No. 10-779

IN THE

Supreme Court of the United States

WILLIAM H. SORRELL ET AL.,

Petitioners,

v.

IMS HEALTH INC. ET AL.,

Respondents.

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

BRIEF OF RESPONDENTS IMS HEALTH INC., VERISPAN, LLC, AND SOURCE HEALTHCARE ANALYTICS, INC.

Thomas R. Julin
Jamie Z. Isani
Patricia Acosta
HUNTON & WILLIAMS LLP
1111 Brickell Ave.
Suite 2500
Miami, FL 33131

Robert B. Hemley
Matthew B. Byrne
GRAVEL AND SHEA
76 St. Paul St., 7th Fl.
Burlington, VT 05402

Thomas C. Goldstein
Counsel of Record
Kevin K. Russell
Amy Howe
Tejinder Singh
GOLDSTEIN, HOWE & RUSSELL, P.C.
7272 Wisconsin Ave.
Suite 300
Bethesda, MD 20814
(301) 941-1913
tgoldstein@ghrfirm.com

QUESTION PRESENTED

Does the First Amendment allow the government to freely permit the publication and use of prescription-history information, but ban the use of the identical information to promote prescription drugs, in order to correct a supposed "imbalance" in the "marketplace for ideas," 2007 Vt. Acts & Resolves No. 80, §§ 1(4), 1(6)?

PARTIES TO THE PROCEEDING BELOW

Petitioners are William H. Sorrell, as Attorney General of the State of Vermont; Peter Shumlin, who succeeded Jim Douglas as Governor of the State of Vermont; and Douglas A. Racine, who succeeded Robert Hofmann as the Secretary of Human Services of the State of Vermont.

Respondents are IMS Health Inc., Verispan, LLC (now SDI Health LLC), and Source Healthcare Analytics, Inc. Respondent Pharmaceutical Research and Manufacturers of America was a plaintiff-appellant below and appears separately as a respondent in this Court.

RULE 29.6 DISCLOSURES

IMS Health Incorporated is wholly owned by Healthcare Technology Intermediate Holdings, Inc., which is wholly owned by Healthcare Technology Intermediate, Inc., which is wholly owned by Healthcare Technology Holdings, Inc. Verispan LLC was succeeded by merger by SDI Health LLC. SDI Health LLC is wholly owned by SDI Health Holdings LLC. Source Healthcare Analytics, Inc. was a wholly owned subsidiary of Wolters Kluwer Health, Inc. when this lawsuit was filed and remained so until August 31, 2009, when it became a wholly owned subsidiary of Wolters Kluwer Pharma Solutions, Inc. No publicly held company owns ten percent or more of the stock of any of these parties.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Regulations

Constitutional Provisions

BRIEF FOR RESPONDENTS IMS HEALTH INC., VERISPAN, LLC, AND SOURCE HEALTHCARE ANALYTICS, INC.

Respondents IMS Health Inc., Verispan, LLC, and Source Healthcare Analytics, Inc. respectfully request that this Court affirm the judgment of the United States Court of Appeals for the Second Circuit.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-67a) is published at 630 F.3d 263. The memorandum opinion and order of the district court (Pet. App. 68a-118a) is published at 631 F. Supp. 2d 434.

JURISDICTION

The judgment of the court of appeals was entered on November 23, 2010. Pet. App. 1a. Petitioners filed a timely petition for a writ of certiorari on December 13, 2010, which was granted on January 7, 2011. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT CONSTITUTIONAL AND STATUTORY PROVISIONS

The First Amendment to the United States Constitution provides, in relevant part:

> Congress shall make no law . . . abridging the freedom of speech . . . .

The Appendix to this brief reproduces the relevant provisions of Vermont law.

STATEMENT OF THE CASE

The State of Vermont generally permits the distribution and use of prescription-history information for any purpose. But absent a prescriber's advance consent, that information may not be used to facilitate the marketing of prescription drugs. The Second Circuit held that this prohibition on the use of truthful information on a matter of public concern violates the First Amendment.

1. The statute at issue in this case, Vt. Stat. Ann. tit. 18, § 4631 ("Act 80"), regulates the distribution and use of information contained in prescriptions ("prescription-history information"). The information includes, for example, the name of the prescriber, the prescribed medication, and the date of the prescription. By law, this prescriber-identifiable data ("PI data") excludes information that could be used to identify the patient. 42 U.S.C. § 1320d-6; 45 C.F.R. pts. 160 & 164.

PI data is the best available means to identify prescribers who tend to use certain medications or to treat patients suffering from particular types of conditions. Vermont law accordingly grants pharmacies, health insurers, benefits managers, and other similar entities that possess PI data ("information providers") *carte blanche* to use and distribute that information for a variety of purposes.

The State itself uses PI data in a "counter-detailing" program to identify and approach physicians to persuade them to use less expensive generic alternatives to brand-name drugs. Vt. Stat. Ann. tit. 18, §§ 4621-22. Act 80 includes a similar provision permitting insurers and benefits managers

to use PI data for "formulary compliance" programs to require or encourage prescribers' use of generics. Vt. Stat. Ann. tit. 18, § 4631(e)(1).

Act 80 also freely permits information providers to distribute PI data to pharmaceutical companies in many circumstances. It permits use of the information for "health care research," including for clinical trials that are populated by identifying physicians who care for multiple patients with a common condition. § 4631(e)(1), (4). The statute also permits drug companies to use PI data to disseminate health and safety messages. § 4631(e)(4).

Under Act 80, other third parties may acquire PI data as well. Both the government and academic researchers use the information for health care research and for the development of health policy. § 4631(e)(1). The statute also authorizes the use of PI data by law enforcement, for example to track over-prescription of narcotics. § 4631(e)(6).

Indeed, under Act 80, information providers generally may disseminate PI data for any purpose. § 4631(d). They may, for example, publish their prescription-history databases on the Internet. Similarly, the researchers and governmental entities that acquire the information are free to publish their data sets. The media is free to acquire the information for research and reporting, and they have done so. *See, e.g.*, Steve Sternberg et al., *In Patient's Hunt for Care, Database "A Place to Start" – National List of Specialists Has a Community Focus*, USA TODAY, May 14, 2009, *available at* www.influentialdoctors.usatoday.com.

Act 80's one restriction is that PI data may not be used for pharmaceutical marketing. Act 80 forbids information providers from communicating PI data for the purpose of "marketing or promoting a prescription drug." § 4631(d) ("the PID Prohibition"). It similarly provides that "[p]harmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug." *Id.* ("the Detailing Prohibition"). The only exception to these prohibitions is that individual prescribers may individually opt in to the use of their PI data for marketing purposes. *Id.*

The PID Prohibition and Detailing Prohibition do not directly prohibit marketing, including the practice of "detailing," in which prescribers can choose to meet with pharmaceutical representatives to learn health and safety information about their products. But the Vermont Legislature stated explicitly that the purpose of the PID Prohibition and the Detailing Prohibition was to make pharmaceutical marketing through detailing more difficult. In the view of the State, detailing is "designed to increase sales, income, and profit," which supposedly can "come[] at the expense of cost-containment activities and possibly the health of individual patients." 2007 Vt. Acts & Resolves No. 80, § 1(3). The Legislature believed that without access to PI data, pharmaceutical companies would find it more difficult to identify and persuade prescribers to use their brand-name products, a decision that could reduce prescribers' use of generic alternatives. Vermont determined to intervene in the

"marketplace of ideas" because it was functioning "in conflict with the goals of the state." *Id.* §§ 1(3), (4).

2. Respondents brought separate suits alleging that Act 80 violated the First Amendment. Respondents IMS Health, Verispan, and Source Healthcare Analytics ("the Publisher Respondents") are among the world's largest publishers of information, research, and analysis for the health care and pharmaceutical industries. As is relevant here, the Publisher Respondents collect and analyze PI data and publish reports that are used for the many diverse purposes permitted under Act 80, as well as the pharmaceutical marketing forbidden by the statute. Respondent Pharmaceutical Research and Manufacturers of America ("PhRMA") is a trade association representing brand-name pharmaceutical companies.

The district court consolidated the cases and upheld Act 80 as a permissible regulation of commercial speech. Pet. App. 68a-118a. On respondents' appeal, the Second Circuit reversed, holding that the statute was invalid even under the intermediate scrutiny applicable to regulations of commercial speech. The court of appeals reasoned that Act 80 does not further an interest in protecting prescribers' privacy because it "does not ban any use of the data other than for marketing purposes, including widespread dissemination to the general public." *Id*. 22a. The statute also does not "advance the state's interest in public health and reducing costs in a material way," given that it equally inhibits the marketing of drugs that are beneficial and cost effective. *Id*. 24a, 29a, 33a. Further, Vermont's effort to "alter the marketplace of ideas by taking out

some truthful information" is "antithetical to a long line of Supreme Court cases." *Id*. 26a. Judge Livingston dissented. *Id*. 35a-67a.

The Second Circuit acknowledged that its decision conflicted with decisions of the First Circuit upholding similar laws enacted by New Hampshire and Maine. *See IMS Health, Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010); *IMS Health, Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009). This Court granted certiorari. 131 S. Ct. 857 (2011).

SUMMARY OF THE ARGUMENT

I. Act 80 is subject to strict scrutiny review under the First Amendment. The statute is a straightforward restriction on truthful speech by information providers, the Publisher Respondents, and pharmaceutical companies on matters of public concern. As Act 80 and its many exceptions demonstrate, PI data plays an important role in medical care, health care research, health policy, and law enforcement. The use of pharmaceutical detailing to reach a targeted medical audience on the basis of PI data specifically conveys essential information to prescribers about the health benefits and safety risks of drugs.

The State's arguments for applying less rigorous constitutional scrutiny lack merit. Vermont does not gain the power to restrict the communication of PI data, as well as the subsequent truthful marketing on the basis of that data, on the theory that it requires prescribers to identify themselves and pharmacies to keep a record of the prescriptions they fill. Act 80 applies to information providers – such as health insurers and benefits managers – that acquire

and record PI data in the ordinary course of their daily businesses wholly apart from any regulatory requirement. Physicians obviously would provide their identity, and pharmacies would obviously maintain records of prescriptions, even absent Vermont's requirements, for numerous reasons. But in any event, the existence of an intrusive regulatory regime simply is not a basis under the First Amendment for imposing further restrictions on the free speech of the regulated party.

Act 80 also is not subject to less rigorous scrutiny on the ground that the statute regulates "commercial speech." The communication of PI data by information providers and the Publisher Respondents is not a solicitation of a commercial transaction. The Detailing Prohibition makes it more difficult for drug companies to locate prescribers who would benefit from learning about their products, but the statute does not regulate the content of the detailers' actual solicitation. If this Court's existing precedents do subject Act 80 to intermediate scrutiny as a regulation of commercial speech, those decisions should be overruled and the Court should hold that all such attempts to insulate individuals from important and truthful information are subject to strict scrutiny under the First Amendment.

II. Act 80 violates the First Amendment. Vermont does not contend that the statute can survive strict constitutional scrutiny. It plainly is not narrowly tailored to fulfill a compelling governmental interest, and non-speech restrictive measures could achieve the same goals. But even under less searching scrutiny, Act 80 is invalid.

A. Vermont maintains that the statute fulfills an important privacy interest in giving prescribers control over the use of their prescription-history information. Measures that are genuinely tailored to protect an important privacy interest are valid under the First Amendment. But Act 80 is not such a statute. The PID Prohibition's many exceptions permit information providers to distribute PI data without the prescriber's consent in almost every instance. They may disseminate that information to pharmaceutical companies, insurers, pharmacy benefits managers, academic researchers, health policy officials, law enforcement agents, and even the general public. For example, through Vermont's "counter detailing" program and Act 80's exception for formulary compliance, the State and private insurers and benefits managers all use PI data to persuade physicians to reject pharmaceutical companies' marketing messages and instead prescribe generic alternatives. The only restriction on the non-consensual use of PI data is that the information cannot be used for marketing by drug companies. The statute thus is not a genuine attempt to protect prescribers' privacy.

Further, the State's interest in giving prescribers such a slight degree of control over the use of their prescription history information cannot justify the very substantial restriction on free speech imposed by Act 80. Vermont looks by analogy to a patient's significant interest in the privacy of her medical records. But all patient-identifying information is stripped from PI data. A physician's prescribing decisions do not reflect personal information but instead are heavily regulated and widely used for

commercial purposes by pharmacies, insurers, and benefits managers, as well as for other purposes by researchers and the government.

For those reasons, as the Solicitor General essentially admits, the statutes that Vermont asserts would be endangered by the Second Circuit's decision in this case are easily distinguishable and in fact only demonstrate that Act 80 is not tailored to advance a substantial privacy interest. In stark contrast to HIPAA and other federal statutes and regulatory regimes that protect important personal privacy interests, Act 80 contains numerous exceptions that freely permit the wide distribution of prescribers' commercial prescription history information.

B. Alternatively, Vermont argues that Act 80 improves public health and reduces health care expenditures. The state legislature reasoned that detailing messages have too much influence on physicians' prescribing decisions. Under the First Amendment, Vermont has no legitimate interest in insulating prescribers from that truthful communication on a matter of public concern. The Constitution forbids such paternalistic efforts to limit the free exchange of information.

Further, Act 80 impermissibly discriminates against the viewpoint of pharmaceutical companies. Just as it restricts pharmaceutical detailing, it simultaneously facilitates communication by the State and insurers to prescribers of the message that pharmaceutical marketing should be rejected in favor of generic alternatives.

Act 80 furthermore is not in any respect tailored to further the State's asserted health-care-related

interests. It impedes all detailing, including when the drug being promoted is *less* expensive and *more* beneficial than available alternatives. Further, Act 80 only restricts the use of PI data; it allows detailing and other pharmaceutical marketing to continue. Finally, the statute irrationally seeks to promote the use of PI data to develop safe and effective new drugs, but then forbids the use of the identical information to promote those very drugs.

The judgment of the Second Circuit accordingly should be affirmed.

ARGUMENT

The Second Circuit's decision preserves fundamental First Amendment principles without threatening the government's power to protect individual privacy, including from improper data mining practices. Vermont's Act 80 is subject to First Amendment scrutiny because it has the purpose and effect of restricting speech on matters of public importance by information providers, the Publisher Respondents, and pharmaceutical companies. That speech is truthful and facilitates the distribution of critical health and safety information. Vermont impermissibly seeks to inhibit that speech because it finds the speech to be too persuasive and contrary to the State's interests.

In contrast to the privacy statutes cited by the State, such as HIPAA, Act 80 does not satisfy First Amendment scrutiny because it obviously is not intended to maintain the confidentiality of any information that is reasonably regarded as private. Act 80 and other Vermont programs facilitate the widespread dissemination of PI data to diverse

entities (including pharmaceutical companies) without the prescriber's consent. Vermont itself uses the same data to try to persuade prescribers to reject pharmaceutical marketing and instead prescribe generic equivalents.

This Court accordingly need go no further to resolve this case than to hold that Vermont's statutory scheme is not tailored to further a significant governmental interest. The precise reach of the government's regulatory power over data mining practices can be left for another day when the Court confronts a statute that is actually designed to protect privacy rather than to restrict speech with which the government disagrees. Because Act 80 is not such a measure, the Second Circuit's judgment should be affirmed.

I. Act 80 Is Subject To Searching Scrutiny Under The First Amendment.

Act 80 is subject to First Amendment scrutiny because it restricts speech on matters of public importance.

A. The Statute Restricts The Constitutionally Protected Speech Of Information Providers, The Publisher Respondents, And Pharmaceutical Companies.

1. Absent the prescriber's consent, the PID Prohibition forbids pharmacies and other entities that possess PI data from communicating that information to third parties, such as the Publisher Respondents, for the purpose of "marketing or promoting a prescription drug." Vt. Stat. Ann. tit. 18,

§ 4631(d). Act 80 also purposefully impedes the speech of the Publisher Respondents: the PID Prohibition prevents them from acquiring the PI data they need to prepare and publish reports that drug companies use to identify the audience for truthful marketing; and the Detailing Prohibition in turn forbids that use of the reports.

The speech of the Publisher Respondents is protected by the First Amendment. The Publisher Respondents do not merely collect, aggregate, and then republish PI data. They devote significant resources to ensure the information is accurate. Then, because "the data in its native state is actually quite raw and not really completely useful," they "have to relate that to useful information," identifying the product, payer, pharmacy, and prescriber, and analyzing that information. J.A. 159 (Fisher). Only through that significant additional effort is the PI data transformed into "a more usable, publishable form," *id.*, that can be usefully employed by the reader. *See, e.g.*, J.A. 470-71 (illustration of a report of PI data).

The Publisher Respondents also regularly conduct detailed studies of PI data – indistinguishable from other scientific analyses, such as the study of aggregate economic data – and produce tailored reports for pharmaceutical companies. Respondents assess the underlying data, and often provide projections and forecasts of trends, including sophisticated regression analyses.

A speaker in any event need not generate additional content to receive the protections of the First Amendment. Whether a speaker "add[s] the linguistic connecting tissue necessary to transform

[a] report's facts into full sentences cannot change" the First Amendment's protections. *Florida Star v. BJF*, 491 U.S. 524, 539 (1989). The Publisher Respondents' contributions to expression certainly are more significant than the selection of which floats should appear in a parade or which stations to broadcast on a cable network, both of which this Court has held to be protected by the First Amendment. *Hurley v. Irish-American Gay, Lesbian, and Bisexual Group of Boston*, 515 U.S. 557 (1995); *Turner Broadcasting Sys. v. FCC*, 512 U.S. 622 (1994).

2. The communication of prescription-history data by the information providers and the Publisher Respondents is constitutionally protected speech. It is a statement of the historical facts of the prescriptions issued by doctors. The party that initially distributes the information – for example, the pharmacy which dispenses the prescribed therapy or a health insurer that collects the information for purposes of reimbursement – is a participant in the events. No one would doubt that the First Amendment would apply fully if Vermont sought to prohibit the *other* party to the transaction – the patient – from discussing the fact of the prescription. There is no logical basis for treating the expression of the pharmacy, insurer, or the Publisher Respondents as categorically different.

It is thus settled that the First Amendment protects the expression, publication, and reporting of facts, including in commercial settings. For example, in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), the Court held that a ban on pharmacists' publication

of the price of prescription drugs violates the First Amendment. Expressly rejecting the state's claim that the statute did not implicate the First Amendment because the advertising "merely reports a fact," the Court reasoned that it is "indispensable" to the "public interest" that there be a "free flow" of "information as to who is producing and selling what product, for what reason, and at what price." *Id.* at 762, 765. *See also, e.g.*, *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (First Amendment protects display of fact of alcohol content on beer labels).

Vermont's suggestion that this Court should now reverse course and deem the exchange of factual information by private parties to be "conduct" unprotected by the First Amendment is unprecedented and dangerous. It amounts to the assertion that the government has the absolute authority, without any constitutional constraint, to restrict the publication of – to cite just a few common examples from our everyday lives – sports scores, weather reports, unemployment statistics, legislative votes, home prices, vehicles' gas mileage, internet addresses, food nutritional data, stock prices, and election returns. Indeed, most reporting on history and contemporary newsworthy events – a terrorist attack, a nuclear meltdown, the election of a President, the crowning of an NCAA champion, and so on – is at bottom the recitation of facts.

Empowered to restrict the dissemination of factual information, the government would have an easy time distorting public discourse and manipulating public opinion. Human thought is a continuum of judgments that rests on our perception of the world around us, and facts are the building

blocks for the development of knowledge on which those judgments rest. For example, the foundation of all of science is a study of, and a search for, facts; thus, scientists would be effectively straitjacketed in their studies if they were allowed to access only the factual data that the government has approved. In the field of politics, Americans decide whether to seek a change in their government based on an array of factual information about, among many other things, the health of the economy and legislative initiatives offered by incumbents and their opponents. As consumers, we choose among products by acquiring factual information about, for example, their health benefits and flavor (for foods), speed and energy efficiency (for machines), and warmth and durability (for clothing). There is no serious argument that the government is free to restrict the dissemination of such information without searching First Amendment scrutiny.

PI data, in particular, is constitutionally protected expression because – as is apparent from the many provisions of Vermont law *encouraging* the data's use – this information has significant value in improving medical care, health care research, the development of health policy, and law enforcement. Further, Act 80 itself is the embodiment of the State's judgment that the use of PI data has a significant effect on the delivery of health care through pharmaceutical marketing. Vermont's disputed value judgment that PI data causes *harm* by facilitating pharmaceutical detailing does not deny the *importance* of that expression for significant health care decisions.

The conclusion that the PID Prohibition is subject to First Amendment scrutiny is significantly reinforced by the fact that its obvious purpose is to restrict yet another form of free speech: marketing by pharmaceutical manufacturers. As the district court recognized, "[T]he whole point of [Act 80] is to control detailers' commercial message to prescribers." Pet. App. 82a. Vermont concluded that the "marketplace for ideas" had to be reshaped because it was functioning "in conflict with the goals of the state." 2007 Vt. Acts & Resolves No. 80, §§ 1(3), (4) (2007). (There is no support for the State's assertion that these findings relate only to a since-repealed provision requiring detailers to provide information on competing products: the findings themselves were never withdrawn and they equally describe the Legislature's rationale in enacting the PID Prohibition and Detailing Prohibition.)

The state Legislature thus explained that its goal was to attack pharmaceutical "marketing programs" because they are "designed to increase sales, income, and profit," which supposedly can "come[] at the expense of cost-containment activities and possibly the health of individual patients." *Id.* § 1(3) (2007). But because a ban on truthful pharmaceutical detailing would obviously violate the First Amendment, *see, e.g.*, *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002), Vermont sought to achieve the same result indirectly. As the Second Circuit correctly recognized, "[t]he statute is therefore clearly aimed at influencing the supply of information, a core First Amendment concern." Pet. App. 16a.

3. Act 80 is also subject to First Amendment scrutiny because it directly restricts pharmaceutical

marketing, which is constitutionally protected. The Detailing Prohibition provides that, absent consent, "[p]harmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug." Vt. Stat. Ann. tit. 18, § 4631(d). Whenever drug companies have employed PI data to identify an audience and to tailor their messages, this provision by its terms prohibits drug companies from engaging in speech.

That restriction is moreover significant. The very premise of Act 80 is that detailing conducted on the basis of PI data is a uniquely persuasive form of communication. The Detailing Prohibition materially interferes with pharmaceutical companies' ability to deliver their messages to a willing audience. Vermont is literally attempting to make it more difficult for drug companies and prescribers to have an intelligent conversation. PI data permits pharmaceutical companies to identify the particular subgroup of physicians who treat patient populations who may benefit from the company's products. The detailer can then select the particular physicians to visit, and tailor a message to their existing prescribing habits.

There is no genuine dispute that the targeted communications between detailers and prescribers that are facilitated by PI data involve an exchange of truthful information on matters of public concern. Pharmaceutical detailers play a central role in conveying medical information to prescribers because under the federal regulatory regime the drug company is itself the principal source of health and safety information. "[M]ost information about a

[drug] that is available in the published literature and in the package[] label comes from the pharmaceutical industry." J.A. 176 (Cole).

Detailers specifically "direct scientific and safety messages to physicians most in need of that information," "including the use, side effects, and risks of drug interactions." Pet. App. 6a. A pharmaceutical detailer will be expected to discuss the results of clinical studies on the company's products, as compared to those offered by competitors. *See, e.g.*, J.A. 218 (Wharton) ("What [physicians] do pay attention to is the articles from the peer-reviewed literature that the drug reps invariably bring to discuss."). "They also may provide information about such things as formulation, what size tablets [are] available, [and] is there anything special for children," making it unnecessary for the physician to "go digging" for that information. J.A. 181 (Cole).

With respect to drug safety, detailers "can serve as an early warning system for problems and alerting . . . people that happen to be using those drugs, about these problems," such as "information about the risk of fetal abnormalities in the children of wom[e]n who are taking antiseizure medications." J.A. 181 (Cole). That is particularly true in states like Vermont, because prescribers in more rural areas may see smaller patient populations and have less contact with other physicians with experience with a particular drug. As one physician who supported Act 80 testified, "[A] good rep is absolutely invaluable, because when you're in the hinterlands, where are you going to get your information about what's going

on with drugs? It's the drug rep." J.A. 218 (Wharton).

All this information is essential to prescribers, who must be aware of complete and current information to provide their patients with appropriate care. A study published by the non-profit Massachusetts Biotechnology Council on the introduction of the drug BANZEL by Eisai Co. is illustrative. *See* Massachusetts Biotech. Coun., *Treatment Delayed is Treatment Denied – The Unintended Consequences of State Laws to Ban the Use of Physician Level Data* (Feb. 1, 2010), *available at* http://www.massbio.org/writable/editor_files/banzel_case_study_2.1.10.pdf. BANZEL is a breakthrough therapy for Lennox-Gastaut Syndrome (LGS), a debilitating form of epilepsy in children that may produce more than one hundred seizures per day. Children with the condition often wear protective helmets with face guards because they fall so frequently; roughly one child dies every day from LGS in the United States. *Id*. at 2-3.

The FDA approved BANZEL to treat LGS in late 2008. Eisai, which had a small sales force, used PI data to identify promptly the physicians who are most likely to treat LGS and thus who would want to make use of the drug. Using the data it "identified a list of 1300 child neurologists and epileptologists – from a universe of 10,000 to 12,000 general neurologists – and was able to target messaging to those physicians most knowledgeable about how to use and evaluate BANZEL in clinical practice." *Id.* at 5. Eisai succeeded in states *other* than New Hampshire, which had recently become the first state to enact a PID restriction and, in so doing, "made

identifying the right physicians very difficult and prevented immediate and direct communication with physicians about the benefits and risks of BANZEL." *Id.* Vermont's subsequently enacted Act 80 would similarly prohibit such efforts to speed the distribution of information regarding other important new drugs. *See id.* at 6 ("As predicted by opponents, and confirmed by Eisai's experience of trying to market BANZEL in New Hampshire, the benefits of this legislation are unknown, while the harm is clear: these laws create inefficiencies in the dissemination of information and may result in delayed access for patients to new products like BANZEL.").

The flow of valuable information in a detailing exchange between the company's representative and a prescriber is moreover a two-way street. In these meetings, prescribers not only receive medical data but also provide drug representatives with information on the efficacy of various treatments, which the companies in turn use to improve the therapies they provide. The drug company acquires important information "because they're in a position to receive feedback about side effects, about unusual situations where the drug is particularly efficacious, about dosing, and they're in a position to collate that feedback and again integrate it in a way that no individual physician is positioned to do." J.A. 176 (Cole).

B. Vermont's Arguments For Applying Lessened Constitutional Scrutiny Lack Merit.

Because Act 80 regulates respondents' fully protected speech, the statute is subject to strict

constitutional scrutiny. The State's arguments for exempting the statute from First Amendment review, or for applying intermediate constitutional scrutiny, are not persuasive.

1. It Makes No Difference That Vermont Requires Pharmacies To Keep A Record Of The Prescriptions They Fill.

There is no merit to "Vermont's primary argument that the State's law should be upheld as a restriction on access to nonpublic information." Vt. Br. 41. The State contends that Act 80 is not subject to First Amendment scrutiny because the government requires prescribers to identify themselves and in turn requires pharmacies to keep records of the prescriptions they fill. *Id*.

The State relies on the principle that the government may refuse to distribute information in its possession for commercial purposes. For example, "campaign donor lists" submitted to the Federal Election Commission and "financial disclosures" submitted by public employees may not be acquired by private parties for commercial purposes. Vt. Br. 39. This Court upheld such measures in *Los Angeles Police Department v. United Reporting Co.*, 528 U.S. 32 (1999), which rejected a facial challenge to a state law that forbade the distribution of California arrest records for commercial purposes. Because the state had imposed "nothing more than a governmental denial of access of information in its possession," this Court held that the case was controlled by the principle that the government may "decide[] not to give out [such] information at all." *Id.* at 40.

This case is obviously very different. Respondents do not claim any "right of access" to PI data. Pharmacies and other information providers are willing providers of that information.

Act 80 also does not control Vermont's own distribution of information. It was critical to this Court's decision in *LAPD* that "[t]his is not a case in which the government is prohibiting a speaker from conveying information that the speaker already possesses." 528 U.S. at 40. Act 80, in stark contrast, restricts *only* speech by private parties. Those private entities – pharmacies, health insurers, and the like – are moreover not fulfilling a public function and are not paid by the government for their services. Their decision to communicate PI data to the Publisher Respondents cannot be analogized to a governmental "subsidy," *LAPD*, 528 U.S. at 43 (Ginsburg, J., concurring), that Vermont can adopt or withdraw whenever it pleases.

Further, Act 80 does not merely "regulate[] *pharmacies'* use of prescription records." *Contra* Vt. Br. 10 (emphasis added). It equally applies to health insurers, pharmacy benefits managers, and other entities that collect PI data in the ordinary course of their business without any regulatory compulsion. Absent Act 80, the Publisher Respondents could acquire PI data from these other sources even if pharmacies were unable or unwilling to provide it.

Vermont makes much of the fact that in *Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984), this Court rejected a First Amendment challenge to a rule requiring that confidential information acquired by a litigant in discovery not be publicly disclosed. Vermont errs in arguing that because the

government requires prescribers to identify themselves on the prescription form, Act 80 can be sustained under the logic of *Seattle Times*. First, the requirement that a prescription record identify the prescriber is not analogous to a court order to maintain the confidentiality of information acquired in discovery. Act 80 seeks to restrict speech whereas the latter is intended to protect confidentiality. It was thus essential to the reasoning of *Seattle Times* that "continued court control over the discovered information does not raise the same specter of government censorship that such control might suggest in other situations." *Id.* at 32.

Prescription-history information is ordinarily disclosed to numerous parties, such as the pharmacy, insurer, benefits manager, and the government. That practice remains true after Act 80. The purpose of Vermont's recordkeeping requirement is not to protect privacy but rather to ensure that PI data will be available to be *disclosed* if later required. By contrast, a confidentiality order in litigation is necessary and permitted only if the disclosing party demonstrates that the information in question must be kept private. *See, e.g.*, *Shingara v. Skiles*, 420 F.3d 301, 305-06 (3d Cir. 2005) (the party seeking a protective order has the burden to show "good cause," *i.e.*, that "disclosure will result in a clearly defined, specific and serious injury;" this burden is not met with mere "broad allegations of harm").

Further, Vermont is simply wrong to assert that it is "undisputed" that "pharmacies have access to and collect prescription information only under the direction and authority of state law." Vt. Br. 22 (quoting Pet. App. 40a (Livingston, J., dissenting)).

The State incorrectly equates its regulatory requirement that pharmacies *retain* prescription records for a certain number of years with a determination that pharmacies would not otherwise *collect* the same information. In fact, prescribers would provide, and pharmacies would record, PI data for numerous reasons. They did so well before the adoption of Vermont's regulatory regime. Pharmacies need to be assured of the prescription's validity, as well as to be able to contact the prescriber in the event of problems with or questions about the prescription. Pharmacies would also collect PI data for the numerous uses that are plain on the face of Act 80, including not just pharmaceutical detailing, but also formulary compliance, health care research, and assisting law enforcement. Insurers, in turn, require the information in order to provide reimbursement.

By analogy, the Internal Revenue Code requires every U.S. taxpayer to keep such records "as are sufficient to establish the amount of gross income, deductions, credits, or other matters required to be shown by such person in any [tax] return." 26 C.F.R. § 1.6001-1(a); *see* 26 U.S.C. § 6001. That recordkeeping requirement does not mean that individuals would fail to keep the records by their own choice, much less that the government has the power to restrict their speech on those personal issues. It would be absurd if the existence of this recordkeeping requirement enabled the government to prohibit individuals from discussing, for example, which charities they support.

As a constitutional matter, Vermont thus incorrectly assumes that government regulation of

conduct – here, the manner in which prescriptions are issued by prescribers and then filled by pharmacies – carries with it a parallel narrowing of First Amendment rights. If anything, the reverse is true. The government generally adopts regulations that address matters of public importance, about which free speech is more critical, not less. But on Vermont's view of the First Amendment, the very fact that the issue implicates the public welfare and therefore requires the adoption of protective regulations would ironically empower the government to restrict speech about that issue. For example, extensive regulatory regimes – including detailed recordkeeping requirements – govern the operations of nuclear power plants, hospitals, chemical waste facilities, and airports. But there is no serious argument that these regulations diminish the right of a willing speaker who possesses that information to use it to discuss a nuclear accident, unexplained hospital death, waste spill, or plane crash.

The sweeping implications of Vermont's contrary position for free speech are obvious. Recordkeeping requirements are pervasive in American law. Employers, for instance, must comply with such provisions under numerous statutes.[1] Businesses

---

[1] *See, e.g.*, 29 U.S.C. § 211 (Fair Labor Standards Act: employer must "make, keep, and preserve such records of the persons employed by him and of the wages, hours, and other conditions and practices of employment maintained by him"); 29 U.S.C. § 657(c)(1) (Occupational Health and Safety Act: employers must "make, keep and preserve . . . records . . . necessary or appropriate for the enforcement of this chapter or

must collect a diverse array of records,[2] as must parties involved in finance.[3] The Environmental Protection Agency has issued literally hundreds of recordkeeping requirements.[4] The records required by the IRS reach almost every facet of personal life including employment, marital status, home ownership, and charitable contributions.

Nor, finally, is there substance to the State's apparent view that Act 80 effectuates a prescriber's

---

for developing information regarding the causes and prevention of occupational accidents and illnesses"); 29 U.S.C. § 1027 (ERISA: employers must maintain records relevant to reports on benefit plans).

[2] *See, e.g.*, 16 C.F.R. § 1130.9 (establishing recordkeeping requirements for manufacturers of durable infant and toddler products); 16 C.F.R. § 1210.17 (same for manufacturers and importers of cigarette lighters); 15 C.F.R. § 762.2 (Export Administration Act: exporters must maintain memoranda, notes, correspondence, contracts, invitations to bid, books of account, financial records, and restrictive trade practice or boycott documents and reports relating to export transactions involving particular commodities and destinations).

[3] *See, e.g.*, 12 C.F.R. § 551.50 (any person who effects securities transactions for customers must maintain for three years chronological records of all trades, as well as complete account records); 17 C.F.R. § 240.17a-1 (record-keeping requirements for national securities exchanges); *id*. § 240.17a-3 (broker-dealers).

[4] For just a few illustrative examples, see*, e.g.,* 40 C.F.R. § 60.107 (specifying reporting and recordkeeping requirements for emissions from petroleum refineries); *id.* § 141.405 (ground water systems); *id.* § 262.40 (generators of hazardous waste); *id.* § 704.11 (Toxic Substances Control Act); *id.* § 157.36 (child-resistant packaging for pesticides).

"right not to speak." Vt. Br. 25. Vermont's requirement that a prescription record identify the prescriber regulates conduct, not speech. The State is merely specifying the mechanism for providing the regulated pharmaceutical to the patient. Vermont obviously believes that the Constitution permits it to require that disclosure, and correctly so. A private party's choice to then report on the disclosed conduct accordingly does not violate the prescriber's rights under the First Amendment, which in any event restricts only the power of the government, not private parties. Disclosure requirements are common in U.S. law – warning labels are obvious examples – and the government obviously cannot then forbid public discussion of the disclosed information.

2. Act 80 Is Not A Regulation Of Commercial Speech.

This Court has specified that "*the test* for identifying commercial speech" is whether the expression "propose[s] a commercial transaction." *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74 (1989) (emphasis added). *See also, e.g.*, *Thompson*, 535 U.S. at 367; *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 423 (1993). That careful formulation tracks the rationale of the commercial speech doctrine: that the government's power to regulate the underlying transaction carries with it regulatory authority to protect consumers by ensuring the accuracy and fairness of its ancillary solicitation. *See Virginia State Bd. of Pharm.*, 425 U.S. at 772-73.

The PID Prohibition plainly is not a regulation of commercial speech. Vermont forbids pharmacies,

insurers, and others from communicating historical information about physicians' prescribing decisions. These speakers are not advertising their products or services, or otherwise soliciting a commercial transaction. Similarly, the Publisher Respondents do not advertise prescription drugs, and their analysis and reporting activities are not analogous to advertising.

The fact that Act 80 regulates the dissemination of PI data and respondents' reports when sold for later commercial use by drug companies does not render that expression "commercial speech" entitled to lessened constitutional protection. "Some of our most valued forms of fully protected speech are uttered for a profit." *Fox*, 492 U.S. at 482. Newspapers and books are obvious examples. *See also, e.g.*, *Riley v. Nat'l Fed'n of Blind of N.C., Inc.*, 487 U.S. 781, 801 (1988) ("It is well settled that a speaker's rights are not lost merely because compensation is received; a speaker is no less a speaker because he or she is paid to speak.").

Nor is communication converted into "commercial speech" by the fact that it is used to facilitate "commerce." Again, the test is whether the communication "proposes" a commercial transaction. *Fox*, 492 U.S. at 475. In our society, in which a capitalist economy plays a central role, communication often will simultaneously serve an array of commercial and non-commercial purposes. A ban on sales of the *Wall Street Journal* to businesses is not a regulation of "commercial speech" on the theory that the readers will use the information contained in the newspaper for marketing or other commercial purposes. Similarly, Vermont could not

restrict the publication of a how-to book on pharmaceutical detailing on the ground that the book's contents constitute "commercial speech."

For essentially the same reason, the Detailing Prohibition is itself a regulation of fully protected speech. There is a substantial argument that a pharmaceutical detailer's communication of a solicitation fits the definition of "commercial speech" under this Court's precedents. But Act 80 does not restrict that activity. As Vermont explains, because PI data "is not part of an advertising message," Vt. Br. 33, Act 80 "does not prohibit detailing, [and] does not prevent detailers from providing information about drugs," *id.* 17. After Act 80, the detailer may provide the *identical* information in the *identical* form about the company's products to the prescriber.

To the extent that this Court instead reads its existing precedents to deem Act 80 a regulation of "commercial speech," then those decisions should be overruled. Several members of this Court have called for the abandonment of intermediate scrutiny, at least "[i]n cases such as this, in which the government's asserted interest is to keep legal users of a product or service ignorant in order to manipulate their choices in the marketplace." *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 197 (1999) (Thomas, J., concurring in the judgment). *See generally Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554-55 (2001) (collecting opinions). This case demonstrates the wisdom of that view. Pharmaceutical detailers provide truthful, non-misleading information about the merits of prescription drugs – such as the results of clinical studies and dosing information – that addresses

matters of public concern. Vermont's efforts to keep that valuable information from physicians are anathema to the First Amendment.

3. Act 80 Is Not Subject To Less Rigorous First Amendment Scrutiny On The Ground That PI Data Is Insufficiently Important.

Finally, there is no merit to Vermont's suggestion that the distribution of an individual prescription-history record is entitled to lessened or no constitutional protection because it does not contribute significantly to public dialogue. The government is not permitted to ban the publication of particular factual information based on a judgment that it is insufficiently important to be expressed. To be sure, in some specific contexts, the First Amendment's protections may vary depending on whether the speech in question addresses a matter of public concern. *E.g.*, *Snyder v. Phelps*, 131 S. Ct. 2107 (2011) (tort claims by persons injured by speech); *Connick v. Myers*, 461 U.S. 138 (1983) (speech by public employees). But with respect to a straightforward regulation of private parties' truthful speech, such as the PID Prohibition, "the general rule is that the speaker and the audience, not the government, assess the value of the information presented." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). For example, in *Florida Star v. BJF*, the Court concluded that the publication of the fact of "the specific identity" of an individual rape victim was constitutionally protected, notwithstanding that the victim's name was not itself "a matter of public significance." 491 U.S. at 536.

In *Dun & Bradstreet, Inc. v. Greenmoss Builders*, 472 U.S. 749, 762 (1985) (plurality opinion), this Court held that a defamation claim arising from one false credit report that was only useful to make an individual credit decision was not subject to the "actual malice" standard applicable to speech on matters of public concern. But Act 80 operates very differently. The statute's purpose is not to prevent communication regarding isolated personal records. Individually identifying information is deleted from the records.

Vermont instead seeks to block the wholesale dissemination and use of *aggregate* prescription-history information about prescribers and drugs, precisely because the information is so central to an important public issue. Its asserted interest lies in making it more difficult for drug companies to engage in marketing based on "physicians' drug use *patterns*" that are determined through the accumulation and mining of PI data in "gross." 2007 Vt. Acts & Resolves No. 80, § 1(22) (emphasis added).

Similarly, the fact that the Publisher Respondents prepare their analyses for a single recipient does not disentitle that speech to First Amendment protection. Because the underlying subject matter – here, the analysis of factual information relating to prescribing history – has tremendous social utility and is constitutionally protected, the government has no authority to forbid its distribution to one person or one thousand. Innumerable companies exist to prepare specialized publications, which the government obviously does not have the power to censor. The First Amendment with its full force applies to a mass-market

publication, a local newspaper, a small newsletter, and indeed a letter written from one friend to another.

II. Act 80 Violates The First Amendment.

If this Court agrees with respondents' principal submission that Act 80 is subject to strict judicial scrutiny under the First Amendment, then the case is over. The statute may be sustained only if Vermont can establish that it is narrowly tailored to promote a compelling interest, and even then only if non-speech-restricting measures will not accomplish that interest. *E.g.*, *United States v. Playboy Entm't Group*, 529 U.S. 803, 804 (2000); *Reno v. ACLU*, 521 U.S. 844, 874 (1997). Vermont does not even attempt to argue that the statute can be sustained under that particularly rigorous standard. In this section, we accept the State's premise that the statute is subject to lessened scrutiny and demonstrate that Act 80 is nonetheless invalid under the First Amendment.

A. Act 80 Cannot Be Justified On The Ground That It Gives Prescribers Control Over The Dissemination Of Their Prescription Histories.

There is no dispute that, although genuine privacy measures restrict free speech by prohibiting the disclosure of factual information, they satisfy First Amendment scrutiny because they are tailored to further a substantial interest in protecting an important expectation of privacy. But the government may not simply deem information to be "private" and selectively ban its disclosure on that basis. The general rule is that the First Amendment privileges a private party's publication of information

that it has lawfully acquired. Otherwise, the government would have a broad power to control almost all news reporting of sensitive facts. *E.g.*, *Bartnicki v. Vopper*, 532 U.S. 514 (2001) (First Amendment protects publication of unlawfully intercepted phone conversation); *Florida Star v. BJF*, 491 U.S. 524 (1989) (name of rape victim); *Smith v. Daily Mail Publ'g Co.*, 443 U.S. 97 (1979) (name of juvenile defendant); *Landmark Comms., Inc. v. Virginia*, 435 U.S. 829 (1978) (identity of judge under investigation); *Okla. Publ'g Co. v. Okla. County Dist. Ct.*, 430 U.S. 308 (1977) (name of juvenile offender); *Cox Broad. Corp. v. Cohn*, 420 U.S. 469 (1975) (name of rape-murder victim).

In this case, Vermont's asserted privacy-related interest is very limited. The State does not express a substantial concern that the distribution of PI data will reveal patient-identifying information. Respondents do not challenge – indeed, they enthusiastically support – the provisions of state and federal law under which "the patient's name is encrypted," Vt. Br. 7, and the disclosure of personal health care information is forbidden for virtually any purpose. Thus, "you can follow an individual over time, but you have no idea who that individual actually is." J.A. 158 (Fisher).[5]

---

[5] Vermont errs in its passing suggestion that if de-identified information were published in "a small-town" in Vermont, then "residents would have little difficulty spotting neighbors, friends, and relatives." Vt. Br. 36-37. If the patient's geographic area is sufficiently small that it risks disclosure of the patient's identity, that information must be encrypted or masked as well. J.A. 248 (Tierney).

Nor does the State seriously argue that the statute protects physicians from intrusion by detailers into medical practices. Act 80 freely permits detailing visits. Furthermore, wholly apart from Act 80, prescribers are "free" to "refuse to meet" with detailers. J.A. 180 (Cole). *See also* J.A. 203 (Kolassa) (access is "totally under [prescribers'] control"); J.A. 217 (Wharton) (physician need not "meet with a pharmaceutical representative to receive samples").

Instead, Vermont's argument is that Act 80 satisfies First Amendment scrutiny because it empowers prescribers to decide for themselves whether PI data should be disclosed. The Legislature thus stated in the twenty-ninth of thirty-one findings that "health care professionals . . . have a reasonable expectation that" PI data "will not be used for purposes other than filling and processing of the

---

To the extent the State's *amici* express the further concern that technology could permit PI data to be re-identified, there is no dispute that the measures used under federal law to de-identify PI data are more sophisticated than under almost any other privacy regime known to the law outside of military and national security matters. Congress mandated that the range of patient-identifiable information be determined by the federal government, rather than the states, and it has not accepted the contention that current de-identification measures are inadequate.

Although Vermont notes in passing that "Dr. Grande[] testified about how this kind of marketing negatively affects patients" by increasing their anxiety in his opinion, Vt. Br. 47, it omits his admission that he had "not conducted any study whatsoever . . . about patient perceptions of the use of doctor identifiable information," J.A. 328-29.

payment for that prescription." 2007 Vt. Acts & Resolves No. 80, § 1(29).

For the reasons that follow, Act 80 cannot be sustained on the basis of Vermont's asserted interest in giving prescribers control over the disclosure of their prescribing decisions.

1. Given The Widespread Use Of PI Data That Is Encouraged And Permitted By Vermont, There Is No Reasonable Fit Between Act 80 And The State's Asserted Interest.

a. As the Second Circuit explained, because Vermont "does not prohibit wide public dissemination of PI data," "the statute plainly does not protect physician privacy." Pet. App. 22a. Act 80 manifestly does *not* "allow[] doctors to block the[se] nonconsensual use[s] of their prescribing histories." *Contra* Vt. Br. 3. In fact, Vermont law encourages far more of those uses, by many more parties, than it restricts. Both in Act 80 and through other programs, the State itself makes widespread use of this information and encourages third parties to do the same. It gives prescribers no control over any of this activity.

Through its academic detailing program, the State contacts physicians to encourage them to use generic alternatives to brand name drugs. Vt. Stat. Ann. tit. 18, § 4622. As the State's counsel explained, Vermont's "multi-payer database has prescriber-identifiable data in it" for use in "the academic detailing program" pursuant to the explicit "exemption under the act for using this kind of data for these purposes." J.A. 313 (Frankel).

Vermont similarly encourages third-party payers in the health care system – for example, insurers and pharmacy benefits managers, as well as the State itself as the payer for Medicaid and Medicare – to use PI data to promote generics over brand-name alternatives. Act 80 permits information providers to distribute PI data for the purpose of "formulary compliance," § 4631(e)(1), which is the process by which health benefits providers require or encourage physicians to prescribe inexpensive generic equivalents or (when no generic is available) less-expensive branded alternatives. PI data is "a part of every program [benefits managers] use[]." J.A. 299 (Frankel).

Vermont also authorizes the entities that possess PI data to provide that information to pharmaceutical companies for use in developing new drugs. Act 80 permits the distribution of this information for "health care research," including for "clinical trials." § 4631(e)(1), (4). The study of PI data thus aids in the "develop[ment of] new drugs." Pet. App. 7a. Pharmaceutical companies acquire PI data to identify the prescribers who treat large numbers of patients who suffer from particular conditions. They approach those prescribers to collect information on the efficacy of existing therapies and, in appropriate cases, to invite the prescriber's patients to participate in supervised clinical trials of drugs that are under development.

Vermont also permits drug companies to acquire PI data to communicate health- and safety-related information. Act 80 permits the distribution of PI data for purposes of "care management educational communications provided to a patient about the

patient's health condition, adherence to a prescribed course of therapy and other information relating to the drug being dispensed, treatment options, [and] recall or patient safety notices." § 4631(e)(4).

Vermont itself actively uses PI data for public health purposes. The State's "Critical Care Management Program" provides for "teams visiting individual physicians and discussing with them the prescriptions that they are making for particular patients." J.A. 446 (Moffatt).

Academic researchers and public health officials also regularly use PI data. Act 80's provision authorizing distribution for "health care research" applies to these efforts as well. § 4631(e)(1). PI data thus plays a significant public health role in "track[ing] disease progression." Pet. App. 6a. The Centers for Disease Control has acquired PI data in the wake of bulletins to physicians regarding flu medications to determine "whether there were still some doctors who were a bit slow [and] still using those medications." J.A. 162 (Fisher). The FDA has acquired PI data to address concerns with drug interactions by determining "the probability that any two medications are being taken and prescribed by multiple doctors or individual doctors." *Id.* 163. PI data has also been used by public health officials "to identify overuse of antibiotics in children, for example," and "to see whether there is a wide use of anthrax prophylactic medicines after the scares that happened in 2001." J.A. 136-37 (Sadek). Researchers have used the data to attempt to establish "a surveillance system to try to predict the prevalence of disease in rural areas across the

country where there is no database that exists today." *Id.* 137.

Vermont furthermore encourages the use of PI data for law enforcement. Act 80 permits the distribution of PI data "to a Vermont or federal law enforcement officer engaged in his or her official duties." § 4631(e)(6). Principally, because analysis of PI data makes it possible to "identify overuse of a pharmaceutical in specific populations," the government employs the "data to monitor usage of controlled substances." Pet. App. 7a. For example, "a firm that sells narcotic analgesics was able to use prescriber-identifiable data to identify physicians that seemed to be prescribing an inordinately high number of prescriptions for their product and they would use that to notify the DEA and other authorities of potential problems." J.A. 204 (Kolassa).

Just as strikingly, Act 80 permits pharmacies, health insurers, and others to distribute or publish PI data without the prescriber's consent for *any* non-marketing purpose. A pharmacy is thus free under Vermont law to publish all of its PI data on the Internet without prescriber consent. Act 80 similarly permits academic researchers and governmental officials to publish the entire databases of PI data underlying their studies, as well as (for government officials) to release them in response to requests under federal and state open records laws.

Finally, the patient herself is under no constraint in her public disclosure of the prescription. Indeed, many patients do share such information with market research information such as The Nielsen Company and the Symphony IRI Group.

b. Vermont's claim that Act 80 fulfills prescribers' expectations that PI data "will not be used for purposes other than filling and processing of the payment for that prescription," 2007 Vt. Acts & Resolves No. 80, § 1(29), is obviously illusory. These many permissible uses of PI data demonstrate that there is no reasonable fit between Act 80 and a supposed state interest in giving prescribers control over the distribution of their PI data. Act 80 violates the principle that

> [w]hen a State attempts the extraordinary measure of punishing truthful publication in the name of privacy, it must demonstrate its commitment to advancing this interest *by applying its prohibition evenhandedly*, to the smalltime disseminator as well as the media giant. When important First Amendment interests are at stake, the mass scope of disclosure is not an acceptable surrogate for injury.

BJF, 524 U.S. at 540 (emphasis added). *See also id.* at 535 ("[I]t is a limited set of cases indeed where, despite the accessibility to the public of certain information, a meaningful public interest is served by restricting its further release by other entities.").

This case also closely parallels *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995), in which this Court unanimously invalidated a restriction on the display of alcohol strength on beer labels, rejecting the government's argument that the provision was necessary to prevent "strength wars" between competing brewers. The Court reasoned that the statute failed to "directly and materially advance its asserted interest because of the overall irrationality

of the Government's regulatory scheme." *Id.* at 488. For example, federal law generally permitted other advertising of the identical alcohol strength information for beer and other alcoholic beverages. The Court concluded that "these exemptions and inconsistencies bring into question the purpose of the labeling ban," given that "other provisions of the same Act directly undermine and counteract its effects." *Id.* at 489. *See also City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 429-30 (1993) (invalidating ban on commercial newsracks that made only minor contribution to city's interest in safety and appearance of sidewalks and that rested on a distinction between commercial and non-commercial newsracks that did not track those interests).

Act 80 suffers from the same flaw, and its many exceptions demonstrate that the statute's genuine purpose is to restrict free speech. As the court of appeals explained:

> 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.

Pet. App. 22a.

Of note, Act 80 does not keep PI data private from *any* party. The pharmaceutical companies who may not use the information for promotion nonetheless may acquire the identical information to engage in safety campaigns or for clinical research.

Vermont nevertheless hopes to suggest that these many other permitted uses of PI data involve "health care purposes." Vt. Br. 11. The relevant point, however, is that they are uses beyond the control of the prescriber. Moreover, they are no more related to "health care" than is pharmaceutical marketing. The State's counter-detailing program, for example, is the mirror image of pharmaceutical companies' detailing of their products.

Vermont also contends that "insurers, both public and private, have this information because of their relationships with the patients they insure." *Id.* 59. The State never explains why the directness of the relationship is relevant. But pharmacies have at least as close a relationship in the relevant respect: filling the prescription. Act 80 moreover allows all the entities that possess PI data to distribute it without consent to third parties, including pharmaceutical companies, academic researchers, public health officials, and law enforcement agents.

2. Physicians Do Not Have A Substantial Privacy Interest In The Small Degree Of Control Granted By Act 80.

The limited additional protection that Act 80 gives physicians over the distribution of information regarding their prescribing decisions is not significant enough to justify the State's prohibition on free speech. It is not surprising that forty-seven

states and the federal government do not recognize such a trivial privacy interest.

What Vermont characterizes as a supposed broad "tradition of confidentiality for all medical records," Vt. Br. 23, in fact relates to the privacy of the *patient's* medical information, including the medical advice she receives. *See id.* 31 (citing decisions recognizing importance of relationship "between doctor and patient," the "physician's communications" with the patient, and "what takes place between him and his patient"). Act 80 gives patients no control over the dissemination of PI data. That is not surprising, because this information is not comparable to personal health records.

Once patient-identifying information is removed, the prescription merely reflects a commonplace event in which the physician may engage dozens of times a day. The information essentially makes it possible for a third party to learn that a particular physician prescribes, for example, Lipitor sixty percent of the time rather than a generic equivalent, or has recently switched to favoring an alternative therapy. *See, e.g.*, J.A. 470. That is not personally sensitive information or a trade secret.

Further, as detailed in the expert testimony at trial, physicians "have no claim to privacy [in] this information" J.A. 279 (Ciongoli), because:

> [i]t's quite clear using the systems that are available in modern medicine that these decisions are widely available. The patient submits the prescription to a pharmacy. . . . The pharmacy submits the material to the insurer who is going to pa[y] for it. . . . The

> hospital on whose computer [the physician] wrote the prescription analyzes [the] prescribing behavior . . . . The formulary committee at the hospital . . . is continually reviewing physician prescribing practices . . . . So any hope that . . . information about [this] prescribing behavior would somehow be privileged or secret is – there is no basis for such a hope in the modern medical system . . . .

J.A. 178-79 (Cole). *See also* J.A. 231 (Wharton) (PI data is in the hands of the patient's "primary care physician, "insurance companies," "pharmacies," "[g]overnment agencies," "Medicare," and "ultimately scientists doing studies on populations"); J.A. 279 (Ciongoli) (no expectation of privacy because physicians "expect and receive letters from the insurance companies and from the state government, federal government, about Medicaid, Medicare, suggesting that [they] use a different drug, usually a generic that's less expensive").

The conclusion that physicians do not have a substantial privacy interest in their prescribing history is significantly reinforced by the very regulatory regime on which Vermont rests its argument. As the Solicitor General explains, "[t]o be sure, physicians' privacy interest in their prescribing practices is diminished . . . by the extensive regulation of those practices under federal and state law." U.S. Br. 29. Prescribers operate within commercial enterprises. Vermont specifically restricts the outcome of the prescribing decision in a substantial proportion of cases, such as by presumptively requiring the use of generic

alternatives. In addition, the State requires the prescriber to provide her identity on the prescriptions provided to pharmacies, which in turn are among the several types of entities that are expressly authorized to distribute PI data for numerous purposes.

The implications of Vermont's contrary view for the government's ability to remove information from the public domain are sweeping. Lawyers may prefer that third parties not know the identity of clients revealed in court filings. Engineers may have a preference that the public not learn of their approach to construction. Teachers may prefer to keep private their lesson plans. Each of these is a tool of a regulated trade, no less than a physician's preference for prescribing certain drugs. Vermont's position, however, would seemingly permit the government to limit their public discussion.

3. The Analogies Cited By Vermont Are Inapposite.

For the foregoing reasons, Vermont errs in relying on several statutes and regulatory regimes that prohibit private parties from disclosing information. All those measures satisfy constitutional scrutiny because they are not intended to restrict speech but instead consistently protect an important privacy interest. The Solicitor General all but acknowledges that, in light of all the contradictions in Vermont law, Act 80 does not function as a genuine privacy statute. "Regardless of whether [Act 80] survives constitutional scrutiny, [the] federal provisions [cited by Vermont] are distinguishable," the United States explains, such that "this Court's analysis of the 'fit' between the

Vermont's statute and the State's legislative objectives should not affect those federal provisions." U.S. Br. 34-35.

Indeed, the statutes cited by Vermont only serve to highlight that Act 80 is not tailored to fulfill an important privacy interest:

- HIPAA prohibits the non-consensual disclosure of personally identifiable health care records except for purposes of providing care or subject to a specific legal requirement, unless the patient has died. 42 U.S.C. § 1320d-6; 45 C.F.R. § 164.512. *See also* 45 C.F.R. § 164.502 (entities "must make reasonable efforts to limit protected health information necessary to accomplish the intended purpose of the use, disclosure, or request").

- FERPA prohibits educational institutions that receive federal funds from releasing personally identifiable records without consent except as necessary to provide and administer educational services or required by law. 20 U.S.C. § 1232g(b).

- The Videotape Privacy Protection Act forbids the non-consensual release of personally identifiable information except as necessary to provide video rental services or as required by law. 18 U.S.C. § 2710.

- The Telecommunications Act requires consent for the disclosure of individually identifiable information except to provide or market the company's own services or to respond to an emergency. 47 U.S.C. § 222.

- The Cable Communications Policy Act forbids the non-consensual release of personally

identifiable consumer information except to provide services to the customer or as required by the government. 47 U.S.C. § 551.

Act 80's purpose and design are fundamentally different from these measures. The goal of Vermont's statute is to restrict pharmaceutical companies' constitutionally protected speech. Act 80 moreover contains sweeping exceptions under which PI data may be provided to third parties without the prescriber's consent. For example, insurers, benefits managers, and others may acquire PI data to engage in academic detailing programs that attempt to persuade physicians about the same subjects as pharmaceutical detailing. The information protected by the federal statutes cited by Vermont is also significantly more private: it relates to individual health and consumer information, as opposed to the records of the provider of a highly regulated professional service.

Vermont also errs in contending that Act 80 cannot be distinguished from "statutes that allow consumers to avoid unwanted mail, unwanted commercial solicitations, and unwanted targeted marketing." Vt. Br. 22. In fact, those measures are very different from Act 80. The federal "Do Not Call" registry does not prevent marketers from acquiring and using analyses of consumer behavior. Conversely, Act 80 does not address the right of prescribers to refuse to meet with detailers, something they are already free to do. The distinction is critical because the measures cited by Vermont rest on the right of an individual to prevent intrusion into her home, coupled with the government's interest in preventing fraudulent

solicitations. *See Rowan v. United States Post Office Dep't*, 397 U.S. 728, 737 (1970) (upholding statute permitting individuals to block mailed solicitations because "the ancient concept that 'a man's home is his castle' into which 'not even the king may enter' has lost none of its vitality"); *Mainstream Mktg. Servs. v. FTC*, 358 F.3d 1228, 1240 (10th Cir. 2004) (upholding national do-not-call registry on ground that it "is designed to reduce intrusions into personal privacy and the risk of telemarketing fraud and abuse that accompany unwanted telephone solicitation"). Act 80 furthers neither of those interests and instead restricts the communication of truthful information about physicians' prescribing practices in violation of the First Amendment.

B. Act 80 Does Not Further A Legitimate Interest In Restricting Pharmaceutical Detailing To Induce Physicians Not To Prescribe Brand-Name Drugs.

Most of the legislative findings underlying Act 80 relate to the State's assertion that pharmaceutical detailing promotes new drugs, which it maintains are more expensive and dangerous than available alternatives. Vermont's concern is not with the accuracy of the drug companies' speech, the truth of which is heavily regulated (including through the potential imposition of criminal penalties) by the Food and Drug Administration, which "closely regulates prescription drug . . . advertising." Vt. Br. 3-4. Nor does Vermont question the legality of the products being promoted, which are similarly carefully studied and approved by the federal government.

Instead, Vermont reasons that a certain (unidentified) subset of the hundreds of brand-name drugs now legally marketed under the supervision of the FDA is dangerous and unnecessarily inflates health care costs, such that Vermonters would be healthier, and the State would spend less money, if doctors prescribed generic drugs instead. Vermont employs two measures to achieve that end: (i) Act 80, which seeks to inhibit pharmaceutical marketing; and (ii) the counter-detailing program, coupled with the related exception for formulary compliance, to encourage physicians to prescribe generic equivalents.

For the reasons that presumably will be set forth in the brief of respondent PhRMA and various supporting *amici*, the State errs in asserting that Act 80 will materially improve health-care outcomes or reduce costs and that it could not achieve those ends through less restrictive means. In sum, as the court of appeals concluded after a careful review of the record, the evidence cited by Vermont "is either speculative or merely indicates that some doctors do not approve of detailing or the use of PI data in detailing." Pet. App. 23a. Indeed, "Vermont's own expert was unaware of *any* instance in which a detailing interaction caused a doctor to prescribe an inappropriate medication." *Id.* (emphasis added).

Here, we focus on two other points. First, Vermont's effort to shape prescribing decisions violates fundamental principles about the free exchange of factual information: it both rests on a paternalistic theory that prescribers will make poor choices based on truthful information, and also impermissibly discriminates between speakers.

Second, there is no reasonable fit between the statute and its stated ends.

1. The Vermont Statutory Scheme Impermissibly Seeks To Distort The Free Flow Of Information On Prescription Drugs.

The principal theory underlying Vermont's adoption of Act 80 was that pharmaceutical detailing will cause physicians to make poor prescribing decisions. The Vermont Legislature was unusually candid. The legislative findings explain how, in its view, pharmaceutical detailing is "often in conflict with the goals of the State":

> The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one-sided nature of the marketing leads to doctors prescribing drugs based on incomplete and biased information, particularly for prescribers that lack the time to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.
>
> . . .
>
> Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.

2007 Vt. Acts & Resolves No. 80, §§ 1(3), (4), (6).

This Court has repeatedly held, including in closely analogous cases, that measures resting on

such paternalistic premises violate the Constitution. The Court's decisions reason that the very point of the First Amendment is to permit individuals to make their own choices on the basis of a free exchange of information that is not distorted by the government's antecedent judgment to limit the body of available information. "It 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." *Virginia State Bd. Of Pharm.*, 425 U.S. at 770.

In *Virginia State Board of Pharmacy*, for example, this Court rejected the State's asserted interest in preventing pharmacies from displaying drug price information, reasoning that "the State's protectiveness of its citizens rests in large measure on the advantages of their being kept in ignorance." 425 U.S. at 769. The speech restriction did "not directly affect professional standards one way or the other. It affects them only through the reactions it is assumed people will have to the free flow of drug price information." *Id.* This Court understood that the First Amendment requires "an alternative to this highly paternalistic approach. That alternative 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." *Id.* at 770.

Similarly, in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), the Court rejected the argument that the First Amendment permits the government to ban pharmacists from

advertising the availability of compounded drugs because those advertisements could lead consumers to make poor health care choices. "We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Id.* at 374. Also closely analogous is *Edenfield v. Fane*, 507 U.S. 761, 766 (1993), which invalidated a ban on in-person solicitation by certified accountants because it "threaten[ed] societal interests in broad access to complete and accurate commercial information."

The court of appeals in this case correctly recognized that Vermont's determination to "alter the marketplace of ideas by taking out some truthful information that the state thinks could be used too effectively" violates the First Amendment. Pet. App. 26a. Vermont's "assumption that doctors would prescribe unnecessary medications" on the basis of drug advertising cannot survive First Amendment scrutiny because it "amounts to a fear that people would make bad decisions if given truthful information." *Western States*, 535 U.S. at 359. If the First Amendment entrusts the pharmacy customers in *Virginia Board of Pharmacy*, the patients informed of compounded drugs in *Western States*, and the lay persons solicited to purchase accounting services in *Edenfield* with those choices, then *a fortiori* it leaves to physicians the judgment of what medicines to prescribe on the basis of the full body of available information, including truthful pharmaceutical marketing.

Having undergone training as rigorous as in any profession, prescribers are highly qualified to use the opportunity presented by the one-on-one detailing exchange to consider, challenge, and assess the information they receive. Detailers provide important information on the results of clinical trials, as well as data on the safety of products. Prescribers – who must agree to meet a detailer in the first instance – are well aware that the source of the information is the product's manufacturer. Physicians consider information "from every place it comes from, whether it's from a colleague or a publication or a pharmaceutical rep or a pharmaceutical executive or a colleague in the pharmaceutical industry, and [they] analyze as professionals that information in the context of its source with all the limitations that those sources impose." J.A. 176 (Cole). Moreover, the prescriber does not make a snap decision to prescribe a drug to her patients – unlike, for example, the sometimes immediate choice of a particular pharmacy (*Virginia Board*) or a specific accountant (*Edenfield*).

The significant imbalance that the Detailing Prohibition creates in the free flow of information to prescribers about the merits of available drug therapies is magnified by two other features of Vermont law: the State's counter-detailing program; and the exemption in Act 80 for "formulary compliance." The Detailing Prohibition inhibits the private promotion of brand name drugs to prescribers. Simultaneously, through the counter-detailing program and formulary exemption, the State finances and facilitates the speech that

encourages physicians to reject pharmaceutical marketing and instead prescribe generic alternatives.

What Vermont briefly and elliptically mentions as "an evidence-based education program for doctors," Vt. Br. 12, in fact is a program that employs PI data to locate prescribers who favor the use of brand-name therapies to urge them to use generic drugs instead. Vermont's Office of Health Access thus "collects its own prescriber-identifiable information" and "sends its own communications to prescribers using" that data, J.A. 427 (Moffatt), to "influence prescribing patterns around the state," *id.* 430. The office was directly involved in the drafting of Act 80, to ensure that "the Legislature adopted language that . . . took into account the business processes within the office of Vermont Health Access in order to avoid the situation [in which its actions] would be unlawful under Act 80." *Id.* 442-43. In counter-detailing, professionals "play the *same role* as the [pharmaceutical] sales representative, usually to promote the use of generics or alternative products." J.A. 212 (Kolassa) (emphasis added).

The statute's parallel "formulary compliance" exemption permits insurers and health benefits managers (including the State itself) to use PI data to pursue the same state-sponsored end. *See, e.g.*, J.A. 211 (Kolassa) ("[I]nsurance companies are using physician-identifiable information to call physicians to try to get them to comply with . . . formularies, [to] try to get them to change their prescribing in a way that may or may not be in the patient's best interests."). "[I]n just the last couple of years," there has been an "amazing" increase in "the amount of information provided by payers, insurers that will

send scientific documents to physicians, will call when physicians are prescribing too much or too little of a product and provide them with information." *Id.* 206 (Kolassa). "Virtually several times a day," a medical practice will "have the experience of insurance companies putting pressure. . . to use one drug instead of another drug." J.A. 231-32 (Wharton). The payers, including Vermont itself, engage in "overt and explicit pressure" in order "to influence behavior . . . to choose the most economical agents that meet[] the need." J.A. 177-78 (Cole).

The State's favoritism of its own viewpoint and that of insurers while simultaneously hobbling the contrary view of pharmaceutical companies violates the First Amendment. The Constitution does not permit the government to so dramatically tilt such a vital debate. "Even under the degree of scrutiny that we have applied in commercial speech cases, decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment." *Greater New Orleans Broad. Ass'n*, 527 U.S. at 193-94.

The government specifically may not inhibit speech on the ground that it considers its influence to be outsized because of the economic forces promoting it. *E.g.*, *McConnell v. FEC*, 540 U.S. 93, 217-18 (2003); *FEC v. Mass. Citizens for Life, Inc.*, 479 U.S. 238, 263 (1986); *Buckley v. Valeo*, 424 U.S. 1, 39-51 (1976). (Vermont's invocation of the fact that pharmaceutical marketers nationally "spend close to $8 billion annually (excluding the cost of free samples) marketing drugs to doctors," Vt. Br 10; 2007 Vt. Acts & Resolves No. 80 § 1(17), is also quite

misleading. The state medical society's resolution endorsing Act 80 explained that "the most recent report by the Vermont Attorney General shows that marketing to physicians by pharmaceutical manufacturers in Vermont for July 1, 2004 – June 30, 2005 totaled $2.17 million." J.A. 376.)

Vermont's interpretation of the First Amendment would in this and many other contexts permit legislatures, which often are the subject of enormous economic influences, to choose one side or the other in economic and social debates through manipulation of free speech, rather than direct regulation. That is a significant temptation. Direct regulation has a substantial and immediate effect on the public and may produce an electoral response. Here, Vermont could have regulated the relevant brand-name drugs, by seeking to forbid state-licensed pharmacists from filling prescriptions for those medications and/or by regulating pharmaceutical prices directly. But instead it chose the significantly less direct route of seeking to influence physicians' prescribing decisions. If Vermont were to actually *ban* the (unidentified) drugs to which it objects, or if it were to force their sale at a price too low for the market to sustain, the many patients who use those drugs would immediately protest and potentially work to vote out of office the legislators who passed such a measure. The Vermont Legislature instead is able to hide behind Act 80 as supposedly nothing more than an effort to combat the supposedly excessive wealth and outsized influence of "big pharma."

Vermont's answer is that Act 80 is not paternalistic because the statute leaves it to the

prescriber to decide whether to permit the use of her PI data in marketing. That is incorrect for two reasons. First, the statute requires the prescriber to make an affirmative request to opt in to the use of her prescribing history for marketing. Act 80 will forbid this use of PI data for the great many prescribers who are agnostic about this practice or who favor it but are uninformed about the statute's operation.

Second, the prescriber's choice rests on a different ground than the paternalistic interest asserted by Vermont. As discussed above, certain physicians object to the use of PI data on the ground that the information should be kept private from drug companies. Those physicians in the main do *not* seek to prevent detailers from providing them with information – a goal that can be addressed through the decision whether to accept detailing meetings. Vermont, by contrast, asserts here an interest in actually inhibiting pharmaceutical companies from providing truthful information about new drugs to prescribers, on the theory that this information will influence the prescribing decision. That is a wholly paternalistic judgment that the State may not make under the First Amendment.

2. Because Act 80 Does Not Prohibit Detailing And Is Not Targeted At More Expensive And Dangerous Drugs, There Is No Reasonable Fit Between The Statute And The State's Health-Care-Related Interests.

Act 80 is also invalid because there is no reasonable fit between the statute and Vermont's

assertion that pharmaceutical detailing results in the over-prescription of brand-name drugs that are too expensive and dangerous.

a. Act 80 is obviously not tailored to the State's interests at all. The statute seeks to inhibit the detailing of *all* brand-name drugs, but Vermont gives no indication whether its interest lies in restricting the promotion of one, five, ten, twenty, or fifty percent of them. Although the State argues that there is "evidence about specific drugs that are or have been widely over-prescribed," Vt. Br. 50, Vermont does not identify more than a handful of the hundreds of brand-name drugs that are currently marketed with FDA approval.

As the Second Circuit explained, "[t]he 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." Pet. App. 30a. There is thus every reason to believe that, with respect to detailing of the overwhelming majority of drugs, the constitutionally protected speech that the statute restricts does not implicate – or actually undermines – the State's interests. The State's position is indistinguishable from the claim that because "some" unidentified subset of cars or foods is dangerous, the government has a sufficient interest to restrict the advertising of all such products, even the many that improve health and safety.

With respect to the State's interest in drug safety, the State's own expert acknowledged that the statute "applies equally to those drugs that are very beneficial to patients and those that might not be." J.A. 374 (Kesselheim). It thus "certainly" would

apply equally to "newly approved drugs which do offer therapeutic improvements over existing drugs," *id.* 352, drugs that "are widely used because of their clinical advancements," *id*. 372, and drugs that "have an improved record of" showing that "patients are more likely to take them as prescribed," which "is important in the prescription of drugs," *id*. 372-73. The expert simply thought "we should give it a shot." *Id*. 375.

Given the rigor of FDA review, Vermont likely has an interest in limiting promotion of only a few – if any – drugs, and the State itself has no idea which those are. With respect to the many other drugs that improve health – as in the BANZEL example above – the statute plainly undermines Vermont's stated goal of improving public health. As the Solicitor General explains:

> Vermont's position depends on the unwarranted view that the dangers of such new drugs outweigh their benefits to patients. Introduction of a new drug requires approval by the FDA, which in turn requires a showing by the manufacturer that the drug is safe and effective for its intended uses in accordance with its labeling.

U.S. Br. 24 n.4.

With respect to cost, Vermont also does not even hint at what proportion of available drugs prescribers should pass over in favor of less expensive therapies, given that the State already "requires pharmacists to dispense a generic form of a drug if available, unless the prescriber requires a brand-name drug." Vt. Br. 4 (citing Vt. Stat. Ann. tit. 18, §§ 4605-06). The State's

expert admitted that Act 80 applies "even when the data would not lead to lower health care costs," because "a brand name drug has no generic equivalent" and "is not the most expensive treatment." J.A. 207 (Kolassa).

Moreover, the State has made no showing that the particular drugs that it believes should not be promoted are in fact the subject of detailing visits using PI data. Many or even most may be promoted only through other forms of advertising. It is impossible to know only because Vermont has no idea which drugs it is actually targeting.

It is therefore not surprising that the State's experts at trial *admitted* that they could not provide "any information about the possible effects of [the statute]," because they did not "have any information about prescriber-identifiable data." J.A. 292-93 (Wazana). They did not have "enough evidence to [state] a substantive opinion" about the statute's cost savings, and offered "no opinion about whether a restriction on prescriber-identifiable data could improve public health." J.A. 339 (Rosenthal). They had "never done a study of prescriber-identifiable data," and relied on literature that had not "assessed in an empirical way [whether] the limits on prescriber data will result in increases or decreases in health costs." J.A. 371 (Kesselheim).

The contrary finding adopted by the Vermont Legislature does not rest on a sound evidentiary basis. The Legislature cherry-picked literature that would support its conclusions. J.A. 257 (Turner). "The literature that's included doesn't include any empirical analysis of prescriber-identifiable data and its relations to health care costs or health care

outcome[s] . . . . [A]t least one of the state's own witnesses says as much." *Id.* The Legislature also focused exclusively on "drugs that were known to be harmful," such as Vioxx, "[b]ut no drugs that have significant therapeutic benefits were ever examined in terms of the impact of the use of prescriber-identified data in detailing. So there was a selection bias in the cases." *Id*. 259.

b. Act 80 is also grossly underinclusive. Vermont argues that "*[d]etailing* encourages doctors to prescribe newer, more expensive, and potentially more dangerous drugs," and that "*marketing* has a proven effect on prescribing decisions." Vt. Br. 49 (quotation omitted) (emphases added). But the State freely permits detailing and other forms of marketing – a point it makes repeatedly in an attempt to suggest that the statute imposes a minimal First Amendment burden. The State has shown no correlation between the one marketing practice restricted by the statute – the use of PI data to tailor detailing messages – and the unnecessary prescribing of more dangerous or unnecessarily expensive drugs.

Further, Act 80 permits even detailing using PI data if the prescriber consents. If the State were consistently pursuing its health-care-related interests, it would not have enacted such a significant exception.

To be sure, Act 80 seeks to make detailing more difficult. But the State's own expert confirmed that a detailer who was "not using prescriber data could still overstate the benefits of the drug." J.A. 372 (Kesselheim). In addition, pharmaceutical manufacturers will compensate for the loss of PI data by expanding other marketing efforts, strongly

suggesting that the statute may accomplish nothing beyond increasing drug companies' marketing costs. When asked, the pharmaceutical companies responded with a "consensus" that was "consistent and unequivocal that if there were a data restriction they would have to increase detailing not decrease detailing." J.A. 269 (Turner). The effect of this greater volume of detailing visits will merely be to disrupt medical practices. J.A. 208 (Kolassa) ("Without physician-identifiable data, they'll continue to market" – not "less effectively, but certainly less efficiently. There will be more sales calls that result in talking to physicians that aren't interested in the product.").

c. Act 80 also functions irrationally because it simultaneously pursues irreconcilable goals. On the one hand, the statute seeks to promote the development (and presumably the subsequent distribution) of new drugs by freely permitting use of PI data without the prescriber's consent by pharmaceutical companies for "health care research," including for "clinical trials." § 4631(e)(1), (4). Vermont thus recognizes the value of PI data for identifying physicians who treat patient populations that can play a useful role in developing new drug therapies. But when that clinical trial is deemed a success, and the FDA approves the marketing of the drug as safe and effective, Act 80 forbids that very drug company from using the same prescription-history information for the purpose of marketing the valuable drug that the company developed using the data. *See* Vt. Br. 39.

The conflict between Act 80's inconsistent goals is palpable. The statute permits a drug company to

use PI data to help identify a pool of patients to assist in the development of a new therapy through a clinical trial. But the company – which knows about the patient population through PI data – cannot then advise the patients' physician about the availability of the potentially lifesaving product that they helped to develop. That makes no sense at all.

CONCLUSION

For the foregoing reasons, the decision of the United States Court of Appeals for the Second Circuit should be affirmed.

Respectfully submitted,

Thomas R. Julin
Jamie Z. Isani
Patricia Acosta
HUNTON & WILLIAMS LLP
1111 Brickell Ave.
Suite 2500
Miami FL 33131

Robert B. Hemley
Matthew B. Byrne
GRAVEL AND SHEA
76 St. Paul St., 7th Fl.
Burlington, VT 05402

Thomas C. Goldstein
Counsel of Record
Kevin K. Russell
Amy Howe
Tejinder Singh
GOLDSTEIN, HOWE & RUSSELL, P.C.
7272 Wisconsin Ave.
Suite 300
Bethesda, MD 20814
(301) 941-1913
tgoldstein@ghrfirm.com

March 24, 2011

APPENDIX

ACT 80 LEGISLATIVE FINDINGS

The general assembly makes the following findings:

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

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

(3) The goals of marketing programs are often in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals comes at the expense of cost-containment activities and possibly the health of individual patients.

(4) The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one-sided nature of the marketing leads to doctors prescribing drugs based on incomplete and biased information, particularly for prescribers that lack the time to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.

(5) The federal Food and Drug Administration (FDA) requires marketing and advertising to be fair and balanced; however, the FDA has limited legal ability to enforce this requirement.

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

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

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

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

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

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

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

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

(13) Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatments for particular conditions. Because of this, physicians frequently rely on information provided by pharmaceutical representatives.

(14) Nearly one-third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors'

prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased therapeutic value. According to the same study, the use of more expensive drugs contributed to 36 percent of the rise in retail prescription spending in 2000 and 24 percent in 2001.

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

(16) According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost $2.2 million to prescribers in Vermont, including consulting fees and travel expenses in 2005. Estimates of total costs of marketing to prescribers in Vermont are $10 million or more, excluding free samples and direct-to-consumer advertising.

(17) In 2004, the pharmaceutical industry spent $27 billion marketing pharmaceuticals in the United States, and spent more than any other sector in the United States on its sales force and media advertising. Over 85 percent of these marketing expenditures are directed at the small percentage of the population that practice medicine.

Pharmaceutical manufacturers spend twice as much on marketing as on research and development.

(18) Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug representatives. It is estimated that there is a pharmaceutical sales representative for every five office-based physicians.

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

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

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

by Chew et al. in the Journal of General Internal Medicine in 2000.

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

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

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

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

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

(27) Added and unwanted pressure occurs when doctors are informed by sales representatives that they are being monitored through messages of appreciation for writing prescriptions, or messages of disappointment that they are not prescribing what was implicitly promised.

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

(29) Health care professionals in Vermont who write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing of the payment for that prescription. Prescribers and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

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

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

TEXT OF § 4631.

§ 4631. Confidentiality of prescription information

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

(b) As used in this section:

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

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

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

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

(5) "Marketing" shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

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

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

(8) "Promotion" or "promote" means any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.

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

(c)(1) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber

to give consent for his or her identifying information to be used for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber's consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent. The department and office may establish rules for this program.

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

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

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

(1) the sale, license, exchange for value, or use, of regulated records for the limited purposes of

pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; or health care research;

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

(3) the transmission of prescription information between an authorized prescriber and a licensed pharmacy, between licensed pharmacies, or that may occur in the event a pharmacy's ownership is changed or transferred;

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

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

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

(7) the sale, license, exchange for value, or use of patient and prescriber data for marketing or promoting if the data do not identify a prescriber, and

there is no reasonable basis to believe that the data provided could be used to identify a prescriber.

(f) In addition to any other remedy provided by law, the attorney general may file an action in superior court for a violation of this section or of any rules adopted under this section by the attorney general. The attorney general shall have the same authority to investigate and to obtain remedies as if the action were brought under the Vermont consumer fraud act, chapter 63 of Title 9. Each violation of this section or of any rules adopted under this section by the attorney general constitutes a separate civil violation for which the attorney general may obtain relief. (Added 2007, No. 80, § 17; amended 2007, No. 89 (Adj. Sess.), § 3, eff. March 5, 2008; 2009, No. 59, § 1.)

EVIDENCE-BASED EDUCATION PROGRAM

§ 4621. Definitions

Except as otherwise specified, for the purposes of this subchapter:

(1) "Department" means the department of health.

(2) "Evidence-based" means based on criteria and guidelines that reflect high-quality, cost-effective care. The methodology used to determine such guidelines shall meet recognized standards for systematic evaluation of all available research and shall be free from conflicts of interest. Consideration of the best available scientific evidence does not preclude consideration of experimental or investigational treatment or services under a clinical investigation approved by an institutional review board.

§ 4622. Evidence-based education program

(a)(1) The department of health, in collaboration with the attorney general, the University of Vermont area health education centers program, and the department of Vermont health access, shall establish an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the extent practicable, the program shall use the evidence-based standards

developed by the blueprint for health. The department of health may collaborate with other states in establishing this program.

(2) The program shall notify prescribers about commonly used brand-name drugs for which the patent has expired within the last 12 months or will expire within the next 12 months. The departments of health and of Vermont health access shall collaborate in issuing the notices.

(3) To the extent permitted by funding, the program may include the distribution to prescribers of vouchers for samples of generic medicines used for health conditions common in Vermont.

(b) The department of health shall request information and collaboration from physicians, pharmacists, private insurers, hospitals, pharmacy benefit managers, the drug utilization review board, medical schools, the attorney general, and any other programs providing an evidence-based education to prescribers on prescription drugs in developing and maintaining the program.

(c) The department of health may contract for technical and clinical support in the development and the administration of the program from entities conducting independent research into the effectiveness of prescription drugs.

(d) The department of health and the attorney general shall collaborate in reviewing the marketing activities of pharmaceutical manufacturing companies in Vermont and determining appropriate

funding sources for the program, including awards from suits brought by the attorney general against pharmaceutical manufacturers.