APPENDIX

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UNITED STATES COURT OF APPEALS,
SECOND CIRCUIT.

Argued: Oct. 13, 2009. Decided: Nov. 23, 2010.

Docket Nos. 09-1913-cv(L), 09-2056-cv(CON).

IMS HEALTH INC., Verispan, LLC, Source Healthcare Analytics, Inc., a subsidiary of Wolters Kluwer Health, Inc., and Pharmaceutical Research and Manufacturers of America,

Plaintiffs-Appellants,

v.

William H. SORRELL, as Attorney General of the State of Vermont, Jim Douglas, in his official capacity as Governor of the State of Vermont, and Robert Hofmann, in his capacity as Secretary of the Agency of Human Services of the States of Vermont,

Defendants-Appellees.

Before FEINBERG and LIVINGSTON, *Circuit Judges*, and KOELTL, *District Judge*.*

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* The Honorable John G. Koeltl, of the United States District Court for the Southern District of New York, sitting by designation.

The petitioners appeal from a judgment of the United States District Court for the District of Vermont (J. Garvan Murtha, Judge) denying the plaintiffs' motions for declaratory relief, injunctive relief, and summary judgment, and upholding Vt. Acts No. 80, § 17 (2007), codified as Vt. Stat. Ann. tit. 18, § 4631 (2007), as amended by Vt. Acts No. 89 (2008) (Act 80, "section 17"). The district court found that the Vermont statute is a constitutionally permissible commercial speech restriction under the test set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 561-66 (1980), and that the statute does not violate the dormant Commerce Clause. Because we find that section 17 is an impermissible restriction on commercial speech under *Central Hudson*, we reverse and remand.

Thomas R. Julin, Jamie Z. Isani, Patricia Acosta, Hunton & Williams LLP, Miami, FL; Robert B. Hemley, Matthew B. Byrne, Gravel & Shea, P.A, Burlington, VT; Thomas C. Goldstein, Akin Gump Strauss Hauer & Feld LLP, Washington, DC, *for Plaintiffs-Appellants IMS Health Inc. and Source Healthcare Analytics, Inc.*

Mark A. Ash, Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, LLP, Raleigh, NC, *for Plaintiff-Appellant Verispan LLC.*

Robert N. Weiner, Jeffrey L. Handwerker, Sarah Brackney Arni, Arnold & Porter LLP, Washington, DC; Karen McAndrew, Linda J. Cohen, Dinse, Knapp & McAndrew, P.C., Burlington, VT, *for Plaintiff-Appellant Pharmaceutical Research & Manufacturers of America.*

William H. Sorrell, Attorney General of the State of Vermont; Bridget C. Asay, Assistant Attorney General; Sarah E.B. London, Kate G. Duffy, David R. Cassetty, Assistants Attorneys General, on the brief, Montpelier, VT, *for Defendants-Appellees*.

JOHN G. KOELTL, District Judge:

The appellants, IMS Health Inc., Verispan, LLC, Source Healthcare Analytics, Inc., and Pharmaceutical Research and Manufacturers of America ("PhRMA") (collectively, "the appellants") challenge a Vermont statute banning the sale, transmission, or use of prescriber-identifiable data ("PI data") for marketing or promoting a prescription drug unless the prescriber consents. In 2007, Vermont enacted the statute at issue, namely Vt. Acts No. 80, § 17 (2007), codified at Vt. Stat. Ann. tit. 18, § 4631 (2007), as amended by Vt. Acts No. 89 (2008) (changing effective date of § 17 from January 1, 2008 to July 1, 2009) (Act 80, "section 17"). The appellants appeal from a judgment of the United States District Court for the District of Vermont (J. Garvan Murtha, *Judge*) finding section 17 to be a constitutional restriction on commercial speech pursuant to *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 561-66 (1980), and finding that section 17 does not violate the Commerce Clause, art. I, § 8, cl. 3, of the United States Constitution.[1] *IMS Health Inc. v. Sorrell*, 631 F.Supp.2d 434 (D.Vt.2009).

[1] The district court also upheld sections 20 and 21 of Act 80, and the appellees do not challenge those holdings on appeal.

On appeal, the appellants argue (1) that section 17 restricts non-commercial speech and cannot withstand strict scrutiny, (2) that even if section 17 restricts only commercial speech, it cannot withstand intermediate scrutiny under *Central Hudson*, and (3) that section 17 violates the dormant Commerce Clause by prohibiting commerce wholly outside of Vermont. The appellees, Vermont Attorney General William H. Sorrell, Vermont Governor Jim Douglas, and Secretary of the Agency of Human Services of the State of Vermont Robert Hofmann, contend (1) that section 17 does not implicate the appellants' First Amendment rights, (2) that even if section 17 is a restriction on the appellants' commercial speech, section 17 survives intermediate scrutiny because it is a narrowly tailored statute that directly advances Vermont's substantial interest in protecting medical privacy, in controlling health care costs, and in promoting public health, and (3) that the appellants lack standing to challenge section 17 under the dormant Commerce Clause and that, in any event, section 17 does not violate the dormant Commerce Clause because it regulates intrastate commerce.

We conclude that because section 17 is a commercial speech restriction that does not directly advance the substantial state interests asserted by Vermont, and is not narrowly tailored to serve those interests, the statute cannot survive intermediate scrutiny under *Central Hudson*. Therefore, we reverse and remand the judgment of the district court.

BACKGROUND

The Vermont legislature passed Act 80 in 2007, intending to protect public health, to protect prescriber privacy, and to reduce health care costs. Section 17 prohibits the sale, license, or exchange for value of PI

data for marketing or promoting a prescription drug, and prohibits pharmaceutical manufacturers and marketers from using PI data for marketing or promoting a prescription drug, unless the prescriber consents. *See* Vt. Stat. Ann. tit. 18, § 4631(a) & (d). As amended, section 17 was effective on July 1, 2009. *See* Vt. Acts No. 89 (2008).

I.

When filling prescriptions, pharmacies in Vermont collect information including the prescriber's name and address, the name, dosage, and quantity of the drug, the date and place the prescription is filled, and the patient's age and gender. Pharmacies sell this PI data to the data mining appellants IMS Health Inc., Verispan, LLC, and Source Healthcare Analytics, Inc.[2] These data mining companies, all located outside of Vermont, aggregate the data to reveal individual physician prescribing patterns and sell it outside of Vermont, primarily to pharmaceutical manufacturers. The PI data sold by the data-mining appellants is stripped of patient information, to protect patient privacy. Appellant Pharmaceutical Research and Manufacturers of America ("PhRMA") is a non-profit association representing pharmaceutical researchers and manufacturers, the primary customers of the data mining appellants.

Pharmaceutical manufacturers market their products through various means, including advertising and detailing. "Detailing" refers to visits by pharmaceutical

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[2] The appellants describe themselves as "publishers," a term that plainly furthers their First Amendment argument. The district court referred to the appellants as "data miners," a term that has been used in other cases. It is undisputed that the appellants collect and pass on information. Their rights depend on what they do rather than what they are called. This opinion will follow the description used by the district court, namely "data miners."

representatives, called detailers, to individual physicians to provide information on specific prescription drugs, including the use, side effects, and risks of drug interactions. Pharmaceutical manufacturers use PI data to identify audiences for their marketing efforts, to focus marketing messages for individual prescribers, to direct scientific and safety messages to physicians most in need of that information, to track disease progression, to aid law enforcement, to implement risk mitigation programs, and to conduct clinical trials and post-marketing surveillance required by the United States Food and Drug Administration ("FDA").

While section 17 in part aims to decrease detailing, prescribers may want to receive the information detailers provide, and, in any event, prescribers are free to decline meetings with detailers.

As the district court noted, pharmaceutical industry spending on detailing has increased exponentially along with the rise of data mining. Detailing is only cost-effective for brand-name drugs. When a patent expires, competitors can introduce bioequivalent generic drugs. Bioequivalent generic drugs are not necessarily identical to the brand name version, but are required to demonstrate an absorption rate between 80 and 125 percent of the brand-name drug. Variations in absorption rates among branded or generic drugs may cause different reactions, such as side effects. The district court also noted that while a brand-name drug is not necessarily better than its generic version, the brand-name drug is typically more expensive.

Pharmaceutical manufacturers are not the only entities that purchase PI data from the data mining appellants, although pharmaceutical manufacturers and marketers are the only customers banned from using PI data in their marketing efforts by section 17. The

state of Vermont itself uses PI data for law enforcement and other state programs. Researchers use PI data to identify overuse of a pharmaceutical in specific populations, to develop new drugs, and to facilitate identification of potential patients to participate in clinical trials. The FDA, the Center for Disease Control, and the federal Drug Enforcement Agency use PI data to monitor usage of controlled substances and to identify prescribers who need time-sensitive safety information. Insurance companies and pharmacy benefit managers use the data to process claims and manage formulary compliance. Moreover, insurance companies and state governments like Vermont's use PI data to encourage the use of cheaper, generic medications–the very medications section 17 seeks to promote. While insurance companies and governments collect their own PI data, their databases are not as thorough as those maintained by the data mining appellants. To preserve the value of their data, data mining companies typically restrict republication of the data they provide their customers. The appellants argue that the sales covered by section 17 are essential to the ability of the data mining appellants to provide PI data for these other, permitted, uses.

II.

a.

The Vermont law was adopted in the wake of a similar statute that had been enacted in New Hampshire, and shortly before another similar statute adopted in Maine.

In 2006 the New Hampshire state legislature passed a statute prohibiting the transmission or use of patient-identifiable and PI data for most commercial purposes. *See IMS Health Inc. v. Ayotte*, 490 F.Supp.2d 163, 170-71

(D.N.H.2007), *rev'd*, 550 F.3d 42 (1st Cir.2008). In relevant part, the statute reads:

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

N.H.Rev.Stat. Ann. § 318:47-f. The stated intent of the statute, passed without any formal legislative findings, was to protect patient and physician privacy and to reduce health care costs. *See Ayotte*, 490 F.Supp.2d at 171, 177. The United States District Court for the District of New Hampshire found the statute unconstitutional because it restricted commercial speech without directly promoting substantial state interests, and despite the existence of alternative approaches to achieve these interests, in violation of the test for restrictions on commercial speech set out in *Central Hudson*. *See Ayotte*, 490 F.Supp.2d at 183.

Maine also enacted a law in 2007 regulating the use of PI data. The legislative findings indicate that the

statute was passed to improve public health, to reduce costs, and to protect patient and prescriber privacy. *See* 22 Me.Rev.Stat. Ann. tit. 22, § 1711-E(1-A, 1-B), *invalidated by IMS Health Corp. v. Rowe*, 532 F.Supp.2d 153 (D.Me.2007), *rev'd*, *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir.2010). The Maine statute prohibits the use of PI data for marketing purposes when the prescriber opts out of its use. In relevant part, it reads:

> [A] carrier, pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purposes, prescription drug information that identifies a prescriber who has filed for confidentiality protection....

22 Me.Rev.Stat. Ann. tit. 22, § 1711-E(2-A). The United States District Court for the District of Maine found the statute unconstitutional because it did not survive intermediate scrutiny despite the opt-out provision. *See Rowe*, 532 F.Supp.2d at 182.

While an appeal of the Maine district court decision was pending, the Court of Appeals for the First Circuit reversed the judgment of the New Hampshire district court and upheld the constitutionality of the New Hampshire statute. *See Ayotte*, 550 F.3d at 64. The majority found that the New Hampshire statute regulated only the conduct of data miners, and therefore did not violate their First Amendment rights. *Id.* at 50-54. Even if the statute did regulate commercial speech, the majority concluded that it would find that the statute survived intermediate scrutiny. *Id.* at 54-60. Concurring in the result, Judge Lipez concluded that the statute regulates commercial speech, but that it survived intermediate scrutiny review. *Id.* at 64-65, 79-102 (Lipez, J., concurring and dissenting).

The Court of Appeals for the First Circuit recently followed its decision in *Ayotte*. It reversed the District Court's preliminary injunction in *Rowe*, and found the Maine statute regulating the use of PI data to be constitutional. *Mills*, 616 F.3d 7.

b.

In 2007, Vermont passed Act 80, section 17, legislation aimed at restricting the use of PI data in pharmaceutical marketing. The state legislature explained that:

> It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

Vt. Stat. Ann. tit. 18, § 4631(a). The statute adopts an opt-in approach, allowing prescribers to opt in to allow the use of their PI data for marketing purposes. *See id.* at § 4631(c)(1). Otherwise, the sale or transfer of PI data for marketing purposes, or the use of PI data for marketing purposes, is prohibited. The statute 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.

Id. at § 4631(d). Marketing is defined by the statute 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 to evaluate the effectiveness of a professional pharmaceutical detailing sales force.

Id. at § 4631(b)(5).

The statute expressly permits the sale, transfer, or use of PI data for multiple other purposes, including 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; health care research; dispensing prescription medications; the transmission of prescription data from prescriber to pharmacy; care management; educational communications provided to a patient, including treatment options, recall or safety notices, or clinical trials; and for certain law enforcement purposes as otherwise authorized by law. *See id.* at § 4631(e)(1)-(7).

The Vermont state legislature issued thirty-one legislative findings in support of the statute. *See* Vt. Acts

No. 80, § 1 (2007). The findings expressly state the legislature's intent to interfere with the marketplace of ideas to promote the interests of the state. For example, the findings note that the legislature views the goals of pharmaceutical marketing as "often in conflict with the goals of the state." *Id.* at § 1(3). The legislature expressed its concern that the "marketplace for ideas on medicine safety and effectiveness is frequently one-sided," leading doctors to prescribe "drugs based on incomplete and biased information." *Id.* at § 1(4). The legislature therefore found that "[p]ublic health is ill served by the massive imbalance in information presented to doctors and other prescribers." *Id.* at § 1(6). Section 17 is the state's attempt to correct what it sees as an unbalanced marketplace of ideas that undermines the state's interests in promoting public health, protecting prescriber privacy, and reducing health care costs.

III.

The data mining plaintiffs filed suit on August 29, 2007 against the Vermont Attorney General, seeking to enjoin enforcement of the statute prior to its taking effect. In November 2007 the action was consolidated with a suit by PhRMA against the appellees seeking declaratory and injunctive relief. An amended complaint was filed on May 14, 2008. After a bench trial, the district court denied the plaintiffs' motions for declaratory and injunctive relief and for summary judgment, and denied as moot the defendants' motions for summary judgment. *See Sorrell*, 631 F.Supp.2d at 464.

The district court found that section 17's restriction of commercial speech survived intermediate scrutiny under *Central Hudson*. *See Sorrell*, 631 F.Supp.2d at 455. The district court likewise found that section 17 did

not violate the dormant Commerce Clause of the United States Constitution.[3] *See id.* at 456-59.

The appellants appealed from the judgment of the district court, arguing that section 17 is either a restriction on speech requiring strict scrutiny, or a restriction on commercial speech that does not survive intermediate scrutiny. The appellants also argue that the statute restricts commercial activities outside of Vermont, in violation of the dormant Commerce Clause. The appellees respond that the statute restricts conduct rather than speech, that even if the statute does restrict commercial speech it survives intermediate scrutiny, and that it does not violate the dormant Commerce Clause. Because we find that section 17 is an improper restriction on commercial speech under the test set forth in *Central Hudson*, we find the statute unconstitutional and reverse and remand.

DISCUSSION

Because this case turns on constitutional issues, our review is *de novo*. *See Boy Scouts of Am. v. Dale*, 530 U.S. 640, 648-49 (2000); *Melzer v. Bd. of Educ. of the City Sch. Dist. of the City of New York*, 336 F.3d 185, 198 (2d Cir.2003).

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[3] The district court also upheld sections 20 and 21 of the Act, creating a program funded by a fee on pharmaceutical manufacturers to educate health care professionals concerning therapeutic and cost-effective utilization of prescription medications, and creating a consumer fraud cause of action for advertisements in Vermont that violate federal law. *See* Vt. Stat. Ann. tit. 33, § 2004 & tit. 9, § 2466a; *Sorrell*, 631 F.Supp.2d at 462, 464. The appellants do not dispute these holdings on appeal, and we do not address them here.

The appellants' principal argument is that section 17 violates their rights under the First and Fourteenth Amendments. *See* U.S. Const. amend. I ("Congress shall make no law ... abridging the freedom of speech...."). The First Amendment has been applied against state action by the Fourteenth Amendment. *See Gitlow v. New York*, 268 U.S. 652, 666 (1925) (incorporating First Amendment freedom of speech against the states under U.S. Const. amend XIV). Because the appellees contend that section 17 merely regulates conduct that is not subject to First Amendment protections, it is necessary to determine whether the statute restricts protected speech before determining whether that restriction is permissible under the First Amendment.

I.

The district court found that section 17 is a restriction on speech, and does not merely regulate the appellants' conduct. *See Sorrell*, 631 F.Supp.2d at 445-47. The appellees argue that the statute is simply a restriction on a commercial practice. They argue that the data miners are buying and selling a commodity, which can be regulated. They concede that the activities of the pharmaceutical companies who seek to use that information to market prescription drugs is a closer question under the First Amendment, but they contend that the statute is nevertheless a restriction on the commercial conduct of the pharmaceutical companies.

We agree with the district court. The First Amendment protects "[e]ven dry information, devoid of advocacy, political relevance, or artistic expression." *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446 (2d Cir.2001). *See also Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761-70 (1976) (drug price information in drug advertisements

is speech); *Universal City Studios*, 273 F.3d at 446-49 (computer program is speech). Furthermore, it is plain that speech in a form that is sold for profit is entitled to First Amendment protection. *See Va. State Bd.*, 425 U.S. at 761.

The Court of Appeals for the First Circuit found that a similar New Hampshire statute was not a restriction on speech, but primarily a restriction on conduct, although it considered the statute only as it affected the activities of data miners rather than pharmaceutical manufacturers. *See Ayotte*, 550 F.3d 50-54. The court therefore considered the statute to be "a species of economic regulation," subject only to rational basis review, which the plaintiffs conceded the law satisfied. *See id.* at 54.

In *Ayotte*, the court treated the New Hampshire statute among the narrow categories of regulations restricting speech that are not entitled to First Amendment protection, in the tradition of *Chaplinsky v. New Hampshire*, 315 U.S. 568, 571-72 (1942), which found lewd, obscene, profane, libelous, and fighting words to be categories of speech wholly outside the protections of the First Amendment. The Court of Appeals interpreted the New Hampshire statute as principally a regulation of conduct because it "restrict[s] the ability of data miners to aggregate, compile, and transfer information destined for narrowly defined commercial ends" in a transaction where the "information itself has become a commodity." *Ayotte*, 550 F.3d at 52-53. The Court of Appeals thought it would "stretch[ ] the fabric of the First Amendment beyond any rational measure" to treat a regulation of information differently from a regulation of "beef jerky" when the information is a product. *Id.* at 53. The majority of the Court of Appeals concluded that it was consistent with the First Amendment for the "legislature ... to level the playing field not by eliminating speech but, rather,

by eliminating the detailers' ability to use a particular information asset–prescribing histories–in a particular way." *Id.* at 54. However, as the Supreme Court recently affirmed, courts do not have "freewheeling authority to declare new categories of speech outside the scope of the First Amendment." *United States v. Stevens*, 130 S.Ct. 1577, 1586 (2010). The obscure distinction between speech and "information asset[s]" is an insufficient basis for giving the government leeway to "level the playing field" subject only to rational basis review.

Here, the legislature explicitly aimed to correct the "massive imbalance in information presented to doctors and other prescribers." Vt. Acts No. 80 § 1(6). The statute specifically decries that "[t]he marketplace for ideas on medicine safety and effectiveness is frequently one-sided...." *Id.* at § 1(4). The statute is therefore clearly aimed at influencing the supply of information, a core First Amendment concern. Instead of mere rational basis review, the First Amendment teaches that courts should assume that truthful commercial information "is not in itself harmful," *Va. State Bd.*, 425 U.S. at 770, and conclude that when a statute aims to restrict the availability of such information for some purposes, that restriction must be judged under the First Amendment.

The appellees also argue that the statute only regulates conduct and not speech because the appellants have no First Amendment right to access non-public health records without consent. However, the appellants have not claimed a First Amendment right to obtain information. They challenge the restriction on their ability to purchase and use information otherwise available to them but for the state's restriction. The statute prevents willing sellers and willing buyers from completing a sale of information to be used for purposes that the state disapproves. Indeed, section 17 does not

prohibit the collection of PI data so long as it is not used for purposes that the state has prohibited.

The appellees rely on the Supreme Court's decision in *Los Angeles Police Department v. United Reporting Publishing Corp.*, 528 U.S. 32 (1999). However, that case illustrates why the appellees' argument is misplaced. In *United Reporting*, the Supreme Court held that restrictions on access to certain police department information were not facially unconstitutional under the First Amendment. *Id.* at 34-37. The Supreme Court noted that, "what we have before us is nothing more than a governmental denial of access to information in its possession." *Id.* at 40. The Court also noted that "[t]his is not a case in which the government is prohibiting a speaker from conveying information that the speaker already possesses." *Id.* In this case, the information is not in the government's possession. Rather, the state seeks to limit the acquisition and use of information in the hands of pharmacies, data miners, and pharmaceutical companies. This is a case about the extent of the permissible governmental regulation of information in the hands of private actors. It is not a case about a claim by private parties to a First Amendment right to access information in government files.

Because we agree with the district court that the statute restricts protected speech, it is necessary to determine whether section 17 violates the appellants' First Amendment rights.

II.

The appellants argue that section 17 restricts noncommercial speech, even though PI data is sold for a profit. They argue that the statute should be subject to strict scrutiny. *See Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 482 (1989) ("Some of our most valued

forms of fully protected speech are uttered for a profit.") The appellees contend, and the district court agreed, that section 17 restricts only commercial speech, and therefore is subject to intermediate scrutiny under the test set out in *Central Hudson*. *See Sorrell*, 631 F.Supp.2d at 447-48. The district court noted that PI data has both commercial and noncommercial uses. *See Sorrell*, 631 F.Supp.2d at 447. The data can be used in research regarding the use of prescription medications, to identify harmful consequences of particular medications, and to warn doctors who have prescribed a particular medication of safety concerns that arise after FDA approval. The data can also be used for the purely commercial purposes of marketing branded prescription drugs.

Section 17 restricts the speech of both the pharmaceutical manufacturers represented by PhRMA, who are prohibited from using Vermont PI data for marketing purposes, and the data mining appellants, who are prohibited from selling or transferring Vermont PI data if the data is to be used for marketing purposes. *See* Vt. Stat. Ann. tit. 18, § 4631(d). We address each in turn.

a.

Section 17 prohibits pharmaceutical manufacturers from using PI data regarding prescriptions written and dispensed in Vermont in their marketing efforts. *See id.* The statute therefore affects manufacturers' ability to promote brand-name drugs to doctors through detailing, for example, by making it harder to identify those physicians for whom the message will be most relevant and to tailor the detailing messages based on individual physicians' prescribing histories.

"The 'core notion' of commercial speech is that 'which does no more than propose a commercial transaction.'" *Anderson v. Treadwell*, 294 F.3d 453, 460 (2d Cir.2002),

quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983). It cannot be seriously disputed that the primary purpose of detailing is to propose a commercial transaction–the sale of prescription drugs to patients. The manufacturers argue, however, that the detailing message includes fully protected speech, specifically "information regarding medical conditions the prescribers treat and [a manufacturer's] innovative treatments for those conditions" and that strict scrutiny should apply here because Section 17 restricts commercial speech that is "inextricably intertwined with otherwise fully protected speech." *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988). However, the mere presence of non-commercial information in an otherwise commercial presentation does not transform the communication into fully protected speech. *See*, *e.g.*, *Bolger*, 463 U.S. at 68 ("We have made clear that advertising which 'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded noncommercial speech."); *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 97 (2d Cir.1998) (holding product label to be commercial speech despite social commentary purportedly communicated by the labeling).

Therefore, although some of the information communicated by detailers might be fully protected in another context, we will analyze section 17 as a restriction on commercial speech with respect to the pharmaceutical manufacturers. *See Bolger*, 463 U.S. at 68 ("A company has the full panoply of protections available to its direct comments on public issues, so there is no reason for providing similar constitutional protection which such statements are made in the context of commercial transactions.").

b.

Section 17 also prohibits data miners from selling or transmitting PI data regarding prescriptions written and dispensed in Vermont if that PI data will later be used for marketing purposes. *See* Vt. Stat. Ann. tit. 18, § 4631(d). Data miners do not themselves use PI data in their own marketing efforts. Rather, data miners are in the business of aggregating and selling the data to pharmaceutical manufacturers, among other entities, so that pharmaceutical manufacturers can use the data in their marketing strategies. The data miners' regulated speech is therefore one step further removed from the marketing goals of the pharmaceutical manufacturers, although it remains a necessary step in the pharmaceutical manufacturers' marketing efforts.

The sale of information is protected by the First Amendment, and is not necessarily commercial speech. *See*, *e.g.*, *Universal City Studios*, 273 F.3d at 446-58 (finding computer program is speech, and not scrutinizing it under the commercial speech doctrine). However, unlike the data miners' sale of PI data here, the computer program in *Universal City Studios* was not a step in a chain intended to influence marketing efforts.

Because this Court finds that section 17's restriction on data miners cannot survive even the lower intermediate scrutiny that applies to regulations of commercial speech, we assume without deciding that the statute restricts the data mining appellants' commercial speech.

III.

Under *Central Hudson*, the government may regulate commercial speech when (1) "the communication is neither misleading nor related to unlawful activity;" (2)

the government "assert[s] a substantial interest to be achieved" by the regulation; (3) the restriction "must directly advance the state interest;" and finally (4) "if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive." *Central Hudson*, 447 U.S. at 564. There is no allegation that the commercial speech regulated by section 17 is either misleading or related to an unlawful activity. Therefore, for the statute to survive intermediate scrutiny, the government must assert a substantial state interest that is directly advanced by the statute, and the regulation must not be more extensive than necessary to achieve the government's interest.

a.

The second prong of *Central Hudson* requires that the state "assert a substantial interest to be achieved by restrictions on commercial speech." *Id.* Vermont alleges that section 17 advances three substantial state interests: (1) "the state's interest in protecting the public health," (2) "protecting the privacy of prescribers and prescribing information," an interest the state sometimes also refers to as an interest in protecting "medical privacy," and (3) the state's interest in containing health care costs in both the private and public sectors. *See* Vt. Stat. Ann. tit. 18, § 4631(a).

The district court found that Vermont's cost containment and public health interests were substantial government interests to justify the statute. *Sorrell*, 631 F.Supp.2d at 449-50. The court found that it was unnecessary to consider whether protecting prescriber privacy was also a substantial government interest. *Id.* at 450. The appellants do not seriously dispute that the state has a substantial interest in protecting public health and containing health care costs, although the appellants

do argue that section 17 does not directly advance these substantial state interests.

The parties dispute whether protecting the privacy of prescribers and prescribing information is a substantial state interest. Section 17 itself refers to "protecting the privacy of prescribers and prescribing information," but the statute plainly does not protect physician privacy. Vt. Stat. Ann. tit. 18, § 4631(a). Physician privacy might be protected if the statute prohibited the collection and aggregation of PI data for any purpose, or if the use of such data were permitted in only rare and compelling circumstances. The statute at issue here, however, does not forbid the collection of PI data in the first instance. Furthermore, the statute does not ban any use of the data other than for marketing purposes, including widespread publication to the general public. There is nothing in the statute that would prevent the use of such data for journalistic reports about physicians.

Vermont contemplates that the data will still be collected and used, albeit for purposes other than marketing. For example, the state acknowledges that the statute permits the use of PI data for "health care research, treatment, and safety-related uses." The statute only imposes restrictions on the sale or use of such data for marketing or promoting a prescription drug. Vermont does not explain how the continued collection of PI data, and its use for non-marketing purposes, is compatible with an alleged interest in protecting physician privacy. Indeed, the concern that patient information can be gleaned from PI data is not reduced in any way by section 17, and the statute does not prohibit wide public dissemination of PI data.

The appellees argue that the state's interest in privacy is "that pharmaceutical marketers should not be exerting undue influence and intruding on the doctor-patient

relationship" by marketing prescription drugs using PI data. According to this argument, the state has an interest in preventing pharmaceutical manufacturers from using PI data to persuade doctors to prescribe brand-name medications "because patient care can be compromised [and] because patient trust in the health care system is undermined." Therefore, what the appellees refer to as "medical privacy" is actually two distinct interests. The first is an interest in the integrity of the prescribing process itself, and the second is an interest in preserving patients' trust in their doctors by preventing patients from believing that their physicians are inappropriately influenced by PI data-driven marketing.

However, the state's asserted interest in medical privacy is too speculative to qualify as a substantial state interest under *Central Hudson*. Intermediate scrutiny requires that the state "demonstrate that the harms it recites are real." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995). On the record in this case, Vermont has not shown any effect on the integrity of the prescribing process or the trust patients have in their doctors from the use of PI data in marketing. Vermont's own expert was unaware of any instance in which a detailing interaction caused a doctor to prescribe an inappropriate medication. To the extent that the record might suggest PI data has damaged the relationship between doctors and patients, the evidence is either speculative or merely indicates that some doctors do not approve of detailing or the use of PI data in detailing. For example, Vermont's expert witness Dr. David Grande opined that the use of PI data "will make patients only feel more anxious about whether or not in fact their interests are being put first," but he had not conducted any studies of patient perception of PI data to support that conclusion.

Therefore, we agree with the district court that Vermont does have a substantial interest in both lowering health care costs and protecting public health. However, the state's asserted interest in "medical privacy" is too speculative to satisfy the second prong of Central Hudson.

b.

The third prong of *Central Hudson* requires that the regulation "directly advance the state interest involved." *Cent. Hudson*, 447 U.S. at 564; *see also Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (describing third prong of *Central Hudson* as "whether the challenged regulation advances these interests in a direct and material way"). "It is well established that 'the party seeking to uphold a restriction on commercial speech carries the burden of justifying it.'" *Edenfield*, 507 U.S. at 770 (alteration omitted) (quoting *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 71 n.20 (1983)). This prong is "critical" and requires invalidating a regulation that restricts commercial speech "'if it provides only ineffective or remote support'" for the government's interest. *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 188 (1999) (quoting *Cent. Hudson*, 447 U.S. at 564).

The Vermont statute cannot be said to advance the state's interests in public health and reducing costs in a direct and material way. Section 17 can advance the state interests in protecting public health and reducing health costs only by the following route: the statute prevents PI data from being transferred from data miners to pharmaceutical manufacturers for marketing purposes, who in turn are prevented from using the data in their marketing efforts. Failure to use PI data in marketing results in less effective marketing for brand-name prescription drugs, some of which–although not all–are

more expensive yet provide no therapeutic advantage over generic alternatives. Less effective marketing will result in doctors writing fewer prescriptions for brand-name prescription drugs, thereby reducing health care costs and protecting public health by minimizing prescriptions for more expensive or less tested medications. The state's own explanation of how section 17 advances its interests cannot be said to be direct. The statute does not directly restrict the prescribing practices of doctors, and it does not even directly restrict the marketing practices of detailers. Rather, it restricts the information available to detailers so that their marketing practices will be less effective and less likely to influence the prescribing practices of physicians.

The appellees have failed to cite to any case from the Supreme Court or this Court that has upheld a regulation on speech when the government interest in the regulation is to bring about indirectly some social good or alter some conduct by restricting the information available to those whose conduct the government seeks to influence. *Cf. Cent. Hudson*, 477 U.S. at 566 n.9 ("We review with special care regulations that entirely suppress commercial speech in order to pursue a nonspeech-related policy."). Regulations of conduct are permitted, but only if the government interest is "unrelated to the suppression of free expression." *United States v. O'Brien*, 391 U.S. 367, 377 (1968). However, the legislative findings are explicit that Vermont here aims to do exactly that which has been so highly disfavored–namely, put the state's thumb on the scales of the marketplace of ideas in order to influence conduct. The legislature found that 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." Vt. Acts No. 80, § 1(4). In other words, the statute seeks to alter the marketplace of ideas by taking out some truthful information that the state thinks could be used too effectively.

The state's approach to regulating the interaction between detailers and doctors is premised on limiting the information available to physicians as a means of impacting their conduct. This approach 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. *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) ("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."); *Va. State Bd.*, 425 U.S. at 770 (alternative to ban on pharmacist advertising "is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them."). Even if section 17 is successful in altering the conduct of physicians in their prescribing practices, the Supreme Court reminds us that "[i]t is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us." *Va. State Bd.*, 425 U.S. at 770; *see also Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002) ("If the First Amendment means anything, it means that regulating speech must be a last–not first–resort.").

The appellees place extensive reliance on *Anderson v. Treadwell*, 294 F.3d 453 (2d Cir.2002). In *Anderson*,

this Court upheld a New York statute banning in-person real estate solicitations of homeowners in certain zones designated by the Secretary of State if the homeowner indicated that the homeowner did not wish to receive such solicitations. *Id.* at 456-58. The statute was designed to prevent "blockbusting"–the practice of obtaining real estate listings by emphasizing that a neighborhood is undergoing a religious, racial, or ethnic change. *Id.* at 457. However, this Court upheld the statute on the basis of the government interest in protecting the privacy of homeowners from harassing real estate solicitations, an interest that is not present here. *See id.* at 461. The statute in *Anderson* directly regulated the potentially harassing sales calls. It directly targeted the harassing visits that were viewed as problematic. The statute in *Anderson* did not ban any entity from transmitting marketing data that would be useful to real estate agents in deciding which homeowners to target. It did not seek to affect the conduct of homeowners by limiting the information available to them. In contrast, section 17 does not ban detailing, even when that detailing is seen as harassment by an individual physician. It does not even restrict such detailing. The opt-in provision of section 17 does not make the statute comparable to the statute in *Anderson*. The opt-in provision in the Vermont statute relates solely to a physician's agreement that the physician's PI data can be used. Physicians in Vermont can always choose to decline to be visited by detailers, even without section 17. The opt-in provision in the statute in *Anderson* was a consent to be solicited by real estate licensees, not a consent to have information used.[4]

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[4] *Anderson* is consistent with those cases that have approved procedures for unwilling listeners to decline to receive speech as less restrictive regulations than those preventing speech unless a listener has affirmatively chosen to receive such messages. *See*,

Because section 17 is an attempt to influence the prescribing conduct of doctors by restricting the speech of others–namely data miners and pharmaceutical manufacturers–it does not directly advance the state's interests in protecting public health and reducing health care costs. Instead, 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, who are not regulated by the statute. This route is too indirect to survive intermediate scrutiny.

c.

Section 17 also fails under the final prong of *Central Hudson*, which requires invalidating the restriction "if the governmental interest could be served as well by a more limited restriction on commercial speech." 447 U.S. at 564.

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e.g., *Martin v. City of Struthers, Ohio*, 319 U.S. 141, 147-49 (1943) (invalidating ban on door-to-door solicitation while noting that regulation banning solicitation when homeowner has indicated a desire not to be disturbed is appropriate); *see also Mainstream Mktg. Servs., Inc. v. F.T.C.*, 358 F.3d 1228, 1242-43, 1246 (10th Cir.2004) (upholding "do not call" list as constitutional restriction on commercial speech in part because consumers actively joining "do not call" registry before commercial telephone calls are barred is less restrictive of speech than requiring consumers to consent to receiving such calls before they could be made).

The Court of Appeals for the First Circuit recently noted that Maine's statute was similar to "do not mail lists" because prescribers are entitled to have their information protected from disclosure only if they choose to seek confidentiality protections. *Mills*, 616 F.3d at 21-22. The Vermont statute at issue in this case, however, uses the broader approach of prohibiting the designated uses of PI data unless a prescriber affirmatively chooses to have that prescriber information made available.

> The Government is not required to employ the least restrictive means conceivable, but it must demonstrate narrow tailoring of the challenged regulation to the asserted interest–"a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served."

Greater New Orleans Broad., 527 U.S. at 188 (quoting *Fox*, 492 U.S. at 480). The burden is on the government to show that it "carefully calculated" costs and benefits of burdening speech. *Id.* While the fit need not be perfect, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson*, 535 U.S. at 371.

The regulation at issue here applies to *all* brand name prescription drugs, irrespective, for example, of whether there is a generic alternative or whether an individual drug is effective or ineffective. This is a poor fit with the state's goal to regulate new and allegedly insufficiently tested brand-name drugs in cases where there are cheaper generic alternatives available. The statute targets the use of PI data to market all brand name prescription drugs, not merely new brand-name drugs or those brand-name medications for which there are generic alternatives.

The appellees argue that the Court should defer to the legislative determination that the statute is a reasonable fit so long as that determination is itself reasonable. The appellees rely on this Court's recent decision in *Clear Channel Outdoor, Inc. v. City of New York*, 594 F.3d 94, 104 (2d Cir.2010), for the proposition that this Court should defer to a government's reasonable

determination regarding how to regulate commercial speech. However, reliance on *Clear Channel* is misplaced because that decision specifically addresses a regulation of commercial billboards, a distinctive method of speech that poses unique problems such as the potential to distract drivers and is therefore particularly amenable to government regulation. *See id.* at 108. This Court stressed the particular government interests involved in "'the law of billboards.'" *Id.* (quoting *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 501 (1981)).

In any event, we need not decide what level of deference is appropriate here. The statute prohibits the transmission or use of PI data for marketing purposes for all prescription drugs regardless of any problem with the drug or whether there is a generic alternative. The statute bans speech beyond what the state's evidence purportedly addresses. It seeks to discourage detailing about new brand-name prescription drugs which may not be efficacious or which may not be more effective than generic alternatives. However, it does that by precluding the use of PI data for the marketing of any brand-name prescription, no matter how efficacious and no matter how beneficial those drugs may be compared to generic alternatives. Even if the Court defers to the legislature's determinations, those determinations cannot support banning speech in circumstances that the state's evidence does not address. The fact that section 17 sweeps beyond Vermont's interests in public health and health care costs undermines the state's argument that the statute is a reasonable fit with its interests.

Moreover, Vermont does have more direct, less speech-restrictive means available. The state could wait to assess what the impact of its newly funded counter-speech program will be, including academic detailing and sample generic vouchers. The state could mandate

the use of generic drugs as a first course of treatment, absent a physician's determination otherwise, for all those patients receiving Medicare Part D funds. All of these means could be targeted at new brand-name drugs particularly when there are alternatives available, unlike section 17's approach that applies to every prescription drug regardless of whether it is a less tested version of an existing medication or a breakthrough drug with no reasonable alternative. All of these alternative means would directly promote the state's interests, although they would do so without impacting First Amendment rights.

The district court found that section 17 satisfied the narrow tailoring requirement of *Central Hudson* because the statute allows prescribers to determine how their PI data would be used, just as the statute at issue in *Anderson* allowed homeowners to determine whether they would receive solicitations from real estate agents. *See Sorrell*, 631 F.Supp.2d at 455 (citing *Anderson*, 294 F.3d at 462). We reject the comparison of section 17 with the statute at issue in *Anderson*, for the reasons explained above. Moreover, the district court did not consider whether there are any reasonable alternatives that would be less speech-restrictive than section 17. While we agree with the district court that *Central Hudson* does not require the state to use the least restrictive means available to it to achieve its goals, this Court has examined the available alternatives in other cases to determine whether there was a reasonable fit between the regulation and the state's asserted interests. *See N.Y. State Ass'n of Realtors, Inc. v. Shaffer*, 27 F.3d 834, 844 (2d Cir.1994) (invalidating regulation banning real estate brokers from soliciting residential property owners in certain designated areas when defendant failed to provide empirical evidence regarding whether less speech-restrictive approaches would sufficiently promote the asserted government interests).

The state argues that section 17 is narrow because it does not ban detailing and is therefore narrower than speech restrictions that have been struck down. *See Ayotte*, 550 F.3d at 53; *id.* at 97 (Lipez, J., concurring). The district court agreed with this reasoning. *See Sorrell*, 631 F.Supp.2d at 455. The statute may be narrow in the sense that it does not prohibit detailing and does not proscribe any particular claim or message. However, the statute does ban a set of messages that Vermont itself contends are particularly effective, namely, messages informed by PI data, and curbs the ability of pharmaceutical manufacturers to market brand-name drugs.

Vermont argues that, unlike other regulations that have been struck down, the statute at issue here does not ban an entire category of speech because doctors can permit their own PI data to be transmitted and used for marketing purposes. *Cf. Alexander v. Cahill*, 598 F.3d 79, 96 (2d Cir.2010) (finding statute banning potentially, but not actually, misleading use of nicknames in attorney advertising an unconstitutional regulation of commercial speech). However, the mere fact that the statute does permit doctors to choose to make their PI data available for marketing purposes, even if a substantial number of doctors would do so, "does not render the disputed provisions any less categorical." *See id.* The statute bans the transmission or use of PI data for marketing purposes, unless the prescriber consents, without regard to whether the data pertains to a prescription drug that is efficacious and whether or not it has a generic alternative. It is the fact that the statute does not distinguish between brand-name drugs, no matter how unique and efficacious, that renders the statute a categorical ban.

The appellees failed to explain how section 17 is no more extensive than necessary to serve its asserted interests in health care costs and public health, or why

the proposed alternatives would be inadequate. The state did present limited testimony at trial relating to these alternatives. For example, Dr. Aaron Kesselheim testified that the pharmaceutical industry's total annual detailing budget was approximately $8 billion and that it was not realistic for Vermont to spend this amount on academic detailing. Dr. Kesselheim also testified that "[formularies, step therapy, and prior authorization] have been in place ... for a few years [but] ... we still see ... overuse of products that potentially place patients at risk." However, the testimony fell far short of demonstrating that the alternatives would be inadequate. Therefore, section 17 cannot survive *Central Hudson* scrutiny because Vermont did "not offer [ ] any reason why these possibilities, alone or in combination, would be insufficient to [achieve the government's interests]." *Thompson*, 535 U.S. at 373.

Vermont does argue in its brief that the statute is narrowly tailored because it "focuses on the specific problem identified by the Legislature: the use of [PI data] to fuel marketing campaigns." However, this argument is not responsive to the inquiry under *Central Hudson*. Vermont has not asserted a substantial state interest in curbing the use of PI data in marketing campaigns. To satisfy the final prong of *Central Hudson*, Vermont must show that section 17 is narrowly tailored to serve the substantial state interests that it contends justify the speech restriction-containing health care costs and protecting public health.

Because the statute restricts speech even with regard to prescriptions of breakthrough brand-name medications for which there are no generic alternatives, and because the state could pursue alternative routes that are directly targeted at encouraging the use of generic drugs the state wishes to promote, the

state has not demonstrated that its interests in protecting public health and containing health care costs could not be as well served by a more limited restriction on speech. Therefore, section 17 cannot survive intermediate scrutiny and is an unconstitutional regulation of commercial speech under the test set forth in *Central Hudson*.[5]

CONCLUSION

For the reasons explained above, we **reverse and remand** the judgment of the district court.

[5] The appellants also argue that section 17 violates the dormant Commerce Clause because it restricts commerce outside Vermont. Because we find section 17 unconstitutional pursuant to the *Central Hudson* test, we need not reach this argument.

Judge LIVINGSTON dissents in a separate opinion.

DEBRA ANN LIVINGSTON, Circuit Judge, dissenting:

Misconstruing Vermont's prescription confidentiality law, Vt. Stat. Ann. tit. 18 § 4631 (2007) (hereinafter "section 17"),[1] as a direct restriction on pharmaceutical marketing, which is indisputably a form of "commercial speech" for purposes of the First Amendment, the majority extends First Amendment protection to data miners and pharmaceutical companies principally challenging a restriction on *access* to otherwise private information. In so doing, the majority not only reaches the wrong result in this case, but creates Circuit precedent likely to have pernicious broader effects in a complex and evolving area of First Amendment law. Because I would find that section 17 permissibly restricts access to information that Vermont requires pharmacies to collect and that the statute has very limited, if any, effects on First Amendment activity, I respectfully dissent.

I.

I begin with common ground: there is no dispute that prescriber-identifiable data–i.e., data which documents the prescribing habits of a particular doctor ("PI data")–is exceptionally valuable to pharmaceutical companies, who make use of it to market their highly profitable brand

[1] While the Vermont law is captioned "Confidentiality of prescription information," it is disingenuously referred to as a "Prescription Restraint Law" by plaintiffs-appellants IMS Health Inc., Verispan LLC, and Source Healthcare Analytics, Inc. Data Mining Appellants' Br. at 2.

name drugs through a process known as "detailing."[2] There also is no dispute that the marketing messages "detailers" deliver in meetings with doctors constitute protected First Amendment activity. Finally, there is no dispute that section 17 does not directly regulate those messages or the marketing practices of detailers. Maj. Op. at 33. Instead, Vermont's law regulates the dissemination of confidential information–specifically, PI data–and the process by which it is collected and sold. Because section 17 targets that process rather than detailing itself, "understanding the sequence of events" section 17 regulates–that is, the process by which PI data travels from the prescription pad to the hands of a pharmaceutical detailer–"is crucial to understanding the statute's legal status." *IMS Health Inc. v. Mills*, 616 F.3d 7, 40 (1st Cir.2010) (Lipez, J., concurring in part and dissenting in part).

Pursuant to Vermont law, every time a pharmacy fills a prescription within the state, it is required to collect certain information about the doctor, the patient, and the medication being prescribed. *See*, *e.g.*, Vt. Bd. of Pharmacy Admin. Rules §§ 9.1, 9.24, 9.26 (eff.Oct.2009).[3] Because that information is so valuable to any number of third parties, including the plaintiffs-appellants in this case, pharmacies, for some time, have made a practice

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[2] As discussed further below, "detailing" involves the face-to-face promotion of a particular brand name drug by sales representatives–known as "detailers"–who are employed by the pharmaceutical company that manufactures and distributes that drug and make in person visits to physicians for the purpose of such promotion.

[3] The state rules are *available at* http://vtprofessionals.org/o pr1/pharmacists/rules/Pharmacy% 20Adopted % 20Rules% 20Effective% 20October% 201,% 202009% 20PDF % 20Version.pdf (last visited Nov. 18, 2010).

of selling it–often without the knowledge or permission of the doctor, let alone the patient–to various third parties, including data mining vendors such as plaintiffs-appellants IMS Health Inc., Verispan, LLC, and South Healthcare Analytics (collectively, the "data mining appellants").[4] These vendors aggregate and compile the data they acquire from pharmacies and then license it to pharmaceutical companies, represented here by plaintiff-appellant Pharmaceutical Research and Manufacturers of America ("PhRMA"), who use the information to guide some of their marketing and in particular, their "detailing," efforts. Specifically, pharmaceutical companies use PI data to identify particular doctors for "detailing," to monitor the success of their detailing efforts, and to compensate individual detailers based on the prescriptions written by the doctors they meet with. Pharmaceutical detailers do not, however, directly reference PI data in their meetings with doctors, and in fact, are prohibited from doing so by the terms of their employers' licensing agreements with the data mining appellants.

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[4] The information commonly sold includes the prescriber's name and address; the name, dosage, and quantity of the drug prescribed; the date and location at which the prescription was filled; and the patient's age and gender. The patient's name is encrypted, but this "de-identified" personal data still permits the data miners to track the patient's use of a drug or drugs over time and to associate this use with a given prescriber, payment source, and pharmacy. Accordingly, even as "deidentified," the data is such that a purchaser would know that "a 50-year-old woman who lives in Central Vermont; has prescriptions filled in Montpelier; [and] is a patient of Dr. Jones in Montpelier ... regularly takes an antidepressant and a cholesterol-lowering drug." Respondents' Br. at 7.

Accordingly, before a detailer ever sets foot in a doctor's office–that is, before the commercial speech the majority focuses on ever occurs–at least three events take place: first, a pharmacy gathers information from patients seeking to fill prescriptions; second, it collects and sells that data to third parties, principally "data vendors" or "data miners" such as appellants here; and third, these data miners repackage that data and license it to pharmaceutical companies. *See generally IMS Health Inc. v. Ayotte*, 550 F.3d 42, 48-49 (1st Cir.2008). Only after these three transactions occur does PI data land in the hands of detailers who then use it to facilitate their detailing efforts.

Troubled by this sequence of events whereby otherwise confidential information ends up in the hands of pharmaceutical detailers and in response to concerns about (1) medical privacy, (2) threats to patient health, and (3) rising health care costs attributable to the widespread use of new brand name prescription drugs (which the record indicates are those most likely to be the subject of extensive detailing efforts) Vermont enacted its prescription confidentiality law. In relevant part, the law prohibits any "health insurer, [ ] self-insured employer, [ ] electronic transmission intermediary, [ ] pharmacy, or other similar entity" from "sell[ing], licens[ing], [ ] exchang[ing] for value" or otherwise "permit[ing] the use" of "prescriber-identifiable information for marketing or promoting a prescription drug" absent the prescriber's consent. The law further prohibits "pharmaceutical manufacturers and [ ] marketers" from "us[ing] prescriber-identifiable information for marketing or promoting a prescription drug" unless the prescriber consents in the manner provided by statute. Vt. Stat. Ann. tit. 18, § 4631(d).

Focusing heavily on that last restriction, the majority begins its analysis at the end of the "sequence of events"–i.e., at the point at which PI data is already in the hands of pharmaceutical companies–and concludes that the law impermissibly "restricts the speech of both the pharmaceutical manufacturers ... who are prohibited from using Vermont PI data for marketing purposes, and the data mining appellants, who are prohibited from selling or transferring Vermont PI data if the data is to be used for marketing purposes." Maj. Op. at 24. The law, however, starts at the *beginning*, and seeks to cut off the flow of PI data at its source: section 17 prohibits any *pharmacy* from "sell [ing] ... prescriber-identifiable information ... [or] permitting its use ... for marketing or promoting a prescription drug." Vt. Stat. Ann. tit. 18, § 4631(d) (emphasis added).[5] Because the restrictions imposed by section 17 begin there, and because that first restriction prevents PI data from ever reaching the hands of plaintiffs-appellants, the principal question to be resolved–and one the majority wholly overlooks–is whether the restriction on *pharmacies* implicates the First Amendment interests of the data miners and pharmaceutical companies before the Court.[6]

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[5] As noted above, the law also prohibits such sales by health insurers, self-insured employers, and electronic transmission intermediaries. *See* Vt. Stat. Ann. tit. 18, § 4631(d). The record, however, is clear that pharmacies are the principal, if not sole, source of the PI data aggregated and then licensed by data mining appellants in this case.

[6] The rules of professional conduct applicable to pharmacies in Vermont place strict limits on the unauthorized release of "patient or practitioner information," defining it as "unprofessional conduct" subject to discipline. *See* Vt. Bd. of Pharmacy Admin. Rules § 20.1(I). Because no pharmacy is a party to this action, neither the First Amendment rights, if any, of pharmacies to sell PI data, nor the impact of these restrictions on the assessment of any such rights need be addressed.

In considering that restriction, I begin with the undisputed fact that Vermont pharmacies have access to and collect prescription information only under the direction and authority of state law. As noted, Vermont requires pharmacies to collect information such as the name of the prescribing doctor, the name and age of the patient, and the drug and dose prescribed. Having mandated the collection of that otherwise highly confidential information, the state unquestionably has an interest in controlling its further dissemination. It is that interest that section 17 effectuates–with respect to appellants, Vermont's law operates principally to prevent them from obtaining otherwise private PI data, and as such, does no more than restrict their unfettered *access* to information. This the First Amendment permits. *See Zemel v. Rusk*, 381 U.S. 1, 17 (1965) (First Amendment "does not carry with it the unrestrained right to gather information").

In finding that section 17 operates principally as a permissible regulation on access to information, I am guided by the Supreme Court's decision in *Los Angeles Police Department v. United Reporting Publishing Corporation*, 528 U.S. 32 (1999). There, a private publishing company challenged a California state law that restricted access to information collected by local police departments respecting those arrested within the state. The Court found that, at least with respect to that plaintiff, the law had no First Amendment implications because it did no more than "regulate[ ] access to information in the hands of the police department." *Id.* at 40. As the Court further noted, "California could decide not to give out arrestee information at all without violating the First Amendment." *Id.*

The majority attempts to distinguish *United Reporting* on the ground that while the California law amounted to "a government denial of access to

information *in its possession*," *id.* (emphasis added), here "the information is not in the government's possession" but instead "in the hands of pharmacies." Maj. Op. at 23. As a preliminary matter, the argument completely disregards the fact that the information is only "in the hands of" pharmacies because the state has directed them to collect it. As such, Vermont's interest in controlling the further dissemination of that information is not conceptually different from California's interest in stemming the further dissemination of information in the hands of local police departments. Under the majority's reasoning, *United Reporting* hinges on the fact that the City of Los Angeles used its own police officers–rather than the private prison or security contractors it might have relied on–to process and house its arrestees. *See* Clifford J. Rosky, *Force, Inc.: The Privatization of Punishment, Policing, and Military Force in Liberal States*, 36 Conn. L.Rev. 879, 903 (2004) (noting the rapid growth of private prisons and their use in more than half the country). I see no basis for reading *United Reporting* that narrowly.

But second, the majority's attempt to distinguish *United Reporting* would lead to the rather startling proposition that the First Amendment rights, if any, of those seeking access to information turn on whom they are requesting it *from*. Under the majority's analysis, for example, the Family Educational Rights and Protection Act–which prohibits universities from disseminating information collected about enrolled students, *see* 20 U.S.C. § 1232g(b)(1)–operates as a permissible restriction on access to information if a request for student records is denied by a public university but implicates the requestor's First Amendment rights if it leads to a denial by a private school. I find that outcome both illogical and untenable. *Cf. United States v. Miami Univ.*, 294

F.3d 797, 820-24 (6th Cir.2002) (interpreting FERPA and rejecting asserted "First Amendment right of access to student records"). Indeed, for the putative *gatherer* of information, the difference is of no discernable let alone constitutional significance. *Cf. Houchins v. KQED, Inc.*, 438 U.S. 1, 11 (1978) ("There is an undoubted right to gather news ... but that affords no basis for the claim that the First Amendment compels others–*private persons or governments*–to supply information." (plurality opinion) (emphasis added)).

No doubt sensing the tenuous nature of that position, the majority argues that appellants "have not claimed a First Amendment right to obtain information" but instead challenge section 17 insofar as it regulates the "use of information" already "in [their] hands." Maj. Op. at 23. *Cf. United Reporting*, 528 U.S. at 40 ("This is not a case in which the government is prohibiting a speaker from conveying information that the speaker already possesses."). The argument rests on a fundamental misunderstanding of section 17–of the "sequence of events" that it regulates. Because, as noted, the majority begins at the end of that sequence, it ignores the fact that section 17 regulates the flow of PI data well before it ever comes to be "in the hands" of appellants. Indeed, under operation of the law, appellants can only possess PI data if they have obtained it from pharmacies on the condition that it not be used for "marketing or promoting of a prescription drug." Having thus obtained PI data with conditions clearly attached, appellants cannot subsequently contend those conditions amount to restrictions on information they "already possess."

I do not question the proposition that different considerations apply where the government is "prohibiting a speaker from conveying information that the speaker already possesses." I simply conclude that none of the

appellants in this case are so affected by operation of section 17. Nor do I pass on the concern–not pressed by appellants here–that *selectively* restricting access to information may raise First Amendment concerns. *United Reporting*, 528 U.S. at 42 (Scalia, J., concurring) (allowing selective access may create "restriction[s] upon speech rather than upon access to government information"); *id.* at 43 (Ginsburg, J., concurring) (selective restrictions on access could "impermissibly burden[ ] speech" where selection is based upon an "illegitimate criterion"). I simply conclude that, based on the record before this Court, section 17 operates as a permissible restriction on access to information that the government has directed pharmacies to collect, and the majority errs in concluding to the contrary.

II.

Because I thus conclude that section 17 should be upheld as a permissible restriction on access to information, I could end my analysis there. The majority, however, proceeds to the question of whether, as applied to appellants, Vermont's law regulates conduct or speech. Because I view that issue as one of some importance, and because I am deeply troubled by the majority's discussion of it, I, too, address the issue in order to express considerable doubt that, as applied to the data mining appellants in particular, section 17 can properly be characterized as a restriction on speech. In considering the law as applied to data miners and pharmaceutical companies, I once again reject the majority's approach and follow the "sequence of events" the law regulates, beginning, here, with the restriction as applied to the data miners.

As a preliminary matter–overlooked by the majority–the parties dispute whether section 17 actually restricts the

data miners *at all*. Indeed, section 17 makes no mention of data miners or vendors. Accordingly, it is not clear to me that data miners have any interests–First Amendment or otherwise–at stake here. Section 17, would, at most, appear to eliminate a substantial market for data miners' services by eliminating the desire of pharmaceutical companies to purchase marketing information the statute prohibits them from using. As the First Circuit recently observed, however, "the First Amendment does not safeguard against changes in commercial regulation that render previously profitable information valueless." *Ayotte*, 550 F.3d at 53 (quoting *Wine & Spirits Retailers, Inc. v. Rhode Island*, 418 F.3d 36, 48 (1st Cir.2005)). Nevertheless, because section 17 restricts "other similar entities" from "sell[ing], licens[ing], or exchang[ing] for value" PI data if the transfer is made "for marketing or promoting a prescription drug," and because a data miner could conceivably be deemed a "similar entity" and thus so regulated, I proceed to consider the law as it might be applied to them.

The question, thus, is whether that restriction, should it be imposed, infringes data miners' First Amendment rights. There are significant reasons to conclude that it does not. As the majority concedes, these data miners–who disingenuously style themselves "publishers" for purpose of this litigation–"do not themselves use PI data" but instead "are in the business of aggregating and selling data." Maj. Op. at 27. Nevertheless, citing our opinion in *Universal City* for the proposition that "[t]he First Amendment protects 'even dry information, devoid of advocacy, political relevance, or artistic expression," Maj. Op. at 19 (citing *Universal City Studios, Inc.*, 273 F.3d at 446) (alteration omitted), the majority concludes that the data miners' sale of that "dry information" constitutes protected speech, even implying that it may constitute *non-commercial* speech. *Id.* at 19, 26.

I do not read *Universal City* to support such a sweeping proposition. There, we observed in dicta that "even dry information" *may* be protected "speech" and held, specifically, that "computer programs constructed from code[ ] *can* merit First Amendment protection," 273 F.3d at 446, 449 (emphasis added); *see also id.* at 445 (noting that in the modern age, this Court has taken "an 'evolutionary' approach ... favoring 'narrow' holdings that would permit the law to mature on a 'case-by-case' basis") (quoting *Name.Space, Inc. v. Network Solutions, Inc.*, 202 F.3d 573, 584 n.11 (2d Cir.2000)). On the facts of that case, we concluded that the computer code in question warranted First Amendment protection because it had the capacity to communicate information to human beings and had promoted both "discourse among computer scholars" and the "exchange of ideas and expression." *Id.* at 448. However, in so doing, we distinguished *Commodity Futures Trading Commission v. Vartuli*, 228 F.3d 74, 111 (2d Cir.2000) (Sack, *J.*), where we found that the computer program in question there did *not* warrant First Amendment protection on the ground that "the values served by the First Amendment were not advanced by [the *Vartuli* code]." *Id.* at 449 (citing *Vartuli* 228 F.3d at 111); *see also Vartuli*, 228 F.3d at 111 (noting that those "values" include "the pursuit of truth, the accommodation among interests, the achievement of social stability, the exposure and deterrence of abuses of authority, personal autonomy and personality development, [and] the functioning of democracy").

Accordingly, the critical question in applying *Universal City* is not merely whether the appellants are engaged in the sale of "dry information" but rather whether they are engaged in a sale of "dry information" that "advance[s]" the "values served by the First

Amendment." *Cf. Vartuli*, 228 F.3d at 111 ("Language serves a variety of functions, only some of which are covered by the special reasons for freedom of speech." (quoting Kent Greenwalt, *Speech and Crime*, 4 Am. B. Found. Res. J. 645, 784 (1980)). Here, there are strong reasons to question whether the data mining appellants are engaged in conduct that meets that standard. As the majority characterizes them, the data mining appellants are in the "business of aggregating and selling data"–data which communicates nothing about them nor allows them to express or communicate anything at all. Maj. Op. at 27.

To be clear, the dissemination of dry information *can* qualify for First Amendment protection. For instance, as we observed in *Universal City*, "courts have subjected to First Amendment scrutiny restrictions on the dissemination of technical scientific information and scientific research." *Universal City*, 273 F.3d at 447 (internal citations omitted); *see also Miller v. California*, 413 U.S. 15, 34 (1973) ("The First Amendment protects works which, taken as a whole, have serious literary, artistic, political, or *scientific* value." (emphasis added)). But here, data mining appellants do not contend on appeal that section 17 precludes them from distributing data to foster scientific or medical research. To the contrary, to the extent Vermont's law applies to them at all, it merely prevents them from licensing their data for a single use–the marketing of prescription drugs. Nor do data mining appellants contend the statute prohibits them from fostering public opinion or debate–to the contrary, as noted above, data mining appellants actually *prohibit* their customers from disclosing the data they license to *anyone* else, much less the general public. As such, I have some difficulty comparing the data they sell to "discourse" or the "exchange of ideas."

The First Circuit, in evaluating a similar law, concluded that PI data was just a product, not distinguishable from the data miners' perspective to widgets, or, as the First Circuit suggested, "beef jerky." *Ayotte*, 550 F.3d at 53. As such, the court found that "this is a situation in which information itself has become a commodity"–an "informational asset." *Id.* at 53; *cf. Reno v. Condon*, 528 U.S. 141, 148 (2000) (sale of collected driver information proper subject of federal regulation because the "information is, in this context, an article of commerce"). Under these circumstances, that court was unwilling to conclude that simply because a party's "product is information" that "any regulation [of that product] constitutes a restriction on speech." *Ayotte*, 550 F.3d at 53. Such an interpretation, it concluded, "stretches the fabric of the First Amendment beyond any rational measure." *Id.*

The majority rejects, out of hand, the First Circuit's "beef jerky" analogy and labels "obscure" its distinction between speech and "information asset[s]." I do not necessarily mean to endorse that court's approach or even its ultimate conclusion. But I am deeply troubled by the fact that the majority opinion–which becomes the first circuit-level opinion to hold that data miners' sale of PI data constitutes First Amendment activity[7]–does not even bother to engage in the fundamental First Amendment analysis our case law requires. The majority offers no cogent reason for why this "dry information"

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[7] While Judge Lipez, concurring in part and dissenting in part in *Ayotte*, argued that the New Hampshire law, as applied to *pharmaceutical companies*' use of PI data, restricted commercial speech, he found it "self-evident" that the data miners' "acquisition, aggregation, and sale of prescriber-identifiable data" is "not speech within the purview of the First Amendment." *Ayotte*, 550 F.3d at 64 (Lipez, J., concurring in part and dissenting in part).

falls into the category the First Amendment protects, nor any discussion of how this "dry information" can be deemed to "advance" the "values served by the First Amendment." *See Vartuli*, 228 F.3d at 111.

To reiterate, I do not question that dry information *may* be of First Amendment importance given the role information frequently plays in forming public opinion or fostering the marketplace of ideas. Indeed, dry information–in the form of a professor's research or a programmer's code–may frequently be of core First Amendment value. But in an era where "increasingly, information is sold as a commodity without being embedded in any practice that could reasonably be regarded as an effort to communicate," Robert Post, *Prescribing Records and the First Amendment–New Hampshire's Data-Mining Statute*, New Eng. J. Med., Feb. 19, 2009 at 745, 746, I am unwilling to presume that simply because a business is engaged in the transfer of information rather than widgets that its activities are automatically entitled to the potent shield of the First Amendment. And I cannot join a majority opinion that offers no principled basis for determining when such conduct should and should not be considered protected First Amendment activity.

With respect to the pharmaceutical companies, section 17 primarily prohibits them from accessing and acquiring PI data for a particular purpose–i.e., for use in marketing–and assuming they do acquire it, prohibits them from using it for that purpose. With respect to the first and primary restriction, I would find for the reasons set forth above, that section 17 operates as a perfectly permissible restriction on *access* to information and thus does not implicate appellants' First Amendment rights. With respect to the second restriction, I note as I did above that to the extent pharmaceutical companies obtain

PI data under the express condition that they cannot use it for marketing purposes, they cannot subsequently be heard to complain that those express conditions-to-receipt operate as restrictions on information already within their possession.

More generally, I question whether First Amendment protection should be afforded to what amounts to a business method or practice, *cf. Wine & Spirits Retailers, Inc. v. Rhode Island*, 481 F.3d 1, 6-7 (1st Cir.2007) (ban on joint advertising strategies permissible restriction on conduct or business method, not speech), one that itself has no expressive quality, but is instead meant at most to facilitate the delivery of other expressive conduct. There is no dispute that the practice of detailing itself–that is, of delivering a marketing message to doctors–constitutes commercial speech. There is also no dispute, however, that pharmaceutical detailers do not refer to PI data in their conversations with doctors. The data is used, instead, to identify doctors most likely to prescribe particular kinds of drugs so that sales pitches may be effectively directed at them, to monitor the success of these detailing efforts by tracking any changes in the prescribing habits of the doctors thereby targeted, and to compensate detailing personnel based on the success of their efforts.

The majority concludes that section 17 impacts pharmaceutical companies' "speech" interests because it "affects manufacturers' ability to promote brand-name drugs to doctors ... by making it harder to identify those physicians for whom the message will be most relevant and to tailor the detailing messages based on individual physicians' prescribing histories." Maj. Op. at 25. However, the majority cites no authority for the proposition that the First Amendment provides protection–let alone, the strong protection the majority affords here–for the

methods of *identifying* an audience, and while the process of "tailoring detailing messages" arguably comes closer to First Amendment activity, the record provides little basis for evaluating the extent to which PI data is actually used in that manner. Accordingly, even if section 17 has some minimal and indirect effect on the manner in which detailers "tailor" those messages, that effect is a very thin reed on which to hang a finding that section 17 restricts First Amendment activity rather than conduct. *Cf. Rumsfeld v. Forum for Acad. & Inst. Rights, Inc. (FAIR)*, 547 U.S. 47, 62 (2006) ("'[I]t has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.'" (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)).

III.

Finally, however, even if I were to conclude that section 17's total effect on detailing was sufficient to constitute a restriction on commercial speech, I would nonetheless uphold the statute because I would find that it complies with the standard set forth in *Central Hudson*.

Under *Central Hudson*, to regulate commercial speech that is "neither misleading nor related to unlawful activity,"[8] the government must (1) assert a "substantial

[8] While Vermont conceded below that the speech at issue here is not "misleading," the record provides some evidence to the contrary. For example, one former sales representative testified that PI data was used to create sales presentations that are "very skewed" and "distorted." Another expert testified that PI data was used to tailor detailing messages such that "information [is] provided in ... a selective manner." The state does not raise the

interest" to be achieved, and demonstrate that (2) the restriction "directly advances" that interest, and (3) the limitation "is not more extensive than necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564-66 (1980); *Anderson v. Treadwell*, 294 F.3d 453, 460-61 (2d Cir.2002). As we have previously observed, the latter two steps "coalesce to require 'a reasonable fit between the legislature's ends and the means chosen to accomplish those ends.'"*Anderson*, 294 F.3d at 462 (quoting *Lorillard Tobacco, Co. v. Reilly*, 533 U.S. 525, 556 (2001)). Accordingly, while *Central Hudson* compels more searching review of a restriction on commercial speech than a restriction on pure conduct, it does not require strict scrutiny. *See id.* at 460 ("[T]he [Supreme] Court has rejected the argument that strict scrutiny should apply to regulations of commercial speech ..., adhering instead to the somewhat less rigorous standards of *Central Hudson*." (collecting cases)).

a.

With respect to the first factor, Vermont identifies three "substantial interests" section 17 advances: (1) an interest in "protecting the public health," (2) an interest in "protecting the privacy of prescribers and prescribing information," and (3) and an interest in "ensur[ing] costs

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issue on appeal and thus I do not consider it here but note only in passing that, if construed as a law meant to restrict *misleading* speech or advertising, section 17 would be subject to far less searching review and would unquestionably be within the bounds of the state's regulatory authority. *See, e.g.*, *Edenfield v. Fane*, 507 U.S. 761, 768 (1993) ("[O]ur cases make clear that the State may ban commercial expression that is ... deceptive without further justification." (collecting cases)).

are contained" in the health care sector. The majority concludes that the first and third constitute "substantial" state interests but that the second is "too speculative" to qualify. Maj. Op. at 31-32. I would conclude that all three constitute "substantial" state interests. With respect to the second, which is the only asserted interest on which the majority and I diverge, I am unable to accept the majority's conclusion that the state's interest in medical privacy is "too speculative" to qualify as a substantial interest. The majority's analysis–which focuses on the evidence, or asserted lack thereof, of section 17's *effect* on medical privacy–is relevant only to whether section 17 "directly advances" the state interest.[9] It has no bearing on whether that interest is real and substantial, an issue which the majority does not directly question. Indeed, neither appellants nor the majority advances any serious argument that the state does *not* have a legitimate and substantial interest in medical privacy, nor am I aware of any. To the contrary, in an era of increasing and well-founded concern about medical privacy and the rampant dissemination of confidential information, the federal government has repeatedly acted on that interest and legislated to protect the privacy of medical records, *see*, *e.g.*, 45 C.F.R. §§ 164.501-164.520 (protecting information collected pursuant to the Health Insurance Portability and Accountability Act); 42 U.S.C. § 2000ff *et seq*. (protecting privacy of genetic information); 42 C.F.R. §§ 431.300,

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[9] For similar reasons, I reject the majority's suggestion that Vermont has no legitimate interest in medical privacy because the state allows the dissemination of PI data for certain non-marketing purposes. The argument, which also bears on the *effectiveness* of section 17 in furthering the interest in medical privacy rather than on the legitimacy of that interest, suggests, at most, that section 17 may be "underinclusive." However, as noted below, underinclusiveness, even if established, is not a basis for voiding a statute under *Central Hudson* analysis.

431.303 (protecting records of Medicaid patients), and thirteen states and the District of Columbia have considered or enacted bills aimed at protecting medical privacy in the very same way Vermont's statute does. *See* Br. of *Amicus Curiae* Elec. Privacy Inf. Ctr. ("EPIC") at 2 (collecting statutes). Accordingly, I would find that all three of the state's asserted interests are "substantial" for purposes of *Central Hudson* and proceed to evaluate whether section 17 "directly advances" those interests.

b.

The second and third prongs of the *Central Hudson* test require us to consider whether the regulation at issue "directly advances" the asserted state interests as well as whether the restriction "is not more extensive than necessary to serve th[ose] interest[s]." *Cent. Hudson*, 447 U.S. at 564, 566. To meet these requirements, the government carries "the burden of establishing a reasonable fit between the [law's] ends and the means chosen to achieve those ends." *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 414 (1993) (internal quotation marks omitted). However, as we have recently observed, a "reasonable fit" is not a "least restrictive means" test, *Clear Channel Outdoor, Inc. v. Atl. Outdoor Advertising, Inc.*, 594 F.3d 94, 104 (2d Cir.2010), and thus we do not ask whether there is "no conceivable alternative" but instead demand "'only that the regulation not burden substantially more speech than is necessary to further the government's legitimate interests.'" *Id.* (quoting *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S.469, 478 (1989)). The critical inquiry, as the district court noted, is therefore whether the restriction on speech is "in reasonable proportion

to the substantial state interest[s] served."[10] *Sorrell*, 631 F.Supp.2d at 454 (internal quotation marks omitted).

With respect to these factors, the government carries the burden of showing that its law furthers at least one interest "in a direct and material way," *Edenfield v. Fane*, 507 U.S. 761, 767 (1993), and accordingly we ask whether the state has demonstrated "that the harms it recites are real and that [the restriction] will alleviate them to a material degree." *Anderson*, 294 F.3d at 462 (internal citation and quotations omitted). In evaluating whether the government has met that burden, the parties dispute the level of deference, if any, we owe to the legislature's determination. Specifically, the parties dispute whether we should apply so-called *Turner* deference and thereby "accord substantial deference to the predictive judgments" of legislative bodies which, as "institution[s][are] far better equipped than the judiciary to amass and evaluate the vast amounts of data bearing upon legislative questions." *Turner Broad. Sys. Inc. v. Fed. Comm. Comm'n*, 520 U.S. 180, 195 (1997) (internal quotation marks and citations omitted). Like the majority,

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[10] As the majority correctly notes, in *Thompson v. Western States Medical Center*, 535 U.S. 357, 371 (2002), the Supreme Court observed that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." However, there is no indication that the Court's observation was meant to displace the entirely consistent principle that *Central Hudson* does not require consideration of every "conceivable alternative" or amount to a "least restrictive means" test. Instead, the *Thompson* court was reacting to the government's failure, there, to "even consider ... any other alternatives"–i.e., to the fact that a restriction on speech "seems to have been the first strategy the Government thought to try." *Id.* at 373; *cf. id.* at 368 (affirming that *Central Hudson* controls and finding "no need in this case to break new ground").

I feel no need to decide the issue, as I would conclude that even without applying *Turner* deference, Vermont meets its burden. Because I feel the majority overstates that burden, however, I explain briefly what I consider the prevailing standard to be.

As appellants correctly note, *Turner* did not address a restriction on commercial speech, a context in which the Supreme Court, independent of *Turner*, has repeatedly urged deference to legislative findings. *See Ayotte*, 550 F.3d at 93 (Lipez, J., concurring in part and dissenting in part) ("[T]he general principle of legislative deference" articulated in *Turner* "also is compatible with the Court's commercial speech precedent."). Specifically, the Court has found that the commercial speech doctrine allows "some room for the exercise of legislative judgment," *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 508 (1996) (plurality opinion), and cautioned that, where a legislature has deemed a particular regulation a properly tailored response to a substantial interest, "we have been loath to second-guess the [g]overnment's judgment to that effect." *Fox*, 492 U.S. at 478. Accordingly, as we recently observed in upholding a commercial speech regulation, "if [a government] determination about how to regulate [commercial speech] is 'reasonable' ... then we should defer to that determination." *Clear Channel*, 594 F.3d at 104. Such deference is "all the more appropriate" where, as here, the law targets a form of commercial speech that has "traditionally been subject to extensive regulation," *Anderson*, 294 F.3d at 463, or where the regulation fits within a broader regulatory or policy framework. *Cf. Clear Channel*, 594 F.3d at 105 ("[I]t is not this Court's role to second guess the City's urban planning decisions.")

Accordingly, in evaluating legislative findings and conclusions in the context of a commercial speech

regulation, we do not necessarily demand hard evidence, particularly, where, as here, the statute had yet to take effect when first challenged, but instead ask "whether the government is able to support its restriction on speech by adduc[ing] *either* empirical support or at least sound reasoning on behalf of its measure." *Ayotte*, 550 F.3d at 93 (Lipez, J., concurring in part and dissenting in part) (internal quotation marks and alterations omitted) (emphasis added); *see also id.* at 55 ("A state need not go beyond the demands of common sense to show that a statute promises directly to advance an identified government interest." (citing *Burson v. Freeman*, 504 U.S. 191, 211 (1992))).

The majority, while declining to determine what level of deference is appropriate, contends that *Clear Channel* should be limited to the context of "commercial billboards." Maj. Op. at 40. There is nothing in the language of that opinion to suggest as much, and indeed, the *Clear Channel* opinion cites *Ward v. Rock against Racism*, 491 U.S. 781 (1989)–a case that did not involve outdoor advertising at all–for the proposition that deference to a government's determination of reasonableness is appropriate. *See Clear Channel*, 594 F.3d at 104. Moreover, as noted above, *Clear Channel* is entirely consistent with a much broader body of our case law making clear that deference to legislative findings in the context of restrictions on commercial speech–and, particularly, commercial speech in a heavily regulated industry–is appropriate.

Accordingly, as I proceed to ask whether section 17 "directly advances" at least one of the three asserted government interests and whether it is "not more extensive than necessary to serve th[ose] interest[s]," I engage in *de novo* review of the record. *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 499 (1984).

But in so doing, I do not substitute my judgment for that of the legislature and instead defer to that body's determinations where "reasonable." *Clear Channel*, 594 F.3d at 94; *see also Ayotte*, 550 F.3d at 93 (Lipez, J., concurring in part and dissenting in part) ("If the government makes the requisite showing, we defer to the legislative judgment to adopt the challenged measure."). Moreover, I am cognizant of the context in which the restriction was passed and examine section 17 "in relation 'to the overall problem the government seeks to correct.'" *Clear Channel*, 594 F.3d at 94 (quoting *Ward*, 491 U.S. at 801). Engaging in such review, I would conclude that the statute directly advances each of the asserted interests in a material manner, and that it is "reasonably proportional" which is to say that it does not burden "substantially more speech than is necessary to further the government's legitimate interests." *Id.* at 104.

c.

First, I would find on this record that section 17 "directly advances" all three of Vermont's asserted substantial interests. With respect to cost containment and the public health, the district court found, and the record supports the finding that, section 17 materially advances both. The record establishes that pharmaceutical companies spend billions to "detail" new brand name prescription drugs that are more expensive, although not necessarily more effective, than generic class equivalents and whose effects and potential risks are less well known than those associated with generic class equivalents. *Sorrell*, 631 F.Supp.2d at 451-54. The record further establishes that detailing works–doctors who are "detailed" are more likely to prescribe new brand name drugs, despite the fact that generic class equivalents are more cost-effective and their risks are better known. *Id.* Finally, the record establishes that PI data is a critical

tool for increasing the effectiveness of detailing. IMS Health, for example, promises "big returns" for its PI data clients, noting that a sample client "increased its market share 86% with PI data." *Id.* at 451.

Vermont thus took the reasonable course of restricting use of that critical tool. By preventing pharmaceutical companies from using PI data, section 17 makes detailing less effective, which in turn, makes it less likely that doctors will prescribe less cost-effective, and potentially riskier brand name drugs over generic class equivalents. That "sound reasoning," which is amply supported by the testimony of expert witnesses–including some of appellants' witnesses–and other evidence adduced by the state, is sufficient to satisfy the second prong of the *Central Hudson* standard. *Ayotte*, 550 F.3d at 93 (Lipez, J., concurring in part and dissenting in part).

The majority, in concluding otherwise, does not dispute any of the state's evidence or contest the district court's findings. Instead, it argues the "route" by which section 17 furthers the state's interests is "too indirect to survive intermediate scrutiny." Maj. Op. at 39. However, it is that very same "route" that the majority travels in order to find a First Amendment implication–and thus a need to apply *Central Hudson*–in the first place. As the majority argues, section 17 implicates First Amendment interests because it restricts access to PI data which in turn "affects manufacturers' ability to [detail] ... by making it harder to identify those physicians for whom the message will be most relevant and to tailor the detailing messages based on individual physicians' prescribing habits." Maj. Op. at 25. In other words, the majority's First Amendment holding is premised on the understanding that section 17 not only travels that route, but travels that route *successfully*–it achieves its purpose of making detailing more difficult and less effective,

which in turn promotes the state's asserted interests in controlling costs and protecting the public health. *Cf. Sorrell*, 631 F.Supp.2d. at 451 ("strongest evidence" that section 17 advances state interests is the fact that "if PI data did not help sell new drugs, pharmaceutical companies would not buy it.") Having found section 17's route sufficiently direct to establish the First Amendment violation in the first place, the majority's conclusion that the statute is too indirect to survive *Central Hudson* is nothing short of bewildering.

No doubt, there are *more* direct ways Vermont could contain costs or promote health, many of them, I note, far more restrictive of detailers' activities and First Amendment conduct than the regulation actually passed. But that is not what the second prong of the *Central Hudson* test requires. Instead, all that standard demands is that the "harms" the state identifies "are real and that [the] restriction will in fact alleviate them to a material degree." *Anderson*, 294 F.3d at 462. I would find, on this record, that Vermont meets that standard. The evidence developed below and unchallenged by the majority here establishes that the harms–i.e., exorbitant health care costs and threats to patient safety–are real, and that section 17, by restricting access to PI data, makes detailing more difficult and less effective, which, in turn, reduces the pressure on doctors to prescribe more expensive, less proven drugs. Indeed, as discussed above, the majority agrees that section 17 is likely to be effective in this regard.

Moreover, I note that I would also find that section 17 "directly advances" the state's third interest–i.e., in "protecting the privacy of prescribers and prescribing information." Without question, the law restricts the flow of otherwise private information about doctors' prescribing habits and the care they provide to their

patients. No party seriously disputes that. Appellants contend that the interest cannot be deemed "directly advanced" because section 17 still permits the sale and use of PI data for other purposes. As a preliminary matter, I note that the record supports the conclusion that section 17 does not just reduce but *dramatically* reduces the spread of PI data. As the district court found, with respect to PI data, pharmaceutical companies are the data mining appellants' "only paying customers." *Sorrell*, 631 F.Supp.2d at 451. More important, what amounts to an "underinclusiveness" argument is not availing in the context of *Central Hudson*, which does not require strict scrutiny. *See Posadas de Puerto Rico Assocs.*, 478 U.S. 328, 342 (1986) (statute's "under-inclusive[ness]" not controlling of determination as to whether it "directly advances" state interests); *Clear Channel*, 594 F.3d at 110 ("[T]he Supreme Court has made clear that underinclusiveness will not necessarily defeat a claim that a stat interest has been materially advanced."). All that *Central Hudson* demands is that a regulation materially advance a real harm, which section 17 plainly does.

Accordingly, I would find that section 17 meets the second *Central Hudson* factor.

d.

The third *Central Hudson* factor requires consideration of whether the statute is "not more extensive than necessary to serve" the asserted state interests. Because, as noted, this "narrow tailoring" requirement is not a "least restrictive means" test, we look only for a fit "that is not necessarily perfect, but reasonable" and ask whether the restriction is one "whose scope is in proportion to the interest served." *Greater New Orleans Broad. Ass'n*, 527 U.S. at 188.

Because we thus look for "proportion[ality]," the inquiry inherently requires us not simply to evaluate the extent to which the statute furthers the state interests, but also to quantify and then balance the actual burden imposed on speech. It is this latter inquiry that the majority wholly sidesteps in its analysis but that I begin with, because to the extent section 17 restricts commercial speech–a finding that, as set forth above, I doubt–the restriction imposed is both minimal and indirect. At most, section 17 indirectly limits the message detailers convey by preventing them from "tailoring" their message based on a particular doctor's past prescribing habits. The law does not otherwise affect the message they deliver, nor does it directly restrict detailing in any way. Indeed, as the majority notes, section 17 "does not ... directly restrict the marketing practices of detailers." Maj. Op. at 34.

Given that minimal and indirect burden on speech, section 17 is inherently distinct from the sorts of "categorical" and direct bans on commercial speech the Supreme Court has previously struck down. *See Ayotte*, 550 F.3d at 97 (Lipez, J., concurring in part and dissenting in part) ("[T]he restriction on speech imposed by the Prescription Act is significantly more limited than similar restrictions on commercial speech that have been considered by the Supreme Court. It is neither a complete ban on the marketing or advertising of a product ... nor a blanket prohibition on in-person solicitation.") (internal citations omitted). It is with that limited burden imposed by section 17 in mind, that I consider the "proportion[ality]" of the law.

I would find that the minimal and indirect burden section 17 imposes on speech is not "more than is necessary to further" the government's three asserted interests. *Clear Channel*, 594 F.3d at 104 (quoting *Fox*,

492 U.S. at 478). The statute directly advances three substantial state interests in material ways, and it does so by imposing exceedingly limited burdens on commercial speech. As such, I find a "reasonable fit" between the burdens imposed and the interests furthered. In so finding, I would note that many of the alternatives proposed by appellants and the majority are actually far *more* restrictive of appellants' activities. For example, the data mining appellants suggest the state could instead "limit advertising of drugs that it concluded were unnecessarily expensive," while the majority suggests, "mandat[ing] the use of generic drugs as a first course of treatment ... for all those patients receiving Medicare Part D funds." Maj. Op. at 42. The state instead adopted a regulation that promotes all three interests without directly regulating speech or the content of detailers' messages, and without unduly interfering in the prescribing habits of doctors. As such, I would find it to be a "reasonable" regulatory choice, one that deserves deference from this Court. *See Clear Channel*, 594 F.3d at 104.

The majority contends that section 17 cannot be deemed "narrowly tailored" because it is overinclusive in several respects. First, the majority contends that section 17 is over-inclusive because it applies "without regard to whether the data pertains to a prescription drug that is efficacious." Maj. Op. at 44. However, the very harm section 17 seeks to avoid is aggressive marketing of drugs whose efficacy *is not yet known* because the drug has not been subject to much actual use or patient experience. Alternatively, the majority contends that section 17 is over-inclusive because it applies even where no generic alternative exists or where a new drug is "unique." The majority's analysis, however, overlooks the state's third asserted interest–that in protecting medical privacy. Because I do not overlook that interest,

I would reject both overinclusiveness arguments on the ground that section 17 furthers the state interest in protecting medical privacy by prohibiting the transfer of PI data for marketing purposes irrespective of whether the brand-name drug being detailed is effective or has a generic equivalent.

Alternatively, the majority contends that section 17 is not "narrowly tailored" because Vermont failed to consider "less speech-restrictive means available." Maj. Op. at 42. As noted, among those "less speech-restrictive" measures the majority posits are mandating the use of generic drugs. Alternatively, the majority suggests that, among other things, Vermont could await the results of a "counter-speech" measure already adopted by the state. First, none of these "less restrictive" means would address all *three* state interests because none would further the state's substantial interest in protecting medical privacy. That alone is grounds for accepting the state's decision not to seriously pursue those alternatives. *Cf. Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 371 (2002) ("[I]f the Government could achieve its interests in a manner that does not restrict speech ... the Government must do so.").

But second, as noted above, many of the less *speech*-restrictive alternatives the majority considers to be "available" are, in fact, far more intrusive restrictions on appellants' business practices or doctors' prescribing habits. And while *Central Hudson* and its progeny make clear that a state may not default to speech restrictions where other, equally effective remedies are available, I do not read that body of law to require a state to adopt far more restrictive and intrusive measures simply because the less restrictive measure imposes an incidental burden on speech.

Finally, where, as here, the state is legislating within an already heavily regulated field, we owe particular deference to the specific regulatory choice the state makes. *See Anderson*, 294 F .3d at 463. Especially in that context, it is not the role of this Court to "second guess" a legislature's decision as to which regulatory approach is best. *See Fox*, 492 U.S. at 478; *Clear Channel*, 594 F.3d at 105. It is, instead, our role to ensure that the restriction chosen is "reasonably proportional" to the interests it furthers. Section 17 meets that standard. Indeed, the majority offers no significant argument to the contrary–it does not engage in proportionality analysis at all–and instead converts the "reasonable proportionality" standard into a far more aggressive form of inquiry which in effect, if not form, bears striking resemblance to strict scrutiny.

I am unwilling to proceed down that road, particularly where, as here, the law restricts the sale and use of an informational product–PI data–and does not directly limit commercial speech. Because I would find that section 17 constitutes a reasonable restriction that satisfies *Central Hudson*, I would defer to the state's conclusion that this particular method of furthering its substantial interests is best. *See Clear Channel*, 594 F.3d at 105. I would thus conclude that to the extent section 17 can be construed as a restriction on commercial speech, it satisfies *Central Hudson* and should therefore be affirmed.

IV.

Because I would find that appellants' First Amendment challenge fails, I briefly address the data mining appellants' additional dormant Commerce Clause challenge. I would reject that challenge as well, substantially for the reasons cogently set forth by the district court. *See Sorrell*, 631 F.Supp.2d at 457-59.

The so-called "dormant Commerce Clause," which refers to the "negative implication" the Supreme Court has long drawn against state interference in Congress' constitutional authority to regulate inter-state commerce, *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 337 (2008), prohibits states from regulating "commerce occurring wholly outside [a] State's borders." *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 332 (1989). In evaluating whether a state law violates the dormant Commerce Clause, the Supreme Court has articulated two primary concerns: first, a concern about "economic protectionism–that is, regulatory measures designed to benefit in-state interests by burdening out-of-state [interests]," *Davis*, 553 U.S. at 337-38 (internal quotation marks omitted); and, second, a concern about "inconsistent legislation" or incompatible cross-state regulatory regimes "arising from the projection of one state regulatory regime into the jurisdiction of another State," *Healy*, 491 U.S. at 337.

Section 17 implicates neither concern. Section 17 does not discriminate against out-of-state entities in favor of in-state competitors nor does it risk imposing regulatory obligations inconsistent with those of other states. Instead it restricts the sale of data collected within the state and the use of that data within the state. That data mining appellants seek to take that data out of state to compile it does not relieve them of restrictions on their in-state purchase of that data and in-state re-sale of that data. *Cf. Mills*, 616 F.3d at 28 (finding similar Maine statute "implicates none" of the "concerns [ ] central to the way the Supreme Court has framed the dormant Commerce Clause in its recent opinions").

Accordingly, I would find no basis in dormant Commerce Clause jurisprudence to disturb Vermont's statute.

V.

In striking down section 17, the majority not only misconstrues a statutory ban on access to private information as a speech restriction, but it then breaks from the law of this Court, first, in labeling data miners' sale of "dry information" protected First Amendment activity, and, second, in applying an aggressive form of *Central Hudson* that affords insufficient deference to legislative findings and determinations. As a result, I cannot and do not sign on either to the majority's outcome or the manner by which it arrives thereto.

As noted above, the transfer of data has become a burgeoning business, with those engaged in such transfers frequently having no intention of engaging in expressive or communicative conduct. For the reasons set forth above, I am unwilling to accept the majority's conclusion that such business operations have an inherent right to invoke the First Amendment as a shield against reasonable regulation simply because their business deals in "dry information" rather than dry goods. Moreover, I express serious concern that the majority's discussion not only of the First Amendment interests at issue here but also of the standard imposed by *Central Hudson* will make it unduly and inappropriately difficult for states to properly and constitutionally regulate in furtherance of substantial interests, including a state's very serious interest in the protection of private information.

I would thus affirm section 17 as a legitimate restriction on access to information and commercial conduct with few, if any, attenuated effects on First Amendment activity. Alternatively, even were I to conclude that section 17 restricts First Amendment activity, in applying *Central Hudson*, I would afford far greater deference to the eminently reasonable legislative judgments the state has made here in furtherance of

several substantial state interests and the reasonably proportional response its statute effects. Accordingly, I respectfully dissent.

UNITED STATES DISTRICT COURT,
D. VERMONT.

Nos. 1:07-CV-188, 1:07-CV-220.

April 23, 2009.

IMS HEALTH INCORPORATED; Verispan, LLC; and Source Healthcare Analytics, Inc., a subsidiary of Wolters Kluwer, Health Inc.,

Plaintiffs,

v.

William H. SORRELL, as Attorney General of the State of Vermont,

Defendant.

Pharmaceutical Research and Manufacturers of America,

Plaintiff,

v.

William H. Sorrell, in his official capacity as Attorney General of the State of Vermont; Jim Douglas, in his official capacity as Governor of the State: of Vermont; and Cynthia D. Laware, in her official capacity as the Secretary of the Agency of Human Services of the State of Vermont,

Defendants.

MEMORANDUM OPINION AND ORDER

J. GARVAN MURTHA, District Judge.

I. *Introduction*

This case is the third in a succession of challenges to legislation in New Hampshire, Maine, and Vermont intending to regulate the collection and use of data identifying health care providers' prescribing patterns. This ruling addresses multiple constitutional challenges to sections 17, 20 and 21 of Vt. Acts No. 80 (2007), as amended by Vt. Acts No. 89 (2008) ("the Act").

For the following reasons, the Court finds the challenged sections withstand the constitutional challenges. Plaintiffs' motions for declaratory and injunctive relief as well as summary judgment (Papers 6, 61, 168) are denied. Defendants' motions for summary judgment (Papers 205, 247, 257) are denied as moot.

II. *Facts*

A. *Introduction*

In 2007, the Vermont Legislature passed Act 80 aimed at protecting public health and containing prescription drug costs. The Act included the following sections, as amended by Act 89, passed in 2008:

- Section 17–prohibiting regulated entities from selling or using prescriber-identifiable data for marketing or promoting prescription drugs unless the prescriber consents, codified at Vt. Stat. Ann. tit. 18, § 4631;
- Section 20–creating an evidence-based education program for health care professionals concerning the therapeutic and cost-effective

utilization of prescription drugs. The program is funded by a fee paid by pharmaceutical manufacturers whose products are sold through Vermont programs, codified at Vt. Stat. Ann. tit. 18, § 4622, Vt. Stat. Ann. tit. 33, § 2004;

- Section 21–creating a consumer fraud cause of action for advertisements printed, distributed or sold in Vermont that violate federal law, codified at Vt. Stat. Ann. tit. 9, § 2466a.[1]

Plaintiffs challenge these sections of the Act as unconstitutional.

B. *Prescription Drug Industry Landscape*

For background information on the prescription drug industry and the practice of detailing, please refer to the thorough and detailed description in Judge Barbadoro's opinion in *IMS Health Inc. v. Ayotte*, 490 F.Supp.2d 163 (D.N.H.2007). *See also IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir.2008); *IMS Health Corp. v. Rowe*, 532 F.Supp.2d 153 (D.Me.2007).

In the course of filling prescriptions, pharmacies acquire prescription information. Certain information, including the prescriber's name and address, the name, dosage and quantity of the drug, the date and place the prescription is filled and the patient's age and gender, is purchased by third parties who, after manipulating the data, sell it to customers, principally pharmaceutical companies. These third-party entities are sometimes referred to as "data mining companies." The manipulated data shows, among other things, details of physicians'

[1] The effective dates of sections 17 and 21 were extended to July 1, 2009.

prescribing patterns in terms of gross number of prescriptions and inclination to prescribe a particular drug.

Pharmaceutical manufacturers collectively spend close to $8 billion a year to market drugs directly to prescribers, employing thousands of sales representatives. The estimated total cost of marketing to Vermont prescribers approximates $10 million, not including samples[2] or direct-to-consumer advertising. Sales representatives provide "details" regarding the use, side effects and risk of interactions of the drug they are selling. For this reason, sales representatives are called "detailers." In addition to "details" and samples, representatives distribute medical literature and give small gifts[3] such as pens, notepads or lunch. Prescribers often rely on information provided by detailers because

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[2] Pharmaceutical companies provide free samples of prescription drugs to prescribers. Samples are valued by prescribers because they enable them to provide medication to patients who could not otherwise afford it, and they also allow prescribers to test new medications. Both uses are valued by pharmaceutical companies because they may lead to long-term prescriptions.

[3] The Vermont Legislature also passed a law, as part of Act 80, requiring pharmaceutical manufacturers to disclose "the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with detailing, promotional, or other marketing activities." Vt. Stat. Ann. tit. 18, § 4632(a)(1). There are exceptions, including samples for distribution to patients and *de minimis* gifts less than $25 in value. *Id.* § 4632(a)(4). This section of the Act is not challenged. In fact, PhRMA's voluntary "Code on Interactions with Healthcare Professionals" states companies should not give gifts to healthcare professionals, regardless of value, unless it helps in the treatment of disease or is educational.

keeping current with the changing landscape of prescription drugs is time-consuming.[4]

Pharmaceutical companies use this prescriber-identifiable data (PI data) as a marketing tool. The data is used principally for "detailing." Detailing is the "face to face advocacy of a product by sales representatives" who visit health care professionals. *Ayotte*, 550 F.3d at 71 (Lipez, J.). Coincident with the phenomenon of "data mining," pharmaceutical industry spending on direct marketing has increased exponentially.

Pharmaceutical sales representatives detail only branded drugs. When a patent expires, competitors introduce generic bioequivalent[5] versions of the drug and detailing is no longer cost-effective. Branded drugs are not necessarily better than generic drugs, however they are usually more expensive.

Against this backdrop, a few states introduced laws restricting the use and sale of PI data for pharmaceutical marketing.

C. *Laws Restricting Prescriber Identifiable Data*

1. *New Hampshire Law*

New Hampshire passed the first statute restricting the use of prescription information in June 2006. The New

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[4] There are approximately 8,000 different prescription pharmaceutical products. *Ayotte*, 550 F.3d at 70 (Lipez, J.)

[5] "Bioequivalent" does not mean identical. Bioequivalent drugs are required to demonstrate an absorption rate between 80 and 125 percent of the branded drug. Variations in absorption rates among branded or generic drugs may cause different reactions, such as side effects. Absorption rates may vary between the generic and branded version of the same drug, as well as between different generic versions.

Hampshire law "expressly prohibit[ed] the transmission or use of both patient-identifiable data and prescriber-identifiable data for certain commercial purposes."[6] *Ayotte*, 490 F.Supp.2d at 170. The Legislature enacted the law "to protect patient and physician privacy and to save the State, consumers, and businesses money by reducing health care costs." *Id.* at 171. The law was passed quickly and without formal legislative findings. *Id.* at 177 n. 12. It did not include manufacturer fees or advertising provisions.

Following a trial, New Hampshire's prescription information law was invalidated by the federal district court in April 2007 because the court determined the law violated the First Amendment. *See Ayotte*, 490 F.Supp.2d at 183.

2. *Maine Law*

Maine followed New Hampshire's lead, passing a law in June 2007 which also restricted the use of prescription

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[6] The statute read, in pertinent part:

> Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used or sold ... for any commercial purpose, except for the limited purposes of pharmacy reimbursement; [etc.].... Commercial purpose includes ... advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force....

N.H.Rev.Stat. Ann. § 318:47-f, *invalidated by IMS Health Inc. v. Ayotte*, 490 F.Supp.2d 163 (D.N.H.2007), *rev'd*, *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir.2008).

information. The Maine Legislature made express findings, outlining the state's interests and specific purposes in enacting the law, which were improving public health, maintaining costs, and protecting the privacy of patients and prescribers. 22 Me.Rev.Stat. Ann. § 1711-E(1-A, 1-B), *invalidated by IMS Health Corp. v. Rowe*, 532 F.Supp.2d 153 (D.Me.2008). Unlike the New Hampshire statute, however, the Maine law was crafted with an "optout" provision. Maine prescribers could elect to prevent pharmaceutical companies from using their individualized prescribing information for marketing, either to them or others. *Rowe*, 532 F.Supp.2d at 165. The law operated by forbidding the sale or use of information for marketing purposes if the prescriber opted out.[7]

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[7] The statute read, in pertinent part: "[A] carrier, pharmacy or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection...." 22 Me.Rev.Stat. Ann. § 1711-E(2-A), *invalidated by IMS Health Corp. v. Rowe*, 532 F.Supp.2d 153 (D.Me.2008).

Marketing was defined in the statute as:

[A]ny of the following activities undertaken or materials or products made available to prescribers or to their employees or agents related to the transfer of prescription drugs from the producer or seller to the consumer or buyer:

(1) Advertising, publicizing, promoting or selling a prescription drug;

(2) Activities undertaken for the purpose of influencing the market share of a prescription drug or the prescribing patterns of a prescriber, a detailing visit or a personal appearance;

(3) Activities undertaken to evaluate or improve the effectiveness of a professional detailing sales force; or

(4) A brochure, media advertisement, or announcement, poster or free sample of a prescription drug.

Id. § 1711-E (1)(F-1).

Following a two-day evidentiary hearing, Maine's prescription privacy law was invalidated by the federal district court in December 2007 because the court determined that, notwithstanding the opt-out provision, the law violated the First Amendment. *See id.* at 183.

3. *First Circuit Court of Appeals*

Both the New Hampshire and Maine District Court decisions were appealed to the First Circuit Court of Appeals. *See* 1st Cir. Dkt. Nos. 07-1945 and 08-1248. The appeal of the Maine decision was stayed while the First Circuit decided the New Hampshire appeal in *IMS Health Inc. v. Ayotte*. In November 2008, the First Circuit issued its decision. *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir.2008). The majority held the New Hampshire law did not violate the First Amendment because it regulated conduct and not speech. *Id.* at 54. However, the majority offered an alternative holding that, if the law implicated First Amendment rights, it is constitutional because it withstands intermediate scrutiny. *Id.* at 60. Judge Lipez concurred in the result, but believed the law did concern First Amendment rights in the first instance and the commercial speech restriction passed constitutional muster. *Id.* at 102 (Lipez, J., concurring and dissenting).

4. *Vermont Law*

Vermont is also engaged in an effort to control health care costs and, in June 2007, the Vermont Legislature passed "An Act Relating to Increasing Transparency of Prescription Drug Pricing and Information." Vt. Acts No. 80 (2007). In support of Act 80, the Legislature compiled a substantial legislative record, including express findings. Like the New Hampshire and Maine law, Act 80 includes a section restricting the use of prescriber-identifiable data for certain commercial uses, namely marketing.

The Vermont Act differs, however, from both New Hampshire's flat ban on the sale or use of PI data for marketing and Maine's "opt-out" ban on the sale or use of PI data for marketing. Section 17 of Act 80, codified at Vt. Stat. Ann. tit. 18, § 4631(d), prohibits regulated entities from selling or using PI data for marketing purposes unless the prescriber consents–an "opt-in" feature. Pharmaceutical manufacturers and marketers are regulated entities under the Vermont law. *Id.*

Section 17 begins with a recitation of the Legislature's purpose in passing the law:

> It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

Vt. Stat. Ann. tit. 18, § 4631(a).

Section 17's pertinent language is found in subsection (d):

> 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....

Id. § 4631(d). Subsection (c) of the law contemplates that prescribers will indicate on their licensing applications or renewal forms whether they consent. *Id.* § 4631(c)(1).

A violation of the law constitutes a violation of the Vermont Consumer Fraud Act (VCFA). *Id.* § 4631(f). Each violation is a separate civil violation for which the Attorney General may seek relief. *Id.* Under the VCFA, if the Attorney General "has reason to believe that any person is using or is about to use any [unlawful] method, act or practice," and determines that proceedings would be in the public interest, he may seek a temporary or permanent injunction. Vt. Stat. Ann. tit. 9, § 2458(a). In addition to injunctive relief, the violator is subject to a civil penalty of not more than $10,000 for each violation. *Id.* § 2461(a).

The law also includes sections imposing a manufacturer fee to be used to fund an academic detailing program and creating a consumer fraud cause of action against pharmaceutical manufacturers for Vermont advertisements that violate federal law.

D. *Present Action*

On August 29, 2007, Plaintiffs IMS Health Inc., Verispan, LLC, Source Healthcare Analytics, Inc. (the data vendor plaintiffs) filed a cause of action against Defendant Vermont Attorney General William H. Sorrell seeking preliminary and permanent injunctive relief prior to January 1, 2008, the initial effective date of the Act. (Paper 1.) On October 22, 2007, Pharmaceutical Research and Manufacturers of America (PhRMA) filed a

cause of action against Defendants Sorrell, Jim Douglas, and Cynthia LaWare seeking declaratory and injunctive relief. PhRMA moved for a preliminary injunction on October 23. (Paper 61.) The case was consolidated with the IMS action in November 2007. PhRMA filed an amended complaint on April 29, 2008. (Paper 221.)

The parties filed cross motions for summary judgment consisting of hundreds of pages of briefing in the spring and summer of 2008. The Vermont Legislature changed the effective date of certain portions of Act 80 to July 1, 2009. The Court combined the motions for preliminary injunction and declaratory relief with a trial on the merits. Rulings on the summary judgment motions were deferred until after the bench trial. The parties agreed the Court could rule on PhRMA's challenge to section 20 of Act 80 without a hearing. (Paper 369.)

The Court held a five-day bench trial from July 28 through August 1, 2008. The parties presented testimony from numerous witnesses and introduced reams of exhibits, including the entire legislative history of Act 80. Both parties filed post-trial memoranda as well as supplemental briefs regarding relevant decisions rendered since the trial, including the First Circuit's decision in *Ayotte* and the Supreme Court's recent decision in *Wyeth v. Levine*, ---U.S. ----, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009).

III. *First Amendment Challenge to Section 17*

Plaintiffs assert subsection (d) of section 17 violates the First Amendment. The First Amendment states, "Congress shall make no law ... abridging the freedom

of speech."[8] U.S. Const. amend. I. Because the First Amendment applies only where a government regulation restricts protected speech, the Court must first determine whether Section 17 restricts speech or merely conduct.

A. *Section 17 Restricts Speech*

The Attorney General seeks to sidestep Plaintiffs' First Amendment challenge completely by taking the position that section 17 does not regulate protected "speech." The Attorney General first argues the First Amendment does not apply to section 17 because PI data is factual information devoid of any protectable expressive quality. Supreme Court and Second Circuit precedent, however, require this Court to extend First Amendment protection to "[e]ven dry information, devoid of advocacy, political relevance, or artistic expression." *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446 (2d Cir.2001). *See, e.g., Roth v. United States*, 354 U.S. 476, 484, 77 S.Ct. 1304, 1 L.Ed.2d 1498 (1957) ("ideas having even the slightest redeeming social importance" are speech); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976) (prescription drug price information is protected speech); *Universal City Studios*, 273 F.3d at 446-49 (computer program is speech). In particular, the Supreme Court has recognized society's "strong interest in the free flow of commercial information" even when there is no "great public interest element." *Va. State Bd.*, 425 U.S. at 764, 96 S.Ct. 1817. PI data is plainly commercial information possessing a degree, however debatable, of social importance. The Court therefore finds prescriber identifiable data is protected "speech" under the First Amendment.

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[8] The First Amendment is applicable to the states through the Due Process Clause of the Fourteenth Amendment.

The Attorney General next contends section 17 eludes First Amendment review because it restricts only the "sale" and "use" of PI data, which constitute non-expressive conduct, but not the data's "disclosure." The Court disagrees. A restriction on disclosure is a regulation of speech, and the "sale" of PI data is simply disclosure for profit. *Bartnicki v. Vopper*, 532 U.S. 514, 526, 121 S.Ct. 1753, 149 L.Ed.2d 787 (2001) (a "prohibition against disclosures is fairly characterized as a regulation of pure speech"). The fact that disclosure occurs by sale does not remove First Amendment protection. The Supreme Court has consistently protected speech "even though it is carried in a form that is 'sold' for profit." *Va. State Bd.*, 425 U.S. at 761, 96 S.Ct. 1817 (internal citation omitted).

Section 17's restriction on the use of PI data is likewise aptly described as a restriction on marketing. Section 17 mandates that "[p]harmaceutical manufacturers and ... marketers shall not use prescriber-identifiable information *for marketing or promoting* a prescription drug unless the prescriber consents." Vt. Stat. Ann. tit. 18, § 4631(d) (emphasis added). It is well-established that even "speech which does no more than propose a commercial transaction," like marketing or advertising, is protected under the First Amendment. *Va. State Bd.*, 425 U.S. at 762, 96 S.Ct. 1817 (internal quotation marks omitted) (advertising of prescription drug prices is protected speech). Section 17's restriction on marketing is not immune to First Amendment review merely because it applies only when detailers use PI data. Indeed, section 17 restricts pharmaceutical detailers' protected speech by exercising control over detailers' ability to target their audience and message. *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir.1999) (regulations prohibiting use of customer information for targeted marketing constitute restrictions on protected commercial speech).

The Attorney General finally argues section 17 is not subject to First Amendment review because its effect on pharmaceutical detailers' speech is "indirect." This reasoning contradicts Supreme Court precedent. The mere fact that section 17 regulates protected speech indirectly does not sweep it from the First Amendment's purview. *Grosjean v. Am. Press Co.*, 297 U.S. 233, 250-51, 56 S.Ct. 444, 80 L.Ed. 660 (1936) (invalidating tax on publications with circulations of 20,000 or more that sold advertising because tax was merely a "deliberate and calculated" pretext for "penalizing the publishers and curtailing the circulation of a selected group of newspapers"); *Minneapolis Star & Tribune Co. v. Minn. Comm'r of Revenue*, 460 U.S. 575, 581-83, 103 S.Ct. 1365, 75 L.Ed.2d 295 (1983) (holding differential taxation of the press unconstitutional due to indirect burden on First Amendment rights). In contrast, legislation regulating economic conduct but affecting speech *incidentally* typically does not raise First Amendment concerns. *See*, *e.g.*, *Rumsfeld v. Forum for Acad. & Inst. Rights, Inc.*, 547 U.S. 47, 62, 126 S.Ct. 1297, 164 L.Ed.2d 156 (2006). In this case, the Attorney General's briefs make clear the effect on speech is section 17's purpose, rather than an unplanned or subordinate side effect. In describing how section 17 will advance the State's substantial interests in protecting privacy, controlling costs, and protecting health, the Attorney General cites the following "evidence":

> Prescriber-identifiable data is used as a tool for aggressive, targeted marketing campaigns that influence doctors to prescribe new, expensive drugs.... Use of the data gives pharmaceutical sales representatives a powerful advantage in trying to sway doctors' prescribing practices. It allows them to target doctors [and] target

> messages.... And these techniques work, to the advantage of pharmaceutical companies ... but to the disadvantage of doctors, the patients they treat, and the state of Vermont. Allowing doctors to prevent the use of their data for marketing ... will reduce Vermont's spending and give Vermonters greater access to affordable health care.

(Paper 412 at 4.) Plainly, the whole point of section 17 is to control detailers' commercial message to prescribers. The Court strains to understand how section 17 would control cost and protect health without the "indirect" effect on detailers' speech. The Court therefore finds section 17 restricts protected speech and must comply with the First Amendment.

B. *Section 17 Is a Commercial Speech Regulation Subject to Intermediate Scrutiny*

The Court must next determine what level of scrutiny applies. Plaintiffs claim section 17 restricts speech that is fully protected under the First Amendment and therefore must survive strict scrutiny. The Attorney General contends the Court should apply *Central Hudson's* analytical framework for assessing governmental restrictions on commercial speech. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980). For the following reasons, the Court finds section 17 restricts commercial speech and applies the test set out in *Central Hudson*.

Plaintiffs contend section 17 regulates pure speech because the sale of PI data does not "fall within the core notion of commercial speech–'speech which does no more than propose a commercial transaction.'" *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60, 66, 103 S.Ct. 2875,

77 L.Ed.2d 469 (1983) (citing *Va. State Bd.*, 425 U.S. at 762, 96 S.Ct. 1817) (internal quotation marks omitted). Plaintiffs appear to reason as follows: Speech which does no more than propose a commercial transaction is protected commercial speech under the First Amendment, therefore protected commercial speech *must* propose a commercial transaction.[9] Neither the Supreme Court nor the Second Circuit have endorsed this position. In fact, "various forms of speech that combine commercial and noncommercial elements" lie "[o]utside this so-called 'core.'" *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 97 (2d Cir.1998).

As the Court explained in Section III.A. above, PI data combines commercial and noncommercial elements. It is factual information with a degree of "redeeming social importance," *Roth*, 354 U.S. at 484, 77 S.Ct. 1304, and also purely commercial information used "to decide whether, how, when, and where to market products." (Paper 409 at 62.) Data vendor Plaintiffs stress that PI data serves both of these purposes. They point out that PI data "substantially improves public health" by showing "professional errors of judgment that can and do cause death, [ ] trends ... about the health and lifestyles of the public at large, and [ ] ways that [pharmaceutical manufacturers] can better serve the public with new or different products." (Paper 409 at 62.) Section 17, however, regulates the disclosure and use of PI data only when it is used in marketing–a decidedly commercial use. It does not regulate use of the data for non-commercial purposes such as "health care research," "educational

[9] Such reasoning is termed "denying the antecedent." It is a "formal fallacy," committed by reasoning in the form: If P, then Q. Not P. Therefore, not Q.

communications," or "safety notices." Vt. Stat. Ann. tit. 18, § 4631(e). Moreover, "the purported noncommercial message is not so 'inextricably intertwined' with the commercial speech as to require a finding that [PI data] must be treated as 'pure' speech." *Bad Frog Brewery*, 134 F.3d at 97 (citing *Bd. of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 474, 109 S.Ct. 3028, 106 L.Ed.2d 388 (1989)). Because section 17 regulates PI data only in connection with commercial speech, the Court finds analysis under *Central Hudson* is the proper test.

Plaintiffs next argue strict scrutiny is required because section 17 is a content-based speech restriction. The Court rejects this argument. By definition, the "Supreme Court's commercial speech doctrine ... creates a category of speech defined by content but afforded only qualified protection...." *Trans Union Corp. v. FTC*, 267 F.3d 1138, 1141-42 (D.C.Cir.2001). *See*, *e.g.*, *City of Cincinnati v. Discovery Network*, *Inc.*, 507 U.S. 410, 113 S.Ct. 1505, 123 L.Ed.2d 99 (1993) (applying intermediate scrutiny to "content based" ban on news racks distributing commercial handbills but not racks distributing newspapers). Indeed, the Second Circuit has explicitly "rejected the argument that strict scrutiny should apply to regulations of commercial speech that are content-specific, [and continues to adhere] instead to the somewhat less rigorous standards of *Central Hudson*." *Anderson v. Treadwell*, 294 F.3d 453, 460 (2d Cir.2002).

C. *The Intermediate Scrutiny Test*

1. *Central Hudson*

The intermediate scrutiny test elucidated by the Supreme Court in *Central Hudson*, 447 U.S. 557, 100 S.Ct. 2343 (1980), applies to truthful, non-misleading

commercial information that does not promote unlawful activity. *Id.* at 566, 100 S.Ct. 2343. Such speech can be limited only if the restriction: (1) supports a substantial government interest; (2) directly advances the asserted interest; and (3) is "not more extensive than is necessary to serve that interest." *Anderson*, 294 F.3d at 460-61 (citing *Central Hudson*, 447 U.S. at 563-66, 100 S.Ct. 2343). The party seeking to uphold a commercial speech restriction bears the burden of proof. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373, 122 S.Ct. 1497, 152 L.Ed.2d 563 (2002).

2. *Deference to Legislature*

The Supreme Court's commercial speech cases allow "the exercise of legislative judgment." *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 508, 116 S.Ct. 1495, 134 L.Ed.2d 711 (1996) (citation omitted). However, "a state legislature does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes." *Id.* at 510, 116 S.Ct. 1495.

The parties have debated at great lengths the nature and amount of deference the Court should accord the predictive judgments and factual findings of the Legislature in passing the challenged sections of the Act. The Attorney General contends the Court should not usurp the Legislature's policymaking role by substituting its judgment for that of elected representatives. (Paper 412 at 9.) He argues the Court's inquiry should be limited to whether there was a reasonable basis for the Legislature's actions after the Court's evaluation of the evidence. *Id.* (citing *Turner Broad. Sys. v. FCC*, 512 U.S. 622, 666, 114 S.Ct. 2445, 129 L.Ed.2d 497 (1994)) [hereinafter *Turner I*]. Plaintiffs respond that Turner I is distinguishable from this case on three grounds: (1) *Turner* I is not a commercial speech case, (2) Congress

had "considerable experience" in the area of regulation, and (3) the voluminous record, developed over years, included extensive studies. (Paper 409 at 46-48.)

Discussing the Turner cases,[10] Judge Lipez noted in Ayotte, "[a]lthough the contexts are different, the general principle of legislative deference also is compatible with the Court's commercial speech precedent." *Ayotte*, 550 F.3d at 93. The Supreme Court applied intermediate scrutiny to the act at issue in the *Turner* cases, noting deference was due to Congress' findings because "the institution is far better equipped than the judiciary to amass and evaluate the vast amounts of data bearing upon legislative questions." *Turner II*, 520 U.S. at 195, 117 S.Ct. 1174. "[C]ourts must accord substantial deference to the predictive judgments" of legislative bodies. *Turner I*, 512 U.S. at 665, 114 S.Ct. 2445 (internal citation omitted). Substantial deference does not mean predictive judgments are "insulated from meaningful judicial review altogether;" the Court has an obligation to exercise independent judgment. *Id.* at 666, 114 S.Ct. 2445. The Court must assure that a legislature has "drawn reasonable inferences based on substantial evidence" in formulating its judgments; not "reweigh the evidence de novo" or replace the legislature's factual predictions with its own. *Id.* The Court will defer to legislative findings, predictions, and judgments to the extent they are reasonable and based on substantial evidence.

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[10] The Court in *Turner* considered whether the "must carry" provisions of the Cable Television Consumer Protection and Competition Act of 1992 violated the First Amendment. The Court issued two decisions: *Turner I*, holding the provisions imposed content-neutral restrictions on speech subject to intermediate scrutiny, 512 U.S. at 661-62, 114 S.Ct. 2445, and *Turner Broad. Sys., Inc. v. FCC*, 520 U.S. 180, 117 S.Ct. 1174, 137 L.Ed.2d 369 (1997)[hereinafter *Turner II*], holding the provisions were consistent with the First Amendment. *Id.* at 185, 117 S.Ct. 1174.

3. *Central Hudson Elements*

Both parties agree that the data vendor plaintiffs disseminate truthful, non-misleading factual information that includes prescriber identifiable data. Therefore, the Court's analysis focuses on the substantiality of the interests asserted by the Legislature in support of section 17 and on whether the restriction on sale and use of PI data directly advances and bears an acceptable fit with the Legislature's substantial interests. Careful consideration of these issues indicates that the State has met its burden to justify section 17's limited restraint on commercial speech.

a. *Substantial Government Interest*

The Attorney General identifies three government interests promoted by section 17: prescriber privacy, cost containment, and protecting public health. The 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.

(1) *Cost Containment and Protecting Public Health*

The Legislature identified both cost containment and protecting public health as interests advanced by the law. The Attorney General contends these interests are substantial. Plaintiffs do not seriously dispute the Legislature has a substantial interest in protecting public health and safety,[11] *see*, *e.g.*, Paper 409 at 51, or cost containment. Instead, Plaintiffs argue that lowering prescription drug costs may harm the public health and

[11] Indeed, they could not because states have always had a substantial interest in promoting the health, safety, and welfare of their citizens.

lead to higher healthcare costs overall because "cheaper is not always better." *Id.* at 53-54. This argument does not squarely address whether the interests themselves are substantial; instead it bears on whether the Legislature's attempt to curb rising prescription drug costs is wise. Healthcare costs, and prescription drug costs in particular, have escalated considerably over the past decade, easily outpacing inflation.[12] Pharmaceuticals expenses top Vermont's publicly-funded health insurance costs, reaching $158 million in 2006. (Defs.' Ex. 182 at 2.) As Judge Selya forcefully explains, "Fiscal problems have caused entire civilizations to crumble, so cost containment is most assuredly a substantial government interest." *Ayotte*, 550 F.3d at 55; *see also id.* at 84 (Lipez, J.) (accepting the state's interests in cost containment and quality health care as substantial). Likewise, this Court holds that Vermont's interests in cost containment and protecting public health are substantial.

(2) *Prescriber Privacy*

Because the Court accepts cost containment and protecting public health as substantial government interests, it need not consider the Attorney General's assertion that protecting prescriber privacy is also a substantial government interest. *Cf. Ayotte*, 550 F.3d at 55 (restricting analysis to cost containment interest for "simplicity's sake"); *Anderson*, 294 F.3d at 461 (declining to consider an asserted interest because the regulatory scheme was sustainable based on another interest).

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[12] Evidence showed that while spending on prescription drugs has increased steadily, averaging near double digit percentage increases over the last decade, the number of prescriptions written has risen by only a few percentage points per year. Therefore, the prices paid for prescription drugs are increasing. (Defs. Ex. 9 at 562-63.).

b. *Advancing the Government Interest*

The Attorney General must prove section 17 advances at least one of the government's substantial interests "in a direct and material way." *Edenfield v. Fane*, 507 U.S. 761, 767, 113 S.Ct. 1792, 123 L.Ed.2d 543 (1993). This showing is not satisfied by "mere speculation or conjecture." *Id.* at 770, 113 S.Ct. 1792. The Attorney General "must demonstrate that the harms it recites are real and that [the] restriction will in fact alleviate them to a material degree." *Anderson*, 294 F.3d at 462 (citing *Edenfield*, 507 U.S. at 770-71, 113 S.Ct. 1792). Underinclusiveness of a regulation alone will not "defeat a claim that a state interest has been materially advanced." *Bad Frog Brewery*, 134 F.3d at 99. A regulation that makes only a "minute contribution" to advancing a substantial interest will not "be considered to have advanced the interest 'to a material degree.' " *Id.* (citing *Edenfield*, 507 U.S. at 771, 113 S.Ct. 1792). Certitude, however, is not required. "A state need not go beyond the demands of common sense to show that a statute promises directly to advance an identified governmental interest." *Ayotte*, 550 F.3d at 55 (citing *Burson v. Freeman*, 504 U.S. 191, 211, 112 S.Ct. 1846, 119 L.Ed.2d 5 (1992)).

As noted above, the Court will defer to legislative findings, predictions, and judgments to the extent they are reasonable and based on substantial evidence. Particularly in a case such as this, where the law affects a traditionally regulated area and is not yet effective, "it is all the more appropriate that we limit our scrutiny of state regulations to a level commensurate with the subordinate position of commercial speech in the scale of First Amendment values." *Anderson*, 294 F.3d at 463 (citing *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 635, 115 S.Ct. 2371, 132 L.Ed.2d 541 (1995)).

The Attorney General argues section 17 directly advances the State's substantial interests to a material degree because it limits the use of PI data in marketing, thus inhibiting sales of new prescription drugs which are more expensive than alternatives and possibly have unknown side effects and risks. (Paper 412 at 30-39.) More specifically, the Attorney General argues: (1) new drugs are not necessarily better than older drugs but are usually more expensive and may pose unknown risks and side effects; (2) detailing is only done for new drugs; (3) PI data is a marketing tool used to make detailing more effective and leads to the over-prescription of costly new drugs; and (4) the law's restriction on the use of PI data will reduce the influence of marketing leading to reduced prescriptions for new drugs, thereby trimming spending on prescription drugs and promoting public health.

Plaintiffs argue section 17 does not directly advance the State's substantial interests because the law uses remote means to accomplish its goal of protecting public health, and the Attorney General has not shown with empirical evidence that the law will reduce healthcare costs in Vermont. (Paper 409 at 55-57.)

(1) *Cost Containment*

The Legislature specifically found new prescription drugs have a higher cost than older drugs but do not necessarily provide additional benefits. Vt. Acts No. 80, § 1(7) (Finding 7). This finding, on its face, is not seriously disputed with regard to cost. *See supra* Section III. C.3.a.(1). The second proposition of Finding 7, that newer drugs often do not provide additional benefits over older drugs, was borne out in the briefing and at trial. Even Plaintiffs' witnesses' testimony supported the finding. For example, Mr. Randolph Frankel, a former employee of a pharmacy benefit manager, testified generic drugs

are as effective as other drugs in the same class for most patients. Dr. Aaron Kesselheim, defendants' witness, testified many new drugs provide little benefit over older drugs.

Only new, branded drugs are detailed because the introduction of generic bioequivalents into the market renders detailing no longer cost effective. PI data is used as a tool to increase the success of detailing. (Defs.' Ex. 246 at 7481-83 (a 2004 IMS document notes purpose of PI data is "big returns" and points to how one pharmaceutical company increased its market share 86% with PI data).) The Legislature found that, coincident with the phenomenon of "data mining," the pharmaceutical industry increased spending on direct marketing to doctors by over 275%. Act 80, § 1(18). The data provides detailers with specific information about doctors' prescribing practices, enabling them to target certain prescribers for their marketing efforts and to tailor presentations to individual prescriber styles, preferences, and attitudes. This information amplifies the influence and effectiveness of detailing, but does not add to its purported educational value. Detailers can provide medical literature and information regarding the drugs they are promoting without the benefit of PI data. The Vermont Medical Society has stated tailored marketing using PI data "is an intrusion into the way physicians practice medicine" and it creates the "possibility that representatives could exert too much influence on prescription patterns." *See* Act 80, § 1(20).

Detailing leads to increased prescriptions for new drugs over generic alternatives which are often more cost-effective. Research shows doctors are influenced by the marketing efforts of pharmaceutical companies. For example, doctors who attend talks sponsored by a pharmaceutical company often prescribe that company's

drug more than competitors' drugs. *See* Tr. 704-06 (testimony of Dr. Ashley Wazana regarding various studies). Though Plaintiffs attempted to show that doctors are not influenced by marketing practices, that point is belied by the nature of the industry, plaintiffs' own documents, and scientific research. The main purpose of detailing is to increase the number of prescriptions written for the drug being promoted. The billions spent each year by pharmaceutical manufacturers on detailing is evidence of its success. Pharmaceutical manufacturers are essentially the only paying customers of the data vendor industry. This is the strongest evidence of the important role of PI data in pharmaceutical detailing. Put simply, if PI data did not help sell new drugs, pharmaceutical companies would not buy it. The Court finds the Legislature's determination that PI data is an effective marketing tool that enables detailers to increase sales of new drugs is supported in the record.

The Legislature chose to counter the over-prescription of expensive new drugs by restricting the use of PI data in pharmaceutical marketing. PI data makes marketing of new drugs more effective–leading to over-prescription of new drugs that may not be better than a generic alternative. The Attorney General presented ample evidence that a shift in prescribing practices from new drugs to generic would result in a significant cost savings to the State. For example, Dr. Meredith Rosenthal testified that a 1% decrease in prescriptions of new patented drugs that do not yet have a generic bioequivalent, but that do have an adequate generic alternative, would lead to a $2 million cost savings to Vermont. (Tr. 954-55.) The Legislature predicted that prescribing decisions made without the covert influence of PI data should lead to a better balance between new and generic prescriptions and an attendant cost savings. *See Turner I*, 512 U.S. at

665, 114 S.Ct. 2445 ("Sound policymaking often requires legislators to forecast future events and to anticipate the likely impact of these events based on deductions and inferences for which complete empirical support may be unavailable."). On this record, the Court will not substitute its judgment for that of the Legislature.

Plaintiffs contend the lack of empirical evidence demonstrating the law will reduce healthcare costs is fatal. They point to testimony that to reliably evaluate the law's impact, the law would have had to be in place for almost a year or as long as five years. (Paper 409 at 56.) First, empirical evidence is not a requirement to withstand the intermediate scrutiny of *Central Hudson* in a case such as this. *Ayotte*, 550 F.3d at 55-59 (noting common sense is enough to show a law "promises directly to advance" a state's interest and holding, though there was no direct evidence, the New Hampshire law was reasonably calculated to advance its interest in reducing health care costs); *Id.* at 94 (Lipez, J.) (concluding the New Hampshire law materially advanced the state's interest in cost containment while acknowledging the state had no empirical data showing how much cost the law would save). Second, Vermont is one of a few states at the forefront in regulating marketing uses of PI data. *See, e.g.*, *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311, 52 S.Ct. 371, 76 L.Ed. 747 (1932) ("a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments") (Brandeis, J., dissenting). Plaintiffs would never allow a law such as section 17 to go into effect without a fight, as demonstrated by prior legal battles in

New Hampshire and Maine.[13] This reality has prevented empirical research on the law's effects. The Court will not hold the State to an unattainable burden.[14]

Plaintiffs also argue the Legislature substituted paternalism for empirical evidence. They contend the Legislature acted paternalistically by assuming "it knows best what doctors should hear and prescribe." (Paper 409 at 57.) They contend the Supreme Court has refused to uphold restrictions on speech predicated on paternalistic notions. In this situation however, the prescribers are aware of their own prescribing histories and, should they wish to be covertly influenced with PI data,[15] they may make use of the opt-in provision, thus allowing detailers to retain the ability to use their PI data for marketing purposes. *Cf. 44 Liquormart*, 517 U.S. at 503, 116 S.Ct. 1495 (noting the First Amendment requires skepticism toward laws "that seek to keep people in the dark for what the government perceives to be their own good"). Providing prescribers with a choice can hardly be deemed paternalistic.

Plaintiffs also argue PI data leads to more efficient detailing because sales representatives can focus on prescribers likely to be interested in the detailed drug

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[13] The New Hampshire law went into effect briefly before being enjoined by Judge Barbadoro. The short period of time it was in effect was not sufficient to conduct meaningful research, as testified to by witnesses of Plaintiffs and the State.

[14] Indeed, Plaintiffs' witness, Dr. Turner, an economist, testified that he was asked to perform a study regarding PI data and its effect on marketing but could not do so.

[15] The data vendor plaintiffs all prohibit detailers from disclosing PI data to a prescriber. Tr. at 136(IMS); Tr. at 194-95 (Verispan); Tr. at 230-31 (Source Healthcare).

because of their specialty and current prescribing habits. Without PI data, detailing would become less focused and more expensive leading to increased drug costs. PI data, however, is not necessary to determine the specialty of a doctor or whether a prescriber would be interested in a particular drug. Plaintiffs' witness, Dr. Thomas Wharton, testified that his practice could avoid sales representatives detailing drugs they do not prescribe by having assistants ask about the drugs being promoted. Also, sales representatives keep detailed information about doctors in their territories, including office hours and specialty, staff, and personal information. If sales representatives are able to track prescriber's favorite sports teams and birthdays, they can easily track a doctor's specialty.

The Attorney General has carried his burden to show that Vermont's interest in reducing health care costs, specifically prescription drug spending, would be furthered to a material degree by section 17.

(2) *Promoting Public Health*

The Legislature, as explained above, also found new drugs often provided little or no benefit over older drugs and was concerned that the unrestricted use of PI data in marketing contributed to over-prescription of new drugs. The evidence supports this finding. Detailing encourages doctors to prescribe newer, more expensive and potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines. Some new drugs make important contributions to health and reduce health care spending, but others may have unknown side effects and risks. Examples are cholesterol drugs–statins–and stomach acid drugs–proton pump inhibitors–such as Nexium and Vytorin. Dr. Kesselheim testified that these new drugs did not provide a therapeutic benefit over

older, very similar drugs available in generic form. In the case of Baycol, a statin, the new drug actually had fatal side-effects. Dr. Wharton testified he usually waits to prescribe a new drug until it has been on the market for awhile unless there is an obvious benefit and low risk associated with it–a situation occurring about 30% of the time in his estimation. In addition to Baycol, the Attorney General presented other examples of new drugs that were extensively prescribed but were removed from the market when serious side effects were later discovered. The most recent and well known example is Vioxx, a pain medication that was widely prescribed but then recalled because its use led to increased risk of cardiovascular issues such as heart attack and stroke.

For patients with certain conditions, such as epilepsy, there may be medical reasons to prescribe a brand-name drug over a bioequivalent generic drug. Section 17 has no effect on doctors' ability to prescribe a brand-name drug. No evidence showed that the law will obstruct or slow the use of a new drug that provides a genuine benefit.

Plaintiffs' laundry list of alternative ways the Legislature could have advanced its substantial interest in protecting public health is irrelevant. The American Medical Association's (AMA) physician data restriction program is also not an adequate remedy for Vermont prescribers. Physicians may not know of the program: only 23% of Vermont physicians belong to the AMA–one of the lowest rates in the nation. Moreover, doctors are not the only prescribers in Vermont–other health care professionals who prescribe drugs may not avail themselves of the program. That other means to accomplish a goal exist does not affect whether the restriction on PI data in section 17 directly advances the State's interest. Different alternatives are not mutually exclusive.

As noted above, the Legislature determined detailing increases the prescription of new drugs, and the Attorney General presented evidence supporting the Legislature's determination that new drugs often confer no therapeutic benefit to patients and sometimes carry risks. Because new drugs often have no therapeutic benefit and may have unknown side effects and risks, inappropriate prescription of new drugs is harmful. The Legislature's decision to restrict the use of PI data in marketing to further their substantial interest in protecting public health is sufficiently direct and material.

c. *Narrow Tailoring*

To survive First Amendment scrutiny, commercial speech restrictions "need only be tailored in a reasonable manner to serve a substantial state interest."[16] *Edenfield*, 507 U.S. at 767, 113 S.Ct. 1792 (citation omitted). The relevant inquiry is whether the commercial speech restriction "is in reasonable proportion" to the substantial state interest served. *Id.*; *see also Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 188, 119 S.Ct. 1923, 144 L.Ed.2d 161 (1999) ("The Government is not required to employ the least restrictive means

[16] Plaintiffs also challenge section 17 as an unlawful prior restraint. (Paper 169.) In the context of a commercial speech restriction, a prior restraint is evaluated under the last element of the *Central Hudson* test. *Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 227-28 (2d Cir.1998). The Court is not convinced section 17 constitutes a prior restraint because any suppression of speech occurs at the discretion of the prescribers who choose not to allow their prescribing histories to be used for marketing purposes. *See United States v. Quattrone*, 402 F.3d 304, 309 (2d Cir.2005) (defining a prior restraint as a law that suppresses speech "or provides for its suppression at the discretion of government officials"). Since Plaintiffs' challenge is facial, and assuming section

conceivable, but it must demonstrate ... 'a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served.'"); *Florida Bar*, 515 U.S. at 632, 115 S.Ct. 2371 ("the 'least restrictive means' test has no role in the commercial speech context").[17]

The Attorney General argues the law satisfies the narrow tailoring requirement of *Central Hudson* because it focuses solely on targeted marketing using PI data. (Paper 412 at 39.) Specifically, the law does not prohibit detailing and restricts the use of PI data only with respect to prescribers who do not want to have their prescribing histories used for marketing. *Id*. at 39-42. He also argues the proposed alternatives are irrelevant and inadequate. *Id*. at 42-43. Plaintiffs argue the law is "a poor fit" because it is over and under inclusive and there are "obvious alternatives" the Legislature could have chosen. (Paper 409 at 59-60.)

In *Anderson*, the Second Circuit upheld a New York statute and regulations restricting in-home real estate solicitations against a First Amendment challenge. The statute and regulations enabled owners in certain areas to request inclusion on a cease and desist list which then prohibited real estate licensees from soliciting the owners for listings. 294 F.3d at 457-58. The court held: "As to reasonable fit, the regulation can hardly be accused of

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17 constitutes a prior restraint, the Court would conclude section 17 is sufficiently narrowly tailored because it regulates commercial speech and pertains to health safety. *Shalala*, 144 F.3d at 228.

[17] See Judge Lipez's thoughtful analysis of recent debate regarding the "reasonable fit" standard of intermediate scrutiny. *Ayotte*, 550 F.3d at 96.

being 'more extensive than necessary'; it is precisely co-extensive with those who are experiencing the particular harm that it is designed to alleviate." *Anderson*, 294 F.3d at 462.

The Vermont Legislature determined that targeted marketing by sales representatives armed with PI data leads to increased prescriptions for new drugs despite the availability of safe and effective cheaper alternatives. The Legislature seeks to limit the overprescription of new drugs to lower prescription drug costs and protect patients from unknown risks and side effects. Section 17, which restricts use of PI data in marketing to certain prescribers, is a targeted response to the harm of overprescription caused by detailers' use of PI data. The law does not prohibit the practice of detailing. Sales representatives are free to provide medical literature and information regarding the drugs they are promoting. Section 17, like the law at issue in *Anderson*, provides prescribers the ability to allow use of their PI data for marketing purposes if they wish. Perfection is not required. The law is in reasonable proportion to the State's interests.

D. *Vagueness and Overbreadth*

Plaintiffs also challenge section 17 as unconstitutionally vague and overbroad. The parties dispute whether Plaintiffs' vagueness and overbreadth challenges are ripe. Regardless, the Court finds section 17 withstands the vagueness and overbreadth challenges on the merits.

The overbreadth doctrine, under which a party whose own activities are unprotected may challenge a statute by showing that it substantially abridges the First Amendment rights of parties not before the court, does not apply in cases involving commercial speech

regulations. *United States v. Caronia*, 576 F.Supp.2d 385, 402 (E.D.N.Y.2008) (citing *Bates v. State Bar of Ariz.*, 433 U.S. 350, 381, 97 S.Ct. 2691, 53 L.Ed.2d 810 (1977)). As the Court has determined section 17 regulates commercial speech, the overbreadth doctrine does not apply.

The Supreme Court recently explained the vagueness doctrine is an outgrowth of the due process clause of the Fifth Amendment, not of the First Amendment. *United States v. Williams*, --- U.S. ----, 128 S.Ct. 1830, 1845, 170 L.Ed.2d 650 (2008). A conviction would fail "to comport with due process if the statute under which it [was] obtained fail[ed] to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement." *Id.* (citation omitted). However, "perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity." *Id.* (citing *Ward v. Rock Against Racism*, 491 U.S. 781, 794, 109 S.Ct. 2746, 105 L.Ed.2d 661 (1989)).

"[T]he mere fact that close cases can be envisioned" does not render a statute vague. *Id.* at 1846. As the Court pointed out, "[c]lose cases can be imagined under virtually any statute," but that issue is addressed by the burden of proof requirement, not the vagueness doctrine. *Id.* (citation omitted).

Plaintiffs argue once the statute is effective, the data vendor plaintiffs' sources will not license to them and their pharmaceutical manufacturer customers will not license PI data from them "for marketing and other purposes." (Paper 409 at 69.) First, as Judge Selya pointed out, "plaintiffs' true complaint [ ] is that in banning this use of their data, we risk drying up the market for their services. To that concern we repeat: the First Amendment does not safeguard against changes in

commercial regulation that render previously profitable information valueless." *Ayotte*, 550 F.3d at 53 (internal quotation and citation omitted). Second, the Attorney General points out that the "data vending" industry is organized around contractual relationships. "Covered entities" are expected to place contractual limits on nonconsensual use of the data for marketing purposes. Contractual limits in the contracts between the data vendor plaintiffs and the covered entities from whom they receive data would protect the covered entities. Pharmaceutical manufacturers and marketers, to whom the data vendor plaintiffs sell PI data, are directly prohibited by section 17 from using PI data for marketing or promoting prescription drugs unless the prescriber has consented. The Attorney General is charged with enforcing section 17, and the Attorney General's position is that contractual limits would suffice to protect covered entities from prosecution. In such circumstances and on a facial challenge, the Court will not presume the law will create a chilling effect. *See Wash. State Grange v. Wash. State Repub. Party*, 552 U.S. 442, 128 S.Ct. 1184, 1194, 170 L.Ed.2d 151 (2008) (explaining deference requires a court to determine whether challenged law could possibly be implemented constitutionally). The Court finds section 17 is not unconstitutionally vague.

IV. *Dormant Commerce Clause Challenge to Section 17*

Data vendor Plaintiffs also claim section 17 is unconstitutional because it violates the dormant Commerce Clause. The Commerce Clause states, "The Congress shall have Power ... to regulate Commerce ... among the several States...." U.S. Const., Art. I, § 8, cl. 3. The Supreme Court long has recognized this affirmative grant of authority to Congress also encompasses an implicit or "dormant" limitation on the authority of the States to enact legislation affecting interstate commerce.

Healy v. Beer Inst., Inc., 491 U.S. 324, 326 n. 1, 109 S.Ct. 2491, 105 L.Ed.2d 275 (1989). Data vendor Plaintiffs challenge only the section 17 provision regulating the sale of raw prescription data.[18] It states:

> 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....

Vt. Stat. Ann. tit. 18, § 4631(d). Data vendors are not directly regulated under the statute. (Paper 340 at 2.) Rather, the statute prohibits pharmacies and other similar entities from selling the raw prescription data in the first instance if it will later be used for marketing.

The prohibited data sale often occurs via a three-step transaction that is the focus of the parties' Commerce Clause arguments. First, a pharmacy in Vermont fills a patient's prescription. The Vermont pharmacy then transmits this raw data to its parent company outside of Vermont, which may also transfer the information to other entities such as insurance companies or prescription benefit managers. The parent company, insurance company or other entity outside of Vermont then sells the information to data vendors who are also located outside Vermont. For example, "IMS Health has its principal

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[18] PhRMA did not raise a Commerce Clause challenge to section 17's provision regulating their "use" of PI data for "marketing or promoting a prescription drug."

place of business in Plymouth Meeting, Pennsylvania. It has an agreement with Rite Aid, which has its principal place of business in Camp Hill, Pennsylvania, to acquire prescription information ... including ... prescriptions dispensed in Vermont and written by prescribers doing business in Vermont." (Paper 300 at 3-4.) According to data vendor Plaintiffs, under this scenario the ultimate sale occurs "wholly outside" Vermont, and is therefore beyond section 17's territorial reach. *Id.* at 4. The Attorney General argues data vendor Plaintiffs have no standing to litigate this claim and that, in any event, the claim fails on the merits.

A. *Standing*

The Attorney General contends data vendor Plaintiffs cannot demonstrate standing to raise a Dormant Commerce Clause challenge because section 17 does not regulate them. Standing under the Commerce Clause is not limited, however, to parties directly regulated by the statute. Rather, "[a] plaintiff must demonstrate 'a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement.' " *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 101 (2d Cir.2003). Data vendor Plaintiffs have shown there is a realistic danger section 17 will have "an immediate damaging effect on their businesses." *Gov't Suppliers Consolidating Servs., Inc. v. Bayh*, 975 F.2d 1267, 1275 (7th Cir.1992) (holding plaintiffs who did not engage in "backhauling" waste nonetheless had standing to challenge restriction on backhauling because of restriction's adverse effect on their businesses). The Court therefore finds the data vendor Plaintiffs have standing to assert a Commerce Clause claim.

B. *Merits*

A state law that regulates commerce occurring wholly outside that state's borders is invalid under the Commerce Clause. *Healy*, 491 U.S. at 332, 109 S.Ct. 2491. This is so "regardless of whether the statute's extraterritorial reach was intended by the legislature" because the "critical inquiry is whether the practical effect of the regulation is to control conduct beyond the boundaries of the State." *Id.* at 336, 109 S.Ct. 2491. "[T]he practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States.... Generally speaking, the Commerce Clause protects against inconsistent legislation arising from the projection of one state regulatory regime into the jurisdiction of another state." *Id.* at 336-37, 109 S.Ct. 2491. Courts reviewing challenges to state statutes must also be mindful, however, that "[t]he dormant Commerce Clause is not a roving license for federal courts to decide what activities are appropriate for state and local government to undertake...." *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 343, 127 S.Ct. 1786, 167 L.Ed.2d 655 (2007). Indeed, courts "should be particularly hesitant to interfere with the [state's] efforts under the guise of the Commerce Clause," where, as here, the statute involves "a field traditionally subject to state regulation." *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 194 (2d Cir.2007) (quoting *United Haulers*, 550 U.S. at 344, 127 S.Ct. 1786). With these principles in mind, the Court considers the parties' claims.

Data vendor Plaintiffs contend section 17 regulates extraterritorial conduct because "[i]t allows pharmacies located in Vermont to transfer prescriber-identifiable

information ... to their out-of-state headquarters but then prevents those out-of-state companies from contracting with the out-of-state publisher plaintiffs" to sell that information. (Paper 300 at 8.) They also note that because section 17 imposes penalties if pharmacies or similar entities "permit the use" of PI data for marketing, covered entities must place contractual limits on purchasers' downstream uses. *Id.* Plaintiffs argue this downstream limitation "projects the laws of Vermont into the contracts executed outside of Vermont and otherwise governed by the laws of other states...." *Id.*

The Attorney General argues section 17 regulates strictly Vermont commerce because the statute applies only to records containing "information or documentation from a prescription dispensed in Vermont and written by a prescriber doing business in Vermont." *See* Vt. Stat. Ann. tit. 18, § 4631(b)(9) (defining "regulated records"). Likewise, the statute regulates only entities doing business in Vermont or licensed by Vermont. *See*, *e.g.*, *id.* § 4631(b)(6) (defining pharmacy). According to the Attorney General, if a business like Rite Aid "does business in Vermont [and] its pharmacies are licensed in Vermont, [ ] it is subject to state regulation in connection with its business practices [in the state].... Those regulations include restrictions on the use and disclosure of Vermont prescription records." (Paper 257-2 at 6.) The Court agrees.

"The limitation imposed by the Commerce Clause on state regulatory power is by no means absolute, and the States retain authority under their general police powers to regulate matters of legitimate local concern, even though interstate commerce may be affected." *Maine v. Taylor*, 477 U.S. 131, 138, 106 S.Ct. 2440, 91 L.Ed.2d 110 (1986) (internal quotation and citation omitted). The Court recognizes section 17 will affect

data vendors located outside Vermont by foreclosing their ability to sell Vermont PI data that ultimately will be used for marketing to Vermont prescribers. Data vendors remain free under section 17, however, to conduct this business in connection with all states other than Vermont. Section 17 does not regulate the sale, price or use of prescription data originating in any other state. Section 17 "regulates only information that originates in Vermont–i.e., prescriber-identifiable data from Vermont prescription records–and conduct that occurs in Vermont–i.e., ... Vermont pharmacies [that] sell, license, exchange, or permit the use of the data, and pharmaceutical manufacturers [that] use the data to market drugs in Vermont."[19] (Paper 340 at 6.)

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[19] Plaintiffs argue section 17 also prohibits using Vermont PI data to market to prescribers outside Vermont. The Court notes as an initial matter that it seems nonsensical, given the inherent value of PI data, to complain that detailers cannot use a Vermont prescriber's data to market drugs to a different prescriber in another state. Indeed, Plaintiffs state that "typical[ly]," pharmaceutical companies like Pfizer use PI data "to make decisions in New York about how to conduct its marketing efforts in Vermont or actually send the information into Vermont so that its sales personnel on the ground in Vermont could use it ... to conduct their marketing efforts." (Paper 300 at 4.) In any case, the Attorney General argues section 17 applies only to uses inside Vermont, (Paper 257-2 at 9), and asks the Court to read the statute in light of the general assumption that legislation applies only within the territorial jurisdiction of the governmental body enacting it. *See Small v. United States*, 544 U.S. 385, 389, 125 S.Ct. 1752, 161 L.Ed.2d 651 (2005) (recognizing general "presumption against extraterritorial application" of federal statutes); *Ayotte*, 550 F.3d at 63 (applying this principle to state statutes). Moreover, the Court is not inclined during pre-enforcement review to speculate about whether or how Vermont might prosecute uses of PI data outside Vermont. *See Richmond Boro Gun Club, Inc. v. City of New York*, 97 F.3d 681, 686 (2d Cir.1996) (discouraging pre-enforcement "as-applied" challenges).

Vermont pharmacies cannot avoid compliance simply by routing data through a parent company's server on its way to data vendors. The Second Circuit made clear that state regulations are not rendered unconstitutional simply because a business uses the internet to conduct transactions. In *SPGGC*, the Second Circuit held that a Connecticut Gift Card Law controlled sales of gift cards to Connecticut consumers, even when the sales were conducted online with an out-of-state seller. 505 F.3d at 195. The court concluded out-of-state sellers were capable of applying the law only to consumers with Connecticut addresses. Thus, the "practical effect" of the Gift Card Law was to control only Connecticut-related commerce. *Id.* Like Connecticut's Gift Card Law, section 17 controls only Vermont-related commerce by "[i]mpos[ing] restrictions on the use of data in Vermont records by Vermont businesses." (Paper 340 at 7.) Because these records are easily identified, businesses outside Vermont would have no difficulty limiting section 17's application.

Plaintiffs contend this case is controlled by *American Booksellers Foundation for Free Expression v. Dean*, 202 F.Supp.2d 300 (D.Vt.2002), *aff'd in part and modified in part*, 342 F.3d 96 (2d Cir.2003). In *Dean*, website operators challenged a state law prohibiting transfer of sexually explicit material to minors. The Second Circuit held the law violated the Commerce Clause because "[a] person outside Vermont who posts information on a website ... cannot prevent people in Vermont from accessing the material.... This means that those outside Vermont must comply with [the statute] or risk prosecution by Vermont." 342 F.3d at 103. The Second Circuit's holding, as in *SPGGC*, turned on whether the regulation was capable of distinguishing in-state and out-of-state targets. Vermont prescription records are

perfectly distinguishable from other states' records, and the Court sees no risk that section 17 will control PI data sales for states other than Vermont.

Finally, Plaintiffs argue section 17 is similar to statutes invalidated in price-tying cases. *See*, *e.g.*, *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 55 S.Ct. 497, 79 L.Ed. 1032 (1935) (invalidating New York statute that had the practical effect of regulating price of milk in other states); *Pharm. Research & Mfrs. of Am. v. Dist. of Columbia*, 406 F.Supp.2d 56 (D.D.C.2005) (invalidating District of Columbia statute that had the practical effect of regulating price of drugs in other states). These cases are inapposite. The statutes at issue in the price-tying cases "project[ed] [their] legislation into [other states] by regulating the price to be paid in that state for [goods] acquired there." *Baldwin*, 294 U.S. at 521, 55 S.Ct. 497. The Supreme Court struck down the statutes because they were merely a guised attempt to "mitigate the consequences of competition between the states." *Id.* at 522, 55 S.Ct. 497. Section 17 is neither discriminatory nor protectionist, and the Court finds Plaintiffs' comparisons unpersuasive. Accordingly, the Court finds section 17 is permissible under the Commerce Clause.

V. *First Amendment Challenge to Section 20*

PhRMA moves for summary judgment contending section 20 violates the First Amendment because it imposes a fee on prescription drug manufacturers to fund an "evidence-based education" program that will "spread a message into which PhRMA member companies have no input."[20] (Paper 168 at 2.) Defendants also moved for summary judgment with respect to section 20. (Paper

[20] The data vendor plaintiffs do not challenge the constitutionality of section 20.

205.) Defendants contend the manufacturer fee and its intended use is constitutional. *Id.* at 1. The parties agreed to allow the Court to decide this issue on the pleadings without a hearing. (Paper 369.)

Section 20, in part, creates an evidence-based prescription drug education program that provides information and education on the therapeutic and cost-effective utilization of prescription drugs to prescribers. Pharmaceutical manufacturers whose products are sold through Vermont programs fund the program by paying fees. Section 20 is codified at Vt. Stat. Ann. tit. 18, § 4622 and Vt. Stat. Ann. tit. 33, § 2004.

PhRMA's challenge to the evidence-based education program is disfavored from the outset. The challenge is a facial challenge because it is brought before the program has been implemented. *Bowen v. Kendrick*, 487 U.S. 589, 600, 108 S.Ct. 2562, 101 L.Ed.2d 520 (1988). Facial challenges fail if a statute has a "plainly legitimate sweep." *Wash. State Grange*, 128 S.Ct. at 1190 (citing *Washington v. Glucksberg*, 521 U.S. 702, 739-40, 117 S.Ct. 2258, 138 L.Ed.2d 772 (1997) (Stevens, J., concurring)). On a facial challenge, courts may not look beyond a statute's facial requirements and must be careful not to speculate about "hypothetical" or "imaginary" cases. *Id.*; *see also Field Day, LLC v. County of Suffolk*, 463 F.3d 167, 174 (2d Cir.2006) ("A 'facial challenge' to a statute considers only the text of the statute itself, not its application to the particular circumstances of an individual.") (citation omitted). The Supreme Court has noted facial challenges are disfavored for a multitude of reasons, such as "the risk of premature interpretation of statutes on the basis of factually barebones records." *Wash. State Grange*, 128 S.Ct. at 1191 (internal quotation and citation omitted).

First Amendment challenges to allegedly compelled expression may fall into one of a few categories. PhRMA's

challenge to one of the intended uses of the manufacturer fee is not a "compelled-speech" case because PhRMA's member companies are not obliged personally to express a message imposed by the government with which they disagree. *See Johanns v. Livestock Mktg. Ass'n*, 544 U.S. 550, 557, 125 S.Ct. 2055, 161 L.Ed.2d 896 (2005). The issue is whether PhRMA's challenge falls into the "compelled-subsidy" category because PhRMA members are required by the government to subsidize a message expressed by a private entity with which they disagree, a type of challenge that has been sustained,[21] or whether it falls into the "government-compelled subsidy of the government's own speech" category, a type of challenge that has been rejected. *Id.* at 557, 562, 125 S.Ct. 2055.

PhRMA argues the manufacturer fee provision violates the First Amendment by compelling PhRMA member companies to subsidize speech with which they do not agree and have no input. PhRMA's argument misses the mark because the government may compel subsidies to pay for speech to which one objects. *Johanns*, 544 U.S. at 559, 125 S.Ct. 2055 ("Compelled support of government–even those programs of government one does not approve–is of course perfectly constitutional ... And some government programs involve, or entirely consist of, advocating a position.") (internal quotation marks omitted) (citation omitted). "The government, as a general rule, may support valid programs and policies by taxes or other exactions binding on protesting parties.

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[21] PhRMA's reliance on *United States v. United Foods, Inc.*, 533 U.S. 405, 121 S.Ct. 2334, 150 L.Ed.2d 438 (2001) is misplaced. The Court struck down the advertising program but its holding was limited by the fact that the speech at issue was presumed to be private speech because the government did not argue the government speech doctrine. *Id.* at 416-17, 121 S.Ct. 2334.

Within this broader principle it seems inevitable that funds raised by the government will be spent for speech and other expression to advocate and defend its own policies." *Id.* (internal quotation marks omitted) (citation omitted). The issue, as noted, is whether the speech which PhRMA member companies are compelled to subsidize is that of private parties or of the government.

PhRMA argues the speech at issue is not "government speech" because "private interests would shape and effectively control the content of the evidence-based standards of care created as part of the evidence-based education program funded by the Manufacturer Fee." (Paper 231 at 2.) They point to the "Blueprint for Health's" provider practice working group as the private interests that will develop the standards. *Id.* at 2-3. The legislation creating the evidence-based education program, however, requires the State Department of Health, in collaboration with other state entities, to establish the program. Vt. Stat. Ann. tit. 18, § 4622(a)(1); *see also id.* § 4621(1). The statute provides, to "the extent practicable," the education program "shall use the evidence-based standards developed by the blueprint for health." *Id.* § 4622(a)(1). The blueprint is an existing entity that focuses on chronic care, *id.* § 701(1), and is headed by an appointed state official, *id.* § 702.

PhRMA's main argument rests on the extent to which the evidence-based standards used in the program will be developed by the blueprint for health. PhRMA focuses on the infrastructure of the blueprint which includes groups consisting of various private actors. Because it does not depend on a facial requirement of the manufacturer fee or evidence-based education program, this argument is misplaced. Instead PhRMA's argument focuses on the possibility the program will be implemented with an unconstitutional amount of private input and the internal

machinations of the blueprint. The Department of Health is responsible for the program the manufacturer fee will fund. The extent to which the program references the applicable standards created by the blueprint, which may have been influenced by private actors, is irrelevant.[22] *See Johanns*, 544 U.S. at 562, 125 S.Ct. 2055 (holding where "the government sets the overall message to be communicated and approves every word that is disseminated, it is not precluded from relying on the government-speech doctrine merely because it solicits assistance from non-governmental sources in developing specific messages.").

Here, as in *Johanns*, the Vermont Legislature has established the overarching message and some of its elements, and left the development of the details to a state agency and the Secretary of Human Services, who in turn may consider material developed by an entity headed by a state official. *See Johanns*, 544 U.S. at 561, 125 S.Ct. 2055.

Additionally, section 20 is "germane" to a "broader regulatory scheme." *Id.* at 558-59, 125 S.Ct. 2055. PhRMA challenges only one small part of this section of the law– the use of a portion of the manufacturer fees collected to fund an evidence-based prescription education program. The section has a "plainly legitimate sweep" as it allocates

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[22] It is possible that the program will include an amount of private influence that a court could find would prohibit the Attorney General from defending its constitutionality with the government speech doctrine. *See Wash. State Grange*, 128 S.Ct. at 1193. Conversely, it is also possible none of the standards developed by the blueprint will be appropriate for use in the new program. PhRMA or any one of its member companies may be able to challenge the law in an as-applied challenge should it feel the program, once implemented, is unconstitutional.

the manufacturer fee predominately to other portions of Act 80, including the support of the disclosure obligations imposed by Vt. Stat. Ann., tit. 18 § 4632 and § 4633 and the government's enforcement of section 17, which the Court also upholds against constitutional challenge.

PhRMA's current challenge is a facial one and the Court will not strike down section 20, or any part of it based on speculation and a factually barebones record. The Vermont Legislature enacted section 20 and the Court assumes the evidence-based education program can be implemented in a constitutional manner. On its face, section 20 does not run afoul of the Constitution.

VI. *PhRMA's Commerce Clause and Preemption Challenges to Section 21*

Plaintiff PhRMA next advances a Commerce Clause and preemption challenge to section 21(c) of Act 80. Section 21(c) creates a cause of action under Vermont's Consumer Fraud Act for prescription drug advertisements that violate federal law. Section 21(c) provides:

> It shall be a prohibited practice under section 2453 of this title for a manufacturer of prescription drugs to present or cause to be presented in the state a regulated advertisement if that advertisement does not comply with the requirements concerning drugs and devices and prescription drug advertising in federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202.

Vt. Stat. Ann. tit. 9, § 2466a(c)(1). PhRMA seeks a ruling that the statute is facially unconstitutional and an injunction preventing its enforcement.

A. *Commerce Clause Challenge*

PhRMA argues section 21(c) violates the Commerce Clause because it "has the practical effect of requiring out-of-state commerce to be conducted at [Vermont's] discretion." *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 102 (2d Cir.2003) (citing *Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d 200, 208-09 (2d Cir.2003)). PhRMA concludes section 21(c) will, in effect, regulate prescription drug advertising in all states because its members typically advertise through national television and print media, and these advertisements could ultimately make a downstream appearance in Vermont. Thus, PhRMA members would need to comply with section 21(c) for all national advertising or risk prosecution if a national advertisement makes its way to Vermont. The Attorney General responds that, irrespective of section 21(c), PhRMA's advertisements must comply with federal law and regulations in all jurisdictions. Thus, section 21(c) on its face imposes no additional "Vermont" standards.

The key to resolving the parties' competing arguments is PhRMA's fundamental premise that section 21(c) will impose substantive standards different from federal law and regulations. This premise derives from PhRMA's prediction that Vermont courts will likely interpret federal law differently than the Food and Drug Administration (FDA)–the federal agency that promulgates and enforces regulations based on federal prescription drug advertising law.

As noted previously, the Court may not engage in such speculation on a facial challenge. *Wash. State Grange*, 128 S.Ct. at 1190 (on facial challenge, courts "must be careful not to go beyond the statute's facial requirements and speculate about 'hypothetical' or 'imaginary' cases.") (citation omitted); *see also Field Day, LLC*, 463 F.3d at

174 (during a facial challenge a court "considers only the text of the statute itself"). Nothing in section 21(c)'s plain language suggests Vermont courts will impose different or additional standards on pharmaceutical advertising compared to federal law. Plaintiff's pre-enforcement facial challenge here is premature. PhRMA's members may properly raise this claim as a defense, however, if and when a member is prosecuted for violating section 21(c). The courts will then have "occasion to construe the law in the context of actual disputes," and avoid "the risk of premature interpretation ... on the basis of factually barebones records." *Wash. State Grange*, 128 S.Ct. at 1190-91 (internal quotation marks and citation omitted). Accordingly, the Court finds section 21(c) is facially permissible under the Commerce Clause and declines to issue an injunction against its enforcement.

B. *Preemption*

PhRMA next argues section 21(c) is preempted because it conflicts with the very federal law it seeks to enforce. PhRMA's rationale again stems from the premise that a state court might impose "potentially different" or "broader" interpretations of federal drug advertising law. These interpretations, PhRMA contends, would interfere with the FDA's specific, comprehensive regulation of drug advertising. The Attorney General argues PhRMA's preemption challenge fails because it is based entirely on impermissible speculation about how Vermont courts will construe the statute and because the Supreme Court has repeatedly sanctioned state law remedies for conduct that violates federal law. The Court agrees.

"[B]ecause the states are independent sovereigns in our federal system, [courts] have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116

S.Ct. 2240, 135 L.Ed.2d 700 (1996). This is particularly true where, as here, "Congress has legislated in a field which the States have traditionally occupied." *Id.* (internal quotation and citation omitted). Accordingly, state law is deemed preempted due to conflict with federal law only "where compliance with both federal and state regulations is a physical impossibility ... or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98, 112 S.Ct. 2374, 120 L.Ed.2d 73 (1992) (internal quotation marks and citations omitted). "The conflict standard for preemption is strict" and requires a "clear demonstration of conflict." *Madeira v. Affordable Hous. Found., Inc.*, 469 F.3d 219, 238 (2d Cir.2006) (internal quotation marks and citation omitted). PhRMA has failed to demonstrate clearly the conflict between federal law and section 21(c).

First, the Court sees nothing in section 21(c)'s plain language evincing a clear conflict with the purposes and objectives of federal drug advertising law. PhRMA predicts Vermont state courts will create a different, potentially broader, reading of federal drug advertising law that will conflict with federal regulation. This preemption claim fails for the same reason PhRMA's Commerce Clause fails–it is based on improper speculation. Supreme Court precedent makes clear that facial challenges must be resolved solely on the basis of the statute's facial requirements, not on speculation, assumption, or prediction. This is particularly true here where the courts have had no occasion to "accord the law a limiting construction to avoid constitutional questions." *Wash. State Grange*, 128 S.Ct. at 1190. Section 21(c)'s language does not necessarily require a state court to decide, in the first instance, whether an advertisement violates federal law. As the Attorney General notes,

Vermont courts could interpret section 21(c) in any number of ways. For example, a Vermont court "might allow a claim to proceed only if the FDA had already determined the advertising violated federal law." (Paper 257-2 at 23.) Thus, it is certainly not a foregone conclusion that Vermont state courts will interpret federal drug advertising requirements differently or more broadly than the FDA. Indeed, PhRMA acknowledges "a court might construe § 21(c) in a manner that avoided these effects." (Paper 303 at 2.)

Accepting the statute's requirements on its face, as this Court must, section 21(c) simply creates an additional remedy for violations of federal prescription drug advertising law. The Court finds, absent federal statutory language indicating the contrary, these remedies are constitutionally permissible.[23] The preemption clause does not "prevent a State from providing a damages

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[23] The Court notes that the Supreme Court's recent decision in *Wyeth v. Levine*, --- U.S. ----, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009), while not directly on point, bolsters this proposition. In *Wyeth*, the Court reaffirmed the strong presumption against preemption of state law causes of action by rejecting a stronger argument for preemption than PhRMA presents here. The Court held that state law product liability claims challenging the adequacy of manufacturer's labeling were not preempted by federal law. Thus, in *Wyeth*, the parties put squarely before the Court the question of whether state tort law imposes different requirements from those imposed by the FDA, and, if so, whether those standards are preempted because they are an obstacle to the FDA's statutory mission. *Id.* at 1201-04. The Court held the tort action at issue in that case was not preempted, despite the fact that different or additional requirements may be imposed. In contrast, section 21(c), on its face, imposes liability only for advertisements that violate federal requirements. In light of the Supreme Court's holding in *Wyeth*, the Court declines to find section 21(c) preempted when the requirements it imposes merely "duplicate" or "parallel" federal requirements. *See Medtronic*, 518 U.S. at 495, 116 S.Ct. 2240.

remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 128 S.Ct. 999, 1011, 169 L.Ed.2d 892 (2008) (citing *Lohr*, 518 U.S. at 495, 116 S.Ct. 2240). Rather than frustrating federal objectives, such remedies "merely provide[ ] another reason for manufacturers to comply with identical existing requirements under federal law." *Lohr*, 518 U.S. at 495, 116 S.Ct. 2240 (internal quotation marks omitted). The Court therefore finds section 21(c) is not preempted by federal drug advertising law and declines to enter an injunction against the statute's enforcement.

VII. *Conclusion*

For these reasons, Plaintiffs' motions for declaratory and injunctive relief as well as summary judgment (Papers 6, 61, 168) are DENIED. Defendants' motions for summary judgment (Papers 205, 247, 257) are DENIED as moot. Defendants' Motion in Limine Seeking Judicial Notice of Certain Documents Pursuant to the Doctrine of "Legislative Facts" (Paper 290) is DENIED as moot.

SO ORDERED.

UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT.

Docket Nos. 09-1913-cv(L), 09-2056-cv(Con)

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 26th day of June, two thousand nine,

Present:

Hon. Barrington D. Parker,
Hon. Richard C. Wesley,
Circuit Judges,
Hon. Miriam Goldman Cedarbaum,*
District Judge.

IMS Health Incorporated, *et al.*,

Plaintiffs-Appellants,

v.

William H. Sorrell, as Attorney General of the State of Vermont, *et al.*,

Defendants-Appellees.

Appellants IMS Health Incorporated, Verispan LLC, and Source Healthcare Analytics, Inc., through counsel, move for a preliminary injunction pending appeal.

Appellant Pharmaceutical Research and Manufacturers of America joins in the motion, which Appellees oppose. Upon due consideration, it is hereby ORDERED that the motion is DENIED. Appellants have not demonstrated "a clear or substantial likelihood of success on the merits." *Sussman v. Crawford*, 488 F.3d 136, 141 (2d Cir. 2007). Briefing should proceed on an expedited basis to be determined by the Clerk's office.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk

By: /s/ Franklin Perz

[*] The Honorable Miriam Goldman Cedarbaum, Senior Judge of the United States District Court for the Southern District of New York, sitting by designation.

UNITED STATES DISTRICT COURT,
D. VERMONT.

Nos. 1:07-CV-188, 1:07-CV-220.

June 5, 2009.

IMS HEALTH INCORPORATED; Verispan, LLC; and Source Healthcare Analytics, Inc., a subsidiary of Wolters Kluwer, Health Inc.,

Plaintiffs,

v.

William H. SORRELL, as Attorney General of the State of Vermont,

Defendant.

Pharmaceutical Research and Manufacturers of America,

Plaintiff,

v.

William H. Sorrell, in his official capacity as Attorney General of the State of Vermont; Jim Douglas, in his official capacity as Governor of the State of Vermont; and Cynthia D. Laware, in her official capacity as the Secretary of the Agency of Human Services of the State of Vermont,

Defendants.

RULING ON MOTION FOR INJUNCTION PENDING APPEAL (Paper 433)

J. GARVAN MURTHA, District Judge.

I. *Introduction*

Plaintiffs IMS Health Inc., Verispan, LLC, and Source Healthcare Analytics, Inc. claim Section 17 of Vermont's Prescription Confidentiality Law, codified at Vt. Stat. Ann. tit 18, § 4631, is unconstitutional. On April 24, 2009, this Court entered Judgment (Paper 431) denying Plaintiffs' motions for declaratory and injunctive relief (Papers 6, 61) as well as for summary judgment (Paper 168). Plaintiffs have appealed that ruling and move for an injunction to enjoin enforcement of Section 17 pending appeal (Papers 433, 435). Defendants oppose their request (Paper 438).

II. *Background*

The Court assumes familiarity with the factual and procedural background of this case as detailed in this Court's April 23, 2009 Memorandum Opinion and Order (631 F.Supp.2d 434 (D.Vt.2009),).

III. *Analysis*

In relevant part, Fed.R.Civ.P. 62(c), provides: "While an appeal is pending from ... [a] final judgment that grants, dissolves, or denies an injunction, the court may suspend, modify, restore, or grant an injunction during the pendency of the appeal." The factors the Court must consider in deciding whether to grant an injunction are: (1) likelihood of success on the merits; (2) irreparable harm to the movant absent an injunction; (3) possibility of substantial harm to other interested parties caused by an injunction; and, (4) the public interest. *N.Y. State*

Rest. Ass'n v. N.Y. City Bd. of Health, 545 F.Supp.2d 363, 365-66 (S.D.N.Y.2008) (quoting *In re World Trade Ctr. Disaster Site Litig.*, 503 F.3d 167, 170 (2d Cir.2007)).

Granting injunctive relief is an extraordinary remedy. *Silverstein v. Penguin Putnam, Inc.*, 368 F.3d 77, 84 (2d Cir.2004). The burden to demonstrate all four factors is on Plaintiffs as the moving parties. Their burden is high because they seek an extraordinary remedy to prevent enforcement of a statute this Court has previously upheld and is presumed valid. *See Brown v. Gilmore*, 533 U.S. 1301, 1303, 122 S.Ct. 1, 150 L.Ed.2d 782 (2001) (Rehnquist, Circuit Justice 2001) (refusing to issue an injunction pending certiorari where applicants sought injunction against enforcement of a "presumptively valid state statute."). The decision to grant an injunction pending appeal is in the Court's discretion. Fed.R.Civ.P. 62(c); *Conn. Hosp. Ass'n v. O'Neill*, 863 F.Supp. 59, 61 (D.Conn.1994).

A. *Irreparable Harm*

Plaintiffs point to the *Elrod v. Burns* line of authority for the proposition that the loss of First Amendment rights, for even a short time, constitutes irreparable injury. 427 U.S. 347, 373, 96 S.Ct. 2673, 49 L.Ed.2d 547 (1976); *see also Tunick v. Safir*, 209 F.3d 67, 87 (2d Cir.2000) (applying *Elrod* presumption in reviewing grant of preliminary injunction). The Court finds persuasive Defendants' argument distinguishing that authority. In the cases Plaintiffs cite, the courts were dealing with a preliminary injunction application instead of an injunction pending appeal after a final decision on the merits. *See Nat'l Ass'n of Mfrs. v. Taylor*, 549 F.Supp.2d 68, 76 (D.D.C.2008); *see also Hsu v. Roslyn Union Free Sch. Dist.*, 85 F.3d 839, 853 (2d Cir.1996) (noting irreparable harm inquiry depends on merits of claim(s)). Here, in contrast, the

Court has thoroughly considered and rejected the merits of Plaintiffs' claim that Section 17 impermissibly burdens First Amendment rights, including the possibility of harm to Plaintiffs' rights. The attempt to resuscitate the same arguments in support of their motion for an injunction pending appeal is unavailing.

Further, the irreparable harm analysis in this case is distinct from other First Amendment cases because the issues are different. Section 17 does not compel speech. *See*, *e.g.*, *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 72 (2d Cir.1996) (holding statute caused irreparable harm by compelling manufacturers' speech). Also, it does not restrict speech on a matter of public concern. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 100 (1st Cir.2008) (noting New Hampshire's similar law "restricts only private communications ... rather than a message disseminated to the public at large") (Lipez, J., concurring). Rather, this Court specifically found the data restricted by Section 17 is used to "covertly influence[ ]" prescribers. (Paper 433, at 31-32.) Most importantly, Section 17 does not prevent the disclosure of all restricted data for all purposes; it prevents only the use of restricted data for marketing purposes.

The Court also is unpersuaded by Plaintiffs' claim of harm flowing from the cost of compliance. As Defendants point out, Plaintiffs have previously complied with this law and a similar law in New Hampshire. Though it may not be as easy as "flipping a switch," (Paper 433 at 6), duplicating a system should not be as costly as creating it in the first instance. *See*, *e.g.*, Paper 433 at 7 (noting Source Healthcare was compliant when Section 17 was effective in 2008 and subsequently "undid" the work when the effective date was changed). Plaintiffs also argue this expended money constitutes irreparable harm because, under the Eleventh Amendment, the government is

immune from damage suits and the expenses cannot be recouped. Spending money to comply with the law is simply a fact of doing business. *See Pennsy Supply, Inc. v. Susquehanna River Basin Comm'n*, No. 1: CV-06-2454, 2007 WL 551573, at *3 (M.D.Pa. Feb. 20, 2007) (plaintiff corporation's costs to comply with a government regulation did not constitute irreparable harm).

For these reasons, the Court rejects Plaintiffs' claims of irreparable harm and finds this factor weighs in favor of denying an injunction pending appeal.

B. *Likelihood of Success on the Merits*

The parties dispute the degree to which Plaintiffs must demonstrate their likelihood of success. Plaintiffs, citing *LaRouche v. Kezer*, 20 F.3d 68, 72 (2d Cir.1994), argue the correct standard is a "substantial possibility, although less than a likelihood, of success." Defendants rely on a recent Supreme Court case, *Nken v. Holder*, --- U.S. ----, 129 S.Ct. 1749, 1761, 173 L.Ed.2d 550 (2009), to argue the correct standard is "a strong showing that [movant] is likely to succeed." The *Nken* Court cites *Hilton v. Braunskill*, 481 U.S. 770, 107 S.Ct. 2113, 95 L.Ed.2d 724 (1987), a 1983 Supreme Court decision discussing Rule 62(c) which states the required standard is "a strong showing that [movant] is likely to succeed on the merits." *Id.* at 776, 107 S.Ct. 2113. As the "strong showing" standard has been applied by the Supreme Court since at least 1983 and reaffirmed as recently as this year, the Court will apply the "strong showing" standard.[1] It is

[1] The Court notes the authority *LaRouche* relied upon for a lower standard, *Hirschfeld v. Bd. of Elections*, 984 F.2d 35, 39 (2d Cir.1993), itself relied upon *Hilton*.

also the standard endorsed by this Circuit in *In re World Trade Center* just two years ago. 503 F.3d at 170; *see also N.Y. State Rest. Ass'n*, 545 F.Supp.2d at 365-66 (quoting *World Trade Center* and applying the "strong showing" standard in denying an injunction pending appeal in a case which included a First Amendment challenge).

In any event, the dispute about the proper standard to apply in evaluating Plaintiffs' showing of likelihood of success on the merits is largely semantic. The "strong showing" of likelihood of success on appeal "will vary according to the court's assessment of the other [stay] factors.... Simply stated, more of one excuses less of the other." *Mohammed v. Reno*, 309 F.3d 95, 101 (2d Cir.2002) (internal quotations and citations omitted) (discussing various formulations used to describe the degree of likelihood of success required).

To prevail on appeal, Plaintiffs must persuade the Second Circuit not only that this Court erred in upholding Section 17, but also that the First Circuit Court of Appeals–which is the only appeals court to consider a similar law–was mistaken in concluding New Hampshire's statute is constitutional. *See Ayotte*, 550 F.3d at 60, 102. Plaintiffs' pending motion presents no new authority to undermine this Court's prior holdings. Instead, they rehash arguments the Court has previously rejected. *See Nat'l Ass'n of Mfrs.*, 549 F.Supp.2d at 75 ("mere repetition of [plaintiff's] arguments does not demonstrate [plaintiff] is any more likely to succeed on the merits of its claims than it was when the Court issued its Memorandum Opinion").

For the above reasons, and because the other factors weigh in favor of denying an injunction pending appeal, the Court finds Plaintiffs have not demonstrated a sufficiently strong showing of likelihood of success on appeal.

C. *Other Factors*

Defendants cogently argue an injunction against implementation of Section 17 would harm the State of Vermont and the public interest because it would delay enforcement of a law intended by the Legislature–and found by this Court–to protect the health of Vermonters and contain health care costs. *See Nken*, 129 S.Ct. at 1757 ("The parties and the public ... are [ ] generally entitled to the prompt execution of orders that the legislature has made final."). Granting the injunction would result in an inordinate delay in implementing the law at the expense of Vermont and its citizens.

Further, the Court declines to issue an injunction to prevent a law from going into effect that has been found to protect public health. Harm to the health of a member of the public outweighs financial harm Plaintiffs claim they will suffer from enforcement of the law. *See, e.g.*, *Drywall Tapers & Pointers of Greater N.Y. Local 1974 v. Local 530 of Operative Plasters' & Cement Masons' Int'l Ass'n*, No. 93-CV-0154, 98-CV7076, 2005 WL 638006, at *12 (E.D.N.Y. Mar. 17, 2005)(refusing to suspend an injunction pending appeal even though defendant's business could fail). The Court is unmoved by the possibility Plaintiffs may not profit as much from the data regulated by Section 17. *See Hodges v. Shalala*, 127 F.Supp.2d 790, 793 (D.S.C.2001) (denying injunction pending appeal where it "would effectively [provide] a grace period [to] continue to collect undeserved monies while exhausting [ ] legal arguments and remedies.").

For these reasons, the Court finds the balance of harms and public interest factors weigh in favor of denying an injunction pending appeal.

IV. *Conclusion*

For the reasons expressed herein, the Court finds Plaintiffs have not satisfied the requirements for an injunction pending appeal under Fed.R.Civ.P. 62(c). Plaintiffs' Motion for Injunction Pending Appeal (Paper 433) is DENIED.

SO ORDERED.

Vt. Stat. Ann. tit. 18, § 4631:

§ 4631. Confidentiality of prescription information

(a) It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

(b) As used in this section:

(1) "Electronic transmission intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices used by health care professionals, prescribers, pharmacies, health care facilities and pharmacy benefit managers, health insurers, third-party administrators, and agents and contractors of those persons in order to facilitate the secure transmission of an individual's prescription drug order, refill, authorization request, claim, payment, or other prescription drug information.

(2) "Health care facility" shall have the same meaning as in section 9402 of this title.

(3) "Health care professional" shall have the same meaning as health care provider in section 9402 of this title.

(4) "Health insurer" shall have the same meaning as in section 9410 of this title.

(5) "Marketing" shall 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.

(6) "Pharmacy" means any individual or entity licensed or registered under chapter 36 of Title 26.

(7) "Prescriber" means an individual allowed by law to prescribe and administer prescription drugs in the course of professional practice.

(8) "Promotion" or "promote" means 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.

(9) "Regulated records" means information or documentation from a prescription dispensed in Vermont and written by a prescriber doing business in Vermont.

(c)(1) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give consent for his or her identifying information to be used for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber's consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent. The department and office may establish rules for this program.

(2) The department or office shall make available the list of prescribers who have consented to sharing their information. Entities who wish to use the information as provided for in this section shall review the list at minimum every six months.

(d) 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.

(e) The prohibitions set forth in subsection (d) of this section shall not apply to the following:

(1) 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;

(2) the dispensing of prescription medications to a patient or to the patient's authorized representative;

(3) the transmission of prescription information between an authorized prescriber and a licensed

pharmacy, between licensed pharmacies, or that may occur in the event a pharmacy's ownership is changed or transferred;

(4) care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy and other information relating to the drug being dispensed, treatment options, recall or patient safety notices, or clinical trials;

(5) the collection, use, or disclosure of prescription information or other regulatory activity as authorized by chapter 84, chapter 84A, or section 9410 of this title, or as otherwise provided by law;

(6) the collection and transmission of prescription information to a Vermont or federal law enforcement officer engaged in his or her official duties as otherwise provided by law; and

(7) the sale, license, exchange for value, or use of patient and prescriber data for marketing or promoting if the data do not identify a prescriber, and there is no reasonable basis to believe that the data provided could be used to identify a prescriber.

(f) In addition to any other remedy provided by law, the attorney general may file an action in superior court for a violation of this section or of any rules adopted under this section by the attorney general. The attorney general shall have the same authority to investigate and to obtain remedies as if the action were brought under the Vermont consumer fraud act, chapter 63 of Title 9.

Each violation of this section or of any rules adopted under this section by the attorney general constitutes a separate civil violation for which the attorney general may obtain relief.

CREDIT(S)

2007, No. 80, § 17; 2007, Adj. Sess., No. 89, § 3, eff. March 5, 2008; 2009, No. 59, § 1, eff. July 1, 2009.

2007 Vt. Laws No. 80 (S. 115):

NO. 80. AN ACT RELATING TO INCREASING TRANSPARENCY OF PRESCRIPTION DRUG PRICING AND INFORMATION.

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. LEGISLATIVE FINDINGS

The general assembly makes the following findings:

(1) The state of Vermont has an interest in maximizing the well-being of its residents and in containing health care costs.

(2) There is a strong link between pharmaceutical marketing activities, health care spending, and the health of Vermonters.

(3) The goals of marketing programs 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 activities and possibly the health of individual patients.

(4) 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 assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.

(5) The federal Food and Drug Administration (FDA) requires marketing and advertising to be fair and

balanced; however, the FDA has limited legal ability to enforce this requirement.

(6) Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.

(7) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects. One example of this is the drug Vioxx, which was removed from the market due to potentially lethal side-effects that were not adequately disclosed initially.

(8) Between 1975 and 2000, 50 percent of all drug withdrawals from the market and "black box warnings" were within the first two years of the release of the drug. One-fifth of all drugs are subject to "black box warnings" or withdrawal from the market because of the serious public health concerns. Marketing which results in prescribers using the newest drugs will also result in prescribing drugs that are more likely to be subject to these warnings and withdrawal.

(9) In 2005, Vermonters spent an estimated $524 million on prescription and over-the-counter drugs and nondurable medical supplies. In 2000, spending was about $280 million. The annual increase in spending during this period was 13.3 percent, which was the highest increase in any health care category.

(10) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm, and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit

plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in Medicaid program.

(11) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

(12) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

(13) 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.

(14) Nearly one-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. According to the same study, the use of more expensive drugs contributed to 36 percent of the rise in retail prescription spending in 2000 and 24 percent in 2001.

(15) According to testimony by Dr. Avorn, M.D., at Brigham and Women's Hospital, detailing affects the cost of medications, because it is generally "confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales. . . . Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products. . . , and contributes to the strain on health care budgets for individuals as well as health care programs."

(16) 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 consulting 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.

(17) In 2004, the pharmaceutical industry spent $27 billion marketing pharmaceuticals in the United States, and spent more than any other sector in the United States 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. Pharmaceutical manufacturers spend twice as much on marketing as on research and development.

(18) 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 representatives. It is estimated that there is a pharmaceutical sales representative for every five office-based physicians.

(19) A significant portion of prescriber time is spent meeting with pharmaceutical representatives. According to a survey recently published in the New England Journal of Medicine, family practitioners reported the highest frequency of meetings with representatives – an average of 16 times per month. To the extent that this meeting time comes at the expense of time spent with patients, quality of care will be negatively affected.

(20) Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives and a few have reported that they felt coerced and harassed. The Vermont Medical Society, an organization representing two-thirds of Vermont doctors, unanimously passed a resolution stating "the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine."

(21) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample. The presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source according to a study by Chew et al. in the Journal of General Internal Medicine in 2000.

(22) Prescriber-identifiable prescription data show details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs.

(23) Prescriber identity data mining allows pharmaceutical companies to track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities.

(24) Monitoring of prescribing practices also allows the sales representatives to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards.

(25) Prescriber-identified data increase the effect of detailing programs. They support the tailoring of presentations to individual prescriber styles, preferences, and attitudes.

(26) Prescriber identified databases of prescribing habits encourage pharmaceutical companies to increase the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity data-mining to target increased attention and manipulative practices toward those doctors that they find would lead to increased prescriptions and profitability, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors who are shown to be especially susceptible to sales messages.

(27) Added and unwanted pressure occurs when doctors are informed by sales representatives 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.

(28) As with the use of consumer telephone numbers for marketing, the trading of prescriber identities linked to prescription data can result in harassing sales behaviors by pharmaceutical sales representatives toward doctors.

(29) Health care professionals in Vermont who 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 of the payment for that prescription. Prescribers and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

(30) The physician data restriction program offered by the American Medical Association (AMA) is not an adequate remedy for Vermont doctors, because many physicians do not know about the program and other health care professionals who prescribe medications may not avail themselves of the AMA program. In addition, approximately 23 percent of Vermont physicians belong to the AMA, which is one of the lowest rates in the nation. Finally, data-mining companies could use other identifiers, including state licensing numbers, to track prescribing patterns.

(31) This act is necessary to protect prescriber privacy by limiting marketing to prescribers who choose to receive that type of information, to save money for the state, consumers, and businesses by promoting the use of less expensive drugs, and to protect public health by requiring evidence-based disclosures and promoting drugs with longer safety records.

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