No. 10-779

IN THE
Supreme Court of the United States

WILLIAM H. SORRELL, AS ATTORNEY GENERAL OF THE STATE OF VERMONT; PETER SHUMLIN, IN HIS CAPACITY AS GOVERNOR OF THE STATE OF VERMONT; AND DOUGLAS A. RACINE, IN HIS CAPACITY AS SECRETARY OF THE AGENCY OF HUMAN SERVICES OF THE STATE OF VERMONT,
Petitioners,
v.

IMS HEALTH INC.; VERISPAN, LLC; SOURCE HEALTHCARE ANALYTICS, INC., A SUBSIDIARY OF WOLTERS KLUWER HEALTH, INC.; AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Respondents.

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

REPLY BRIEF FOR PETITIONERS

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Although drug companies undoubtedly would like to know which doctors do (and do not) prescribe their drugs, the First Amendment affords them no right to access that nonpublic information without consent. Doctors' prescribing information may well make pharmaceutical marketing strategies more successful, as would knowledge of competitors' marketing plans and patient prescription information. Yet drug companies have no First Amendment right to obtain trade secrets, eavesdrop on competitors' calls, or buy patient data. That nonpublic information is not lawfully available. Vermont's law similarly restricts commercial access to nonpublic, highly regulated information without doctors' consent.

Respondents and their *amici* often describe a law different from what Vermont enacted, one that prevents contact with doctors, bans advertising, or censors newspapers. These inaccurate descriptions of the law and the record require correction before we address the controlling legal questions.

First, the charge of "paternalism" cannot be squared with either doctors' support for this law or the law itself. The law gives doctors control over use of their prescribing histories for marketing directed at them. Far from "derogatory" (PhRMA Br. 2), Vermont's consent-based law treats doctors as trusted professionals.[1]

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[1] *E.g.*, JA376-83, 407-08, 411; Vermont Medical Society et al. (VMS) Br. 22 ("[A]dverse public health and cost-containment outcomes reflect the breakdown in the integrity of the physician-patient relationship caused by the use of [prescriber-identifiable] data by pharmaceutical marketers."); Ass'n of American Physicians & Surgeons Br. 13 (physicians' "professional independence" compromised by "constant monitoring by the pharmaceutical industry"); New England Journal of Medicine et al. (NEJM) Br. 41 (physicians "best suited" to

Second, while respondents and their *amici* claim to advocate "transparency," the commercial trade of prescription data is anything but open. Pharmacies do not tell doctors their information is sold for marketing. JA253-54. Data vendors do not allow dissemination of their "proprietary" data. JA85, 135. Drug companies train detailers to monitor doctors using prescription information, but "pretend [they] don't know" that information when talking to doctors. JA341-43, 462-63. Nothing in this statute reduces transparency.[2] Nor does it restrict the content or viewpoint of a detailer's message. Rather, by allowing doctors to control the use of their information, it transforms a "covert" marketing practice, App. 92a, into an open, voluntary exchange.

Third, Vermont's limited restriction on nonconsensual use of prescription data for advertising will not thwart healthcare research. The statute does not restrict access to data by researchers. Vt. Stat. Ann. tit. 18, § 4631(e)(1). Moreover, respondents and their *amici* substantially overstate the use of respondents' *prescriber-identifying* data products for non-marketing purposes. JA141-42, 156; App. 92a. Although respondents may allow some researchers free access to their data, such selective access hardly makes those databases essential to scientific research. *Contra* Sullivan et al. Br. 11-12. Medical researchers testified that respondents' data is too expensive to

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decide "these complex matters of science and health policy"). No physicians' organization supports respondents here.

[2] Respondents and their *amici* claim a company could not find New Hampshire specialists in pediatric epilepsy because of that state's prescription-data marketing law. *E.g.*, Massachusetts Biotechnology Council et al. Br. 13-17. A simple Internet search identifies such specialists.

use and identified other sources of research data. JA370; A-1225, 1246-47; *infra* n.8.

Fourth, in seeking to cast separate regulation of insurers and pharmaceutical manufacturers as "viewpoint discrimination," respondents ignore that drug companies and health insurers do different work, have different access to information, have dissimilar relationships with patients and providers, and are differently regulated *across the healthcare system*. Respondents also overlook that they can communicate any messages they want to doctors. Pharmaceutical manufacturers produce and sell drugs; unlike insurers, they do not contract with patients or doctors, they do not get information directly from either, and they do not pay for healthcare. "Equal footing" (PhRMA Br. 32) between the companies that sell drugs and the companies that insure patients is not a practical reality, much less a constitutional requirement.

I. VERMONT'S RESTRICTION ON ACCESS TO PRESCRIPTION DATA DOES NOT WARRANT HEIGHTENED SCRUTINY.

Pharmacies have prescription information because they are licensed participants in a closely regulated system for the approval, sale, and dispensing of prescription drugs. Doctors and patients do not voluntarily provide prescriptions to pharmacies; by law, they must provide this sensitive information to obtain medicine. Pet. Br. 4-5, 28-30; U.S. Br. 14-15. As the United States explains (at 14), this regulatory context gives Vermont "wide latitude to regulate the manner in which [prescription information] will be disseminated and used by private parties." Respondents thus have no protected right to purchase prescription records for private commercial use. And

there is no basis for applying strict scrutiny, IMS Br. 20-21, to a restriction on the proprietary, nonpublic use of this data. *See Snyder v. Phelps*, 131 S. Ct. 1207, 1215 (2011); *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 758-59 (1985) (plurality op.).

A. The law regulates nonpublic information.

A prescription is a healthcare record that reflects a doctor's treatment decision for a patient. Respondents offer no persuasive explanation why this private information, produced involuntarily by doctors and patients, should be deemed the protected "speech" of pharmacies and data vendors.

Respondents assert that, because prescription records are held by pharmacies, any restriction on the sale or use of those records restricts protected speech. Patients, they say, are free to discuss their prescriptions, so "there is no logical basis," IMS Br. 13, for a First Amendment rule treating pharmacies and data vendors differently from patients. The logical difference is that patients speak about themselves, but pharmacies and data vendors sell information collected involuntarily from others. That fact was crucial in *Seattle Times*, where a protective order prevented the newspaper from publishing information it gained only through compelled discovery. *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 32 (1984).[3]

Vermont does not advocate a "recordkeeping" exception to the First Amendment. IMS Br. 25. The

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[3] As PhRMA observes, the *Seattle Times* Court applied intermediate scrutiny. Unlike this law, however, the protective order banned publication on a matter of "public interest." 467 U.S. at 31.

point is not that pharmacists must keep records, but that *other people* must give pharmacists information. Doctors and patients have a privacy interest in the further use of sensitive information they are compelled to provide for a specific governmental purpose but have not chosen to make public. Where the government has "coerced production of information," *Seattle Times*, 467 U.S. at 35, restrictions on its further use are restrictions on access, not speech.

IMS's description (at 13) of the "communication of prescription-history data" by pharmacies as fully protected speech erroneously assumes healthcare providers have a First Amendment right to disclose their records. That unspoken assumption lacks support in tradition, logic, or common sense. Confidentiality rules for healthcare providers (and others) have long co-existed with the First Amendment. Whether redacted or not, medical records have not been considered the "speech" of healthcare providers. *See United States v. Aguilar*, 515 U.S. 593, 606 (1995) (First Amendment protections lessened when one "voluntarily assumed a duty of confidentiality").

Treating prescription records as the protected "speech" of pharmacies also disregards the interests of doctors in controlling the nonconsensual use of their prescribing histories. If a prescription is speech, surely the prescribing physician has a more substantial interest in that speech than the pharmacist. *See Wooley v. Maynard*, 430 U.S. 705, 714 (1977) (rights to "speak" and "refrain from speaking" are "complementary"). Respondents assert that doctors have no First Amendment interests here because prescription regulations govern doctors' conduct, not speech. IMS Br. 27. Whether writing a prescription is conduct or speech, doctors have an interest in

controlling the nonconsensual use of their information for marketing. Respondents' argument, however, is consistent with Vermont's position: regulations that govern the transfer of prescription information restrict conduct, not speech.

Finally, respondents assert that pharmacies would collect doctors' prescribing information absent regulation. Yet pharmacies do not require customers to identify themselves or their doctors when purchasing over-the-counter drugs – even drugs that once required a prescription. Whatever information pharmacies might request without prescription requirements, no one would be forced to provide it.

B. Strict scrutiny is unwarranted and would undermine numerous laws.

Vermont's limited restriction on the use of doctors' prescribing information does not restrict protected speech. If the Court concludes otherwise, however, it should reject respondents' call for "searching scrutiny" because the law supposedly restricts speech on "matters of public importance." IMS Br. 11.

1. The *Snyder* Court's analysis, echoing longstanding precedent, forecloses that claim. There, the Court distinguished speech on matters of public concern, which "occupies the highest rung of the hierarchy of First Amendment values," from "matters of purely private significance," for which "First Amendment protections are often less rigorous." 131 S. Ct. at 1215 (quotations omitted). The Court cited *Dun & Bradstreet*'s credit report as involving "speech of only private concern" – the report was issued "solely in the individual interest of the speaker and its specific business audience" and "was sent to only five subscribers . . . who were bound not to disseminate it further." *Id.* at 1216 (quotations omitted).

In "content, form, and context," *id.*, the data products sold by the IMS respondents are equivalent to the *Dun & Bradstreet* credit report. The information is drawn from records that are traditionally confidential and their reports are produced for specific subscribers – indeed, "for a single recipient," IMS Br. 31 – for a specific business purpose. Subscribers may not disclose the information to others. JA135, 152-53. Respondents fail to explain how this proprietary, nonpublic data could play a role in any public discourse. *E.g.*, JA135 (IMS restricts "sharing of [their] information" to "protect [their] rights to sell [it] to other people").

The overall context, meanwhile, could not be further from a protest "designed . . . to reach as broad a public audience as possible." *Snyder*, 131 S. Ct. at 1217. Respondents' use of prescribing data is intentionally concealed from public view. App. 92a; JA166-67, 455, 463 (detailers not permitted to disclose data to doctors); JA514, 522, 527-29 ("confidential" and redacted industry documents describing use of data). This marketing practice, if speech at all, is plainly not speech on a matter of public concern.

2. Respondents unpersuasively contend that their "searching scrutiny" argument would have no impact on other privacy laws. *E.g.*, IMS Br. 7-8. Not so. A ruling that the acquisition and proprietary use of prescribing information is fully protected speech would apply with equal force to other laws.[4] Pro-

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[4] *See* Chamber of Commerce Br. 11-12 (Do-Not-Track legislation); Ass'n of National Advertisers, Inc. et al. Br. 6; Appellees' Reh'g Pet. at 14, *IMS Health Inc. v. Mills*, No. 08-1248 (1st Cir. filed Aug. 18, 2010) (arguing *Mills* could justify "legislation prohibiting the use of many different types of information for targeted marketing").

tected consumer, patient, and financial information is: typically in the possession of a private business; a "statement of the historical facts" of transactions that can be "exchange[d]" between "private parties"; and potentially used for purposes such as marketing or research. IMS Br. 13-16, 22.

If respondents were correct, then privacy laws generally would be subject to strict scrutiny, including: (1) FCC restrictions on nonconsensual use of customer information for marketing; (2) restrictions on using credit-card-purchasing information for marketing, Illinois et al. Br. 13; (3) FTC restrictions on using credit-history information for targeted marketing; (4) federal restrictions on using campaign donor lists for marketing; (5) proposed restrictions on the tracking of Internet use; and (6) restrictions on financial institutions' use of personal financial information. *See* Pet. Br. 30, 35, 39. This position is plainly untenable, but it logically follows from respondents' argument that a pharmacy's sale of nonpublic prescription records to data vendors is fully protected speech.

3. IMS incorrectly implies (at 33) that laws like HIPAA forbid "virtually any" use of protected information. Typical HIPAA notices list more than 20 categories of possible uses of *patient* information without consent – including "drug utilization review," "compliance programs," other communications with insurers regarding payment, "health oversight activities," research, law enforcement, and public health.[5] *See also infra* p. 14. Respondents' abbreviated description of privacy laws, IMS Br. 45-46, omits these and other statutory exemptions allowing many uses

[5] Walgreens, Notice of Privacy Practices, http://www.walgreens.com/topic/help/general/noticeprivacypractices.jsp.

of protected information while restricting others. *See* Pet. Br. 30 (FERPA and DPPA); *see also* Illinois et al. Br. 16. Respondents also omit mention of restrictions on the marketing uses of otherwise public information and regulations that allow information to be used only for certain kinds of marketing. *See* Pet. Br. 39-40.

II. RESTRICTING THE MARKETING USE OF HEALTHCARE INFORMATION IS NOT VIEWPOINT DISCRIMINATION.

Vermont regulates health insurers differently from data vendors and pharmaceutical manufacturers. That has nothing to do with viewpoint discrimination and everything to do with the reality of healthcare. Unlike respondents, insurers:

- get healthcare information directly from patients and providers in the ordinary course of business;
- are legally and contractually obligated to manage benefits and pay for patient care;
- necessarily use confidential patient and provider information to perform these tasks;
- are regulated by state and federal laws governing the business of insurance, including communications with patients and confidentiality of information;
- are purchasers of healthcare services, including prescription drugs, not sellers.

These basic facts about the healthcare system demonstrate why any law regulating use of healthcare information must treat healthcare insurers differently from marketers. HIPAA does the same. *See infra* p. 14. Insurers have concomitant obligations to use the healthcare information they receive and to protect its confidentiality. Marketers do not.

To prop up their claim of "viewpoint discrimination," respondents ignore these facts. They describe Vermont's law as a form of "invidious" discrimination because it allows insurers to continue to use the information they obtain from patients and providers in ways that are expected, intended, and required. PhRMA Br. 28. Put another way, respondents assert a First Amendment right to have "equal" access to the healthcare information that insurers obtain directly from patients and providers. Neither facts nor precedent support the recognition of such a right.

A. Administering insurance is not marketing.

Respondents' "viewpoint" argument relies principally on statutory exemptions allowing use of information for purposes related to patient care (including payment) and management of health insurance benefits. The exemptions use healthcare terms of art, such as "utilization review" and "formulary compliance." Vt. Stat. Ann. tit. 18, § 4631(e)(1). These are not "euphemis[ms]" for marketing. PhRMA Br. 29. They describe conduct that is standard in the industry and often required by law. "Utilization review" is the review of healthcare services for clinical appropriateness and is required of public and private health insurers. *E.g.*, Vt. Stat. Ann. tit. 33, § 1998(a)(2) (Medicaid); Health Care Admin. R. 10.202(C) ("utilization review standards" required to approve or deny care).[6] Drug formularies, also known as preferred drug lists, are likewise required for the Medicaid program. Vt. Stat. Ann. tit. 33, § 1998(a)(1).

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[6] "Utilization review" is defined by Vermont Banking, Insurance, Securities and Health Care Administration (BISHCA) Health Care Administration Rule 10.103(UU), http://www.bishca.state.vt.us/sites/default/files/REG-H-10.000.pdf.

Such insurance activities are not marketing. "Formulary compliance" informs doctors and patients about the drugs the insurer will pay for and the steps necessary to obtain coverage. "Utilization review" may require a second opinion or prior authorization for certain procedures. *See supra* p. 10 n.6. Respondents' witness described utilization review as "look[ing] broadly at practices and whether they're consistent with various guidelines." A-123 (Cole). An IMS witness observed that these practices help correct inefficiencies that result from the separation of selection, payment, and end-use among doctors, insurers, and patients. *See* A-265-67 (Frankel) ("doctors aren't aware of the cost of the drugs"). In short, although insurers necessarily evaluate doctors' treatment decisions, insurers are not marketing or advertising prescription drugs, and suggesting this conduct is the same as marketing is false. PhRMA Br. 27-30.

Respondents also incorrectly premise their discrimination claim on an argument that "academic detailers" or "counterdetailers" use prescribing data to influence doctors. Vermont's voluntary, evidence-based education program for doctors, created by the same Act containing the Prescription Confidentiality Law,[7] does not use prescribing data to target doctors. *Contra* IMS Br. 2, 53; PhRMA Br. 13. Nor does the

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[7] Act 80, §§ 14 (creating Vt. Stat. Ann. tit. 18, § 4622 ("Evidence-Based Education Program")), 20 (funding program). The full text of Act 80 is available at http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2008/acts/ACT080.htm. Because PhRMA sought to enjoin the program, JA71-72, it had not yet been funded at the time of trial. The program has now been funded and doctors may volunteer to participate. *See* http://www.med.uvm.edu/ahec/downloads/VTAD_overview_2010.07.08.pdf.

program "advertis[e]" drugs. PhRMA Br. 43. PhRMA confuses the program with the fee that funds several activities, including enforcement activities related to pharmaceutical advertising. Vt. Stat. Ann. tit. 33, § 2004a.[8]

Similarly, respondent data vendors misquote testimony from Joshua Slen when they purport to describe the evidence-based education program. IMS Br. 53. Slen, Vermont's Medicaid director, in fact testified that the Medicaid program "does not at this point in time have a counterdetailing or detailing effort." JA429. Slen also testified about letters Vermont sent to doctors informing them of "clinical decision[s]" to add or remove drugs from the Medicaid formulary. JA429-32.[9] Respondents cannot transform this correspondence, which is necessary to avoid disruption of patient care, into "counterdetailing" simply by repeatedly using that term.

PhRMA draws on non-record sources about the purported use of prescriber information by insurance companies and "counterdetailers" outside Vermont.

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[8] There is no evidence the State's "multipayer" database – which limits access to prescriber data – is used for any detailing. *E.g.*, Vt. Stat. Ann. tit. 18, § 9410(b) (database "shall contain unique patient and provider identifiers"); BISHCA Reg. H-2008-01, § 8(C) & App. J (prescriber identities only available for research; researchers must apply and sign confidentiality agreements), http://www.bishca.state.vt.us/sites/default/files/REG-H-08-01.pdf. *See also* http://www.bishca.state.vt.us/healthcare/health-insurers/vermont-healthcare-claims-uniform-reporting-and-evaluation-system-vhcure (listing all applications for access, none by academic detailers).

[9] Respondents assert that Slen testified that Vermont sends these communications to doctors "to influence prescribing patterns"; in fact, he repeatedly disagreed with that characterization. *Compare* IMS Br. 53 *with* JA428, 431-32.

PhRMA Br. 8-9, 12. The State had no opportunity to test these new assertions at trial. The Court has repeatedly noted its "reluctan[ce]" to "invalidate legislation on the basis of its hypothetical application to situations not before the Court." *Nat'l Endowment for the Arts v. Finley*, 524 U.S. 569, 584 (1998) (quotations omitted). PhRMA cannot succeed on a facial challenge by pointing to non-record, untested assertions about what may be happening in other states.

B. Healthcare laws necessarily regulate insurers and drug companies differently.

Understanding the different players in the healthcare system and the ways in which they are regulated reveals that PhRMA's claim of "discrimination" is nothing but rhetoric. What respondents describe as a "fully protected First Amendment right to be on an equal footing" with insurers (PhRMA Br. 32) is really this: an asserted right for drug companies and data vendors to have the same access to healthcare information that insurers have by virtue of their relationships with patients and doctors. Even if drug companies and insurers are somehow competing "speakers" – which they are not – that would not support such a right. Drug companies and data vendors do not have contractual relationships with doctors and patients, do not pay for patient care, and doctors and patients do not give them information. Simply because drug companies would like to have the same information as insurers does not mean they have a First Amendment right to buy it without doctors' consent.

Adopting respondents' "equal footing" argument would call into question the Food, Drug, and Cosmetic Act and HIPAA, because those laws treat pharmaceutical manufacturers differently from health insur-

ers and other "healthcare marketplace participants." PhRMA Br. 32. The FDA directly regulates the speech of drug companies, but not insurers, even when they communicate about drugs. PhRMA Br. 10; JA193; 21 C.F.R. § 202.1(*l*). HIPAA denies patient information for marketing without patient consent, 45 C.F.R. § 164.508(a)(3), but allows insurers and others to use patient information for "treatment, payment, or health care operations," *id*. § 164.506(a), "utilization review," *id.* § 164.501, "public health activities," and "health oversight activities," *id.* § 164.512(b), (d).[10] PhRMA's own examples show that insurers are permitted to use not just provider information, but patient information, in their communications with doctors. PhRMA Br. 12. If respondents were correct, these laws would be unconstitutional. That absurd result only highlights why their "equal footing" claim fails. The First Amendment permits states to distinguish between using prescription data to pay for and administer healthcare to patients and using the data to market drugs to doctors.

C. Vermont's law applies evenhandedly to prescription drug marketing.

Vermont's law imposes no restrictions on the messages that respondents may communicate about their products to doctors or the public. Even without a doctor's consent, drug companies can use aggregated Vermont prescription data for marketing to Vermont doctors generally. And the law treats all pharma-

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[10] HIPAA exempts from "marketing" communications: describing "a health-related product or service (or payment for such product or service)" provided by the entity's plan; "for treatment"; or "for case management or care coordination." 45 C.F.R. § 164.501.

ceutical manufacturers, brand-name and generic, the same. PhRMA's effort to set up its marketing as a disfavored "viewpoint" is mistaken. If "buy drug X" can even be called a viewpoint, the opposing viewpoint comes from competitors saying "no, buy drug Y." The statute treats these "views," whether expressed by Merck, Pfizer, or their generic competitors, the same.

Moreover, the statute does not apply "*solely*" to pharmaceutical manufacturers. PhRMA Br. 28. No covered entity – which includes pharmacies, health insurers, and similar entities – may sell prescriber data, or permit the use of such data for marketing (by anyone), without the doctor's consent. Although the record shows only that pharmaceutical manufacturers "market" or "promote" prescription drugs, to the extent other entities engage in marketing, the law prevents use of prescribing data for that purpose.

The Court has never suggested that regulation addressed to a specific class of products or services discriminates on the basis of viewpoint. *See*, *e.g.*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618 (1995); *see also R.A.V. v. City of St. Paul*, 505 U.S. 377, 388-89 (1992) (states may regulate advertising of one industry). And in *Los Angeles Police Department v. United Reporting Publishing Corp.*, the Court upheld a statute barring access to arrest records for use to "sell a product or service." 528 U.S. 32, 35, 40 (1999) (quotations omitted). Justice Ginsburg distinguished that permissible restriction from one "based on an illegitimate criterion such as viewpoint." *Id.* at 43 (Ginsburg, J., concurring).

Nor has the Court held that an otherwise permissible regulation of advertising offends the First

Amendment because it does not extend to speech that is not advertising. There are "rung[s]" on the "hierarchy of First Amendment values," *Carey v. Brown*, 447 U.S. 455, 466-67 (1980), and commercial speech does not receive the same protection as other speech, *Bd. of Trs. v. Fox*, 492 U.S. 469, 477 (1989). Respondents complain that the statute exempts healthcare research, but they do not explain why that is evidence of viewpoint discrimination. Research is not commercial speech, and the statute allows use for research without regard to viewpoint. Research may be supported by public funds, industry, or academic institutions, and may reach conclusions that support use of a drug, disfavor use of that drug, or neither. The fact that certain noncommercial uses of data are permitted does not transform a restriction on use for marketing into viewpoint discrimination.

In short, no precedent supports respondents' claim that the marketing of a product category, here prescription drugs, is a protected "viewpoint" for First Amendment purposes. A viewpoint is "a specific premise, a perspective, a standpoint from which a variety of subjects may be discussed and considered." *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 831 (1995). The Court has observed that pharmacists "do[] not wish to editorialize on any subject" but "simply" communicate the "idea" of selling drugs. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761 (1976). The same is true of detailers marketing prescription drugs: they seek to communicate the "idea" of selling drugs.

D. Respondents' "legislative intent" argument is unpersuasive.

Respondents unpersuasively argue that a few sentences in the 31 legislative findings together with emails and testimony from legislative witnesses,[11] PhRMA Br. 29, 35, make Vermont's law unconstitutional.

1. Act 80 is an omnibus healthcare bill amending or creating 19 statutes with 66 subparts. Section 1 contains the legislative findings for all of these changes to Vermont's laws. The Prescription Confidentiality Law, found in § 17, initially included a since-repealed provision that required pharmaceutical marketers to make disclosures to doctors.[12] Pet. Br. 12-13. The Act also created an evidence-based education program and established a state-law remedy for drug advertising that violates federal law. Act 80 §§ 14, 20; *supra* n.7.

The findings that respondents claim render the Prescription Confidentiality Law unconstitutional are properly understood in the context of all of these provisions. Respondents speculate that certain sentences were directly linked in the minds of legislators to both § 17 of Act 80 and to the current, substantially amended version of the statute.[13] That theory differs from respondents' previous contention that Finding 4, which mentions the "marketplace of ideas," was a basis for the evidence-based education program and the repealed compelled-disclosure

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[11] Sean Flynn was a legislative witness, A-581, not staff. The emails appended to PhRMA's brief were excluded from the trial record. A-4939-40.

[12] The original text of § 4631(f) is available at http://www.leg.state.vt.us/docs/legdoc.cfm?URL=/docs/2008/acts/ACT080.htm.

[13] *See* 2008 Vt. Acts & Resolves No. 89, § 3; Pet. Br. 12-13.

provision. *E.g.*, JA66; PhRMA Compl. ¶¶ 4, 8, No. 1:07-cv-00220 (filed Oct. 22, 2007), ECF No. 1. And respondents have suggested the findings do not apply to the amended statute. Pls.' Post-Trial Br. 50, No. 1:07-cv-00188 (filed Sept. 29, 2008), ECF No. 409. In all events, as the Court has said, "[i]nquiries into congressional motives or purposes are a hazardous matter." *United States v. O'Brien*, 391 U.S. 367, 383 (1968).

2. A statute that allows doctors to control the use of their prescribing information for marketing is either constitutional, or not. Review should focus on what the statute does, not on a hunt for "impermissible motive" or evidence of "hostility" in the legislative record. PhRMA Br. 33. The Court "eschew[ed]" this type of "guesswork" in *O'Brien*, 391 U.S. at 384. The law's text and the findings attached to Act 80 demonstrate at least one motive unrelated to expression – the privacy of medical information. Vt. Stat. Ann. tit. 18, § 4631(a); *e.g.*, Finding 29 (reasonable expectation that prescription information "will not be used for purposes other than the filling and processing of the payment for that prescription"). If the law's constitutionality turns on the wording of certain findings or pieces of legislative history, then it "could be reenacted in its exact form" based on a "wiser" record. *See O'Brien*, 391 U.S. at 384. The Court has rejected respondents' approach to constitutional interpretation.

3. Respondents' objections to the findings and legislative witnesses also are greatly overstated.[14]

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[14] The *O'Brien* Court disregarded legislative history that expressly disapproved of public anti-war protests. *See* 111 Cong. Rec. 19,746, 19,871, 19,872, 20,433 (1965), *cited at* 391 U.S. at 385.

True, the legislature expressed concern that the unmatched resources devoted to pharmaceutical marketing contribute to rising costs and disserve patients. Many doctors, researchers, and consumer groups share that opinion, as does the Congressional Budget Office, and it is supported by research and reports of improper – sometimes illegal – marketing practices. JA376-83, 411; VMS Br. 29-33; NEJM Br. 34-37; AARP Br. 25-33; Pet. Br. 53 & n.17; *infra* p. 24. Calling these views "pejorative[]," PhRMA Br. 35, is a dressed-up way of saying that the legislature violates the First Amendment merely by taking testimony that criticizes marketing, even when the testimony is true. That cannot be the law.

III. PERMITTING DOCTORS TO DECIDE WHEN THEIR PRESCRIBING PRACTICES MAY BE USED FOR MARKETING IS CONSTITUTIONAL.

Vermont's law is consistent with core First Amendment principles. It protects the exchange of information between a willing speaker and a willing listener, and it allows "the speaker and the audience, not the Government, . . . to assess the value" of the information. *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 195 (1999). Vermont's law does not prevent drug companies from marketing or prevent detailers and doctors from discussing prescribing practices. Nor does it deny drug companies access to all information about prescribing practices in Vermont. Instead, it prevents drug companies from obtaining nonpublic information about doctors without their consent. That modest restriction satisfies intermediate scrutiny.

A. This consent-based measure is coextensive with doctors' privacy interest in avoiding unwanted marketing tactics. The legislature went no further

than necessary – it allowed doctors to approve or disapprove these marketing practices. This Court has never struck a consent-based law under the First Amendment and has suggested that, when the government can implement consent-based restrictions, it must. *See United States v. Playboy Entm't Grp.*, 529 U.S. 803, 815 (2000). Here, the legislature engaged in the kind of careful tailoring the Court's commercial speech cases require. *Cf. Lorillard*, 533 U.S. at 561-66 (invalidating almost complete ban that lacked "careful calculation of the speech interests involved").

Respondents now object to Vermont's "default" rule, saying the law is unconstitutional because prescribers must "affirmatively" consent. PhRMA Br. 45; IMS Br. 56. They did not raise this below. And respondents argue that Maine's "opt-out" statute, which requires doctors to register to stop use of their prescribing information, also violates the First Amendment. *See IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010), *petition for cert. pending*, No. 10-984 (filed Jan. 28, 2011). In any event, in this pre-enforcement facial challenge, the statute only requires that the State "solicit" consent on licensing applications. Vt. Stat. Ann. tit. 18, § 4631(c). Implementation of that mandate is left to the administrative process, which respondents have not challenged. *See Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 444 (2008).

B. Respondents unpersuasively assert the law cannot satisfy *Central Hudson* because it does not place enough restrictions on uses of prescription information. IMS Br. 35, 40-41.

1. Respondents mistakenly focus on this statute in isolation, never acknowledging that other measures also prevent dissemination of prescription

information. Vermont's pharmacy regulations, which mandate confidentiality of prescription records, cannot reasonably be read to permit pharmacies to publish records revealing doctors' prescribing information, and there is no evidence they have done so. JA142. Publication also risks re-identification of patients. *See* Pet. Br. 5-6, 36-37.[15] Other Vermont laws also restrict access to prescriber-level data. *See*, *e.g.*, Vt. Stat. Ann. tit. 1, § 317(c)(38) (no disclosure of prescriber-identifiable data under public records act, except for certain medical research and law enforcement purposes); *id.* tit. 18, § 9414(f) (no disclosure of patient or provider identities obtained from performance reviews); *id.* § 4284 (no public disclosure of and limited law enforcement access to prescription monitoring program for controlled substances).

2. Respondents complain that the law allows uses of prescribing data in the "healthcare marketplace," PhRMA Br. 42, ignoring that patients and doctors intend for prescriptions to be used for healthcare purposes. Indeed, the healthcare uses of doctors' prescribing information are the same as the healthcare uses of patient information: treatment, coordination of care, formulary compliance, utilization review, claims processing, payment, and even public health and research purposes. *See supra* pp. 10-11, 14. Doctors and patients expect and intend

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[15] Respondents' *amici* explain that respondents typically do not use the more protective HIPAA "Safe Harbor" standard for de-identification, and instead use a statistical method that depends on the "anticipated recipient" of the data. El Emam & Yakowitz Br. 6-7. *Amici* also cite Dr. Latanya Sweeney's research to support their claim that the risk of re-identification is low, *id.* at 13-18, but Dr. Sweeney has recently published a reply forcefully disagreeing with this conclusion. *See* http://dataprivacylab.org/projects/identifiability/pharma2.pdf.

these uses of healthcare information, but they do not expect (or even know) that third parties purchase the information and use it as a marketing tool. "[B]oth the common law and the literal understandings of privacy encompass the individual's control of information concerning his or her person." *U.S. Dep't of Justice v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 753, 763 (1989) (privacy interest in rap-sheet despite being mostly "a matter of public record").[16]

3. The legislature followed this Court's guidance in tailoring the statute to address the use of prescribing data for marketing. The "needed leeway" afforded under *Central Hudson* applies to commercial speech, an area "traditionally subject to governmental regulation." *Fox*, 492 U.S. at 481 (quotations omitted). And *Central Hudson*'s progeny caution against regulations that restrict too much speech. *E.g.*, *Lorillard*, 533 U.S. at 564-65; *Fox*, 492 U.S. at 480. Here, the record showed that non-marketing uses of prescribing data are limited and the data is not publicly available – in fact, respondents prohibit its disclosure. JA135, 152-53, 248, 255. The statute is appropriately tailored to address the State's interest in avoiding the nonconsensual use of prescribing data for marketing. *See Burson v. Freeman*, 504 U.S. 191, 207 (1992) (plurality op.) ("States adopt laws to address the problems that confront them. The First Amendment does not require States to regulate for problems that do not exist.").

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[16] Most data collectors provide "limited purpose" privacy protections. *See*, *e.g.*, U.S. Census Bureau, *Our Privacy Principles*, http://www.census.gov/privacy/data_protection/our_privacy_principles.html.

The federal Do-Not-Call Registry is similarly tailored. It restricts only *commercial* solicitations, not charitable or political solicitations. And the Registry permits commercial solicitations to consumers with established relationships to a business. *Mainstream Mktg. Servs. v. FTC*, 358 F.3d 1228, 1234, 1240 (10th Cir. 2004); *see also Mills*, 616 F.3d at 20 (analogizing law to do-not-call lists).

4. This case is nothing like *Greater New Orleans*, where laws permitted, for example, advertisements by tribal casinos but barred advertisements by casinos owned by non-Indians. 527 U.S. at 193. The problem there was different treatment of casinos despite "virtually identical messages." *Id.* at 194. The Court did not suggest it was problematic to regulate advertising differently than other speech, or other activities, related to gambling.

C. The record fully supports the district court's conclusion that Vermont's law advances the State's interests in costs and safety. App. 95a-99a. *Accord IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008) (costs). Record evidence establishes that new drugs are the most marketed, and their over-prescription contributes to rising costs and safety risks. Witnesses described the marketing and over-prescription of new drugs like the statin Baycol (linked with fatalities); Vytorin (subsequently shown to offer no significant benefit despite billions of dollars in sales); and Vioxx (widely over-prescribed before being withdrawn for safety reasons). A-207-08; JA238-39, 356-58, 366-67. Respondents' witness Dr. Wharton said he waits before prescribing new drugs unless he sees an "obvious benefit" and an "obvious low risk" – features he said exist in only 20-30% of drugs. A-207. This is consistent with the State's experts, who testi-

fied that decreasing use of prescriber-identifiable data to market new drugs will help prevent their over-prescription and reduce costs. Pet. Br. 49-54.

Numerous sources support that conclusion. *E.g.*, U.S. Br. 25-26 (law will reduce costs); JA411 (Landry); VMS Br. 30-33; NEJM Br. 34-37. A recent congressional report (*cited in* PhRMA Br. 3) concluded that promotional efforts of the pharmaceutical industry, including detailing, "may . . . lead doctors to prescribe brand-name medications that are more expensive than alternatives." Cong. Budget Office, *Promotional Spending for Prescription* Drugs 1, 6-7 (2009) (CBO) (greatest detailing expenditures for statins, antidepressants, and atypical antipsychotics; products mostly promoted in "first few years" after FDA approval).

Respondents casually assert that Vermont focuses on "a handful" of examples of over-prescribed new drugs, IMS Br. 57, but those examples resulted in deaths and billions of dollars in unnecessary costs. JA238, 366-69. *See also* AFSCME et al. Br. 5-14 (prescriber-identifiable data in off-label marketing); CBO at 2 n.2 ("several recent cases" of questionable pharmaceutical marketing).

The State's interests in promoting safety and reducing costs are clearly substantial. Respondents' "speech interest" – access to nonpublic information to refine their marketing tactics – is remote at best. Balancing those interests plainly weighs in favor of upholding Vermont's law.

CONCLUSION

The court of appeals' judgment should be reversed.

Respectfully submitted,

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