No. 10-779

IN THE

Supreme Court of the United States

WILLIAM H. SORRELL,
ATTORNEY GENERAL OF VERMONT, *et al.*,
Petitioners,

v.

IMS HEALTH, INC., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF FOR RESPONDENT PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

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QUESTION PRESENTED

With the express goal of rectifying a perceived imbalance in the marketplace of ideas for the appropriate use of pharmaceuticals, Vermont law bars a pharmaceutical company from speaking about its drugs to physicians or other healthcare professionals if the company's representative has used information about the doctors' historical prescribing practices to facilitate that speech. 18 V.S.A. § 4631(d). The Vermont law does not restrict insurance companies, the State, or anyone else from commercially using a prescriber's history to influence a prescriber's behavior. The question presented is whether that law violates the First Amendment.

RULE 29.6 STATEMENT OF CORPORATE DISCLOSURE

Pharmaceutical Research and Manufacturers of America discloses that it has no parent corporation and no publicly held company owns 10% or more of its stock.

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INTRODUCTION

Vermont's law is based on the view that pharmaceutical manufacturers are too persuasive in their communications with physicians. The law thus seeks to alter "[t]he marketplace for ideas on medicine safety and effectiveness," 2007 Vt. Acts & Resolves No. 80 ("Act 80"), § 1(4), even though manufacturers' speech is truthful, non-misleading, and extensively regulated by the Food and Drug Administration ("FDA"); even though physicians are trained to use their medical judgment in the best interest of patients; and even though physicians have total control over whether, when, and how they communicate with manufacturers. In order to correct a perceived "massive imbalance in information presented to doctors," *id*. § 1(6), the law restricts pharmaceutical companies' use of prescriber data, which the State identified as a tool that helps make manufacturers' speech influential.

The law permits, however, other commercial actors to use prescriber data to influence prescriber behavior. Vermont thus excepted from the law insurance companies, itself, and others whose cost-containment message the State favors. The law's findings, purpose, and operation exemplify an invidious motive to discriminate against pharmaceutical companies and their viewpoint.

This law does not protect personal information, and the law is not directed at the non-disclosure of a physician's prescription history. Rather, the law attempts to shield doctors from the speech of pharmaceutical companies while permitting other healthcare participants to inject commercial influences into the doctor-patient relationship.

Vermont's law also rests on the illegitimate premise that physicians are not making what the State considers to be the optimal prescription decisions for their patients. The law is based on derogatory assumptions about doctors and the counter-intuitive notion that doctors will make better decisions about patient health if they are deprived of FDA-regulated speech about FDA-approved drugs. The First Amendment prevents a State from impeding the flow of truthful and non-misleading information based on such paternalistic assumptions.

STATEMENT

A. *The Pharmaceutical Marketplace*

1. Respondent Pharmaceutical Research and Manufacturers of America ("PhRMA") is a non-profit association of the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's members develop and manufacture life-saving and life-enhancing new medicines. New drugs significantly contribute to the quality of life by advancing therapeutic gains in the treatment of disease. Cong. Budget Office, *Research and Development in the Pharmaceutical Industry* 37 (2006) ("2006 CBO Report").

In recent years, new medicines have accounted for 40% of the increase in human life span. Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries, 1982–2001*, at 19 (Nat'l Bureau Econ. Res. Working Paper No. 9754, 2003). For cancer patients, for example, life expectancy increased approximately three years between 1980 and 2000, and up to 86% of those gains are attributable to new treatments. Eric Sun et al., *The Determinants of Recent Gains in Cancer Survival: An Analy-*

sis of the Surveillance, Epidemiology, and End Results (SEER) Database, 26 J. Clinical Oncology (May 20 Supp.) 6616 (2008); *see also* C.A. App. 156-57 (testimony of Lori Reilly, Vice President of Policy & Research for PhRMA, discussing advancements in the treatment of HIV/AIDS, diabetes, and hypertension).

Research-based drug companies are responsible for almost all advances in the development of prescription medicines. Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 2-3 (1998) ("1998 CBO Report"); *see also* C.A. App. 149, 157 (testimony of Peter Barton Hutt, former FDA Chief Counsel). Pharmaceutical companies invest billions annually in research and development. PhRMA, *2010 Pharmaceutical Industry Profile* 26 fig.8 (2010), *available at* http://www.phrma.org/sites/default/files/159/profile_2010_final.pdf ($65.3 billion in 2009). Those expenditures vastly exceed the amount dedicated to promotion and marketing. Cong. Budget Office, *Promotional Spending for Prescription Drugs* 2 (2009) ($20.5 billion in 2008).

Sponsors of new medicines must submit voluminous new drug applications to the FDA that demonstrate the safety and effectiveness of proposed drugs. *See* 21 U.S.C. § 355. It takes an average of 14 to 16 years to complete the drug development process, and roughly only 1 in 5,000 compounds identified as potential medicines ever reaches market. C.A. App. 135. On average, the cost to develop a single new drug is $2 billion. J.A. 188. For most medicines, sales profits do not exceed the costs of development. 1998 CBO Report, *supra*, at xv.

Generic drug manufacturers do not develop new medicines but rather produce copies of innovator drugs whose patents have expired. *Id.* at 2; 21 U.S.C. § 355(j). To obtain FDA approval, a generic manufacturer must demonstrate only that its drug is "bioequivalent" to a pioneer drug within an 80-125% range. 21 U.S.C. § 355(j)(8)(B); Pet. App. 6a, 72a. Developing and obtaining approval of a generic drug on average costs between $100,000 and $500,000. C.A. App. 140, 149 (Hutt testimony). Generic drugs sell for 20% to 80% less than the innovator drugs they copy, *id.* at 149, and upon entry quickly gain market share at the expense of innovator drugs. 2006 CBO report, *supra*, at 16. For example, the anti-depressant Prozac lost over 80% of its U.S. sales to generics in the first month after its patent expired. *Id.*

Even drugs still under patent face a highly competitive marketplace. J.A. 191, 205. Patented drugs compete with other patented drugs in the same therapeutic class (*e.g.*, anti-diabetic drugs, cholesterol-lowering drugs, etc.). 2006 CBO Report, *supra*, at 12-13; J.A. 191, 205-06, 232, 353-54. For instance, within the class of cholesterol-lowering drugs, patented drug Crestor competes with patented drug Lipitor. While both drugs are statins that block an enzyme that causes the liver to produce cholesterol, the two drugs differ in their indications for use, dosages, and side effects, any of which could make them more or less appropriate for certain patients. *Compare Crestor: Highlights of Prescribing Information* (2010), *available at* http://www1.astrazeneca-us.com/pi/crestor.pdf, *with Lipitor: Highlights of Prescribing Information* (2009), *available at* http://www.pfizer.com/files/products/uspi_lipitor.pdf. Crestor and Lipitor also compete with patented cholesterol-

lowering drugs that are not statins, like Zetia, which lowers cholesterol by blocking its absorption from food. Merck, Cholesterol Medicine, http://www.zetia.com/ezetimibe/zetia/consumer/index.jsp (last visited Mar. 24, 2011).

Patented drugs also may compete with non-bioequivalent generic products within the same therapeutic class. J.A. 205-06, 232, 353-54. Thus, Crestor and Lipitor compete with simvastatin (the generic version of Zocor, an innovator statin whose patent has expired). Simvastatin treats cholesterol by blocking the same enzyme, but has different indications, dosages, and side effects. *See Zocor (simvastatin): Highlights of Prescribing Information* (2010), *available at* http://www.merck.com/product/usa/pi_circulars/z/zocor/zocor_pi.pdf.

Switching from an innovator drug to a non-bioequivalent generic drug often poses risks. *See*, *e.g.*, *Significant 30 Percent Increase in Relative Risk of Cardiovascular Events or Death*, WorldPharmaNews, Sept. 5, 2007, http://www.worldpharmanews.com/pfizer/71-significant-30-percent-increase-in-relative-risk-of-cardiovascular-events-or-death (discussing study showing that switching patients from Lipitor to simvastatin was associated with a 30% increase in the relative risk of heart attacks, strokes, certain heart surgeries, or death); Bryan R. Cote & Elizabeth A. Peterson, *Impact of Therapeutic Switching in Long-Term Care*, 14 Am. J. Managed Care SP23, SP25 (2008) (more than three-quarters of clinicians said it was common for a patient's new drug to be less effective after a therapeutic switch, and almost half said side effects typically increased after a switch).

2. A physician's choice of the right drug for a particular patient is a complicated and patient-

specific decision that is not typically subject to mathematical precision. The same medicine may work well for one patient but not for another patient with the same condition. As Thomas D. Wharton, M.D., Chief of Cardiology at Exeter Hospital, testified at trial, a patient's individual characteristics, such as age and medical history, may make a particular drug more or less risky than other drugs in the same therapeutic class. J.A. 214. Choosing the appropriate medicine requires a doctor's specialized knowledge of the drug treatment options, including side effect profiles, potential interactions with other medications, medical guidelines, the evolving medical literature, and other new developments. *Id.* at 213-14; *id.* at 175 (testimony of Andrew James Cole, M.D., Dir. of Epilepsy Service, Massachusetts General Hospital and Harvard Medical School).

Physicians are trained to use their best medical judgment in making prescription decisions for their patients. *See, e.g.*, Am. Med. Assoc., *Code of Medical Ethics: Opinion 10.015* (2001), *available at* http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion10015.shtml. In making those decisions, physicians consider information from a variety of sources, including medical journals, scientific meetings, colleagues, pharmaceutical companies, and private and public payers. J.A. 175 (Cole testimony), 215-16 (Wharton testimony), 274 (testimony of A. Kenneth Ciongoli, M.D., neurologist and former Associate Professor of Neurology at Vermont College of Medicine).

In a survey commissioned by PhRMA, physicians reported that the following factors had a "great deal" of influence on their prescribing decisions: 92% reported clinical knowledge and experience; 88%, the

patient's unique situation; 35%, insurance formularies; and only 11%, pharmaceutical representatives. PhRMA, *The Facts About Pharmaceutical Marketing & Promotion* 3-4 (2008) ("*Pharmaceutical Marketing*"), *available at* http://www.phrma.org/sites/default/files/159/marketing_and_promotion_facts_071108_final.pdf; *accord* Tufts Ctr. for the Study of Drug Dev., *Outlook 2008*, at 5 (2008), *available at* http://csdd.mtufts.edu/_documents/www/Outlook2008.pdf (survey showing 68% of physicians consider continuing medical education "very important" in prescribing decisions; 43%, information from peers; 37%, insurers' coverage decisions; and 13%, information from pharmaceutical companies).

Insurance companies and government healthcare programs utilize highly effective mechanisms to influence physicians to prescribe the least costly medicine potentially appropriate. Those insurers adopt schedules of drugs called "formularies" or "preferred drug lists" under which they will provide reimbursement. Formularies and preferred drug lists frequently offer lower patient co-payments for generic drugs or other "preferred" medications. J.A. 306, 315-16. Public and private insurers also have "step therapy" requirements that cover a brand name drug only after the prescriber initiates a lower cost alternative and that alternative fails. *Id.* at 232.

Insurance companies and government programs often bar prescriptions of a brand-name drug for which there is a lower cost alternative unless the company or program gives "prior authorization." *E.g.*, *id.* at 433 (deposition of Joshua Slen, Dir., Office of Vt. Health Access ("OVHA")). The Vermont Medicaid program maintains a Preferred Drug List that uses step therapy and prior authorization require-

ments to influence prescribing patterns. *Id.* at 433, 436; C.A. App. 2454-55, 2503-07.

In a 2002 survey by the Boston Consulting Group, 54% of physicians reported that formularies have a major impact on their prescribing decisions. *Pharmaceutical Marketing*, *supra*, at 3. Similarly, a 2003 study in the *New England Journal of Medicine* found that when insurers moved certain cholesterol-lowering statins to a less-preferred formulary tier, about half of patients switched to statins on preferred tiers. Haiden A. Huskamp et al., *The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending*, 349 New Eng. J. Med. 2224, 2228 (2003); *see also* J.A. 200 (Reilly testimony describing a study finding that "about a third of doctors don't even talk to patients [about a medication] when a given medication isn't covered in a patient's formulary"); *id.* at 319 (testimony of Randolph Frankel, Vice President of External Affairs for IMS Health) ("[P]roducts that don't get on formularies are virtually wiped out.").

Private insurers, States, and academic institutions also fund counter-detailing programs that encourage physicians to prescribe generic or lower cost drugs. J.A. 211-12, 313, 369-70, 375. In counter-detailing, healthcare professionals visit doctors "to promote the use of generic or alternative products." *Id.* at 212 (testimony of Eugene Kolassa, Ph.D.). For example, the pharmacy benefit company AdvancePCS's counter-detailing program sent out 150 employees to visit 20,000 of the nation's top prescribers each year. Marc Kaufman, *Doctors Hear Alternatives To Drug-Firm Sales Pitches*, Wash. Post, Aug. 5, 2002, at A01. One AdvancePCS pharmacist explained that the goal "is to discuss with doctors the drugs they're prescribing

to make sure the patients are getting the most appropriate — and least expensive — medications." *Id.*

The University of Vermont administers Vermont's counter-detailing program, entitled the "Evidence-Based Education Program." 18 V.S.A. §§ 4621-4622. That program "provide[s] information and education on the therapeutic and cost-effective utilization of prescription drugs" to physicians. *Id.* § 4622(a)(1). Funding for the program is lodged in an "evidence-based education and *advertising* fund." 33 V.S.A. §§ 2004(b), 2004a(a) (emphasis added).

B. *Use Of Prescriber Data By Pharmaceutical Manufacturers, Insurance Companies, State Healthcare Programs, And Counter-Detailers To Influence Prescriber Behavior*

1. Innovator pharmaceutical companies promote new medicines to doctors through one-on-one discussions, sometimes called detailing. In these discussions, "representatives provide 'details' regarding the use, side effects and risk of interactions of the drug they are selling." Pet. App. 71a; *accord* J.A. 175-76. Representatives often provide reprints of clinical studies published in peer-reviewed medical literature, as well as other scientific and safety-related information regarding the company's medicines. J.A. 218, 222, 273. Visits typically last only a few minutes, *id.* at 273, 287, and physicians control whether and how much time to schedule with detailers, *id.* at 203, 220, 364, 465-66. Many doctors find the visits useful in "keeping current with the changing landscape of prescription drugs." Pet. App. 72a.

Detailing focuses on patented medicines because detailing generally is no longer cost effective once the

medicine's patent expires and competitors introduce bioequivalent generics. *Id.* at 72a, 91a. For similar reasons, and because all States mandate or allow substitution of a bioequivalent generic drug unless overridden by a physician, generic drug manufacturers do not detail their products to physicians. *Id.*; Jesse C. Vivian, *Generic Substitution Laws*, U.S. Pharmacist, June 2008, at 30 tbl.2, *available at* http://www.uspharmacist.com/content/s/44/c/9787/ (aggregating generic substitution laws).

Under federal law, a "false or misleading" statement by a pharmaceutical manufacturer to a physician about a drug renders the drug misbranded and exposes the company to criminal penalties. 21 U.S.C. § 352(a); J.A. 189-93 (Hutt testimony). Pharmaceutical representatives may not recommend or suggest to a physician any use that is not in the FDA-approved labeling. 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5. The representative must also present a brief summary that reflects a "fair balance" between information about the drug's efficacy and about its safety. J.A. 190; *see also* 21 C.F.R. § 202.1(e)(5)(ii). By contrast, FDA regulations do not apply to counter-detailers' or insurance companies' communications with doctors about drug safety and efficacy. J.A. 193.

2. Innovator manufacturers often use doctors' prescribing histories to target their visits with physicians. Pet. App. 18a, 91a. Pharmacies sell prescription information to data aggregation companies, including respondents IMS Health, Inc., Verispan, LLC, and Source Healthcare Analytics, Inc. *Id*. at 5a. Federal law requires pharmacies to remove the patient's name, social security number, and any other information "[w]ith respect to which there is a reasonable basis to believe the information can be

used to identify the individual." 45 C.F.R. § 160.103; *see* Health Insurance Portability and Accountability Act ("HIPAA"), 42 U.S.C. § 1320d-2; J.A. 157, 249, 304. For example, the patient's zip code must be removed if it could be used to identify the individual. 45 C.F.R. § 164.514(b)(2)(i)(B); J.A. 248. Data vendors aggregate the information to show a physician's total prescriptions of each type of drug over a given time. Pet. App. 5a, 70a-71a; *see also* J.A. 524 (example aggregated prescriber data report).

This aggregate data helps manufacturers identify those physicians who would likely be interested in educational messages about the medicines the companies offer, and then tailor a specific message when communicating with those physicians. Pet. App. 6a, 81a-82a. For example, by reviewing aggregate prescription history reports, a company can determine whether a neurologist treats patients for one, some, or all of the following conditions: stroke, Parkinson's disease, dementia, multiple sclerosis, or epilepsy. J.A. 182-83 (Cole testimony); 286 (Ciongoli testimony). Similarly, not all cardiologists treat diabetes, and prescriber data enables a company that makes diabetes medicines to avoid detailing those cardiologists who do not treat diabetes. J.A. 225 (Wharton testimony). PhRMA's expert witness Dr. Kolassa testified that without prescriber data, "[t]here will be more sales calls that result in talking to physicians that aren't interested in the product. There will be opportunities missed with physicians that could find the . . . new information useful and important, but they won't get it because the company was unaware that the physician used that drug." J.A. 208.

3. All other major market participants regularly use prescriber history information to influence physi-

cians' prescription decisions. Private insurance companies and government healthcare programs use the information to target doctors to persuade them to prescribe lower-cost drugs. Pet. App. 7a. They use the information to monitor and enforce compliance with formularies, step therapy, and prior authorization requirements by contacting doctors who prescribe brand-name products (which may be on a higher tier of the formulary) or who have a higher than average number of requests for prior authorization. *Id*.

For instance, Medco, one of the nation's largest pharmacy benefits managers, has encouraged physicians to prescribe generic drugs by sending them generic samples and quarterly mailings with statistical progress reports that track their individual generic substitution rate. Medco, *2007 Drug Trend Report* 72 (2007), *available at* http://medco.mediaroom.com/index.php?s=64&cat=5; *see also* J.A. 322 (Frankel testimony). Blue Cross Blue Shield of Michigan mailed doctors a list of patients who were taking Lipitor or Lescol, two brand-name cholesterol-lowering drugs, and offered the doctors $100 for each patient who switched to simvastatin, a non-bioequivalent generic. Vanessa Fuhrmans, *Doctors Paid To Prescribe Generic Pills*, Wall St. J., Jan. 24, 2008, at B1. In a PhRMA-commissioned survey, 80% of physicians reported having been asked to switch a prescription to a non-bioequivalent substitute. *See Pharmaceutical Marketing*, *supra*, at 4.

The State of Vermont uses prescriber information to communicate with prescribers regarding drug utilization and adherence to the Preferred Drug List and prior authorization requirements for Medicaid and other state-funded healthcare programs. J.A.

428-30, 432-36, 441-42 (Slen testimony); *id.* at 446-48 (deposition of Sharon Moffatt, Acting Commissioner of the Vermont Department of Health). For instance, Vermont confronted prescribers "with a list of their patients who were receiving prescriptions for [statin and proton pump inhibitor] medications that would be considered non-preferred" and asked them "to convert patients to a preferred alternative." OVHA, Pharmacy Unit, *Therapeutic Equivalency Pilot Program Legislative Report* 2 (2010), *available at* http://dvha.vermont.gov/budget-legislative/therapeutic-equivalency-pilot-report-january-2010.pdf.

Vermont also maintains a "multi-payer" database containing prescriber-identifiable information from private and public insurance plans in Vermont. J.A. 312-13. The State's Evidence-Based Education Program can use that database to target and "advertis[e]" the State's message to prescribers. 33 V.S.A. § 2004a; 18 V.S.A. § 9410; J.A. 312-13.

C. *The Vermont Law*

1. In 2007, the Vermont legislature deliberated banning the sale, license, transfer, or use of prescriber-identifiable data as a means to reduce the influence of drug marketing on physicians. C.A. App. 1655-58. On April 30, 2007, a federal district court held that a similar New Hampshire ban on the use of prescriber data violated the First Amendment. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007), *rev'd*, 550 F.3d 42 (1st Cir. 2008).

In the immediate aftermath of that decision, the Vermont Legislature adopted 31 findings that purported to lay out the harms to society from pharmaceutical manufacturers' speech. Act 80, § 1 (Pet. App. 134a-140a). Those findings were drafted in large

part by American University Professor Sean Flynn. Ex. 115 to Flynn Dep. (May 2, 2007 Flynn email to state officials attaching "datamining findings"), *infra* App. 12a-17a; Ex. 113 to Flynn Dep. (May 1, 2007 Flynn email to state officials), *infra* App. 1a-11a.

The findings declare that "[t]he marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors." Act 80, § 1(4). The findings blame this perceived problem on the amount of money that pharmaceutical companies spend on their communications with physicians. *Id*. § 1(17)-(18). The findings thus conclude that pharmaceutical manufacturers are too effective in persuading doctors to prescribe costly drugs. *Id.* § 1(2), (6), (13)-(15), (19), (22)-(27), (30).

The legislature further found that pharmaceutical marketing threatens the State's interest in cost-containment and possibly patient health. It observed that "[t]he goals of marketing are often in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress towards these goals comes at the expense of cost-containment activities and possibly the health of individual patients." *Id*. § 1(3). The findings complained that the speech of pharmaceutical companies is focused on new medicines that are presumptively more dangerous than older, typically generic, drugs. *Id.* § 1(7), 1(8), 1(14).

The legislature further concluded that manufacturers' speech inhibited Vermont physicians from exercising their independent medical judgment. *Id.* § 1(4) ("prescribers . . . lack the time for substantive research" and thus rely on manufacturers' speech);

id. § 1(13) ("Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatment for particular conditions."); *id.* § 1(19) ("To the extent that this meeting time [spent with sales representatives] comes at the expense of time spent with patients, quality of care will be negatively affected.").

The legislature also expressed the desire to protect doctors from unwanted speech. Vermont noted that "[s]ome doctors in Vermont are experiencing an undesired increase in aggressiveness of pharmaceutical sales representatives and a few have reported that they feel coerced and harassed." *Id.* § 1(20); *accord id.* § 1(28). Vermont explained that this concern was heightened "when doctors are informed by sales representatives that they are being monitored." *Id.* § 1(27). Vermont also declared that the use of prescription information was "an intrusion into the way physicians practice medicine." *Id*. § 1(20).

2. Against that backdrop, Vermont passed Section 4631 of Title 18 of the Vermont Statutes Annotated to ban the release of prescriber data for pharmaceutical marketing or promotion absent prescriber consent. Section 4631(d) provides:

> A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records containing prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents as provided in subsection (c) of this section. Pharmaceutical

> manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section.

The statute defines "[m]arketing" to include "advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force." *Id.* § 4631(b)(5). The law defines "[p]romotion" or to "promote" as "any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance." *Id.* § 4631(b)(8). Subsection (c) provides for procedures by which prescribers may consent to the use of their prescription data for drug marketing and promotion when applying for or renewing their licenses. *Id*. § 4631(c).

Subsection (e) exempts from the ban "the sale, license, exchange for value, or use, of regulated records for the limited purposes of pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; or health care research," as well as various other uses. *Id.* § 4631(e)(1).

Pharmaceutical manufacturers that speak to Vermont-licensed doctors after using prescriber-identifiable data are subject to penalties under the

Vermont Consumer Fraud Act. *Id.* § 4631(f); 9 V.S.A. § 2466a(a). These penalties include civil penalties of not more than $10,000 for each violation. 9 V.S.A. § 2458(b)(1). The Act also authorizes the Attorney General of Vermont to seek injunctive relief. *Id.* § 2458(a).

D. *Proceedings Below*

1. In August and October 2007, the data vendor respondents and PhRMA, respectively, initiated the instant suits challenging several provisions of Act 80. One such provision required pharmaceutical manufacturers marketing using prescriber-identifiable data to make specified disclosures about their products and competing therapies. Act 80, § 17(f) (repealed). On March 5, 2008, Vermont repealed that provision and added the second sentence of Section 4631(d). 2008 Vt. Acts & Resolves No. 89, § 3.

After consolidating the two cases and holding an evidentiary hearing, the district court upheld the Vermont law. Pet. App. 68a-118a. The court observed that "the whole point of [the statute] is to control detailers' commercial message to prescribers." *Id*. at 82a. The district court upheld the law under the factors identified in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), reasoning that "[t]he law is sustainable on the State's cost containment and public health interests, which are substantial, but prescriber privacy is not a sufficient interest to justify the law." Pet. App. 87a; *cf. id*. at 88a (declining to address asserted interest in protecting prescriber privacy).[1]

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[1] Respondent PhRMA also sought to invalidate Act 80, § 20 (codified at 33 V.S.A. § 2004(a)), which requires pharmaceutical manufacturers to fund the State's Evidence-Based Education

2. A divided panel of the Second Circuit reversed and held that the law was unconstitutional under *Central Hudson*. *Id.* at 1a-67a. The court of appeals rejected the State's asserted interest in "protecting the privacy of prescribers and prescribing information" because "the statute does not ban any use of the data other than for marketing purposes, including widespread publication to the general public" and "the concern that patient information can be gleaned from [prescriber-identifiable] data is not reduced in any way" by the law. *Id*. at 22a. The court further held that the law does not "advance the state's interest in public health and reducing costs in a direct and material way." *Id.* at 24a.

The court explained that the statute "seeks to alter the marketplace of ideas by taking out some truthful information that the state thinks could be used too effectively." *Id*. at 26a. That purpose, the court observed, "is antithetical to a long line of Supreme Court cases stressing that courts must be very skeptical of government efforts to prevent the dissemination of information in order to affect conduct." *Id*. The court emphasized that "the statute restricts protected speech when uttered for purposes the government does not approve of in order to reduce the effectiveness of marketing campaigns and, ultimately, alter the behavior of prescribers." *Id.* at 28a.

The court reasoned that the law is "a poor fit with the state's goal to regulate new and allegedly insufficiently tested brand-name drugs in cases where there

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Program, and Act 80, § 21 (codified at 9 V.S.A. § 2466a), which added penalties for certain violations of federal or state advertising regulations. The district court held that these sections were not facially invalid. Pet. App. 108a-118a. PhRMA did not appeal those holdings.

are generic alternatives available." *Id.* at 29a. The court explained that "the statute restricts speech even with regard to prescriptions of breakthrough brand-name medications for which there are no generic alternatives, and . . . the state could pursue alternative routes that are directly targeted at encouraging the use of generic drugs." *Id.* at 33a.

Judge Livingston dissented. *Id.* at 35a-67a. In her view, the statute reflected "a legitimate restriction on access to information and commercial conduct with few, if any, attenuated effects on First Amendment activity." *Id*. at 66a.

SUMMARY OF ARGUMENT

I. The First Amendment prohibits a State from imposing discriminatory burdens on speech because the State disfavors a speaker or message. Under the exacting scrutiny accorded to such laws, Vermont may not impose a discriminatory ban on speaking with physicians using prescriber data. Pharmaceutical manufacturers, private and public insurers, and counter-detailers alike use prescription information to encourage physicians to change their prescription behavior by advancing the speakers' views on drug safety and efficacy. These healthcare market participants engage in the same speech content, the same use of prescriber data to influence prescribing decisions, and with the same economic motive to change prescriber behavior.

Vermont's law, however, facially discriminates against the speech of pharmaceutical manufacturers. The law bans manufacturers from speaking to physicians based on prescriber data unless the doctor has previously authorized such use on his licensing form. 18 V.S.A. § 4631(c), (d). No such ban applies to

insurance companies and other market participants that use the same data to convey their views about medicines to physicians. *Id.* § 4631(e).

The State disfavors the message of drug companies because that message competes with the message of other market participants that the State favors. Manufacturers express, consistent with FDA regulations, that their newer medicines offer treatment advantages over other and often older medicines, while the State prefers speakers that urge doctors to prescribe cheaper drugs first and see if they fail before treating a patient with a new drug. Regardless of the merits of this public debate, the First Amendment bars the government from picking sides by restricting speech.

The law's statement of intent and findings reveal the State's motive to balance a perceived "one-sided" marketplace by suppressing the message of drug manufacturers and by "promot[ing]" the message of speakers with the same purported biases as manufacturers. Act 80, § 1(4), 1(6), 1(31); 18 V.S.A. § 4631(a). The legislature expressed remarkably frank animus towards pharmaceutical companies and a paternalistic attitude that doctors cannot be trusted to make the best treatment decisions for their patients unless the State filters out truthful information.

Vermont's law violates the principle of viewpoint neutrality that is the foundational underpinning of the First Amendment. The First Amendment has never tolerated laws based on blatant animus towards a speaker and its views. Here the discrimination is all the more offensive to the First Amendment because the law seeks to restrict a massive swath of truthful, beneficial, and FDA-regulated speech concerning whether drugs can save or improve

human life in an area marked by scientific and medical complexity and rapid technological evolution. And the law is irrationally based on the assumption that highly sophisticated and trained physicians are not well-equipped to decide what is in the best interest of their patients. Because the purpose and effect of Vermont's law is so plainly illegitimate, there is no basis for subjecting such a law to anything less than strict scrutiny.

II. The law in all events fails intermediate scrutiny under *Central Hudson*. Vermont's asserted interest in prescriber privacy is illusory. The law permits widespread disclosure of prescription history information so long as it will not be used by a pharmaceutical company to communicate with doctors. Indeed, the law is designed to encourage a myriad of other healthcare entities to use the information to influence doctors to prescribe the cheapest medicine that could be considered medically appropriate.

The law is also based on the illegitimate notion that doctors need the State's help in preventing undesirable communications. Physician offices and hospitals are not locations where doctors sit captive and defenseless against sales representatives. Doctors can and do refuse to meet with sales representatives. Doctors can and do dictate the time, place, and terms of any meeting.

The State's interest in protecting doctors' professional decisions is not substantial, and certainly is less weighty than an interest in protecting personal information. An aggregated list of drugs prescribed in a doctor's professional capacity is not akin to an individual's own medical or financial information. And the widespread uses of prescriber information to influence prescriber behavior that are permitted by

the law vitiate any abstract interest in protecting a doctor's professional privacy.

Vermont's law does not directly advance public health or cost containment. The public health justification depends on the flawed premise that new FDA-approved drugs are presumptively bad for patients. Vermont's interests are rooted in a paternalistic attitude that this Court has resoundingly rejected. The government cannot stem the flow of information out of a fear that it will induce people to make unwise decisions. The State has more direct tools for reducing pharmaceutical costs without significantly burdening speech.

III. The law does not escape First Amendment review as a restriction on access to government information. Prescription records are not government records. Extensive government regulation does not turn privately created, privately collected, and privately possessed records into the government's own records. Pharmacies collect prescriber data not simply because of government regulation, but also for independent business reasons such as obtaining reimbursement from insurers.

The First Amendment bars the government from restricting access even to information in its own files if the restriction is designed to suppress speech or disfavored viewpoints. *Los Angeles Police Dep't v. United Reporting Publ'g Corp.*, 528 U.S. 32 (1999). The Court in *Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984), similarly confirmed that a restriction on the publication of records must be unrelated to the suppression of speech. Vermont's law is both viewpoint-discriminatory and designed to suppress the speech of pharmaceutical manufacturers. It accordingly violates the First Amendment.

ARGUMENT

I. VERMONT'S VIEWPOINT-DISCRIMINATORY LAW IS PRESUMPTIVELY INVALID

Vermont's law seeks to interfere with the "marketplace for ideas on the safety and efficacy of medicine." Act 80, § 1(4). To that end, Section 4631 burdens the speech of pharmaceutical manufacturers because the State believes that their speech is too effective at conveying a message to physicians that the State disfavors. That law is viewpoint-discriminatory and is subject to strict scrutiny.

A. *Laws Disfavoring Speakers And Viewpoints Presumptively Violate The First Amendment*

1. "[A]bove all else, the First Amendment means that government has no power to restrict expression because of its message. . . ." *Police Dept. of Chicago v. Mosley*, 408 U.S. 92, 95 (1972). "The principle of viewpoint neutrality . . . underlies the First Amendment itself." *Bose Corp. v. Consumers Union, Inc.*, 466 U.S. 485, 505 (1984). Thus, "[l]aws designed or intended to suppress or restrict the expression of specific speakers contradict basic First Amendment principles." *United States v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 812 (2000); *accord Citizens United v. Fed. Election Comm'n*, 130 S. Ct. 876, 898 (2010) (The government cannot engage in "attempts to disfavor certain subjects or viewpoints" or to "distinguish among different speakers, allowing speech by some but not others.").

The First Amendment "presumptively places" viewpoint discrimination "beyond the power of the government" because of "the specter that the government

may effectively drive certain ideas or viewpoints from the marketplace." *Simon & Schuster, Inc. v. Members of the N.Y. State Crime Victims Bd.*, 502 U.S. 105, 116 (1991). "Government action that stifles speech on account of its message . . . pose[s] the inherent risk that the Government seeks not to advance a legitimate regulatory goal, but to suppress unpopular ideas or information or manipulate the public debate through coercion rather than persuasion." *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994).

"Viewpoint discrimination is thus an egregious form of content discrimination. The government must abstain from regulating speech when the specific motivating ideology or the opinion or perspective of the speaker is the rationale for the restriction." *Rosenberger v. Rector & Visitors of the Univ. of Va.*, 515 U.S. 819, 829 (1995); *id*. ("When the government targets not subject matter, but particular views taken by speakers on a subject, the violation of the First Amendment is all the more blatant.").

Exacting scrutiny applies to viewpoint discrimination even where the First Amendment generally accords less protection to the speech. For example, "fighting words" rank low on the scale of First Amendment protection, but the government may not discriminate among fighting words by banning some but not others. *R.A.V. v. City of St. Paul*, 505 U.S. 377, 386 (1992). Similarly, the intermediate scrutiny applied to a restriction on the time, place, and manner of speech is premised on the restriction being "justified without reference to the content of the regulated speech." *Clark v. Cmty. for Creative Non-Violence*, 468 U.S. 288, 293 (1984). It necessarily follows that for speech about the safety and efficacy

of FDA-approved medicines, a subject open to public debate, the government may not "license one side of a debate to fight freestyle, while requiring the other to follow Marquis of Queensberry rules." *R.A.V.*, 505 at 392; *see also id.* at 388-89 (although "a State may choose to regulate price advertising in one industry but not in others," it "may not prohibit only that commercial advertising that depicts men in a demeaning fashion").

2. The First Amendment's protection of the marketplace of ideas extends to speech undertaken with a commercial motive. "It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366 (2002) (alteration in original) (quoting *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976)). In *Central Hudson*, this Court adopted an intermediate level of review for commercial speech on the theory that commercial speakers are better equipped to ensure accuracy in their messages and are less likely to be chilled by government regulation. 447 U.S. at 564 n.6. *But see* Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech?*, 76 Va. L. Rev. 627, 634-68 (1990).

Several Justices have expressed concern that *Central Hudson*'s multi-part test gives "insufficient protection to truthful, nonmisleading commercial speech." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 572 (2001) (Kennedy, J., concurring in part and concurring in the judgment, joined by Scalia, J.). Justice Thomas in particular has emphasized that laws restricting speech are *per se* illegitimate when "the government's asserted interest is to keep legal

users of a product or service ignorant in order to manipulate their choices in the marketplace." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 518 (1996) (Thomas, J., concurring in part and concurring in the judgment); *see also Thompson*, 535 U.S. at 377 (Thomas, J., concurring); *Lorillard*, 533 U.S. at 575 (Thomas, J., concurring in part and concurring in the judgment); *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 197 (1999) (Thomas, J., concurring in the judgment).

A majority of Justices, moreover, have concluded heightened protection is necessary for commercial speech restrictions that are intended to drown out a truthful but disfavored message or that discriminate among commercial speakers and points of view. "Precisely because bans against truthful, non-misleading commercial speech rarely seek to protect consumers from either deception or overreaching, they usually rest on the offensive assumption that the public will respond 'irrationally' to the truth." *44 Liquormart*, 517 U.S. at 503 (opinion of Stevens, J., joined by Kennedy and Ginsburg, JJ.); *accord Lorillard*, 533 U.S. at 576-77 (Thomas, J., concurring in part and concurring in the judgment).

Thus, "a state legislature does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes." *44 Liquormart*, 517 U.S. at 510 (opinion of Stevens, J., joined by Kennedy, Thomas, and Ginsburg, JJ.); *accord id.* at 517 (Scalia, J., concurring in part and concurring in the judgment) ("I . . . share Justice Stevens's aversion towards paternalistic government policies that prevent men and women from hearing facts that might not be good for them.").

Despite strong reservations about the continuing validity of *Central Hudson*, this Court has found "no need to break new ground" and overrule that decision because it has invalidated the laws before it even under the test of *Central Hudson*. *See Thompson*, 535 U.S. at 368 (drug compound advertising); *Lorillard*, 533 U.S. 525 (tobacco product advertising); *Greater New Orleans*, 527 U.S. 173 (casino advertising); *44 Liquormart*, 517 U.S. 484 (liquor price advertising); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (beer labeling); *Edenfield v. Fane*, 507 U.S. 761 (1993) (accountant direct solicitation); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993) (advertising circulars in public places); *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983) (mail advertising of contraceptives).

Although Vermont's law fails the test of *Central Hudson*, *see infra* pt. II, this case vividly illustrates why laws that disfavor certain speakers and messages are anathema to the First Amendment and should be subject to strict scrutiny. Such laws, including those targeted at commercial entities, gravely threaten the First Amendment's core purpose to protect the competitive marketplace of ideas. This Court's cases "have recognized the dangers that attend governmental attempts to single out certain messages for suppression." *44 Liquormart*, 517 U.S. at 501 (opinion of Stevens, J., joined by Kennedy and Ginsburg, JJ.); *see Greater New Orleans*, 527 U.S. at 193-94 ("Even under the degree of scrutiny that [is] applied in commercial speech cases, decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment."). Given the intrinsic illegitimacy of a legislative motive to burden speech based on viewpoint, there is no basis for

reviewing such laws under anything less than strict scrutiny. A purpose "to exclude the expression of certain points of view from the marketplace of ideas [is] so plainly illegitimate [as to] immediately invalidate the [law]." *City Council v. Taxpayers for Vincent*, 466 U.S. 789, 804 (1984).

B. *Vermont's Law Discriminates Against Pharmaceutical Manufacturers Based On Content And Viewpoint*

1. The statute provides that "[p]harmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug" unless the physician has consented by submitting a form to the State. 18 V.S.A. § 4631(d). The law discriminates against the speech and message of one, and only one, participant in this marketplace: pharmaceutical manufacturers. And the law does so in an invidious and transparent manner. The provision bars speech based on a physician's prescription history without prior consent *solely* when that speech involves "marketing" or "promotion" of a prescription drug, and *solely* when that promotional speech is by a pharmaceutical manufacturer.

Those prohibitions encompass any activity to "influence or evaluate the prescribing behavior" of a physician, "evaluate the effectiveness" of employees, or "advertise or publicize a prescription drug." *Id.* § 4631(b)(5), (8). But Section 4631(e) permits the same uses of the same prescription information, without meeting the consent requirements of Section 4631(c), when used to further the commercial interests of payers seeking to influence or evaluate prescriber behavior.

The only requirement is that these favored speakers use prescriber data to engage in speech that relates to "prescription drug formulary compliance," "patient care management," "utilization review," or "health care research." *Id.* § 4631(e)(1). Professor Flynn, a legal advisor to the Vermont legislature and principal author of the findings, described these categories as "the good uses" of prescriber data. Ex. 113 to Flynn Dep., *infra* App. 2a. The exceptions thus euphemistically refer to the same activities that the law otherwise deems impermissible "promotion" when undertaken by a pharmaceutical company.

For instance, while pharmaceutical companies may not use a physician's prescribing history to fashion the message to a doctor "you should consider drug X to treat patients with high cholesterol because X offers treatment advantages over drug Y," the law permits insurance companies and the State, with no less an economic motive, to use the same information to shape the counter message to doctors "you should consider drug Y to treat patients with high cholesterol because it's cheaper than drug X." While pharmaceutical companies are barred from using prescription data to tailor their message unless physicians have consented in advance on their state licensing forms, no such speech burdens are imposed on insurance companies, the State, or anyone else that uses the same information to further a message the State favors.

The law allows insurance companies, the State, academic counter-detailers and anyone other than a pharmaceutical company to use detailed prescription information to influence or evaluate the prescribing behavior of a physician, evaluate the effectiveness of employees, or publicize the qualities of a drug,

i.e. those categories of speech that the law bans when made by pharmaceutical companies. 18 V.S.A. § 4631(b)(5), (b)(8), (d). In short, all market participants use prescriber data to engage in competing speech about drug safety and efficacy. Manufacturers promote new drugs, while others promote the cheapest treatment that could be considered medically appropriate. But the law singles out manufacturers' speech for disfavored treatment.

Vermont inexplicably suggests that the law blocks all "commercial" uses of prescriber data. Pet. Br. 23, 30, 39, 40 n.12; *accord* Br. for the United States as Amicus Curiae 30 ("U.S. Br."). Insurance companies have no less a financial motive than pharmaceutical manufacturers when they use prescriber data to discuss drug safety and selection with physicians. And Vermont enacted the law based on its own financial motive to decrease the effectiveness of speech that competed with the State's preferred message of cost-containment.

2. The law's discriminatory nature exposes that the law does not protect against intrusion into the doctor-patient relationship. The law allows the State, private insurers, counter-detailers, and anyone else except pharmaceutical companies to recommend to doctors how they should practice medicine. Vermont refers to this speech as "patient care management" as long as the drug manufacturer is not the speaker. 18 V.S.A. § 4631(e)(1). The statute paves the way for public and private payers with economic incentives to promote the use of cheaper drugs to use prescriber data to inject "commercial" influences into the doctor-patient relationship. Pet. Br. 23, 26-27, 39, 40 n.12; U.S. Br. 30. Similarly, insurance companies, the State, and academics engage in the "non-

consensual" use of prescriber data. Pet. Br. 23, 26, 30-31, 36, 45. In other words, they may speak freely to physicians even when the physicians' licensing or renewal forms do not manifest consent for prescriber data to be used for that purpose.

The record is replete with testimony recounting the unwanted pressure that insurers exert on doctors to prescribe cheaper drugs. One of PhRMA's experts, Dr. Kolassa, testified that insurance companies send physicians scientific literature and other information to influence prescription decisions, and that insurers "will call when physicians are prescribing too much or too little of a product." J.A. 206. He also explained that "insurance companies are using physician-identifiable information to call physicians to try to get them . . . to change their prescriptions in a way that may or may not be in the patient's best interests." J.A. 211. Dr. Wharton similarly observed that "[v]irtually several times a day" his office received "pressure" from insurance companies to use one drug instead of another. J.A. 232. The legislature similarly heard a witness, Dr. Carol Boerner, say this about the influence of insurance companies: "It's no longer what's the best thing for the patient. It's what their health plan will let you do for them." C.A. App. 1182.

The State's discriminatory motive is confirmed by Section 4631(a). That provision announces the State's intention to achieve its public health, cost containment, and privacy goals "through the *promotion* of less costly drugs and ensuring prescribers receive *unbiased* information." 18 V.S.A. § 4631(a) (emphasis added). The State apparently perceives neither irony nor First Amendment infirmity in a law whose terms restrict speech by one biased speaker

in order to promote competing speech by another equally biased speaker. The First Amendment, however, proceeds on the opposite assumption that regardless of the motive of the speaker, in "an uninhibited marketplace of ideas . . . truth will ultimately prevail." *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 390 (1969). This law violates pharmaceutical companies' fully protected First Amendment right to be on an equal footing with other healthcare marketplace participants in communicating with physicians about the potential therapeutic benefits of drugs.

Vermont's law apparently even makes illegal the pharmaceutical companies' use of prescriber data to disseminate important safety messages to physicians. 18 V.S.A. § 4631(b)(8) (defining "promote" to include "publicize a prescription drug"). Pharmaceutical manufacturers routinely use prescriber information for the rapid and efficient communication of scientific and safety messages to physicians. *E.g.*, J.A. 181 (Cole testimony), 209 (Kolassa testimony). For example, after identifying new side effects or risks associated with a medicine or changing its labeling, companies use prescriber information to identify relevant prescribers and alert them through "Dear Healthcare Professional" letters. J.A. 241 (testimony of Jeffrey Robertson, Wyeth Pharmaceuticals), 280 (Ciongoli testimony); *see also* 21 C.F.R. § 200.5.

Both Vermont and the United States suggest that Section 4631(e)(4) permits manufacturers to use prescriber data to contact *doctors* with safety notices and drug recalls. *See* Pet. Br. 11; U.S. Br. 20-21. That provision applies to "care management educational communications provided *to a patient*." 18 V.S.A. § 4631(e)(4) (emphasis added). Vermont thus has, at a minimum, chilled pharmaceutical manu-

facturers from communicating critically important safety messages to treating physicians. This chilling effect is yet another reason to apply heightened scrutiny.

3. The law's history confirms that Vermont acted with an impermissible motive "to alter the marketplace of ideas by taking out some truthful information that the state thinks could be used too effectively." Pet. App. 26a. The legislative findings express hostility to pharmaceutical manufacturers and the messages they convey. The State viewed such speech as too pervasive, too well-funded, and most of all, too effective at influencing doctors in the marketplace of ideas on medicine and safety. And if those motives were not bad enough, the legislature proceeded based on a mistrust of physicians' ability to prescribe drugs in the best interests of their patients.

The legislature advanced the following illustrative findings to support a ban on the use of prescriber data for drug marketing:

- The goals of marketing are often in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals comes at the expense of cost-containment and possibly the health of individual patients. Act 80, § 1(3).
- The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one-sided nature of the marketing leads to doctors prescribing drugs based on incomplete and biased information,

particularly for prescribers that lack the time to perform substantive research. *Id*. § 1(4).

- Public health is ill served by the massive imbalance in information presented to doctors. *Id*. § 1(6).
- Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatments for particular conditions. Because of this, physicians frequently rely on information provided by pharmaceutical representatives. *Id*. § 1(13).
- Nearly one-third of the five-fold increase in U.S. spending of drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased therapeutic value. *Id*. § 1(14).
- A significant portion of prescriber time is spent meeting with pharmaceutical representatives. . . . To the extent that this meeting time comes at the expense of time spent with patients, quality of care will be negatively affected. *Id*. § 1(19).

The legislative record compiled by the State similarly is replete with hostility to the influence and effectiveness of pharmaceutical manufacturers' speech. For instance, the Vermont Medical Society objected to "the possibility that representatives could exert too much influence on prescription patterns." J.A. 377. By contrast, the Society's Vice President for Policy explained that "we don't have any problem with the

insurance companies having that information. It's that when it goes to the data mining companies, to the manufacturing companies . . . , we don't think that's real good." J.A. 400.

The State drew support from academics and physicians who pejoratively objected to pharmaceutical manufacturers' revenues and advertising expenditures. C.A. App. 5050-51, 5061-62, 5066-67, 5076-78. The State also compiled reports that pharmaceutical companies used prescriber data to tailor their marketing efforts to be effective in persuading physicians to prescribe new medicines. *Id*. at 5055-58, 5063-65, 5068-70, 5086-93, 5096, 5129. The State heard from doctors such as Dr. Boerner, who testified that "[i]t is disgusting and really demeaning when a drug rep can say . . . I know you're not using my product. I'm a five-foot four lady. . . . [I]t's intimidating. . . . [I]t's another layer of the horror of practicing medicine these days and it shouldn't be that way." *Id.* at 5118-19, 5132, 5134; *accord* Pet. Br. 13-14 (quoting Dr. Boerner's testimony). The legislature apparently did not probe why doctors who did not want to meet with pharmaceutical representatives could not simply decline to meet with them.

The State and its amici ask the Court to attribute the legislative findings to a now-repealed provision that compelled manufacturers to engage in speech when detailing. Pet. Br. 52; U.S. Br. 33. But it would be passing strange for this Court to ignore the findings that the State passed in order to defend the very provision before this Court.

As discussed, the legislature enacted the findings in the immediate aftermath of a district court's decision that had invalidated a virtually identical New Hampshire restriction on use of prescriber data

for drug marketing purposes. The New Hampshire lawsuit had nothing to do with any compelled speech. *See supra* pp. 13-14; C.A. App. 4745 (testimony of Legislative Council staffer Robin Lunge) ("We added findings because of what the New Hampshire court said in their decision, yes."); Vt. C.A. Br. 27 ("[I]n 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 law].").

Thus, Professor Sean Flynn drafted the "datamining" findings to buttress the constitutionality of the ban on the use of prescriber data. *See supra* pp. 13-14. The Legislative Council advised the legislature that the findings were "Legal Fixes" to the law in the event that respondent IMS and other data vendors brought suit as they had done in New Hampshire. C.A. App. 4328; *id*. at 4745 (Lunge testimony). The repealed provision, by contrast, did not involve "data mining," much less the use of prescriber data by pharmaceutical manufacturers. Act 80, § 17(f) (C.A. App. 4065).

The findings are neither specific nor limited to the repealed compelled-speech provision. Nor did Vermont alter its findings when it repealed the compelled-speech provision, even though Vermont otherwise amended the statute to add the second sentence of Section 4631(d) restricting the speech of only pharmaceutical companies. And common sense dictates that even if the findings motivated Section 4631's compelled speech provision, the State enacted all the provisions of Section 4631 with the same impermissible hostility to pharmaceutical companies and their point of view.

Vermont was unabashed about the anti-speech findings when it defended the prescriber data law in the lower courts, *i.e.*, after the State repealed the compelled speech provision. Vermont filed extensive annotated legislative findings in the district court that devoted fifteen pages to support the need to correct the "one-sided marketplace" and "massive imbalance" in that marketplace. C.A. App. 5084-99. The State similarly cited the findings favorably in the court of appeals, including the finding opposing the "one-sided marketplace of ideas." Vt. C.A. Br. 27-28 (citing Act 80, § 1(4)).

Citing *United States v. O'Brien*, 391 U.S. 367 (1968), Vermont suggests that legislative motive is irrelevant. Pet. Br. 54. *O'Brien* holds, however, that an improper motive will not invalidate an otherwise viewpoint-neutral restriction on conduct with an expressive element. 391 U.S. at 383. Here, the law discriminates against pharmaceutical manufacturers and their message. The law is thus "presumed to be unconstitutional." *Rosenberger*, 515 U.S. at 828; *see*, *e.g.*, *Playboy Entmt. Grp.*, 529 U.S. at 812. Similarly, given the impermissible discrimination based on viewpoint, the State's findings are not entitled to deference. *Cf. Turner Broad. Sys.*, 512 U.S. at 662-65 (according deference to legislature's predictive judgments for content-neutral time, place, and manner restrictions).

4. Vermont asserts that the law restricts only commercial conduct because the law does not completely ban detailing by pharmaceutical companies. Pet. Br. 26-27, 33, 43-45, 54-56. As the district court observed, however, "the whole point" of the law "is to control detailers' commercial message to prescribers." Pet. App. at 82a. Vermont thus defends

its law on the theory that it decreases the power, influence, and effectiveness of manufacturers' speech. Vermont argues that its law reduces the "influence" of manufacturers' speech on doctors' prescribing practices, Pet. Br. 49; that the law prevents detailers from using prescriber data that "amplifies influence of marketing," *id.*; and that the law is necessary because prescriber data allows "targeted messages . . . to persuade the doctor to change the medicines being prescribed to patients," *id.* at 56-57. Vermont cannot credibly maintain that the First Amendment does not apply to its law, but that if the First Amendment does apply, Vermont's law passes muster because it will be effective at suppressing speech that the State does not like.

The First Amendment limits the government's power to impose discriminating burdens on speech based on message and speaker even if the government does not directly ban the speech itself. "[A] law or policy permitting communication in a certain manner for some but not for others raises the specter of content and viewpoint censorship." *City of Lakewood v. Plain Dealer Pub.*, 486 U.S. 750, 763 (1988). In *Minneapolis Star & Tribune Co. v. Minnesota Commissioner of Revenue*, 460 U.S. 575, 592-93 (1983), this Court invalidated an ink tax that affected a small group of newspapers by indirectly burdening the newspapers' speech.

Similarly, *Simon & Schuster, Inc.*, 502 U.S. at 115-16, invalidated a "Son of Sam" law that made it less profitable for criminals to write about their crimes. *See also Ark. Writers' Project, Inc. v. Ragland*, 481 U.S. 221, 229-30 (1987) (invalidating sales tax on general interest magazines but not newspapers or specialized journals); *Pitt News v. Pappert*, 379 F.3d

96, 111-12 (3d Cir. 2004) (Alito, J.) ("The threat to the First Amendment arises from the imposition of financial burdens that may have the effect of influencing or suppressing speech, and whether those burdens take the form of taxes or some other form is unimportant.").

Similarly, laws may not burden speech to reduce the effectiveness of one viewpoint. The Court thus has made clear that the government may not regulate the use of sound trucks, a tool for amplifying speech, "based on hostility — or favoritism — towards the underlying message expressed." *R.A.V.*, 505 U.S. at 386; *see City of Lakewood*, 486 U.S. at 764.

Here, the law works as intended by Vermont only if it will reduce the influence of marketing on physicians by depriving manufacturers of a tool that makes their speech (and the speech of other market participants) more effective. That manufacturers remain free to detail without the data does not save the statute. The logic of the State's theory would permit a State to ban the use of a microphone for some speakers but not others as long as the State did not ban the speech itself. Because Vermont's prohibition on the use of prescriber data "favor[s] one speaker over another," *Rosenberger*, 515 U.S. at 828, it violates the First Amendment.

II. VERMONT'S LAW FAILS INTERMEDIATE SCRUTINY

The law in all events does not survive *Central Hudson*'s intermediate standard. Under *Central Hudson*, a governmental restriction on commercial speech that is truthful and not related to unlawful activity must "directly advance" a "substantial" governmental interest and must not be "more

extensive than is necessary to serve that interest." 447 U.S. at 564-66. The State bears the burden of "demonstrat[ing] that the harms it recites are real and that the restriction will in fact alleviate them to a material degree" and cannot rest on "mere speculation and conjecture." *Edenfield*, 507 U.S. at 770-71.[2]

A. *The Asserted Interest In Prescriber Privacy Does Not Justify The Speech Restriction*

The law purports to protect a doctor's privacy interest in her prescribing history and to "reduc[e] undue commercial influences in the doctor-patient relationship." Pet. Br. 47. In the State's view, pharmaceutical promotion intrudes on the doctor-patient relationship because it influences the prescriber's behavior. *Id*. at 46-47. That justification falls far short under *Central Hudson*.

1. The State's asserted interest in prescriber privacy is illusory. The law permits the disclosure of prescriber-identifiable data for any purpose whatsoever, regardless of whether the prescriber has manifested consent under Section 4631(c), as long as the speech is not by a pharmaceutical company that is "marketing or promoting a prescription drug." 18 V.S.A. § 4631(d). The law thus allows an unlimited number of speakers to purchase and use prescriber-identifiable data and to contact doctors based on that data. It leaves *Consumer Reports* or equivalent periodicals free to contact prescribers at their workplaces based on such data and to reprint the data in articles rating doctors. Groups opposed to the use of certain pharmaceuticals may contact doctors based

[2] The State has not contended that the speech here is untruthful or misleading. Pet. App. 21a.

on the data and publish doctors' prescribing histories at will.

Vermont's law likewise permits pharmacies to sell the data to promote non-prescription drugs (*e.g.*, over-the-counter medicines or homeopathic remedies) or to publish prescribing histories to inform their customers where to find doctors experienced with particular products. Indeed, nothing in the law purports to prohibit outright harassment of doctors. The law is directed at one goal and one goal only: to suppress the speech of pharmaceutical companies.

The United States reads Section 4631(a) to ban the transfer of prescriber data without limitation, *i.e.*, even when not for drug marketing or promotion purposes. U.S. Br. 5, 12 n.1. That reading, however, conflicts with the law's primary purpose to prevent pharmaceutical manufacturers from effectively marketing their drugs to physicians. And if the government's reading is based on the absence of a comma after the phrase "nor permit the use of regulated records containing prescriber-identifiable information" in the first sentence of Section 4631(d), this Court has made clear that it "will not attach significance to an omitted comma" at the end of a series. *United States v. Bass*, 404 U.S. 336, 340 n.6 (1971); *cf. U.S. Nat'l Bank v. Ind. Ins. Agents*, 508 U.S. 439, 454 (1993) (punctuation errors may be ignored).

The United States' view also conflicts with Vermont's reading of the law. The State informed the district court that "the law prohibits the sale or use of prescriber-identifiable data for the purpose of marketing prescription drugs." Defs.' Post-Trial Brief 6 (Dkt. 412). The State likewise advised the court of appeals that the law "does not prevent data vendors from acquiring prescriber-identifiable data or selling

the data to pharmaceutical manufacturers." Vt. C.A. Br. 52. Vermont stressed to the court of appeals that "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*. (emphasis in original; internal quotation marks omitted). The court of appeals, not surprisingly, held that "[t]he statute only imposes restrictions on the sale or use of such data for marketing or promoting a prescription drug." Pet. App. 22a; *accord id*. at 10a-11a.

2. Vermont argues that, as a practical matter, prescriber history information is not disseminated to the general public. Pet. Br. 36-39. But the fact that the law on its face does nothing to maintain the confidentiality of the information calls into question whether physician privacy in the abstract was the legislature's true concern, as opposed to simply protecting doctors from what the State thought was too much speech from pharmaceutical companies. In all events, prescriber data is quite "public" within the healthcare marketplace. And within that marketplace, the exceptions in Section 4631(e) make clear that the law does not protect physician privacy.

In other words, regardless of whether Section 4631(d) generally bans the transfer of prescriber data for all purposes, subsection (e) is an express exemption that allows a myriad of commercial speakers to use prescriber data in the name of activities like "patient care management" or "drug utilization review." Those activities inject "commercial influences in the doctor-patient relationship." Pet. Br. 47. This regime accordingly is "so pierced by exemptions and inconsistencies that the Government cannot hope to exonerate it." *Greater New Orleans*, 527 U.S. at 190.

Vermont argues that insurance companies are different from pharmaceutical manufacturers because patients and doctors supply prescriber data directly to insurers. Pet. Br. 58-59. But that distinction does not justify the discrimination. As an initial matter, academic counter-detailers are not insurers and thus do not receive prescription information from doctors or patients. In any case, the statute does not require physicians to manifest consent on their licensing forms to the use of prescriber data by insurers (or anyone else other than drug manufacturers) to influence their prescribing decisions or discuss the relative costs and benefits of particular medicines.

The legislature found that doctors "have a reasonable expectation that information in [a] prescription . . . will not be used for purposes other than the *filling and processing of the payment for that prescription*." Act 80, § 1(29) (emphasis added). Section 4631(e) does not purport to limit the use of prescriber information to the filling of a prescription or payment processing for an insured individual patient. Section 4631(e) permits the use of prescriber data by *anybody* for "patient care management."

Similarly, academic counter-detailers, which again are not insurers, engage in "education and advertising" when they use prescriber data to meet with doctors to influence prescriber behavior. 33 V.S.A. § 2004(b). The goal of counter-detailing "is to use the pharmaceutical industry's detailing methods to steer physicians toward the older, less-expensive, but still appropriate medication choices." Kevin B. O'Reilly, *New Reps, New Rap: The Counter-Detailers*, amednews.com, Sept. 24, 2007, http://www.ama-assn.org/amednews/2007/09/24/prsa0924.htm. Insurers do not limit their use of prescriber data to the processing

of payments for individual prescriptions. *See supra* pp. 11-13; *e.g.*, *Blue Cross and Blue Shield Plans Act in Response to 'Pharmaceutical Industry Promo Tactics,'* Drugs.com, June 30, 2003, http://www.drugs.com/news/blue-cross-blue-shield-plans-act-response-pharmaceutical-industry-promo-tactics-3327.html (describing insurer sending "registered pharmacists to physician offices" to "explain[] the effectiveness and value of generics" and to give physicians "reports on their prescribing patterns compared to their peers").

3. Vermont's purported interest in shielding doctors from the commercial influences of marketing suffers from an additional defect. Laws based on the fear that truthful information will have an "effect upon . . . its recipients" have long been inherently suspect. *Va. State Bd. of Pharmacy*, 425 U.S. at 773; *accord Linmark Assocs., Inc. v. Township of Willingboro*, 431 U.S. 85, 94 (1977) (invalidating restriction when government thought that speech "will cause those receiving the information to act upon it"). Similarly, the First Amendment "'does not permit the government to prohibit speech as intrusive.'" *Bolger*, 463 U.S. at 72 (quoting *Consolidated Edison Co. v. Pub. Serv. Comm'n*, 447 U.S. 530, 542 (1980)). Hostility to a message is not a justification for burdening speech. *E.g.*, *Snyder v. Phelps*, 131 S. Ct. 1207, 1219 (2011); *Forsyth Cnty. v. Nationalist Movement*, 505 U.S. 123, 134 (1992); *Bolger*, 463 U.S. at 71.

In invalidating a ban on advertisements mailed to the home in *Bolger*, this Court explained that recipients could avert any intrusion through "the short, though regular, journey from mail box to trash can." 463 U.S. at 72 (internal quotation marks omitted). *A fortiori*, the State may not restrict speech to

protect doctors at their offices from unwanted communication. The power of a doctor to avoid unwanted visits is plenary: doctors have complete and unfettered control over the speech directed to them, including whether to meet with a detailer, with whom to meet, when, under what conditions, and for how long. *See*, *e.g.*, J.A. 203, 220, 364, 465-66. Use of prescriber information can influence a doctor only if the physician affirmatively lets the sales representative into his office in the first place.

For similar reasons, cases upholding a federal "do not mail" list, *Rowan v. U.S. Post Office Dep't.*, 397 U.S. 728 (1970), and "do not call" list, *FTC v. Mainstream Mktg. Serv. Inc.*, 345 F.3d 850 (10th Cir. 2003), are inapposite. Those restrictions protect against unwanted communications directed at the home. Those laws also do not restrict speech unless and until an individual affirmatively registers for protection. *See Rowan*, 397 U.S. at 737 ("[T]he mailer's right to communicate is circumscribed only by an affirmative act of the addressee."); 16 C.F.R. § 310.4; 47 C.F.R. § 64.1200. The same is true of the Maine law relied upon by the State (Pet. Br. 21, 46, 48). *See* Me. Rev. Stat. Ann. tit. 22 § 1711-E; *IMS Health Inc. v. Mills*, 616 F.3d 7, 16-17 (1st Cir. 2010), *pet. for cert. filed*, No. 10-984 (Jan. 28, 2011).

By contrast, Vermont's default rule restricts speech automatically unless and until the prescriber affirmatively denotes consent on a government form. That difference is significant because, as Vermont undoubtedly knew, people are less likely to take affirmative action than accept the default rule. *See*, *e.g.*, Cass R. Sunstein, *Boundedly Rational Borrowing*, 73 U. Chi. L. Rev. 249, 263-65 (2006).

The State likewise offers a misplaced analogy to a car salesman who knows a customer's past vehicle purchases. Pet. Br. 46. Pharmaceutical representatives do not haggle with doctors over price, and the doctor does not consume the drug but instead receives medical information relevant to courses of treatment for her patients. Representatives convey scientific and medical information about life-saving and life-enhancing drugs, and the purpose of the prescriber-identifiable data is to help the representative focus the message to the audience most likely to find it useful. In *Edenfield*, this Court invalidated a state restriction on speech by accountants where the audience consisted of "sophisticated and experienced business executives" who are "less susceptible to manipulation" and the speech was "conducive to rational and considered decisionmaking." 507 U.S. at 775. That reasoning applies here.

Vermont erroneously suggests that aggregate prescriber history is inherently private like a "bank account number." Pet. Br. 14. Prescriber data relates solely to a doctor's professional practice; it is not personal information. The data is stripped of any information that could be used to identify any patient, *supra* pp. 10-11, and is aggregated across numerous patients and time periods. The data does not reveal details of any doctor-patient relationship. Rather, the data shows a professional attribute akin to the doctor's specialty, educational background, office location, or professional affiliation — none of which are private, as the State apparently has recognized in another context. *See, e.g.*, http://healthvermont.gov/hc/med_board/profile_search.aspx (searchable database of Vermont physician information, including location, specialty, education, teaching, publications, professional activities, disciplinary

actions, and license and hospital restrictions). Just as an individual has a lesser expectation of privacy in the workplace than in his home, *New York v. Burger*, 482 U.S. 691, 700 (1987); *cf. City of Ontario v. Quon*, 130 S. Ct. 2619 (2010), the State's interest in protecting professional information is less substantial than its interest in protecting personal information.

The State's interest is also reduced because multiple entities have access to a doctor's prescriptions, including the pharmacy where the patient fills the prescription, the insurer or pharmacy benefit manager that receives a claim for reimbursement, the drug utilization or formulary committee at the hospital where the patient received the prescription, and any persons to whom those entities disclose such information, such as academic detailers and researchers. J.A. 179 (Cole testimony). As Dr. Ciongoli explained, "I really have no claim to privacy with this information. I expect and receive letters from the insurance companies and from the state government, federal government, about Medicaid, Medicare, suggesting that I use a different drug." J.A. 279; *see also* J.A. 179 (testimony of Dr. Cole that he is "well aware that pharmaceutical companies become aware of my prescribing habits, albeit, without the patient's name attached").

Vermont claims the State's purported interest in protecting a doctor's prescribing decision from outside influences is of a "deeper dimension" than an interest in preventing the dissemination of prescriber information in general. Pet. Br. 46. As discussed, however, the law permits unfettered intrusion into the doctor-patient relationship by government healthcare programs, private insurers, and counter-detailers without any showing that the doctor has consented to

their use of the data. Having crippled the "deeper" privacy interest in protecting doctors from economically motivated communications, Vermont can hardly seek refuge in a concededly lesser-included privacy interest in the information generally.

Finally, to the extent Vermont's asserted privacy concern is rooted in the supposedly "covert" nature of pharmaceutical companies' use of prescription data, Pet. Br. 38, an alternative exists that "could advance the Government's asserted interest in a manner less intrusive to [pharmaceutical companies'] First Amendment rights." *Rubin*, 514 U.S. at 491; *e.g.*, *Thompson*, 535 U.S. at 371-73. Vermont can simply inform physicians that pharmaceutical companies — just like the State, counter-detailers, and insurance companies — use prescription history information to communicate with doctors.

4. Although the State did not defend its law below on the basis of *patient* privacy, it and some amici speculate that pharmaceutical companies' use of prescriber-identifiable data could threaten the medical privacy of individual patients. Pet. Br. 36-37 & n.11; *e.g.*, Br. for the Vermont Medical Society, et al., as Amicus Curiae 23-27; Br. of the New England Journal of Medicine, et al., as Amicus Curiae 7-10 ("NEJM Br."). But HIPAA already requires pharmacies to de-identify and encrypt information regarding patients before sending the data to others. *Supra* pp. 10-11.

Vermont conceded below that it was "not aware of any instance in which a specific patient's identity was discovered through review [by pharmaceutical companies] of prescriber-identifiable, patient-de-identified data." Response to PhRMA's Request for

Admission No. 70 (May 30, 2008). And to the extent that amici complain about threats to patient privacy from mining of prescription data, one of the amici identifies *insurance companies* as the culprits. NEJM Br. 8-9. Because Vermont's law does not restrict insurance companies' use of medical information, the risk of exposure of patient information "is not reduced in any way" by Vermont's law. Pet. App. 22a.

B. *The Asserted Interests In Public Health And Cost Containment Do Not Justify The Speech Restriction*

The Vermont law cannot be upheld on the theory that it advances the State's asserted interests in public health and lowering healthcare costs by preventing the "over-accelerat[ion]" of new drugs. Pet. Br. 49.

1. As far as the State's interest in protecting public health, the First Amendment does not permit a State to restrict FDA-regulated speech on the theory that the speech furthers the sale of FDA-approved drugs that save lives and combat disease. In *Virginia State Board of Pharmacy*, this Court made clear that the State is not entitled to assume that physicians will "overprescribe" a drug based on its advertising. 425 U.S. at 766 n.21. The United States also explains that Vermont's public health justification is fatally flawed because it "depends on the unwarranted view that the dangers of such new drugs outweigh their benefits to patients." U.S. Br. 24-25 n.4.

The State points to two drugs that were removed from the market a number of years ago after previously unanticipated risks became known. Pet. Br. 50. But Vermont has no basis for concluding that all

new medicines are presumptively dangerous, much less too dangerous for manufacturers to discuss with doctors in conversations regulated by the FDA. In any event, Vermont's law does not directly advance public health because the law applies equally to medicines that are the best in their class or that have no generic competition. The law applies to breakthrough cancer drugs, Alzheimer's treatments, and HIV drugs alike.

More fundamentally, Vermont's public health rationale is premised on the illegitimate assumption that doctors, armed with truthful and non-misleading information about new drugs, will make bad prescription decisions. That premise is "antithetical to a long line of Supreme Court cases stressing that courts must be very skeptical of government efforts to prevent the dissemination of information in order to affect conduct." Pet. App. 26a.

In *Thompson*, this Court rejected the notion that advertising of compounded drugs "would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway." 535 U.S. at 374. The Court explained that such a paternalistic rationale rests first "on the questionable assumption that doctors would prescribe unnecessary medications," and second, on "a fear that people would make bad decisions if given truthful information about compounded drugs." *Id.* This Court resoundingly "rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Id*.

Likewise, in *Greater New Orleans*, the Court invalidated statutes barring advertising of casino gambling

in jurisdictions that allowed gambling. The Court reasoned that the laws "sacrifice[d] an intolerable amount of truthful speech about lawful conduct," and violated the "presumption that the speaker and the audience, not the Government, should be left to assess the value of accurate and non-misleading information about lawful conduct." 527 U.S. at 194-95; *accord Edenfield*, 507 U.S. at 767 ("the speaker and the audience, not the government, [should] assess the value of the information presented"); *44 Liquormart*, 517 U.S. at 503 (opinion of Stevens, J.) ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.").

2. The State's reliance on cost-containment fares no better. In Vermont's view, manufacturers spend too much money on influential advertising that leads to the prescription of medicines covered by public and private insurance. *Supra* pp. 13-16, 33-37; Act 80, § 1(2)-(4), (9)-(11), (14)-(18), (26); *accord* Pet. Br. 14-15; 49-50; U.S. Br. 25-26. It is far from clear, however, that such interests may justify a restriction on speech. As discussed, the State cannot limit speech on the theory that FDA-approved speech causes doctors to overprescribe FDA-approved drugs. A State similarly may not use its regulatory power to restrict advertising on the theory that the State pays for the product being advertised. And it should go without saying that a State does not have a legitimate interest in restricting the speech of one industry to save money for another industry.

In any event, the State's interest in cost-containment does not justify the law. Vermont's *Central Hudson* analysis depends on the notion that if physi-

cians would only communicate less with manufacturers and more with speakers pushing the message of cost-containment, they would prescribe the cheapest medicine for their patients, all other factors about patient health being equal. That view, however, does not accord with the practice of medicine. No two patients are alike; medicines are not one-size-fits-all; and new medicines are designed to be an improvement over older medicines in terms of medical efficacy, less or different side effects, absorption rates, ease of administration, and the like. *Supra* pp. 5-6. If the State disagrees and thinks that older medicines are almost always equally medically effective, it has ample means at its disposal to relate that information to physicians, *see infra* pp. 53-55, and market forces already exist for private actors to impart such information. But the one thing that the State cannot do is impede the flow of truthful, nonmisleading, FDA-regulated information to physicians.

Vermont's statute impinges on pharmaceutical companies' speech even when there is no generic substitute available for the condition that the pharmaceutical manufacturer's medicine treats; even when the manufacturer's medicine is not the most expensive treatment; even when the manufacturer's medicine is a medical breakthrough or the only, or most effective, treatment for a particular disease; and even when the use of a manufacturer's medicine would reduce overall medical costs. J.A. 207, 372-74; Pet. App. 29a-30a. For instance, although newer medicines may be more expensive at the point of sale than older or generic drugs in the same therapeutic class, the efficacy of a new medicine can yield substantial long-term savings by reducing other healthcare costs like hospital visits. As Dr. Wharton explained at trial, "an ace inhibitor that is generic

that lowers blood pressure may be cheaper at the outset than an ace inhibitor that's branded but gets into the blood vessel wall and lowers heart attack, stroke, death and diabetes. Readmission for heart attack is awfully expensive." J.A. 230; *see also id.* at 207-08 (Kolassa testimony); Frank R. Lichtenberg, *Benefits and Costs of Newer Drugs: An Update* 1 (Nat'l Bureau Econ. Res. Working Paper No. 8996, 2002).

For those reasons, the United States is wrong in suggesting that the costs of new drugs exceed their benefits "because less expensive generic alternatives generally are therapeutically equivalent to their branded counterpart." U.S. Br. 26. As discussed, the statute applies to drugs without therapeutic alternatives, and non-bioequivalent generics are often not as effective and may be riskier than newer drugs. *Supra* p. 5.

Vermont and the United States argue it would be impractical to limit the law to the promotion of drugs that the State has deemed too costly or too risky. Pet. Br. 58; U.S. Br. 26-27. That argument only highlights the State's paternalistic view that physicians prescribe costly and unnecessarily risky medicines because they listen too much to drug manufacturers instead of exercising their best medical judgment. This Court's cases require the government "to open the channels of communication" before stemming the flow of truthful, non-misleading, and FDA-regulated communications to physicians. *Va. State Bd. of Pharmacy*, 425 U.S. at 770. "If the First Amendment means anything, it means that regulating speech must be the last — not first — resort." *Thompson*, 535 U.S. at 373.

As discussed, Vermont has an academic counter-detailing program that educates and advertises to doctors about the State's views on the merits of innovator versus generic drugs. *Supra* pp. 8, 9, 13. Vermont could also require prescribers to receive additional education conveying the State's message that doctors should consider cost in making treatment decisions.

3. Vermont has other extensive programs that promote the State's asserted interest in reducing healthcare costs without burdening speech. Vermont has a generic substitution law that requires pharmacists to fill prescriptions with an available bioequivalent generic unless the prescriber expressly specifies otherwise. 18 V.S.A. § 4605. Generic drugs are dispensed to Vermont Medicaid patients 97.7% of the time when the doctor prescribed their bioequivalent brand. C.A. App. 310. Vermont uses a Preferred Drug List, step therapy, and prior authorization processes to increase generic drug usage. J.A. 429-30, 432-36, 441-42; C.A. App. 2454-55, 2503-07. Vermont participates in a multi-state program to negotiate favorable supplemental Medicaid rebates with pharmaceutical companies in addition to those required by federal law. 33 V.S.A. § 1998; C.A. App. 3066-67. Vermont also requires that prescribers of prescription drugs be alerted when the patent of a particular drug has recently expired or is due to expire. *See* 18 V.S.A. § 4622(a)(2).

As part of Act 80, the State enacted additional cost-saving programs. Vermont established a program to distribute vouchers for samples of generic drugs. Act 80, §§ 15, 15a. The State estimated that spending $270,000 on generic vouchers could produce annual savings of $27 million. C.A. App. 4351. Act 80

further requires pharmaceutical manufacturers to disclose to the State the prices of drugs dispensed in Vermont. Act 80, § 6. Vermont's Department of Health also must educate Vermonters about the availability of lower-priced prescription drugs through a federal drug discount program. *Id*. § 16. And Vermont began a therapeutic substitution program that encourages doctors to switch to cheaper drugs for proton pump inhibitors and statins. *Supra* pp. 9, 12-13.

Vermont has not demonstrated that these programs cannot adequately serve the State's asserted interests. Indeed, Vermont enacted Section 4631(d) without giving any of the Act 80 programs an opportunity to work.

III. VERMONT CANNOT ESCAPE FIRST AMENDMENT REVIEW BASED ON ITS REGULATION OF PHARMACIES

Vermont argues that because the government requires the creation of private prescription records that are submitted to pharmacies, the State can pick and choose among the actors who may speak using prescriber data without any inquiry into whether such law comports with the First Amendment. Pet. Br. 22-41. But this Court's precedents foreclose the creation of such a "First Amendment Free Zone." *United States v. Stevens*, 130 S. Ct. 1577, 1585 (2010).

1. In *Los Angeles Police Department v. United Reporting Publishing Corp.*, 528 U.S. 32 (1999), this Court held that the First Amendment was not implicated by a California law that limited public access to arrestees' addresses. The Court reasoned that the law represented "a governmental denial of access to

information in its possession." *Id*. at 40. The Court further explained that "[t]his is not a case in which the government is prohibiting a speaker from conveying information that the speaker already possesses." *Id*.

Here, Vermont seeks to impose speech restrictions based on the use of prescription records that are privately created, privately collected, and privately owned. The State's attempt to analogize a pharmacy to a government contractor is also inapt. Pet. Br. 28-29. The filling of prescriptions is not a sovereign function.

2. Even if prescription records were treated as government records, the State's viewpoint-based regulation of those records violates the First Amendment. Although the Court upheld the viewpoint-neutral law at issue in *United Reporting*, eight Justices expressed that a State may not restrict access to government records based on viewpoint. The concurring opinion of Justices Scalia and Thomas explained that any "restriction upon access that *allows* access [to one class of favored persons] . . . , but at the same time *denies* access to persons who wish to use the information for certain speech purposes" may "in reality" constitute "a restriction upon speech rather than upon access to government information." 528 U.S. at 42.

The concurring opinion of Justices Ginsburg, O'Connor, Souter, and Breyer stated that the government may not parcel out access to information "based on an illegitimate criterion such as viewpoint." *Id.* at 43. They observed that "California could not, for example, release address information [of arrestees] only to those whose political views were in line with the party in power." *Id.* The dissenting opinion

of Justices Stevens and Kennedy similarly echoed that any law indentifying a disfavored person based on their viewpoint "would clearly be invalid." *Id*. at 46. The opinion also observed that "by allowing such widespread access to the information, the State has eviscerated any rational basis for believing that [the law] will truly protect the privacy of [arrestees]." *Id.*

Those principles compel the invalidation of Vermont's law. As discussed, Vermont set out to suppress the speech of pharmaceutical companies to elevate the voice of other speakers that communicate with physicians about drug safety and efficacy. Vermont did not distinguish between commercial and non-commercial uses of prescription data. And the State's decision to permit the widespread use of prescriber data to intrude on the doctor-patient relationship (except by pharmaceutical manufacturers), exposes that the law cannot be justified as a privacy law.

The United States curiously states that "respondents have not pressed a selective-access claim." U.S. Br. 16 n.3. PhRMA's central theme in the district court was the discriminatory nature of the law. C.A. App. 61, 364; Pls.' Proposed Findings of Fact & Conclusion of Law 34-35, 47 (Dkt. 409); PhRMA's Reply Br. Regarding *Ayotte* 4 (Dkt. 423). PhRMA emphasized the same theme in the court of appeals, PhRMA C.A. Br. 30-34 ("Section 17 Restricts Truthful Speech Based on the Viewpoint Expressed and the Speaker Expressing It"), and in response to the petition, PhRMA Resp. Br. 7-9. *See also* Pet. App. 16a.

3. The State's reliance on its licensing of pharmacies is also misplaced. Even though state law requires pharmacies to collect prescription information, pharmacies independently collect that informa-

tion to submit to insurance companies for reimbursement. The federal government also independently requires the maintenance of such records. U.S. Br. 13-14. In any event, even were the State correct in its premise, dispensing with the First Amendment would not follow.

In *Seattle Times*, this Court held that a protective order restricting a party from publicizing information it obtained through civil discovery did not violate the First Amendment. 467 U.S. at 37. *Seattle Times* does not suggest that whenever a private party's possession of information stems from government compulsion, the government may restrict further communication of that information without implicating the First Amendment, as Vermont suggests. Pet. Br. 20, 24, 28-29, 34. To the contrary, the Court twice made clear that any restriction of speech must further an interest "*unrelated to the suppression of expression*" and survive an intermediate standard of review. *Seattle Times*, 467 U.S. at 32, 34 (emphasis added).

Significantly, the protective order in *Seattle Times* was facially neutral and applied without regard to content, viewpoint, or identity of speaker. 467 U.S. at 27 (prohibiting public disclosure "in any way"). Here, the district court found that Section 4631's "whole point" is to "control detailers' commercial message to prescribers." Pet. App. 82a. Vermont's law is not "unrelated to the suppression of expression." *Seattle Times*, 467 U.S. at 32, 34. Rather, as discussed, because the law discriminates against viewpoint and speaker, it is subject to strict scrutiny and is presumptively invalid.

The nature and purpose of Vermont's law to suppress speech and discriminate among speakers

and viewpoints also addresses Vermont's admonition that invalidating Vermont's law could call into question various federal laws protecting personal information. Pet. Br. 35. The constitutionality of privacy laws such as HIPAA does not turn on whether the records belong to the government or the degree of government regulation over the record-holder. Indeed, the laws cited by Vermont pertain to records that did not come into the record-holder's possession by government compulsion. *See*, *e.g.*, 20 U.S.C. § 1232g(b) (educational records); 47 U.S.C. § 551(c)(1) (cable television viewing information).

The validity of those laws turns on the weighty interest in an individual's personal privacy and the means by which the law protects that interest. Here, with an illegitimate motive to suppress speech, Vermont enacted a law that discriminates based on viewpoint and identity of the speaker and does not directly and materially advance the State's asserted interests. For good reason, the United States expresses confidence that whatever may be the fate of Vermont's statute, federal privacy laws are materially distinct. U.S. Br. 11, 33-35.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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March 24, 2011

APPENDIX

Sean Flynn

From: Sean Flynn
Sent: Tuesday, May 01, 2007 2:57 PM
To: 'Robin Lunge'; Sharon Treat
Cc: hams@communitycatalyst.org
Subject: RE: NH decision ideas

Attachments: IMS memo.doc

[File attachment icon]
IMS memo.doc (141KB)

Here is a note on the decision.

On your ideas:

1. Add findings articulating the state interests & how this meets those. State interests:

YES, A must. Especially on harassing of doctors.

A. does it still make sense to pursue dr. privacy as an interest even though it was rejected?

Yes. But needs more testimony and support. Legislative facts trump judicial facts. So create a record and find harassing of doctors based on the datamining.

B. Consider whether doctors have an IP right to prescribing practices & articulate protecting their IP interest as a compelling state interest

Well, we don't love this. But it may be possible. See the definition of trade secret.

C. Articulate the cost-containment in the PRIVATE market as a state interest since only medicaid was discussed.

YES.

[Exhibit No. 113 Stamp]

D. public health – the tie between unbiased information & public health needs to be clearer.

YES. Making an exception for "good" uses of data will also help.

2: Narrow tailoring:

A. public health – consider whether we can narrow the scope by allowing evidence-based marketing (using title 18 definition), but not marketing information that isn't supported by independent studies & sources; consider whether marketing which also includes best practices as defined through state's evidence-based ed program could be allowable. In other words, try to target marketing which is biased, but allow unbiased.

I like this if it can work. I included it in my memo.

B. cost-containment – add something about cost parameters? allow marketing if it shows how the cost compares with the generics?

Maybe forced speech issues. But also maybe worth a try.

3. Opt in – how does this narrow in a way that is tailored to an interest OTHER than Dr. privacy? I'm not getting that . . . I don't see how it's a narrowing that promotes public health or cost-containment. . . .

It helps meet the narrow tailoring requirement because it does not ban speech to doctors who want it. Like a do not call list.

Indeed, you could have a do not call list for detailers.

4. Have testimony after the draft comes out on the record.

Yes.

Statement in response to decision in IMS v. Ayotte, NH District Court, No. CV-06-280-PB (April 30, 2007) Sean Flynn Associate Director, Program on Information Justice and Intellectual Property

Yesterday, a New Hampshire District Judge stated that our constitution prevents New Hampshire from implementing the same common sense data privacy laws that restrict the trade in prescription records as currently exist in all of Europe and several Canadian provinces. Those laws prohibit datamining companies from selling information to pharmaceutical companies that contain doctors' names and other identifying information. Instead, the companies can only compile and use information in aggregated "blocks" so as to protect the identity of specific doctors and their prescribing habits.

Judge Barbadoro's opinion striking down New Hampshire's ban on the trading of prescriber-identified data is sweeping and disturbing in many respects. The decision sweeps far beyond established First Amendment precedent and is sure to be appealed by the State of New Hampshire. The decision does contain some reasoning that can be of guidance to states seeking policy solutions to the excesses of detailing and datamining in the pharmaceutical industry. On the whole, however, the opinion is unwelcome news to states and health care policy advocates.

The New Hampshire Act was passed against the background of evidence showing that nearly a 'third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to the increased efficacy of pharmaceutical marketing efforts that shift doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and

more expensive treatments, which often have little or no increased therapeutic value. One key change has been the recent ability of large datamining companies to purchase computerized prescription records from insurers and pharmacies and then sell that information to pharmaceutical companies to track every prescription a doctor writes. Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug reps. There is now a pharmaceutical sales representative for every five office-based physicians in the U.S. In 2004, the industry spent $27 billion on drug marketing (more than any other sector in the U.S. on its sales force or media advertising), over 85 percent of which was targeted at doctors.

Judge Baradoro begins his reasoning with a rejection of New Hampshire's argument that the Prescription Information Law does not restrict speech because it regulates "uses" (*i.e.* sale and trade in), of prescriber-identifiable information, rather than First Amendment protected speech. He specifically rejected New Hampshire's comparison of the law with the Act upheld by the Supreme Court in Bartnicki v. Vopper, 532 U.S. 514 (2001).

In Bartnicki, the Court struck down a section of the statute that constituted a "naked prohibition against disclosures" of information obtained through a wiretap, but approved of the section of the law that penalized any person who "uses . . . the contents of" a wiretapped communication. The court recognized cases holding that the use prohibition made it unlawful to "use an illegally intercepted communication . . . to create a competing product," "in trading in securi-

ties," "to prepare strategy for contract negotiations," or "to discipline a subordinate." 'These prohibitions did not implicate the First Amendment, the Court explained, because "the prohibition against the 'use' of the contents of an illegal intraception" is "a regulation of conduct."

Like the Act in Barnicki, the New Hampshire act allows a broad range of disclosures of prescription information for non-commercial uses, but bans the trade of such information for marketing and other commercial purposes. But the judge rejected this distinction, holding that "The law is [ ] a speech restriction because it limits both the use and disclosure of prescriber-identifiable data for commercial purposes."

The court further held that the Act would subject to First Amendment scrutiny even it was a restriction on conduct because it "restricts speech by preventing pharmaceutical companies from using prescriber-identifiable information both to identify a specific audience for their marketing efforts and to refine their marketing messages. Such laws are subject to First Amendment interests of their pharmaceutical company customers."

Importantly, the court did hold that the act was a commercial regulation subject to the commercial speech doctrine, rather than the strict standard applied to political and other non-commercial speech. It explained:

In understanding why this is so, it is important to bear in mind that the challenged law only restricts the transmission or use of prescriber-identifiable information for certain commercial purposes. It does not prevent anyone from transmitting or using the

information for law enforcement purposes, research purposes, educational purposes, compliance review purposes, or for any non-commercial purpose. In short, the law is a commercial speech restriction under Central Hudson because it restricts only speech that is "solely in the individual interest of the speaker and its specific business audience," Dun Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749, 762 (1985) (plurality opinion).

Other courts, including the courts in U.S. West, Inc. v. Fed. Commc'n Comm'n, 182 F.3d 1224, 1232 (10th Cir. 1999) and Trans Union Corp. v. Fed. Trade Comm'n, 245 F.3d 809, 018 (D.C. Cir. 2001) (applying intermediate scrutiny to ban on sale of targeted marketing lists), have held that regulations restricting use of customer information for marketing purposes regulate speech protected by the First Amendment. But the New Hampshire District Court went far beyond the holdings of these cases by striking down the act as being based on an insufficient government interest in protecting data privacy rather than on the existence of other more narrowly tailored means to address the interest. Those previous cases explicitly affirmed opt in or opt out programs that require a company to abide by the wishes of consumers in trading their identifying data. The New Hampshire court did not leave this same policy avenue open in its opinion because it held that New Hamshire lacks a sufficient interest to even legislate in this area. This aspect of the opinion is extremely broad and is likely to be subject to a vigorous appeal.

The so-called commercial speech doctrine requires that truthful commercial speech that does not promote unlawful activity can be limited only if it (1) is in support of a substantial government interest,

(2) 'directly advances the government interest asserted,' and (3) 'is not more extensive than is necessary to serve that interest.

The Court first explained that it found an insufficient record supporting the Act. It stated:

There is nothing in the record, however, to support a conclusion that the legislature had established expertise in the regulation of prescriber-identifiable data. Moreover, it acted quickly after the bill was introduced, received hearing testimony by numerous individuals who had yet to review proposed amendments, made no express findings either on the record or incorporated into the statute, failed to discuss alternative measures that would not restrict speech, and cited no evidence as to how effective the restriction might prove to be.

It then rejected the government's professed interest in protecting the privacy interests of doctors in their records. Distinguishing away a host of laws that protect consumer's privacy in their identity to avoid unwanted and harassing sales calls, e.g. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 18 U.S.C., 26 U.S.C., 29 U.S.C., and 42 U.S.C.) (patient medical information); Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq. (2000) (credit reporting information); Family Educational Rights and Privacy Act of 1974, 20 U.S.C. § 1232g (2000 & Supp. III 2003) (educational information); Video Privacy Protection Act of 1988, 18 U.S.C. 2710 (2000) (video rental information); Cable Communications Policy Act of 1984, Pub. L. No. 99-549, 90 Stat. 2779 (subscriber information), the court held that doctors do not have a similar valid interest in avoiding the harassing sales calls of detailers that are augmented

by the trade of their prescribing patterns to pharmaceutical companies. The court specifically mentioned the lack of evidence offered at trial proving that the information is "pressed with such frequency or vehemence as to intimidate, vex, or harass the recipient," Edenfield, 507 U.S. at 769.

This finding by the court is particularly disturbing and far reaching. In other instances noted above, legislatures and courts have found valid interests of consumers in having their identity and purchasing habits kept private without their consent to avoid harassing sales tactics. Yet with medicines, the doctor is the one making the consuming choices – the doctor literally "prescribes" the medicine that the ultimate consumer purchases. Thus it is the doctor who is the target of over 80% of the nearly $30 billion spent on pharmaceutical marketing every year. This appears to be an area where a fuller record by state legislatures could help build a better factual background for subsequent legislation.

The judge further found that the law does not directly control health costs and promote public health because, despite evidence showing that billions of dollars every year are spend on needless drug shifting toward more expensive brand name drugs driven by marketing, not all marketing driven shifts are bad and the "ban on the use of prescriber-identifiable data affects both helpful and harmful brand-name prescribing practices in the same way." The court held:

Accordingly, the State simply does not have a substantial interest in shielding them from sales techniques that enhance the effectiveness of truthful and non-misleading marketing information. Instead, if the State is concerned that truthful detailing is

causing health care providers to make inadvisable prescribing decisions, "the remedy to be applied is more speech, not enforced silence," Whitney v. California, 274 U.S. 357, 377 (1927) (Brandeis, J. concurring).

Finally, the court found that there are other effective measures to regulate the ill effects of detailing. Specifically, the court stated that

> if legislators are concerned that pharmaceutical companies are improperly using samples, gifts, meals, end other inducements to promote inadvisable prescribing practices, they can address this perceived problem by following other states that have adopted laws that limit such practices. See, e.g., Minn. Stat. Ann. § 151.461 (2007); Cal. Health and Safety Code § 119402(d)(1) (2007). Second, if legislators fear that pharmaceutical detailing is simply too effective to go unrebutted, they can require the State to enter the intellectual marketplace in several different ways with competing information that will help health care providers balance and place in context the sales messages that detailers deliver. . . . see, e.g., W. Va. Code Ann. § 5-16C-9(5) (2006) (authorizing state to develop counter-detailing programs); or they can require health care providers to regularly participate in continuing medical education programs that are specifically designed to provide practitioners with the best available information concerning the advantages and disadvantages of prescribing generic drugs rather than brand-name drugs. Finally, if legislators are concerned that pharmaceutical companies are using prescriber-identifiable data to drive up Medicaid drug costs, they can address the issue directly by properly implementing a Medicaid Pharmacy Program (preferred drug list) that takes into account

the cost-effectiveness of brand-name drugs when compared with non-bioequivalent generic alternatives.

At bottom, the opinion suggests several steps that states interested in regulating the ill effects of detailing might pursue:

- states interested in regulating the trade in prescriber-identifiable prescription information need to create a fuller record explaining how frequently detailing based on datamining has become harassing to doctors in ways that prohibiting datamining without their consent will halt;
- states may consider more narrowly tailored mans to stop data trading, for example permitting the information to be released to pharmaceutical companies if the doctor has explicitly consented to the release;
- states should include specific findings on the adequacy of alternative measures, including licensing detailers, prohibiting false and misleading detailing, use of Medicaid formularies, bans on gifts, and counter-detailing programs;
- states may consider bolstering an expectation of privacy in prescription records by including statutory findings and inviting testimony that doctors do not and should not expect that their prescriptions will be used for purposes other than to fill and process prescriptions;
- target the most harmful and biased uses of datamining, e.g. by allowing their use for evidence-based marketing, but not use for marketing information that isn't supported

by independent studies sources (this may make the statute closer to the Barnicki "use" regulation);

- states may consider alternative regulations, such as licensing and regulating detailers to cut down on the most abusive practices including gifts, pushing off-label uses, making misleading statements, etc.

Ultimately, the New Hampshire decision only binds New Hampshire and is likely to be headed for appeal. Other states may legislate in this area and create conflicting precedents that will have to be unified by the First Circuit and ultimately the Supreme Court.

Sean Flynn

From: Sean Flynn
Sent: Wednesday, May 02, 2007 7:51 AM
To: 'Robin Lunge'; PTaormina@aarp.org; jbrill@atg.state.vt.us; Sharon Treat; mmongan@vtmd.org
Subject: RE: Weds. 8:15a.m. - private meeting

Attachments: datamining findings.doc

[File attachment icon]
datamining findings.doc (53 KB)

Here are some more ideas for findings.

——Original Message——

From: Robin Lunge (mailto:rlunge@leg.state.vt.us]
Sent: Tuesday, May 01, 2007 5:43 PM
To: PTaormina@aarp.org; jbrill@atg.state.vt.us: Sharon Treat; mmongan@vtmd.org: Sean Flynn
Subject: Weds. 8:15a.m. - private meeting
Importance: High

High Priority

Hey folks–

Attached is a CONFIDENTIAL amendment I have prepared for House Health Care for you to review. I have permission to share it with the people on this email, so please do not share it outside of your offices.

Would you be available for a private meeting with Rep Harry Chen, Rep Steve Maier & Rep Sarah Copeland-Hanzas at 8:15am tomorrow morning? The meeting will be at the JFO building (1 Baldwin) on the 2nd floor in the conference room. Sean & Sharon - if you are available, let me know & we can use the following conference service: [conference number and pin redacted].

If you use the document in preparing your testimony to HHC, please remove the leg council header & footer. Since we are selectively sharing this, it would politically sensitive if you could date it after it was released publically (which will probably be tomorrow 10:30am).

Also, I am adding a couple of things to the amendment tonight - a change in the generic pilot so that statins don't have to be first & a report on cost-savings.

THANKS!
Robin

Robin Lunge
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[Exhibit No. 115 Stamp]

- This Act is necessary to protect prescriber privacy, save money for the State, consumers, and businesses, and promote public health.

PRESCIBER PRIVACY

- Most doctors in Vermont that write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing the payment for that prescription. Doctors and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.
- Many doctors in Vermont are experiencing a dramatic and undesired increase in the aggressiveness of pharmaceutical sales representatives over the last decade, which has become coercive and harassing, coincident with the rise of presciber identity data mining in the pharmaceutical industry in the 1990s.
- Prescriber identity data mining allows pharmaceutical companies to track to track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities.
- Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug reps. It is estimated that there is a pharmaceutical sales representative in Vermont for every five office-based physicians in Vermont.

- In 2004, the pharmaceutical industry spent $27 billion marketing pharmaceuticals in the U.S., and spent more than any other sector in the U.S. on its sales force and media advertising. Over 85 percent of these marketing expenditures are directed at the small percentage of the population that practice medicine.
- According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost $2.2 million to prescribers in Vermont, including fees and travel expenses in 2005. Estimates of total costs of marketing to prescribers in Vermont are $10 million or more, excluding free samples and direct-to-consumer advertising.
- Physician identity data mining facilitates and encourages coercive and harassing pharmaceutical marketing practices.
- Presciber identified databases of prescribing habits encourage pharmaceutical companies increase the *quid pro quo* nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity datamining to target increased attention and harassing and coercive practices toward those doctors that it finds are most profitable, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors that are proven to be especially susceptible to sales messages.

- Monitoring of prescribing practices also allows the sales representative to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards.
- Added coercion and harassment occurs when doctors are informed that they are being monitored - through messages of appreciation for writing prescriptions, or messages of disappointment that they are not prescribing what was implicitly promised.
- Like the trading of consumer phone numbers linked to spending pattern data, the trading of prescriber identities linked to prescription data encourages harassing and unethical sales behaviors by pharmaceutical sales representatives toward doctors.

COST

- In 2005, Vermonters spent an estimated $524 million on prescription and over the counter drugs and medical supplies. In 2000, spending was about $280 million. The annual increase in spending during this period was 13.3 percent.
- Nearly a third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased therapeutic value.
- Only brand name companies have incentives to spend the billions of dollars per year it costs to market drugs directly to doctors.

PUBLIC HEALTH

- Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.
- The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that only brand name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one sides nature of the marketing leads to doctors prescribing drugs with imperfect, misleading and biased information, particularly for prescribers that lack the time or initiative to perform substantive research assessing whether the messages they are receiving from pharmaceiutical representatives is full and accurate.
- Doctors are frequently encouraged by pharmaceutical sales representatives to prescribe medicines in ways that have not been approved by the Federal Food and Drug Administration, that are misleading as to the full benefits or risks of the products, that are not backed by scientific evidence, and that otherwise do not directly promote public health.
- This state does not have sufficient resources to effectively counter misleading pharmaceutical sales messages with counter-speech. While physician educational efforts are being undertaken by Vermont, it is also necessary to regulate the most harmful sales practices and uses of physician prescribing information to temper the market flaws in inherent in pharmaceutical advertising.