No. 08-1202

IN THE
Supreme Court of the United States

IMS HEALTH, INC. *et al.*,

Petitioners,

v.

AYOTTE,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF OF AMICI CURIAE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PHRMA) AND BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) IN SUPPORT OF PETITIONERS

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Pharmaceutical Research and Manufacturers of America (PhRMA) and Biotechnology Industry Organization (BIO), as *amici curiae*, urge that the Court grant the writ of certiorari requested by Petitioners because the ruling below impairs not only Petitioners' First Amendment rights, but also those of PhRMA's and BIO's members.[1]

INTEREST OF *AMICI CURIAE*

PhRMA is a voluntary, non-profit association that represents the country's leading pharmaceutical and biotechnology research companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.[2] PhRMA member companies are leading the search for new cures. In 2008, PhRMA members invested approximately $50.3 billion to develop new medicines. PhRMA's mission is to advocate policies that encourage these efforts by

[1] The parties have consented in writing to PhRMA's and BIO's participation. Copies of those consents have been filed with the Clerk of the Court. Counsel of record for all parties received notice of PhRMA's and BIO's intention to file an *amicus curiae* brief at least 10 days prior to the due date for this *amicus curiae* brief. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

[2] A list of PhRMA's current membership can be found at http://www.phrma.org/about_phrma/member_company_list/members/.

pharmaceutical and biotechnology research companies to create life-saving and life-enhancing new medications for patients.

BIO is the world's largest biotechnology organization, providing advocacy, business development, and communications services for more than 1,250 members.[3] BIO members include biotechnology companies, academic institutions, state technology centers, and related organizations in the United States and more than 30 other nations. BIO members are involved in research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. A majority of BIO members engage in biomedical research, and to date, such companies have introduced 254 new medicines.

PhRMA and BIO are well situated to address the issues presented in this petition. The restrictions in New Hampshire's "Prescription Information Law," N.H. Rev. Stat. Ann. § 318:47-f, are intended to obstruct important communications by biopharmaceutical manufacturers (including PhRMA and BIO members) using prescriber data, including communications designed to market their drugs efficiently. The Prescription Information Law also hampers biopharmaceutical manufacturers in targeting scientific and safety messages at health care providers who most need information about particular drugs. Moreover, the Prescription Information Law may make it economically infeasible for Petitioners to publish this data, effectively

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[3] A list of BIO's current membership is at http://bio.org/members/biomembers.asp.

denying this information to research organizations (including BIO members) who previously received it free of charge.

Although the Prescription Information Law does not by its terms regulate or penalize biopharmaceutical manufacturers, its intended effect is to restrict the discussions that biopharmaceutical company representatives have with physicians — in the words of the parallel statute enacted in Vermont, to rectify a perceived imbalance in "the marketplace of ideas." Vermont Act 80, § 1(4). In determining that the Prescription Information Law regulates only conduct, the First Circuit ignored the intent of the New Hampshire Legislature not only to restrict speech of biopharmaceutical manufacturers, but to do so based on the viewpoint they express —the most invidious form of First Amendment violation. Particularly given that three states have enacted, and another 14 are considering, similarly discriminatory legislation, PhRMA and BIO have a significant interest in this Court's resolution of the issues, before the First Circuit's erroneous decision encourages further infringements on the free speech of their members.

SUMMARY OF ARGUMENT

The purpose and effect of the Prescription Information Law is to facilitate speech the government favors and to obstruct speech it dislikes. The First Amendment does not permit such government incursions on free speech. Although the Prescription Information Law does not directly bar biopharmaceutical manufacturers from using prescriber

data, it prohibits Petitioners from selling the information to them — but only if the manufacturers use it to promote their drugs. At the same time, the Prescription Information Law permits transfer of the data to speakers besides manufacturers for commercial uses in influencing doctors *not* to prescribe brand-name drugs. The legality of the transfer therefore depends on the identity of the customer and what the customer communicates.

This restriction of the truthful speech of biopharmaceutical manufacturers cannot withstand intermediate scrutiny, because the State cannot establish that it directly advances substantial state interests in a manner no more extensive than necessary. Rather than undertaking the searching inquiry this Court has mandated, the First Circuit shifted the burden of proof to Petitioners and even then assessed only whether the law was "reasonably calculated" to advance the State's asserted interests. Proper application of intermediate scrutiny demonstrates that the Prescription Information Law does not directly advance the State's asserted interests and is far more extensive than necessary.

ARGUMENT

I. The Intent And Effect Of The Prescription Information Law Is To Restrict Speech Of Biopharmaceutical Manufacturers

A. The Prescription Information Law Seeks To Suppress Speech On The Basis Of Viewpoint

In upholding the Prescription Information Law, the First Circuit concluded that the Petitioners' "acquisition, aggregation and sale" of prescribing history information, Pet. App. 16, described as "upstream" activity, was not speech, Pet. App. 12, 26.[4] Petitioners have demonstrated that their communication of prescribing histories to biopharmaceutical manufacturers and others is in fact speech protected by the First Amendment. But of more pressing import to PhRMA and BIO, the First Circuit also erred in its alternative evaluation of the "downstream" effect of the Prescription Information Law on speech between biopharmaceutical manufacturers and physicians. The First Circuit conducted this analysis even after acknowledging that, because "no detailer or doctor is a plaintiff here," judicial restraint counseled that "adjudication of that aspect of the law . . . await a proper plaintiff." Pet. App. 24.

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[4] The District Court in Vermont reached a contrary result, concluding that "prescriber identifiable data is protected 'speech' under the First Amendment." *IMS Health Inc. v. Sorrell*, Case 1:07-cv-00188-jgm, 2009 WL 1098474, at *5 (D. Vt. Apr. 23, 2009).

Indeed, the central purpose of the Prescription Information Law is to restrict the speech of biopharmaceutical manufacturers. As Judge Lipez noted in his concurrence/dissent, "the 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." Pet. App. 51 (emphasis added); *see also IMS Health, Inc. v. Sorrell*, 2009 WL 1098474, at *6 ("Plainly, the whole point of section 17 is to control detailers' commercial message to prescribers.").

That this issue arises in the context of healthcare cannot obscure the First Amendment violation. If the State had barred the sale of Nielsen ratings to fast food advertisers to prevent them from targeting shows that appeal to young adults, there would be no doubt the restriction violated the First Amendment, even though it did not directly regulate advertisers. The Prescription Information Law is at least as serious an infringement of speech. Although it does not directly bar biopharmaceutical manufacturers from using prescriber information or impose penalties on them, it prevents entities like Petitioners from selling it to them for use in promoting their drugs. Depriving a speaker of the tools to speak effectively, for the express purpose of preventing it from delivering a particular message, violates the First Amendment. *Cf. Grosjean v. Am. Press Co.*, 297 U.S. 233, 250 (1936) (license tax violated First Amendment "because, in the light of its history and of its present setting, it is seen to be a deliberate and calculated device in the guise of a tax to limit the

circulation of information to which the public is entitled"); *see generally Minneapolis Star & Tribune Co. v. Minn. Comm'r of Revenue*, 460 U.S. 575, 585 (1983) ("[D]ifferential treatment, unless justified by some special characteristic of the press, suggests that the goal of the regulation is not unrelated to suppression of expression, and such a goal is presumptively unconstitutional."); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 564 (2001) (restrictions on modes of advertising violated First Amendment).

New Hampshire's discrimination based on the viewpoint of speech is flagrant. The Prescription Information Law prohibits transfer of prescriber data for purposes of promoting sales of prescription drugs, but permits it for other purposes that influence a doctor's prescribing decision and further the commercial interests of speakers, such as the State and health insurers. *See* Pet. App. 77 ("In effect, the statute prohibits the use of prescriber-identifiable data for all purposes related to detailing, but seeks to preserve access to the data for other uses — including commercial purposes." (Lipez, J., concurring in part, dissenting in part)). To put it starkly, the Prescription Information Law bars Petitioners from selling their prescriber identifiable data to a biopharmaceutical manufacturer that seeks to use it to tell a New Hampshire doctor, "Prescribe this drug." But Petitioners could sell the same information to an insurance company that, with no less commercial motive, could use it to tell the same doctor, "Do *not* prescribe this drug." The First Amendment does not allow the government to facilitate speech it favors and obstruct speech it disfavors. *See Greater New Orleans Broad. Ass'n v.*

United States, 527 U.S. 173, 193-94 (1999) (noting impermissibility of choosing between speakers in commercial marketplace).

The First Circuit condoned this favoritism in concluding that New Hampshire could properly seek to "level the playing field" of speech concerning pharmaceutical products by restricting the communications of one of the players, biopharmaceutical manufacturers. Pet. App. 25. Such legislative control of the *free* marketplace of ideas is no more permissible than if the state barred advertising by brand-name soda companies to "level the playing field" for store brand soda. A state cannot ban speech — including commercial speech — simply because it is effective. As Justice Brandeis recognized, the essential feature of the marketplace for ideas is that if one viewpoint is prevailing, "the remedy to be applied is more speech, not enforced silence." *Whitney v. California*, 274 U.S. 357, 377 (1927) (Brandeis, J., concurring). In particular, the government may not impede the dissemination of truthful information based on a paternalistic view that the speech may lead others — in this case, trained medical professionals — to make certain decisions. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002) ("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."); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.");

Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976) ("It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if freely available, that the First Amendment makes for us."); *see also Edenfield v. Fane*, 507 U.S. 761, 767 (1993) ("[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented."); *Greater New Orleans*, 527 U.S. at 195 (noting "presumption that the speaker and the audience, not the Government, should be left to assess the value of accurate and nonmisleading information about lawful conduct").

B. The Prescription Information Law, As The Legislature Intended, Would In Fact Obstruct The Free Speech Of Biopharmaceutical Manufacturers

The premise underlying the Prescription Information Law is that biopharmaceutical manufacturers use prescription histories to target physicians for sales calls and to tailor sales presentations to the practice of those physicians. By denying data to biopharmaceutical companies, the State theorizes, the Prescription Information Law will deprive the companies of this "advantage," making the messages conveyed less individualized and hence less effective. In other words, the ban will force biopharmaceutical manufacturers to change their speech to prescribing physicians.[5]

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[5] To be sure, Petitioners feel the immediate brunt of New Hampshire's effort to suppress the lawful and non-misleading (Cont'd)

Because of the restrictions imposed on entities such as Petitioners, biopharmaceutical companies will no longer have information on the prescribing history of individual New Hampshire doctors to facilitate discussions between detailers and doctors in New Hampshire, to provide doctors the most useful scientific information, and to focus on those doctors — such as the ones who prescribe the drug most frequently — who will derive the greatest benefit from learning more about the drug. In restricting truthful messages that biopharmaceutical manufacturers, guided by prescriber

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(Cont'd)
speech of biopharmaceutical manufacturers. The statute directly limits Petitioners' ability to speak; it bars them from communicating the information they collected, based on the downstream speech of their clients. Petitioners' communications, New Hampshire has determined, enable biopharmaceutical companies to sharpen their messages to physicians. By choking off Petitioners' communications to manufacturers, New Hampshire seeks to choke off the communications of manufacturers to doctors. Both levels of restriction violate the First Amendment. Both are interconnected, and — contrary to the First Circuit's holding on standing — both were appropriately part of Petitioners' claims. *Craig v. Boren*, 429 U.S. 190, 194 (1976) (Article III standing because statute inflicts "a direct economic injury through the constriction of [the] buyers' market"); *Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004) (Court is "quite forgiving with these criteria [for third-party standing] in certain circumstances," including First Amendment cases); *Sec'y of State of Md. v. Joseph H. Munson Co.*, 467 U.S. 947, 958 (1984) (third-party standing because "[t]he activity sought to be protected is at the heart of the business relationship between [plaintiff] and its clients, and [plaintiff's] interest in challenging the statute are completely consistent with the First Amendment interests of the [third parties] it represents").

identifiable data, convey to physicians, the Prescription Information Law may render detailing visits less efficient and less informative, which means that New Hampshire physicians could be deprived of information on new medications.

Indeed, that is the intended purpose of the statute. But the unintended consequence may be that Petitioners and other entities covered by the Prescription Information Law stop transferring prescribing data to biopharmaceutical manufacturers for *any* purpose, commercial or otherwise, for fear of being held responsible if companies in fact use the data commercially. In addition to using the prescriber data for marketing, biopharmaceutical manufacturers use these data to prioritize the release of public safety news alerts, including alerts regarding newly discovered side-effects; to disseminate information to prescribers; to implement prescription recall programs; to determine which products to develop and license; and to accelerate the development of new drugs based on the needs of the marketplace. Pet. App. 74 n.29 (citing Stipulation of Facts at 4-5), 107.[6] The Prescription Information Law may make prescriber data unavailable for these non-marketing uses. Moreover, if Petitioners cannot, as a

[6] Because biopharmaceutical companies use prescriber data for these non-marketing purposes, any commercial aspect of their communications using this data is "inextricably intertwined with otherwise fully protected speech." The communications are therefore subject to strict scrutiny. *Riley v. Nat'l Fed'n for the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988). As the Prescription Information Law cannot survive intermediate scrutiny, *see* pp. 13-23, *infra,* it follows *a fortiori* that it cannot withstand strict scrutiny.

practical matter, sell biopharmaceutical companies their data on New Hampshire physicians, it is not clear that it will be economically feasible for them to publish the data at all. The result could be that many non-profit and research organizations — who have received this information free of charge — will also no longer have access to it. That result would further undermine the public health.

The adverse impact of the First Circuit's validation of the Prescription Information Law may spread beyond New Hampshire. Similar statutes in two other states have already been challenged: (1) in Maine, the district court enjoined the statute, and the appeal was stayed pending the First Circuit's decision on the Prescription Information Law; and (2) in Vermont, the district court held that the statute restricted the speech of both data publishers and biopharmaceutical manufacturers, but satisfied intermediate scrutiny. The District Court in Vermont relied extensively on the First Circuit decision in this case, thus repeating the same errors. *See*, *e.g.*, *IMS Health, Inc. v. Sorrell*, 2009 WL 1098474, at *8, *10, *12. Legislation is pending in approximately 14 other states. Notwithstanding the idiosyncrasies of the New Hampshire statute and First Circuit precedent, legislatures in other states may view the decision below as a green light to abridge the free speech of biopharmaceutical manufacturers. However misguided these judgments may be, the failure of this Court to provide clarity now could result in additional burdens on the First Amendment rights of biopharmaceutical manufacturers. It could also place this Court in the position of having ultimately to invalidate the laws of many states rather than just one.

II. The Prescription Information Law Cannot Withstand Intermediate Scrutiny Under *Central Hudson*

A. The First Circuit Did Not Undertake The Searching Inquiry Required By *Central Hudson*

Central Hudson and its progeny put the burden on the State to establish that a restriction of truthful, non-misleading commercial speech "directly" advances "substantial" state interests in a manner "not more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); *see also 44 Liquormart*, 517 U.S. at 508-12; *Thompson*, 535 U.S. at 371-73. The First Circuit was not true to *Central Hudson* here. Instead, the Court invented a standard more akin to rational basis review. For example, rather than evaluating whether the State had proven that the Prescription Information Law "directly advanced" the professed goal of reducing health care costs, *Central Hudson*, 447 U.S. at 566, the First Circuit considered only whether "the state adequately demonstrated that the Prescription Information Law is *reasonably calculated* to advance its substantial interest in reducing overall health care costs within New Hampshire." Pet. App. 38. Under this standard, the State could abridge free speech if it rationally but wrongly thought that doing so would somehow further the State's interest.

Moreover, instead of considering whether the State had established that the Prescription Information Law

was "not more extensive than necessary to serve that interest," *Central Hudson*, 447 U.S. at 566, the First Circuit evaluated only whether Petitioners had "identified an alternative to the Prescription Information Law that promises to achieve the goals of the law without restricting speech." Pet. App. 41. It was not Petitioner's burden, however, to identify such alternatives. This Court has repeatedly held that this burden resides with the State. *See*, *e.g.*, *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) ("Government carries the burden" of justifying law regulating commercial speech.); *Edenfield*, 507 U.S. at 762 (Government has burden of showing "the harms it recites are real and that its restriction will in fact alleviate them.").

Intermediate scrutiny under the First Amendment demands a far more rigorous inquiry into the reliability and substantiality of the evidence supporting the restriction on speech. *See*, *e.g.*, *Gonzales v. Carhart*, 550 U.S. 124, 165 (2007) ("The Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake."); *Sable Commc'ns of Cal., Inc. v. FCC*, 492 U.S. 115, 129 (1989) ("Deference to a legislative finding cannot limit judicial inquiry when First Amendment rights are at stake." (internal quotations omitted)). It requires a searching and independent review. The First Circuit's review was not searching. It was not independent. And it was not the inquiry demanded by *Central Hudson*. Had the Court undertaken the requisite assessment —which Petitioners in fact had standing to pursue — it could not have upheld the Prescription Information Law.

B. The Prescription Information Law Does Not Directly Advance The State's Asserted Interests And Is Far More Extensive Than Necessary

The State's asserted interest in the Prescription Information Law is lowering health care costs. Relying on speculation, the Legislature postulated that prohibiting the transfer of prescriber data would make detailers less persuasive in speaking with physicians. That poorer advocacy would result in physicians prescribing fewer of the more-expensive brand-name drugs. That, in turn would lower health care costs. This chain of causation contains only weak links.

First, it is inappropriate to consider only the costs of prescription drugs, as New Hampshire did, and not to assess whether appropriate use of those drugs lowers other health care costs. Thus, the Legislature should have assessed whether non-drug treatments are available, whether particular brand-name drugs are more effective, whether they reduce expensive hospitalizations, whether they improve quality of life, and whether they extend life.[7] No authority suggests

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[7] Available empirical evidence demonstrates that use of newer drugs decreases total treatment costs, increases longevity, and improves quality of life. *See*, *e.g.*, Frank R. Lichtenberg, *The Effect of Using Newer Drugs on Admissions of Elderly Americans to Hospitals and Nursing Homes: State-level Evidence from 1997 to 2003*, 24 SUPPL. 3 PHARMACOECONOMICS 5, 21-23 (2006) (as age of drugs in therapy increased, hospital admissions and expenditures increased and discharges decreased); Frank R. Lichtenberg, *Are the Benefits of Newer*

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that a state has a legitimate interest, much less a substantial one, in lowering what it or the public pays for prescription drugs, without considering the consequent costs and burdens.

Even if the State's narrow focus on reducing the amount of brand-name drugs prescribed in New Hampshire did delimit an appropriate state interest, New Hampshire had to show that the Prescription Information Law "*directly* advance[d]" that interest. *Central Hudson*, 447 U.S. at 564 (emphasis added). The key word is "directly."

This Court made clear in *Central Hudson* that "the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Id.* The Court reiterated in *Edenfield* that "mere speculation or conjecture" is insufficient to fulfill these requirements. 507 U.S. at 770. And, in *Rubin,* the Court emphasized that this requirement is "critical;

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Drugs Worth Their Cost? Evidence from the 1996 MEPS, 20 Health Affairs 241, 248 (2001) (as usage of newer drugs increases, reductions in non-drug expenditures greatly exceeds increase in drug expenditures, yielding net decrease of health care expenditures); Frank R. Lichtenberg, *The Value of New Drugs: The Good News in Capsule Form*, The Milkin Institute Review, Fourth Quarter 2003, 22-25 (2003) (prescribing newer drugs increased longevity, decreased total treatment costs, and improved quality of life); Frank R. Lichtenberg, *The Effect of New Drug Approvals on HIV Mortality in the US, 1987-1998*, 1 Economics and Human Biology 259, 265 (2003) (increase in new drugs for HIV played key role in decline of HIV mortality).

otherwise, 'a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.'" 514 U.S. at 487 (quoting *Edenfield*, 507 U.S. at 771); *see also Va. State Bd. of Pharm.*, 425 U.S. at 766-68 (ban on advertising drug prices would not directly advance state's goals of maintaining professionalism among licensed pharmacists and protecting patient health); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 368, 377 (1977) (advertising ban would not protect quality of attorneys' work but would increase legal fees). The First Circuit's holding, however, permits experimental infringements on protected speech — infringements based on hope and conjecture. *See* Pet. App. 36-37 ("[W]e must allow the state legislature some leeway to experiment with different methods of combating a social and economic problem of growing magnitude."). In failing to require actual proof that such restrictions would directly advance the government's interest, the First Circuit strayed from the precedents of this Court, *see Edenfield*, 507 U.S. at 770, and of other Circuits. *See, e.g.*, *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 100 (2d Cir. 1988) (state must "marshal[] some empirical evidence to support its assumptions");[8] *Midwest Media Prop., L.L.C. v. Symmes Tp., Ohio*,

[8] Relying exclusively on the First Circuit's decision in this case, the District Court of Vermont mistakenly failed to address this controlling Second Circuit precedent. *See IMS Health Inc. v. Sorrell*, 2009 WL 1098474, at *12 ("[E]mpirical evidence is not a requirement to withstand the intermediate scrutiny of *Central Hudson* in a case such as this." (citing *IMS Health v. Ayotte*, 550 F.3d 42, 55-59 (1st Cir. 2008))). Thus, this decision is already creating confusion in other courts.

503 F.3d 456, 475 (6th Cir. 2007) (standard "depends neither on obviousness nor common sense" but "requires *some* evidence to establish that a speech regulation addresses actual harms with some basis in fact"); *Mason v. Fla. Bar*, 208 F.3d 952, 957-58 (11th Cir. 2000) (noting need for actual evidence).

As the District Court correctly found, New Hampshire did not make the showing *Central Hudson* requires. First, there is no evidence that restricting the transfer of prescriber data to biopharmaceutical manufacturers to prevent sales representatives from tailoring their presentations to individual physicians will actually reduce prescriptions of brand-name drugs. Physicians, not surprisingly, base prescribing decisions on a variety of factors specific to each patient, such as age, allergies, prior responses to drugs, and the like. Physicians obtain information for these decisions from various sources, not merely from in-person meetings with pharmaceutical representatives. In the decades that detailers have called on physicians, no state has previously sought to restrict these communications as New Hampshire has. Thus, the Legislature's prediction that doctors will change their behavior in the face of such restrictions rests on no historical experience.

In the place of experience, the State relies on two paternalistic assumptions to support its assertion that restricting communication of truthful information to physicians will decrease inappropriate prescribing of brand-name drugs: *one,* that the State cannot trust highly trained, well-educated, medical professionals to make appropriate decisions regarding which drugs to prescribe to their patients, and *two,* that without the

paternalistic protection of the State, these trained medical professionals cannot resist the wiles of detailers. The overbreadth of these assumptions highlights their logical infirmity. They apply across the board, no matter how accomplished the physician, no matter how powerful the drug, no matter how truthful and honest the sales representative, and no matter how onerous the federal criminal penalties for false or misleading statements in the marketing of prescription drugs. *See* 21 U.S.C. §§ 321(m), 331(a), 333(a), 352(a) (2007); 21 C.F.R. § 202.1 (2008).

Second, as noted, the Prescription Information Law would make detailing less efficient, because biopharmaceutical companies could not determine with the same accuracy which prescribers most want to hear about a given product. Companies could well respond by having sales representatives call on more physicians, including physicians whom prescriber data previously indicated were unlikely to be interested, to ensure that they still reach those who are interested and who would benefit from the meeting. The inefficiency could increase marketing costs, but there is no explanation of how or why that would translate into reduced healthcare costs. Indeed, the Legislature had no empirical evidence that its restrictions would lower the overall cost of prescription drugs. *See* Pet. App. 192 ("Because the Attorney General has failed to prove that any reductions in health care costs that may result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care, I am unable to endorse her argument that the Prescription Information Law can be justified as a cost containment measure.").

Third, as discussed, the Prescription Information Law targets only one subset of healthcare expenditures. If the restriction caused doctors to prescribe fewer brand-name drugs than is optimal, overall health expenditures could increase, even if prescription drug costs decrease. Again, the Legislature had no empirical evidence whatsoever suggesting that the Prescription Information Law would decrease overall health care costs. *See id.*

Central Hudson also demands that the State demonstrate a reasonable fit between the limitation on speech and the interest asserted — *i.e.*, that the restriction is narrowly tailored to achieve the desired objective. *Lorillard*, 533 U.S. at 528. This Court has instructed that if a state "could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Thompson*, 535 U.S. at 371; *see also id.* at 373 ("If the First Amendment means anything, it means that regulating speech must be the last — not the first — resort."); *44 Liquormart*, 517 U.S. at 509-10 ("*Posadas* clearly erred in concluding that it was 'up to the legislature' to choose suppression over a less speech-restrictive policy."). In *Central Hudson*, this Court invalidated a ban on advertising of electricity because, though important, the government's interest in reducing the use of energy did not "justify suppressing information about electric devices or services that would cause no net increase in total energy use." 447 U.S. at 570. The Prescription Information Law similarly imposes a sweeping ban on the transfer of prescriber data for commercial use by biopharmaceutical companies and fails to differentiate between beneficial and "harmful" detailing.

Biopharmaceutical companies market their products in many ways. In restricting the transfer of prescriber-identifiable data, the Prescription Information Law addresses, albeit indirectly, only one of them — visits to physicians by sales representatives. Detailers' meetings with physicians can be helpful and scrupulously candid. Or they might be unhelpful and lacking in candor. If so, the physician likely would not invite the sales representative back and the representative could be subject to federal law penalties if the information presented is found to be untruthful, inaccurate, or misleading. But the Prescription Information Law draws no distinction between truth and falsity. It prevents both candid and un-candid sales representatives from using prescriber-identifiable data. The Prescription Information Law thus prevents helpful, honest detailing by sales representatives who use prescriber-identifiable data, while leaving untouched any unhelpful sessions by detailers who do not use such information. Insofar as New Hampshire seeks to ensure that physicians receive appropriate information about prescription drugs, the Prescription Information Law is both over- and under-inclusive. Moreover, though designed to encourage prescribing of cheaper generic drugs instead of expensive brand-name products, the Prescription Information Law applies even when a brand-name drug has no generic equivalent, when two brand-name drugs are being compared, and when an improved version of a brand-name drug is being compared to its earlier version. And, though designed to decrease the cost of healthcare, the Prescription Information Law restricts speech even when the brand-name drug is not the most expensive treatment. Indeed, it restricts speech even when the

use of a brand-name drug would reduce overall healthcare costs.

This was not a case where New Hampshire exhausted its other options. The State failed even to test obvious alternatives to the Prescription Information Law which do not restrict speech. The State could have addressed its concerns by, for example, implementing an academic detailing program to inform physicians about generic drugs and about the methods used to market prescription drugs.[9] The State could have required prescribers to receive training about marketing as a part of their continuing medical education. It could have sent "Dear Healthcare Professional" letters to educate prescribers. It could have more aggressively implemented measures such as comprehensive drug formularies, prior authorization, and step therapies. And it could have supported industry ethical codes. Although the dissent touted the resources that biopharmaceutical companies devote to marketing, the Court did not consider, and the Legislature made no effort to evaluate, the vast resources of the health insurance industry, which has every incentive to discourage prescribing of brand-name drugs.

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[9] Since enactment of the Prescription Information Law, New Hampshire has required the development of an "evidence-based prescription drug education program." N.H. Rev. Stat. Ann. § 126-A:5(XVII) (eff. June 3, 2008). However, the Legislature did not implement and test the effectiveness of this option before enacting the Prescription Information Law.

As noted, rather than requiring New Hampshire to show why these less restrictive and more direct means of advancing the State's interests were inadequate or infeasible, the First Circuit imposed the onus on Petitioners to establish the superiority of less restrictive alternatives. *See* Pet. App. 41. But under the First Amendment, the speaker does not have to prove that its free speech should be protected. Rather, the state must justify its abridgement of First Amendment rights. *See Edenfield*, 507 U.S. at 770. As this Court has made clear, plaintiffs only needed to show that other less restrictive means "might be possible." *Thompson*, 535 U.S. at 372. It was the State's burden to show that they were not.

To let the First Circuit's revision of the *Central Hudson* test stand would countenance infringement of the First Amendment rights of both Petitioners and biopharmaceutical manufacturers. It could also signal to other states that federal courts need *not* undertake the "independent and searching inquiry" mandated by *Central Hudson* into First Amendment violations, that any "limitation on expression" need not be "designed carefully to achieve the State's goal," *Central Hudson*, 447 U.S. at 564, and that states need not constrain their intervention into the commercial marketplace of ideas. This Court should grant review now to prevent these affronts, rather than risk having to undo them later.

CONCLUSION

For the foregoing reasons, the Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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