No. 10-779

IN THE

Supreme Court of the United States

WILLIAM H. SORRELL,
ATTORNEY GENERAL OF VERMONT, *et al.*,
Petitioners,

v.

IMS HEALTH INC., *et al.*,
Respondents.

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

BRIEF OF *AMICUS CURIAE* ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS IN SUPPORT OF PETITIONERS

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February 28, 2011

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

Prescription drug records, which contain information about patients, doctors, and medical treatment, exist because of federal and state regulation in this highly regulated field. This case is about information from prescription records known as "prescriber-identifiable data." Such data identifies the doctor or other prescriber, links the doctor to a particular prescription, and reveals other details about that prescription. Pharmacies sell this information to data mining companies, and the data miners aggregate and package the data for use as a marketing tool by pharmaceutical manufacturers. The law at issue in this case, Vermont's Prescription Confidentiality Law, affords prescribers the right to consent before information linking them to prescriptions for particular drugs can be sold or used for marketing. The Second Circuit held that Vermont's law violates the First Amendment, a holding that conflicts with two recent decisions of the First Circuit upholding similar laws.

The question presented is:

Whether a law that restricts access to information in nonpublic prescription drug records and affords prescribers the right to consent before their identifying information in prescription drug records is sold or used in marketing runs afoul of the First Amendment.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

TABLE OF AUTHORITIES—Continued

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INTEREST OF *AMICUS CURIAE* [1]

Since 1943, the Association of American Physicians & Surgeons ("AAPS") has been dedicated to the highest ethical standards of the Oath of Hippocrates

[1] This brief is filed with the filed written consent of all parties. Pursuant to its Rule 37.6, counsel for *amicus curiae* authored this brief in whole, and no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amicus*, its members, or its counsel make a monetary contribution to the preparation or submission of this brief.

and to preserving the sanctity of the patient-physician relationship along with the practice of private medicine. Its motto, "omnia pro aegroto," means "all for the patient." As a non-profit, national group of thousands of physicians, AAPS has filed numerous amicus curiae briefs in noteworthy cases like this one. *See, e.g.*, *Stenberg v. Carhart*, 530 U.S. 914, 933 (2000) (citing an AAPS amicus brief); *Springer v. Henry*, 435 F.3d 268, 271 (3d Cir. 2006) (citing an AAPS amicus brief in the first paragraph of the decision); *United States v. Rutgard*, 116 F.3d 1270 (9th Cir. 1997) (reversal of a sentence as urged by an amicus brief submitted by AAPS).

STATEMENT OF FACTS

A Vermont statute prohibits the sale, license, or exchange for value of prescriber-identifiable (PI) medication data for the purpose of marketing or promoting a prescription drug. The Vermont statute also prohibits pharmaceutical manufacturers and others from using PI data for marketing or promoting a prescription drug. The prescriber may consent and allow use of this data. *See* Vt. Stat. Ann. tit. 18, § 4631(a) & (d).

In the absence of the statute, pharmaceutical companies use PI data for "detailing" physicians' offices in order to promote their specific, highly profitable brand medications. *IMS Health v. Sorrell*, 2010 U.S. App. LEXIS 24053, at *6 (2d Cir. Nov. 23, 2010). "Detailing" consists of a sales representative for a pharmaceutical company engaging in face-to-face, in-person promotion with a prescriber of that company's profitable brand drugs. *Id.* The pharmaceutical industry spends $8 billion annually on detailing activities. *Id.* at *47. Access to the prescribing de-

tails of the prescriber is obviously extremely valuable to the pharmaceutical companies in targeting specific physicians, and in tailoring the sales pitch.

SUMMARY OF ARGUMENT

"Commercial speech" is an oxymoron unworthy of First Amendment protection. The term and concept itself was not even recognized by this Court until the 1970s. Until then the concept had been unanimously rejected by this Court, and properly so. Commercial speech is ancillary to commercial conduct, and thus is undeserving of any First Amendment protection.

This case illustrates how far the doctrine of commercial speech has drifted from any legitimate moorings. Companies that rifle through private prescription records, and then profit from selling the data, claim a First Amendment right to do so. As a result sales representatives show up at doctors' offices with intimidating knowledge of their prescribing practices, without their consent. In assessing a challenge to a law that limited this commercial activity, lower courts engaged in policy considerations and balancing tests that seem to produce a different outcome every time. That is because commercial speech is actually conduct, and the immense confusion in this field should be dispelled by removing commercial speech from First Amendment analysis.

In the wake of *Citizens United*, which confirms that corporations have a First Amendment right to political speech, there is no justification for specially protecting commercial speech too. *Citizens United v. FEC*, 130 S. Ct. 876 (2010). If the pharmaceutical industry – one of the most politically active of all industries – does not like the Vermont statute, then it can spend money in the next election cycle to

disseminate its side of the story. That is real First Amendment speech, not the commercial activity at issue in this case.

The Vermont statute limits the exploitation of prescriber-identifiable prescription data, which is a commercial activity completely devoid of any speech traditionally protected by the First Amendment. Data mining does not facilitate discourse or the exchange of ideas, and in fact inhibits what people say and do for fear their privacy will be invaded. Data mining is as much conduct as electronic gambling is, and that could hardly be described as free speech.

The Vermont statute actually protects a constitutional right rather than infringe on one: the right to informational medical privacy already recognized by this Court, in furtherance of the patient-physician relationship. It is fully constitutional to protect a constitutional right against commercial exploitation.

ARGUMENT

Data mining with prescriber-identifiable prescription records is not free speech protected by the First Amendment. The harvesting and selling of medical record data amount to conduct, not speech, and can be regulated under the "rational basis" standard. The Vermont statute at issue here does not infringe on any First Amendment rights, and should not have been invalidated by the lower court.

The judicially created protection of "commercial speech," which is less than 40 years old, should be revisited and overturned. The *Central Hudson* balancing test for commercial speech has proved to be completely malleable and utterly unworkable, and should be cast aside. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980).

Electronic medical records and other aspects of medical practice should not be vulnerable to easily distorted claims of free speech under the First Amendment. The only "commercial speech" worthy of First Amendment protection is already safeguarded by *Citizens United* as well as the Free Press Clause.

The irony is that the Vermont statute protects another constitutional right: the right to informational privacy, as recognized by this Court in *Whalen v. Roe*, 429 U.S. 589 (1977). Vermont has a legitimate interest in protecting that privacy by prohibiting certain exploitation of prescriber-identifiable data. The decision below should be reversed so that the Vermont law may be enforced.

I. DATA MINING IS NOT FREE SPEECH PROTECTED BY THE FIRST AMENDMENT.

This Court has never held that data mining – or anything remotely similar to data mining – constitutes free speech under the First Amendment. Free speech protection should not be expanded so far afield from its traditional areas of discourse and the exchange of ideas.

It is axiomatic that the First Amendment protections apply to speech rather than conduct. U.S. Const. amend. I ("Congress shall make no law … abridging ***the freedom of speech***") (emphasis added). Data mining, in contrast, consists of substantial labor unlike typical free speech, including database programming and data analysis. Data mining is valuable, not for the content of any expressive speech, but for the "heavy lifting" that goes into it and extracts useful information. Large companies build fortunes based on this labor-

intensive activity, utilizing expensive computer hardware and significant levels of computer programming. But none of this is free speech. *Cf. Feist Publ'ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 352-64 (1991) (rejecting, without dissent, the "sweat of the brow" doctrine and thereby denying copyright protection to a listing of telephone numbers).

This Court has emphasized that it "is possible to find some kernel of expression in almost every activity a person undertakes – for example, walking down the street or meeting one's friends at a shopping mall – ***but such a kernel is not sufficient to bring the activity within the protection of the First Amendment***." *City of Dallas v. Stanglin*, 490 U.S. 19, 25 (1989) (emphasis added). Data mining is more conduct than speech.

Data mining is not the sort of "symbolic conduct" like flag-burning to which this Court has extended First Amendment protection. *See Texas v. Johnson*, 491 U.S. 397, 413 (1989). There is nothing symbolic or expressive at all about data mining. Rather, it consists of sophisticated, sometimes laborious work in culling and analyzing data for useful purposes. This Court has repeatedly rejected the argument "that an apparently limitless variety of conduct can be labeled 'speech' whenever the person engaging in the conduct intends thereby to express an idea." *United States v. O'Brien*, 391 U.S. 367, 376 (1968).

While data mining itself is lawful, it can easily lead to unlawful invasions of privacy. There are no secrets in the electronic sharing of medical record data, and there is no First Amendment interest in facilitating the breaches of privacy that can result from such data sharing. *See Truchinski v. United States*, 393 F.2d 627, 634 (8th Cir.), *cert. denied*, 393

U.S. 831 (1968) (rejecting a First Amendment challenge to a law prohibiting the use of interstate facilities to commit state criminal offenses); *Martin v. United States*, 389 F.2d 895, 897 (5th Cir.), *cert. denied*, 391 U.S. 919 (1968) (upholding the constitutionality of the Federal Anti-Wagering Law, because gambling was an illegal activity where the wager was placed).

As explained by the dissent below, the Vermont statute "merely prevents [defendants] from licensing their data for a single use – the marketing of prescription drugs." *IMS Health v. Sorrell*, 2010 U.S. App. LEXIS 24053, at *67 (Livingston, J., dissenting) The Vermont statute does not:

> "prohibit[] them from fostering public opinion or debate – to the contrary, as noted above, data mining appellants actually *prohibit* their customers from disclosing the data they license to *anyone* else, much less the general public.

Id. (emphasis in original). The dissent below properly concluded, "I have some difficulty comparing the data they sell to 'discourse' or the 'exchange of ideas.'" *Id.*

The concluding observation of this Court in *Feist* is equally apt here: "'great praise may be due to the plaintiffs for their industry and enterprise in publishing this paper, yet the law does not contemplate their being rewarded in this way.'" *Feist*, 499 U.S. at 364 (quoting *Baker v. Selden*, 101 U.S. 99, 105 (1880)). Likewise, the First Amendment simply "does not contemplate" protecting the activity at issue here.

II. "COMMERCIAL SPEECH" IS AN OXYMORON THAT SHOULD BE EXCLUDED FROM FIRST AMENDMENT PROTECTION.

The term "commercial speech" is an oxymoron, just as an expression "conduct speech" would be. Many judicial references to *Central Hudson* are to distinguish it rather than be guided by it. *See, e.g.*, *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339 (2010) (distinguishing *Central Hudson* in holding that bankruptcy attorneys may be required to make certain disclosures in advertisements). The doctrine of "commercial speech" has simply outlived its usefulness, and it is time to discontinue whatever little currency it may still have.

The basic test for "commercial speech" – the *Central Hudson* balancing factors – resulted in a different outcome with respect to the Vermont, New Hampshire and Maine data mining statutes each time a new opinion was rendered. *See IMS Health, Inc. v. Sorrell*, 2008 U.S. Dist. LEXIS 47454 (D. Vt. June 17, 2008), *rev'd*, 2010 U.S. App. LEXIS 24053 (2d Cir. Nov. 23, 2010) (inconsistent results for Vermont data mining law); *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2007), *rev'd*, *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010) (inconsistent results for Maine data mining law); *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 170-71 (D.N.H. 2007), *rev'd*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009) (inconsistent results for New Hampshire data mining law). This pattern does not exemplify "Rule of Law"; rather, these repeatedly inconsistent results demonstrate that there is a fallacy in the underlying legal standard. Such lack of clarity cannot be attributed to the

First Amendment itself, which by its terms provides bright-line protection for speech that fosters the exchange of ideas, and no protection for conduct. Data mining is the latter, and removing it from First Amendment protection would dispel the confusion.

The *Central Hudson* test requires First Amendment protection for commercial speech if a balancing of the following factors weighs in favor of the speech:

> (1) "the communication is neither misleading nor related to unlawful activity;" (2) the government "assert[s] a substantial interest to be achieved" by the regulation; (3) whether the restriction "directly advance[s] the state interest;" and (4) whether "the governmental interest could be served as well by a more limited restriction on commercial speech."

Central Hudson, 447 U.S. at 564 (restrictions "cannot survive" if they fail the above test).

This test – judicially created only 31 years ago – has proven to be unworkable. *See, e.g.*, *44 Liquormart v. R.I.*, 517 U.S. 484, 517 (1996) (Scalia, J., concurring) (noting agreement with "Justice Thomas's discomfort with the *Central Hudson* test, which seems ... to have nothing more than policy intuition to support it"). In practice, the *Central Hudson* test has amounted to little more than the courts second-guessing policy determinations already made by state legislatures with respect to commercial activity.

True First Amendment speech cannot be prohibited based on a judicial finding that it is "misleading", and by including such an assessment the *Central Hudson* test is contrary to the very principles that the First Amendment defends: the right to unregulated speech. It is not the proper role for the judiciary to assess

which speech should be deemed "misleading" and thereby censored. There is no role under the Constitution for the judiciary to determine whether speech can be censored because it is "misleading". Free speech depends on the people deciding what is true or false, after a full and robust discourse.

The need to replace the *Central Hudson* test is highlighted by this case, where the *more* truthful the speech is, the more objectionable and privacy-invading it becomes. There would be less objection to receiving a mailing about a random medical condition that one does not have, compared with receiving marketing material about a personal medical condition that one wanted to keep private. Yet the *Central Hudson* test is completely oblivious to this nuance, and the court below found its first prong to be fully satisfied by data mining.

For most of our nation's history – including its most productive period of economic development during the Gilded Age – there was no First Amendment protection for commercial speech. Such denial of protection continued through the post-World War II economic boom. "We are equally clear that the Constitution imposes no such restraint on government as respects purely commercial advertising." *Valentine v. Chrestensen*, 316 U.S. 52, 54 (1942). That ruling was unanimous.

It was not until 1976 that this Court found – over the dissent of future Chief Justice Rehnquist – that the First Amendment included a broad new protection for commercial speech. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976) (invalidating a restriction on pharmacies' advertisement of pricing information). Subsequent decisions have extended that hold-

ing to advertising for attorney services, and promotion of contraceptives. See *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60 (1983) (extending First Amendment protection to contraceptive advertising); *In re R.M.J.*, 455 U.S. 191 (1982) (extending First Amendment protection to attorney advertising); *Bates v. State Bar of Ariz.*, 433 U.S. 350 (1977) (same).

Denying First Amendment protection to the pharmaceutical industry seeking access to physicians' prescribing records hardly leaves the industry helpless. Under *Citizens United*, the industry can promote its interests with political speech during elections. *Citizens United v. FEC*, 130 S. Ct. 876 (2010). Pro-consumer laws, and laws against restraint of trade, are more direct vehicles for challenging interference with the free market. The First Amendment is a clumsy tool for addressing laws that are fundamentally economic regulations.

The case at bar concerning the privacy-invading use of prescription records presents a welcome opportunity to reexamine commercial speech doctrine. If a State can prohibit "misleading" advertising on the rationale that its dissemination causes harm to the public, then it should also be able to prohibit truthful commercial information on the same basis. Millions of people seem to enjoy activities like smoking, gambling or drinking, despite being harmful to society. It hardly matters whether the advertising is deemed "misleading" or not; what matters is the costly and destructive impact that the dubious conduct being advertised has on the public.

The First Amendment expressly delineates the only kind of "commercial speech" deserving constitutional protection: speech by the (commercial) press. The commercial speech doctrine of recent vintage

should not supplant what the First Amendment expressly states.

III. GRAVE CONSTITUTIONAL DIFFICULTIES ARISE IF THERE IS A FIRST AMENDMENT RIGHT TO EXPLOIT MEDICAL RECORDS.

A constitutional right to *medical record* privacy, as protected by physicians, has been recognized by this Court. *Whalen v. Roe*, 429 U.S. 589 (1977); *cf. Jaffee v. Redmond*, 518 U.S. 1, 9-10 (1996) (establishing a federal common law evidentiary privileged to protect certain psychiatric records). Finding a First Amendment right for commercial exploitation of medical records would raise grave constitutional difficulties, and chill the patient-physician relationship. A foray into this thicket is unnecessary here, and should be avoided by confirming that the Vermont statute is constitutional.

"***Unquestionably***, some individuals' concern for their own privacy may lead them to avoid or to postpone needed medical attention." *Whalen*, 429 U.S. at 602 (emphasis added). While there are assurances below that patient identifiers are removed from the prescription data, patients may have good reason to fear a breach in their privacy if their records are being bought and sold with impunity, as the court below found was facilitated by the First Amendment.

This Court has emphasized that there is an "imperative need for confidence and trust" between the patient and his or her physician, such that "a physician must know all that a patient can articulate in order to identify and to treat disease; barriers to full disclosure would impair diagnosis and treatment." *Trammel v. United States*, 445 U.S. 40, 51 (1980).

That confidence and trust have been put in jeopardy by the decision below.

In this era of the internet and private investigators, a sighting of a prominent person in a doctor's office can be the source of blogging by an observer in the waiting room before the office visit even concludes. If prescription data are readily obtainable about the physician, then conclusions can be additionally drawn with a fair degree of certainty about a treatment plan. It will not be long before traditionally private, highly confidential information finds its way to the front page of a tabloid or a website or into a political campaign. De-identification of personal information may help, but it can hardly be considered airtight.

Beyond the privacy interests of the patient, there is also the important consideration of the professional independence of the physician without being subjected to constant monitoring by the pharmaceutical industry as Big Brother. Physicians themselves do not forfeit all their own rights to professional autonomy simply by being a physician. "Being a member of regulated profession does not, as the government suggests, result in a surrender of First Amendment rights." *Conant v. Walters*, 309 F.3d 629, 637 (9th Cir. 2002), *cert. denied*, 540 U.S. 946 (2003). The unlimited sale and distribution of prescription data would undoubtedly have an intimidating effect on physicians, as any pharmaceutical company could file an anonymous or confidential complaint with a medical board based on prescribing patterns unfavorable to the pharmaceutical company.

The Fifth Circuit recently held against the Texas Medical Board on procedural grounds in a lawsuit by this *amicus curiae* to challenge its handling of

anonymous and confidential complaints against physicians. *Ass'n of Am. Phys. & Surgs. v. Texas Med. Bd.*, 627 F.3d 547, 553 (5th Cir. 2010) (noting allegations of "abuses perpetrated on physicians by means of anonymous complaints"). A sales representative could increase his company's revenue by analyzing prescription data and arranging for complaints to be filed against physicians who are not prescribing his company's products. Physicians would reasonably fear retaliation in Texas and elsewhere by aggressive pharmaceutical companies willing to game the system. The ultimate victims of this transfer of physician autonomy to the pharmaceutical industry are the patients deprived of honest medical judgment.

The Vermont statute is a sensible limitation on the dissemination of highly confidential information, in protection of the traditional practice of medicine against distortion by the pharmaceutical industry. The court below erred in invalidating a commercial regulation for "the process by which [sensitive medical information] is collected and sold." *IMS Health v. Sorrell*, 2010 U.S. App. LEXIS 24053, at *50 (Livingston, J., dissenting).

CONCLUSION

The decision below should be reversed.

Respectfully submitted,

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