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

BRIEF FOR RESPONDENT PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

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QUESTION PRESENTED

With the express goal of rectifying a perceived "imbalance" in speech favoring brand-name pharmaceuticals in the "marketplace for ideas," Vermont law bars the commercial exchange of information about doctors' historical prescribing practices for marketing or promoting a prescription drug, and the law similarly bars pharmaceutical manufacturers from marketing or promoting a prescription drug to doctors when such speech is based on information about the doctors' historical prescribing practices. 18 V.S.A. § 4631(d). The question presented is whether the Vermont law violates the First Amendment.

RULE 29.6 STATEMENT OF CORPORATE DISCLOSURE

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

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STATEMENT

Vermont enacted the law at issue in this case with the express purpose to correct what the legislature perceived as the "massive imbalance in information presented to doctors and other prescribers." Pet. App. 135a (Vt. Acts No. 80 § 1(6)). Section 17 of Act 80, as amended by Act 89, prohibits the private commercial exchange of records containing prescriber-identifiable data "for marketing or promoting a prescription drug" unless a prescriber consents. 18 V.S.A. § 4631(d). That provision also states that "pharmaceutical manufacturers and pharmaceutical

marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug" unless the prescriber consents. *Id*.

The Second Circuit correctly held that section 17 violates the First Amendment. The court of appeals explained that section 17 "seeks to alter the marketplace of ideas by taking out some truthful information that the state thinks could be used too effectively." Pet. App. 26a. The law imposes civil penalties on pharmaceutical companies, and only pharmaceutical companies, that speak to doctors using prescriber-identifiable data. Section 17 thus does not impose such penalties on speakers the State favors, such as insurance companies and academics, who are free under the law to use prescriber-identifiable data for commercial purposes without penalty. Nevertheless, the decision below conflicts with the decisions of the First Circuit involving substantially similar speech restrictions, and the question presented is an issue of recurring importance. This Court's review would therefore be appropriate.

A. The Pharmaceutical Marketplace

1. Respondent PhRMA is a non-profit association of the country's leading research-based pharmaceutical and biotechnology companies that produce brand-name prescription drugs. PhRMA's members develop and manufacture life-saving and life-enhancing new medicines that are promoted, prescribed, and sold in Vermont and throughout the country and in many parts of the world.

Research-based pharmaceutical and biotechnology companies are responsible for almost all innovation in prescription drugs. PhRMA's member companies

invest billions in research and development every year—approximately $45.8 billion in 2009—as they strive to develop new life-saving products. *See* PhRMA, *2010 Pharmaceutical Industry Profile* 26 (2010), *available at* http://www.phrma.org/profiles_and_reports. Brand-name pharmaceutical companies invest on average $2 billion to develop a new drug. C.A. App. 137. Generic drug manufacturers, by contrast, do not conduct independent research or development of new drugs, but rather produce unbranded versions of brand-name drugs once the drug's patent protection expires. *Id.* at 157. Developing and obtaining approval of a generic drug generally costs between $100,000 and $500,000. *Id.* at 140, 149.

Pharmaceutical manufacturers communicate with physicians and other health care professionals about their drugs through a variety of means, including one-on-one discussions between individual pharmaceutical company representatives and doctors and other prescribers about specific prescription drugs. This practice is sometimes called "detailing," *i.e.*, the "face to face advocacy of a product by sales representatives." Pet. App. 72a (quoting *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 71 (1st Cir. 2008) (Lipez, J. concurring)); *see also id*. at 71a ("Sales representatives provide 'details' regarding the use, side effects and risk of interactions of the drug they are selling.").

Manufacturers tailor their communications with doctors based on a doctor's prescribing history or "prescriber-identifiable data." Pet. App. 91a; *see also id.* at 18a. When pharmacies in Vermont and other States fill a prescription, the pharmacies store information in their computer systems about that prescription, including the prescriber's name and

address; the drug's name, dosage, and quantity; the date and place the prescription is filled; and the patient's age and gender. *Id.* at 5a. For a profit, pharmacies then sell this information to various companies, including respondents IMS Health, Inc., Verispan, LLC, and Source Healthcare Analytics, Inc. (collectively, "IMS"). IMS aggregates the data to reveal the prescribing history for each individual physician and offers the information for sale to pharmaceutical companies and other purchasers. *Id.*

Manufacturers purchase prescriber-identifiable data to identify the set of prescribers who would be most interested in their educational messages about the medicines they offer and to tailor their messages to the needs of the particular prescriber. *Id.* at 6a. For example, a pharmaceutical representative who specializes in diabetes medicines may use prescriber-identifiable data to identify those physicians in her region who write a significant number of prescriptions for diabetes or cardiology medications (and thus, likely treat a large number of diabetes patients). Thus, as the Attorney General of Vermont asserted to the district court, drug manufacturers use prescriber-identifiable data for their "targeted marketing campaigns . . . to sway doctors' prescribing practices." *Id*. at 81a; *id*. at 81a-82a ("It allows them to target doctors [and] target messages. . . . And these techniques work . . . .").

Pharmaceutical manufacturers also use prescriber-identifiable data to direct scientific and safety messages regarding particular drugs to physicians. *Id.* at 6a. For example, when a company identifies a new side effect or risk associated with a medicine or changes the labeling of a prescription drug, it often alerts prescribers of the development through "Dear

Healthcare Professional" letters. The manufacturer identifies recipients of these mailings using prescriber-identifiable data. Manufacturers also use prescriber-identifiable data to ensure that pharmaceutical representatives reinforce the information contained in safety communications with those doctors who prescribe the product. *See* C.A. App. 215, 3153-54, 3159-60, 3402-03, 3754-55.

Vermont concedes that communications by pharmaceutical company representatives to prescribers are truthful and not misleading. Pet. App. 21a. Moreover, many doctors find discussions with pharmaceutical representatives useful for determining the appropriate drug for a particular medical condition. *Id*. at 71a-72a; C.A. App. 123-25, 173, 196-97. Choosing an appropriate drug for a patient requires knowledge of the treatment options, including not only the side effect profiles of drugs, but also their potential interactions with other medications, as well as medical guidelines for the appropriate treatment of specific disorders, the evolving medical literature, and other new developments. C.A. App. 122-23, 161-62, 192-95. Physicians obtain this information from many sources, including medical journals, scientific meetings, colleagues, and pharmaceutical representatives.

Act 80 thus contains a finding that "physicians frequently rely on information provided by pharmaceutical representatives" in determining "which drugs are the best treatment for particular conditions." Pet. App. 136a (Vt. Acts No. 80 § 1(13)). Doctors who do not find communications with pharmaceutical representatives useful can and do choose not to interact with representatives. C.A. App. 125, 173, 299.

2. While manufacturers are the primary purchasers of prescriber-identifiable data, other entities purchase or use prescriber-identifiable data to facilitate their communications with prescribers. For example, private insurance companies and government-sponsored healthcare programs, such as Medicare or Medicaid, use prescriber-identifiable data to induce physicians to prescribe generic drugs. Pet. App. 7a. An insurance company, to increase its profits, might have a representative contact a prescriber who has high rates of prescribing brand-name drugs to try to influence the doctor to prescribe drugs that cost the insurance company less money. C.A. App. 123, 188, 3032-33, 3051-52.

Insurance companies and government healthcare programs use prescriber-identifiable data in other ways to encourage the prescription of generic drugs. For example, insurance companies and health care programs have adopted lists of drugs for which they will reimburse the patient or provider (termed "formularies") to encourage the prescription of the least expensive drug that is medically appropriate for the patient. *Id.* at 267, 286. Insurance companies and healthcare programs offer lower co-payments for generic or lower cost drugs, creating financial pressure for patients to request and doctors to prescribe those preferred drugs. *Id.* at 123, 265-69. Some health insurance plans have adopted "step therapy" requirements, under which the plan will cover the cost of a brand name drug only after the prescriber initiates treatment with a generic drug or lower cost alternative and that initial therapy fails. *Id.* at 353, 3051-52.

And insurance companies and programs often bar prescriptions of a brand-name drug for which there is a generic or lower cost alternative unless the company or program gives "prior authorization" in advance. *Id.* at 123, 267-68. These insurance companies and health care programs enforce compliance with formularies, step therapy, and prior authorization requirements by reviewing prescriber-identifiable data and contacting those doctors who continue to prescribe brand-name products (which may be on the higher tier of the formulary) or who have a higher than average number of requests for prior authorization. Pet. App. 7a; C.A. App. 287.

B. Section 17's Discriminatory Restrictions On Speech

1. Section 17 bars speech based on prescriber-identifiable data *solely* when that speech promotes prescription drug marketing or promotion and *solely* when the speech is by pharmaceutical manufacturers. Thus, section 17 does not restrict the use of prescriber-identifiable data for promotional activities except when undertaken by pharmaceutical manufacturers, including the marketing of prescription drugs by speakers other than pharmaceutical manufacturers. Pet. App. 6a ("[P]harmaceutical manufacturers and marketers are the only customers banned from using PI data in their marketing efforts by section 17."). Moreover, section 17 expressly permits the for-profit exchange of prescriber-identifiable data by insurance companies and state healthcare programs to ensure compliance with their formularies. 18 V.S.A. § 4631(e)(1).

Vermont enacted the speech restrictions in section 17 with the explicit intent to correct what the legislature perceived was a "massive imbalance in informa-

tion presented to doctors and other prescribers." Pet. App. 135a (Vt. Acts No. 80 § 1(6)). Finding that "[t]he marketplace for ideas on medicine safety and effectiveness is frequently one-sided," *id.* (Vt. Acts No. 80 § 1(4)), Vermont enacted section 17 with the express intent of altering pharmaceutical manufacturers' communications to prescribers regarding their products.

To further this improper goal, section 17 provides that "[p]harmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents." 18 V.S.A. § 4631(d). Section 17 also prohibits the sale, license, or exchange of prescriber-identifiable data by specified entities, including "an electronic transmission intermediary" such as IMS, unless the prescriber consents. *Id.* Entities such as IMS also may not "permit the use of" prescriber-identifiable data for "marketing or promoting a prescription drug," unless the prescriber consents. *Id.*

Section 17 defines "marketing" to include:

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

Id. § 4631(b)(5). "Promotion" is in turn broadly defined to include "any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement

or announcement, poster, free sample, detailing visit, or personal appearance." *Id.* § 4631(b)(8). Thus, section 17's prohibition against speech by pharmaceutical manufacturers is so overbroad that it potentially prohibits a manufacturer from using prescriber-identifiable data to convey to prescribers recent peer-reviewed scientific literature or to communicate to prescribers safety or risk information.

Drug manufacturers that engage in speech in Vermont based on prescriber-identifiable data are subject to substantial penalties. Violations of Section 17 subject manufacturers to penalties under the Vermont Consumer Fraud Act. *Id.* § 4631(f); 9 V.S.A. § 2466a(a). These penalties include, but are not limited to, civil penalties of not more than $10,000 for each violation. 9 V.S.A. § 2458(b)(1). The Act also authorizes the Attorney General of Vermont to seek a temporary or permanent injunction. *Id.* § 2458(a).

2. Section 17 expressly permits speech based on prescriber history information for 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." 18 V.S.A. § 4631(e)(1). Thus, while Section 17 bars a pharmaceutical representative, based on prescriber-identifiable data, from discussing a brand name drug with a doctor, the law permits a health insurer, with no less commercial motive and based on that same prescriber-identifiable data, to encourage the same doctor to prescribe generic drugs as part of the insurer's "prescription drug formulary compliance." *Id.*

C. Proceedings Below

1. On October 22, 2007, PhRMA filed this suit for declaratory and injunctive relief in the United States District Court for the District of Vermont, on the ground that section 17 violated the First and Fourteenth Amendments to the United States Constitution. Following an evidentiary hearing, the district court denied respondents' motions for declaratory and injunctive relief. Pet. App. 68a-118a. The court recognized that section 17 restricts the speech of both pharmaceutical manufacturers and IMS. *Id.* at 80a-82a. In fact, the court explained that "the whole point of section 17 is to control detailers' commercial message to prescribers." *Id*. at 82a.

The district court held, however, that the law survived First Amendment scrutiny under the factors identified for commercial speech restrictions. Pet. App. 87a. In so holding, the court found that "[t]he law is sustainable on the State's cost containment and public health interests, which are substantial, but prescriber privacy is not a sufficient interest to justify the law." *Id*.; *cf. id*. at 88a (declining to address asserted interest in protecting prescriber privacy).

2. A divided panel of the Second Circuit reversed. *Id.* at 1a-67a. The majority agreed with the district court that section 17 restricts speech. *Id*. at 14a-17a. The Second Circuit then analyzed section 17 as a restriction on the commercial speech of pharmaceutical manufacturers and IMS and found that section 17 failed the *Central Hudson* test. *Id.* at 17a-20a.

The court of appeals rejected the State's asserted interest in "protecting the privacy of prescribers and prescribing information." *Id.* at 22a-23a. The court explained that "the statute does not ban any

use of the data other than for marketing purposes, including widespread publication to the general public" and that "the concern that patient information can be gleaned from [prescriber-identifiable] data is not reduced in any way by section 17." *Id*. at 22a.

And, although the court of appeals determined that Vermont's cost containment and public health interests were substantial government interests, the court concluded that the Vermont statute does not "advance the state's interest in public health and reducing costs in a direct and material way." *Id.* at 24a. The court observed that "the statute restricts protected speech when uttered for purposes the government does not approve of in order to reduce the effectiveness of marketing campaigns and, ultimately, alter the behavior of prescribers, who are not regulated by the statute. This route is too indirect to survive intermediate scrutiny." *Id.* at 28a.

The court of appeals also concluded that section 17 is "a poor fit with the state's goal to regulate new and allegedly insufficiently tested brand-name drugs in cases where there are cheaper generic alternatives available." *Id.* at 29a. The court reasoned that "the statute restricts speech even with regard to prescriptions of breakthrough brand-name medications for which there are no generic alternatives, and because the state could pursue alternative routes that are directly targeted at encouraging the use of generic drugs." *Id.* at 33a.

Judge Livingston dissented. *Id.* at 35a-67a. In her view, section 17 reflects "a legitimate restriction on access to information and commercial conduct with few, if any, attenuated effects on First Amendment activity." *Id*. at 66a.

ARGUMENT

The court of appeals correctly held that section 17 infringes upon the speech of pharmaceutical manufacturers and fails intermediate scrutiny under *Central Hudson*. PhRMA nevertheless agrees with petitioner that this Court's review would be appropriate. The courts of appeals are divided on the question of whether state laws that have the effect of prohibiting pharmaceutical representatives from communicating with doctors when their speech is tailored based on prescriber-identifiable data violate the First Amendment. Moreover, the question presented here is a recurring one, as three States have enacted similar laws and several other States have considered or may be considering their own prescriber-identifiable data restrictions.

A. The Court Of Appeals Correctly Held That Section 17 Of Act 80 Impermissibly Restricts The Speech Of Pharmaceutical Manufacturers

1. The Second Circuit and the district court were both correct in analyzing section 17 as a restriction on speech. Pet App. 14a-17a; *id.* at 79a-82a. As the court of appeals recognized, there are two forms of speech at issue in this case: IMS's communication of its aggregated prescriber-identifiable data, and the subsequent speech by pharmaceutical manufacturers to prescribers. *Id.* at 18a. While PhRMA agrees that the court of appeals correctly determined that section 17 restricts IMS's speech, PhRMA focuses here on the distinct speech interest of pharmaceutical manufacturers and pharmaceutical marketers that section 17 clearly restricts.

The imposition on pharmaceutical manufacturer speech is evident on the face of the law. The legislative findings expressly admit that Vermont intended section 17 to rectify what the legislature adjudged the "one-sided nature" of the free "marketplace for ideas on medicine safety and effectiveness." Pet. App. 134a (Vt. Acts No. 80 § 1(4)). Toward that end, section 17 bars a pharmaceutical manufacturer from marketing and promoting its drugs based on prescriber-identifiable data, but permits other entities, including private health insurers and government-sponsored healthcare programs, to use the very same information in their communication efforts to promote the use of generic drugs. 18 V.S.A. § 4631(d), (e)(1). In fact, in the same bill that contained section 17, the Vermont legislature funded an academic detailing program that uses prescriber-identifiable data to educate doctors about the State's views on the appropriate prescription of brand-name and generic drugs. 18 V.S.A. § 4622; 33 V.S.A. § 2004.

In other words, an insurer, for commercial reasons, can use the prescriber-identifiable data to tell a physician, "Consider prescribing a generic drug," while a pharmaceutical company, with no greater commercial motive, cannot use the same information to tell the same physician, "Consider prescribing our branded drug." Thus, section 17 seeks to suppress the disfavored viewpoint of pharmaceutical manufacturers by limiting their speech. As the court of appeals observed, the Vermont legislature's explicit intent to "put the state's thumb on the scales of the marketplace of ideas in order to influence conduct . . . is antithetical to a long line of Supreme Court cases stressing that courts must be very skeptical of government efforts to prevent the dissemination of

information in order to affect conduct." Pet. App. 25a-26a.

Furthermore, each court that has analyzed the effect on pharmaceutical manufacturers of laws limiting the transmission and use of prescriber-identifiable data has concluded that such laws restrict the manufacturers' speech. Pet App. 14a-17a; *id.* at 79a-82a; *IMS Health, Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007); *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2008). Section 17 also imposes penalties on pharmaceutical companies that promote their medicines to physicians after using prescriber-identifiable data. 18 V.S.A. § 4631(d), (f). Indeed, the purpose of the law, and the only way for it to work as the legislature intends, is to dilute the message of pharmaceutical companies to physicians. Thus, as the district court noted, "the whole point of section 17 is to control detailers' commercial message to prescribers." Pet. App. 82a.

2. Although the court of appeals was ultimately correct in striking down section 17, the court erred in holding that the law restricts purely commercial speech. Relying on this Court's decision in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983), the Second Circuit held that "the mere presence of non-commercial information . . . does not transform the communication into fully protected speech." Pet. App. 19a. Therefore, "although some of the information communicated by detailers might be fully protected in another context," the court analyzed section 17 as a restriction on the commercial speech of pharmaceutical manufacturers. *Id.*

As the Second Circuit recognized, however, the all-encompassing definitions of "marketing" and "promotion" in section 17 sweep in communications between

pharmaceutical manufacturers and prescribers regarding medical conditions that prescribers treat and regarding a company's innovative treatments for those conditions. *Id.* The law thus potentially encompasses educational, safety, and risk communications about a company's medicines. *See supra* pp. 4-5; 18 V.S.A. § 4631(b)(5), (8). Thus, the "marketing and promotion" covered by the Vermont Act extends to communications far beyond those proposing a commercial transaction.

Given that any commercial message by pharmaceutical manufacturers is "inextricably intertwined with otherwise fully protected speech," the communications as a whole are subject to strict scrutiny. *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988). This case provides an appropriate vehicle for this Court to make clear that speech by pharmaceutical manufacturers that provides prescribers with information regarding drug safety and treatments for medical conditions is subject to strict scrutiny, even if it is presented in the context of marketing or promoting a prescription drug.

3. Assuming *arguendo* that section 17 restricts solely commercial speech, the majority correctly held that section 17 cannot survive intermediate scrutiny. "[T]he First Amendment stands against attempts to disfavor certain subjects or viewpoints. Prohibited, too, are restrictions distinguishing among different speakers, allowing speech by some but not others." *Citizens United v. Federal Election Comm'n*, 130 S.Ct. 876, 898 (2010) (internal citations omitted); *see also United States v. Stevens*, 130 S.Ct. 1577, 1584-85 (2010) ("[T]he First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its

content [and its] guarantee of free speech does not extend only to categories of speech that survive an ad hoc balancing of relative social costs and benefits."). "While the law is free to promote all sorts of conduct in place of harmful behavior, it is not free to interfere with speech for no better reason than promoting an approved message or discouraging a disfavored one, however enlightened either purpose may strike the government." *Hurley v. Irish-American Gay, Lesbian and Bi-Sexual Group of Boston*, 515 U.S. 557, 579 (1995). Nor does the First Amendment permit the government to play favorites by silencing the speakers it dislikes while blessing speech by speakers the government favors. *See Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 193-94 (1999) ("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.").

In particular, the government may not impede the dissemination of truthful information based on a paternalistic prediction that the speech may lead others—in this case, highly trained medical professionals—to make decisions the State does not like. The First Amendment requires reviewing courts "to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996). "[T]he speaker and the audience, not the government, [should] assess the value of the information presented." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993); *accord Greater New Orleans*, 527 U.S. at 195 (noting the "presumption that the speaker and the audience, not the Government, should be left to assess the

value of accurate and non-misleading information about lawful conduct").

In *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), for example, this Court invalidated a federal ban on advertising compounded drugs that the government believed "would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway." *Id*. at 374. The Court rejected "the questionable assumption that doctors would prescribe unnecessary medicines" and held that the "fear that people would make bad decisions if given truthful information about compounded drugs" could not justify a ban on commercial speech. *Id*. The Court underscored that it had repeatedly "rejected the notion that the Government has an interest in preventing the dissemination of truthful information in order to prevent members of the public from making bad decisions with the information." *Id.* Likewise, in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc*., 425 U.S. 748 (1976), this Court held that States may not prevent pharmacies from advertising prices of drugs, explaining that a State may not keep "the public in ignorance of the entirely lawful terms that competing pharmacists are offering" because the State thinks access to that information "is not in [the consumers'] best interests." *Id*. at 770.

4. Section 17 bans the speech of one set of disfavored participants in the marketplace of ideas, pharmaceutical companies, and stifles one set of disfavored messages, speech educating physicians about brand-name medicines. The premise that highly-trained physicians cannot be trusted to make the appropriate decisions for their patients is the

only connection Vermont offers between prescriber-identifiable data and the costs of healthcare and public health. To accept the State's assumption that it knows best what doctors should hear and prescribe would turn the First Amendment on its head.

To sustain such a paternalistic restriction of speech based on the viewpoint and identity of the speaker, Vermont, at the very least, had to satisfy the four-prong test set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980). In fact, in the last three cases this Court has decided involving restrictions on commercial speech, the Court has suggested that repudiating the *Central Hudson* standard in favor of a "more straightforward and stringent test for assessing the validity of governmental restrictions on commercial speech" may be appropriate. *Greater New Orleans*, 527 U.S. at 184; *accord Thompson*, 535 U.S. at 367-68; *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554 (2001). But in each case, the Court found it unnecessary to take that step because "*Central Hudson*, as applied in our more recent commercial speech cases, provides an adequate basis for decision." *Greater New Orleans*, 527 U.S. at 184; *accord Thompson*, 535 U.S. at 368 (quoting *Greater New Orleans*, 527 U.S. at 184); *Lorillard*, 533 U.S. at 554-55 (same). While leaving open the prospect of a stricter test, this Court thus has required the government to prove that any restriction on truthful and non-misleading speech directly advances a substantial state interest and is no "more extensive than is necessary to serve that interest." *Thompson,* 535 U.S. at 357 (quoting *Central Hudson*, 447 U.S. at 566).

5. Section 17 does not directly advance any substantial governmental interest. "The statute does not

directly restrict the prescribing practices of doctors, and it does not even directly restrict the marketing practices of detailers. Rather, it restricts the information available to detailers so that their marketing practices will be less effective." Pet. App. 25a. That route is "too indirect to survive intermediate scrutiny" and is "antithetical to a long line of Supreme Court cases stressing that courts must be very skeptical of government efforts to prevent the dissemination of information in order to affect conduct." *Id.* at 26a, 28a (citing *44 Liquormart,* 517 U.S. 484 at 503; *Va. State Bd. of Pharmacy*, 425 U.S. at 770; *Thompson*, 535 U.S. at 373).

Section 17 also fails the requirement that the State demonstrate that the restriction on speech is no more extensive than necessary to further the State's interest. *Central Hudson*, 447 U.S. at 569-70. "If the First Amendment means anything, it means that regulating speech must be the last – not first – resort." *Thompson*, 535 U.S. at 373.

Section 17 "is a poor fit with the state's goal." Pet. App. 29a. The law sweeps in detailing that is appropriate and useful, thereby suppressing speech that is broader than required to accomplish the State's purported interests. For example, section 17 restricts speech by pharmaceutical representatives even when there is no generic available for the condition that the pharmaceutical manufacturer's drug treats, even when the manufacturer's drug is not the most expensive treatment, even when the manufacturer's drug is a medical breakthrough or the only, or most effective, treatment for a particular disease, and even when the use of a manufacturer's drug would reduce overall medical costs. Pet. App. 29a; C.A. App. 175, 177, 182. Some new drugs are clinical advancements

that make important contributions to the public health and result in an overall reduction in health care spending, if, for example, the new drug prevents a patient from having surgery. Pet. App. 95a; CA App. 353. Section 17 thus is significantly over-inclusive.

At the same time, section 17 is significantly under-inclusive. The law fails to restrict communications that are not undertaken with prescriber-identifiable data, even if that detailing would lead to the prescription of newer, more expensive brand-name drugs, even if the promotion is harassing or aggressive, or even if the drug being promoted is relatively dangerous or has a poor safety profile.

6. Largely abandoning the asserted state interests advanced below, petitioner in this Court attempts to justify section 17's speech restrictions as a means to protect the privacy of prescribers who do not wish to be contacted. Pet. 22-23. Neither the First Circuit in *IMS Health, Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), nor the Second Circuit in this case, however, recognized such a privacy interest. *See* Pet. App. 23a; *Ayotte*, 550 F.3d at 55. And while the First Circuit in *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010), recognized a protected right for prescribers to avoid unwanted communications from pharmaceutical representatives based on their prescribing histories, the court limited its holding and found this substantial interest was "particular to the Maine statute." *Id.* at 20.

The First Circuit emphasized the "opt-in" nature of the Maine law, which limits detailers' access to an individual prescriber's data only if the prescriber affirmatively opts for this protection. *Id.* at 16-17. The court held that "Maine's opt-in confidentiality

mechanism is . . . a less restrictive means of vindicating prescriber's interest," and "avoid[s] concerns about paternalism in the First Amendment context." *Id.* at 22. The Vermont statute, by contrast, is an opt-out scheme whereby pharmaceutical representatives may only use prescriber-identifiable information to communicate with prescribers if the prescribers have affirmatively given consent. 18 V.S.A. § 4631(d).

Moreover, the *Mills* court erred in recognizing this privacy interest on the grounds that "[l]ike laws implementing 'do not call' lists, Maine advances this interest by allowing its prescribers to join a list to stop their data from being licensed, used, sold, transferred or exchanged for this unwelcome purpose." *Mills*, 616 F.3d at 20. The cases upholding a federal "do not mail" list, *Rowan v. U.S. Post Office Dep't*, 397 U.S. 728, 736-38 (1970), and "do not call" list, *FTC v. Mainstream Mktg. Serv., Inc.*, 345 F.3d 850, 854-55 (10th Cir. 2003), concern communications directed at the *home*, a place traditionally entitled to special privacy protection. *See, e.g.*, *Frisby v. Schultz*, 487 U.S. 474, 484 (1988). Petitioners do not cite any cases for the proposition that individuals have a protected privacy interest against being professionally contacted in the workplace.

Even if Vermont does have an interest in protecting either doctors' prescribing information or their freedom from being contacted in the workplace, section 17 does not advance those interests. Section 17 does not protect the privacy of prescriber-identifiable data. Rather, the law permits the disclosure of prescriber-identifiable data for *any* purpose whatsoever, regardless of whether the prescriber consents, as long as the speech is not by a pharmaceutical company that is "marketing or

promoting a prescription drug." 18 V.S.A. § 4631(d). Similarly, the law permits pharmaceutical manufacturers to contact physicians based on prescriber-identifiable data for purposes other than marketing or promoting drugs.

Section 17 is thus not designed to protect against unwanted communications. The law allows an unlimited number of outside speakers to purchase and use prescriber-identifiable data and to contact doctors based on that data. The Act thus leaves *Consumer Reports* or equivalent periodicals free to contact prescribers at their workplaces based on such data and to reprint the data in articles rating doctors. Groups opposed to the use of certain drugs are free to contact doctors based on the data and to publish doctors' prescribing histories in the newspaper. Government officials or insurance company representatives also may use prescriber-identifiable data to promote products to prescribers.

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

Vermont also attempts to justify its law on the theory that pharmacies collect the information only by virtue of state law. Pet. 2, 18-19. That argument is a red-herring. Nothing in state law would otherwise restrict pharmacies from collecting and selling the information for profit as the pharmacies see fit.

Moreover, the law on its face applies to private companies other than pharmacies, including "[a] health insurer, a self-insured employer, an electronic transmission intermediary . . . or other similar entity." 18 V.S.A. § 4631(d). Vermont does not contend that the State requires those entities to collect prescriber-identifiable data.

And, as discussed, the law permits the sale of prescriber-identifiable data to *any* entity and for *any* purpose, other than to pharmaceutical companies that want to educate doctors about prescription drugs. In short, medical privacy is a blatant pretext that fails to mask the overt discrimination against one message (prescription drug marketing) and one set of participants in the marketplace of ideas (pharmaceutical manufacturers).

B. This Case Provides An Appropriate Vehicle For Resolving The Conflict In The Courts Of Appeals

Although the court of appeals' decision is correct, PhRMA agrees with the petitioner that this Court's review would be warranted to make clear that the First Amendment prohibits States such as Vermont from restricting the speech of pharmaceutical manufacturers. The courts of appeals are divided on the question of whether laws restricting the use of prescriber-identifiable data violate the First Amendment. The issue is recurring, as three States have already enacted such laws and other States are considering similar legislation. *See* Pet. 26-27. And, PhRMA's status as a party in this case makes this case an appropriate vehicle for addressing the question presented.

1. The courts of appeals are divided on the issue of whether laws restricting the dissemination and use of

prescriber-identifiable data to tailor speech from pharmaceutical representatives to doctors violate the First Amendment. In contrast to the Second Circuit in this case, the First Circuit upheld similar laws in New Hampshire and Maine. *See Ayotte*, 550 F.3d 42; *Mills*, 616 F.3d 7. In upholding the New Hampshire and Maine laws, which were challenged by IMS but not PhRMA, the First Circuit focused on the "acquisition, aggregation, and sale" of prescribing history information by IMS (described by the court as "upstream" activity) and declined to address the effect of the restrictions on the speech of pharmaceutical representatives (described by the court as "downstream" activity). *Ayotte*, 550 F.3d at 48, 50. The First Circuit concluded that the New Hampshire and Maine laws regulated the conduct, not the speech, of IMS. *Id.* at 52; *Mills*, 616 F.3d at 19.

Yet there was no question that the Maine and New Hampshire laws, like Vermont's law, are designed to advance the State's asserted interests only if they succeeded in diluting the speech of pharmaceutical representatives. *See Ayotte*, 550 F.3d at 64-65 (Lipez, J., concurring in part, dissenting in part) ("[T]he New Hampshire Legislature chose to regulate the upstream transactions because it wanted to alter the message used by pharmaceutical detailers in pursuing a downstream transaction with health care professionals. In other words, the Act was designed to limit the speech of those detailers.").

In the alternative, the First Circuit concluded that the New Hampshire and Maine statutes restrict at most commercial speech and that the laws satisfied intermediate scrutiny, despite the fact that the statutes also sought to inhibit communications advocating the use of brand name prescription drugs,

while permitting insurers to use the same information to promote the use of generic equivalents to those same prescription drugs. *Ayotte*, 550 F.3d at 54-60; *Mills*, 616 F.3d at 19-23. This case thus provides an excellent opportunity for the Court to resolve the conflict between the courts of appeals over the appropriate standard of review and validity of laws restricting pharmaceutical manufacturers' speech based on prescriber-identifiable data.

2. The question is of recurring significance that warrants this Court's review. As discussed, in addition to Vermont, New Hampshire and Maine restrict the transfer or use of prescriber-identifiable data for the purpose of restricting the speech of pharmaceutical manufacturers based on that information. *See* N.H. Rev. Stat. Ann. § 318:47-f (prohibiting the "transfer" or "use" of prescription data for purposes of "any activity that could be used to influence sales or market share of a pharmaceutical product."); Me. Rev. Stat. Ann. tit. 22, § 1711-E ("[A] carrier, pharmacy, or prescription drug information intermediary may not license, use, sell, transfer or exchange for value, for any marketing purpose, prescription drug information that identifies a prescriber who has filed for confidentiality protection").

Massachusetts, moreover, imposes such restrictions by regulation. 105 Mass. Code Regs. § 970.005(2)(g) (placing restrictions on the use of "non-patient identified prescriber data" by a "pharmaceutical manufacturing company," including requiring that manufacturers "give health care practitioners the opportunity to request that their prescriber data: i. be withheld from company sales representatives, and ii. not be used for marketing purposes"). As set forth in the petition, more than two dozen additional

States have introduced or may be considering introducing legislation containing similar restrictions. Pet. at 26-27. Review would clarify the constitutional validity of such restrictions.

3. Unlike the decisions by the First Circuit addressing the laws of New Hampshire and Maine, this case is an appropriate vehicle to address the issue presented. PhRMA, representing the interests of pharmaceutical manufacturers, is a party in this case. The First Circuit acknowledged the absence of any pharmaceutical manufacturer defendant and cited potential standing concerns as the basis for declining to address the effect of the New Hampshire law on the "downstream" speech of pharmaceutical representatives to doctors. *Ayotte*, 550 F.3d at 49; *see also* Pet. App. 43a-44a (Livingston, J., dissenting).

This case provides no such obstacle because PhRMA is a party challenging the law here. Moreover this case followed a lengthy evidentiary hearing and thus the record regarding the effect of section 17 on pharmaceutical representative speech has been fully developed.

Moreover, unlike Vermont, the New Hampshire and Maine laws are directed on their face to the conduct of IMS and do not on their face restrict the speech of pharmaceutical manufacturers or impose penalties on them for speaking to doctors when their speech has been shaped by knowledge of the doctors' prescribing histories. *Ayotte*, 550 F.3d at 49; *Mills*, 616 F.3d at 18. By contrast, Vermont's law on its face prohibits pharmaceutical manufacturers from marketing and promoting their drugs if such speech is based on prescriber-identifiable data. 18 V.S.A. § 4631(d). Moreover, in Vermont, the legislative findings demonstrate explicitly the State's intent to

hinder the speech of pharmaceutical manufacturers by proclaiming the statutory goal to control the "marketplace of ideas on medicine safety and effectiveness." Pet. App. 134a (Vt. Acts No. 80 § 1(4)); *id.* (Vt. Acts No. 80 § 1(3)) ("The goals of marketing programs are often in conflict with the goals of the state."); *id.* at 135a (Vt. Acts No. 80 § 1(6)) ("Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.").

This case thus squarely presents the question of whether restrictions on the speech of pharmaceutical manufacturers is unconstitutionally restrained by the prescriber history information laws. The Second Circuit correctly invalidated Vermont's viewpoint-based discrimination, and this case affords the Court an appropriate opportunity to resolve the conflict in the circuits below on a question of national significance.

CONCLUSION

The petition for certiorari should be granted.

Respectfully submitted,

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