease the likelihood that physicians will be swayed by targeted

marketing to prescribe unnecessary - and more expensive - brand-name drugs.

b. The district court's evaluation of the evidence

The district court concluded that, notwithstanding this evidence, the State's showing was insufficient to establish a link between the Prescription Act and cost-containment because other evidence showed that more expensive brand-name drugs will, at times, be the better therapeutic choice.<sup>59</sup> The court acknowledged that "substantial deference" must be given to a legislature's

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<sup>59</sup> The court explained its reasoning on the cost-containment interest as follows:

I am also unconvinced by the Attorney General's argument that the Prescription Information Law directly promotes the State's interest in containing health care costs. The Attorney General appears to assume that any health care cost savings that will result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care. However, this proposition is far from self-evident. Non-bioequivalent generic drugs are not always as effective as brand-name alternatives. Moreover, even in cases where non-bioequivalent generic drugs will work as well or better than a brand-name alternative for most patients, there may be some patients who will benefit by taking the branded medication. Yet, a ban on the use of prescriber-identifiable data affects both helpful and harmful brand-name prescribing practices in the same way. Because the Attorney General has failed to prove that any reductions in health care costs that may result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care, I am unable to endorse her argument that the Prescription Information Law can be justified as a cost containment measure.

490 F. Supp. 2d at 180-81.

predictive judgments "[w]hen a quality record establishes that the legislature conducted an extensive investigation, acquired considerable expertise in the regulated area, and incorporated express findings into the approved statute." 490 F. Supp. 2d at 177 n.12 (citing Turner Broad. Sys., Inc. v. FCC, 520 U.S. 180, 186 (1997)). However, the court questioned the extent of the Legislature's investigation before adopting the initiative, noting, inter alia, that it acted quickly after the bill was introduced, made no express findings on the need for the legislation, and "cited no evidence as to how effective the restriction might prove to be." 490 F. Supp. 2d at 177.

I am mindful that regulations that suppress commercial speech must be carefully evaluated. Nonetheless, the district court held the Attorney General to a higher standard of proof than is required by Supreme Court precedent. While a state legislature "does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes," 44 Liquormart, 517 U.S. at 510, the Court's commercial speech cases "recognize some room for the exercise of legislative judgment." Id. at 508. To earn that deference, the State must offer probative evidence that suppressing speech is essential to achieving its goal. However, a state legislature cannot reasonably be expected to undertake an investigation of the scope conducted by Congress in connection with the federal legislation

at issue in Turner Broadcasting, the case cited by the district court, to justify a limited restriction on commercial speech. See Turner Broad. Sys., 520 U.S. at 187 (noting that the record included "tens of thousands of pages" of materials acquired during three years of Congressional preenactment hearings, as well as additional expert submissions, sworn declarations, testimony, and industry documents).

In Turner Broadcasting, the Court observed that, given the exhaustive record, Congress's findings were entitled to "deference in part because the institution is far better equipped than the judiciary to amass and evaluate the vast amounts of data bearing upon legislative questions." 520 U.S. at 195 (internal quotation marks and citations deleted). Although the contexts are different,<sup>60</sup> the general principle of legislative deference also is compatible with the Court's commercial speech precedent. The question here, as there, is whether the government is able to support its restriction on speech by "'adduc[ing] either empirical support or at least sound reasoning on behalf of its measure[]." Turner Broad. Sys., 512 U.S. at 666 (quoting Century Commuc'ns

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<sup>60</sup> Turner Broadcasting addressed the "must-carry" provisions of the Cable Television Consumer Protection and Competition Act of 1992. In its first decision in the case, the Court held that the provisions imposed content-neutral restrictions on speech that were subject to intermediate scrutiny. Turner Broad. Sys., Inc. v. FCC, 512 U.S. 622, 661-62 (1994). In its second decision, the Court concluded that the provisions were consistent with the First Amendment. 520 U.S. at 185.

Corp. v. FCC, 835 F.2d 292, 304 (D.C. Cir. 1987)); see Florida Bar v. Went For It, Inc., 515 U.S. 618, 628 (1995) ("[W]e do not read our case law to require that empirical data come to us accompanied by a surfeit of background information. Indeed, in other First Amendment contexts, we have permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and 'simple common sense.'") (citations omitted). If the government makes the requisite showing, we defer to the legislative judgment to adopt the challenged measure.

The Attorney General has no empirical data showing the extent of the influence of prescriber-specific information on physicians' decision-making; nor can she document how much money the Prescription Act will save the State or consumers. The regulation was the first of its kind in the country, and it had been in effect for less than a year when the district court invalidated it. It is unreasonable in these circumstances to expect the Attorney General to provide extensive quantifiable data that might only become available after the statute has been in place for some time. I have described evidence here that establishes a plausible cause-and-effect relationship between targeted detailing and higher drug prices. What is missing is hard evidence of the global extent of this relationship. Clearly,

it will be important going forward for the State to try to measure the cost-containment effect of its initiative, and it is possible that this ongoing assessment will indicate that the measure is not as effective as the State had hoped.

However, at this juncture, the Attorney General has established a factual basis justifying the initiative. She has adduced significant testimony based on relevant empirical research concerning the impact of detailing generally, supplemented by the personal experience of both prescribers and detailers, strongly indicating that sales pitches based on specific prescribing patterns have a particularly persuasive impact on drug choice. The extent of this empirical and anecdotal evidence, particularly in light of the Act's limited restriction on speech, distinguishes this case from those in which the Supreme Court has found more sweeping bans on commercial speech to be inadequately justified. For example, the Court in Edenfield noted the absence of any studies or anecdotal evidence to support a ban on in-person solicitation by accountants. 507 U.S. at 771. In Shapero v. Kentucky Bar Ass'n, 486 U.S. 466 (1988), which rejected a ban on direct-mail solicitations by lawyers, the State "assembled no evidence attempting to demonstrate any actual harm caused by targeted direct mail," Florida Bar, 515 U.S. at 629. See also U.S. West, Inc., 182 F.3d at 1237 (noting that the government had



presented "no evidence" showing that the harm to either of its two asserted interests "is real").

Moreover, as I have recounted, evidence from multiple sources indicated that the expense of unnecessary brand-name prescribing has in the past ranged into the billions of dollars nationally.<sup>61</sup> This substantial evidence of needless spending, combined with evidence that detailing with prescriber-identifiable data contributes to that outcome, is enough to show that the Prescription Act "targets a concrete, nonspeculative harm," Florida Bar, 515 U.S. at 629, and that the Attorney General has sufficiently demonstrated that the State's interest in cost-containment would be furthered "to a material degree" by the limitation on speech it seeks to achieve through the Prescription Act.<sup>62</sup> See, e.g., City of Los Angeles v. Alameda Books, Inc., 535

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<sup>61</sup> In summarizing the need for the legislation, Dr. Avorn testified:

I think the problem we're concerned with - and I think the legislation was designed to address - is that we have this epidemic of over-priced drugs just eating the lunch of the older drugs that are both cheaper and safer; and that's not an opinion. That's simply looking at what's happened in the field of hypertension treatment, what's happened with the anti-platelet drug like Plavix. Now, Plavix is an okay drug, and we recommend it in a number of settings but not for everyone who sometimes feels their legs are heavy, like the commercials say; and Plavix costs 160 times what aspirin costs.

<sup>62</sup> It is particularly difficult to predict the long-term impact of eliminating targeted detailing from the pharmaceutical sales representative's marketing tools. In a submission to the district court, amici pointed to one potentially significant byproduct of

U.S. 425, 426 (2002) ("[A] municipality may rely on any evidence that is 'reasonably believed to be relevant' for demonstrating a connection between speech and a substantial, independent government interest."); cf. Turner Broad. Sys., 512 U.S. at 666 ("[T]he obligation to exercise independent judgment when First Amendment rights are implicated is not a license to reweigh the evidence de novo, or to replace Congress' factual predictions with our own. Rather, it is to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence.").

Importantly, the district court made no finding that the Attorney General had failed to establish a relationship between detailers' use of prescriber-identifiable data and increased health costs.<sup>63</sup> Instead, the court concluded that the Attorney General had failed to show that the Act advanced the State's

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lowered prescription drug costs. They cited studies showing that consumers, particularly older adults, sometimes forego filling or renewing prescriptions because of their cost, leading to higher long-term health care costs. See AARP Memorandum to Dist. Ct., at 13 ("'The consequences of cost-related medication underuse include increased emergency department visits, psychiatric admissions and nursing home admissions, as well as decreased health status.'") (quoting John D. Piette, et al., Cost Related Medication Underuse Among Chronically Ill Adults: the Treatments People Forego, How Often, and Who is at Risk, 94 Am. J. Pub. Health 1782 (2004)). Although the extent of such behavior may not be readily determined, such studies support the State's view that lowered drug costs will favorably impact health care expenditures.

<sup>63</sup> Indeed, as noted earlier, the court "accept[ed] her major premise that pharmaceutical companies use prescriber-identifiable data to make detailing more persuasive." 490 F. Supp. 2d at 180.

interest because any cost savings might be offset by compromised health care for patients who would in fact benefit from the use of more expensive brand-name drugs.

It does not matter that detailing with prescriber-identifiable data sometimes has positive effects. The Attorney General's evidence indicated that the health care benefits of such marketing described by plaintiffs are largely achievable in other ways. News reports, for example, would highlight truly groundbreaking new therapies in a timely way and, indeed, pharmaceutical detailers with knowledge of physicians' medical specialties presumably would not need access to prescribing histories to effectively promote such innovations.<sup>64</sup> Early adopters could be expected to respond quickly with an interest in trying the new medications - effectively identifying themselves to the sales representatives.<sup>65</sup> In addition, as I already have

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<sup>64</sup> Dr. Sadowsky of the New Hampshire Medical Society expressed the view that alternative means existed for learning about new drugs: "I think that the vast majority of physicians are aware pretty quickly through the literature, through the medical literature about any new miracle drugs." Dr. Sobelson agreed: "I don't think I need a detailer at all to make me aware of [a breakthrough drug]. . . . [Y]ou can read about it in the New York Times, but I also certainly heard about it [a new drug for treating Alzheimer's disease] at conferences, from colleagues, from the sources of information that I really want to hear about." See also Day 3, PM Session, at 57-58 (testimony of Dr. Avorn) (noting that, for "the important new drugs, you don't really need to have this big marketing push if it's a really meaningful clinical advance").

<sup>65</sup> Randolph Frankel, a drug marketing specialist and IMS vice president, acknowledged that "provider-level data is [not] the only way to find things out, but it does add another and a significant

observed, the statute does not bar drug companies from alerting prescribers to newly discovered problems with their medications. In other words, I see no message or interest of consequence that is foreclosed by the regulation.<sup>66</sup> Cf. Thompson, 535 U.S. at 376 (noting that "the amount of beneficial speech prohibited by the [statute]" would be "enough to convince us that the . . . advertising provisions were unconstitutional"); Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173, 194 (1999) (noting that the statute at issue "sacrifices an intolerable amount of truthful speech about lawful conduct when compared to all of the policies at stake").<sup>67</sup> Thus, the fact that

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level of efficiency or effectiveness in terms of how you do it. . . . [I]f these data disappeared, pharmaceutical companies would find some other way to approve how they allocate, how they target, and how they message."

<sup>66</sup> Plaintiffs suggest that the Act may result in prescriber-identifiable data becoming completely unavailable, an outcome that all parties would likely consider undesirable. Plaintiffs theorize that the pharmaceutical companies would be unwilling to pay substantial sums for information they cannot use in marketing, eliminating the data miners' biggest customers - thereby cutting off the commercial funding that subsidizes the research and other non-commercial uses of the data. However, the statute allows many commercial uses of the data and, even where reliance on specific prescriber information is prohibited, the drug companies may rely on permissible forms of aggregated data (by speciality and zip code). Thus, the prospect that prescriber data will no longer be available for any purpose is too speculative to undermine the State's interest.

<sup>67</sup> Dr. Avorn offered the following observation: "If they can't make their argument on the basis of the data justifying the use of their drug and it requires knowing the doctor's prescribing habits to make that case, then I would say that's not a case that ought to get made. It ought to be about the data and the merits of the

detailing with prescriber-identifiable data may at times have a positive effect on health care does not negate the Act's role in advancing the State's interest in cost-containment.

### **C. Narrow Tailoring**

In evaluating the narrow tailoring prong of the Central Hudson inquiry, the Court typically has asked "whether the extent of the restriction on protected speech is in reasonable proportion to the interest served." Edenfield, 507 U.S. at 767; see also Greater New Orleans Broad. Ass'n, 527 U.S. at 188 ("The Government is not required to employ the least restrictive means conceivable, but it must demonstrate narrow tailoring of the challenged regulation to the asserted interest - 'a fit that is not necessarily perfect, but reasonable' . . . .") (quoting Bd. of Trustees of State Univ. of N.Y. v. Fox, 492 U.S. 469, 480 (1989)); Florida Bar, 515 U.S. at 632 ("[T]he 'least restrictive means' test has no role in the commercial speech context.").

This "reasonable fit" standard of intermediate scrutiny has drawn criticism. See Thompson, 535 U.S. at 367-68 (noting that "several Members of the Court have expressed doubts about the Central Hudson analysis and whether it should apply in particular cases"); Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 554-55 (2001) (same); Greater New Orleans Broad. Ass'n, 527 U.S. at 184 (recognizing the advocacy among judges, scholars and others for "a

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product, not about my professional history."

more straightforward and stringent test for assessing the validity of governmental restrictions on commercial speech").<sup>68</sup> However, the Court majority has adhered to the Central Hudson approach, observing repeatedly that, in the particular case at issue, "there is no need to break new ground" in assessing the validity of the challenged governmental restrictions on commercial speech. See Thompson, 535 U.S. at 368; Lorillard Tobacco Co., 533 U.S. at 554-55; Greater New Orleans Broad. Ass'n, 527 U.S. at 184.

Nonetheless, the debate on Central Hudson's continuing viability seems to have influenced the Court's application of its framework. Multiple commentators have observed that intermediate scrutiny under Central Hudson has "come to resemble closely the 'narrowly tailored' requirement of strict scrutiny." Troy L. Booher, Scrutinizing Commercial Speech, 15 Geo. Mason U. Civ. Rts. L.J. 69, 77 (2004); see also R. Michael Hoefges, Regulating Professional Services Advertising: Current Constitutional Parameters and Issues Under the First Amendment Commercial Speech Doctrine, 24 Cardozo Arts & Ent. L.J. 953, 989 (2007) (noting that recent precedent arguably "has pushed the fourth prong of the Central Hudson analysis closer than ever before to the least-

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<sup>68</sup> Justice Thomas has been particularly adamant in contending that no distinction should be drawn between commercial and noncommercial speech: "I do not see a philosophical or historical basis for asserting that 'commercial' speech is of 'lower value' than 'noncommercial' speech. Indeed, some historical materials suggest to the contrary." 44 Liquormart, 517 U.S. at 522 (Thomas, J., concurring).

restrictive-means requirement of strict constitutional scrutiny"); Emily Erickson, Disfavored Advertising: Telemarketing, Junk Faxes and the Commercial Speech Doctrine, 11 Comm. L. & Pol'y 589, 602 (2006) ("[T]he broader trend has been one of higher scrutiny for commercial speech cases."); Elizabeth Spring, Sales Versus Safety: The Loss of Balance in the Commercial Speech Standard in Thompson v. Western States Medical Center, 37 U.C. Davis L. Rev. 1389, 1404 (2004) ("[T]he Court is now applying the Central Hudson test in a manner approaching strict scrutiny review.").

Indeed, in Thompson, a 5 to 4 decision, Justice Breyer in dissent chastises the majority for applying the commercial speech doctrine "too strictly" in striking down a statute prohibiting the advertising of compounded drugs. 535 U.S. at 388. In finding that the regulation was not narrowly tailored, the majority proposed a variety of non-speech alternatives that the Government could have adopted to meet its objectives. The justices observed that "[i]f the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." Id. at 371. From Justice Breyer's perspective, however, the majority "too readily assume[d] the existence of practical alternatives." Id. at 388.

This case does not require us to decide if Thompson represents a departure in the Court's application of the narrow

tailoring prong of Central Hudson. As I shall explain, even as applied by the majority in Thompson, Central Hudson's narrow tailoring requirement is satisfied here. As an initial matter, the restriction on speech imposed by the Prescription Act is significantly more limited than similar restrictions on commercial speech that have been considered by the Supreme Court. It is neither a complete ban on the marketing or advertising of a product or its price, see, e.g., Thompson, 535 U.S. at 360 (compounded drugs); 44 Liquormart, 517 U.S. at 489 (retail price of alcoholic beverages), nor a blanket prohibition on in-person solicitation, see, e.g., Edenfield, 507 U.S. at 763 (accountants); Ohralik, 436 U.S. at 448-49 (attorneys). Pharmaceutical sales representatives may continue to pitch their drugs directly to doctors and other health care providers, and the only message proscribed is one that incorporates an awareness of the doctor's prescribing practices. The detailers also may continue to use prescriber data provided by the plaintiffs for marketing, so long as the data aggregates prescribing patterns by speciality and zip code and not by individual provider. Thus, this case does not trigger the "special concerns [that] arise from 'regulations that entirely suppress commercial speech in order to pursue a nonspeech-related policy,'" 44 Liquormart, 517 U.S. at 500 (quoting Central Hudson, 447 U.S. at 566 n.9).



Despite the Act's limited scope, the plaintiffs maintain that it is broader than necessary to serve the State's objective and that it thus fails the narrow tailoring test. For multiple reasons, I reject the plaintiffs' contention and conclude that the State has met its burden of justifying the Prescription Act. The inadequacy of alternatives to satisfy the State's interests, the context of private communications, and the limited impact on the message sought to be disseminated lead me to conclude that New Hampshire has established "a 'reasonable fit' between its abridgment of speech and its . . . goal," 44 Liquormart, 517 U.S. at 507.

#### 1. Inadequacy of Alternative Measures

The plaintiffs argue that the State's cost-containment objective could have been achieved through measures that did not impact protected speech at all. The district court agreed and noted that, for example, the Legislature could have addressed the issue by "properly implementing" a Medicaid Pharmacy Program that takes into account the cost-effectiveness of brand-name drugs. 490 F. Supp. 2d at 182. The court pointed out that New Hampshire's current program requires authorization for Medicaid patients to obtain certain drugs and that state regulations allow cost considerations to be taken into account when deciding which drugs should be subject to the authorization. 490 F. Supp. 2d at 182. As a result, the court concluded that the State could

prevent unnecessary expenditures on brand-name drugs by denying authorization requests for more expensive drugs that are no more effective than cheaper alternatives. Id.

This proposal and the other non-speech alternatives proposed by the parties and the district court lack equivalency with the Prescription Act in accomplishing the State's cost-containment goal. In response to the district court's suggestion that legislative changes be made in the Medicaid program, the Attorney General argues that such measures would not respond to the State's broader concern that physicians' drug choices for all patients are distorted by the detailers' access to prescriber-identifiable data.<sup>69</sup> In addition, the Attorney General maintains that formularies also are affected by pharmaceutical detailing, citing evidence that physicians request additions to such lists even when the added drugs have "little or no therapeutic advantage over existing formulary drugs." Wazana, supra, at 375.

The court's other suggestions - requiring the State "to enter the intellectual marketplace" with its own information about proper drug choices; mandating participation in continuing medical education programs; or limiting the samples, meals and other

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<sup>69</sup> The plaintiffs elicited testimony that placing drugs on a Medicaid formulary list has a spillover effect on "the cash market" as well, Day 1, PM Session, at 29 (testimony of Hossam Sadek, IMS senior vice president), but the State reasonably could conclude that it could not rely on that secondary impact to achieve its objective.

ingratiating gifts provided by detailers to prescribers - are similarly imperfect. The Attorney General argues that the State lacks comparable resources to directly counter commercial detailing - for which the pharmaceutical companies spend billions of dollars<sup>70</sup> - and the district court at trial noted Avorn's testimony that relying on medical education programs would be difficult because "it would be hard to find the right people and . . . [t]here would be disputes over what the content is."<sup>71</sup>

I acknowledge that the suggestion that the State prohibit courtesy samples and other gifts to prescribers is not as easily dismissed. That prohibition could be implemented unilaterally and without expense to the State. Like the Prescription Act, such a ban would be directly aimed at diminishing the persuasive force of the detailers' message. As described above, the record contains evidence that the perks have a subtle influence on physicians' decision-making, increasing their affinity for particular sales representatives - and, presumably, for those representatives' drugs. In fact, a number of states have passed laws requiring that gifts to prescribers be

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<sup>70</sup> She further argues that "such a solution would simply treat the symptom," while the statute "is an effort to treat the disease itself." Brief at 43.

<sup>71</sup> Avorn testified that the pharmaceutical industry funds about 65 percent of continuing medical education and that one challenge of such an approach would be to decide "[w]ho gets to decide what the right message is."

publicly disclosed, and, as with the use of prescriber-identifiable data, professional guidelines have been adopted to reduce or eliminate such benefits.

While similar in intent, however, a ban on gifts and the ban on the use of prescriber-identifiable data are not interchangeable means of achieving the State's goal of cost-containment. The samples and gifts are merely a preparatory step in the marketing process; while they may increase the prescribers' susceptibility to the sales pitch, the State reasonably concluded that it is the sales pitch itself that has the most troubling effect on the prescribers' drug choice - and is most urgently in need of regulation. See Appellant's Brief at 42 (asserting that pharmaceutical companies use prescriber-identifiable data "to subtly manipulate physicians, in ways physicians are often unaware, to change their prescriptions for reasons other than the clinical needs of patients") (citing Avorn Declaration, at 9-11).<sup>72</sup>

Moreover, Avorn testified that the remedies proposed by the district court "have been tried, not necessarily in New Hampshire, in particular, but nationally in terms of trying to restrict the freebies, trying to provide doctors with other means

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<sup>72</sup> I note, in addition, that the State reasonably could reject a ban on samples because free medication allows many individuals to receive more effective treatments than they otherwise could afford. Although the evidence showed that not all doctors favor the distribution of free samples, the benefits of sampling would allow the State to conclude, on balance, that other cost-cutting measures would be preferable.

of learning, requiring that doctors take continuing ed courses."

Avorn opined that the Prescription Act

was not just a flippant, oh, let's see what happens with this. It was more of a sense of people have tried everything they can try and we still have this massive distortion of what doctors are prescribing and what the State, and its citizens, are paying for drugs because of the very heavily and very effective promotional strategies that are going on out there; and this seemed like - given that those other avenues are probably not going to be viable, that this seemed to be a way of preserving the company's ability to give me their best shot in their sales argument, but not to do so with a kind of knowledge that really shouldn't have anything to do with teaching me something . . . .

I am thus satisfied that the State has eliminated the possibility that "alternative forms of regulation that would not involve any restriction on speech would be more likely to achieve the State's goal," 44 Liquormart, 517 U.S. at 507 (emphasis added). To the contrary, Avorn's summary of other initiatives indicates that the State reasonably concluded that its legislation provided the only effective approach for achieving its objective.

In responding to the proposed alternatives through argument and evidence, the Attorney General in this case took steps that the majority in Thompson found lacking in the government's presentation there. The Court observed that "[n]owhere in the legislative history of the [Act] or petitioners' briefs is there any explanation of why the Government believed forbidding advertising was a necessary as opposed to merely

convenient means of achieving its interests." 535 U.S. at 373. The Court commented that "there is no hint" that the government had considered the alternatives proposed by the Court, or any other strategies. Id. In this case, the State offered expert evidence at trial and argued in its briefs on appeal in defense of its view that alternative strategies would not suffice. Thus, unlike in Thompson, the State has amply rebutted any impression that regulating speech was the first, or only, strategy it thought to try. Cf. id.

## 2. Focus on Private Communications

It is also significant that the Prescription Act restricts only private communications between the pharmaceutical detailer and prescribers, rather than a message disseminated to the public at large. In evaluating whether the Prescription Act advanced the State's cost-containment interest, the district court noted the Supreme Court's rejection in Thompson of a government interest "'in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.'" 490 F. Supp. 2d at 181 (quoting Thompson, 535 U.S. at 374); see also 44 Liquormart, 517 U.S. at 503 ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.").

This case differs from those in which the Court has rejected advertising bans that restrict the exchange of ideas in the "commercial marketplace." The Prescription Act neither "protects" the public from information about drugs nor prevents truthful advocacy by pharmaceutical representatives. Instead, it prevents sales representatives from crafting personal marketing messages on the basis of data that credible evidence indicates has been used to unduly influence prescribing choices. The Supreme Court on multiple occasions has reviewed regulation of such direct solicitations, upholding restrictions where the context raised concerns about the impact of the marketing on the recipient. See Edenfield, 507 U.S. at 765 ("There are, no doubt, detrimental aspects to personal commercial solicitation in certain circumstances. . . .").

Two such cases provide a helpful contrast and offer guidance in this case. In Ohralik, the Court upheld a bar against in-person solicitation of prospective clients by lawyers in "'situation[s] that breed[] undue influence,'" 436 U.S. at 449 (quoting Bates v. State Bar of Ariz., 433 U.S. 350, 366 (1977)). Ohralik involved two young victims of an automobile accident, one who was approached while she was still hospitalized and the other on the day she was released from the hospital. Id. at 450-51. The Court found that the State's compelling interest in "preventing those aspects of solicitation that involve fraud,

undue influence, intimidation, overreaching, and other forms of 'vexatious conduct'" justified the limited restriction on speech. Id. at 462. The Court further observed that "it hardly need be said that the potential for overreaching is significantly greater [than in the sale of ordinary consumer products] when a lawyer, a professional trained in the art of persuasion, personally solicits an unsophisticated, injured, or distressed lay person." Id. at 464-65.

By contrast, the Court concluded in Edenfield that a ban on face-to-face solicitation by certified public accountants ("CPAs") did not survive First Amendment scrutiny. 507 U.S. at 765. Although noting that face-to-face commercial solicitation may have "detrimental aspects," id., the Court also recognized that, "[i]n the commercial context, solicitation may have considerable value," id. at 766. Among the advantages listed by the Court were "direct and spontaneous communication between buyer and seller," "enabl[ing] the seller to direct his proposals toward those consumers who he has reason to believe would be most interested in what he has to sell," and providing buyers "an opportunity to explore in detail the way in which a particular product or service compares to its alternatives in the market." Id. The Court ultimately found that the risks inherent in the Ohralik context did not exist in the accountant setting:

Unlike a lawyer, a CPA is not "a professional trained in the art of persuasion." A CPA's



training emphasizes independence and objectivity, not advocacy. The typical client of a CPA is far less susceptible to manipulation than the young victim in Ohralik. Fane's prospective clients are sophisticated and experienced business executives who understand well the services that a CPA offers. In general, the prospective client has an existing professional relation with an accountant and so has an independent basis for evaluating the claims of a new CPA seeking professional work.

Id. at 775 (citations omitted). The Court thus concluded that "the ends sought by the State are not advanced by the speech restriction," and that the rule against in-person solicitation "infringe[d] upon Fane's right to speak, as guaranteed by the Constitution." Id. at 777.

In relevant respects, this case falls between Ohralik and Edenfield. Although the recipients of the marketing messages at issue here are, unlike in Ohralik, highly trained professionals, the solicitor in question - the pharmaceutical detailer - is schooled in the art of persuasion, like the lawyers in Ohralik. Unlike in Edenfield, there is substantial evidence that the detailer's persuasion has an impact and that confining the marketing interaction in the manner required by the Prescription Act would advance the State's interest. The detailer often has knowledge of drug details that are not readily available to the physician, and the evidence supports the State's view that adding prescriber-identifiable data into the mix lends weight to the detailer's message - and increases the likelihood that the

targeted prescriber will choose the brand-name drug being promoted by the detailer.

This is not to suggest that the detailer's message is generally inaccurate or misleading. The advantage provided by prescriber-identifiable data may only be to refocus the emphasis of the presentation. But where the record shows a real risk that "one-sided" presentations may give marketers "undue influence," the appropriateness of limiting speech veers much closer to Ohralik than Edenfield. See 44 Liquormart, 517 U.S. at 498 (commenting that the State "may restrict some forms of aggressive sales practices that have the potential to exert 'undue influence' over consumers"); Ohralik, 436 U.S. at 462 (noting state's legitimate interest in "preventing those aspects of solicitation that involve fraud, undue influence, intimidation, overreaching, and other forms of 'vexatious conduct'") (emphasis added).

### 3. Calculation of Costs and Benefits

I already have described the alternative ways in which prescribers will have access to the helpful information that may no longer be available to them from pharmaceutical detailers as a result of the Prescription Act. See supra Section IV.B.2.b. The statute therefore suppresses only a small amount of beneficial speech. "On the whole, then, the challenged regulation . . . indicate[s] that [the State] "'carefully calculated" the costs and benefits associated with the burden on speech imposed by its

prohibition.'" Greater New Orleans Broad. Ass'n, 527 U.S. at 188 (quoting Discovery Network, 507 U.S. at 417 (quoting Fox, 492 U.S. at 480)); see also U.S. West, Inc., 182 F.3d at 1238.

In this context, I conclude that the State has met its burden to justify the limited restraint on commercial speech imposed by the Prescription Act.<sup>73</sup>

## V.

There remains the plaintiffs' Commerce Clause challenge to the Act. I part company with my colleagues on that challenge because the majority's discussion of the issue, and its ready acceptance of the Attorney General's statement about the scope of the Act, further undermine the value of the majority's decision. There is a puzzling disconnect between the Attorney General's contention that the Act governs only transactions that take place within New Hampshire and the plaintiffs' contention that all of the conduct that the Act purports to regulate occurs outside the State. On the record before us, we do not have an adequate foundation for evaluating that disconnect and its implications for the Commerce Clause analysis. I therefore would remand this case

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<sup>73</sup> I join the majority's discussion of the plaintiffs' contention that the statute is unconstitutionally vague, other than its statement in footnote 9 invoking standing doctrine.

to the district court with instructions to address the Commerce Clause issue in the first instance.<sup>74</sup>

Under the Attorney General's interpretation of the statute - that the Act reaches only transactions that occur within New Hampshire - no Commerce Clause problem would exist. See Alliance of Auto. Mfrs. v. Gwadowsky, 430 F.3d 30, 35 (1st Cir. 2005) (explaining that, in evaluating whether a statute has impermissible extraterritorial reach, courts are obliged to adopt any reasonable construction consistent with the Constitution). The majority summarily deems that narrowing construction "reasonable," commenting that "it would make no sense to read the statute to regulate out-of-state transactions when the upshot of doing so would be to annul the statute." Yet a literal application of that narrowing construction would appear to leave the Act with negligible impact - hardly a reasonable outcome.

It is undisputed that none of the plaintiffs' transactions take place within New Hampshire. The district court found that "IMS and Verispan obtain all of their prescription information, including information on prescriptions filled in New Hampshire, from computers that are located outside of New Hampshire." 490 F. Supp. 2d at 166. At trial, the court

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<sup>74</sup> The district court's First Amendment ruling made it unnecessary for it to evaluate the parties' legal arguments concerning the vagueness and Commerce Clause challenges.

described the factual record on the Commerce Clause question as follows:

It's undisputed that prescriptions are generated in the state. It's undisputed that the prescriptions are filled within the state. It's undisputed that the pharmacies where they're filled [are] based in the state. It's undisputed that the pharmacy, as a part of its routine practices, unassociated with the sale of this information to pharmaceutical companies or IMS, transfers the information in the ordinary course of its business from a data center in the state to data centers outside the state. That the IMS software and Verispan software is applied to it outside the state. That it is then transferred from the [pharmacy] to IMS or Verispan outside the state, and it is thereafter sold to pharmaceutical companies and other clients outside the state.

The parties agreed that this summary, with some variations, was accurate and also agreed with the court's understanding that "the factual record that bears on the Commerce Clause question is undisputed."

Given these undisputed facts, however, it is unclear how much, if any, of the activity that the statute explicitly proscribes occurs within New Hampshire. For example, the "routine" transfer of prescriber-identifiable information from a local New Hampshire pharmacy to the pharmacy's out-of-state headquarters does not appear to be prohibited by the Act. Arguably, that electronic transfer would not be for an impermissible "commercial purpose" - involving, inter alia, "advertising, marketing, promotion, or any activity that could be

used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force." Consequently, the data would be outside New Hampshire before any transaction described by the Act occurs. The district court's factual summary suggests that most prescriber-identifiable data leaves New Hampshire in this permissible manner.

That understanding of the facts underlies the plaintiffs' argument that the Act seeks to prohibit the licensing, transfer, use, or sale of data identifying New Hampshire prescribers wherever such activity occurs. Plaintiffs' counsel explained their position during a colloquy with the court at trial:

The State has said, this doesn't apply outside of the state. . . . [O]ur reply to that has been . . . if it doesn't prohibit these transactions outside of the state, then the statute really loses all of its force and effectiveness. Because if Rite Aid's pharmacy in New Hampshire can transfer to its parent in Pennsylvania and its parent can transfer to IMS or Verispan in Pennsylvania, that's not prohibited. And then they can transfer it to Pfizer, wherever Pfizer's headquarters are outside of New Hampshire; and if Pfizer can then use it outside of New Hampshire for all of these various purposes that are prohibited, then there's absolutely no force or effect to this statute. And I think what the State is really arguing is that . . . all these transfers outside of the state, they are prohibited.

This statement stops one step short of demonstrating the most critical flaw in the Attorney General's narrowing construction of the Act. If her view of the Act were correct, not only could Pfizer buy and use New Hampshire data outside of New Hampshire "for all these various purposes that are prohibited," but the Act also would pose no barrier to the use of such data by detailers inside New Hampshire. This would be so because the Act does not apply to detailers and, as noted above, the undisputed facts suggest that the detailers routinely obtain the data from entities whose acquisition of the information, according to the Attorney General, was not restricted by the Act. Hence, the detailers' use of prescriber-identifiable data in New Hampshire doctors' offices would appear to involve no violation of the Prescription Act. In taking an indirect route toward its goal of regulating detailers' communications, presumably to avoid the First Amendment concerns that would be triggered by a direct restriction on speech, the Legislature may not have accomplished what it intended.

Of course, the Attorney General may believe that her concession that the Act does not apply to out-of-state transactions is not problematic because of her view that the Act bars detailers from using prescriber-identifiable data in their communications with New Hampshire prescribers if that data originated in New Hampshire, regardless of whether the

pharmaceutical company purchased the information inside or outside of the state. Indeed, that understanding of the Act's scope is suggested by the Attorney General's comments during the parties' colloquy with the district court:

The reality of the situation here is we have . . . national chain pharmacies moving into the State of New Hampshire, setting up their own places of business, hiring pharmacists, hiring managers, establishing a place of business in the State of New Hampshire and then obviously agreeing to abide by the laws of the State of New Hampshire when they establish a place of business in this state; and then in the course of their business, they're collecting . . . these data. They're moving these data out of the state, for whatever purpose, in full knowledge of . . . the laws of the State of New Hampshire . . .

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Under this view of the law, New Hampshire places an embargo on the use of the prescriber-identifiable data before it is first released by the pharmacies. The Attorney General apparently contemplates that New Hampshire pharmacies and similar entities would be permitted to license, transfer, use or sell the information they accumulate only on the condition that the data not be used downstream for the prohibited commercial purposes.

However, the disconnect that I described earlier remains. The explicit language of the Act does not appear to impose such a restriction on the original transfers of data by New Hampshire pharmacies to entities outside the state. The Act proscribes only the transfer of prescriber-identifiable data for



the specified commercial purposes. The transfer of data by New Hampshire pharmacies beyond New Hampshire's borders typically may not implicate those prohibitions. Transactions involving those commercial purposes occur farther downstream, and, so far as the record shows, primarily outside the state. Frankly, I am not sure that the Attorney General understood the import of her statement that the Act regulates only in-state transactions. Nor, given the state of the record, do I understand the majority's statement that, when the Act is interpreted as the Attorney General proposes, it "may result in a loss of profit to out-of-state data miners due to the closing of one aspect of the New Hampshire market for their wares." To the contrary, the statute's impact in New Hampshire appears negligible if it truly governs only transactions that occur within the state.

Although the Attorney General's concession was an attempt to sidestep the plaintiffs' Commerce Clause challenge, there may be an argument that such a step was unnecessary. When a state statute regulates commerce "wholly beyond the boundaries of the enacting state," it usually is invalid per se. Alliance of Auto. Mfrs., 430 F.3d at 35. Yet not every impact on interstate commerce is prohibited. "[T]he dormant Commerce Clause[] is not absolute and in the absence of conflicting legislation by Congress, 'the States retain authority under their general police powers to regulate matters of legitimate local concern, even

though interstate commerce may be affected.'" Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 311 (1st Cir. 2005) (quoting Maine v. Taylor, 477 U.S. 131, 138 (1986)). Moreover, whether extraterritoriality is impermissible in every instance, or whether it transgresses the dormant Commerce Clause only when the challenged statute is discriminatory or protectionist in nature, appears to be another relevant consideration. See Peter C. Felmlly, Comment, Beyond the Reach of States: The Dormant Commerce Clause, Extraterritorial State Regulation, and the Concerns of Federalism, 55 Me. L. Rev. 467, 491 (2003) (noting that recent Supreme Court cases considering the dormant Commerce Clause suggest an increased "focus on the territorial reach of state legislation . . . in stark contrast to the long-established concentration on state regulations that are discriminatory or protectionist in nature").

I have said enough to demonstrate the complexity of the Commerce Clause issue and the inadequacy of the record. There are missing details about how the prescriber-identifiable data generated by New Hampshire pharmacies flows to corporate offices out of state and the purpose of that information flow. The parties appear to have different assumptions about those details and their legal significance. Moreover, the plaintiffs' argument on the Commerce Clause spans only two and one-half pages in their sixty-page brief. The Attorney General's response is equally

terse. I think it unwise to address the Commerce Clause issue based on a cursory briefing that provides neither legal analysis nor developed application of the law to the limited facts of record. Although the parties agreed at trial that the facts on the Commerce Clause claim were undisputed and that no further evidence was needed to resolve it, the plaintiffs do not address that evidence in any meaningful way in their briefs and the Attorney General does not address the evidence at all. The district court did not reach the claim.

Our comment about a similarly bare Commerce Clause claim in Wine & Spirits II also should guide us here: "This sophisticated area of law requires developed argumentation, with evidentiary support." 481 F.3d at 15 (noting that the Supreme Court had "label[ed] as a 'critical consideration' regarding extraterritorial reach claims the 'overall effect of the statute on both local and interstate commerce'" (quoting Healy v. Beer Inst., Inc., 491 U.S. 324, 337 n.14 (1989))). I therefore would remand this case to the district court on the Commerce Clause issue.

## VI.

I summarize my conclusions:

1. The prudential standing doctrine is inapplicable in the circumstances of this case, where the core First Amendment issue was vigorously litigated and comprehensively considered by

the district court, and where the Prescription Information Act's constitutionality cannot be assessed without addressing its impact on the communications between detailers and prescribers;

2. The Act restricts commercial speech that is protected by the First Amendment, and the Attorney General therefore bears the burden of demonstrating that the statute satisfies the Central Hudson test;

3. Although the State has failed to prove that the Act is justified by substantial interests in privacy and quality health care, it has met its burden to show that the Act directly advances its interest in containing the cost of prescription drugs and is not more extensive than necessary to accomplish that objective.

4. Like the majority, I find the Prescription Act sufficiently clear to withstand plaintiffs' vagueness challenge when construed narrowly, consistent with its legislative history and applicable precedent.

5. The plaintiffs' contention that the Act violates the dormant Commerce Clause should be considered by the district court in the first instance. We should remand the case for that purpose.