

# United States Court of Appeals For the First Circuit

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No. 08-1248

IMS HEALTH INCORPORATED, VERISPAN, LLC, and SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of WOLTERS KLUWER HEALTH, INC.,

Plaintiffs, Appellees,

v.

JANET T. MILLS, as Attorney General for the State of Maine,

Defendant, Appellant.

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ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MAINE

[Hon. John A. Woodcock, Jr., U.S. District Judge]

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Before

Lynch, Chief Judge,  
Lipez and Howard, Circuit Judges.

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Thomas A. Knowlton, Assistant Attorney General, with whom Janet T. Mills, Attorney General of the State of Maine, Paul Stern, Deputy Attorney General, Nancy Macirowski, Assistant Attorney General, and Thomas C. Bradley, Assistant Attorney General, were on brief for appellants.

Thomas C. Goldstein, with whom Thomas R. Julin, Jamie Z. Isani, Patricia Acosta, Hunton & Williams LLP, Jack H. Montgomery, Bernstein, Shur, Sawyer & Nelson, P.A., Mark A. Ash, and Smith Anderson Blount Dorsett Mitchell & Jernigan LLP, were on brief for appellees.

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August 4, 2010

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**LYNCH, Chief Judge.** This case involves constitutional challenges to a Maine statute enacted to reduce health care costs and protect prescribers' data privacy. In Maine and elsewhere, each time a prescription from a physician or other licensed prescriber is given to a pharmacy, the pharmacy obtains a number of facts that identify the prescriber. Data put together from multiple transactions involving the same prescriber reveal certain patterns and preferences, including her prescribing history, her choice of particular brand-name drugs versus their generic equivalents, and the likelihood she will adopt new brand-name drugs.

Plaintiffs challenge the constitutionality of 22 Me. Rev. Stat. Ann. tit. 22, § 1711-E(2-A), which allows prescribers licensed in Maine to choose not to make this identifying information available for use in marketing prescription drugs to them. Section 1711-E(2-A) does not directly prohibit any marketing practices. Rather, it prohibits certain entities from licensing, using, selling, transferring, or exchanging this information for a marketing purpose if the prescriber has opted to protect the confidentiality of her prescribing data. Me. Rev. Stat. Ann. tit. 22, § 1711-E(2-A).

Plaintiffs, companies that collect vast amounts of identifying data about individual prescribers and aggregate the data into reports and databases for use when marketing

pharmaceutical products, are covered in the text of the law, as are others. See id. § 1711-E(1)(A)(I). Immediately after section 1711-E(2-A)'s enactment in 2008, and before its enforcement, plaintiffs sued Maine's attorney general in the federal district court of Maine under 42 U.S.C. § 1983, claiming that section 1711-E(2-A)'s restrictions on the licensing, use, sale, transfer, or exchange of Maine prescribers' identifying data for a marketing purpose are unconstitutional limitations on protected speech under the First Amendment; that these restrictions are unconstitutionally vague and overbroad under the First and Fourteenth Amendments; and that the law also regulates transactions outside of Maine in violation of the dormant Commerce Clause. On December 21, 2007, the district court granted plaintiffs a preliminary injunction and prohibited Maine from enforcing section 1711-E(2-A) on the basis of plaintiffs' First Amendment claims. See IMS Health Corp. v. Rowe, 532 F. Supp. 2d 153, 183 (D. Me. 2007).<sup>1</sup>

This case comes to us in an unusual posture. Maine is not the only state to have restricted plaintiffs' use of prescriber-identifying data, and this is not the first time plaintiffs have made these constitutional claims. On November 18, 2008, after the district court granted plaintiffs a preliminary injunction in this case, this court upheld a similar, but not

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<sup>1</sup> The district court also enjoined Maine from enforcing parts of section 1711-E implementing section 1171-E(2-A). See Rowe, 532 F. Supp. 2d at 183.

identical, New Hampshire statute against plaintiffs' constitutional challenges, a ruling that binds this panel. See IMS Health Inc. v. Ayotte, 550 F.3d 42 (1st Cir. 2008), cert. denied, 129 S. Ct. 2864 (2009). In the meantime, the district court's injunction has remained in effect during this appeal, and Maine has never implemented section 1711-E(2-A).

We reject all of plaintiffs' constitutional challenges to section 1711-E(2-A). Plaintiffs' First Amendment challenges fail for the reasons stated in Ayotte: the statute regulates conduct, not speech, and even if it regulates commercial speech, that regulation satisfies constitutional standards. They also fail for reasons not present in Ayotte. The Maine statute constitutionally protects Maine prescribers' choice to opt in to confidentiality protection to avoid being subjected to unwanted solicitations based on their identifying data. We also reject the argument that the statute is void for vagueness.

Plaintiffs' argument that section 1711-E(2-A) is unconstitutional under the dormant Commerce Clause if applied to plaintiffs' out-of-state use or sale of opted-in Maine prescribers' identifying data also fails. We interpret the Maine statute using Maine's principles of statutory construction and hold that section 1711-E(2-A) regulates prescription drug information intermediaries' out-of-state use or sale of opted-in Maine prescribers' data. We hold that this interpretation does not raise constitutional

concerns under the dormant Commerce Clause, which might necessitate a narrower reading of the statute under the doctrine of constitutional avoidance.

The Supreme Court's current dormant Commerce Clause jurisprudence does not leave Maine powerless to protect Maine prescribers who have sought to prevent the use of their identifying data in transactions that also cause substantial in-state harms, including increased health care costs. The statute constitutionally reaches plaintiffs' out-of-state transactions as a necessary incident of Maine's strong interest in protecting opted-in Maine prescribers from unwanted solicitations, a policy that Maine also rationally believes will lower its health care costs. Nor, we hold, would section 1711-E(2-A)'s regulation of prescription drug information intermediaries' out-of-state use or sale of opted-in Maine prescribers' identifying data raise constitutional concerns as a disproportionate burden on interstate commerce under Pike v. Bruce Church, Inc., 397 U.S. 137 (1970).

#### I. Factual Background

The relevant facts are undisputed.<sup>2</sup>

Prescriber-identifying data is used for many purposes, but this case concerns restrictions on only one of those uses:

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<sup>2</sup> These facts rely in part on this court's discussion of the same industry, and plaintiffs' role in that industry, in our 2008 Ayotte opinion. The parties have relied heavily on those facts and the record from Ayotte.

pharmaceutical manufacturers' use of the data to send their pharmaceutical sales representatives to personally market particular drugs to particular prescribers, a practice known as "detailing." Section 1711-E defines "detailing" as "one-to-one contact with a prescriber or employees or agents of a prescriber for the purpose of increasing or reinforcing the prescribing of a certain drug by the prescriber." Me. Rev. Stat. Ann. tit. 22, § 1711-E(1)(A-2).

Detailing is a massive and expensive undertaking for pharmaceutical manufacturers, which spend billions of dollars a year to have some 90,000 pharmaceutical sales representatives make weekly or monthly one-on-one visits to prescribers nationwide. Stephanie Saul, Doctors Object as Drug Makers Learn Who's Prescribing What, N.Y. Times, May 4, 2006, at A1. Each pharmaceutical manufacturer's detailers market particular pharmaceutical products in particular regions. A single prescriber is visited by an average of twenty-eight detailers a week; an average of fourteen detailers a week call on a single specialist.

Prescriber-identifying data is a valuable tool in a detailer's arsenal of sales techniques. With it, pharmaceutical manufacturers can pinpoint the prescribing habits of individual prescribers in a region and target prescribers who might be

persuaded to switch brands or prescribe more of a detailer's brand of products.<sup>3</sup> See Saul, supra, at A1.

During their one-on-one visits to prescribers, detailers distribute upwards of \$1 million worth of free product samples per year, along with branded promotional materials and pamphlets about the different conditions their particular products can be used to treat. Detailers use prescriber-identifying data to do these things more effectively; every sales pitch can be tailored to what the detailer knows of the prescriber based on her prescribing history. The central objective is to get prescribers to adopt the pharmaceutical product the detailer is marketing and to build brand loyalty. This goal is not only explicit; it is how detailers earn bonuses. See Saul, supra, at A1.

Some prescribers, in Maine and elsewhere, welcome these interactions. Detailers, they say, provide them with studies relevant to their practices, useful free samples, and targeted data about how widely certain new drugs have been prescribed by others. They find that detailers provide helpful comparisons of competing drugs used to treat the same conditions and information about new

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<sup>3</sup> When Merck marketed Vioxx, for example, it used a wealth of prescriber-identifying data to create monthly reports on individual prescribers in each detailer's assigned territory. The reports showed how many Merck versus non-Merck drugs the prescriber prescribed and estimated how many of these prescriptions could be substituted for Merck products. Merck then tracked its detailers' progress in converting prescribers in their territories to the Merck brand and gave detailers bonuses based on Merck's sales volume and market share in the detailer's territory.

drugs or more effective alternatives to the prescriptions they currently prescribe. These prescribers say they are immune to detailers' influence and see no conflict of interest.

Significantly, though, other prescribers have strenuously objected that detailing intrudes into their prescribing decisions. Detailers, these prescribers insist, should not be able to use their prescribing histories to target them for unwelcome marketing calls. An article by a senior vice president of the American Medical Association (AMA) and an executive of plaintiff IMS Health noted that physicians "complain bitterly" about detailers "who wave data in their faces" and challenge them with their own prescribing histories when they fail to prescribe more of the product the detailer has been advertising. R. A. Musacchio & R. J. Hunkler, More Than a Game of Keep-Away, Pharmaceutical Executive, May 2006. The head of California's state medical association has reported that prescribers have been "outraged that people came into their office and talked to them about how many times they prescribed a particular drug." Saul, supra, at A1. Aggregated survey data confirms that physicians have a predominantly negative view of detailing. See P. Manchanda & E. 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, 788-91 (2005).

Many Maine prescribers have openly objected to detailing. A survey by the Maine Medical Association in 2006 revealed that a majority of Maine physicians did not want pharmaceutical manufacturers to be able to use their individual prescribing histories for marketing purposes. One Maine prescriber explained that she felt that "it intrudes upon my privacy and my work life for drug companies to buy my information, without my permission, for marketing purposes." She has "ask[ed] to be removed from mailing lists and telephone call lists" and "would like to have the similar option of not allowing my professional information to be sold to drug companies for marketing purposes."

Detailers' use of prescriber-identifying data, however, is only the final step in a series of transactions that begin with the acquisition and aggregation of massive amounts of individual prescribers' identifying data. Pharmaceutical manufacturers lack direct access to prescriber-identifying data. That fact has fueled an enormously profitable, multilayered market for acquiring, aggregating, packaging, and selling these data primarily for detailing. Plaintiffs are the middlemen of this market.

When filling prescriptions, individual pharmacies accumulate data about the prescriptions individual prescribers have made, usually for insurance reimbursement. Pharmacies that are part of national chains normally transfer these data to the chain's central data warehouse. Each pharmacy, and even each pharmacy

chain, is only one piece of a bigger picture; individual prescribers, or their patients, may make prescriptions at many different pharmacy locations.

This is where plaintiffs come in. Plaintiff companies are prescription drug information intermediaries that mine specialized data. They contract with numerous pharmacies and, to a lesser degree, insurance companies and other carriers, to buy their raw data. Under those contracts, the pharmacy's computer software collects data it sends to plaintiffs. The software encrypts patient-identifying data so that plaintiffs cannot identify individual patients by name, but it captures information directly identifying prescribers by name and address and shows details about the particular drugs prescribed.

Plaintiffs receive and aggregate data from these various sources and then compile reports and databases. They assemble a complete picture of individual prescribers' prescribing histories by cross-referencing prescriber names with publicly available databases, including the AMA's database of medical doctors' specialties. See Saul, supra, at A1. Plaintiffs admit that most of their reports and databases are destined--and designed--for pharmaceutical manufacturers to instruct detailers where to focus

their efforts, identify which prescribers to target, and assess detailers' effectiveness.<sup>4</sup>

Plaintiffs then license or sell these specialized databases and reports to pharmaceutical manufacturers, a lucrative business that yielded revenues of \$1.75 billion for plaintiff IMS Health alone in 2005.<sup>5</sup> Id. Plaintiffs' products are the building blocks of the reports pharmaceutical manufacturers generate for individual detailers, who use them to target prescribers in their assigned areas.

## II. The Maine Law

To date, Maine appears to be one of only three states that have limited detailers' access to prescribers' identifying data. See Me. Rev. Stat. Ann. tit. 22, § 1711-E(2-A); N.H. Rev. Stat. Ann. § 318:47-f; Vt. Stat. Ann. tit. 18, § 4631(d). Like its counterparts in New Hampshire and Vermont, the Maine law, section 1711-E(2-A), does so indirectly: in relevant part, it states that "a carrier, pharmacy or prescription drug information intermediary," as defined in the statute, "may not license, use, sell, transfer or exchange for value, for any marketing purpose,

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<sup>4</sup> Plaintiffs also sell or license other databases and reports to other clients, including governments, nonprofit organizations, and research institutions.

<sup>5</sup> Pharmaceutical manufacturers may also use plaintiffs' data for other purposes, like to send out alerts about particular drugs to prescribers who have been prescribing it or for research and development.

prescription drug information that identifies a prescriber who has filed for confidentiality protection."<sup>6</sup> Me. Rev. Stat. Ann. tit. 22, § 1711-E(2-A). Maine's law regulates the different layers of the market for prescriber-identifying information, but it does not prohibit detailing, nor does it purport to prohibit speech by detailers to prescribers.

Unlike similar laws in New Hampshire and Vermont, the central feature of the Maine law is to limit detailers' access to an individual prescriber's identifying data only if the prescriber has affirmatively opted for this protection.<sup>7</sup> See id.

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<sup>6</sup> "Marketing" includes "[a]dvertising, publicizing, promoting or selling a prescription drug;" "activities undertaken for the purpose of influencing the market share of a prescription drug or the prescribing patterns of a prescriber, a detailing visit or a personal appearance;" "[a]ctivities undertaken to evaluate or improve the effectiveness of a professional detailing sales force;" or "[a] brochure, media advertisement or announcement, poster or free sample of a prescription drug." Id. § 1711-E(1)(F-1).

"Marketing" does not include pharmacy reimbursement, formulary compliance, pharmacy file transfers in response to a patient request or as a result of the sale or purchase of a pharmacy, patient care management, utilization review by a health care provider or agent of a health care provider or the patient's health plan or an agent of the patient's health plan, and health care research." Id.

<sup>7</sup> This circuit upheld New Hampshire's statute, which categorically prohibits certain entities, including plaintiffs, from licensing, transferring, using, or selling any prescriber-identifying data for a commercial purpose. N.H. Rev. Stat. Ann. § 318:47-f; Ayotte, 550 F.3d at 47. The Vermont statute instead prohibits certain entities from selling, licensing, exchanging, or permitting the use of records containing prescriber-identifying data when marketing or promoting prescription drugs unless the prescriber has affirmatively consented to such uses. See Vt. Stat. Ann. tit. 18, § 4631(d); IMS Health Inc. v. Sorrell, 631 F. Supp. 2d 434, 443-44 (D. Vt. 2009).

A "prescriber" is "a person who is licensed, registered or otherwise authorized in the appropriate jurisdiction to prescribe and administer drugs in the course of professional practice." Me. Rev. Stat. Ann. tit. 22, § 1711-E(1)(G-1). As other sections of § 1711-E make clear, the "appropriate jurisdiction" means prescribers licensed and located in Maine: the provision is designed to protect only "prescribers in the health care system of this state." Id. § 1711-E(1-B). Only these Maine prescribers can opt in, and even opted-in prescribers' identifying data can be used for any purpose other than detailing. See id.

Maine enacted section 1711-E(2-A) to achieve three stated "compelling state interests: to improve the public health, to limit annual increases in the cost of health care and to protect the privacy of . . . prescribers in the health care system of this State."<sup>8</sup> Id. § 1711-E(1-A). The Maine legislature found that "[p]atients and prescribers have requested that the legislature provide a mechanism for protecting the confidentiality of identifying prescription drug information from use for marketing purposes." Id. § 1711-E(1-A)(B). "Across the nation," the legislature further found, "data companies purchase for marketing purposes computerized prescription drug records from pharmacies and insurers that identify prescribers," and they sell these records

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<sup>8</sup> The Maine law contains a separate provision protecting patient-identifiable data, which plaintiffs do not challenge. See Me. Rev. Stat. Ann. tit. 22, § 1711-E(2).

"to prescription drug manufacturers that use personally identifying prescriber information to attempt to influence prescribers to prescribe higher priced drugs," resulting in higher health care costs. Id. § 1711-E(1-A)(C). "Restricting the use of prescriber identifying information," the Maine legislature found, "will act to decrease drug detailing that targets the prescriber, thus increasing decisions to prescribe lower priced drugs and decisions made on the basis of medical and scientific knowledge and driving down the cost of health care." Id. § 1711-E(1-A)(D).

Section 1711-E(2-A) operates as follows. In its first step, Maine prescribers who object to being targeted by pharmaceutical detailers may register for confidentiality protection.<sup>9</sup> See Me. Rev. Stat. Ann. tit. 22, § 1711-E(4). Maine prescribers can opt in for confidentiality protection in application materials with the relevant Maine licensing board. Id. § 1711-E(4)(A). Those materials must inform Maine prescribers that "prescription drug information that identifies the prescriber is used for marketing purposes by carriers, pharmacies and prescription drug information intermediaries" and must give prescribers the option of protecting the confidentiality of their

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<sup>9</sup> Plaintiffs' fleeting assertion that section 1711-E's definition of a "prescriber" encompasses any prescriber anywhere is flatly contradicted by section 1711-E's statement of purpose, which states that the statutes' goals include "to protect the privacy of . . . prescribers in the health care system of this State." Me. Rev. Stat. Ann. tit. 22, § 1711-E(1-B).

identifying information through one of three methods.<sup>10</sup> Id. § 1711-E(4)(A)(1). When a prescriber opts in, the relevant Maine licensing board must place the individual's name on a list that is submitted every month to the Maine Health Data Organization, an independent state executive agency.<sup>11</sup> Id. § 1711-E(4)(A)(2).

When patients of an opted-in Maine prescriber fill their prescriptions, the pharmacy still collects the prescriber's identifying data and may transfer it to a central data center. The law does not, by its terms, affect this transaction.

Section 1711-E(2-A) does regulate transactions between those pharmacies (or pharmacy data centers) and prescription drug information intermediaries like plaintiffs. Section 1711-E(2-A) prohibits pharmacies from selling, transferring, or licensing opted-in Maine prescribers' identifying data for a marketing purpose, unless the prescriber revokes the protection. See id. § 1711-E(2-A), (4)(A)(3).

Once plaintiffs obtain prescriber-identifying data from pharmacies, plaintiffs generate certain databases and reports

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<sup>10</sup> Those methods are (1) by signing and submitting an enclosed form to the Maine Health Data Organization; (2) by manually or electronically checking a box on the form; or (3) by linking to the Maine Health Data Organization website and filling out an electronic form. Id. § 1711-E(4)(A)(1).

<sup>11</sup> The Maine Health Data Organization maintains a health information database to benefit Maine citizens and develops data collection policies. Me. Rev. Stat. Ann. tit. 22, § 8703(1); id. § 8704(1)(A).

designed to facilitate detailing. If plaintiffs include opted-in Maine prescribers' identifying data in these products, they have "used" the data for a marketing purpose, in violation of section 1711-E(2-A). See id. § 1711-E(2-A). Section 1711-E(2-A) also prohibits plaintiffs from selling or licensing (to pharmaceutical manufacturers) only the portion of these databases and reports containing opted-in Maine prescribers' identifying data. See id.

Once pharmaceutical manufacturers obtain these detailing-oriented databases and reports, they generate individualized reports for detailers, who then use individual prescribers' data to target prescribers in Maine. Section 1711-E(2-A) does not explicitly limit detailers' use of prescriber-identifying data, but the earlier stages of regulation are meant to prevent this information from getting to detailers for use in marketing.

A violation of section 1711-E(2-A)'s prohibitions is a violation of the Maine Unfair Trade Practices Act, id. § 1711-E(3), and, under that act, the Maine Attorney General can enjoin the practice and levy civil penalties of \$10,000 per violation, Me. Rev. Stat. Ann. tit. 5, § 209.<sup>12</sup> The law is not subject to criminal enforcement.

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<sup>12</sup> Though neither party has addressed who may enforce the Maine Unfair Trade Practices Act, it is undisputed that the attorney general can enforce section 1711-E on behalf of individuals through section 209 of the act.

Section 1711-E(2-A) was to go into effect on January 1, 2008, id. § 1711-E(2-A), but because plaintiffs obtained a preliminary injunction before then, Maine has been prevented from enforcing it. See Rowe, 532 F. Supp. 2d at 157. As of September 2009, notwithstanding the injunction, 259 Maine prescribers have opted in for confidentiality protection.

### III. First Amendment

We reject plaintiffs' First Amendment challenge to the Maine law. Plaintiffs' claims fail for the same reasons we rejected their nearly identical First Amendment challenge to New Hampshire's similar statute in Ayotte. Plaintiffs' arguments here fail for another, independent reason. Maine has set up an opt-in scheme for prescribers licensed in Maine. Even assuming arguendo that the Maine law restricts protected commercial speech and not conduct, we hold that it directly advances the substantial purpose of protecting opted-in prescribers from having their identifying data used in unwanted solicitations by detailers, and thus Maine's interests in lowering health care costs.

#### A.

In Ayotte, this circuit held that New Hampshire's restrictions on plaintiffs' licensing, use, sale, transfer or exchange of all New Hampshire prescribers' identifying data regulate conduct, not speech, and thus the First Amendment does not protect plaintiffs' conduct. 550 F.3d at 51-54.

Ayotte alternately held that even if the New Hampshire law regulates speech, plaintiffs are at best engaged in commercial speech and the law survives intermediate scrutiny under Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980). Id. at 54-60. Ayotte also held that reducing health care costs is a substantial government interest; the court did not reach New Hampshire's two other asserted interests, protecting citizens' health and protecting the confidentiality of patients' and prescribers' identifying data. Id. at 55. The New Hampshire law directly advances health care cost reduction given record evidence showing that detailing increases prescription drug costs, that detailers' effectiveness is bound up with their use of individual prescribers' histories, and that reducing detailers' access to prescribers' data would make prescribers less responsive to detailers' efforts to market costly brand-name drugs. Id. at 55-58. Finally, Ayotte found that New Hampshire's law is no more restrictive than necessary to advance the state's interest in containing costs, though its prohibitions extend to all New Hampshire prescribers' identifying data. Id. at 58-60.

Maine's law, which was modeled in part on New Hampshire's, regulates the same kind of conduct for the same three purposes: reducing health care costs in Maine, protecting Maine patients' health, and protecting Maine patients' and prescribers' identifying data from unwanted uses in Maine. Me. Stat. Rev. Ann.

tit. 22, § 1711-E(A-1). Indeed, section 1711-E(2-A) differs from the New Hampshire law only in ways that weaken plaintiffs' First Amendment and other challenges. Unlike New Hampshire's law, the Maine law only prohibits plaintiffs from licensing, using, selling, transferring or exchanging data identifying prescribers licensed in Maine who have opted-in for confidentiality protection. See id. § 1711-E(2-A). Unlike New Hampshire's legislature, the Maine legislature included specific findings that limiting detailers' use of Maine prescribers' identifying data would reduce health care costs, ensure Maine prescribers' decisions were based on unbiased medical and scientific evidence, and protect Maine prescribers from unwanted detailing visits. Compare id. § 1711-E (1-A), with N.H. Rev. Stat. Ann. § 318:47-f. Maine also introduced evidence into the record to show how section 1711-E advances Maine's three asserted interests.

Plaintiffs concede that Ayotte forecloses their First Amendment challenge and that the district court's injunction, which was granted based on their First Amendment claims before Ayotte was decided, cannot be affirmed on those grounds. Plaintiffs nonetheless reiterate shorthand versions of the same arguments this court rejected in Ayotte: that their use, sale, and licensing of prescriber-identifying information is speech, not conduct, and that it is protected speech warranting strict scrutiny, not merely

commercial speech.<sup>13</sup> Their alternate claim, that the Maine law cannot survive intermediate scrutiny as commercial speech because Maine has not introduced any evidence that the law will actually reduce health care costs, is contradicted by Ayotte's reasoning, and the record in this case supports Ayotte's conclusion. See 550 F.3d at 55-58. There is no basis for considering these arguments anew.

We reject plaintiffs' contention that United States v. Stevens, 130 S. Ct. 1577 (2010), undermines Ayotte's holding. Stevens held that speech in the form of video depictions of animal fighting is not categorically unprotected by the First Amendment, see id. 1585-87. By contrast, Ayotte's initial holding was that the New Hampshire law primarily regulated conduct, not speech. 550 F.3d at 51-54. Ayotte did suggest that any speech regulated was of such minimal value that it likely fell outside of First Amendment protections. Id. at 51-52. That suggestion, though, was in service of Ayotte's holding that the New Hampshire statute regulated conduct, not speech, an argument not at issue in Stevens.

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<sup>13</sup> Plaintiffs' overbreadth argument, not addressed by the district court, consists of the bare assertion that the Maine law is overbroad because it prohibits the use of prescriber-identifying data when marketing all prescription drugs, not just those drugs without any obvious financial or health benefit to patients. That argument is at best an assertion that section 1711-E(2-A) is not narrowly tailored enough to serve Maine's interest in reducing health care costs. We rejected an analogous claim in Ayotte, see 550 F.3d at 59-60, and the argument has no relevance to our alternate holding in Part III.B.

Further, Ayotte's alternate holding was that the New Hampshire law would be upheld even if it regulated protected speech. Id. at 54-60.

B.

We reject plaintiffs' First Amendment challenge to the Maine law for a further reason particular to the Maine statute and independent of Ayotte. Even if the Maine law regulates protected speech, section 1711-E(2-A) directly serves Maine's substantial interest in vindicating Maine prescribers' rights to avoid unwanted targeting by detailers in Maine on the basis of their individual prescribing histories.

This purpose is not solely about protecting prescribers' expectation that their identifying data will remain categorically private. See Rowe, 532 F. Supp. 2d. at 170-72. Prescribers' also have a privacy interest in avoiding unwanted solicitations from detailers who have used their individual prescribing data to identify and target them. Maine's stated interest, in turn, is in shielding those Maine-licensed prescribers who object to this invasive use of their identifying information and who have opted in to a system of protection the state provides. Me. Rev. Stat. Ann. tit. 22, § 1711-E(1-A)(B), (1-B), (B). Like laws implementing "do not call" lists, Maine advances this interest by allowing its prescribers to join a list to stop their data from being licensed, used, sold, transferred or exchanged for this unwelcome purpose.

If section 1711-E(2-A) regulates protected speech at all, it regulates commercial speech, which the Supreme Court has defined to include "expression related solely to the economic interests of the speaker and its audience." Central Hudson, 447 U.S. at 561. This circuit and others continue to apply this definition. See Ayotte, 550 F.3d at 54; see also United States v. Philip Morris USA Inc., 566 F.3d 1095, 1143 (D.C. Cir. 2009); BellSouth Telecomms., Inc. v. Farris, 542 F.3d 499, 504 (6th Cir. 2008); Procter & Gamble Co. v. Amway Corp., 242 F.3d 539, 552 (5th Cir. 2001).

Plaintiffs' purported regulated "speech" consists of data contained in databases and reports that plaintiffs have designed to facilitate detailing. This is economically motivated content tailored to a commercial use, namely, to help pharmaceutical manufacturers better market brand-name prescription drugs to particular prescribers. Cf. Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 66-68 (1983) (suggesting that use for an advertising purpose and the speaker's economic motivations are relevant indicia of commercial speech). Plaintiffs' collections of prescriber-identifying data, if speech at all, would be commercial speech: their purpose is to "facilitate the marketing of . . . services to individual customers." U.S. W. Inc. v. FCC, 182 F.3d 1224, 1233 n.4 (10th Cir. 1999).<sup>14</sup>

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<sup>14</sup> Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749 (1985), held that a consumer credit report made available by a reporting agency to particular subscribers received less First

Under the Central Hudson framework, commercial speech is protected if it is "neither misleading nor related to unlawful activity." 447 U.S. at 564. That is not at issue here. Still, protected commercial speech can be restricted if the "asserted governmental interest is substantial," "the regulation directly advances the governmental interest asserted," and the restriction "is not more extensive than necessary to serve that interest." Id. at 566; see also Ayotte, 550 F.3d at 55.

Assuming the opt-in statute regulates protected commercial speech, Maine meets the test for restricting that speech. Maine has a substantial interest in protecting its prescribers from unwanted solicitations by detailers in Maine based on their prescribing histories. "The unwilling listener's interest in avoiding unwanted communication," the Supreme Court has held, "has been repeatedly identified in our cases," and it is "an aspect of the broader 'right to be let alone' that one of our wisest

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Amendment protection because it was "solely in the individual interest of the speaker and its specific business audience." Id. at 762. Though not explicitly labeled commercial speech, the Supreme Court nonetheless concluded that "many of the same concerns that argue in favor of reduced constitutional protection in those areas apply here as well." Id. at 762 n.8.

Applying these principles in an analogous context, the D.C. Circuit held that a blanket prohibition on an intermediary's sale of targeted marketing lists identifying particular consumers with desired characteristics was subject to lesser scrutiny. See Trans Union Corp. v. FTC, 245 F.3d 809, 818 (D.C. Cir. 2001). The reports and databases plaintiffs prepare to facilitate detailing are indistinguishable from these cases for First Amendment purposes. Still, we use the Central Hudson framework.

Justices characterized as 'the most comprehensive of rights and the right most valued by civilized men.'" Hill v. Colorado, 530 U.S. 703, 716-17 (2000) (quoting Olmstead v. United States, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting)).

Maine has a substantial interest in vindicating this right by allowing Maine-licensed prescribers to avoid being subjected to unwelcome advertisements and solicitations. The Supreme Court has recognized this interest in the context of "do not mail" lists.<sup>15</sup> See Rowan v. U.S. Post Office Dep't, 397 U.S. 728, 736-38 (1970) (holding that a federal "do not mail" list served "the very basic right to be free from sights, sounds, and tangible matter we do not want"); see also FTC v. Mainstream Mktg. Servs., Inc., 345 F.3d 850, 854-55 (10th Cir. 2003) (recognizing the government's "substantial interest" in protecting individual privacy through the federal "do not call" list). It undoubtedly extends to protecting Maine prescribers who do not want their data used to facilitate unwanted solicitations. See Trans Union Corp. v. FTC, 245 F.3d 809, 818 (D.C. Cir. 2001) (recognizing the government's "substantial interest" in "protecting the privacy of

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<sup>15</sup> Though many of these unwanted solicitations invade individuals' right to be left alone in their homes, a location accorded special protection, Hill formulated this right as one that applies more broadly, with special but not exclusive force in the home. Hill, 530 U.S. at 717.

consumer credit information" by preventing its use in targeted marketing lists).<sup>16</sup>

Section 1711-E(2-A) advances this interest directly. Both the record evidence and common sense show that "the harms [Maine] recites are real" and that the law "will in fact alleviate them to a material degree." Ayotte, 550 F.3d at 55 (quoting Edenfield v. Fane, 507 U.S. 761, 770-71 (1993)). Time and again, the record establishes, Maine prescribers have not merely complained about being subjected to detailing; they have identified detailers' use of their personal prescribing histories as a singularly objectionable practice. Maine's legislature found that many prescribers had demanded legislative action to protect their identifying data from this unwanted use. § 1711-E(1-A)(B). Section 1711-E(2-A) does not, and need not, directly or categorically prohibit detailing to address this harm. Rather, Maine provides exactly the protections that Maine prescribers have requested and allows prescribers to choose whether to invoke them.

Maine's opt-in confidentiality mechanism is also a less restrictive means of vindicating prescribers' interests in not having their information used in detailing. See Ayotte, 550 F.3d

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<sup>16</sup> This reasoning also disposes of plaintiffs' assertion that section 1711-E(2-A) is a prior restraint on their speech because it allows prescribers to prevent plaintiffs from transferring or using their data. That argument rests on the mistaken assumption that plaintiffs have an absolute right to obtain prescriber-identifying data and to use it to facilitate unwelcome detailing practices.

at 59. Targeted prohibitions are by definition less restrictive than a categorical ban. See United States v. Playboy Entm't. Group, Inc., 529 U.S. 803, 815 (2000); see also Mainstream Mktg. Servs., Inc. v. FTC, 358 F.3d 1228, 1242-43 (10th Cir. 2004). Opt-in mechanisms like the "do not call" list are narrowly tailored by nature: they "restrict only calls that are targeted at unwilling recipients." Mainstream Mktg. Servs., 358 F.3d at 1242; see also Fraternal Ord. of Police v. Stenehjem, 431 F.3d 591, 599 (8th Cir. 2005); Nat'l Fed'n of the Blind v. FTC, 420 F.3d 331, 342 (4th Cir. 2005); Bland v. Fessler, 88 F.3d 729, 733 (9th Cir. 1996). Opt-in mechanisms also avoid concerns about state paternalism in the First Amendment context. They regulate speech (if speech at all) only when private individuals choose not to be subject to certain kinds of communications, not simply because the state has identified particular communications as harmful. Bland, 88 F.3d at 733.

Plaintiffs cursorily assert that Maine could have regulated detailers' free samples to prescribers, educated doctors, or implemented formulary controls as alternatives to section 1711-E(2-A). Ayotte rejected these alternatives as ineffective ways to advance a state's interest in health care costs. 550 F.3d at 59-60. These alternatives do virtually nothing to advance Maine's interest in protecting opted-in Maine prescribers' identifying data

from use in detailing.<sup>17</sup> Our analysis also disposes of plaintiffs' assertion that section 1711-E violates the Fourteenth Amendment as an economic constraint unrelated to legitimate state interests.

#### IV. Vagueness

Plaintiffs also argue that section 1711-E(2-A)'s prohibition on the use, transfer, licensing, sale, or exchange of opted-in prescriber-identifying data "for any marketing purpose" is unconstitutionally vague. Plaintiffs' brief claims that they "simply sell the information" to pharmaceutical manufacturers, and they have no intent to market or advertise pharmaceutical products to prescribers themselves. Plaintiffs assert that the law is unconstitutionally vague because they cannot know whether "any marketing purpose" refers to their motivation in selling or licensing the information or to pharmaceutical manufacturers' ultimate purpose in obtaining the data.

Even if there were possible ambiguity in section 1711-E(2-A)'s terms, the law is still not void for vagueness. Statutory ambiguity is a regular byproduct of legislative drafting, but the

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<sup>17</sup> Plaintiffs also introduced evidence on an AMA initiative that allows medical doctors to signal that they do not want their prescribing data used in detailing. But the AMA has no real power to limit plaintiffs' and other intermediaries' use of this data; compliance is monitored only through complaints to the AMA, and enforcement depends on plaintiffs and other intermediaries' goodwill prevailing over the strong financial incentives to use this data. Moreover, the AMA scheme does not cover a host of prescribers like nurse practitioners or osteopathic physicians, who might want to protect their prescribing data but are ineligible for the AMA scheme.

vagueness doctrine invalidates only statutes whose terms are "so uncertain that persons of average intelligence would have no choice but to guess at [their] meaning and modes of application." United States v. Nieves-Castaño, 480 F.3d 597, 603 (1st Cir. 2007) (quoting United States v. Councilman, 418 F.3d 67, 84 (1st Cir. 2005) (en banc)) (internal quotation marks omitted); see also Ridley v. Mass. Bay Transp. Auth., 390 F.3d 65, 93 (1st Cir. 2004). Whatever ambiguity lurks in the phrase "any marketing purpose," the law's lengthy definition of the term "marketing," see supra note 6, surely provides enough of a benchmark to satisfy due process.

Further, this purported ambiguity does not exist on the facts: plaintiffs, at minimum, intend for their databases and reports to facilitate detailing. Plaintiffs portray themselves as unwitting middlemen that sell prescriber-identifying information to their clients with no knowledge or control of its ultimate use. Plaintiffs' depositions and statements at oral argument reveal instead that they are well aware that the primary and intended use of their reports and databases is in detailing.

#### V. Dormant Commerce Clause

Plaintiffs' final constitutional challenge is that section 1711-E(2-A), "as it is applied to the transactions in which they engage out of the state and are shown by the record evidence,"

violates the dormant Commerce Clause.<sup>18</sup> Because plaintiffs obtained an injunction before section 1711-E(2-A) went into effect, however, the state has not promulgated regulations under this section, there is no state decisional law, and the law has never been applied.<sup>19</sup>

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<sup>18</sup> The Commerce Clause, which gives Congress the authority to "regulate Commerce . . . among the several States," U.S. Const. art I, § 8, cl. 3, also carries negative or implicit consequences for states' authority to regulate interstate commerce, referred to as the "dormant Commerce Clause." There is no claim that Congress has acted and that Maine's statute must fail on that basis.

<sup>19</sup> In recent years, the Supreme Court has sharply distinguished between facial and as-applied challenges, stringently limiting the availability of the former. See, e.g., Wash. State Grange v. Wash. State Republican Party, 552 U.S. 442, 450-51 (2008); see also G.E. Metzger, Facial Challenges and Federalism, 105 Colum. L. Rev. 873, 878-80 (2005) (questioning whether the Supreme Court follows this doctrinal position in practice).

We did not address this distinction in Ayotte: plaintiffs' dormant Commerce Clause challenge to the New Hampshire statute there was plainly identified as a facial challenge. See Ayotte, 550 F.3d at 63.

Here, plaintiffs say they are not making any facial challenge. There is some question as to whether plaintiffs' pre-enforcement challenge can be properly characterized as an as-applied challenge. Plaintiffs have introduced record evidence showing that their use or sale of opted-in Maine prescribers' identifying data occurs outside Maine and that they are "prescription drug information intermediaries" and thus potentially subject to regulation under section 1711-E(2-A). But plaintiffs argue that the law applies to their transactions only based on their statutory construction.

We accept plaintiffs' characterization of their argument as a challenge only to section 1711-E(2-A) as it applies to plaintiffs, as prescription drug information intermediaries, and not as to pharmacies and other entities. See Milavetz, Gallop & Milavetz, P.A. v. United States, 130 S. Ct. 1324, 1339 & n.7 (2010). We also assume arguendo that plaintiffs' challenge is not subject to the restrictions on facial challenges. But we cannot accept plaintiffs' assertion that section 1711-E(2-A) applies to their out-of-state transactions without engaging in our own statutory analysis. Here, the issue is not whether plaintiffs belong to a class of entities that section 1711-E(2-A) plainly regulates extraterritorially; it is how to interpret section 1711-E(2-A)'s

Plaintiffs assert that they are "prescription drug information intermediaries" as defined in section 1711-E, and Maine does not dispute this. Cf. Milavetz, Gallop & Milavetz, P.A. v. United States, 130 S. Ct. 1324, 1339 & n.7 (2010).

Plaintiffs' challenge presents questions of whether section 1711-E(2-A) would be interpreted under Maine law to apply to plaintiffs' out-of-state use or sale of opted-in Maine prescribers' identifying data, including whether the rule of constitutional avoidance requires the statute to be interpreted not to apply to plaintiffs' out-of-state transactions.<sup>20</sup> As a matter of law, we hold that the statute applies to plaintiffs' out-of-state use or sale of opted-in Maine prescribers' identifying data and that the statute does so constitutionally. We also reject plaintiffs' claim at oral argument that we should leave the district court's injunction in place and remand this claim for further proceedings.

Plaintiffs interpret section 1711-E(2-A) to apply to their out-of-state transactions based on their construction of its text. They claim that the regulation violates the so-called "extraterritoriality" branch of the dormant Commerce Clause, which

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intended scope. Cf. id. at 1339.

<sup>20</sup> We do not decide whether section 1711-E(2-A) applies to pharmacies' or pharmaceutical manufacturers' out-of-state transactions involving opted-in Maine prescribers. There is no indication that these entities cannot effectively assert their own rights insofar as they are affected by section 1711-E(2-A).

they say prohibits direct regulation of interstate commerce that occurs wholly outside a state's borders. In the alternative, plaintiffs assert, this regulation violates the Pike balancing test "because it does nothing to advance in-state interests and imposes a heavy burden on interstate activity."

We reject plaintiffs' arguments. We interpret section 1711-E(2-A)'s scope by applying the rules of statutory construction that the state's highest court would follow. Ayotte, 550 F.3d at 61; see also Adar v. Smith, 597 F.3d 697, 714 (5th Cir. 2010). We hold, based on the text and legislative backdrop of section 1711-E(2-A) and Maine's canons of statutory construction, that section 1711-E(2-A) regulates plaintiffs' out-of-state use or sale of opted-in Maine prescribers' identifying data.

We further hold that this interpretation of the statute does not raise constitutional concerns under the dormant Commerce Clause. The Supreme Court's current dormant Commerce Clause jurisprudence is concerned with preventing economic protectionism and inconsistent regulation, not with enforcing geographical limits on states' exercise of their police power that necessarily regulate commerce. Even under the extraterritoriality branch of the dormant Commerce Clause, the Supreme Court has not barred states from regulating any commercial transactions beyond their borders that involve their own citizens and create in-state harms. Nor does the Maine law create constitutional concerns under the Pike balancing

test. Plaintiffs have not shown any disproportionate burden on interstate commerce, and the law creates substantial in-state benefits for those Maine prescribers who have affirmatively asked Maine to protect their identifying data and for Maine in its efforts to lower health care costs.

A. Section 1711-E(2-A)'s Text and Setting

The text of the statute shows section 1711-E(2-A) was intended to apply to plaintiffs' out-of-state use or sale of opted-in Maine prescribers' identifying data. The statutory text shows that section 1711-E(2-A) was designed to address a significant problem occurring in Maine, whose solution has some cross-border implications. The law is concerned only with "prescribers in the health care system of [Maine]," Me. Rev. Stat. Ann. tit. 22, § 1711-E(1-B), not prescribers anywhere in the United States, and specifically those prescribers who have opted in to Maine's "mechanism for protecting the confidentiality of identifying prescription drug information from use for marketing purposes," id. § 1711-E(1-A)(B). The statute further recognizes that these marketing uses occur "[a]cross the nation" when "data companies purchase for marketing purposes computerized prescription drug records from pharmacies and insurers that identify prescribers." Id. § 1711-E(1-A)(C). The statutory text also identifies specific harms arising from these transactions--invasions of prescribers'

privacy, increased health care costs, and harms to public health-- as occurring in Maine. See § 1711-E(1-B).

Section 1711-E(2-A)'s context confirms that the Maine Legislature intended to reach plaintiffs' out-of-state conduct because of its substantial connections to Maine and because it causes harms exclusively in Maine. Section 1711-E(2-A) targets a series of underlying transactions that cause these harms, which start and end in Maine, even if all the transactions covered in order to effectuate the statute's purposes do not occur in Maine. Maine prescribers' prescriptions are primarily, if not exclusively, filled at Maine pharmacies. Data from those Maine pharmacies are ultimately transferred to prescription drug information intermediaries like plaintiffs through contractual arrangements. Plaintiffs' subsequent use and sale of Maine prescribers' identifying data to generate detailing-oriented databases and reports may occur outside Maine, but those activities are bound up with pharmaceutical manufacturers' ultimate use of the information in detailing that targets Maine prescribers in Maine.

The law also takes effect only if Maine prescribers affirmatively indicate that they want Maine to protect the confidentiality of their identifying information. See id. § 1711-E(1)(G-1), (2-A), (4). Every intermediate step is limited to transactions involving these prescribers' identifying data. See id. § 1711-E(2-A). The law's ultimate effect is to prevent

detailers with Maine routes from targeting Maine prescribers with their own prescribing histories. Id. § 1711-E(1-A), (1-B).

B. Presumption against Extraterritoriality

Our interpretation of section 1711-E(2-A) also comports with Maine's canons of statutory construction. Maine, like other states, generally presumes its statutes do not apply extraterritorially in the absence of contrary indications of legislative intent. See Holbrook v. Libby, 94 A. 482, 483 (Me. 1915); see also 73 Am. Jur. 2d Statutes § 250 (2010). That presumption is overcome here: the Maine Legislature plainly intended section 1711-E(2-A) to regulate plaintiffs' out-of-state use or sale of opted-in Maine prescribers' identifying data.<sup>21</sup>

Maine's presumption against extraterritoriality reflects inherent limitations on the scope of states' sovereign regulatory powers. See Stavis Ipswich Clam Co. v. Green, 236 A.2d 708, 712 (Me. 1968). This presumption is not a per se rule because those state powers are not mechanically limited to conduct occurring within a state's physical borders. As one learned commentator has noted, "[i]n practice, states exert regulatory control over each other all the time . . . . [A] state's geographic territory does not mark the outer limit of its legitimate regulatory concern."

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<sup>21</sup> In Ayotte, this court held that the presumption against construing New Hampshire's statute to apply extraterritorially had not been overcome, not least because the New Hampshire Attorney General insisted that New Hampshire only sought to regulate conduct within its borders. 550 F.3d at 63-64.

G.E. Metzger, Congress, Article IV, and Interstate Relations, 120 Harv. L. Rev. 1468, 1521-22 (2007). Indeed, an entire body of conflict of laws cases apply state laws to extraterritorial conduct. See K. Florey, State Courts, State Territory, State Power: Reflections on the Extraterritoriality Principle in Choice of Law and Legislation, 84 Notre Dame L. Rev. 1057, 1073-74 (2009).

Maine, like other states, has construed its laws to apply to extraterritorial conduct with a substantial impact in or connection to Maine's residents or licensees. See, e.g., State v. Hayes, 603 A.2d 869, 870 (Me. 1992) (upholding the extraterritorial enforcement of Maine's lobster laws to vessels registered in Maine); Dissell v. Trans World Airlines, 511 A.2d 441, 444-45 (Me. 1986) (applying Maine's worker's compensation statute to require an out-of-state airline to further compensate a flight attendant stationed and injured out of state but residing in Maine because of sufficient contacts with Maine).<sup>22</sup> Section 1711-E(2-A)'s application to plaintiffs is within Maine's sovereign authority.

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<sup>22</sup> Other states have similarly recognized that "a state may have the power to legislate concerning the rights and obligations of its citizens with regard to transactions occurring beyond its boundaries." N. Alaska Salmon Co. v. Pillsbury, 162 P. 93 (Cal. 1916); see also Sexton v. Ryder Truck Rental, Inc., 320 N.W.2d 843, 854 (Mich. 1982); 73 Am. Jur. 2d Statutes § 250 (2010). Numerous types of state statutes have extraterritorial effect. See, e.g., State v. Flores, 188 P.3d 706, 710 (Ariz. Ct. App. 2008) (criminal laws); Boca Petroco, Inc. v. Petroleum Realty II, LLC, 678 S.E.2d 330, 333-34 (Ga. 2009) (lis pendens statutes); Heath Consultants, Inc. v. Precision Instruments, Inc., 527 N.W.2d 596, 607 (Neb. 1995) (antitrust law).

C. Constitutional Avoidance and the Dormant Commerce Clause

Finally, we reject the argument that section 1711-E(2-A)'s application to prescription drug information intermediaries' out-of-state use or sale of opted-in Maine prescribers' identifying data would raise constitutional concerns under the dormant Commerce Clause.<sup>23</sup> Under Maine and federal law, we must "avoid an unconstitutional construction of a statute if a reasonable interpretation of the statute would satisfy constitutional requirements." Anderson v. Town of Durham, 895 A.2d 944, 951 (Me. 2006) (quoting Bagley v. Raymond Sch. Dep't, 728 A.2d 127, 133 (Me. 1999)) (internal quotation marks omitted). There is no need for constitutional avoidance here.

We begin with the Supreme Court's current dormant Commerce Clause jurisprudence, which provides no foundation for plaintiffs' contention that Maine's regulation of their out-of-state use or sale of opted-in Maine prescribers' data would raise constitutional concerns. The dormant Commerce Clause sets two complementary boundaries for states' regulatory powers over

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<sup>23</sup> The Maine Attorney General has argued that the law regulates persons or entities over whom Maine can exercise personal jurisdiction. That interpretation states a limitation on any extraterritorial application of a statute: it must comport with the requirements of the Due Process and Full Faith and Credit Clauses. Allstate Ins. Co. v. Hague, 449 U.S. 302, 308 (1981). Plaintiffs have not argued that section 1711-E(2-A)'s application to their out-of-state transactions would violate those provisions. But that does not by definition alleviate constitutional concerns under the dormant Commerce Clause, which serves different purposes. Quill Corp. v. North Dakota, 504 U.S. 298, 312-13 (1992).

commerce. On one hand, states cannot interfere with Congress's constitutional authority over interstate commerce by enacting laws that seriously impede interstate commerce, even when Congress has not acted. See Dep't of Revenue v. Davis, 553 U.S. 328, 337-38 (2008).<sup>24</sup> On the other hand, states "retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." Maine v. Taylor, 477 U.S. 131, 138 (1986) (quoting Lewis v. BT Inv. Managers, Inc., 447 U.S. 27, 36 (1980)) (internal quotation marks omitted). Further, in fields traditionally subject to state regulation, federal courts "should be particularly hesitant to interfere with [states'] efforts under the guise of the Commerce Clause." United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 344 (2007) (alterations in original).

As to the first of these boundaries, "the dormant Commerce Clause is driven by concern about 'economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.'" Davis, 553 U.S. at 337-38 (quoting New Energy Co. of Ind. v. Limbach, 486 U.S. 269,

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<sup>24</sup> This limitation on states' powers is grounded in the historical origins of the Commerce Clause, which gives Congress the power to "regulate Commerce . . . among the several States." U.S. Const. Art I, § 8, cl. 3. The Framers saw this as an essential element of the Constitution to avoid the "economic Balkanization" that had prevailed under the Articles of Confederation, under which states had enacted rampant tariffs and other trade barriers at the price of national economic unity. See Davis, 553 U.S. at 337-38; Granholm v. Heald, 544 U.S. 460, 472 (2005).

273) (1988)). Similar concerns about hidden protectionism and excessive barriers to interstate trade arise when states enact laws likely to subject entities engaged in interstate commerce to incompatible cross-state regulatory regimes, see CTS Corp. v. Dynamics Corp. of Am., 481 U.S. 69, 88-89 (1987); S. Pac. Co. v. Ariz. ex rel. Sullivan, 325 U.S. 761, 767-68 (1945), or laws with minimal in-state benefits and a disproportionate impact on interstate commerce, see Pike, 397 U.S. at 142.

These concerns are central to the way the Supreme Court has framed the dormant Commerce Clause in its recent opinions. The Maine law implicates none of them. Maine's regulation of prescription drug information intermediaries' out-of-state use or sale of opted-in Maine prescribers' data does not discriminate against out-of-state entities in favor of in-state competitors, nor do plaintiffs so argue. Maine's law does not risk imposing regulatory obligations inconsistent with those of other states. No other states have erected competing regulations, much less opposing regulations requiring the transfer of Maine prescribers' data.<sup>25</sup> This is simply not an example of a state engaged in economic protectionism. Cf. Davis, 553 U.S. at 337-39.<sup>26</sup>

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<sup>25</sup> Though New Hampshire and Vermont's laws differ somewhat from Maine's, neither purports to regulate any prescriber anywhere.

<sup>26</sup> Nor, as we discuss below, would this interpretation of section 1711-E(2-A) result in excessive burdens on interstate commerce relative to in-state benefits.

Maine's interests, on the other hand, are precisely the kind of traditional state concerns that the Supreme Court has identified as falling outside the reach of the dormant Commerce Clause. See Davis, 553 U.S. at 342; United Haulers, 550 U.S. at 344-45. States are "vested with the responsibility of protecting the health, safety, and welfare of [their] citizens." United Haulers, 550 U.S. at 342. To serve those interests, states exercise the kind of local autonomy essential to federalism. "The essence of our federal system is that within the realm of authority left open to them under the Constitution, the States must be equally free to engage in any activity that their citizens choose for the common weal." Davis, 553 U.S. at 338 (quoting Garcia v. San Antonio Metro. Transit Auth., 469 U.S. 528, 546 (1985)) (internal quotation marks omitted).

Maine has a uniquely strong interest in protecting Maine prescribers who have invoked Maine's regulatory authority through the opt-in scheme. Cf. CTS, 481 U.S. at 89. Maine has done so because these commercial transactions also harm the public health and increase Maine's health care costs. In advancing these interests, Maine has regulated in a traditional area of state concern without undercutting other states' regulatory schemes or encroaching on their interests. Maine's choice must be respected.

The Maine statute falls outside the central concerns of the Court's dormant Commerce Clause jurisprudence for another

reason. Maine has not shifted the costs of regulation to other states whose voters cannot affect its legislative choices, nor does the Maine law "hand local businesses a victory they could not obtain through the political process." United Haulers, 550 U.S. at 345. Maine's political processes produced this statute, and Maine voters can, if they disagree, reverse this policy.

Plaintiffs ignore these foundational principles; indeed, plaintiffs ignore virtually every Supreme Court dormant Commerce Clause case after 1989. Instead, plaintiffs say section 1711-E(2-A)'s application to their conduct would violate an infrequently applied strand of the dormant Commerce Clause loosely labeled extraterritoriality.<sup>27</sup> Its central premise is that "a statute that directly controls commerce occurring wholly outside the boundaries of a State exceeds the inherent limits of the enacting State's authority and is invalid regardless of whether the statute's extraterritorial reach was intended by the legislature." Healy v. Beer Inst., Inc., 491 U.S. 324, 336 (1989) (emphasis added); see

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<sup>27</sup> Extraterritoriality has been the dormant branch of the dormant Commerce Clause. Despite a host of subsequent dormant Commerce Clause cases, see, e.g., Davis, 553 U.S. 328; United Haulers, 550 U.S. 330; Am. Trucking Ass'ns, Inc. v. Mich. Pub. Serv. Comm'n, 545 U.S. 429 (2005); Granholm, 544 U.S. 460, the Supreme Court last mentioned the doctrine in a paragraph of a 2003 decision to reject its applicability. The Court pointedly referred to it as "[t]he rule that was applied in Baldwin and Healy," cases decided in 1935 and 1989. Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 669 (2003) (citing Healy, 491 U.S. 324; Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935)). We nonetheless assume this doctrine remains viable. See State Oil Co. v. Khan, 522 U.S. 3, 20 (1997). Even so, plaintiffs' challenge fails.

also Alliance of Auto Mfrs. v. Gwadowsky, 430 F.3d 30, 35 (1st Cir. 2005). Plaintiffs further suggest that this doctrine applies not to the Maine law as applied to prescription drug information intermediaries but to their atomized transactions only. Plaintiffs make no attempt to square these principles with the Court's current dormant Commerce Clause jurisprudence or to explain how these principles fit with its central concerns. In any event, this doctrine is inapplicable.

Whatever the present scope of the extraterritoriality doctrine, it clearly does not require per se invalidation of all extraterritorial applications contained within state statutes regulating commerce.<sup>28</sup> Section 1711-E(2-A) does not regulate wholly extraterritorial commercial transactions. Its regulation of plaintiffs' use or sale of opted-in Maine prescribers' data affects only Maine prescribers and regulates transactions that impact Maine, with incidental effects elsewhere. It is instead one of "an infinite variety of cases in which regulation of local matters may

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<sup>28</sup> Some circuits have simply framed the doctrine in terms of concerns with preventing economic protectionism or inconsistent regulatory regimes, see, e.g., Cloverland-Green Spring Dairies, Inc. v. Penn. Milk Mktg. Bd., 462 F.3d 249, 262-63 (3d Cir. 2006); Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 81-83 (1st Cir. 2001), aff'd sub nom. Pharm. Research & Mfrs. of Am., 538 U.S. 644, or have suggested that the Court's cases do not dictate "the notion that direct and facial regulation of extraterritorial transactions is absolutely banned," Alliant Energy Corp. v. Bie, 336 F. 3d 545, 547-50 (7th Cir. 2003); see also J. Goldsmith & A. Sykes, The Internet and the Dormant Commerce Clause, 110 Yale L.J. 785, 789-90 & n.26 (2001).

also operate as a regulation of commerce," requiring "appraisal and accommodation of the competing demands of the state and national interests involved." S. Pac. Co., 325 U.S. at 768-69.<sup>29</sup>

The Supreme Court has applied the so-called extraterritoriality doctrine sparingly, and in ways that only reinforce the conclusion that Maine can regulate plaintiffs' out-of-state use and sale of Maine prescribers' identifying data. The Court has only struck down two related types of statutes on extraterritoriality grounds. The first are price-affirmation statutes that force regulated entities to certify that the in-state price they charge for a good is no higher than the price they

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<sup>29</sup> Limitations on states' regulation of extraterritorial commerce have been justified because "one State's power to impose burdens on the interstate market . . . is also constrained by the need to respect the interests of other States." BMW of N. Am. v. Gore, 517 U.S. 559, 571 (1996) (internal citation omitted); see also Healy, 491 U.S. at 336-37.

That has never meant that states are powerless to regulate all transactions beyond their borders, including transactions involving their citizens. States' interests may justify extraterritorial regulation in contexts ranging from taxation under the dormant Commerce Clause, see, e.g., MeadWestvaco Corp. ex rel. Mead Corp. v. Ill. Dep't of Revenue, 553 U.S. 16, 24-25 (2008), to the enforcement of criminal and tort law, see, e.g., Young v. Masci, 289 U.S. 253, 259 (1933); Strassheim v. Daily, 221 U.S. 280, 285 (1911) (Holmes, J.); see also Bigelow v. Virginia, 421 U.S. 809, 834-35 & 834 n.2 (1975) (Rehnquist, J., dissenting).

The Edgar v. MITE plurality reasoned that "[t]he limits on a State's power to enact substantive legislation are similar to the limits on the jurisdiction of state courts." 457 U.S. at 643 (plurality opinion). But the expansion of personal jurisdiction beyond the rigid geographical rules of Pennoyer v. Neff, 95 U.S. 714 (1877), to the nexus-oriented approach of International Shoe Co. v. Washington, 326 U.S. 310 (1945), only reinforces the fact that states' jurisdiction--whether legislative or adjudicatory--is not categorically limited to their territory in any context.

charge out of state. See Healy, 491 U.S. at 337-40; Brown-Forman, 476 U.S. at 582-84; Baldwin, 294 U.S. at 521-22. The second are statutes that "force an out-of-state merchant to seek regulatory approval in one State before undertaking a transaction in another." Healy, 491 U.S. at 337; see also Edgar v. MITE Corp., 457 U.S. at 627, 642-43 (plurality opinion). Even these statutes are not invariably struck down. See CTS, 481 U.S. at 88-89 (upholding a statute regulating takeovers of corporations with a strong in-state nexus by limiting the acquisition of control shares).

The Maine law is easily distinguishable from the invalidated statutes. Those state statutes--unlike section 1711-E(2-A)--raised independent concerns about protectionism under established strands of the dormant Commerce Clause.<sup>30</sup> Moreover, unlike the Maine law, none of the invalidated statutes dealt with harms caused exclusively inside the regulating state. Nor were the invalidated statutes limited to regulating transactions with a significant inherent connection to the regulating state, and involving its own professional licensees. Those differences, and

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<sup>30</sup> The challenged price-affirmation laws were also deemed unconstitutional because they discriminated against out-of-state entities in favor of in-state competitors, see Healy, 491 U.S. at 340-41; Baldwin, 294 U.S. at 522, or because of their protectionist effects for consumers, Brown-Forman, 476 U.S. at 580. Likewise, only a plurality in Edgar v. MITE would have invalidated on extraterritoriality grounds the challenged Illinois law, which required companies to obtain regulatory approval for takeover bids of corporations with no real relation to Illinois. See 451 U.S. at 641 (plurality opinion). The majority only invalidated the law as an excessive burden on interstate commerce under Pike. Id. at 644.

not the mere fact that those statutes directly regulated out-of-state transactions, explain why the Supreme Court deemed those statutes wholly extraterritorial.<sup>31</sup>

Plaintiffs' attempt to analogize the Maine law to these cases fails. The Supreme Court has previously distinguished and upheld a state statute that regulated out-of-state commercial transactions with a clear in-state nexus and impact. See CTS, 481 U.S. at 93.<sup>32</sup> Other circuits have upheld similar laws on this

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<sup>31</sup> Baldwin involved a New York price affirmation statute that required out-of-state milk buyers to certify that they paid out-of-state milk producers no more than what New York producers received. See 294 U.S. at 519. The Court deemed the law an impermissible attempt to project New York's pricing regime on other states because it had no "direct and certain" relationship to New York's asserted interest in ensuring a supply of sanitary milk, id. at 524, and the asserted purpose of protecting local farmers' economic welfare was impermissibly protectionist, id. at 523.

In Edgar v. MITE, the plurality found the Illinois corporate takeover bid law had a "sweeping extraterritorial effect" because it would "regulate a tender offer which would not affect a single Illinois shareholder" and thus reached conduct in which Illinois had no conceivable interest. 457 U.S. at 642 (plurality opinion).

Likewise, the price affirmation statutes in Healy and Brown-Forman were not limited to transactions involving the regulating state; they made in-state prices that out-of-state shippers charged for alcohol contingent on the price those shippers charged elsewhere. See Healy, 491 U.S. at 326-27; Brown-Forman, 476 U.S. at 576. The only in-state interest served by such laws, the Court suggested, was to illegitimately protect local interests. See Healy, 491 U.S. at 340-41; Brown-Forman, 476 U.S. at 580.

<sup>32</sup> In CTS, the Supreme Court rejected an extraterritoriality challenge to an Indiana statute limiting out-of-state tender offerors' acquisition of control shares in certain corporations. The Court reasoned that the law was limited "only to corporations incorporated in Indiana" with substantial numbers of shareholders in Indiana, and therefore "every application of the Indiana Act will affect a substantial number of Indiana residents, whom Indiana indisputably has an interest in protecting." 481 U.S. at 93.

basis. See, e.g., Quik Payday, Inc. v. Stork, 549 F.3d 1302, 1308-09 (10th Cir. 2008); S. Union Co. v. Mo. Pub. Serv. Comm'n, 289 F.3d 503, 507-08 (8th Cir. 2002); Baltimore Gas & Elec. Co. v. Heintz, 760 F.2d 1408, 1421-27 (4th Cir. 1985); cf. Am. Booksellers Found. v. Dean, 342 F.3d 96, 103-04 (2d Cir. 2003). That reasoning, not the broad rule plaintiffs try to derive from Healy and its antecedents, governs here.<sup>33</sup> Under these circumstances, we hold that section 1711-E(2-A)'s regulation of plaintiffs' conduct does not raise constitutional concerns under the extraterritoriality branch of the dormant Commerce Clause.

Finally, we reject plaintiffs' alternate contention that section 1711-E(2-A) would raise constitutional concerns under Pike if applied to plaintiffs' out-of-state transactions.<sup>34</sup> Plaintiffs

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<sup>33</sup> This holding does not put our circuit at odds with a recent panel opinion of the Seventh Circuit. Midwest Title Loans, Inc. v. Mills invalidated on extraterritoriality grounds a provision of an Indiana statute that forbade lenders that solicited or advertised their lending services in Indiana from making title loans to Indiana residents, unless they obtained a license from Indiana (and thereby agreed to be bound by Indiana's restrictions on the kind of loans permitted). See 593 F.3d 660, 662, 669 (7th Cir. 2010). Midwest Title reasoned that states should not be allowed to control interstate commerce to prevent their citizens from engaging in out-of-state conduct that the regulating state (but not the citizens themselves) deems harmful. See id. at 663-65, 666, 669.

The Maine law does not raise similar concerns. It regulates only data from those Maine prescribers who have asked Maine to protect their data. It does not force other states to apply the regulating state's paternalistic regulatory choices even when its residents want to engage in prohibited conduct elsewhere.

<sup>34</sup> We need not decide whether the Pike balancing test requires courts to look to the relative benefits and burdens of the

did not make this argument to the district court; their brief on appeal cursorily asserts that the law has no in-state benefits and only out-of-state costs. That is waiver. See Mass. Museum of Contemporary Art Found. v. Büchel, 593 F.3d 38, 65 (1st Cir. 2010).

This claim is also meritless. "State laws frequently survive this Pike scrutiny," Davis, 553 U.S. at 339, and section 1711-E(2-A) is no exception. To date, 259 Maine prescribers out of Maine's 7,500 total prescribers have opted in to Maine's confidentiality protections. Section 1711-E(2-A)'s regulation of plaintiffs' transactions would confer clear in-state benefits by enabling those prescribers to avoid unwanted targeting in Maine.

Nothing suggests that the costs to interstate commerce would be disproportionate in relation to these benefits. The loss of several hundred data points in Maine, out of some 7,500 total Maine prescribers and 1.5 million prescribers nationwide, is unlikely to seriously impact the marketability of plaintiffs' products. Nor have plaintiffs shown that the costs of complying with section 1711-E(2-A)'s protections meaningfully burden interstate commerce. There is no obvious reason why cross-

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statute as a whole or only to its effect on prescription drug information intermediaries. Plaintiffs have provided no data about range of prescription drug information intermediaries subject to section 1711-E(2-A) or the relative proportion of overall business transacted in Maine versus outside it. Plaintiffs' Pike challenge arguably fails on that basis alone; the Pike balancing test is about burdens on the interstate market as a whole, not about burdens on particular firms. Even looking only to the law's impact on plaintiffs' out-of-state transactions, the argument fails.

referencing the Maine Health Data Organization's list of opted-in Maine prescribers to avoid using or selling this data would prove particularly costly or difficult, let alone enough to warrant invalidation of a state law. We also heed the cautionary note the Court sounded in Davis: federal courts have less institutional competence than states in measuring the costs and benefits of particular state regulatory schemes. See 553 U.S. at 355-57.

VI.

The judgment of the district court is reversed, and the case is remanded with instructions to dismiss the case with prejudice. Costs are awarded to the defendant.

**-Concurring Opinion Follows-**

**LIPEZ, Circuit Judge**, concurring in the judgment. The Maine statute at issue here, like the New Hampshire law we considered in IMS Health Inc. v. Ayotte, 550 F.3d 42 (1st Cir. 2008), is a creative effort to meet escalating concerns about the high cost of prescription drugs and the way they are marketed. Other states have passed or considered similar legislation. See, e.g., IMS Health Inc. v. Sorrell, 631 F. Supp. 2d 434, 446 (D. Vt. 2009) (addressing a Vermont statute);<sup>35</sup> IMS Health Corp. v. Rowe, 532 F. Supp. 2d 153, 180 n.41 (D. Me. 2008) (noting initiatives in other states); Michael Heesters, Comment, An Assault on the Business of Pharmaceutical Data Mining, 11 U. Pa. J. Bus. L. 789, 791 (2009) (same). The two statutes that we have reviewed, along with Vermont's, are aimed at restricting the messages that may be presented by pharmaceutical detailers to prescribers. Because these provisions have the purpose and effect of regulating the content of speech, their compatibility with the First Amendment is a challenging issue that inevitably will be considered by the Supreme Court.

The statutes specifically seek to prevent pharmaceutical detailers from using the prescribing histories of individual health care professionals in their marketing approach to prescribers. In the view of the States, these individualized sales pitches result

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<sup>35</sup> The decision in Sorrell has been appealed to the Second Circuit, and oral argument in the case (No. 09-1913) was heard on October 13, 2009.

in the over-prescription of high-priced, brand-name drugs, thereby needlessly increasing public expenditures on prescription drugs and, at times, harming patient health.<sup>36</sup> In an effort to minimize the First Amendment implications of their content-based goal, Maine and New Hampshire attempted to cut off access to the prescribing information at its source. Hence, the statutes prohibit the sale, transfer or other dissemination of prescriber-identifiable information among pharmacies and other data-collecting entities for marketing purposes, but impose no direct limitation on the drug companies or sales people who do the actual marketing.<sup>37</sup> The States insist that the laws thus regulate conduct, not protected speech.

As I explained in Ayotte, it begs reality to characterize these laws as regulations of conduct. Maine's statute, like New Hampshire's, must be judged for what it is - a

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<sup>36</sup> Each statute operates slightly differently. The New Hampshire law imposes an outright prohibition on the sale or use of prescriber-identifiable data for marketing purposes. N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006). Maine's statute imposes such a prohibition only for prescribers who choose to prevent their prescribing information from being used to market prescription drugs to them - the so-called "opt-out" approach. Me. Rev. Stat. Ann. tit. 22, § 1711-E(2-A). Vermont's law has an "opt-in" feature, prohibiting certain entities from selling or using prescriber-identifiable data for marketing or promoting prescription drugs unless the prescriber consents. Vt. Stat. Ann. tit. 18, § 4631.

<sup>37</sup> The Vermont statute limits the exchange of prescriber-identifiable information among the same entities as the New Hampshire and Maine provisions, but it also bars pharmaceutical manufacturers and marketers from using the information for marketing or promoting a prescription drug unless the prescriber consents. See Vt. Stat. Ann. tit. 18, § 4631(d).

restriction on protected speech subject to the demands of the First Amendment. That view has been validated by the Supreme Court's recent decision in United States v. Stevens, 130 S. Ct. 1577 (2010). See infra Section II. However, as construed by the State, Maine's law also has a substantial ripple effect beyond Maine's borders that requires review under the dormant Commerce Clause. By shifting the statute's focus away from the activity considered harmful - the detailers' interactions with prescribers in Maine - to the earlier sales of the data, the Legislature in practical effect targeted transactions that occur primarily outside the State.

I agree with the majority that this out-of-state reach is not fatal. I write separately, however, to highlight the unusual relationship between the First Amendment and Commerce Clause issues. Indeed, after examining the law's impact on interstate commerce, I conclude that the First Amendment is the appropriate battleground for constitutional analysis as these cases move through the courts.

### **I. The First Amendment-Commerce Clause Dance**

As a reflection of the analytic difficulties posed by New Hampshire's and Maine's laws on the use, sale and other dissemination of prescriber-identifiable data, their provisions are baffling even to their proponents. New Hampshire's Attorney General asserted in Ayotte that the law should be construed to

govern only in-state transactions, see 550 F.3d at 63-64, an interpretation that renders the statute largely irrelevant because the transfers of data the statute purports to restrict occur almost entirely out-of-state. Maine, by contrast, concedes that its similarly worded provision reaches out-of-state activity. At oral argument, however, when pressed about the statute's reach, the State's counsel asserted that section 1711-E(2-A) would cover the pharmaceutical detailers' use in Maine of the prescriber-identifiable data - even though the law appears to have been designed precisely to avoid directly restricting the detailers' speech to prescribers.

Counsel noted, for example, that "use in Maine is what the statute is directed at and that would be proscribed regardless of whether or not [an out-of-state] transaction before that was subject to the Act." Counsel also stated that, "[i]f the assumption is that the transaction between IMS or one of the other plaintiffs and the drug companies occur[s] totally outside the State, then what the statute covers is the subsequent use in Maine by the detailer." That explanation is at odds with my previous understanding of the State's construction of the statute, which explicitly applies to "a carrier, pharmacy or prescription drug information intermediary" ["PDII"] - not to pharmaceutical companies and their employees. That explanation is also at odds with the district court's reading of the law. See Rowe, 532 F.

Supp. 2d at 169 ("The Law does not make illegal a drug company's use of opt-out prescriber information for marketing purposes. . . . The Law forbids the PDIIIs from selling opt-out data for marketing, but it does not prohibit the pharmaceutical companies from using the data for marketing.").<sup>38</sup>

Although the plaintiffs also state in their brief that drug companies fall within the statute's definition of a PDII, that construction departs from plain language and ordinary usage. It may be, as plaintiffs' counsel explained at oral argument, that a drug manufacturer could be treated as a PDII when it transacts directly with pharmacies or other sources of prescription data. As a general matter, however, drug companies are not PDIIIs, and classifying them as such when they are not acting in that capacity is not a defensible reading of the statute. Thus, my assumption throughout is that the statute does not directly regulate drug manufacturers and their employees, including detailers, unless the drug manufacturer acts as its own PDII.

The confusion over how the statutes operate arises from the States' attempts to achieve indirectly its ultimate objective - limiting the content of the detailers' messages. By restricting the dissemination of prescriber-identifiable data rather than the

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<sup>38</sup> The majority in this case makes the same assumption: "Section 1711-E(2-A) does not explicitly limit detailers' use of prescriber-identifying data, but the earlier stages of regulation are meant to prevent this information from getting to detailers for use in marketing."

detailers' messages themselves, the States hoped their laws would be evaluated as restrictions on conduct rather than speech. The First Amendment consequences of regulating the content of speech do not disappear, however, simply because the regulation operates indirectly. See infra. In this instance, the indirection has only made the constitutional inquiry more complex.

In particular, the States' approach magnified the Commerce Clause implications of the legislation because the targeted transfers of prescriber-identifiable data for marketing purposes occur primarily outside of both New Hampshire and Maine. Evidently feeling caught in a constitutional bind, the New Hampshire Attorney General construed her state's statute to govern only in-state transactions - effectively stripping the law of any impact. Although Maine has rejected such a narrow construction, it is still scrambling to define the reach of its legislation.

In my view, the States should have confronted directly the First Amendment challenges of what they sought to do. Their indirect approach has not avoided First Amendment scrutiny, yet they have generated the Commerce Clause complications that we must address here. Those complications might have been avoided with more straightforward laws addressing the States' concerns about pharmaceutical detailing.

## II. The First Amendment

I recognize that the majority decision in Ayotte is binding precedent for the proposition that the statute at issue here, like the statute in Ayotte, regulates conduct, not speech. See United States v. Rodríguez, 527 F.3d 221, 224 (1st Cir. 2008) ("As a general rule, newly constituted panels in a multi-panel circuit are bound by prior panel decisions closely on point."). I must re-emphasize, however, my strong disagreement with the Ayotte majority's conclusion that statutes such as those of New Hampshire and Maine regulate conduct, rather than constitutionally protected speech. The purpose of both laws is to restrict truthful - but, in the States' view, undesirable - messages communicated by pharmaceutical detailers to prescribing health care professionals. The State of Maine admits that restricting such speech is precisely its objective. Cf. Sorrell, 631 F. Supp. 2d at 446 ("Plainly, the whole point of [Vermont's statute] is to control detailers' commercial message to prescribers."). The laws achieve this purpose by regulating the transfer of factual information. It cannot reasonably be argued that these laws, with this ultimate purpose, do not constitute restrictions on speech. See Ayotte, 550 F.3d at 81-82 (Lipez, J., concurring and dissenting) (citing cases); Sorrell, 631 F. Supp. 2d at 446 ("The mere fact that [Vermont's similar provision] regulates protected speech indirectly does not sweep it from the First Amendment's purview."); Laurence

H. Tribe, Legal Backgrounder, The Fatal First Amendment Flaw in Prescription Restraint Statutes (Wash. Leg. Found., Washington, D.C.), Dec. 11, 2009, available at [http://www.wlf.org/publishing/publication\\_detail.asp?id=2125](http://www.wlf.org/publishing/publication_detail.asp?id=2125) (noting that the Supreme Court has "recognized that obstructing access to the informational building blocks of speech is every bit as pernicious an abuse of governmental power over the free flow of information and ideas as is restricting the resulting speech itself").

In reaching its conclusion in Ayotte that laws such as these are "outside the ambit of the First Amendment," 550 F.3d at 52, the majority equated transfers of prescriber-identifiable information with the limited categories of speech, such as obscenity and fighting words, that lie "outside the compass of the Free Speech Clause by virtue of longstanding tradition." Id. at 51-52. In making that comparison, the majority repeatedly discounted the value of the expression that it acknowledged the New Hampshire statute might regulate, describing such "putative speech" as "items of nugatory informational value" and "of scant societal value." Id. at 52.

However, in a recent decision considering a challenge to a law criminalizing depictions of animal cruelty, the Supreme Court firmly rejected the notion that the First Amendment's guarantee of free speech "extend[s] only to categories of speech that survive an

ad hoc balancing of relative social costs and benefits." Stevens, 130 S. Ct. at 1585. The Court explained that the exclusion of categories of speech from the protection of the First Amendment has occurred only in "special case[s]." Id. at 1586; id. at 1584 (listing the "few limited areas" where "the First Amendment has permitted restrictions upon the content of speech" (quotation marks and citation omitted)). Although observing that other categories of speech may yet be identified as unprotected based on historical practice, the Court stated that its prior decisions "cannot be taken as establishing a freewheeling authority to declare new categories of speech outside the scope of the First Amendment." Id. at 1586.

These prescriber-information cases involve the right to disseminate truthful information - a classic form of protectible speech activity, even when done for a fee - and the right to use that information in crafting a marketing message. Stevens confirms that such speech may not be excluded from First Amendment protection "on the basis that [it] is not worth it," 130 S. Ct. at 1585, and labeling speech as conduct does not make that exclusion any more permissible.

Hence, while Ayotte governs the First Amendment analysis in this case, I adhere to my view that what is at stake is protectible speech, not conduct. The relevant First Amendment question is thus whether Maine, like New Hampshire, has adequately

justified the limited restraint on commercial speech imposed by its statute. Here, as in Ayotte, I conclude that the State has done so.

Maine asserts three "compelling state interests" in support of section 1711-E(2-A): "to improve public health, to limit annual increases in the cost of health care and to protect the privacy of patients and prescribers" in the State's health care system. Me. Rev. Stat. Ann. tit. 22, § 1711-E(1-B). Although I agree that these interests are substantial in theory, I doubt that the record supports the State's contention that the challenged statute in fact advances all of them. I am particularly skeptical of the privacy interest.

The Maine law neither prohibits the practice of pharmaceutical detailing nor prevents the widespread use of any prescriber's prescribing histories. See Rowe, 532 F. Supp. 2d at 170 ("The Attorney General's expert [prescriber] witnesses acknowledged that insurance companies, governmental agencies, quality assurance committees, utilization reviewers, and others have the right and responsibility to assess their prescribing patterns."); id. at 173 ("[T]he new Law does not prevent the pharmacies from transferring exactly the same information to the PDIIIs, so long as the information is not ultimately used for marketing."). Detailers may continue to devise marketing strategies based on the prescribing patterns of prescribers who do

not choose to bar the marketing use of their information, meaning that the one-on-one meeting with a prescriber who has invoked the law's protection may include references to the histories of colleagues within the same town or even the same practice. See id. at 171.

Given the wide, permissible dissemination of the prescribing information, and the continued allowance of targeted one-on-one detailing, prescriber privacy does not appear to be meaningfully advanced by this statute. Accord Rowe, 532 F. Supp. 2d at 173 ("The Law only marginally advances the governmental interest in prescriber privacy."). I therefore disagree with the majority's analysis of the State's "interest in preventing its prescribers from being subjected to unwanted solicitations by detailers in Maine on the basis of their prescribing histories." The statute does not protect a "right to be let alone"; it merely protects prescribers who consent to interactions with detailers from exposure to one type of message. The prescribers may have particular distaste for sales pitches based on their own prescribing histories, but that discomfort - whether or not properly labeled an issue of "privacy" - seems inadequate to justify a content-based restriction on truthful speech of public concern. See Rowe, 532 F. Supp. 2d at 170 ("Prescribers' prescribing patterns are . . . a matter of public concern.").

In any event, the State's brief gives short shrift to both the privacy and public health interests, and I find it unnecessary to closely examine the record on those two interests because the State's substantial interest in reducing health care costs in Maine is sufficient to justify the statute within the commercial speech framework. Cf. Ayotte, 550 F.3d 88-96; Sorrell, 631 F. Supp. 2d at 449-454 (finding that Vermont's statute advances the State's interests in both cost containment and protecting public health). Relying on evidence similar to that introduced in Ayotte, the State argues that detailing is "significantly more successful when detailers use prescriber-identifiable data," and that reduced access to physicians' prescribing histories will reduce the likelihood that prescribers in Maine will prescribe "unnecessary and more expensive brand-name drugs." I will not rehearse in detail the nature of the evidence presented on this issue at the Maine legislative hearings or before the district court. It suffices to say that the record "establishes a plausible cause-and-effect relationship between targeted detailing and higher drug prices," Ayotte, 550 F.3d at 93, and that "the Attorney General has [thus] 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 [section 1711-E(2-A)]," id. at 94.

To satisfy the First Amendment, the statute also must meet the narrow tailoring prong of the Central Hudson inquiry. See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980). Without the benefit of our decision in Ayotte, the district court concluded that the Maine law "substantially fails" the narrow tailoring requirement. Rowe, 532 F. Supp. 2d at 176. That judgment is wrong largely for the same reasons that it was wrong in Ayotte.

In concluding that the law is more extensive than necessary to serve the State's interest in decreasing the influence of drug company representatives, the district court emphasized that the State did not address the concern that detailers "inappropriately influenc[e] Maine prescribers by showering them with gifts in implicit exchange for prescriptions." Id. It also pointed out that prescribers are "[t]rained as professionals" "to perform a sophisticated and critical public health function." Id. at 177. It stated that these trained professionals "have access to a broad range of sources to evaluate whether to prescribe a drug for a particular patient." Id. Therefore, the law unnecessarily protects them "from being influenced by their own practice patterns." Id. Specifically on the cost issue, the district court observed that "some branded drugs end up being more cost effective to the system as a whole than their generic or branded counterparts." Id. at 178. In that sense, the court stated, the

Maine law fails to "discriminate between beneficial detailing and harmful detailing." Id. (quotation marks and citation omitted). The court thus concluded that "ban[ning] truthful information about opt-out prescribers' prescription patterns is to overreach and restrict more speech than is necessary to address the problem of harmful detailing." Id.

The district court's narrow tailoring assessment does not adequately take into account the premise from which it must proceed, i.e., that the State has shown that restricting the use of prescriber-identifiable data advances at least one of its asserted interests - controlling the spiraling cost of prescription drugs. The court seems to assume that the alternatives it describes will be just as effective in advancing that goal.

As I have explained, the State's evidence in both Ayotte and here supports the view that, despite the expertise of medical professionals, detailers are able to influence prescribing decisions. I also explained in Ayotte why the State could properly conclude that alternative methods for achieving its cost-containment objective that would not burden speech, including restricting courtesy samples and other gifts, were not equivalent. As I noted there, "[t]he 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." 550 F.3d at 99.<sup>39</sup>

The fact that detailing at times has beneficial effects does not undermine the State's conclusion that, on balance, its harms outweigh its benefits - particularly where the State reasonably could find that the benefits of the messages about prescription drugs that are disseminated by detailers are "largely achievable in other ways." 550 F.3d at 95-96<sup>40</sup>; see also Rowe, 532 F. Supp. 2d at 177. Notably, the State's restriction on speech is

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<sup>39</sup> Moreover, Dr. Jerry Avorn, who also served as an expert in this case, testified in Ayotte that other approaches had been tried "nationally in terms of trying to restrict the freebies, trying to provide doctors with other means of learning, requiring that doctors take continuing ed courses," but that these strategies did not eliminate "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." 500 F.3d at 99.

<sup>40</sup> I described in Ayotte some of the ways in which such messages would continue to reach prescribers:

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. Early adopters could be expected to respond quickly with an interest in trying the new medications - effectively identifying themselves to the sales representatives. In addition, . . . the statute does not bar drug companies from alerting prescribers to newly discovered problems with their medications.

550 F.3d at 95 (footnotes omitted). Doctors also testified that they learned about new drugs from medical literature, conferences, and colleagues. Id. at 95 n.64

significantly more restrained than other marketing or advertising bans that have been considered by the Supreme Court. See Ayotte, 550 F.3d at 97 (citing cases involving more comprehensive restrictions). As I described in Ayotte, the private setting of the targeted messages also is relevant to the narrow tailoring inquiry:

This case differs from those in which the Court has rejected advertising bans that restrict the exchange of ideas in the "commercial marketplace." The [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.

550 F.3d at 100.

Indeed, the narrow tailoring element of the Central Hudson test is arguably more easily satisfied here than in Ayotte because the statute bars the marketing use of prescribing histories only for prescribers who affirmatively choose not to have their data used for marketing purposes - narrowing the impact on protected speech. Although the State's cost-containment objective would have modest success, at best, if few Maine prescribers choose to restrict the use of their prescribing data, the restriction on protected speech also would be modest in that situation. I see no

constitutional barrier to the State's judgment that restricting the use of prescriber-identifiable data in the detailing messages of only some of its prescribers would be beneficial.<sup>41</sup>

In sum, the considerations I addressed in Ayotte to evaluate "'whether the extent of the restriction on protected speech is in reasonable proportion to the interest served,'" 550 F.3d at 96 (quoting Edenfield v. Fane, 507 U.S. 761, 767 (1993)), apply here as well: "[t]he 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." 550 F.3d at 98. My review of these factors leads me to the same conclusion: the State "has established a 'reasonable fit' between its abridgement of speech and its . . . goal." Id. at 98 (quotation marks and citation omitted); see also Sorell, 631 F. Supp. 2d at 455 (finding the Vermont statute to be "in reasonable proportion to the State's interests").

Hence, like New Hampshire, Maine has met its burden to justify the limited restraint on commercial speech imposed by section 1711-E(2-A).

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<sup>41</sup> The district court noted that, because the Maine statute gives prescribers the option to allow use of their information, the pharmaceutical companies might provide incentives to prescribers in an attempt to persuade them not to opt out - creating an even more troubling relationship between prescribers and drug manufacturers. Rowe, 532 F. Supp. 2d at 174 n.31; id. at 176 n.35. In my view, such a scenario is too speculative to factor into the analysis.

### **III. The Commerce Clause**

This case confirms the view I expressed in Ayotte that the plaintiffs' Commerce Clause challenge raised a serious issue that should not have been addressed in that case on the basis of the limited record and the parties' cursory briefing. Maine distances itself from the nonsensical construction of the New Hampshire statute that was advanced by the New Hampshire Attorney General and accepted by the Ayotte majority,<sup>42</sup> admitting that its statute inevitably reaches out of state to regulate sales of data about prescriptions written in Maine. Indeed, the activity restricted by the Maine statute, logically construed, occurs almost entirely beyond the State's borders.<sup>43</sup>

#### **A. The Activities Regulated by the Statute**

Understanding the sequence of events implicated by section 1711-E(2-A) is crucial to understanding the statute's legal status. To begin with the end, the statute is designed to prevent pharmaceutical detailers working in Maine from using information

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<sup>42</sup> The New Hampshire Attorney General urged the court to read the act to "'relate only to activity that takes place domestically,'" and the panel majority adopted that view despite recognizing that, so construed, the law "may not accomplish very much." Ayotte, 550 F.3d at 63, 64.

<sup>43</sup> Although the Attorney General at oral argument attempted to avoid committing to any specific extraterritorial reach for the statute, I agree with the majority that "[t]he text of the statute by its terms shows section 1711-E(2-A) was intended to apply to plaintiffs' out of state use or sale of opted-in Maine prescribers' identifying data."

about the prescribing habits of Maine prescribers to present targeted, and therefore more persuasive, sales pitches to those prescribers. The statute does not, however, regulate the detailers' interactions with the prescribers. Instead, the State seeks to achieve its objective indirectly by, in effect, placing a red flag on information about prescriptions written by Maine prescribers who opt into the statute's protection. The red-flagged information may not be used, sold or transferred "for any marketing purpose" by pharmacies, insurers and other entities that acquire it in the course of their business.<sup>44</sup>

In practical effect, that prohibition rarely limits any commercial transactions in Maine. This is so because local Maine pharmacies routinely transfer their prescription information electronically to their out-of-state headquarters.<sup>45</sup> Although the red flag is attached to the information when those transfers are made, the statutory prohibition does not affect this first movement of the data because it is not "for any marketing purpose." Most prescriber-identifiable data leaves the State in this permissible manner. The data is next transferred from the out-of-state

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<sup>44</sup> The statute also prohibits licensing or exchanging the information for value. For the sake of simplicity, I will refer primarily to the prohibitions on the sale or transfer of the data.

<sup>45</sup> The record indicates that, other than the data from one small supplier in Maine, the prescriber-identifiable information obtained by the plaintiffs is transferred in the ordinary course of business from retail stores located in Maine to the pharmacy chains' out-of-state headquarters.

pharmacy headquarters to the data mining companies - the plaintiffs in this case - who also are located outside of Maine.<sup>46</sup> The red flag imposes a significant restriction on those out-of-state transactions. Although data miners use prescription information for other reasons, including to generate reports for government and other nonprofit recipients, the most lucrative aspect of their business is to aggregate the information into reports that can be sold to pharmaceutical companies for use in marketing.<sup>47</sup>

Hence, the pharmacies and data miners, although not themselves using the prescriber-identifiable data to market drugs, presumably must impose a contractual obligation on their customers not to use the information for that purpose in order to fulfill their obligations under section 1711-E(2-A). See Rowe, 532 F. Supp. 2d at 169 n.18 ("[T]he PDIIIs are assigned the responsibility to limit the pharmaceutical companies' use of the opt-out prescriber data."). How the State would enforce the statute if a pharmaceutical manufacturer does not abide by such a contract with

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<sup>46</sup> An IMS senior vice president testified that the company contracts with Rite Aid at its headquarters in Pennsylvania and with CVS at its headquarters in Rhode Island. IMS is based in Plymouth Meeting, Pennsylvania.

<sup>47</sup> Drug companies also have non-marketing uses for prescriber-identified data, including determining the need for new drugs and implementing prescription recall programs. Ayotte, 550 F.3d at 74 n.29. Still, at oral argument, plaintiffs' counsel stated that "[n]inety-five percent of what we do in selling to a pharmaceutical manufacturer is so that it can use the information for marketing and detail."

a data miner is unclear. Perhaps the data miners would be deemed liable for failing to enforce the obligation unless they took action against the offending drug company; such action might include a refusal to continue selling the information to the company.<sup>48</sup>

Whatever the specific mechanism for enforcement of the statute's prohibition, the statute's objective is to prevent the use of any prescriber-identifiable data obtained by the drug companies in sales pitches by the detailers in Maine who are the statute's real target.<sup>49</sup> As my description of the process reveals, however, achieving that objective involves raising the red flag in transactions that almost all occur beyond Maine's borders. Nearly all of the transfers between the information possessors - the

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<sup>48</sup> The district court described the "burden on pharmacies and PDIIIs to police their customers" as follows:

They can still sell the opt-out information, but they cannot do so if their customers, the pharmaceutical companies, are going to use the information for a purpose that the Law prohibits. If the PDIIIs successfully police their contracts with the pharmaceutical companies, as the Law contemplates, the pharmaceutical companies will not be able to include opt-out prescriber information in marketing their products. If they do not, then they, not the pharmaceutical companies, are subject to sanction.

532 F. Supp. 2d at 169.

<sup>49</sup> The State argues that the record contains no evidence about the transactions between the plaintiff data miners and the drug manufacturers. IMS, however, asserts in its brief that none of its subscribers are located in Maine, and it cites the testimony of Hossam Sadek, a senior vice president of the company, who stated that he knew of no IMS customers in the State.

pharmacies and data miners - and the information recipients - the data miners and pharmaceutical companies - are made out of state. So too are any contractual promises by the recipients to abide by the statute's limitation.

The plaintiffs complain that this significant extraterritorial effect is impermissible under the dormant Commerce Clause. The State, however, maintains that the statute has only a "spillover effect" beyond its borders, and it argues that the law applies only to "entities either located in Maine or having nexus with Maine," i.e., those sufficiently connected to the State to meet the requirements for personal jurisdiction. The State asserts that it is "irrelevant" that the main computers of the large retail pharmacy chains are located outside Maine because Maine is the source of the restricted information, and the electronic prescription data is initially entered into in-state computers. The State further emphasizes that the prescriptions are written by prescribers licensed by Maine and filled almost exclusively by State-licensed pharmacies, giving Maine a substantial interest in governing the dissemination and use of the prescription data.

The difficulty of evaluating the parties' competing depictions of section 1711-E(2-A) begins with the choice of an appropriate framework for analysis.

## B. Identifying the Correct Analytical Approach

The Supreme Court has articulated various "protocol[s] for dormant Commerce Clause analysis," Dep't of Revenue of Ky. v. Davis, 553 U.S. 328, 338 (2008), none of which seems fully apt here. This is plainly not an instance of discriminatory purpose or treatment in which the statute should be deemed per se invalid because it favors in-state over out-of-state interests. See, e.g., Alliance of Auto. Mfrs. v. Gwadowsky, 430 F.3d 30, 35-36 (1st Cir. 2005) (noting that the "core purpose" of the dormant Commerce Clause is "to prevent states and their political subdivisions from promulgating protectionist policies" (quotation marks and citation omitted)). The law imposes the same burden on every competitor, and out-of-state entities would gain no advantage by relocating to Maine.<sup>50</sup>

Plaintiffs, unsurprisingly, have relied primarily on the extraterritoriality doctrine, and the proposition that a statute may be deemed per se invalid if it "directly controls commerce occurring wholly outside the boundaries of a State." Healy v. Beer Inst., Inc. 491 U.S. 324, 336 (1989); see also Wine & Spirits

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<sup>50</sup> Price controls that favor in-state businesses, assessments that function as protective tariffs, and regulations that cap in-state prices for goods produced out of state are classic examples of measures that run afoul of this aspect of the dormant Commerce Clause. See, e.g., Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 669-70 (2003); Or. Waste Sys., Inc. v. Dep't of Env'tl. Quality, 511 U.S. 93, 99 (1994); Healy v. Beer Inst., Inc., 491 U.S. 324, 336 (1989).

Retailers, Inc. v. Rhode Island ["Wine & Spirits II"], 481 F.3d 1, 15 (1st Cir. 2007); Pharm. Research & Mfrs. of Am. v. Concannon ["PhRMA"], 249 F.3d 66, 79-80 (1st Cir. 2001), aff'd sub nom. Pharm. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644 (2003). Such laws may subject activities to more than one state's regulations, leading to the possibility of conflicting obligations. See, e.g., Healy, 491 U.S. at 336-37; CTS Corp. v. Dynamics Corp. of Am., 481 U.S. 69, 88-89 (1987); Peter C. Felmly, Comment, Beyond the Reach of States: The Dormant Commerce Clause, Extraterritorial State Regulation, and the Concerns of Federalism, 55 Me. L. Rev. 467, 509 (2003) (observing that the extraterritoriality "principle ensures that a state will not overstep its bounds and unreasonably trample upon the authority of another sovereign"). Plaintiffs also invoke the so-called Pike balancing test, which is applied to laws that regulate evenhandedly and have only "incidental" effects on interstate commerce. See Pike v. Bruce Church, Inc., 397 U.S. 137, 142 (1970);<sup>51</sup> see also United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 346 (2007).<sup>52</sup>

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<sup>51</sup> The Court in Pike held that, when a statute regulates evenhandedly to effectuate a legitimate local purpose, and has only incidental effects on interstate commerce, "it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." 397 U.S. at 142.

<sup>52</sup> I disagree with the majority's assertion that the plaintiffs have waived any Pike balancing argument. Given the similarity of the inquiries under the different strands of the dormant Commerce Clause, I see no reason to disregard the argument here.

Neither of these latter alternatives is a good fit for the present circumstances. The per se extraterritoriality analysis may appear literally applicable, given that the statute's red flag has a direct impact almost exclusively on out-of-state commerce. Yet, as I observed in Ayotte, "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 [a] relevant consideration." 550 F.3d at 105 (citing Felmly, supra, at 491). The Maine law does not by its terms impose restraints on non-domestic businesses, and the imbalance between in-state and out-of-state effect is a matter of happenstance not design. The statute does not seek to achieve conformity between in-state and out-of-state commerce.<sup>53</sup> Additionally, there is no risk of conflict

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<sup>53</sup> The pursuit of such consistency is a feature of the most prominent Supreme Court extraterritoriality precedents. In Healy, 491 U.S. at 335, the challenged Connecticut statute expressly required out-of-state shippers to affirm that their Connecticut prices were no higher than the prices being charged in bordering states, and the New York statute at issue in Brown-Forman Distillers Corp. v. New York State Liquor Authority, 476 U.S. 573, 579 (1986), required liquor producers and distillers doing business in the State to affirm comparable in-state and out-of-state pricing. In Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511 (1935), the Court struck down the New York Milk Control Act, which prescribed minimum prices for milk that had the effect of setting out-of-state milk prices. Id. at 524. In line with those cases, the Seventh Circuit recently struck down an Indiana law that subjected out-of-state loans entered into by Indiana residents to the requirements of Indiana's consumer law if the out-of-state creditor had advertised or solicited sales in Indiana. Midwest Title Loans, Inc. v. Mills, 593 F.3d 660, 662, 667-68 (7th Cir. 2010).

with other states' regimes. No other State has a stake in the use of prescriber-identifiable data in Maine or any obvious interest in the use of Maine prescriber information in their own locales.

Indeed, it is arguable that, despite the statute's impact on commercial transactions that occur almost entirely out of state, the commerce it controls is not "wholly outside [Maine's] boundaries." Healy, 491 U.S. at 336. The subject matter of the law is data that both originates in Maine and is intended for marketing use in Maine. Maine's aim is to regulate on a matter of public welfare only within Maine. Cf. Midwest Title Loans, Inc. v. Mills, 593 F.3d 660, 667-68 (7th Cir. 2010) (invalidating Indiana statute that sought to protect Indiana residents from predatory lending practices by businesses located in other states). On the other hand, it is difficult to characterize the statute's effect on out-of-state commerce as "incidental" when its prohibition in fact has its primary impact outside the State. See, e.g., Healy, 491 U.S. at 336 ("The critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State.").

The various labels ordinarily are invoked because they are associated with different levels of scrutiny. We have observed that a statute that regulates evenhandedly "engenders a lower level of scrutiny," Wine and Spirits II, 481 U.S. at 11 (quotation marks and citation omitted), while "[a] statute is per se invalid if it

regulates commerce wholly outside the state's borders," id. at 15. Identifying the appropriate label should not distract us, however, or bog us down at the threshold of analysis. Despite the different protocols for dormant Commerce Clause inquiry, the Supreme Court has observed that "there is no clear line separating" the various types of state regulation and that the same "critical consideration" applies to each category: "the overall effect of the statute on both local and interstate activity." Brown-Forman Distillers Corp. v. New York State Liquor Auth., 476 U.S. 573, 579 (1986) (referring to regulations that are "virtually per se invalid under the Commerce Clause, and the category subject to the Pike v. Bruce Church balancing approach"); see also Healy, 491 U.S. at 337 n.14 (noting the same "critical consideration" in determining "whether the extraterritorial reach of a statute violates the Commerce Clause"); Am. Booksellers Found. v. Dean, 342 F.3d 96, 102 (2d Cir. 2003).

This dual concern is an inevitable byproduct of our system of federalism. The Court has often remarked in its dormant Commerce Clause cases that States "retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." Maine v. Taylor, 477 U.S. 131, 138 (1986) (quotation marks and citation omitted); see also, e.g., Davis, 553 U.S. at 338; cf. Garcia v. San Antonio Metro. Transit Auth., 469 U.S. 528, 546 (1985). Hence, in

reviewing a statute challenged under the dormant Commerce Clause, we are always guided by "the Constitution's special concern both with the maintenance of a national economic union unfettered by state-imposed limitations on interstate commerce and with the autonomy of the individual States within their respective spheres." Healy, 491 U.S. at 335-36 (footnote omitted).

Indeed, even the "rigorous form of review" applicable to discriminatory legislation allows exemption for a statute that "furthers a legitimate local objective that cannot be served by reasonable non-discriminatory means." Wine and Spirits II, 481 F.3d at 11. Local needs also must qualify the "near-fatal rule of per se invalidity" for statutes that regulate extraterritorially. See Felmy, supra, at 492; id. at 488 (observing that "[o]ne may infer" from language in CTS Corp., 481 U.S. at 93, that "where a state has a significant interest in regulating a particular aspect of interstate commerce, it may do so, regardless of the extraterritorial effect of the legislation, if the regulation also affects a substantial number of in-state residents").

I thus see the most relevant and appropriate question as simply whether Maine's interests are sufficiently weighty to justify any burdens its law imposes on interstate commerce. Whatever the label and however we describe the level of scrutiny, the outcome here is the same.

### **C. Assessing the Local Interest and the Burden on Interstate Commerce**

As discussed in Section II above, I agree that the State has a substantial interest in reducing the cost of prescription drugs for its residents and that the State could reasonably conclude that section 1711-E(2-A) advances that interest by regulating the dissemination of information revealing the prescribing histories of Maine's licensed health care providers. Cf. Ayotte, 550 F.3d at 94-95. The statute's importance to the State is no different in the context of a Commerce Clause inquiry than in the First Amendment setting.

The other side of the balance is not the same, however. The conclusion that the statute is "narrowly tailored" under the Central Hudson test for commercial speech, see 447 U.S. at 566, does not tell us whether the provision impermissibly burdens interstate commerce. As I have described, the statute does in fact regulate specific activities that occur mostly out of state. The impact on the plaintiffs is not merely "spillover" from a prohibition directed at others; they are among the categories of entities - PDIIIs - affected directly by the statute.

Moreover, the statute's impact on PDIIIs is potentially enormous. Sales of prescriber-identifiable data are the bread-and-butter of the medical data mining business, producing \$1.75 billion in revenue for plaintiff IMS Health alone in 2005. Although only three states have thus far enacted laws designed to limit

detailers' access to prescribers' identifying information, they are at the front of a wave of similar legislation. See Rowe, 532 F. Supp. 2d at 180 n.41 (noting testimony that seventeen to twenty other states were considering similar laws); Heesters, supra, at 791 (stating that "numerous other states have [bills] that similarly restrict the sale of prescription drug data that are currently pending in legislative committees").

Hence, a conclusion that section 1711-E(2-A) comports with the dormant Commerce Clause could eventually lead to elimination of any market for prescriber-identifiable data, which the plaintiffs have argued would jeopardize the viability of their businesses. See Ayotte, 550 F.3d at 95 n.66 ("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.").<sup>54</sup> Plaintiff IMS asserts that it will cost hundreds of thousands of dollars for it to adjust its systems to comply with the statute's restrictions; plaintiff Source Healthcare estimated that it would spend 10,000 employee hours to comply with Maine's and Vermont's laws.

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<sup>54</sup> The fact that only 259 of Maine's 7,500 prescribers opted into the statute's confidentiality protection during the period in which it has been suspended by the preliminary injunction tells us little about the law's likely impact. More activity presumably will occur once the injunction is lifted.

The "possible effects on the profits of the individual manufacturers" is not, however, the concern of the dormant Commerce Clause. PhRMA, 249 F.3d at 84. Our court previously has observed that "the Commerce Clause . . . 'protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations.'" Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 313 (1st Cir. 2005) (quoting Exxon Corp. v. Gov. of Md., 437 U.S. 117, 127-28 (1978)); see also PhRMA, 249 F.3d at 84 ("[T]he fact that a law may have devastating economic consequences on a particular interstate firm is not sufficient to rise to a Commerce Clause burden." (quotation marks and citations omitted)). Even if the statute meant the demise of the data-mining industry as a whole - an outcome I doubt, see infra note 22 - any ill-effects from that result would "relate[] to the wisdom of the statute, not to its burden on commerce." Exxon Corp., 437 U.S. at 128. The point is perhaps more easily understood in a different context. If, for example, every state decided to ban the use of firecrackers because of the risk of injury, the dormant Commerce Clause would not trump the legislative safety concerns and insulate the fireworks industry from extinction.

Neither national uniformity nor any of the other traditional concerns underlying the dormant Commerce Clause are implicated here. The law does not "erect barriers against interstate trade," Lewis v. BT. Inv. Managers, Inc., 447 U.S. 27,

35 (1980), and its target is not "interstate commerce" as such. Rather, the transactions governed by the statute are restricted only because they are subsidiary steps in the regulation of in-state activity.<sup>55</sup> Indeed, the law's effect on individual businesses would be no different if every PDII were based in Maine. Nor does Maine's decision to restrict the use of certain prescriber-identifiable data make similar legislation more or less appropriate or necessary in other states. There is nothing in Maine's statute that affects other states' choices about whether, or how, to regulate prescriber-identifiable data within their own borders. As the Supreme Court observed in Exxon Corp., "[t]he evil that appellants perceive in this litigation is not that the several States will enact differing regulations, but rather that they will all conclude that [similar] provisions are warranted." 437 U.S. at 128. However, "[i]n the absence of a relevant congressional declaration of policy, or a showing of a specific discrimination against, or burdening of, interstate commerce, we cannot conclude that the States are without power to regulate in this area." Id. at 128-29.

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<sup>55</sup> The "subsidiary" nature of the out-of-state transactions is, of course, a function of the statute's purpose to restrict speech in Maine. Although that in-state speech objective strengthens the State's Commerce Clause position, the indirect regulatory strategy - as I have explained - creates the First Amendment-Commerce Clause dance and unnecessarily complicates the constitutional analysis.

Nor do I see a way in which Maine could have promoted its interest "'with a lesser impact on interstate activities,'" Minnesota v. Clover Leaf Creamery Co., 449 U.S. 456, 471 (1981) (quoting Pike, 397 U.S. at 142) - a factor that is considered in Pike balancing. See, e.g., U & I Sanitation v. Columbus, 205 F.3d 1063, 1070-71 (8th Cir. 2000). If Maine had regulated only in-state activity - directly barring detailers working in Maine from using the opted-out prescribers' data in their sales pitches - the impact on data miners would be the same. In such a regime, the out-of-state data miners would not be prohibited from selling the prescriber-identifiable data for marketing purposes, but the pharmaceutical companies would have no reason to buy it.<sup>56</sup>

In sum, I conclude that section 1711-E(2-A) survives dormant Commerce Clause scrutiny even though in practical effect it regulates activity that occurs primarily beyond Maine's borders.

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<sup>56</sup> The actual impact on the plaintiffs of legislation regulating the use of prescriber-identifiable data remains to be seen. As the district court noted, the law "does not prevent the pharmaceutical companies from marketing their products and the companies may resort to more general, less tailored marketing." Rowe, 532 F. Supp. 2d at 174. It thus may be that the demand for aggregated data about prescribing trends will change, but not dry up. For example, the statute appears to permit detailers to use aggregated data based on specialities or zip codes. See Ayotte, 550 F.3d at 95 n.66. Moreover, if empirical data gathered in the future on the statute's impact shows that less particularized, less efficient detailing is negating the cost savings Maine hopes to achieve, the State may be persuaded to change its approach to the problem. Cf. Clover Leaf Creamery Co., 449 U.S. at 473 n.17 ("The existence of major in-state interests adversely affected by [a law] is a powerful safeguard against legislative abuse.").

The burden on interstate commerce (the reduction in the value of a particular type of business) is not the kind of burden that raises constitutional concerns. To the extent that burden is relevant to the Commerce Clause analysis, it is easily outweighed by the State's substantial interest in bringing the cost of prescription drugs - and health care expenses in general - under control. Cf. Pharm. Care Mgmt. Ass'n, 429 F.3d at 312 (describing a law aimed at "reduc[ing] the costs of, and increas[ing] the public's access to, prescription drugs" as "designed to deal with 'one of the serious problems of our time'").

I therefore agree that the judgment of the district court should be reversed.

#### **IV. The Focus of Future Litigation**

This case has allowed us to put to rest the Commerce Clause challenge that was not properly teed up in Ayotte. In addition, in the period between our reviews of New Hampshire's and Maine's similar statutes, Stevens has reinforced my view that laws regulating the messages of pharmaceutical detailers restrict protectible speech, not conduct. Thus, as more of these cases evolve across the country, the legal argument and factual development should be framed by the Supreme Court's commercial speech doctrine under the First Amendment.

That doctrine is the subject of ongoing debate among commentators and in the courts, including within the Supreme Court.

Much of the ferment focuses on the narrow tailoring prong of the Central Hudson inquiry and how close the fit must be in any commercial speech case between the State's interest and the challenged restriction on speech. See Greater New Orleans Broad. Ass'n, Inc. v. United States, 527 U.S. 173, 184 (1999) (recognizing the advocacy among judges, scholars and others for "a more straightforward and stringent test for assessing the validity of government restrictions on commercial speech"); see also Thompson v. W. States Med. Ctr., 535 U.S. 357, 388 (2002) (Breyer, J., dissenting) (chastising the majority for applying the commercial speech doctrine "too strictly" in finding that a statute prohibiting the advertising of compounded drugs was not narrowly tailored); Ayotte, 550 F.3d at 96-97 (discussing "the debate on Central Hudson's continuing viability"); Elizabeth Spring, Note, 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.").

In addition, there is a claim by some that these particular laws should not be assessed as regulations of commercial speech, with the lesser scrutiny that attends such measures, but rather as content-based regulations of truthful speech "on matters of profound public importance." Tribe, supra; see also Rowe, 532

F. Supp. 2d at 167 n.14 (describing as a "thorny question" whether Maine's content-based regulation should be given intermediate or strict scrutiny and raising the possibility that "the speech here is not purely commercial speech and is subject to strict scrutiny" because it is "a matter of public concern"); cf. Tribe, supra ("Even if the prescription restraint laws were subject to the more forgiving standard applicable to regulations of purely commercial speech, however, they would still be unconstitutional because they violate the core principle that the government may not restrict even commercial communication merely to block the dissemination of truth."). Although in Ayotte I I found no merit in the argument that New Hampshire's statute should be analyzed as a content-based restriction on speech subject to strict scrutiny, see Ayotte, 550 F.3d at 83 n.47; accord Sorrell, 631 F. Supp. 2d at 447-48,<sup>57</sup> the contrary view has worthy proponents and undoubtedly deserves close consideration.

Yet another source of difficulty is the quality of the record a state legislature must amass to prove that a statute advances its interest and extends no more broadly than necessary to achieve its objectives. I concluded in Ayotte that the district court had held the Attorney General to an overly demanding standard

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<sup>57</sup> The district court in Sorrell observed that, "[b]y definition, the 'Supreme Court's commercial speech doctrine . . . creates a category of speech defined by content but afforded only qualified protection.'" 631 F. Supp. 2d at 447-48 (quoting Trans Union Corp. v. FTC, 267 F.3d 1138, 1141-42 (D.C. Cir. 2001)).

of proof. Here, too, the court underestimated the strength of the State's showing. As I explained in Ayotte, a state legislature's investigation cannot reasonably be expected to match the exhaustive investigation Congress conducts in connection with complex federal legislation. See 550 F.3d at 92-93 (referring to the "'tens of thousands of pages' of materials" acquired during three years of Congressional hearings on provisions of the Cable Television Consumer Protection and Competition Act of 1992).

Although the extent of the required proof may differ, the question in both federal and state contexts is the same: "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[.]'" Id. at 93 (quoting Turner Broad. Sys., Inc. v. FCC, 512 U.S. 622, 666 (1994)). A further complexity, however, is whether "the general principle of legislative deference" should operate the same way in both settings, despite differences in the scope of the underlying record. Id. In Turner Broadcasting, the Supreme Court observed that 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." Turner Broad. Sys., Inc. v. FCC, 520 U.S. 180, 195 (1997) (quotation marks and citation omitted).

The district court in this case puzzled over the appropriate level of deference for the legislature's findings, noting the subtle "distinction between judicial deference and judicial respect to a legislature in a First Amendment case." 532 F. Supp. 2d at 178. It noted the Ayotte trial court's conclusion that the legislature's "predictive judgments" were "entitled to respect, but not deference, because there was nothing in the record 'to support a conclusion that the legislature had established expertise in the regulation of prescriber-identifiable data.'" Id. (quoting IMS Health Inc. v. Ayotte, 490 F. Supp. 2d 163, 177 n.12 (D.N.H. 2007)).<sup>58</sup> Yet the court also cited the Supreme Court's statement in Turner Broadcasting that "the 'obligation to exercise independent judgment when First Amendment rights are implicated is not a license to reweigh the evidence de novo, or to replace [legislative] factual predictions with our own.'" Id. at 178-79. Indeed, the Supreme Court has "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.'" Florida Bar v. Went For It, Inc., 515 U.S. 618, 628 (1995) (citations omitted).

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<sup>58</sup> The district court in Vermont also was faced with competing arguments about "the nature and amount of deference" that should be afforded to "the predictive judgments and factual findings of the Legislature." Sorrell, 631 F. Supp. 2d at 448-49.

The legislative records in New Hampshire and Maine were necessarily limited. Given the novelty of their statutes, neither State could offer "empirical data showing the extent of the influence of prescriber-specific information on physicians' decision-making" or proving the cost-cutting impact of their provisions. 550 F.3d at 93. Both States, however, adduced evidence of the impact of detailing generally and presented anecdotal evidence "strongly indicating that sales pitches based on specific prescribing patterns have a particularly persuasive impact on drug choice." Id. at 94; Rowe, 532 F. Supp. 2d at 172. New Hampshire offered expert evidence in defense of its view that alternative strategies, less burdensome on speech, would not suffice. Ayotte, 550 F.2d at 100. At this point in time, such evidence was sufficient in each case to "establish[] a factual basis justifying the initiative." Id. at 94. Equivalent evidence may not be enough to support the adoption of similar legislation in other states, however, if more extensive quantifiable data becomes available. Cf. Ayotte, 550 F.3d at 93-94 ("[I]t 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.").

Without a doubt, the States must have flexibility to experiment with measures that will help them address the serious

problem of spiraling drug costs. At the same time, the restriction of speech based on its content is a serious constitutional matter. The tension between those principles in laws such as those enacted in New Hampshire, Maine and Vermont presents a challenge to the Supreme Court's commercial speech jurisprudence that warrants the Court's attention and guidance.