09-1913-cv (L)
IMS Health Inc. V. Sorrell

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term, 2009

(Argued: October 13, 2009 Decided: November 23, 2010)

Docket No. 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.*

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

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

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.

Judge Livingston dissents in a separate opinion.

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.

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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 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

[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."

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 re-publication 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.

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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.

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).

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]

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

[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, 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.

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.

> 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]

[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.

CONCLUSION

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

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 name drugs through a

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[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.

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

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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/opr1/pharmacists/rules/Pharmacy%20Adopted%2

valuable to any number of third parties, including the plaintiffs-appellants in this case, pharmacies, for some time, have made a practice 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

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0Rules%20Effective%20October%201,%202009%20PDF%20Version.pdf (last visited Nov. 18, 2010).

[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 "de-identified," 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.

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.

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]

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 –

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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.

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" 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

[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).

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 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

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[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 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)).

[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 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

[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

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, 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.

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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.

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

[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

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, I feel no need to decide the issue, as I would

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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 *Cental Hudson* controls and finding "no need in this case to break new ground").

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 regula-

tion," *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 "underinclusive[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 restric-

tions 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 interstate 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.