No. 08-1202

MAY 27 2009

In The
Supreme Court of the United States

IMS HEALTH, INC. and VERISPAN, LLC,

Petitioners,

v.

KELLY A. AYOTTE, As Attorney General
Of The State Of New Hampshire,

Respondent.

**On Petition For A Writ Of Certiorari
To The United States Court Of Appeals
For The First Circuit**

BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTIONS PRESENTED

1. Whether the First Circuit correctly held that the Prescription Information Law regulates conduct, not First Amendment protected speech, of data miners.

2. Whether the First Circuit, in its alternative holding, correctly applied the *Central Hudson* test in holding that the Prescription Information Law passes constitutional muster.

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STATEMENT OF THE CASE

1. The New Hampshire legislature enacted the Prescription Information Law ("PIL")[1] in 2006 as a measure to control health care costs in New Hampshire, to protect the health and safety of New Hampshire's citizens, and to protect the privacy of doctors and patients who use prescription drugs. Before the PIL came into effect, data mining companies such as Petitioners IMS Health and Verispan were able to purchase information from pharmacies about what individual physicians prescribed to their patients. The data mining companies would aggregate the information and sell it to pharmaceutical companies for use in their marketing activities. Pharmaceutical companies used the information to target doctors for office visits by sales representatives (called "detailing"). Detailing is generally confined to high-margin, high profit drugs, for which the manufacturer has a substantial incentive to increase sales. Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products, and contributes to the strain on health care budgets for individuals as well as health care programs, especially Medicaid.

Pharmaceutical manufacturers invest considerable resources in marketing efforts; for example, in 2000, the industry spent around $15.7 billion on

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[1] 2006 N.H. Laws 328, codified at N.H. Rev. Stat. § 318:47-f, N.H. Rev. Stat. § 318:47-g, and N.H. Rev. Stat. § 318-B:12.

marketing, $4 billion of which was dedicated to direct-to-physician strategies. In fact, the large pharmaceutical companies spend a higher proportion of their revenues on promotion, marketing, and administration than the proportion spent on research and development. Detailing in particular has a significant effect on physician prescribing behavior, yet physicians are often unaware of the substantial impact manufacturer promotional activities have on their prescription practices. The purpose of all this contact and communication by detailers is not to provide an unbiased review of the evidence, but rather to enhance sales of a given company's product, whether or not it is the most appropriate or cost-effective choice.

Because of its powerful effect on physicians' prescribing practices, detailing by pharmaceutical sales representatives has significant economic and clinical consequences for the health care system. Physicians' use of targeted prescriptions increases substantially after visits with sales representatives. This has important effects on the cost of medications since detailing is generally confined to high-margin, high profit drugs, for which the manufacturer has a substantial incentive to increase sales. The effect of detailing in driving physicians' prescribing practices to the newest, most costly products can also have an important effect on patients' clinical outcomes. Because full understanding of a drug's side effect profile may not be complete when the drug is first approved for marketing, detailing encourages the prescription of

new products that might be riskier to patients than known agents on the market.

The New Hampshire legislature sought to curb this escalating problem by enacting the PIL which, among other things, prohibits the use, transfer, license, or sale of prescription information containing prescriber-identifiable data for certain commercial purposes. By preventing the use of prescriber specific prescription information in detailing physicians, the Act would cause a shift in the message being provided by pharmaceutical representatives. Conversations between detailers and physicians would be less tailored by the detailer and his or her primary interest in the market share of the drug being promoted, and would focus more on the science of the drug. The PIL's restrictions are very narrowly targeted. The PIL does not prevent Petitioners from continuing to gather and analyze prescriber-identifiable information, nor does it prevent them from publishing, transferring, and selling this information to whomever they choose so long as the recipient does not use the information for marketing.

2. Petitioners filed an action for declaratory and injunctive relief in the United States District Court for the District of New Hampshire. Petitioners asserted that the PIL violates the First Amendment, the Commerce Clause, and is void for vagueness. No pharmaceutical companies joined the action. After a bench trial, the district court issued an order on April 30, 2007, ruling that the PIL violates Petitioners' First Amendment right to engage in commercial

speech, and enjoined its enforcement. Pet. App. 152-199. The Court made no ruling regarding IMS Health and Verispan's Commerce Clause claim. *Id.*

The respondent appealed, and the First Circuit Court of Appeals reversed. Pet. App. 1-51. The First Circuit first addressed the issue of standing and held that Petitioners lack standing to assert the First Amendment rights of pharmaceutical detailers and physicians. Pet. App. 13-14. The court explained that "[a] party ordinarily has no standing to assert the First Amendment rights of third parties." Pet. App. 13 (quoting *Wine & Spirits Retailers, Inc. v. Rhode Island*, 418 F.3d 36, 49 (1st Cir. 2005)). The First Circuit rejected Petitioners' argument that the exception laid down in *Craig v. Boren*, 429 U.S. 190, 194-95 (1976), applied because there was "no indication in the record that pharmaceutical companies, detailers, or physicians are somehow incapable of or inhibited from vindicating their own rights." Pet. App. 15. Recognizing this Court's willingness to relax third-party standing in the First Amendment context, the First Circuit noted that "this relaxation evinces nothing more than a receptiveness to facial attacks on allegedly overbroad laws," and that otherwise, hindrance remains a necessary prerequisite. *Id.* The court stated that it would therefore restrict its analysis to "whether the data miners' activities – the acquisition, aggregation, and sale of prescriber-identifiable data – constitute speech or conduct and whether New Hampshire's legitimate governmental interests are

sufficient to counterbalance any speech rights inherent therein." Pet. App. 16.

The First Circuit then turned to "the relatively narrow question" of whether the PIL's restrictions on transfers of prescriber-identifiable information from pharmacies to data miners and data miners to pharmaceutical companies regulate the conduct or speech of data miners. Pet. App. 19, 22. The court recognized that while "pure informational data can qualify for First Amendment protection," Pet. App. 19, there are "species of speech-related regulations that effectively lie beyond the reach of the First Amendment," Pet. App. 20. "[W]hy or how these content-based prohibitions manage to escape First Amendment scrutiny" the court described as a "doctrinal mystery." Pet. App. 21. The First Circuit provided its own explanation as follows:

> In our view, the most natural explanation for this phenomenon is that this complex of de facto exceptions derives from a felt sense that the underlying laws are inoffensive to the core values of the First Amendment – inoffensive because they principally regulate conduct and, to the extent that they regulate speech at all, that putative speech comprises items of nugatory informational value. It is this unusual combination of features that distinguishes these laws and places them outside the ambit of the First Amendment.

Pet. App. 21-22. The court concluded that the restriction the PIL places on the data miners' activities falls

outside the First Amendment as "a restriction on the conduct, not the speech, of the data miners," describing the data miners' activities as "a situation in which information itself has become a commodity." Pet. App. 22-23. The First Circuit rejected Petitioners' assertion that the PIL limits the free flow of information, noting that the PIL "simply does not prevent any information-generating activities" because Petitioners "may still gather and analyze this information; and may publish, transfer, and sell this information to whomever they choose *so long as that person does not use the information for detailing.*" Pet. App. 23-24 (emphasis in original). The court recognized that Petitioners' true complaint was not the free flow of information, but rather their ability to turn a profit, a concern that the First Amendment does not safeguard against. Pet. App. 24.

Limiting its analysis to the restrictions the PIL places on data miners' activities,[2] the First Circuit held that "the challenged portions of the Prescription Information Law fall outside the compass of the First Amendment. They thus engender rational basis review as a species of economic regulation." Pet. App. 26. Because Petitioners conceded that the PIL survived rational basis review, the First Circuit held that their challenge under the Free Speech Clause failed. *Id.*

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[2] The court left open the question of whether the PIL restricts First Amendment protected speech of detailers or doctors. Pet. App. 24.

3. The First Circuit went on to provide an alternative ground for its decision. Pet. App. 26-42. Again restricting its analysis to the activities of data miners, the court reasoned that even if "the acquisition, manipulation, and sale of prescriber-identifiable data comes within the compass of the First Amendment," such transactions are commercial speech, if speech at all. Pet. App. 27. The First Circuit rejected Petitioners' narrow definition of commercial speech limited to activities "propos[ing] a commercial transaction," *see Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74 (1989), in favor of the broader definition adopted by this Court in *Central Hudson Gas & Electric Corp. v. Public Service Commission,* 447 U.S. 557, 561 (1980) (defining commercial speech as "expression related solely to the economic interest of the speaker and its audience"). Pet. App. 27-28.

The First Circuit then proceeded to apply the *Central Hudson* test. Examining whether the government had advanced a substantial state interest in support of the PIL, the court observed that the State had identified three interests served by the PIL: "[1] maintaining patient and prescriber privacy, [2] protecting citizens' health from the adverse effects of skewed prescribing practices, and [3] cost containment." Pet. App. 28. For simplicity's sake, the court restricted its analysis to the third of these interests. *Id.* Noting that "[f]iscal problems have caused entire civilizations to crumble," the First Circuit concluded that "cost containment is most assuredly a substantial governmental interest." Pet. App. 28.

Next, the First Circuit examined the second step of the *Central Hudson* test: whether the regulation directly advances the State's interest. The court explained that while the State "must demonstrate that the harms it recites are real" and that the restrictions at issue "will in fact alleviate them to a material degree," certitude is not required. Pet. App. 29. The court observed that "the state's evidence falls into three evidentiary subsets"; (1) "evidence showing that detailing increases the cost of prescription drugs"; (2) evidence "showing that prescribers' histories enhance the success of detailing"; and (3) "evidence indicating that, notwithstanding these escalating costs, detailing does not contribute to improved patients' health." Pet. App. 29-30. Thus, the State reasoned that "stripping detailers of the ability to use prescribers' histories as a marketing tool" will decrease the amount of more expensive brand-name drugs dispensed, thus reducing or containing overall costs. Pet. App. 30.

As to the first subset of evidence, the First Circuit found it "unarguable" that detailing increases the cost of prescription drugs, noting "[t]he fact that the pharmaceutical industry spends over $4,000,000,000 annually on detailing bears loud witness to its efficacy." Pet. App. 30-31. The court also found that "[t]estimony adduced at trial reinforced these common-sense conclusions." Pet. App. 31. Turning to the second and third step in the analysis, the First Circuit summarized the evidence presented by each side at trial and found that

> [t]he state provided competent evidence that detailing increases the prescription of brand-name drugs, that brand-name drugs tend to be more expensive, that detailers' possession of prescribing histories heightens this exorbitant effect, that many aggressively detailed drugs provide no benefit vis-à-vis their far cheaper generic counterparts, and that detailing had contributed to pharmaceutical scandals endangering both the public health and the public coffers.

Pet. App. 34-35. While admitting that the State's evidence was "not overwhelming," Pet. App. 33, the First Circuit found that the district court "subjected the state to a level of scrutiny far more exacting than is required for commercial speech," Pet. App. 34. The First Circuit also criticized the district court for "disregard[ing] the constraints under which states operate in formulating public policy on cutting-edge issues," noting that "New Hampshire was the first state to deny detailers access to prescribing histories." Pet. App. 35-36. Thus, the evidence the district court demanded of the State "simply does not exist." Pet. App. 36. The First Circuit found it appropriate to "allow the state legislature some leeway to experiment with different methods of combating a social and economic problem of growing magnitude." Pet. App. 36-37. The court rejected Petitioners' attack on the sufficiency of the legislative record, finding it "fanciful to suggest that the congressional record in *Turner* [*Broadcast Systems v. FCC*, 520 U.S. 180, 199 (1997)] represents the threshold for deference." Pet.

App. 37. "Given the contents of the legislative record," the First Circuit found that "deference is in order." *Id.*

Thus, on the second step of the *Central Hudson* test, the First Circuit "conclude[d] that 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.

Finally, the First Circuit turned to the third *Central Hudson* question: "whether the regulation is no more extensive than necessary to serve the state's interest in cost containment." *Id.* Applying the rule set forth in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002) – that regulating speech must be a last resort – the First Circuit considered, and rejected, the three alternative measures suggested by the district court. Pet. App. 38-41. The court reasoned that (1) a ban on gifts to physicians would target a harm the legislature did not deem central to its aims, and would have the unintended consequence of cutting off the flow of free samples which are often dispensed by physicians to indigent patients; (2) a program of "counter-detailing" by the State was not a feasible solution given that pharmaceutical companies spend over $4,000,000,000 per year on detailing; and (3) retooling the State's Medicaid program in the manner suggested by the district court was impracticable, incomplete, and would be an attempt to remedy compromised prescribing habits of physicians after the fact. Pet. App. 39-40. The First Circuit concluded that neither Petitioners nor the

district court had identified an appropriate alternative, and held that the PIL "is no more restrictive than necessary to accomplish [its] goals." Pet. App. 41.

Having held that the challenged portions of the PIL survive intermediate scrutiny, Pet. App. 41, the First Circuit turned to Petitioners' contention that the PIL is void for vagueness, Pet. App. 42-46, and Petitioners' Commerce Clause challenge, Pet. App. 46-50. The First Circuit rejected both claims, holding that the PIL "is sufficiently clear to withstand [Petitioners'] vagueness challenge," Pet. App. 43, and that the PIL is susceptible to a construction that does not violate the Commerce Clause, Pet. App. 48-50.

In conclusion, the First Circuit reversed the decision of the district court and vacated the injunction against enforcement of the PIL. Pet. App. 50-51.

4. Judge Lipez issued a separate opinion concurring in part and dissenting in part. Pet. App. 51-151. While he agreed with the majority's conclusion that Petitioners' activity "is not speech within the purview of the First Amendment," he disagreed with the majority's refusal to address what he described as "the First Amendment issue at the core of this case," namely, "whether the Act restricts protected commercial speech *between detailers and prescribers* and, if so, whether the State can justify that restriction under" the *Central Hudson* test. Pet. App. 51-52 (emphasis added). After examining the issue of standing, Pet. App. 52-63, Judge Lipez went on to address the

First Amendment issue avoided by the majority, Pet. App. 86-97. He concluded that because the PIL indirectly targets the speech of detailers in their sales messages to prescribers, the regulation "is a limitation on commercial speech, and the State consequently must bear the burden of demonstrating that it satisfies the *Central Hudson* test." Pet. App. 96. Applying that test, he concluded that the PIL survives intermediate scrutiny. Pet. App. 151. He agreed with the majority that the PIL is sufficiently clear to withstand Petitioners' vagueness challenge. *Id.* With regard to Petitioners' Commerce Clause claim, he would have remanded the case to the district court for it to address the issue in the first instance. Pet. App. 142.

5. The First Circuit denied Petitioners' request for rehearing and rehearing en banc, Pet. App. 201, as well as Petitioners' request to stay mandate pending filing for writ of certiorari. Petitioners then filed an emergency application to the Honorable David Souter to stay mandate pending certiorari, which was denied.

REASONS FOR DENYING THE PETITION

Contrary to Petitioners' assertions, the First Circuit decision in this case does not threaten the "basic economic viability of the Internet" or publications such as the daily stock report of the *Wall Street Journal*. In ruling that Petitioners' conduct falls outside

the protections of the First Amendment, the First Circuit considered the specific nature of the information exchanges regulated by the PIL. The court found that transfers of prescriber-identifiable information "undertaken to increase one party's bargaining power in negotiations" were not the sort of exchanges valued by the Supreme Court's First Amendment jurisprudence. Pet. App. 26. This may not hold true for other forms of informational exchanges occurring through the Internet or traditional media.[3] The First Circuit expressly declined to issue a more expansive ruling, explaining: "Were the state capable of forbidding every use of information regardless of the specific nature of either the use or the information, the state's power to control the flow of information would be nearly absolute." Pet. App. 18.

Petitioners have failed to identify any grounds warranting a grant of certiorari in this case. They first assert that the First Circuit's ruling that their data mining activities fall outside the protection of the First Amendment warrants review because it is in irreconcilable conflict with this Court's First Amendment precedent and because of the impact such a rule will have on the free flow of information. The decision

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[3] With regard to the *Wall Street Journal* and other such publications, there is a vast difference between silencing the media whose sole purpose is communicating information to the *public*, and prohibiting the dissemination of information from one private company to another private company for economic gain. Pet. App. 23-24.

below, however, fully comports with relevant First Amendment precedent and is limited to the PIL's regulation of data mining activities, making it unlikely that it will have the wide-reaching effects on the free flow of information suggested by Petitioners.

Next, Petitioners assert that the case implicates a conflict in the circuits concerning the proper definition of "commercial speech," and would also provide this Court with the opportunity to revisit whether commercial speech should remain subject to lessened First Amendment protection. This case would provide a poor vehicle for any further refinement of the *Central Hudson* framework given the First Circuit's ruling on standing. This Court has been reluctant to adopt an all-purpose test to distinguish commercial from noncommercial speech under the First Amendment, and the First Circuit's narrow holding in this case does not implicate the concerns raised by some Members of this Court regarding the *Central Hudson* analysis. Moreover, the First Circuit's *Central Hudson* analysis appears in the court's alternative ground for reversal; thus, if this Court agrees that Petitioners' data mining activities fall outside the protection of the First Amendment, then there would be no need to reach the issues relating to the definition of commercial speech and the appropriate level of judicial scrutiny for legislation restricting such speech. In any event, Petitioners' challenge to the First Circuit's *Central Hudson* analysis amounts to nothing more than a request for error correction, and thus does not merit a grant of certiorari.

Finally, Petitioners assert that the daily impact of the PIL on their activities and the adoption of similar statutes in other states necessitate this Court's prompt review of the statute's constitutionality. Reviewing the statute in the context of this case, however, would not resolve all potential First Amendment challenges that could arise from this or other similar statutes. Because the First Circuit limited its analysis to the PIL's effects on data mining activities only, the statute's effect on communications between detailers and doctors remains subject to future challenge. Because no pharmaceutical company is a party to this case, the record below is insufficient to address the First Amendment issues detailers could raise in a future challenge. Considering the First Circuit's limited holding and the lack of a complete record, this case is a poor vehicle through which to address the First Amendment issues raised by the PIL. A review by this Court of the constitutionality of the PIL is better left for another case.

Accordingly, the petition for a writ of certiorari should be denied.

I. THE FIRST CIRCUIT'S HOLDING THAT THE PRESCRIPTION INFORMATION LAW DOES NOT IMPLICATE THE FIRST AMENDMENT RIGHTS OF DATA MINERS DOES NOT CONFLICT WITH THE DECISIONS OF THIS COURT

The First Circuit's holding that the PIL regulates conduct, not speech, was not necessary to its decision

and not in conflict with this Court's precedents. The decision does not conflict with precedent of this Court establishing that purely factual matters of public interest may claim First Amendment protection. The First Circuit expressly recognized that "pure informational data can qualify for First Amendment protection." Pet. App. 19 (citing *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-47 (2nd Cir. 2001), and *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976)). The decision below fully comports with relevant First Amendment precedents; Petitioners simply disagree with how the First Circuit applied those precedents to the facts of this case. Thus, Petitioners' challenge to the First Circuit's decision that data mining activities fall outside the protection of the First Amendment is nothing more than a request for error correction by this Court. In any event, Petitioners greatly overstate the import of the court's first holding. The First Circuit went on to fully consider the commercial speech arguments and held that the law satisfies *Central Hudson*. Indeed, the concurring judge agreed with the majority regarding the application of *Central Hudson*.

1. The First Circuit's holding does not hinge on the *factual* nature of the data being regulated; rather, the court found that the statute regulates conduct, not speech, because it does not prevent any information-generating activities. The PIL does not prevent Petitioners from gathering and analyzing prescriber-identifiable information, nor does it prevent them

from publishing, transferring, and selling this information to whomever they choose so long as the recipient does not use the information for marketing. Thus, the PIL does not prevent Petitioners from *communicating* information; rather, the PIL's restrictions affect the *value* of that information as a commodity in the marketplace due to the restrictions it places on the *recipient's* use of the information. The PIL's restrictions on a third party's use of information do not abridge these Petitioners' freedom of speech under the First Amendment.[4]

The PIL is distinguishable from advertising regulations. Unlike advertising regulations, which restrict the dissemination of information *about* commercial transactions, the PIL regulates commercial transactions themselves. It is the communicative nature of advertising that brings such speech within the ambit of First Amendment protection. *See Central Hudson*, 447 U.S. at 563 ("The First Amendment's concern for commercial speech is based on the informational function of advertising."). While an advertisement constitutes "speech" within the scope of the First Amendment because it expresses a message by "propos[ing] a commercial transaction," *see Virginia*

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[4] As mentioned earlier, the First Circuit held that the Petitioners lacked standing to assert the First Amendment rights of pharmaceutical detailers and physicians, and thus restricted its analysis to whether data miners' activities constitute speech or conduct. The First Circuit left open the question of whether the PIL restricts First Amendment protected speech of detailers or doctors. Pet. App. 24.

Pharmacy, 425 U.S. at 762, the actual transaction which follows is not the expression of a message, commercial or otherwise, and therefore does not fall within the First Amendment's protection, *see Ohralik v. Ohio State Bar Assoc.*, 436 U.S. 447, 455 (1978) (recognizing that "*expression*[*s*] concerning purely commercial transactions ha[ve] come within the ambit of the [First] Amendment's protection") (emphasis added). Regulating commercial transactions themselves does not implicate the First Amendment. *See 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 499 (1996) (recognizing the State's power to regulate commercial transactions as a justification to regulate commercial speech linked to those transactions: "The entire commercial speech doctrine, after all, represents an accommodation between the right to speak and hear expressions *about* goods and services and the right of government to regulate the sales *of* such goods and services.") (Emphasis in original) (citation omitted). The fact that the commodity being regulated in this case is a collection of information does not bring the data miners' activities within the protections of the First Amendment. *See Rumsfield v. Forum for Academic and Institutional Rights, Inc.*, 547 U.S. 47, 126 S. Ct. 1297, 1308 (2006), quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949) ("[I]t has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed."); *see also Reno v. Condon*, 528 U.S. 141, 148 (2000)

(holding that data is a "thing in interstate commerce").

The First Circuit's decision does not conflict with this Court's decisions in *Thompson*, 535 U.S. 357, *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749 (1985), and *LAPD v. United Reporting Publishing Corp.*, 528 U.S. 32 (1999), none of which addressed the speech/conduct question. In *Thompson*, an advertising case, this Court did not consider whether the statute at issue restricted speech protected by the First Amendment because the parties agreed that the statute prohibited commercial speech. 535 U.S. at 366. Similarly, in *Dun & Bradstreet*, a defamation action, the issue of what constitutes speech under the First Amendment did not arise. 472 U.S. 749. The issue was not whether the defamatory statements at issue constituted speech protected by the First Amendment, but rather whether the statements involved matters of public concern which would restrict the damages the plaintiff could obtain. *Id.* at 757-63. Finally, in *United Reporting* the Ninth Circuit did not consider whether a private publishing service's provision of arrest records to its customers constituted speech versus conduct, but rather whether its use of the information constituted commercial speech versus fully-protected First Amendment speech. 146 F.3d 1133, 1136 (9th Cir. 1999). On appeal to the Supreme Court, the police department "concede[d] that if [the publishing service] independently acquires the data, the First Amendment protects its right to communicate it to others." *United Reporting*,

528 U.S. at 46. Thus, the speech/conduct question at issue in the instant case was not considered in *United Reporting*.

2. The First Circuit's ruling that the PIL regulates Petitioners' conduct, not protected speech, also does not conflict with the rulings of other circuits. Although the Second Circuit held in *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, that "computer code, and computer programs constructed from code *can* merit First Amendment protection," *id.* at 449 (emphasis added), the Court recognized that computer programs do not *always* communicate speech protected by the First Amendment, *id.* at 448-49 (discussing *Commodity Futures Trading Commission v. Vartuli*, 228 F.3d 94, 109-12 (2nd Cir. 2000)). In *Vartuli*, the Second Circuit considered the *manner* in which a computer program was used, and denied First Amendment protection to the program in that case even though it was expressed in words. *Vartuli*, 228 F.3d at 111.

Petitioners also suggest that the First Circuit's decision conflicts with rulings of the D.C. Circuit. However, none of the cases Petitioners cite, *Nat'l Cable Television Ass'n, Inc. v. FCC*, 555 F.3d 996 (D.C. Cir. 2009), *Trans Union LLC v. FTC*, 295 F.3d 42 (D.C. Cir. 2002), and *Trans Union Corp. v. FTC*, 245 F.3d 809, *reh'g denied*, 267 F.3d 1138 (D.C. Cir. 2001), *cert. denied*, 536 U.S. 915 (2002), address the speech/conduct question. In *Nat'l Cable*, all parties proceeded on the basis that there was a regulation of commercial speech. 555 F.3d at 1000. Similarly, in *Trans*

Union, the D.C. Circuit applied First Amendment scrutiny without considering the threshold question of whether the sale of target marketing lists constitutes protected speech. 245 F.3d at 818. Because the speech/conduct question was not raised or addressed in those cases, they do not directly conflict with the First Circuit's ruling that the PIL regulates data miners' conduct, not First Amendment protected speech.

Although the Tenth Circuit *did* directly address the threshold question for application of the First Amendment in both *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232-33 (10th Cir. 1999) and *Lanphere & Urbaniak v. Colorado*, 21 F.3d 1508, 1512-13 (10th Cir. 1994), *cert. denied*, 513 U.S. 1044, those cases are distinguishable. The companies challenging the regulations at issue in *U.S. West* and *Lanphere* directly sought to use the information for their own marketing; therefore, the effect of the regulations on their First Amendment speech rights are more analogous to the rights of pharmaceutical detailers, not data miners. The First Circuit here did not consider whether the PIL restricts First Amendment protected speech of pharmaceutical detailers, leaving that question unanswered.

The First Circuit correctly concluded that the restriction the PIL places on the data miners' activities falls outside the First Amendment as a restriction on the conduct, not the speech, of the data miners. The court's holding does not conflict with decisions of this Court or the rulings of other circuits,

and does not warrant review by this Court. Moreover, the holding is not necessary to the decision since the court went on to fully consider the commercial speech argument.

II. THE FIRST CIRCUIT CORRECTLY RULED IN ITS ALTERNATIVE HOLDING THAT THE PIL PASSES CONSTITUTIONAL MUSTER

As an alternative ground for its holding, the First Circuit ruled that even if the data miners' activities come within the compass of the First Amendment, such transactions constitute commercial speech, if speech at all, and the PIL survives intermediate scrutiny. Petitioners claim this holding warrants review on two grounds. First, Petitioners assert it provides an opportunity for this Court to clarify the definition of "commercial speech," and to revisit whether commercial speech should remain subject to lessened First Amendment protection. Second, Petitioners erroneously contend that the First Circuit's holding that the PIL survives First Amendment scrutiny was wrong.

A. This Case Does Not Provide Occasion For This Court to Revisit the Commercial Speech Doctrine

This Court has not adopted an all-purpose test to distinguish commercial from noncommercial speech under the First Amendment. Although the Court first defined the category of commercial speech as "speech

which does no more than propose a commercial transaction," *Virginia Pharmacy*, 425 U.S. at 762, in later opinions the Court has "also suggested that such lesser protection was appropriate for a somewhat larger category of commercial speech – 'that is, expression related solely to the economic interests of the speaker and its audience.'" *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 422 (1993) (quoting *Central Hudson*, 447 U.S. at 561). The Court has recognized "the difficulty of drawing bright lines that will clearly cabin commercial speech in a distinct category," *Discovery Network*, 507 U.S. at 419, noting that "ambiguities may exist at the margins of the category of commercial speech," *Edenfield v. Fane*, 507 U.S. 761, 765 (1993). This Court has been reluctant, for good reason, to reduce the doctrine to any simple rule or determinate criteria,[5] and it should decline to do so now.

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[5] [The] Court has in its commercial speech doctrine persistently gestured toward the "common sense" distinction between commercial speech and speech at the First Amendment's core. The evaluations of "commonsense" are complex, contextual, and ultimately inarticulate; the Court's appeal to common sense acknowledges that the achievement of constitutional purposes cannot be reduced to any simple rule or determinate criteria. The judgments of common sense ultimately revolve around questions of social meaning; they turn on whether the utterance of a particular speaker should be understood as an effort to engage public opinion or instead simply sell products.

(Continued on following page)

Nor does this case provide occasion for this Court to revisit the applicability of *Central Hudson*'s intermediate scrutiny standard. For almost 30 years, this Court has consistently applied the intermediate scrutiny called for in *Central Hudson* in assessing First Amendment challenges to regulations of commercial speech. Although several Members of the Court have expressed concerns about the applicability of this standard and whether it should apply in particular cases, *see Thompson*, 535 U.S. at 367-68 (citing opinions in which Justices expressed doubts about the *Central Hudson* analysis), there is no need for the Court to break new ground in this case. In arguing that the PIL should be subjected to greater scrutiny than is called for by *Central Hudson*, Petitioners focus on the alleged social benefit of detailing. The First Circuit, however, did not consider the PIL's effect on speech between detailers and physicians, finding that Petitioners lack standing to assert the First Amendment rights of pharmaceutical detailers and physicians. The First Circuit's decision in this case, therefore, does not implicate the concerns raised by Petitioners, and thus it does not provide a useful vehicle for resolving any such doubts about *Central Hudson*. *Central Hudson* provides an adequate basis for decision in this case.

Robert Post, *The Constitutional Status of Commercial Speech* 48 UCLA L. Rev. 1, 18 (2000) (quotations, citations, and footnotes omitted).

B. The First Circuit's Application of *Central Hudson* Does Not Conflict With the Decisions of This Court or the Other Courts of Appeals

Petitioners erroneously contend that the First Circuit's decision "strays so far from accepted First Amendment principles as to merit this Court's review." To the contrary, the First Circuit's application of *Central Hudson* was straightforward and fully consistent with this Court's commercial speech precedents.

Central Hudson provides the following test for determining the constitutionality of a commercial speech restriction: If commercial speech is neither misleading nor related to unlawful activity, State regulation of that communication survives First Amendment scrutiny if (1) the State asserts a substantial interest to be achieved by the regulation; (2) the restriction directly advances the State interest involved; and (3) the governmental interest cannot be served by a more limited restriction on commercial speech. *Central Hudson*, 447 U.S. at 564.

Petitioners claim that the First Circuit's application of this test departed from relevant precedent in three ways. First, with regard to the "substantial interest" prong of the *Central Hudson* analysis, Petitioners assert that the First Circuit's ruling gives precedential sanction to a paternalistic agenda. Second, Petitioners contend that the First Circuit reached its decision on the second prong of the

analysis by giving improper deference to the State legislature and by failing to defer to the findings of the district court. Finally, Petitioners assert that the First Circuit erred in ruling that the PIL is no more restrictive than necessary, arguing it is both under- and over-inclusive. The First Circuit's decision, however, is consistent with the decisions of this Court. Regardless, this argument amounts to nothing more than a request for error correction, and thus does not merit a grant of certiorari.

1. The First Circuit's ruling that cost containment is a substantial governmental interest is constitutionally sound

1. Petitioners take portions of the decision below out of context in arguing that the First Circuit gives precedential sanction to a paternalistic agenda. Contrary to Petitioners' suggestions, the First Circuit did not conclude that the PIL satisfies the "substantial interest" requirement of *Central Hudson* based on the State's attempt to "improve the quality of interactions between detailers and physicians" by "level[ing] the playing field." These quoted passages appear in other portions of the First Circuit's opinion, not the court's application of *Central Hudson*. While recognizing that New Hampshire cited three separate governmental interests to be achieved by the PIL, the First Circuit expressly limited its analysis of the first prong of *Central Hudson* to the State's interest in cost containment. Pet. App. 28-29. The "paternalistic

goals" Petitioners criticize relate to the State's asserted interest in "protecting citizens' health from the adverse effects of skewed prescribing practices," an interest which the First Circuit did not address. *See* Pet. App. 28.

The State has an interest in health care costs directly in its role as Medicaid payor, and in controlling the cost of health care to its citizens. The First Circuit's ruling that cost containment suffices to satisfy the first prong of the *Central Hudson* test does not warrant review by this Court.

2. Petitioners erroneously assert that the First Circuit held they lacked standing to challenge this asserted governmental interest because Petitioners themselves do not engage in detailing. Again, Petitioners take portions of the First Circuit opinion out of context. The First Circuit held that Petitioners "must assert their own rights and explain how those rights are infringed by the operation of the Prescription Information Law." Pet. App. 16. The court went on to note that "this restriction on *jus tertii* rights does not prevent consideration of New Hampshire's interest in combating detailing." Pet. App. 16-17. Petitioners contort this straightforward ruling, mistakenly interpreting it as precluding Petitioners from disputing the State's interest in containing costs by limiting detailing. Nothing in the First Circuit's opinion supports this interpretation. To the contrary, the opinion describes Petitioners' evidence regarding the alleged positive effects of detailing, Pet. App. 30, 32-33, demonstrating that the court did in fact

consider Petitioners' argument that the PIL does not advance a cognizable state interest. The First Circuit's ruling on standing did not preclude Petitioners from disputing the State's assertion that it has a substantial interest in containing costs by limiting detailing, and does not warrant review by this Court.

2. The First Circuit's conclusion that the PIL directly advances the State's interest in cost containment does not warrant review by this Court

1. The First Circuit's application of the second prong of the *Central Hudson* test was fully consistent with this Court's commercial speech precedents. Contrary to Petitioners' contentions, the First Circuit did not hold that "New Hampshire need not justify the PIL through an adequate evidentiary record." Pet. 30. The court required the State to "demonstrate that the harms it recites are real and that [the] restriction will in fact alleviate them to a material degree." Pet. App. 29 (quoting *Edenfield*, 507 U.S. at 770-71). The court did not simply defer to legislative judgment, but rather carefully reviewed the evidence presented below and determined for itself that the evidence sufficiently demonstrated that the PIL satisfied the second prong of the *Central Hudson* test.[6] Pet. App. 29-38.

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[6] The court correctly rejected Petitioners' challenge to the lack of empirical research. *See Turner Broadcast Sys. v. FCC*,

(Continued on following page)

This prong of *Central Hudson* requires a fact-intensive analysis that was given careful attention by both the majority and the concurring judge, and they both reached the same conclusion: the PIL is a narrow, targeted restriction that accomplishes the State's interest. Judge Lipez noted "evidence from multiple sources indicated that the expense of unnecessary brand-name prescribing has in the past ranged into the billions of dollars nationally." Pet. App. 123. He aptly concluded that

> [t]his substantial evidence of needless spending, combined with evidence that detailing with prescriber-identifiable data contributes to that outcome, is enough to show that the [PIL] 'targets a concrete, non-speculative harm,' and that the Attorney General has sufficiently demonstrated that the State's interest in cost-containment would be furthered 'to a material degree' by the limitation on speech it seeks to achieve through the Prescription Act.

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512 U.S. 622, 665 (1994) ("Sound policymaking often requires legislatures to forecast future events and to anticipate the likely impact of these events based on deductions and inferences for which complete empirical support may be unavailable."); *New State Ice Co. v. Liebman*, 285 U.S. 262, 311 (1932) ("a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments") (Brandeis, J., dissenting). Judge Lipez in his concurring opinion likewise found it "unreasonable in these circumstances to expect the Attorney General to provide extensive quantifiable data that might only become available after the statute has been in place for some time." Pet. App. 121.

Id. (citations omitted). Moreover, "the prohibited uses are narrowly defined," *Id.* at 77, such that "no message or interest of consequence . . . is foreclosed by the regulation."

Petitioners' disagreement on the sufficiency of the evidence does not warrant review by this Court.

2. Nor is this case a good vehicle for this Court to resolve the conflict in the circuits surrounding the application of *Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 514 (1984), because the ultimate outcome of *this* case would not be any different had the First Circuit held *Bose*'s *de novo* review standard inapplicable. It was the application of law to the facts that guided the court's conclusion in this case, not a contradictory view of the facts than the district court's. As the First Circuit pointed out, "[t]he raw facts are largely undisputed." Pet. App. 4; *see also* Pet. App. 63 (Lipez, concurring and dissenting) (drawing heavily on the recitation of facts set out by the district court and noting "[t]hose facts are largely undisputed; the parties primarily contest their legal significance"); *compare* Pet. App. 153-75 (district court's facts section) *to* Pet. App. 4-8 (First Circuit's background section). The First Circuit's reliance on the district court's factual findings is apparent from its cite to the district court's fact section as support for its description of detailing. *See* Pet. App. 4 n.1. Because the First Circuit found the fact to be largely undisputed, this case provides a poor vehicle for this Court to address the circuit conflict surrounding *Bose*.

3. The First Circuit's conclusion that the PIL satisfies the "reasonable fit" requirement does not warrant review by this Court

Petitioners erroneously contend that the PIL is simultaneously under- and over-inclusive in the speech it restricts, and thus cannot achieve the State's goals. This prong of the *Central Hudson* test does not require the government to adopt the least restrictive means necessary to serve the State's interests, but instead requires only a "reasonable fit" between the government's purpose and the means chosen to achieve it. *Fox*, 492 U.S. at 480. The PIL satisfies this requirement.

1. Petitioners' claim that the PIL is under-inclusive stems from an argument the State made in responding to Petitioners' Commerce Clause claim. The district court did not rule on that claim. On appeal to the First Circuit, the State argued that the Commerce Clause claim was not properly before the court because the district court had not ruled on the issue, and Petitioners had not filed a cross-appeal. Nevertheless, the First Circuit ruled on the issue, holding that the PIL does not violate the Commerce Clause because it can be interpreted "to affect only domestic transactions." Pet. App. 49. This interpretation of the PIL, however, "may not accomplish very much," Pet. App. 50, and leaves the PIL with "negligible impact," Pet. App. 143 (Lipez, C.J., concurring and dissenting), because pharmacies transmit the

data to data centers *outside* of New Hampshire before selling the data to Petitioners.

The PIL need not be given such a narrow construction in order to survive Petitioners' Commerce Clause challenge. Interpreting the PIL as affecting transactions outside of New Hampshire would not violate the Commerce Clause so long as the statute is construed as applying only to records originating in New Hampshire, and as regulating only entities doing business in New Hampshire. *See IMS Health Inc. et al. v. Sorrell*, 2009 WL 1098474, *17-19 (D. Vt. April 23, 2009). New Hampshire pharmacies should not be permitted to avoid compliance with the PIL simply by routing data through data centers outside of New Hampshire before selling the data to Petitioners. The PIL should be interpreted as affecting transactions outside New Hampshire when they involve prescriptions originating in New Hampshire.[7] Interpreting the PIL in such a way allows the statute to accomplish what the State legislature intended,

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[7] Judge Lipez aptly noted that he was "not sure that the Attorney General understood the import of her statement that the Act regulates only in-state transactions." Pet. App. 148. Given that the proceedings below focused almost exclusively on the First Amendment issues, *see* Pet. App. 149 (Lipez, C.J.) (noting the parties only briefly addressed the Commerce Clause claim in their briefs to the First Circuit: "the plaintiffs' argument on the Commerce Clause spans only two and one-half pages in their sixty-page brief. The Attorney General's response is equally terse."), the State should not be held to an interpretation that would "leave the Act with negligible impact."

and addresses Petitioners' concerns that the statute is under-inclusive.

Nor is the PIL over-inclusive. Petitioners' argument that the PIL "equally applies when the detailing identifies a less expensive alternative" fails to take into account the realities of pharmaceutical detailing. The district court found that "[d]etailing is generally used only to market prescription drugs that are entitled to patent protection," Pet. App. 163, and the First Circuit noted that detailing "is time-consuming and expensive work, not suited to the marketing of lower-priced bioequivalent generic drugs," Pet. App. 6. Petitioners' argument that the PIL is over-inclusive because it inhibits competition between patent-protected brands is also unpersuasive since the PIL affects all brands equally, and therefore does not advantage any one brand over another.

2. Petitioners place undue emphasis on the First Circuit's citation to *Posadas de P.R. Associates v. Tourism, Co.*, 478 U.S. 328 (1986), in its analysis of the third prong of the *Central Hudson* test. The First Circuit cites *Posadas* only once, in rejecting one of the district court's suggested alternative measures: counter-detailing. Pet. App. 40 (citing *Posadas* in support of the statement: "It is not a ground for striking down a commercial speech regulation that some counter-informational campaign, regardless of the cost, might restore equilibrium to the marketplace of ideas"). The First Circuit did not conclude that it was "up to the legislature" to decide whether to achieve its interests through counter-detailing;

rather, the court found that measure to be infeasible "as a matter of simple economics."[8] Pet. App. 39. The First Circuit's cite to *Posadas* does not "breathe life" into that aspect of the case that has been abrogated, and in any event, the brief reference to the case does not warrant review by this Court.

III. THE NATURE OF THE LOWER COURT DECISION MAKES THIS CASE A POOR VEHICLE FOR CERTIORARI

Even if the Court were otherwise to determine that the circumstances of this case raise some compelling issues, the nature of the First Circuit's decision makes this case a poor vehicle for resolving those questions. First, the court provided two grounds for its decision; therefore, should this Court grant certiorari, it cannot simply address the First Circuit's speech-conduct holding, but must also perform a *Central Hudson* analysis. Second, the First Circuit's dormant Commerce Clause ruling creates confusion over the scope of the PIL which complicates the First Amendment review. Third, issues of standing complicate this case due to the fact that PhRMA never filed suit in New Hampshire, yet PhRMA is attempting to bring its perspective into the case by filing an amicus brief. Fourth, the First Circuit restricted its

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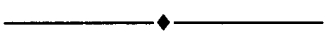
[8] Given that pharmaceutical companies spend over $4,000,000,000 annually on detailing, the First Circuit reasonably concluded that a program of counter-detailing by the State was not a feasible solution.

Central Hudson analysis to only one of New Hampshire's three asserted interests served by the PIL: cost containment. The State identified two other interests served by the PIL: maintaining patient and prescriber privacy, and protecting citizens' health from the adverse effects of skewed prescribing practices. This Court would either have to decide whether the regulation directly advances those interests without the benefit of the First Circuit's review, or remand for another round of proceedings. Finally, review of these issues is premature. Both Vermont and Maine have passed similar statutes which have been challenged on similar grounds. Given that the issues are pending in other cases and there is no direct split, there is no pressing need for a grant of certiorari at this time.



CONCLUSION

The petition for writ of certiorari should be denied.

Respectfully submitted,

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