09-1913-cv(L)

09-2056-cv(CON)

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

IMS HEALTH INCORPORATED, VERISPAN, LLC, SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of Wolters Kluwer Health, Inc., and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Plaintiffs-Appellants,
v.
WILLIAM H. SORRELL, as Attorney General of the State of Vermont, JIM DOUGLAS, in his official Capacity as Governor of the State of Vermont, and ROBERT HOFMANN, in his capacity as Secretary of the Agency of Human Services of the State of Vermont,
Defendants-Appellees.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

BRIEF OF APPELLEES

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ISSUES PRESENTED FOR REVIEW

1. Whether, consistent with the First Amendment, Vermont may restrict the nonconsensual commercial use of data that identifies doctors and other health care professionals in prescription drug records?

2. Whether the dormant Commerce Clause allows Vermont to restrict the use of data in prescription drug records, where the drugs are prescribed by Vermont doctors and dispensed within the state?

STATEMENT OF THE CASE

To promote public health, reduce health care costs, and protect medical privacy, the Vermont Legislature adopted a restriction on the commercial use of certain data taken from non-public prescription drug records. *See* Vt. Stat. Ann. tit. 18, § 4631 (SPA-67-69). Specifically, the Prescription Confidentiality Law[1] restricts the use of data that identifies the doctor (or other prescriber) who prescribed the drug to the patient. *Id.* § 4631(d). This identifying data may be used for marketing and promoting prescription drugs only if the prescriber consents. *Id.*

The three data-vendor plaintiffs, IMS Health, Verispan, and Source Healthcare, filed suit in August 2007, claiming the law violated the First Amendment and the dormant Commerce Clause. PhRMA, a trade organization for pharmaceutical manufacturers, filed its own lawsuit not long after, and asserted a similar First Amendment claim. PhRMA also pursued other claims that it has dropped on appeal,

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[1] Plaintiffs invented the label "Prescription Restraint Law." IMS Br. 2. The statute is captioned "An Act relating to prescription confidentiality." 2007 Vt. Acts & Resolves, No. 80, § 17.

including an effort to block implementation of a program to educate doctors about prescribing practices. *See* SPA-49-60.

The district court consolidated the two cases and held a five-day bench trial in July 2008. The court heard testimony from numerous witnesses and admitted "reams of exhibits" into evidence. SPA-12. The court also allowed several months of post-trial briefing, including briefs in response to the First Circuit's decision upholding a similar New Hampshire law. A-53-55; *see IMS Health Inc. v. Ayotte,* 550 F.3d 42 (1st Cir. 2008), *cert. denied,* 129 S. Ct. 2864 (2009).

The district court then issued a decision upholding the Prescription Confidentiality Law. Treating it as a regulation of commercial speech, the court applied the *Central Hudson* test. SPA-17-38. The court concluded that the law (1) directly advances the State's interests in protecting public health and reducing health care costs and (2) is narrowly tailored to achieve those interests. SPA-23-38. The court also concluded that the law regulates Vermont transactions and thus does not violate the dormant Commerce Clause. SPA-40-49.

Plaintiffs appealed and moved for an injunction barring enforcement of the law pending appeal. The district court denied the injunction, reasoning in part that public health concerns outweigh plaintiffs' economic interests. A-5156. A panel of this Court also denied plaintiffs' motion, concluding that plaintiffs did not "demonstrate[] a clear or substantial likelihood of success on the merits." DE 6/26/09 (quotation omitted). The law became effective July 1, 2009.

FACTS

Pharmaceutical manufacturers use data mined from non-public prescription drug records in aggressive marketing campaigns designed to increase the number of prescriptions written for new and expensive brand-name drugs. Although plaintiffs largely disregard this fact, the evidence in the legislative record and in the trial record is compelling – and often uncontroverted. Data mining is a "covert" marketing tool used to target doctors, monitor the success of sales techniques, and compensate sales representatives based on the number of brand-name prescriptions written by doctors in their territories. SPA-27-31. The practice invades the privacy of the doctor-patient relationship and leads

to the unjustified, costly, and sometimes risky over-prescription of new drugs. The record shows how data mining works and proves that this narrowly tailored law directly advances the State's interests in medical privacy, cost containment, and public health.

I. Data mining and pharmaceutical marketing

The record provides a wealth of detail showing how data is taken from prescription records without consent and then used to "covert[ly] influence" doctors' prescribing decisions. SPA-29.

A. Collection of identifying data from non-public health records

Because the government regulates the dispensing of prescription drugs, pharmacies acquire detailed health and other identifying information from patients and doctors. By law pharmacies must obtain this information and adopt policies to protect confidentiality. A-222-23; Vt. Board of Pharmacy Administrative Rules, Pt. C, §§ 5.3, 18.1.2.8, 19.1, 19.3.1.9 (eff. Aug. 15, 2003).[2]

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[2] Available at: http://www.vtprofessionals.org/opr1/pharmacists/rules/Pharmacy%20Rules%20Currently%20in%20Effect.pdf

A few years ago, nationwide news reports publicly revealed the little-known practice of prescription-drug data mining. *E.g.,* A-4218. Data mining companies (called "data vendors" in the industry, *see* A-220) pay pharmacies for data from prescription records. A-221. The data includes "the prescriber's name and address, the name, dosage and quantity of the drug, the date and place the prescription is filled and the patient's age and gender." SPA-3; *e.g.,* A-78; A-99-100; A-3833.

The patient's name is encrypted, but even so, this de-identified patient information is monitored. A-99-101; A-3822. The encryption programs allow data vendors to "track [a] person over time and determine behaviors" – including the drugs prescribed and the doctors who wrote the prescriptions. A-101-102. Verispan testified that it has "track[ed] the activities of over two hundred million" patients, A-98, and explained that its "linking codes" allow Verispan to "link up" any of what it calls "the five P's" – the patient, product, prescriber, payer, and pharmacy. A-100-101.

The data thus discloses substantial information about specific doctor-patient relationships. Jane Doe's records, for example, might

show a 50-year-old woman who lives in central Vermont; has prescriptions filled in Montpelier; is a patient of Dr. Jones in Montpelier; and regularly takes an antidepressant and a cholesterol-lowering drug. The data would also reveal other prescriptions, treatment by other doctors, and changes in treatment over time.

Along with treatment of specific patients, the data shows doctors' "prescribing patterns." SPA-4. Prescribing patterns include the number of prescriptions written for particular drugs and classes of drugs, and typical choices for first-line therapy, switches in treatment, and drug combinations. Going back to Dr. Jones in the example above, data vendors see how often Dr. Jones prescribes cholesterol-reducing drugs; how often she prescribes certain drugs in that class; and whether she typically uses one drug as first-line therapy. Data vendors track this information over time and compare (or "segment") doctors based on prescribing practices. *E.g.,* A-102-103; A-3779-3801, A-3832-3835 (promotional materials describing data vendors' products). According to Verispan's witness, "if you consider the marketplace a game that for-

profit companies are taking on, our data . . . . [is] essentially the scoreboard." A-103.

Doctors and patients have no choice but to provide this treatment information to pharmacies for patients to obtain necessary health care. Until Vermont's law took effect on July 1, 2009, no pharmacy or data vendor had ever asked a doctor (or a patient) for consent for the use of this identifying information in marketing.

B. Licensing of the data and prohibition on disclosure

After data vendors purchase and edit this data, the companies license its use to pharmaceutical companies – in exchange for a substantial fee. A-83, A-106. Data vendors are not publishers, although they claim that label, because they do not make prescriber-identifiable data available to the public. *See* Black's Law Dictionary (8th ed. 2004) (to "publish" means to "distribute copies (of a work) to the public"). Data vendors' licensing agreements expressly *prohibit* publication or disclosure of prescriber-identifiable data. A-93; A-109; A-118.

Indeed, the data vendors "all prohibit detailers from disclosing PI data to a prescriber." SPA-31 n.15. A sales representative may not talk

to a doctor about the doctor's own prescribing practices. The data may "not be shared with anyone." A-3398.

C. Use of the data as a marketing tool

Pharmaceutical manufacturers use prescriber-identifiable data "as a marketing tool." SPA-5; *see generally* A-3779-3853 (industry materials describing marketing uses of data); A-3863-3875 (IMS articles promoting use of data); *see also, e.g.,* A-3890-3892, A-3902-3908, A-3923-3926, A-3967-3972, A-3975, A-4002-4011 (sales training materials). Pharmaceutical manufacturers are "essentially the only paying customers of the data vendor industry," SPA-29, and they use the data solely or principally for marketing prescription drugs, A-112; A-217. Other uses are incidental, and some companies disclaim any use other than marketing. *See, e.g.,* A-217 (data used only for marketing); A-3443-3444 (data not used for safety alerts or recalls);
A-215 (for safety alerts, data used only for follow-up after alert is sent out "broad and fast"); A-3445-3446 (data not used for clinical trials; "it would be inappropriate to identify clinical trial investigators based upon" prescribing data).

Prescriber-identifiable data is used for detailing. "Detailing is the 'face to face advocacy of a product by sales representatives' who visit health care professionals." SPA-5 (quoting *Ayotte,* 550 F.3d at 71 (Lipez, J., concurring)). Pharmaceutical manufacturers employ thousands of sales representatives and spend close to $8 billion dollars each year (not counting the cost of free samples) marketing drugs to doctors. SPA-4; A-211; A-3808; A-3858. "Coincident with the phenomenon of 'data mining,' pharmaceutical industry spending on direct marketing has increased exponentially." SPA-5.

This massive marketing effort is focused almost entirely on brand-name drugs that retain patent-protection. Under federal law, when a drug's patent expires, generic competitors may enter the market through an abbreviated drug approval process. Generic drugs cost far less money than brand-name drugs, so once a generic version is available, the original manufacturer's marketing efforts generally cease. SPA-5; A-309; A-3389; A-3143-3144; A-3267-3268. *See also infra* 18-21 (discussing generic drugs).

Prescriber-identifiable data is used to maximize sales and market share before a drug loses patent protection. IMS promotes its products as "reaping big returns" for pharmaceutical manufacturers and explains how companies increase their market share – in one case, by 86%. SPA-27; A-3872-3875. The point of using the data is to increase prescriptions and revenue – and data vendors are not shy about pointing this out. For example, Source Healthcare says that prescriber-identifiable data gives detailers "access to your most valuable prescribers," which in turn leads to "more prescriptions," and "increased revenue and profits." A-3799-3800. This theme is repeated throughout the industry materials: use of the data increases sales. *See, e.g.,* A-3790; A-3794; A-3813; A-3824-3826; A-3832; A-3843. IMS puts it bluntly: the use of prescriber-identifiable data "*maximize[s] the revenue per call and scripts per detail*." A-3834 (emphasis added).

The data is not used to educate doctors. SPA-28. Instead, it is used covertly, SPA-29-30, in an effort to influence doctors' prescribing practices – to *change* the drugs they prescribe to their patients. *E.g.,* A-319-322. As explained by a witness who used prescriber-identifiable

data "almost every day" as a sales representative, A-316, the goal of detailing is to "shift[] the physician's prescribing patterns" without the physician "being significantly aware of how or why" the shift occurred, A-320. Sales representatives do not, of course, reveal their information about doctors' prescribing practices; rather, they "pretend [they] don't know" while making use of the data to develop a sales pitch that places the product "in the best possible light." A-324, A-320.

The record contains detailed information (from both industry sources and academic research) about how prescriber-identifiable data is used to sway doctors' prescribing choices without their knowledge. *See generally* A-3779-3853 (data-vendor documents); A-3863-3875 (trade articles); A-3882-4019 (pharmaceutical marketing materials); A-319-329 (former sales representative's testimony); A-106-109, A-113-116 (data-vendor testimony); A-295-297, A-340-342, 347-350 (expert testimony); A-4301-4314, A-4223, A-4188-4190, A-4198-4206, A-4352-4356, A-4225-4229, A-4218-4222, A-4318-4322, A-2027-2029, A-4230-4236 (legislative record). Space allows for only a brief summary of these practices.

Frequent updates to detailers on prescribing trends for individual doctors. Information on doctors' prescribing practices is provided rapidly, with data available on a weekly basis. A-113, A-3781. Sales representatives track the detailed prescribing practices of doctors in their sales territories. A-106; A-113-115; A-3820; A-3781-3790; A-3213-3218; A-3828-3845. For example, they get email "alerts" telling them that certain prescribers are "underperforming" and others have stopped using the company's products. A-3831. Sales representatives use this information to plan their sales calls and strategies. A-320; A-4005-4007; A-3902-3904; A-3937.

Targeting "high-value" prescribers. Pharmaceutical manufacturers and their sales representatives use prescriber-identifiable data to target certain "high-value" prescribers for more attention. These are doctors that prescribe a lot of drugs and have the potential to drive market share. A-115-116; A-319; A-3829; A-3837; A-3839; A-3820; A-3799-3800; A-3812; A-3921; A-3937. Sales representatives are taught to focus on "the highest potential prescribers," A-3799, not to look for doctors who may need information about a product. This focus on "high prescribers"

means other doctors do not get information about new drugs. A-284; *see* A-3918, A-3921, A-3931, A-3199, A-3387-3388, A-3923-3926 (marketing documents). As one company puts it, sales representatives should focus on those "Top Potential Physicians that can help move share" and doctors who do not drive market share should be "deleted" from the sales representative's target list. A-4002-4007.

Using data to adapt marketing messages for maximum sales impact. As IMS says, prescribing data "can drive tailored brand messages and strategies that resonate strongly with physicians." A-3873. So, sales representatives use prescribing data to "craft their marketing message in a way that contrasts their product with what the physician is currently prescribing" and to "push the physician's behavior toward their product." A-296. A former sales representative explained how he developed a sales message using the data, but never mentioned the competitor drugs prescribed by a doctor by name. A-322. He described that kind of sales presentation as "true" but "very skewed" and "distorted." A-322; *see also* A-296 (expert testimony on how sales

representatives use data to provide information in "a selective manner").

Monitoring the effectiveness of sales techniques. Because pharmaceutical manufacturers get so much information about doctors' prescribing practices, they are able to monitor the effectiveness of marketing strategies. Data reports "help quickly show the impact on physician prescribing of market events and promotional activities." A-3782. Weekly prescriber reports allow sales representatives to correlate sales activity with prescriber activity and gauge the effectiveness of marketing. A-107-108; A-114; A-3789; A-3828; A-3832; A-3839-3940; A-3782-3790. They can decide whether a doctor is "responding positively" to a message or "promotional tactic," A-3798, and "tailor their message appropriately." A-3786.

Implementing specific marketing tools. Pharmaceutical manufacturers use prescriber-identifiable data to implement and evaluate specific marketing tools like gifts, drug samples, and lectures. A-297; A-323; A-327; A-3828-3829; A-3844. For example, drug samples are calibrated to encourage new prescriptions without supplanting paid

prescriptions for the drug. A-3404-3405; A-3874; A-3828. Sales teams use the data to implement physician speaker programs (nominally educational), with the goal of increasing "market share." A-4011.

Compensating sales representatives based on sales quotas. A lead trial witness for IMS opined that the "two most important questions" facing a sales representative are "(1) How much am I getting paid?, and (2) What do I need to do to make more money?" A-93, A-3874. Prescriber-identifiable data answers these questions, *id.*, and "motivate[s] sales reps by providing instant feedback." A-3848-3849. Indeed, pharmaceutical manufacturers routinely use the data to measure sales performance, and typically 20-25% of compensation is based on sales quotas. A-216-217; A-3640-3642, A-3710; A-3462-3467; A-3143-3145. The point is not merely that sales representatives are compensated based on sales, but that prescriber-identifiable data is used to aggressively push sales representatives to sell more drugs. The "payout calculator" is a concrete illustration. A-3318-3319. Monthly data reports show projected payout information for sales representatives – "the best part of the report!" A-3892. To get paid

"100%," the sales representative must "achieve 100%" of the sales goal. The sales representative can also "set a stretch goal based on your desired incentive payout. . . . Plug in your desired payout and the calculator will show what volume or share you will need to achieve to get there." A-3891.

This use of the data expressly links compensation with the need to "move" doctors "in the right direction." A-3904. Managers identify doctors that sales representatives visit but "are not writing for you." A-3902. They provide specific advice like: "These are important doctors in your territory, but they are really dragging down your share. If you move 10 of these doctors by 5 percentage points, you will hit your goal easily." A-3903.

II. Impact on prescribing practices and the doctor-patient relationship

This nonconsensual, covert use of prescriber-identifiable data in marketing threatens medical privacy, contributes to rising health care costs, and increases potential risks for patients. The State's evidence, including the testimony of its well-qualified and independent experts, is

addressed more fully in Part II of the Argument. The following summary shows the strength of the State's case.

A. Brand-name drugs and generic drugs

Some background information about prescription drugs provides the necessary context for the evidence and arguments that follow.

As explained above, after FDA approval, a pharmaceutical manufacturer markets a new patented drug with a right to a period of market exclusivity. On average, the manufacturer has 11.5 years to market the drug without competition. Then generic manufacturers may introduce "bioequivalent" versions of the same drug. A-136-137; A-309. Generic competition drives down prices substantially. *Id.* For most patients, generic drugs are equally safe and effective.[3] A-189; A-280. Pharmacists routinely substitute bioequivalent generic drugs for brand-name drugs, unless a doctor specifies otherwise. Thus, sales of a brand-

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[3] Generic drugs are not identical to brand-name drugs. The FDA has standards for bioequivalence. A-136-137. For certain conditions like epilepsy, "there may be medical reasons to prescribe a brand-name drug" even where a generic bioequivalent is available. SPA-34; A-343. Vermont's law "has no effect on doctors' ability to prescribe a brand-name drug." SPA-34.

name drug generally drop off substantially once generic versions enter the marketplace. SPA-27; A-309-310.

Key to understanding the evidence in this case, however, is the distinction between drugs that are bioequivalent (the patented drug and its later direct generic competitors) and drugs that are therapeutic equivalents. A-309. Drugs are organized into therapeutic classes. Within these classes, several drugs may provide substantially the same benefit and be considered therapeutic equivalents. A-309. Some of those drugs may be available as generics. A-342. However, unlike a bioequivalent generic drug, a therapeutic equivalent is not the same drug and may not be substituted by a pharmacist. A-309.

A critical fact, accepted by the Legislature, the district court, and plaintiffs' own witnesses, is that new drugs are not necessarily better than existing, older drugs in a therapeutic class. SPA-27; *see also* A-4040; A-280; A-342; A-311. The FDA generally does not require any showing that a new drug is "better than or even equivalent to drugs on the market." A-342. Rather, the manufacturer must show the drug "is more effective than placebo in a . . . small trial of a limited number of

patients." *Id.* Many newly approved drugs offer little or no therapeutic improvements over existing drugs, including older drugs available as generics. A-342; A-311. Plaintiffs' own witnesses agree that within the same therapeutic class, most generic drugs have the same therapeutic value for patients as branded drugs. A-280; A-189.

Moreover, an added benefit for older drugs is that their use is better understood and they carry fewer risks. A-345. "Multiple studies" show that newly approved drugs "can present increased risks to patients." A-344. New drugs are tested in small populations comprised of people who, in general, are healthier than the people who receive the drug after it is approved. When the drug is prescribed more widely to people who have more co-morbidities (multiple illnesses) and who take more drugs, other risks and side effects are revealed. A-344. Also, new drugs may be approved based on a specific marker like lowering cholesterol, not on health outcomes like heart attack or stroke. *Id.* After approval, "new safety concerns" can emerge, new warnings may be added, and some drugs may be withdrawn from the market. A-344-345. Serious "black box" warnings and drug recalls are more likely in the

first few years a drug is on the market. After a drug has been on the market for a number of years, its use and side effects are better understood. *Id.*

B. Rising prescription drug costs and potential for savings

As the district court found, both health care costs and prescription drug costs "have escalated considerably over the past decade, easily outpacing inflation." SPA-23. Moreover, while spending on prescription drugs has risen steadily, at double-digit rates, "the number of prescriptions written has risen by only a few percentage points per year. Therefore, the prices paid for prescription drugs are increasing." SPA-23 n.12; A-117; A-3804-3805.

Shifting prescribing practices even slightly in favor of generic drugs would provide substantial savings for Vermonters. Annual spending on prescription drugs in Vermont is about $480 million dollars, and a brand-name drug costs, on average, $70 more per prescription than a generic drug. A-310-311. Shifting prescribing practices in favor of generics by just 1% would save over $2 million each year. SPA-29; A-311.

C. Influence of marketing using prescriber data on prescribing practices

Pharmaceutical marketing has a negative influence on prescribing practices. SPA-28; A-243, A-248; A-256, A-258-259; A-341-342. Marketing influences doctors to prescribe new drugs that are more expensive than equally effective older drugs, and to prescribe new drugs contrary to recommendations of accepted treatment guidelines. SPA-28, SPA-33; *see, e.g.,* A-243-244 (describing studies); A-312 (Nexium as case study); A-342, A-346, A-348 (examples: proton pump inhibitors, Vioxx, and hypertension drugs). The district court squarely rejected plaintiffs' effort to minimize the influence of their marketing efforts, noting that "[r]esearch shows doctors are influenced" by marketing and plaintiffs' contrary claim "is belied by the nature of the industry, plaintiffs' own documents, and scientific research." SPA-28. One expert doctor summed up the influence of marketing using prescriber-identifiable data this way: "[P]harmaceutical marketing practices have a very strong impact on physician's prescribing habits. And this data helps pharmaceutical sales representatives attune their messages for the highest advertising and promotional effect." A-341-342. As the lower court found, the use of

prescriber-identifiable data "amplifies the influence and effectiveness of detailing but does not add to its purported educational value." SPA-28.

D. Over-prescription of new drugs

Because the use of prescriber-identifiable data in marketing campaigns leads to inappropriate prescribing of new drugs, restricting its use will reduce both health care costs and unnecessary risks to patients. SPA-29; SPA-33. The use of the data as a marketing tool leads to the "over-prescription" of new drugs and "over-accelerat[es]" the uptake of a new drug when the drug first enters the market. A-348. The district court accurately summed up the State's comprehensive evidence on this point, explaining how "new drugs often have no therapeutic benefit" and "sometimes carry risks." SPA-35; *see also* SPA-33 (citing plaintiffs' witness, Dr. Wharton). Detailing using prescriber-identifiable data thus leads to the "over-prescription" of new drugs that are "more expensive" and "potentially more dangerous" than generic alternatives. SPA-28-34.

E. Medical privacy and the doctor-patient relationship

Although the district court did not address the State's privacy interest, SPA-24, the evidence also shows that the nonconsensual use of prescriber-identifiable data in marketing undermines medical privacy. Pharmaceutical companies use extremely detailed information about doctors' prescribing practices – including their treatment of specific, though anonymous, patients – to influence doctors for the purpose of selling drugs. *See supra* 4-17. Doctors objected sharply to this "invasion of the physician's privacy," A-1433, and described prescribing data as "the most powerful weapon that pharmaceutical marketers have." A-2022. In its resolution supporting the law, the Vermont Medical Society advocated for confidentiality and privacy in the doctor-patient relationship. A-4197. According to the Medical Society, the "use of prescription information by sales representatives is an intrusion into the way physicians practice medicine." *Id*.

III. Legislative response

Contrary to plaintiffs' assertions, the Vermont Legislature gave the proposed legislation full consideration and compiled a detailed record in support of the law.

A. Legislative deliberations

Vermont was the third state to consider restricting the use of prescriber-identifiable data in marketing prescription drugs. SPA-5-7. Before the 2007 legislative session, the Vermont Medical Society unanimously endorsed a resolution asking the Legislature to end the practice. A-4197. The Medical Society urged legislators to adopt this reform. *Id.*; A-594-598; A-685-687; A-796-800; A-841-845; A-1070-1075; A-1433-1438.

Over the course of the 2007 session, the Legislature devoted substantial time to investigating the manner in which prescription drug data is used, without consent, for the marketing of prescription drugs. The Legislature's analysis was part of a broader look at the issue of rapidly escalating spending on prescription drugs. Multiple legislative committees spent months amassing and reviewing information and

testimony from a broad range of interested parties. *See, e.g.,* A-4125-4129, A-4336-4344, A-4473-4475, A-1486-1874 (summaries of hearings, witnesses, issues, and draft bills). Witnesses included public officials, the Medical Society, doctors, prominent scholars, consumer groups, trade organizations, pharmacists, data vendors, PhRMA and some of its members, and other interested persons and groups. A-4126-4128, A-4343-4344 (witness lists); *see generally* A-405-1482 (thousands of pages of committee hearing transcripts). Several of plaintiffs' trial witnesses provided legislative testimony or reports. *E.g.,* A-4609(Frankel); A-2103-2149 (Turner).

While the Legislature was considering the proposed bill, the district court in New Hampshire invalidated that state's ban on the use of prescriber-identifiable data for marketing prescription drugs. (That decision was overturned by the First Circuit in 2008.) The House committee working on the bill reviewed the court's ruling and changed the bill to respond to certain concerns raised by the court. *See, e.g.,* A-4368 (legal scholar addressing New Hampshire ruling). The committee adopted findings based on the record developed over the preceding

months and set forth a clear statement of the Legislature's intent. A-4040-4044. The committee also narrowed the bill, changing it from a ban on the use of prescriber-identifiable data in marketing to a provision that allows prescribers to decide whether their data may be used for marketing prescription drugs.[4] A-1680-1685. The final law included these changes. 2007 Vt. Acts & Resolves, No. 80, § 17 (statute as originally enacted) (A-4062-4065); 2008 Vt. Acts & Resolves, No. 89, § 3 (amending statute) (A-4074-4076).

B. Legislative findings

As noted above, in response to the New Hampshire District Court's observation about the lack of findings in support of that state's law, the Legislature adopted detailed findings supporting the Prescription Confidentiality Law. 2007 Vt. Acts & Resolves, No. 80, § 1 (A-4040-4044). The findings reflect the Legislature's core concerns: that the use of prescriber-identifiable data intrudes on the doctor-patient

[4] At the New Hampshire hearing, that court had suggested that a law based on prescriber consent would likely be upheld. A-4678-4683.

relationship, contributes to increased spending on prescription drugs, and harms patient health. A-4044 (Finding 31).

The Legislature's findings about medical privacy describe the marketing practices of pharmaceutical companies and the objections of doctors to the use of prescriber-identifiable data as a marketing tool. The findings acknowledge the Medical Society's strong support for the measure and doctors' belief that this marketing tactic intrudes on the doctor-patient relationship. A-4043-4044 (Findings 20-29).

Given the State's keen interest in controlling health care costs, the Legislature looked closely at the use of prescriber-identifiable data to push doctors to prescribe the newest and most expensive new drugs. Consistent with the evidence discussed above, the findings describe the way marketing drives unnecessary drug costs. A-4040-4041 (Findings 3-4, 7, 9, 14-18). The legislative record also detailed the potential risks of new drugs, and the Legislature's findings accordingly address patient safety and public health. A-4040-4041 (Findings 7-8).

PhRMA wrongly asserts that these findings contain "pervasive" errors. PhRMA Br. 20. The fact that plaintiffs' witnesses disagreed with

certain findings at trial does not make them erroneous. The State canvassed the legislative record and submitted to the district court a document that summarizes the evidence in support of each finding. A-5044-5141 (Annotated Legislative Findings). PhRMA fails to acknowledge, much less rebut, the State's presentation of this evidence from the legislative record. *See* PhRMA Br. 20-22. With the minor exception of the description of a study referenced in Finding 14 (*see* A-5112), the findings are firmly grounded in the legislative record. For a summary of the evidence supporting the findings challenged by PhRMA, see A-5100-5102; A-5106-5107; A-5112-5117; A-5121-5232.

C. The statute

The Prescription Confidentiality Law creates two narrow restrictions on use of prescriber-identifiable data in prescription records. First, absent the prescriber's consent, covered entities (principally pharmacies and insurers) cannot "sell, license, or exchange for value" a prescriber's identifying information or "permit the use" of a prescriber's identifying information for marketing or promoting a prescription drug. Vt. Stat. Ann. tit. 18, § 4631(d). Second,

pharmaceutical manufacturers and pharmaceutical marketers cannot "use" a prescriber's identifying information for marketing or promoting a prescription drug without the prescriber's consent. *Id.* Prescribers may consent at any time and are asked about the issue on their license application and renewal forms. *Id.* § 4631(c). The law specifically exempts use of the data for other purposes, including health care research, treatment, and safety-related uses such as "recall or patient safety notices." *Id.* § 4631(e)(1), (4).

The law applies only to the records of prescriptions written by a Vermont prescriber and dispensed within Vermont, *id.* § 4631(b)(9), and restricts only the use of information identifying the prescriber, *id.* § 4631(d), (e)(7). As relevant to this case, the statute regulates pharmacies (who obtain prescribing data in the course of their business) and pharmaceutical manufacturers (who use the data in marketing). The law does not regulate data vendors. *See id.*

IV. District court's decision

Over five days of trial, the district court heard from eighteen witnesses and admitted "reams of exhibits, including the entire

legislative history." SPA-12. The lower court viewed the law as a regulation of commercial speech, and, after "[c]areful consideration," found that Vermont satisfied the requisite intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission,* 447 U.S. 557, 566 (1980). SPA-22.

The court held that the State's interests in controlling health care costs and improving patient safety are both substantial. SPA-24. As to costs, the court found that prescriber-identifiable data "amplifies the influence and effectiveness of detailing" and that "[d]etailing leads to increased prescriptions for new drugs over generic alternatives which are often more cost-effective." SPA-28. The court grounded this conclusion in industry documents, SPA-27-28, testimony of the State's experts, Dr. Kesselheim, Dr. Wazana, and Dr. Rosenthal, SPA-27-30, and relevant testimony from plaintiffs' witnesses, *e.g.,* SPA-27 (noting Mr. Frankel's testimony that "generic drugs are as effective as other drugs in the same class for most patients").

The court likewise found that the law directly advances the State's interest in promoting public health, because "inappropriate prescription

of new drugs is harmful." SPA-35. The court recounted evidence about drugs like Baycol and Vioxx, which were widely and unnecessarily over-prescribed before being withdrawn from the market for safety reasons. SPA-33 (citing Drs. Kesselheim and Wharton). "Detailing encourages doctors to prescribe newer, more expensive, and potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines." SPA-33.

Turning to *Central Hudson's* narrow tailoring requirement, the court found that the law's "limited restraint," SPA-22, is "in reasonable proportion to the State's interests." SPA-38. The law is "a targeted response to the harm of overprescription caused by detailers use of" prescriber-identifiable data. SPA-37.

Lastly, the court rejected the data vendors' dormant Commerce Clause claim. The court concluded that the law only regulates information that originates in Vermont and conduct that occurs in Vermont – that is, it regulates Vermont pharmacies and pharmaceutical manufacturers that market drugs in Vermont. SPA-46.

STANDARD OF REVIEW

The district court's legal conclusions are reviewed *de novo*. With respect to the district court's findings of fact on "crucial" issues, the more rigorous standard of review for First Amendment cases – as set forth in *Bose Corp. v. Consumers Union,* 466 U.S. 485, 499 (1984) and *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Group of Boston,* 515 U.S. 557, 567 (1995) – may displace the "clearly erroneous" standard of Fed. R. Civ. P. 52(a). Under this standard, the Court "make[s] an independent and searching inquiry of the entire record." *Guiles v. Marineau,* 461 F.3d 320, 324 (2d Cir. 2006). In *Commodity Futures Trading Commission v. Vartuli,* this Court described as "arguable" whether *Bose* applies in the commercial speech context. 228 F.3d 94, 108 & n.7 (2d Cir. 2000). Because the *Bose* standard is intended to avoid "'a forbidden intrusion on the field of free expression,'" *Guiles,* 461 F.3d at 324 (quoting *Hurley,* 515 U.S. at 568), it may not be an essential part of the intermediate scrutiny that applies to regulations of commercial speech. *Cf. Bd. of Trs. of State Univ. of N.Y. v. Fox,* 492 U.S. 469, 477

(1989) (commercial speech occupies "subordinate position in the scale of First Amendment values").

Even if it applies, the *Bose* standard only requires "fresh examination of crucial facts," *Hurley,* 515 U.S. at 567, namely, the district court's findings that the law directly advances the State's interests and is narrowly tailored for those purposes. *Bose* review does not displace the district court's evaluation of witness credibility. *DiBella v. Hopkins*, 403 F.3d 102, 116 (2d Cir. 2005) (applying "traditional deference" to factfinder's "underlying credibility determinations" under *Bose* review). Nor does it alter the Court's usual deferential review of ordinary historical facts. *See Bose*, 466 U.S. at 561 n.31 ("it is not actually necessary to review the 'entire' record to fulfill the function of independent appellate review"). The Court should thus apply the clearly erroneous standard to the vast majority of the facts found below, including facts about the acquisition and sale of data, its use in marketing, the impact of detailing on prescribing practices, and the cost of this marketing practice as measured both in dollars and in unnecessary health risks. The Court should also accept the lower court's

implicit weighing of the credibility and persuasiveness of the witnesses, as reflected in the district court's reliance on the State's witnesses and rejection of factual claims made by plaintiffs. *See, e.g.,* SPA-27-29; SPA-31 & nn.13-15; SPA-32; SPA-33-35.

SUMMARY OF ARGUMENT

Vermont's restriction on the nonconsensual use of prescriber-identifiable data is constitutional. To begin with, this law represents at most a minimal intrusion on First Amendment interests. Plaintiffs' covert use of prescriber-identifiable data as a marketing tool forms no part of the "free exchange of ideas the First Amendment is designed to protect." *Denver Area Educ. Telecomms. Consortium v. FCC,* 518 U.S. 727, 740 (1996); *cf. Vartuli,* 228 F.3d at 111 (describing reasons for protection of speech). The law's "limited restraint," SPA-22, does not suppress information, ban advertising, or undermine "the public's interest in receiving accurate commercial information." *44 Liquormart, Inc. v. Rhode Island,* 517 U.S. 484, 496 (1996) (plurality op.); *see also Ayotte,* 550 F.3d at 100 (Lipez, J., concurring).

Moreover, unlike the "broadly based bans" on commercial speech invalidated in other cases, *see 44 Liquormart,* 517 U.S. at 497 (plurality op.), Vermont's law protects against the nonconsensual use of identifying data in health care records. This is not public information and plaintiffs do not have a First Amendment right to force doctors to give up their identifying information to be used in marketing campaigns.

Even assuming, as the lower court found, that Vermont's law restricts commercial speech, the statute readily withstands review. A regulation of commercial speech must (1) serve a substantial state interest; (2) directly advance that interest; and (3) be narrowly tailored, that is, not more extensive than necessary to serve the government's interest. *See Central Hudson,* 447 U.S. at 566; *Anderson v. Treadwell,* 294 F.3d 453, 460-61 (2d Cir. 2002). The latter two elements "coalesce to require 'a reasonable fit between the legislature's ends and the means chosen to accomplish those ends.'" *Anderson,* 294 F.3d at 462 (quoting *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 556 (2001)). The burden rests with the State to prove "that the harms it recites are real and that

its restrictions will in fact alleviate them to a material degree," *Edenfield v. Fane,* 507 U.S. 761, 771 (1993), but the Supreme Court recognizes a wide range of adequate justifications, including studies, anecdotes, history, consensus, and "simple common sense." *Lorillard,* 533 U.S. at 555 (quotation omitted).

Here, a detailed evidentiary record shows that the problem of aggressive and intrusive, targeted marketing using prescriber-identifiable data is real. It causes unnecessary, expensive, and potentially risky over-prescription of new drugs. It also invades doctors' privacy and intrudes on the doctor-patient relationship. The statute's narrow restriction on the commercial use of prescriber-identifiable data targets these harms identified by the State and goes no further. After careful and independent review of the evidence, the district court correctly concluded that the law survives intermediate scrutiny. SPA-19-38.

The district court's ruling finds strong support in the First Circuit's decision rejecting the data vendors' similar challenge to New Hampshire's data mining law. *Ayotte,* 550 F.3d at 60. In its ruling –

barely mentioned by plaintiffs – the *Ayotte* court reasoned, first, that New Hampshire's law principally regulates commercial conduct, not speech, and second, that even if the law regulates commercial speech, it satisfies intermediate scrutiny. *Id.* at 50-61. Judge Lipez concurred, concluding that New Hampshire met the demands of intermediate scrutiny, and providing a detailed discussion of the relevant evidence. *Id.* at 88-102 (Lipez, J., concurring). The record in this case is stronger than the record in *Ayotte,* and the reasoning of both the majority and concurring opinions is persuasive authority here.[5]

Plaintiffs neither address *Ayotte* nor distinguish this Court's decision in *Anderson v. Treadwell,* 294 F.3d 453 (2d Cir. 2002). In *Anderson,* the Court upheld an ordinance that allowed homeowners in certain neighborhoods to block real estate solicitations. *Id.* at 464. The *Anderson* plaintiffs argued that the law was content-based and subject to strict scrutiny. They also claimed the law was "underinclusive" because it applied only to real estate solicitations. The Court rejected

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[5] *Ayotte* was expedited in the district court, *see* 550 F.3d at 48, and New Hampshire had little time to develop the record through discovery.

both arguments. *See id.* at 460, 463. The Court upheld the "resident-activated restriction" as "precisely co-extensive with those who are experiencing the particular harm that it is designed to alleviate." *Id.* at 462. Such a restriction, the Court observed, "entirely avoids" any concern about "paternalism" because "it applies only where homeowners elect to seek its protection." *Id.* at 464.

The district court recognized the relevance of *Anderson* to this case, and relied upon the decision in rejecting several of plaintiffs' arguments. SPA-19, SPA-37-38. Yet plaintiffs repeat those same arguments here, claiming Vermont's law is "paternalistic," "content-based," and "under-inclusive," without attempting to explain or distinguish *Anderson. See, e.g.,* IMS Br. 31-34, 49-51; PhRMA Br. 33, 37, 48. Plaintiffs likewise advance arguments squarely rejected by *Ayotte,* without attempting to explain any error in the First Circuit's reasoning. Plaintiffs' incomplete and unpersuasive briefing provides no reason to overrule the district court or to depart from the holdings of *Anderson* and *Ayotte.*

Plaintiffs' dormant Commerce Clause argument is no more successful than their First Amendment claims. Vermont's law regulates the use of data from prescriptions written by Vermont physicians and dispensed within Vermont. It is "neither discriminatory nor protectionist," SPA-48, and does not affect the sale or use of prescriber-identifiable data for states other than Vermont.

Plaintiffs have not come close to satisfying their heavy burden in sustaining a facial challenge to Vermont's law. *See, e.g., Wash. State Grange v. Wash. State Republican Party*, 128 S. Ct. 1184, 1190-91 (2008) (disfavored nature of facial challenges). The district court's decision should be affirmed.

ARGUMENT

I. The Court's review of the Prescription Confidentiality Law should be informed by the law's limited scope and minimal intrusion on First Amendment interests.

Vermont's law gives doctors the right to limit the commercial use of their identifying information in non-public prescription drug records. This kind of "limited restriction" is readily distinguishable from "more sweeping bans on commercial speech" that the Supreme Court has invalidated. *Ayotte,* 550 F.3d at 94 (Lipez, J., concurring). Before turning to the substantial body of evidence that justifies Vermont's law, *see infra* Part II, the State begins by showing why, contrary to plaintiffs' assertions, this law treads lightly, if at all, on expression protected by the First Amendment.

The separate opinions in *Ayotte* and the district court's opinion below show that, indeed, the first question in this case is whether the law restricts any speech protected by the First Amendment. SPA-13-16; *Ayotte,* 550 F.3d at 50-54; *id.* at 79-83 (Lipez, J., concurring). It does not. Plaintiffs do not have a First Amendment right to access identifying information in non-public health records and use it for

marketing without consent. Assuming some First Amendment scrutiny is required, however, the law at most restricts commercial speech. There is no plausible basis for applying strict scrutiny. And plaintiffs' claims of "impermissibl[e] paternalis[m]" and "suppression of information," IMS Br. 20, are unfounded. This statute is "significantly more limited" than other restrictions on commercial speech; it does not ban marketing, price advertising, or in-person solicitation, and it does not "restrict the exchange of ideas." *Ayotte,* 550 F.3d at 97, 100 (Lipez, J., concurring). Thus, even if the Court applies intermediate scrutiny, the Court's review should be informed by the narrow scope of the law.

A. Data vendors and pharmaceutical companies have no First Amendment right to access non-public health records without consent.

Plaintiffs' claims are premised on the mistaken theory that they have an unrestricted First Amendment right to access data from non-public health records, without the consent of the doctor (whose identity they seek) or the patient (whose encrypted health information is used for marketing). For a concrete illustration, imagine the following. A pharmaceutical sales representative stops into a pharmacy in

Montpelier, Vermont. He tells the pharmacist, "I'm trying to promote some drugs to Dr. Jones, the internist with the office across the street. Give me a list of all the drugs Dr. Jones prescribed in the last three months, and while you're at it, tell me the date of the prescription and the age and gender of the patients. Here's a hundred bucks for your trouble." Dr. Jones is shopping in the pharmacy and hears this exchange. She objects, telling the pharmacist, "I don't want you to share that information, and I don't think my patients do either. These prescription records are health records and you are supposed to maintain their confidentiality." According to plaintiffs, the answer from the pharmacist is this: "I know you object and I know that no one has asked your patients about this, but I have a First Amendment right to sell data from my prescription records, even data that identifies you, and he has a First Amendment right to buy it."

This claim that the First Amendment protects a right to access and use health care records without consent should not be accepted by the Court, for at least three reasons: (1) privacy protections for health records do not trigger First Amendment review; (2) giving doctors – not

the government – the right to control the use of doctors' prescribing data does not restrict plaintiffs' speech; and (3) the consent requirement principally restricts commercial conduct.

1. Courts, legislatures, and health care professions have long recognized the confidentiality of health care records, including prescription drug records. In Vermont, for example, laws and regulations protect the confidentiality of the doctor-patient relationship and specifically protect prescription records against disclosure. *See, e.g.*,Vt. Stat. Ann. tit. 12, § 1612 (2009) (patient's privilege); *id.* tit. 18, § 1852(a)(7) (2009) (patients have "right to expect that all communications and records pertaining to his or her care shall be treated as confidential"); *id.* § 4211 (restricting disclosure of prescription records of regulated drugs); Vt. Board of Pharmacy Administrative Rules, Pt. C, §§ 5.3, 18.1.2.8, 19.3.1.9 (eff. Aug. 15, 2003) (confidentiality requirements). Federal law also protects the confidentiality of health care records. 42 U.S.C. § 1320d-6; 45 C.F.R. § 164.502.

In exchange for their license, pharmacists accept the confidentiality rules that govern their profession. And in Vermont, those confidentiality rules limit the use of prescriber-identifiable data. Pharmacists no more have a First Amendment right to sell prescription records for commercial use than doctors have a right to sell their patient information. *Cf. Mastrovincenzo v. City of New York,* 435 F.3d 78, 85 (2d Cir. 2006) ("Courts must determine what constitutes expression within the ambit of the First Amendment and what does not." (quotation omitted)).

In their filings below, plaintiffs asserted that licensed professionals may not be required to "forfeit speech rights." Doc. 306 at 14. Yet confidentiality rules are common, not just for doctors and pharmacists but for lawyers, accountants, and other professionals. *See, e.g.,* Vt. Rules of Professional Conduct, Rule 1.6 (confidentiality); Vt. Stat. Ann. tit. 26, § 82(a) (limiting disclosure of client information by accountants without consent). The paucity of litigation challenging these restrictions shows how little controversy exists on the subject. And when they have been challenged, courts have held that

confidentiality rules do not implicate the First Amendment. *See, e.g., Am. Motors Corp. v. Huffstutler*, 575 N.E.2d 116, 120 (Ohio 1991) ("as a *quid pro quo* for the privilege of being licensed to practice law, an attorney surrenders a fraction of the right of free speech guaranteed under the First Amendment"); *Pitre v. Curhan*, No. CIV.A.00-0053, 2001 WL 770941, *4 (R.I. Super. Ct. July 10, 2001) (unpub.) ("by choosing to engage in the practice of medicine [health care providers] have surrendered a portion of their free speech rights; no "protected right" to disclose "privileged health care information"); *Acosta v. Richter*, 671 So. 2d 149, 156 (Fla. 1996) (statute restricting disclosure of health care records did not violate First Amendment). Justice Stewart once observed that "[o]bedience to ethical precepts may require abstention from what in other circumstances might be constitutionally protected speech." *In re Sawyer*, 360 U.S. 622, 646-47 (1959) (Stewart, J., concurring) ("I doubt that a physician who broadcast the confidential disclosures of his patients could rely on the constitutional right of free speech to protect him from professional discipline.").

Although the Supreme Court has struck down some professional licensing rules on First Amendment grounds, those cases address restrictions on the ability to advertise one's services. *See, e.g., Edenfield v. Fane*, 507 U.S. 761 (1993) (CPA advertising); *Bates v. Arizona*, 433 U.S. 350 (1977) (attorney advertising); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976) (price advertising). The Supreme Court has not applied First Amendment scrutiny to a confidentiality rule for a licensed profession – much less to a rule that protects the privacy of non-public health care records.

The fact that plaintiffs encrypt patients' names in the records they buy and sell does not negate the State's ability to further protect the privacy of these records. A prescription itself is a non-public patient health care record that contains private information about the doctor-patient relationship. Even plaintiffs do not assert a First Amendment right for pharmacists to sell photocopies of patients' prescriptions to any willing buyer. Likewise, pharmacists have no First Amendment right to sell – and plaintiffs have no First Amendment right to buy – an

electronic copy of the prescription, even with the patient's name redacted.

2. Nor do plaintiffs have a First Amendment right to obtain prescriber-identifiable data *without the prescriber's consent*. The "essential thrust of the First Amendment is to prohibit improper restraints on the *voluntary* public expression of ideas." *Harper & Row, Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 559 (1985) (quotation omitted); *Wooley v. Maynard*, 430 U.S. 705, 714 (1977) (freedom of speech "includes both the right to speak freely and the right to refrain from speaking at all"). The Supreme Court has not recognized any First Amendment right to the nonconsensual use of identifying data for marketing purposes. *Cf. Zemel v. Rusk*, 381 U.S. 1, 17 (1965) ("The right to speak and publish does not carry with it the unrestrained right to gather information.").

While the Supreme Court has not considered a case precisely like this one, two decisions about the use or disclosure of personal identifying information are relevant. In the first, the Supreme Court rejected a First Amendment argument by data miners seeking access to

identifying information for arrestees. *See Los Angeles Police Dep't v. United Reporting Publ'g Corp.*, 528 U.S. 32, 40 (1999). Under California law, a person seeking an arrestee's address had to declare that it would be used for one of five purposes, and would not be used to sell a product or service. *Id.* at 35. The Supreme Court turned away a facial challenge to the law, holding that it was "not an abridgment of anyone's right to engage in speech, be it commercial or otherwise, but simply a law regulating access to information in the hands of the police department." *Id.* at 40.

Just so here. The Prescription Confidentiality Law does not restrict plaintiffs' speech, but rather allows *prescribers* to control the use of their own identifying information for marketing purposes. While *United Reporting* addressed the use of data held by a government agency, access to data in prescription records held by licensed, regulated pharmacies is not significantly different. The pharmacy obtains the data only because the government requires pharmacies to track the identities of customers and prescribers. The right to freedom of speech, which "presupposes a willing speaker," *Va. State Bd.*, 425

U.S. at 756, should not be used to compel doctors to disclose their prescribing practices for marketing purposes. Although "[t]here is an undoubted right to gather news 'from any source by means within the law,' . . . that affords no basis for the claim that the First Amendment compels others – private persons or governments – to supply information." *Houchins v. KQED, Inc.*, 438 U.S. 1, 11 (1978) (quoting *Branzburg v. Hayes*, 408 U.S. 665, 681-82 (1972)). The Sixth Circuit rejected a challenge to the Family Educational Rights and Privacy Act, because there is no "First Amendment right of access to student disciplinary records." *United States v. Miami Univ.*, 294 F.3d 797, 820-23 (6th Cir. 2002); *see also Amelkin v. McClure*, 330 F.3d 822, 827 (6th Cir. 2003) (statute restricting access to accident reports does not "restrict or even regulate expression" but "simply restricts *access* to confidential information possessed by the government"). Likewise, there is no First Amendment right to obtain doctors' prescribing data without consent.[6]

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[6] Several courts of appeals have treated laws requiring consent for the use of data as commercial speech regulations subject to intermediate

The Supreme Court also addressed the commercial use of identifying data when it upheld the Driver's Privacy Protection Act, a federal law that prohibits states from allowing commercial use of identifying data from drivers' licenses, absent the individual's consent. *Reno v. Condon*, 528 U.S. 141, 148 (2000). Rejecting a federalism challenge, the Court in *Reno* described "identifying information from license records" as no more than a "thing" in commerce. *Id.* at 148 (noting information was sold for use by entities "engaged in interstate commerce to contact drivers with customized solicitations"). *Reno* does not address First Amendment issues, but *Reno* unquestionably treats identifying data used for solicitations as a product traded in the commercial marketplace. *See id.* The prescriber-identifiable data at issue here is also a "thing" in commerce, bought and sold among pharmacists, data miners, and pharmaceutical companies. Congress has decided that drivers get to decide whether their identifying

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scrutiny. *See infra* Part I.B. Those rulings do not address access to health care records, nor do they address the special case of identifying data supplied to pharmacies involuntarily, as part of a government regulatory regime.

information is used for marketing. Vermont's law gives doctors the same control over their information.

3. Given the precise restrictions imposed by the Prescription Confidentiality Law and the facts about data mining supplied in the record, this Court should hold that the law regulates commercial conduct, not speech. As the *Ayotte* court correctly concluded, a restriction on the use of prescriber-identifiable data is a regulation only of the commercial conduct of data vendors, not their speech. 550 F.3d at 52-53. Vermont's law, like New Hampshire's, does not prevent data vendors from acquiring prescriber-identifiable data or selling the data to pharmaceutical manufacturers. The law "simply does not prevent any information-generating activities" because the data vendors may continue to acquire, edit, and "sell this information to whomever they choose, *so long as that person does not use the information for detailing*." *Id.* at 53. The restriction on use for detailing does not limit the speech of data vendors at all; "the restriction here is on the conduct (detailing) not on the information with which the conduct is carried out." *Id.*

Plaintiffs' assertions to the contrary are rhetoric, not fact. Data vendors buy and sell data as a thing in commerce, pursuant to contracts that already strictly control the uses of prescriber-identifiable data. SPA-39, SPA-31 & n.15; A-93 (IMS prohibits sharing data with third parties, including doctors, to "protect the value of the information"); A-109 (Verispan); A-118 (Source Healthcare). In his concurring opinion in *Ayotte,* Judge Lipez called it "self-evident" that the "acquisition, aggregation, and sale of prescriber-identifiable data" by data vendors is "not speech within the purview of the First Amendment." 550 F.3d at 64 (Lipez, J., concurring). The law's regulation of the use of data by pharmaceutical manufacturers does not restrict the speech of data vendors; it is a regulation of the commercial marketplace. *See id.* at 52-53.[7]

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[7] The Court's statement in *Universal City Studios, Inc. v. Corley,* 273 F.3d 429, 446 (2d Cir. 2001), that "even dry information, devoid of advocacy, political relevance, or artistic expression, has been accorded First Amendment protection," does not conflict with *Ayotte. Corley* does not address the commercial acquisition and sale of identifying data. *Cf. Vartuli,* 228 F.3d at 111-12 (automatic trading system not protected speech; noting need for "careful and particularized analysis").

The *Ayotte* court did not address the possible First Amendment rights of pharmaceutical manufacturers, because no manufacturer was a plaintiff in that case. The line between conduct and speech is closer on this issue because, as the district court concluded, one goal of the Prescription Confidentiality Law is to influence pharmaceutical marketing practices. SPA-28; SPA-14.

Notwithstanding this purpose, however, the law is a restriction on commercial conduct, because the law regulates the *nonconsensual use* of identifying data about particular persons. Prescriber-identifiable data is used as a marketing tool, to target messages and doctors, manage and compensate sales representatives, and track the success of marketing techniques. *See supra* 4-17. These are commercial practices, distinct from the advertising message itself. Prescriber-identifiable data is not disclosed to doctors as part of an advertising message. SPA-31 n.15.[8]

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[8] For this reason, a restriction on the use of prescriber-identifiable data is distinguishable from the restriction on advertisement placement at issue in *Lorillard Tobacco.* There*,* the Supreme Court held that a restriction on the height of in-store tobacco advertisements restricted speech, not conduct, because the State intended to "regulate *directly* the

In rejecting this argument, the district court relied upon *U.S. West, Inc. v. FCC,* 182 F.3d 1224, 1232 (10th Cir. 1999). In *U.S. West,* the Tenth Circuit held that an FCC rule requiring customer consent for the marketing use of telephone calling history was a restriction on commercial speech. *See also Sorenson Commc'ns, Inc. v. FCC,* 567 F.3d 1215, 1225 (10th Cir. 2009) (following *U.S. West*). The *U.S. West* court reasoned that a restriction on targeted marketing is a restriction on commercial speech, relying in part on Supreme Court cases that address the right of an audience to receive a message. *See* 182 F.3d at 1232. But requiring consent for the use of a person's data in targeted marketing does not restrict any marketing to a *willing audience.* A law like this one, that does not block solicitations but allows doctors to restrict the nonconsensual use of their data, should be treated as a regulation of commercial conduct.

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communicative impact of indoor advertising." 533 U.S. at 567 (emphasis added).

B. There is no basis for applying strict scrutiny here.

Even if the Court agrees that the Prescription Confidentiality Law restricts some protected speech, there is no basis for applying strict scrutiny to a law that regulates, at most, commercial marketing practices. *See* SPA-19; *Ayotte,* 550 F.3d at 54. Plaintiffs' arguments on this point are unpersuasive.

1. PhRMA erroneously contends that the law restricts noncommercial speech conveying risk and safety information to prescribers. PhRMA Br. 28. In fact, the law only restricts the use of prescriber-identifiable data for marketing and promoting prescription drugs. SPA-18; Vt. Stat. Ann. tit. 18, § 4631(b)(5) & (8), (d). The law expressly exempts recalls and patient safety notices, *id.* § 4631(e)(4), and thus PhRMA is wrong to suggest that it applies to "Dear Healthcare Professional" letters that alert doctors and patients to safety risks. *See* PhRMA Br. 28. PhRMA's assertion that these safety communications are covered by the statute is contrary to the statute's

plain language. *See* SPA-18 (statute does not apply to "safety notices").[9] Likewise, the data vendors' assertion that the statute prohibits communication about drug risks, drug safety, and disease management, IMS Br. 25-26 n.2, ignores the statute's clear exemptions. Vt. Stat. Ann. tit. 18, § 4631(e)(1), (4) (allowing, among other things, use for drug recalls, patient safety notices, treatment options, patient care management, health care research, and information provided to patient about patient's health condition).

2. PhRMA also suggests that any restriction on the use of prescriber-identifiable data for detailing is subject to strict scrutiny because detailers convey scientific or health information as part of their advertising messages. PhRMA Br. 28. PhRMA is wrong on this point and its reliance on *Riley v. National Federation of the Blind,* 487 U.S.

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[9] Pharmaceutical manufacturers do not typically use the data to send these letters, but instead put out a "blast of information" "broad and fast" to get a warning out to as many providers as possible. A-215; *see, e.g.,* A-3443 (data not used for safety alerts or recall notices). Also, few doctors keep records organized in such a way that they can easily identify which of their patients take a particular drug. Typically pharmacists send recall notices to patients. A-2203. Nonetheless, if pharmaceutical manufacturers seek to use prescriber-identifiable data to send recall notices and safety alerts, they may do so.

781 (1988), is misplaced. *Riley* addressed a regulation of charitable solicitations, not advertising. In that context, the Supreme Court held that mandatory disclosure of paid fundraising agreements could not be treated as a commercial speech regulation separate from the regulation of fully protected charitable solicitations. *Id.* at 788. The Supreme Court has rejected PhRMA's expansive reading of *Riley*. *See Bd. of Trs. of State Univ. of N.Y. v. Fox,* 492 U.S. 469, 474-75 (1989) (Tupperware parties that touched on educational topics were commercial speech; distinguishing *Riley*); *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 67-68 (1983) (pamphlets advertising birth control were commercial speech even though they discussed "important public issues" like family planning). This Court, likewise, has held that advertising that includes social commentary is nonetheless commercial speech where the advertising "identif[ies] a specific product and serve[s] the economic interest of the speaker." *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.,* 134 F.3d 87, 97 (2d Cir. 1998).

The purpose of detailing is to promote specific drugs and increase sales of those drugs, *see supra* 4-17, and thus detailing is

unquestionably commercial speech. PhRMA's contrary assertion not only disregards the record, but contravenes the arguments advanced by its own members in recent overtime-pay litigation. In those cases, pharmaceutical manufacturers contend that detailers are salespeople and therefore exempt from overtime pay under the Fair Labor Standards Act. A district court in this circuit has endorsed the industry's position, holding that the function of sales representatives "is to call on physicians in order to persuade them to write prescriptions for [defendant's] products." *Novartis Wage and Hour Litig.*, 593 F. Supp. 2d 637, 654 (S.D.N.Y. 2009), appeal docketed, No. 09-0437-cv (2d Cir. Feb. 2, 2009); *see also Baum v. AstraZeneca LP*, 605 F. Supp. 2d 669, 683 (W.D. Pa. 2009) ("primary purpose of [sales representative's] visits was to obtain, via a persuasive close, a physician's commitment to write more prescriptions"; "[representative] asked physicians to prescribe AstraZeneca products on every sales call"), appeal docketed, No. 09-02150 (3d Cir. April 24, 2009).[10] A detailer's effort to sell a product is commercial speech.

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[10] The State cites these rulings only to show the glaring inconsistency

3. The data vendors' claim that the law "forbids publication of truthful information on a matter of tremendous public concern" is contravened by the record and bears no relationship to the statutory language. IMS Br. 22. To begin with, data vendors do *not* publish prescriber-identifiable data. To "publish" means to distribute copies of a work "to the public." Black's Law Dictionary (8th ed. 2004). Data vendors license the use of data for a fee, pursuant to contracts that prohibit disclosure to anyone. There is no matter of "public concern" here; the data is taken from non-public health records and used as a covert marketing tool. Sales representatives are not even allowed to discuss the data with a doctor. SPA-31 n.15. Moreover, the data vendors consistently rely on an inaccurate description of the statute. The statute does not prohibit the acquisition or sale of data by data vendors. It

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between PhRMA's claims about detailing in this case, *see* PhRMA Br. 27-29, and the arguments advanced by PhRMA's members. In the *Baum* case, AstraZeneca argued that its sales representatives "were obviously employed for the purpose of making sales." 605 F. Supp. 2d at 677. Manufacturers have lost some overtime cases, but those rulings likewise show that manufacturers view sales representatives as making sales. *See, e.g., Kuzinski v. Schering Corp.*, 604 F. Supp. 2d 385, 395 (D. Conn. 2009), appeal docketed, No. 09-1945-cv (2d Cir. May 1, 2009).

restricts the use of data for marketing prescription drugs. Vt. Stat. Ann. tit. 18, § 4631(e)(1).

The district court properly focused on the use of the data by pharmaceutical manufacturers because that is what the law regulates – not, as the data vendors claim, their data-gathering activities. The law does not regulate data vendors at all. *See id.* § 4631(d); SPA-68. And it does not "prohibit[] the dissemination" of information. IMS Br. 27. Data vendors may acquire prescriber-identifiable data from pharmacies and sell the data to pharmaceutical manufacturers, so long as the data is not used for marketing prescription drugs. *See Ayotte,* 550 F.3d at 53 (law does not restrict acquisition and sale of data, only its use in detailing). To the extent the law restricts any speech – a point the State does not concede – it restricts the commercial speech of pharmaceutical manufacturers, who may no longer use prescriber-identifiable for detailing. *See id.* at 53 (affected speech is "communications between detailers and doctors"). Detailing is advertising, and falls within the definition of commercial speech. *See, e.g., Anderson,* 294 F.3d at 460 (real estate solicitations "properly characterized as commercial speech"

even though they combine "commercial and noncommercial elements"; relying on "common-sense distinction" between commercial and noncommercial speech (quotation omitted)).

4. Plaintiffs also try to justify strict scrutiny by arguing that a restriction on the use of prescriber-identifiable data for advertising is content-based and is a "prior restraint." IMS Br. 28-29. Both arguments are inconsistent with First Amendment precedent. The "Supreme Court's commercial speech doctrine . . . creates a category of speech defined by content but afforded only qualified protection." *Trans Union Corp. v. FTC*, 267 F.3d 1138, 1141-42 (D.C. Cir. 2001). This Court has specifically "rejected the argument that strict scrutiny should apply to regulations of commercial speech that are content-specific." *Anderson*, 294 F.3d at 460; *see also City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 416 (1993) (applying intermediate scrutiny to content-based regulation that restricted newsracks for commercial handbills). As for the prior restraint argument, this Court's precedents show that a claim of prior restraint in a commercial speech case does not change the level of scrutiny. *Nutritional Health Alliance v. Shalala*, 144 F.3d 220,

227-28 (2d Cir. 1998) (analyzing prior restraint argument as part of *Central Hudson* test).[11] In any event, the law is not a prior restraint; it does not "restrain" the prescription in advance, and it gives control over use of the data to doctors, not state officials. *See, e.g., United States v. Quattrone,* 402 F.3d 304, 309 (2d Cir. 2005) (prior restraint "suppresses speech – or provides for its suppression at the discretion of government officials – on the basis of the speech's content and in advance of its actual expression").

5. The commercial use of identifying data taken from non-public health records is nothing like the use of published news reports about publicly available stock prices. IMS Br. 27. The data vendors avoid discussing restrictions far more analogous to this one, because those analogies expose the weakness of their position. Data vendors could assert precisely the same argument to justify acquiring and selling data from credit card transactions, bank records, credit reports, video rentals, school records, and even other patient health care records. All

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[11] The State does not concede that prior restraint doctrine applies to commercial speech. The Supreme Court has suggested it does not. *Central Hudson*, 447 U.S. at 571 n.13.

of that data is, after all, "truthful information" that could be used to "guide [businesses'] commercial decisions." IMS Br. 27. And all of that data is similarly protected. *See, e.g.,*15 U.S.C. § 6802(b) (financial institution customers' right to opt-out of disclosure of personal information); 18 U.S.C. § 2721 (restricting disclosure of driver information without consent); 42 U.S.C. § 1320d-6 (prohibiting use and disclosure of "individually identifiable health information"); 18 U.S.C. § 2710(b) (prohibiting disclosure of "personally identifiable information concerning" consumer of video rental establishment without consent); 47 U.S.C. § 551(c)(1) (prohibiting disclosure of "personally identifiable information" concerning cable subscriber without consent); 18 U.S.C. § 2702(c) (restricting use of internet subscriber information without consent); 20 U.S.C. § 1232g(b) (prohibiting release of educational records without consent); Vt. Stat. Ann. tit. 8, §§ 10201-10205 (financial privacy); *id.* tit. 9, § 2480e (credit reports).[12]

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[12] Plaintiffs suggested below that protection of personal privacy might survive strict scrutiny. That response is inadequate, for two reasons. First, it is far from clear that consumer privacy laws would regularly satisfy the rigors of strict scrutiny. *Cf. Sorenson,* 567 F.3d at 1225

Courts have, however, repeatedly held that privacy laws are subject to no more than intermediate scrutiny. *E.g., Trans Union LLC v. FTC*, 295 F.3d 42, 53 (D.C. Cir. 2002) (upholding Gramm-Leach-Bliley privacy rules, including restriction on disclosure of consumer account numbers); *Trans Union Corp. v. FCC*, 245 F.3d 809, 818 (D.C. Cir. 2001) (upholding restriction on creation of targeted marketing lists under Fair Credit Reporting Act); *see also Sorenson,* 567 F.3d at 1225 (applying intermediate scrutiny to opt-in privacy rule). Plaintiffs do not even acknowledge this precedent, much less provide a plausible reason to reject it. Vermont's law is, at most, a restriction on commercial speech and strict scrutiny has no place here.

C. The narrow scope of the law counsels in favor of upholding it.

Perhaps recognizing that the State's evidence is both persuasive and sufficient to satisfy ordinary review under the *Central Hudson* test, plaintiffs suggest that this particular regulation of commercial speech is

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(invalidating privacy rule under intermediate scrutiny). Second, privacy laws typically extend to businesses and professionals, for example by protecting bank records, credit card records, and educational records.

so "paternalistic," discriminatory, or broad that it must simply be invalidated "*a fortiori*." IMS Br. 33; *id.* at 28, 31-34; PhRMA Br. 31-33. Plaintiffs have this point exactly backward. The law is "significantly more limited" than other regulations of commercial speech, *see Ayotte,* 550 F.3d at 97 (Lipez, J., concurring), and its "limited scope," *id.,* should inform the Court's analysis.

Much of plaintiffs' argument is premised on mistaken allegations of content and viewpoint discrimination. Again, this Court in *Anderson* rejected the claim that content-based restrictions on commercial speech are subject to heightened scrutiny. 294 F.3d at 460. Commercial speech is defined by its content, and there is nothing unusual about content-based distinctions in this context. *See, e.g., Nat'l Cable & Telecomms. Ass'n v. FCC,* 555 F.3d 996, 1000-02 (D.C. Cir. 2009) (upholding content-based restriction on transfer of telephone customer calling information); *Verizon California, Inc. v. FCC,* 555 F.3d 270, 275 (D.C. Cir. 2009) (upholding content-based restriction on marketing). As for the claim of viewpoint discrimination, the statute by its terms is neutral and nondiscriminatory. It regulates the advertising and promotion of

prescription drugs – all prescription drugs, brand-name or generic. In this way it is indistinguishable from the regulation upheld in *Anderson,* which applied to all real estate solicitations. 294 F.3d at 457. If plaintiffs contend that the regulation of advertising discriminates on the basis of viewpoint, that is simply another version of plaintiffs' unsuccessful content-discrimination claim; every regulation of advertising may be described the same way. A restriction on tobacco advertising does not discriminate on the basis of viewpoint merely because the restriction does not apply to non-commercial speech about smoking. PhRMA's complaint seems to be that the statute fails to regulate non-commercial speech by persons who do not advertise or market prescription drugs. *See* PhRMA Br. 31 (discussing academic institutions, insurers, and health programs). That is not a logical objection to a restriction on commercial speech.

Plaintiffs' other flawed argument is that the law suppresses information and is thus "impermissibly paternalistic." IMS Br. 31; PhRMA Br. 33. Absent from this argument is any explanation of how allowing doctors to control the use of their own information in

marketing can possibly be described as paternalistic. The government is not making this decision; if doctors "wish to be covertly influenced with PI data," they may elect that choice. SPA-31. The law does not suppress any information. *See Ayotte,* 550 F.3d at 54 (legislature addressed problems with detailing "not by eliminating speech" but by restricting particular use of "prescribing histories").

Both the majority and concurring opinions in *Ayotte* recognize that restrictions on the use of prescribing data do not have a significant impact on speech. While plaintiffs analogize this case to *Thompson v. Western States Medical Center,* 535 U.S. 357 (2002), *Edenfield v. Fane,* 507 U.S. 761 (1993), and *44 Liquormart Inc. v. Rhode Island,* 517 U.S. 484 (1996), the First Circuit described these restrictions as "a world apart from [those] statutes that have been struck down in the interest of provid[ing] a forum where ideas and information flourish." *Ayotte,* 550 F.3d at 53 (quotation omitted). In his thoughtful concurrence, Judge Lipez likewise distinguished "those [cases] in which the Court has rejected advertising bans that restrict the exchange of ideas in the 'commercial marketplace.'" *Id.* at 100. "The Prescription Act neither

'protects' the public from information about drugs nor prevents truthful advocacy by pharmaceutical representatives." *Id.* (Lipez, J., concurring).

It bears noting that the First Circuit reviewed and upheld a somewhat broader restriction, because New Hampshire's law does not allow doctors to opt-in to the use of their data in marketing. *Id.* at 47. Vermont's provision for prescriber choice makes plaintiffs' arguments even less persuasive in this case.

II. The Prescription Confidentiality Law readily survives intermediate scrutiny under *Central Hudson*.

The Prescription Confidentiality Law is narrow in scope and is targeted at a concrete harm: the nonconsensual use of prescriber-identifiable data for marketing prescription drugs. The Vermont Legislature's decision to restrict this use of prescriber-identifiable data is grounded in a substantial record that shows: (1) an invasion of medical privacy and interference with the doctor-patient relationship; (2) risks to patient health caused by over-prescription of new prescription drugs; and (3) increased health care costs caused by unnecessary prescriptions for expensive new drugs.

Given this record, the district court properly upheld the law under the *Central Hudson* test. To begin with, the district court correctly applied intermediate scrutiny by scrutinizing the reasonableness of the evidentiary record and not – as plaintiffs urged – usurping the policymaking role of the Legislature. The Prescription Confidentiality Law directly advances substantial state interests and is narrowly tailored, and is thus a constitutional restriction on commercial speech. *See Anderson,* 294 F.3d at 460-61 (setting out *Central Hudson* test).

A. The district court properly applied intermediate scrutiny by exercising independent judgment while affording some deference to the findings and predictive judgments of the Vermont Legislature.

Plaintiffs' principal argument on appeal is that the district court failed to exercise independent judgment and improperly deferred to the Vermont Legislature. *E.g.,* IMS Br. 34 (claiming district court "avoided deciding" *Central Hudson* test); PhRMA Br. 34-35 (claiming district court "diluted its review" and did not require State to prove its case). This argument does a disservice to the district court's careful evaluation of the evidence. Plaintiffs' claims should be rejected because: (1) the district court conducted an independent review; (2) intermediate

scrutiny allows a measure of deference to legislative judgments; (3) plaintiffs' other assertions about review of commercial speech restrictions are meritless; and (4) deference is appropriate based on this record.

1. Plaintiffs' unfounded assertion that the district court "avoided deciding" key issues, *see* IMS Br. 34, should be disregarded, as should any suggestion that the district court failed to conduct an "independent review" of the evidence, PhRMA Br. 35. These statements have no basis in the record. Far from avoiding deciding whether the law directly advances substantial state interests, the district court gave "[c]areful consideration" to those issues and held that the State "met its burden to justify" the law's "limited restraint on commercial speech." SPA-22. The court noted repeatedly the State's burden to prove its case. *E.g.*, SPA-20, SPA-22, SPA-32. After reviewing the evidence related to cost containment, the court found that the Attorney General "carried his burden to show that Vermont's interest in reducing health care costs, specifically prescription drug spending, *would be furthered to a material degree*" by the law. SPA-32-33 (emphasis added).

Plaintiffs likewise provide an inaccurate description of the district court's decision to afford some deference to the Legislature's factual predictions. The phrase "overriding deference," IMS Br. 38, is found nowhere in the lower court's opinion. The court conducted a "'meaningful judicial review'" and applied its "'independent judgment.'" SPA-21-22 (quoting *Turner Broad. Sys. v. FCC, (Turner I)*, 512 U.S. 622, 666 (1994)). The court acknowledged that the State does not have "'broad discretion'" to suppress speech. SPA-20 (quoting *44 Liquormart,* 517 U.S. at 508). At the same time, the district court recognized room for "'the exercise of legislative judgment'" and declined to "'reweigh the evidence de novo'" or "'replace the legislature's factual predictions with its own.'" *See* SPA-20 (quoting *44 Liquormart,* 517 U.S. at 508); SPA-22 (quoting *Turner I,* 512 U.S. at 666). As explained below, this measured approach – neither "overriding" deference to nor usurpation of the legislative role – is exactly the level of independent judgment called for by intermediate scrutiny.

2. The requirement that courts leave room for the reasoned judgments and predictions of the political branches under *Central*

Hudson is not a novel argument – it is a built-in feature of intermediate scrutiny. The *Central Hudson* standard gives the political branches "needed leeway" to shape regulations on commercial speech that satisfy the "reasonable fit" requirement. *Fox*, 492 U.S. at 481. This standard comports with the deference to reasoned, predictive legislative judgments outlined by the Supreme Court in its *Turner* decisions. In the *Turner* cases, the Supreme Court reviewed a federal law that requires cable television operators to carry a certain number of local broadcast television channels on their systems. *Turner I*, 512 U.S. at 626. The Court concluded that the "must-carry" rules were not content-based and thus were subject only to intermediate scrutiny. *Id.* at 652-53, 661-62. Under this intermediate standard, "courts must accord substantial deference to the predictive judgments of Congress." *Turner I,* 512 U.S. at 665; *see also Turner Broad. Sys. v. FCC, (Turner II),* 520 U.S. 180, 211 (1997).

The *Turner* opinions stress a combination of "independent judgment" with deference to legislative decision-making:

> Th[e] obligation to exercise independent judgment when First Amendment rights are implicated is not a license to

> reweigh the evidence *de novo*, or to replace Congress's factual predictions with [the Court's] own. Rather, it is to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence.

Turner I, 512 U.S. at 666. The question for the court is not whether the legislative determination is "correct" as "an objective matter." *Turner II*, 520 U.S. at 211. "Rather, the question is whether the legislative conclusion was reasonable and supported by substantial evidence in the record." *Id.*

The *Turner* standard for intermediate scrutiny applies equally to review of commercial speech restrictions. The Supreme Court has described its two frameworks for intermediate scrutiny under the First Amendment as "substantially similar." *Lorillard,* 533 U.S. at 554. In fact, the Court has held that scrutiny of commercial speech regulations cannot be more stringent than review of time, place, and manner regulations. *United States v. Edge Broad. Co.,* 509 U.S. 418, 429 (1993) ("validity of restrictions on commercial speech should not be judged by standards more stringent than those applied to . . . time, place, or manner restrictions"); *Fox,* 492 U.S. at 477-78 ("least-restrictive-means" test does not apply to commercial speech; "it would be incompatible

with the asserted subordinate position [of commercial speech] in the scale of First Amendment values to apply a more rigid standard" under *Central Hudson* (quotation omitted)); *see also id.* at 477 ("'commercial speech [enjoys] a limited measure of protection'" and "is subject to 'modes of regulation that might be impermissible in the realm of noncommercial expression'" (quoting *Ohralik v. Ohio State Bar Ass'n,* 436 U.S. 447, 456 (1978)); *Ayotte,* 550 F.3d at 93 (Lipez, J., concurring) ("general principle of legislative deference . . . is compatible with [Supreme Court's] commercial speech precedent"); *see also 44 Liquormart,* 517 U.S. at 508 (plurality op.) (recognizing "some room for the exercise of legislative judgment").

Fox confirms the "ample scope of regulatory authority" for the political branches to restrict commercial speech. 492 U.S. at 477. The *Central Hudson* standard takes "account of the difficulty of establishing with precision the point at which restrictions become more extensive than their objective requires, and provide[s] the Legislative and Executive Branches needed leeway in a field (commercial speech) traditionally subject to governmental regulation." *Id.* at 481 (quotation

omitted); *see also SKF USA, Inc. v. U.S. Customs and Border Protection,* 556 F.3d 1337, 1358 (Fed. Cir. 2009) (*Central Hudson* "does not require perfect correspondence of means and ends"). This Court's decision in *Anderson* takes a similar approach. "[P]articularly where the standards and conduct of professionals have traditionally been subject to extensive regulation by the States, 'it is all the more appropriate that we limit our scrutiny of state regulations to a level commensurate with the subordinate position of commercial speech.'" *Anderson,* 294 F.3d at 463 (quoting *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 635 (1995)).

The Court's review should thus recognize the Legislature's policymaking role and its discretion to weigh competing evidence and make reasoned factual predictions. *See, e.g., Fox,* 492 U.S. at 477-80 (describing role of legislative judgment; holding that, within bounds of "reasonable fit" requirement, Court "leave[s] it to governmental decisionmakers to judge what manner of regulation may best be employed"); *Lorillard,* 533 U.S. at 555-56, 561 (noting wide range of adequate justifications under *Central Hudson* standard; upholding finding as not based on "mere speculation and conjecture").

3. Plaintiffs' arguments against any deference whatsoever are an effort to transform *Central Hudson* into a form of strict scrutiny, and should be rejected. Plaintiffs rely heavily on *44 Liquormart* and repeatedly cite the plurality opinion in that case as precedent. It is not; and the Court's later cases do not endorse the plurality's stringent standard for certain commercial speech restrictions. *Lorillard,* 533 U.S. at 554. Moreover, this case is nothing like *44 Liquormart,* which struck down a complete ban on price advertising for a legal product. 517 U.S. at 489. The plurality advocated for stricter scrutiny not of all commercial speech regulations, but of those laws that "entirely prohibit[] the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process." *Id.* at 501 (plurality op.). The plurality distinguished the "complete speech ban" at issue in that case from regulations of "aggressive sales practices," including practices that give marketers "undue influence." *Id.* at 498, 501 (plurality op.). Even under the reasoning of the *44 Liquormart* plurality, the Prescription Confidentiality Law readily withstands scrutiny, because it restricts an

aggressive marketing tool without banning the dissemination of information about prescription drugs.

Plaintiffs mistakenly assert that other circuits have refused to afford deference to legislative judgments under *Central Hudson*. IMS Br. 38. In fact, all three judges on the First Circuit panel in *Ayotte* agreed that a measure of deference is consistent with the *Central Hudson* standard. 550 F.3d at 58 (while legislature does not have "unfettered discretion," "some leeway" and "elbow room" is appropriate); *id.* at 93 (Lipez, J., concurring) (similar). In *Pagan v. Fruchey,* the Sixth Circuit declined to defer to the state legislature in the absence of *any* evidence or legislative history. 492 F.3d 766, 774-75 (6th Cir. 2007). That unremarkable ruling is not relevant here, where a detailed record supports the State's position. The other case cited by plaintiffs has been "implicitly overruled" by the Supreme Court and is no longer good law. *See Cal-Almond Inc. v. U.S. Dep't of Agric.,* 192 F.3d 1272, 1274, 1277 (9th Cir. 1999).

4. PhRMA advances a confusing argument that suggests, simultaneously, that Vermont's legislative process was too rushed to

merit deference and that the district court did not allow PhRMA to present evidence about this process. PhRMA Br. 40-43. The parties stipulated to the legislative record as submitted to the district court at trial. *See, e.g.,* SPA-65. The district court neither excluded legislative history from evidence, nor prevented plaintiffs from addressing the sufficiency of the legislative record and findings. The evidence cited by PhRMA in support of its argument, PhRMA Br. 42 (citing A-1666-1754), is evidence from the legislative record admitted at trial. Plaintiffs' suggestion that they were somehow barred from inquiring into parts of the legislative record, PhRMA Br. 42, is contrary to plaintiffs' stipulations below and unsupported by the record. SPA-65 (IMS counsel: "we've agreed to what the legislative record consists of"); A-4943 (plaintiffs' unsuccessful proffer of deposition testimony that was *not* in legislative record).

If PhRMA seeks reversal of the district court's ruling excluding certain evidence from outside the legislative record, see PhRMA Br. 42, that claim of error is not set forth with sufficient clarity and should be denied as inadequately briefed. *See, e.g., Norton v. Sam's Club*, 145 F.3d

114, 117 (2d Cir. 1998) (issues not sufficiently argued in the briefs are waived). In any event, the district court's ruling was unobjectionable. Plaintiffs sought to question legislative witnesses at trial about whether they believed that their testimony at committee hearings supported legislative findings. A-4943; A-4720-4721; *see also* PhRMA Br. 20. The district court correctly held that the proffered evidence was not relevant. Plaintiffs were free to argue that the legislative record did not support the findings and to present substantive evidence challenging the findings. SPA-64-66.

Plaintiffs' assertion that the legislative process was too rushed to qualify for deference is wrong. The Vermont Legislature held dozens of hearings over four months and compiled a substantial record. *See supra* 25-29. Plaintiffs' criticism of legislative participation by "outsiders with a stake in the legislation," PhRMA Br. 42, is groundless. Peter Hutt, a lobbyist for the pharmaceutical industry and trial witness for PhRMA, testified that he has participated in drafting "all of the major pharmaceutical legislation" since 1962, including the Hatch-Waxman Act. A-134, A-136. As shown by Mr. Hutt's candid testimony, the

participation of interested stakeholders in the drafting of a law is common – indeed, plaintiffs themselves lobbied the Legislature on this bill. A-4583-4619. And the First Circuit properly rejected the effort to "convert[] the issue of deference into a mechanical counting of days and pages," *Ayotte,* 550 F.3d at 58. What matters, as the First Circuit recognized, is the "content of the legislative record," *id.,* and the record here fully supports the Vermont Legislature's actions.

B. The law directly advances the State's substantial interest in protecting medical privacy.

The law protects a real and substantial privacy interest. The Legislature's findings on this issue reflect the views of the doctors who supported the law. *See* A-4043-4044 (Findings 20, 22-29); A-5118-5121 (Annotated Legislative Findings). Indeed, the medical profession articulated a strong interest in protecting medical privacy. The Medical Society called the use of "physician prescriber profiles" in marketing "an intrusion into the way physicians practice medicine" and expressed concern for "confidentiality and privacy" in the doctor-patient relationship. A-4197. The physicians who testified in person at the Legislature were sometimes blunter. One called the practice

"demeaning," and another saw "no public good whatsoever" for the industry to have data about what he prescribes to his patients. A-1183, A-1304. The director of the Medical Society testified that Vermont doctors view the practice as an "invasion of the physician's privacy" and "don't want the market[ers] to have that information." A-1433, A-1435. Media reports and information from other states reflected similar objections by doctors. A-4224; A-4262; A-4323; A-4191.

In contending this interest is not substantial, plaintiffs offer a cramped view of the privacy interests at stake. The data that pharmacies sell to the data-vendor plaintiffs contains extraordinarily detailed information about doctors and the patients they treat. Data vendors not only obtain the doctor's identifying information but also link that information to (de-identified) patient information, allowing them to track prescribing practices over time and for specific patients. Pharmaceutical manufacturers then use the information to convince doctors to write more prescriptions for the drugs they sell. *See supra* 4-17. As a Maine doctor aptly stated, his prescribing habits are

"monitored" so pharmaceutical companies can try to "subvert what I do." A-4224.

The considered views of these physicians show how crucial this privacy interest is. Doctors did not support the law to avoid personal embarrassment. Their concern was much more serious: that pharmaceutical marketers should not be exerting undue influence and intruding on the doctor-patient relationship in this way. A-4197; A-4224; A-4225; A-4323. The trial testimony of the state's expert Dr. Grande complements the legislative record on this point. Dr. Grande explained how undue commercial influence undermines the doctor-patient relationship. The greater the influence of marketing, including marketing with the advantage conferred by this extremely detailed information, the more likely that the patient's interests may not be put first. This matters not only because patient care can be compromised but because patient trust in the health care system is undermined. Allowing doctors to prevent this marketing practice promotes medical professionalism and helps protect the integrity of the doctor-patient relationship. A-297.

The harm identified by the State – the use of the data without consent – is "real" and the restriction on nonconsensual use of the data alleviates that harm "directly and to a material degree." *See Anderson,* 294 F.3d at 462; *cf. Individual Reference Servs. v. FTC,* 145 F. Supp. 2d 6, 43 (D.D.C. 2001) (identifying harm as "use and disclosure of [customer data] without the consent of the consumer"), *aff'd sub nom*. *Trans Union LLC v. FTC*, 295 F.3d 42 (D.C. Cir. 2002). Just as the homeowners in *Anderson* could choose whether or not to receive real estate solicitations, doctors may decide whether or not to allow the use of their information for marketing purposes. The law is "precisely co-extensive with those who are experiencing the particular harm that it is designed to alleviate." *Anderson*, 294 F.3d at 462; *see* SPA-37.

Plaintiffs barely address medical privacy in their briefs. Below, they advanced the unpersuasive claim that, as professionals, doctors have no legitimate privacy interests. In fact, many privacy protections extend to businesses and professionals, including financial privacy laws and protections for educational records. The Supreme Court has recognized a substantial state interest in protecting potential business

clients from unwanted solicitations. *Edenfield*, 507 U.S. at 763, 769. The Court struck down a solicitation ban in *Edenfield* not because businesses have no privacy interests, but because a mere phone call from an accountant asking for business did not raise significant privacy concerns. *Id.* at 775-76. Here, the challenged statute does not bar solicitation but the use of non-public information for marketing and advertising purposes without consent. Doctors have a legitimate privacy interest in avoiding that practice.

PhRMA makes a similarly unconvincing argument that the law does not protect privacy because it allows the use of prescribing data for other purposes, like filling and paying for the prescription. PhRMA Br. 48. PhRMA fails to point out that patient information is disclosed for many of these purposes as well; under this reasoning, a law would protect medical privacy only if it effectively prevented the patient from getting treatment. In any event, the statute targets precisely the harm identified by the Legislature: the invasion of privacy when non-public prescribing information is used for marketing purposes. Plaintiffs appear to suggest that the statute should be broader and restrict *more*

speech than necessary to achieve the State's interest. This Court rejected similar reasoning in *Anderson,* where it upheld a restriction on real estate solicitations as a privacy measure, even though other solicitations were allowed. 294 F.3d at 463-64. Here, as in *Anderson,* the regulation addresses a "'more acute problem'" identified by a "high volume" of complaints. *Id.* at 464 (quoting *Metromedia, Inc. v. City of San Diego,* 453 U.S. 490, 511 (1981)). *Cf. Trans Union,* 245 F.3d at 819 ("regulation is not fatally underinclusive simply because an alternative regulation, which would restrict *more* speech or the speech of *more* people, could be more effective" (quotation and citation omitted)).

C. The law directly advances the State's substantial interests in reducing health care costs and protecting public health.

The law reflects the Legislature's finding that "new drugs often provide[] little or no benefit over older drugs" and its concern that the use of prescriber-identifiable data in marketing "contribute[s] to the over-prescription of new drugs." SPA-33; A-4040-4044. "Detailing encourages doctors to prescribe newer, more expensive and potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines." SPA-33. The evidence shows that, by restricting marketing

with prescriber-identifiable data, the law directly advances the State's interests in controlling health care costs and protecting public health.

1. Controlling health care costs

Substantial and persuasive evidence shows that the use of prescriber-identifiable data in marketing drives up the costs of prescription drugs. All three judges on the *Ayotte* panel agreed with this conclusion, *see* 550 F.3d at 56-58; *id.* at 89-90 (Lipez, J., concurring), as did the Vermont Legislature, the New Hampshire Legislature, the Maine Legislature, and the district court below, *see* SPA-6-7; SPA-23; SPA-28-29. The evidence shows, first, that detailing succeeds in persuading doctors to prescribe more expensive brand-name drugs, SPA-28-29; second, that prescriber-identifiable data makes detailing more effective as a marketing tool, SPA-27-29; and third, that consumers and the State can save substantial sums without affecting the quality of health care by shifting prescribing practices to less expensive generic drugs, SPA-29-30. Plaintiffs barely even address this evidence, much less provide a persuasive reason for rejecting the district court's findings.

a. "Detailing works." *Ayotte,* 550 F.3d at 56. As the district court found, "[d]etailing leads to increased prescriptions for new drugs over generic alternatives which are often more cost-effective." SPA-28; *see also Ayotte,* 550 F.3d at 56 (detailing "succeeds in inducing physicians to prescribe larger quantities of brand-name drugs"). This finding is neither a "theory," an "assumption" nor an exercise in "paternalism," as plaintiffs wrongly imply. PhRMA Br. 44, 48. It is a fact – and plaintiffs' attempt to prove otherwise "is belied by the nature of the industry, plaintiffs' own documents, and scientific research." SPA-28; *see also Ayotte,* 550 F.3d at 101 (Lipez, J., concurring) ("there is substantial evidence that the detailer's persuasion has an impact"). The district court's finding is fully supported by the evidence, including testimony from respected scholars who based their conclusions on peer-reviewed research.

Dr. Ashley Wazana, who testified at trial, authored an important study in the Journal of the American Medical Association that showed the influence of marketing on doctors. The district court found persuasive Dr. Wazana's testimony about research that proves the

influence of marketing on doctors. SPA-28; A-244. Dr. Wazana explained that doctors are influenced to prescribe brand-name drugs instead of generic drugs and to request that brand-name drugs be added to hospital formularies. He also testified that doctors typically underestimate the influence of marketing on their prescribing choices. A-243. Plaintiffs object that Dr. Wazana did not testify about the specific provisions of Act 80 – but that is not what he was asked to do. Here, as in *Ayotte*, *see* 550 F.3d at 56, Dr. Wazana's research is relevant because it proves that detailing influences the prescribing practices of doctors.

Dr. Wazana's findings are echoed by the State's other experts and the legislative record. Dr. Avorn, Professor of Medicine at Harvard Medical School, told the Legislature that "a great deal of evidence demonstrates that commercial forces play a disproportionate role in shaping [doctors'] knowledge and prescribing decisions." A-4304. "Detailing," Dr. Avorn observed, "is a highly effective marketing strategy." *Id.* According to Dr. Grande, research in social science and marketing confirms that pharmaceutical detailing is an effective way to

influence doctors. A-296. Dr. Kesselheim testified at trial that pharmaceutical marketing practices have a very strong impact on physicians' prescribing practices. A-341-342, A-352; *see also Ayotte,* 550 F.3d at 88-89 (Lipez, J., concurring) (evidence about the influence of detailing).

And lastly on this point, the "billions spent each year by pharmaceutical manufacturers on detailing is evidence of its success." SPA-29; *see also Ayotte,* 550 F.3d at 56 (money spent on detailing "bears loud witness to its efficacy"). No industry would devote these kinds of resources to marketing unless the marketing works.

b. The use of prescriber-identifiable data "amplifies the influence and effectiveness of detailing but does not add to its purported educational value." SPA-28. The record unequivocally supports this point. The strongest evidence, in fact, came from the data vendors and pharmaceutical manufacturers. Their own promotional and internal documents show how prescriber-identifiable data is used as a marketing tool to maximize the prescriptions written for the products

being marketed. *See supra* 9-17. As IMS puts it, the point is to "maximize the revenue per call and scripts per detail." A-3834.

A journal article in the legislative record explains how "script tracking" works with a concise summary from a pharmaceutical training guide: data reports are "used to identify which products are currently in favor with the physician" and "develop a strategy to change those prescriptions into Merck prescriptions." A-4354-4355. Marketers try to "identify physicians who are most susceptible to marketing" and to target messages based on their prescribing habits and their beliefs. A-4355. Trade publications in the pharmaceutical industry openly explain these tactics. *See id.* (citing articles). The district court relied on one Pharmaceutical Executive article, written by the IMS executive who testified at trial. *See* SPA-27. In his article, Mr. Sadek promoted his companies' data products as "reaping big returns" and increasing market share substantially. A-3872-3874.

The unvarnished facts about detailing using prescriber-identifiable data, as reflected in industry documents, trade publications, and evidence from former detailers, are more than enough to prove the

State's point. The use of prescriber-identifiable data in detailing "enables detailers to increase sales of new drugs." SPA-29. That is the point of using the data, and, as the district court observed, "if PI data did not help sell new drugs, pharmaceutical companies would not buy it." SPA-29.

The State nonetheless bolstered its case with persuasive expert testimony from researchers who have studied pharmaceutical marketing and the use of prescriber-identifiable data. Dr. Grande testified that the use of prescriber-identifiable data amplifies the influence of marketing. Sales representatives use their knowledge of prescribing habits to tailor messages that present information in a selective fashion. They also use the data to measure the success of various sales practices, such as free samples. A-297. Dr. Kesselheim concurred in this analysis, concluding that the data helps sales representatives attune their messages for the highest advertising and promotional effect. A-341-342; *see also Ayotte,* 550 F.3d at 56 (prescribing histories make detailing "more adversarial").

Plaintiffs do not rebut this evidence about the use of prescriber-identifiable data, nor could they, as much of it comes from their own documents and witnesses. Their principal argument below, which they assert in passing here, is that the use of prescriber-identifiable data allows sales representatives to "focus on prescribers likely to be interested in the detailed drug because of their specialty and current prescribing habits." SPA-32. Based on the evidence, the district court correctly rejected this assertion. Sales representatives are trained to track professional and personal details about doctors, from specialty areas to favorite sports teams. They can easily call a doctor's office and ask if a doctor is interested or prescribes a particular drug – and do not need prescriber-identifiable data for that purpose. *Id.*

The last and possibly strongest piece of evidence to rebut any claim that the use of prescriber-identifiable data is educational or informative is this: no one tells the doctors about the data. As the district court found, the data is used covertly. SPA-31. No sales representative may walk into a doctor's office and say, "I see you are prescribing this generic statin to many of your patients. Here's how our

product compares favorably to that drug." The secret use of the data in marketing is an "aggressive sales practice," *see 44 Liquormart*, 517 U.S. at 501 (plurality op.), not an educational effort. *See Ayotte,* 550 F.3d at 54 (data is "tool for tipping the balance of bargaining power in [detailers'] favor"); *id.* at 90-91 (Lipez, J., concurring) (citing evidence that targeted detailing is "more aggressive and persuasive, and thus more potent than regular detailing").

c. Restricting the use of prescriber-identifiable data will save money by shifting prescribing practices from brand-name drugs to equally effective generic drugs. The evidence shows that marketing drives prescribing practices to brand-name drugs even though generic drugs are often equally effective and cheaper. There is no "missing link" in this case. PhRMA Br. 45. The only evidence the State cannot provide – because it is impossible – is an empirical study testing the effects of the law on prescription drug costs. SPA-30-31 & nn.13-14 (study cannot not be done; plaintiffs' expert was unable to do study); *Ayotte,* 550 F.3d at 58 (First Amendment does not require state to present evidence that "simply does not exist"); *id.* at 93 (Lipez, J.,

concurring) ("unreasonable" to require State to present evidence that would only be available after statute is in effect). The State supported this law with a breadth and depth of evidence that readily distinguishes this case from others in which the *Central Hudson* standard has not been satisfied. *See also Ayotte,* 550 F.3d at 94 (Lipez, J., concurring) (extent of "empirical and anecdotal evidence" distinguishes case).

The record includes, first, specific empirical evidence about new drugs that offer little or no therapeutic benefit over existing drugs but nonetheless have been widely prescribed because they are heavily marketed by pharmaceutical companies.

> ***Nexium,*** a top-selling drug, is a proton-pump inhibitor. It is essentially the same product as an earlier drug, Prilosec, and treatment outcomes with the two drugs are essentially the same. Prilosec is now available as an inexpensive generic. There is no reason to prescribe Nexium as first-line therapy in the vast majority of patients. Yet Nexium is frequently prescribed and very profitable for its manufacturer. Based on a 50-state study, Medicaid programs could have saved approximately $800 million

from 2001 to 2005 if generic Prilosec had been prescribed in place of Nexium and brand-name Prilosec. The maker of Nexium "cash[ed] in on a very large market share" in part because of "good marketing." A-311-12 (Dr. Rosenthal); A-342, A-349-50 (Dr. Kesselheim); A-3856 (Nexium revenues).

Lipitor, a statin drug for lowering cholesterol, is the best-selling drug in the world. Lipitor offers certain benefits but is nonetheless over-prescribed based on marketing. It is more effective than other statins at lowering cholesterol in a limited group of patients, those who have had a heart attack and are at risk of another attack. For the majority of patients, however, Lipitor has not been shown to be more effective than other statins on the market, and some of those other statins are available as inexpensive generics. Lipitor is overused and inappropriately prescribed. A-342, A-352 (Dr. Kesselheim).

Calcium channel blockers came on the market in the 1990s as a treatment for hypertension. Pharmaceutical manufacturers made a concerted effort, through detailing, to promote the use of

the drugs as first-line therapy. Treatment guidelines, however, recommended a generic diuretic as first-line therapy. A study sponsored by the National Institutes of Health, called ALLHAT, showed that the diuretic was as effective at reducing blood pressure as the calcium channel blocker and associated with better outcomes, including lower incidence of heart failure. Notwithstanding the lack of evidence supporting their use as first-line treatments, calcium channel blockers were widely prescribed. The use of these drugs instead of less expensive medications for controlling blood pressure cost government programs billions of dollars. A-343, A-348-49 (Dr. Kesselheim); A-4306-4307 (legislative record).[13]

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[13] The ALLHAT study was published in the Journal of the American Medical Association. Plaintiffs' witness Dr. Wharton claimed at trial that a recent study sponsored by Novartis, a pharmaceutical manufacturer, undermined the conclusions of the ALLHAT study. The State's expert, Dr. Kesselheim, disagreed with this analysis of the then-unpublished Novartis study. The two studies compared different drugs, and the Novartis study employed a less effective diuretic. Moreover, the source of funding for a study can be associated with its results, and the Novartis study was funded by the pharmaceutical industry. A-343-344. The Novartis-sponsored study, called Accomplish, was published after

Vytorin is a "heavily marketed" drug intended to treat high cholesterol. The drug had billions of dollars in sales, although plaintiffs' own witness, Dr. Wharton, testified that research did not support its use and he did not prescribe it. Vytorin has fallen "out of vogue" based largely on unfavorable test results released not long before trial. A-199, A-208.

Vioxx illustrates both the safety risks of new drugs (discussed further below) and the unnecessary costs driven by pharmaceutical marketing. Vioxx was approved for pain control, but studies showed it was no more effective in controlling pain than over-the-counter ibuprofen. Vioxx's potential benefit was a possible decrease in the risk of gastrointestinal bleeding in certain patients who have a history of or particular risk for that problem. Yet Vioxx immediately became a "blockbuster" drug, "far over-

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trial. Consistent with Dr. Kesselheim's testimony, the authors of the Accomplish study have explained that the two studies are "fundamentally different" trials. Kenneth A. Jamerson & Michael A. Weber, *Authors Reply to Correspondence: Benazepril plus Amlodipine or Hydrochlorothiazide for Hypertension*, 360(11) New England J. Med. 1149-50 (March 12, 2008).

prescribed," with first-year sales alone of $769.6 million. It was inappropriately prescribed to people for whom it had no potential benefit because doctors were influenced by the marketing of the drug. The cost was enormous, because Vioxx cost several dollars per pill, the same as a bottle of generic ibuprofen. A-344-46 (Dr. Kesselheim); A-3856.

Second, the State's experts testified that the use of prescriber-identifiable data in marketing campaigns contributes to inappropriate prescribing and unnecessary spending. Dr. Kesselheim explained how the use of prescriber-identifiable data in marketing "over-accelerate[s]" the use of a new drug. A-348. Doctors learn about new drugs and their intended populations and indications from many sources. Marketers, however, use prescriber-identifiable data as "inside information" to "guide the promotional and advertising aspects" of their message. A-347. This practice allows pharmaceutical manufacturers to "over-influence" physicians' prescribing practices and accelerate a new drug's uptake when the drug first enters the market. A-348. For example, by using prescriber-identifiable data to understand what pain control

medications prescribers were using, detailers promoting Vioxx were able to tailor their messages and talk about the use of Vioxx for pain control. The same kind of marketing happened with calcium channel blockers. Limiting this marketing practice will decrease inappropriate use and over-prescription of new drugs, and avoid substantial overcharges for government health care budgets and other payors, A342; A-347-350.

Third, the State presented concrete evidence of the substantial savings available from even a modest increase in the appropriate prescribing of generic drugs. At present, about 62% of prescriptions written in Vermont are filled with generic drugs. Increasing this rate by just 1% would save Vermont $2 million annually. SPA-29; A-310-11.

On a less detailed record than the one presented here, the First Circuit found "substantial evidence" to support the State's interest in reducing health care costs. 550 F.3d at 58; *see also id.* at 94 (Lipez, J., concurring) ("substantial evidence of needless spending, combined with evidence that detailing with prescriber-identifiable data contributes to

that outcome"). Based upon Vermont's thorough and persuasive evidentiary showing, this Court should reach the same conclusion.

2. Promoting public health

As shown above, Vermont proved the same case here that New Hampshire proved in *Ayotte*: the use of prescriber-identifiable data for marketing prescription drugs drives up health care costs, because the expensive new drugs that are marketed are frequently no better than inexpensive generic drugs. *See Ayotte,* 550 F.3d at 60. Vermont's evidence is not limited to cost, however. The evidence also shows that "[b]ecause new drugs often have no therapeutic benefit and may have unknown side effects and risks, inappropriate prescription of new drugs is harmful." SPA-35.

New drugs pose greater risks than older drugs, because their use and side effects are not fully understood. Plaintiffs' own expert, Dr. Wharton, testified that he usually waits to prescribe a drug until it has been on the market for a while unless there is an obvious benefit and no risk – and that happens only about 30% of the time. SPA-33; A-207. The problem with new drugs, as Dr. Kesselheim confirmed, is that risks and

side effects often become apparent only after the drug is marketed. Most drug recalls and serious "black box" warnings happen within the first few years after a drug is approved by the FDA. A-345.

The over-prescription of new drugs poses a risk to public health because too many patients are unnecessarily exposed to these uncertain risks. Vioxx illustrates the potential harm when marketing pushes accelerated uptake of a new drug. Vioxx had serious side effects, including increased risk of heart attacks, that were not recognized when the drug was approved. Because Vioxx was so widely over-prescribed to patients for whom it was not indicated, many more patients were exposed to those risks before the drug was removed from the market. A-345-48 (Kesselheim). The statin drug Baycol is another example of a new drug that was "determinedly promoted" and widely prescribed before its risks were understood. Other statins were already on the market, so there were many alternatives to prescribing Baycol. The drug turned out to have serious and sometimes fatal side effects, and it was later removed from the market. A-348 (Kesselheim); A-207-208 (Wharton); A-4218-4221 (article describing marketing of Baycol with

prescriber data). The over-prescription of new drugs is a public health problem and this law furthers the Legislature's public health interest in a manner that is "sufficiently direct and material." SPA-35.

3. Plaintiffs' failure to persuasively rebut this evidence

Plaintiffs spend little time addressing this evidence, but they do contend briefly that either the State's witnesses were not qualified or their own witnesses were more persuasive. IMS Br. 39-42; PhRMA Br. 45-47 & n.12. In fact, the State's witnesses were highly qualified and far more independent and credible than the witnesses presented by plaintiffs. For the most part, the State's witnesses gave opinions they had previously developed in their research and their unpaid legislative testimony. A-341 (Kesselheim); A-248-249 (Wazana); A-293-294 (Grande). The district court repeatedly cites to the testimony provided by the State's witnesses, showing that the court found their testimony relevant and persuasive. *E.g.,* SPA-27-29, SPA-33-34.

Plaintiffs' witnesses were mostly industry employees, consultants, and attorneys. *See* A-134 (Mr. Hutt, long-time industry lawyer and lobbyist); A-184-185 (Dr. Kolassa, highly paid consultant in

pharmaceutical marketing); A-166 (Ms. Reilly, in-house lawyer at PhRMA, involved in PhRMA's lobbying efforts); A-225, 231 (Dr. Turner, economist with $150,000 grant from IMS); A-77-78; A-96-97; A-110; A-260-261 (Mr. Sadek, Mr. Fisher, Ms. Livingston, Mr. Frankel, all data-vendor employees). In the less-restrictive confines of a bench trial, these witnesses frequently testified about matters beyond their expertise; for example, lawyers and marketing specialists opined about medical treatments. *E.g.,* A-155-157 (Reilly); A-269-270 (Frankel); A-140 (Hutt); A-179-180 (Kolassa). But given their backgrounds, lack of expertise, and potential bias, the district court was justified in discounting their testimony.

Plaintiffs also presented testimony from three medical doctors. A-191 (Wharton); A-119 (Cole); A-390 (Ciongoli). As set forth in the district court's opinion, Dr. Wharton's testimony about new drug risks supported the State's case. SPA-33. For the most part, however, the testimony from these doctors was not particularly relevant, because doctors who endorse this marketing practice may consent.

C. The law is narrowly tailored and satisfies the "reasonable fit" requirement of *Central Hudson*.

A restriction on commercial speech is "narrowly tailored" if it is in "reasonable proportion" to the State's interests. *Edenfield,* 507 U.S. at 767; *see Anderson,* 294 F.3d at 460. The Prescription Confidentiality Law is carefully designed to advance each of the three interests promoted by the law and to do so without restricting "substantially more speech than is necessary." *Fox*, 492 U.S. at 478 (quotation omitted). The law focuses on the specific problem identified by the Legislature: the use of data from non-public health care records to fuel marketing campaigns and intrude on the privacy of the doctor-patient relationship.

Plaintiffs try to attack this narrowly tailored law by promoting other public health policies as alternatives. The sheer number and variety of these policy proposals – everything from mandatory doctor education programs to drug vouchers to multi-state drug purchasing pools – suggests the flaw in plaintiffs' approach. They have lost sight of the problem identified by the Legislature and they fail to plausibly explain how any of their proposed alternatives would actually serve the

Legislature's purposes. *See Ayotte,* 550 F.3d at 60 (proposed alternatives would not "prevent detailers from exerting so much influence").

1. Plaintiffs mistakenly equate the narrow tailoring requirement of *Central Hudson* with the least-restrictive-means test. IMS Br. 47-49; PhRMA Br. 55. The U.S. Supreme Court and this Court have rejected that argument. *Fox,* 492 U.S. at 477-78; *Anderson*, 294 F.3d at 460. A restriction on speech is narrowly tailored for purposes of *Central Hudson* if it represents "'a reasonable fit between the legislature's ends and the means chosen to accomplish those ends.'" *Anderson,* 294 F.3d at 462 (quoting *Lorillard*, 533 U.S. at 556); *see Edenfield,* 507 U.S. at 767 (restriction "need only be tailored in a reasonable manner to serve a substantial state interest"). The D.C. Circuit recently reiterated this point, holding that the government: need not adopt the least restrictive means, "demonstrate a perfect means-end fit," or "satisfy a court that it has chosen the best conceivable option." *Nat'l Cable,* 555 F.3d at 1002. "The only condition is that the regulation be proportionate to the interests sought to be advanced." *Id.*

2. The scope of the restriction on speech is a key part of the "reasonable fit" analysis. As the *Ayotte* court recognized, restrictions on the use of prescriber-identifiable data are substantially narrower than other commercial speech restrictions that have struck down by the Supreme Court. 550 F.3d at 53; *id.* at 94-97 (Lipez, J., concurring). The law "foreclose[s] no message or interest of consequence," *id.,* and does not prevent detailers from "provid[ing] medical literature and information regarding the drugs they are promoting," SPA-28; *see also Ayotte,* 550 F.3d at 97 (Lipez, J., concurring) ("sales representatives may continue to pitch their drugs directly to doctors").

And, because of the consent provision, the law does not restrict any marketing to a willing audience. On this point, the Court's analysis in *Anderson* is both persuasive and controlling. Like the real estate solicitation law upheld in *Anderson*, this law allows the person targeted by marketing – the doctor – to control the marketing practice. It thus "can hardly be accused of being 'more extensive than necessary.'" 294 F.3d at 462 (citing other consent-based restrictions); *see also Mainstream Marketing Servs. v. FTC,* 358 F.3d 1228, 1242 (10th Cir.

2004) ("The Supreme Court has repeatedly held that speech restrictions based on private choice (i.e. – an opt-in feature) are less restrictive than laws that prohibit speech directly.").

3. Plaintiffs' list of supposed alternatives is nothing more than a list of possible ways to improve health care outcomes and reduce health care spending. This "laundry list" is irrelevant because none of the proposals have anything to do with the problems caused by the use of non-public health care information for marketing prescription drugs.

Moreover, plaintiffs' argument on this point is particularly puzzling because their list of proposed "alternatives" is almost entirely drawn from existing Vermont laws. Plaintiffs' own witness, Mr. Frankel, called Vermont a "pioneer" in efforts to control health care costs. A-267. Plaintiffs identify *no less than 12 programs* that Vermont already has. PhRMA Br. 52-54; IMS Br. 45-48. Nine were in place before the Prescription Confidentiality Law took effect, some for decades. *E.g.,*1978 Vt. Acts & Resolves No. 127, at 76-80 (adopting generic substitution and formularies). Two programs (the gift ban and the pilot program for therapeutic substitution) took effect on the same

day as this law. Vt. Stat. Ann. tit. 18, § 4631a (2009); Vt. Stat. Ann. tit. 18, § 4605 (2009). The other program, academic detailing, Vt. Stat. Ann. tit. 18, § 4622, was passed together with the Prescription Confidentiality Law but PhRMA sued to block its implementation. SPA-49. The argument that Vermont was required under *Central Hudson* to adopt programs it already has is illogical.[14]

Plaintiffs try to avoid this obvious flaw in their argument by suggesting Vermont's programs are "untested." PhRMA Br. 52. If the relevant "test" is whether existing laws help reduce health care costs, then plaintiffs' argument boils down to this: no restrictions on pharmaceutical marketing are permissible, even if those restrictions reduce health care costs, because other laws also reduce health care costs in other ways. That is not the legal standard.

4. Finally, plaintiffs return to their argument that the law fails because it does not restrict enough speech. IMS Br. 50-51 (complaining

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[14] The data vendors' subsequent assertion that "Vermont did not enact any of the[se] measures," is inexplicable. IMS Br. 50. Plaintiffs themselves cite to the relevant Vermont statutes. *Id.* at 45-48.

that law does not ban detailing).[15] On the contrary, the law is precisely targeted at the nonconsensual use of prescriber-identifiable data in marketing. While it is true that this is a "subset of all marketing," PhRMA Br. 51, the Legislature's chosen restriction is "precisely co-extensive" with the harm identified. *Anderson,* 294 F.3d at 462. And, in any event, "underinclusiveness will not necessarily defeat a claim that a state interest has been materially advanced." *Id.* at 463; *see also Mainstream Marketing,* 358 F.3d at 1238-39 (same).

III. The law does not violate the dormant Commerce Clause.

The data-vendor plaintiffs assert that Vermont cannot regulate the sale or use of identifying information for prescriptions dispensed in Vermont, because Vermont pharmacies send that information to out-of-state computer servers before selling it. As the State pointed out below, this interpretation of the dormant Commerce Clause would wipe out state-law privacy protections for consumer information in financial records, credit reports, insurance files – in fact, it would mean the State

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[15] The data vendors' assertion that the district court "seemed to recognize" the statute as "incoherent" is false. IMS Br. 50. The district court said nothing of the kind.

could not protect the privacy of *patient* information in health care records. Any of this consumer information can be sent to computer servers located outside the consumer's home state. The data vendors make no effort to reconcile their Commerce Clause theory with state consumer protection laws. In any event, their argument fails on the merits and for lack of standing.

A. The law regulates Vermont businesses and Vermont transactions.

While ordinarily standing is addressed before the merits, that order is reversed here, because an explanation of the merits helps illustrate why the data vendors lack standing to bring this facial challenge. Another preliminary point is also important. PhRMA does not assert a Commerce Clause challenge to the law's restriction on the use of data by pharmaceutical manufacturers. That fact makes the data vendors' claim virtually meaningless, because even if they succeeded on this claim, their customers still cannot use the data in marketing.

Turning to the merits, a dormant Commerce Clause challenge may be premised on one of three assertions: (1) the law "discriminates on its face against interstate commerce," *United Haulers Ass'n v.*

Oneida-Herkimer Solid Waste Mgmt. Auth., 127 S. Ct. 1786, 1793 (2007); (2) impermissibly burdens interstate commerce, *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); or (3) regulates commerce entirely outside the State's borders, *Healy v. Beer Inst., Inc.,* 491 U.S. 324, 332 (1989). The data-vendor plaintiffs' claim falls into the last category. They mistakenly contend that Vermont's law regulates "entirely extraterritorial activities." IMS Br. 57. In fact, the law has no impermissible extraterritorial reach and plaintiffs have not satisfied the stringent requirements for a facial challenge under the dormant Commerce Clause.

1. The law does not regulate commerce occurring entirely outside of Vermont. Rather, it regulates the use of data from a regulated Vermont transaction. The entities regulated by the law – health insurers, self-insured employers, electronic transmission intermediaries, pharmacies, and similar entities, Vt. Stat. Ann. tit. 18, § 4631(d) – all conduct business in Vermont. Pharmacies and health insurers are licensed by Vermont. *See id*. § 4631(b)(6), (b)(4). The statute governs the use of prescriber-identifiable data in "regulated

records," which are prescription drug records for prescriptions dispensed in Vermont or written by Vermont prescribers. *Id.* § 4631(b)(9),(d). The statute thus governs Vermont businesses and Vermont transactions – for purposes of this case, pharmacies doing business in and licensed by Vermont. (The data vendors purchase prescriber-identifiable data from pharmacies. IMS Br. 60.) Vermont pharmacies acquire prescription data in Vermont and enter it into computers physically located in Vermont. A-222.

The data-vendor plaintiffs premise their Commerce Clause argument solely on the fact that Vermont pharmacies transfer data to computer servers outside the state before selling it to data vendors. IMS Br. 60; A-221. The data vendors focus on their business practices, saying they "do not make sales inside of Vermont nor do they acquire information from inside of Vermont." IMS Br. 60. That fact is irrelevant, because *the law does not regulate data vendors*. Vermont may regulate the practices of Vermont pharmacies with respect to Vermont transactions. A licensed Vermont pharmacy that does business in the State is subject to all Vermont laws that govern the dispensing of

prescription drugs, including the collection and security of prescription records. *See* A-222 (CVS witness testifying that Vermont regulates collection and storage of prescription information); Vt. Stat. Ann. tit. 26, §§ 2021-2064 (pharmacy licensing statutes); Vt. Pharmacy Board Rules, Part C, §§ 5.3, 18.1.2.8, 19.1, 19.8 (confidentiality rules). As the district court held, a Vermont pharmacy cannot avoid regulation "simply by routing data through a parent company's server on its way to data vendors." SPA-46-47. "The fact that an ordinary commercial transaction happens to occur in cyberspace does not insulate it from otherwise applicable state consumer protection laws." *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 195 (2d Cir. 2007).

The district court properly relied on this Court's ruling in *SPGGC* as controlling the outcome here. The *SPGGC* plaintiffs argued that Connecticut's consumer protection law regulating gift cards could not apply to gift cards sold on the internet because that would be "inherently extraterritorial." 505 F.3d at 195. This Court rejected that argument, noting that the seller of gift cards had a "readily available" means of distinguishing between consumers protected by the law and

those outside its scope – billing addresses. *Id.* Likewise, pharmacies may readily separate identifying information for Vermont prescribers from unregulated data from other states and conduct their business transactions accordingly.

The Prescription Confidentiality Law is easily distinguished from the cases cited by plaintiffs. This is not a price-tying law – indeed, it is "neither discriminatory nor protectionist," SPA-48 – and the district court correctly held that the Supreme Court's price-tying cases are "inapposite." SPA-48 (discussing *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 526 (1935), and other price-tying cases). Plaintiffs' reliance on *American Booksellers Foundation v. Dean,* 342 F.3d 96 (2d Cir. 2003), is similarly misplaced. In *Dean,* the Court invalidated a state law that restricted transfers of sexually explicit material to minors, because a "person outside Vermont who posts information on a website . . . cannot prevent people in Vermont from accessing the material." 342 F.3d at 103. In *SPGGC,* the Court distinguished *Dean* on the ground that internet gift card sellers may readily distinguish Connecticut residents from other persons based on their credit card billing addresses. 505

F.3d at 195. Likewise, as the district court concluded, Vermont prescription records are "perfectly distinguishable" from non-Vermont records. SPA-48. Vermont's law does not affect the use of prescriber-identifiable data taken from prescription records in other states.

Both the Supreme Court and this Court have cautioned against expansive use of the Commerce Clause to limit state consumer protection laws. Consumer protection is a traditional field of state regulation and courts therefore "'should be particularly hesitant to interfere with the [State's] efforts under the guise of the Commerce Clause'" in this context. *SPGGC*, 505 F.3d at 194 (quoting *United Haulers*, 127 S. Ct. at 1796). This reasoning applies with special force to this case, because plaintiffs' novel Commerce Clause theory has consequences for all state laws that protect information privacy. The Court should reject plaintiffs' invitation to use the Commerce Clause as a "roving license," *United Haulers,* 127 S. Ct. at 1796, to undermine state laws that protect consumers' privacy.

2. Plaintiffs' facial challenge is speculative and premature. Because this is a facial challenge, SPA-46 n.19, the Court must look only to the

"facial requirements" of the statute and may not "speculate about 'hypothetical' or 'imaginary' cases." *Wash. State Grange*, 128 S. Ct. at 1190; *see also Field Day, LLC v. County of Suffolk*, 463 F.3d 167, 174 (2d Cir. 2006) ("A 'facial challenge' to a statute considers only the text of the statute itself, not its application to the particular circumstances of an individual."). On its face, § 4631 regulates the actions of entities that do business in Vermont and restricts certain uses of information obtained from Vermont transactions. Plaintiffs must show that the law *necessarily* regulates out-of-state commerce in all of its applications to sustain their pre-implementation facial challenge. *See United States v. Salerno*, 481 U.S. 739, 745 (1987); *United States v. Sage*, 92 F.3d 101, 106 (2d Cir. 1996) (applying *Salerno* standard to facial Commerce Clause challenge). Plaintiffs cannot meet this heavy burden.

B. Plaintiffs lack standing for this claim.

A "plaintiff must demonstrate standing for each claim he seeks to press," *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006), and the data-vendor plaintiffs do not have standing for this claim. As the

preceding discussion shows, the data vendors seek to litigate the Commerce Clause rights of pharmacies. They cannot do so.

The district court found standing, SPA-43, but its analysis mistakenly focused on plaintiffs' injury, as opposed to the nature of the right asserted. The cursory discussion of standing in *Government Suppliers Consolidating Servs. v. Bayh,* 975 F.2d 1267, 1274-75 (7th Cir. 1992), is flawed for the same reason. The relevant question is not whether the data vendors allege an injury, but whether they may litigate the Commerce Clause rights of Vermont pharmacies. A "plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975); *see also Campbell v. Louisiana*, 523 U.S. 392, 397 (1998) ("general reluctance to permit a litigant to assert the rights of a third party"). So-called third-party standing is permitted only where "three preconditions [are] satisfied: (1) the [party asserting the claim] suffered an injury in fact; (2) he had a close relationship to the [third parties]; and (3) there was some hindrance to the [third parties] asserting their own rights." *Campbell*,

523 U.S. at 397 (quotations omitted); *see also Mid-Hudson Catskill Rural Migrant Ministry, Inc. v. Fine Host Corp.,* 418 F.3d 168, 174 (2d Cir. 2005) (plaintiff seeking third-party standing must satisfy prudential requirements, including showing hindrance to other party's ability to protect its own interests).

Here, nothing prevents major corporations like Rite Aid and CVS from asserting their own interests, particularly given their financial stake, *see* A-222. *See Mid-Hudson Catskill,* 418 F.3d at 174 (organization lacked standing to litigate members' rights absent hindrance to members' ability to protect own interests); *cf. Ayotte,* 550 F.3d at 49-50 (data vendors lacked standing to litigate rights of pharmaceutical manufacturers). No pharmacy has challenged Vermont's authority to regulate the use of prescription drug records and the Court should not reach out to decide the issue in the absence of a proper plaintiff.

CONCLUSION

The district court's ruling upholding the constitutionality of the Prescription Confidentiality Law should be affirmed.

Dated: September 1, 2009

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of 21,000 words granted by order of the Court dated August 19, 2009. This brief contains 20,809 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office Word 2007 in 14 point Century Schoolbook style.

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ANTI-VIRUS CERTIFICATION

In the matter of *IMS Health Inc. v. Sorrell*, Docket No. 09-1913-cv (L), I, Bridget C. Asay, certify that I used McAfee VirusScan Enterprise Edition 8.5.0i, Scan Engine Version (32-bit): 5300.2777; DAT Version 5451.0000 to scan for viruses the PDF version of the Brief of Appellees that was submitted in this case as an email attachment to <briefs@ca2.uscourts.gov> and that no viruses were detected.

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I hereby certify that on this 1st day of September, 2009, I caused copies of Brief of Appellees to be served upon all parties by sending two copies by overnight courier to counsel of record for:

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ADDENDUM

ADDITIONAL JOINT APPENDIX PAGE CITES FOR CERTAIN MATERIALS FROM THE LEGISLATIVE RECORD (JOINT EXS. 1-3)

Page