No. 10-779

In the Supreme Court of the United States

WILLIAM H. SORRELL, ATTORNEY GENERAL OF THE STATE 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 FOR THE ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether a state law that prohibits the resale of lawfully obtained de-identified prescription-history information for purposes of marketing pharmaceutical products violates the First Amendment?

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INTEREST OF *AMICUS CURIAE*

Amicus curiae the Association of Clinical Research Organizations ("ACRO") respectfully submits this brief in support of respondents.[1] ACRO represents the world's leading clinical research organizations ("CROs"). Its members provide specialized services that are integral to the discovery and development of medicines, biologics, and medical devices. Each year, ACRO's members conduct thousands of clinical trials and provide related drug development services in more than 115 countries while ensuring the safety of nearly two million research participants.

Since its founding in 2002, ACRO has been committed to strengthening public understanding of and confidence in clinical research and to highlighting CROs' expertise in all aspects of clinical research. ACRO represents the CRO industry globally in dealings and interactions with pharmaceutical, biotech, and medical device companies, regulators and legislators, peer associations, academic organizations, patient groups, the media, and the public.

As a leading voice for safe and ethical clinical trials, ACRO works globally with these various stakeholders to explore new research and development paradigms and to promote better and more efficient clinical trial

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[1] The parties have consented to the filing of this brief, and letters of consent have been lodged with the Clerk of the Court, in accordance with Supreme Court Rule 37.2(a). Under Supreme Court Rule 37.6, no counsel for any party has authored this brief in whole or in part, and no person or entity, other than ACRO or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

processes. The association looks to demonstrate the strategic value of clinical outsourcing and the important contributions CROs make as partners in the development of new medicines and new treatments.

Efforts by Vermont and other states to prevent the truthful use of de-identified prescriber information for "detailing" prompts ACRO's appearance as *amicus curiae*. Such efforts are antithetical to the First Amendment. Moreover, were such efforts to succeed, the data at issue and similar de-identified health data sets would not be collected at all. As a result, these data would not be available for use in clinical research, which ultimately would have an adverse effect on public health by depriving scientists, public health experts, clinicians, and CROs (among others) of data essential to developing new medicines, conducting and designing clinical trials, and ensuring drug safety.

ARGUMENT

At issue in this case is that section of Vermont's Confidentiality of Prescription Information statute, Vt. Stat. Ann. tit. 18, § 4631 ("Prescriber Information statute"), which prohibits health care analytics companies, such as IMS and Wolters Kluwer Pharma Solutions, and pharmaceutical companies from using prescriber identifiable ("PI") data in any manner to facilitate the marketing or promotion (even if truthful) of name brand prescription medicines. As others have described, pharmaceutical companies often use PI data to more efficiently direct their detailing efforts for a particular medicine to physicians that currently prescribe alternative medicines.

Vermont imposes this restriction despite the fact that the statute generally *permits* the distribution and use of PI data for a wide variety of other purposes. Vt. Stat. Ann. tit. 18, § 4631(e). Vermont therefore prohibits the communication, publication and reporting of medically-relevant factual information because the state disfavors the pharmaceutical companies' viewpoint.

Vermont's justification for this intrusion on the free flow of truthful information is that prohibiting PI data-based detailing—and effectively limiting the free flow of truthful information—actually benefits public health, because detailing allows pharmaceutical sales representatives to in effect confuse physicians into inappropriately prescribing new (brand name) medicines even though older, less expensive medicines would be equally suitable. This contention necessarily suggests that using PI data to target physicians who use alternative medicines for the same indications (a typical use of PI data in detailing) will proportionally increase treatment costs by increasing the use of newer (and presumably more expensive) medicines.

I. The Statute Prohibits Speech

As an initial matter, Vermont contends that § 4631 does not restrict speech (and hence does not directly implicate the First Amendment) but rather does nothing more than restrict the dissemination of certain information that is in the *government's* possession. Pet. Br. at 22-23 (citing *Los Angeles Police Dep't v. United Reporting Publ'g Corp.*, 528 U.S. 32 (1999)); *see also id.* at 26 ("The commercial use of nonpublic information is better described as commercial conduct than

commercial speech.") (citation omitted). That contention does not withstand scrutiny.

First, the information at issue is not in the government's possession but is rather in the possession of pharmacies and other private actors. While it is true that Vermont (and the federal government) "compels" pharmacies to collect PI data, it cites no cases in which this Court has held that a *private* entity is forbidden from disseminating lawfully obtained information simply because that information is collected under a pre-existing regulatory regime. No party disputes that the government has the right, and in many cases the responsibility, to control the use of information that it has collected from private industry once that information is in its possession. But ACRO is unaware of any case in which it has ever been suggested that the mere requirement to maintain records transforms those records into government property while in the hands of the private actor. Indeed, such a contention makes no sense because pharmacies could collect this data voluntarily; absent a government mandate to keep records of the prescriptions they dispense, pharmacies can and do keep such records as a matter of accepted health care and business practices. The state's position that it can control or block these data streams because the data exists only because the government compelled their creation thus fails at its foundational premise.

Second, *United Reporting* did not actually resolve the issue of whether a statute that allows access to certain information for "scholarly, journalistic, [and] political" purposes, but not for commercial use, was constitutional with respect to its commercial use restriction. 528 U.S. at 41 (Scalia, J., concurring) ("I

understand the Court's opinion as not addressing the as-applied challenge to the statute, and as leaving that question open upon remand. That seems to me a permissible course . . . ."). Rather, the Court acknowledged only that "at least for purposes of *facial invalidation*" the statute in question "[was] not an abridgement of anyone's right to engage in speech . . . but simply a law regulating access to information in the hands of the police department." *Id.* at 40 (emphasis added). *United Reporting* therefore addressed only the narrow question of when a facial challenge was appropriate. Vermont therefore mistakenly argues that *United Reporting* either mandates reversal here or stands for the broad proposition that consistent with the First Amendment the government may deny information to a particular group, even when the information is generally available to others.

Even if (in defiance of common sense and sound record-keeping practices) pharmacies would not have obtained the PI data absent government regulation, the state certainly does not have unlimited power to dictate who could and could not have access to it. Paraphrasing Justice Ginsburg's concurrence in *United Reporting*:

> [O]nce [Vermont] decides to make [the information] available to the public, there are no doubt limits to its freedom to decide how that [information] will be distributed. [Vermont] could not, for example, release . . . information

> only to those whose political views were in line with the party in power.

United Reporting, 528 U.S. at 43 (Ginsburg, J., concurring) (citing *Bd. of Comm'rs Wabaunsee Cnty. v. Umbehr*, 518 U.S. 668 (1996)).

Section 4631 operates precisely in the impermissible manner posited by Justice Ginsburg in *United Reporting*. It permits PI data to be *unconditionally* disseminated to virtually any organization related to health care and public health, except respondents and certain other similarly disfavored entities, who are forbidden from using the data for a purpose with which Vermont disagrees.

This case is likewise not analogous to *Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984), in which this Court upheld a protective order prohibiting the parties from disclosing information they obtained through discovery to a newspaper. Although the information was obtained through governmental processes, this Court did not—as Vermont contends here—hold that the First Amendment was not implicated. *Id.* at 37 (Brennan, J., concurring) ("The Court today recognizes that pretrial protective orders, designed to limit the dissemination of information gained through the civil discovery process, are subject to scrutiny under the First Amendment."). Rather, the Court recognized that litigants continue to enjoy the protections of the First Amendment (perhaps limited) but those protections must be balanced against other substantial government interests—which in *Seattle Times* was the government's substantial interest in permitting broad discovery in civil litigation. *Id.* at 34-35.

In short, there is no merit to Vermont's contention that § 4631 is merely a restriction on access to information. *See also Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762, 765 (1976) (reporting of facts implicates First Amendment concerns because there is a "public interest" in the "free flow" of "information as to who is producing and selling what product, for what reason, and at what price"); *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 . . . .").

II. Vermont's Prescriber Information Statute Violates the First Amendment

A. Strict Scrutiny Should Be Applied

Although correct in its ultimate disposition of the case, the Second Circuit erred in concluding that the speech at issue involved "commercial speech" and therefore applying the intermediate scrutiny test from *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980) ("*Central Hudson*"). Indeed, the mere fact that the speaker is a corporation or that the speech relates to a corporate transaction does not automatically make the speech commercial speech. *See, e.g.*, Eugene Volokh, *Freedom of Speech and Information Privacy: The Troubling Implications of a Right to Stop People From Speaking About You*, 52 Stan. L. Rev. 1049, 1082-83 (2000) ("Under the 'speech that proposes a commercial transaction' analysis, communication of information about customers by one business to another is not commercial speech. It

doesn't advertise anything, or ask the receiving business to buy anything from the communicating business. It poses no special risk of the speaker misleading or defrauding the listener, beyond those risks present with fully protected speech generally. The recipient business does intend to use the information to more intelligently engage in commercial transactions, but that's equally true of businesspeople reading Forbes.") (citations omitted). Rather, it is necessary to consider whether the speech at issue is merely proposing a commercial transaction, for example, where the speaker is simply conveying an offer or advertising a product. *Id.* at 1082 ("In fact, every one of the Court's dozens of commercial speech cases has involved speech that advertises a product or service . . . .").

Here, the restriction in § 4631 is not limited to such situations. Rather, § 4631 broadly forbids communications about PI data if the substance of the communications relates in any manner to the marketing or promoting of medicines. Because the commercial message is "inextricably intertwined with otherwise fully protected speech"—the merits of the particular pharmaceutical product at issue—§ 4631 is subject to strict scrutiny even if the speech occurs in the commercial context. *See, e.g.*, *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988). There is no dispute that the statute would not survive strict scrutiny.

B. The Statute Fails Intermediate Scrutiny In Any Event

Even were the Court to conclude that the speech at issue involves principally commercial speech, § 4631

does not survive under *Central Hudson* because § 4631 does not directly and materially advance any substantial state interest.

Vermont asserts that § 4631 advances three "substantial state interests"—protecting public health, safeguarding prescriber privacy, and reducing health care costs. Pet. Br. at 45-54. The core of the dispute is whether § 4631 directly and materially advances any of them. As the Second Circuit correctly held, the answer is no.

Protecting Public Health. Section 4631 does not directly and materially advance the protection of public health. Vermont starts from the unsubstantiated premise that pharmaceutical marketing has an undue influence on physicians' prescribing decisions. From there, it leaps to the conclusion that the public health is served by eliminating that influence. The tenuous connection between these two assumptions is apparent as Vermont offers only that "'[d]etailing encourages doctors to prescribe newer, more expensive, and potentially more dangerous drugs instead of adhering to evidence-based treatment guidelines.'" Pet. Br. at 49 (quoting App. 95a). Vermont offers no evidence that new medicines are not rigorously tested before approval, are generally more dangerous, are necessarily less efficacious, or have comparatively higher long-term costs as compared to existing alternatives.[2]

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[2] Indeed, one recent study found that for new drugs approved by the FDA between 1994 and 2002, the median time between when the manufacturers filed a application to begin human trials and

Even the United States, although joining Vermont as an *amicus*, concedes that § 4631 does not directly advance the protection of public health. U.S. Br. at 24 n.4. As the United States correctly observes, Vermont's assertion that the dangers of new medicines outweigh their benefits is unsubstantiated and unwarranted in light of the strict FDA regulatory process in place for introducing new medicines, which "requires a showing that the drug is safe and effective for its intended uses in accordance with its labeling." *Id.* (citing 21 U.S.C. § 355).

Indeed, § 4631 blocks the advancement of public health. PI data are used by a wide array of organizations, including pharmaceutical companies, CROs, academic researchers, public health agencies, and government law enforcement agencies, among others. For CROs, pharmaceutical companies, academic researchers, and other health researchers directly involved in the development of new medicines, PI data are important and useful in conducting this work. Without this data, it would be more difficult for these groups to design clinical trials to test new medicines, identify doctors to participate in clinical trials, recruit patients who would most likely benefit from a new treatment, and compare the efficacy of new medicines to those already on the market. While it would be possible to design and develop clinical trial programs without PI and other de-identified health data, researchers would find the process more

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when they received FDA approval was approximately six years. *See* S. Keyhani, et al., *Trends in Drug Development Time and Price (2005) (Acad. Health Meeting 2005; 22: abstract no. 3676)*, *available at* http://gateway.nlm.nih.gov/MeetingAbstracts/ma?f=103623139.html.

expensive and subject to delay, which, in some cases, could compromise the sustainability of the research project altogether.

PI data make it possible for CROs and others to conduct clinical trials more efficiently because this data accelerate finding patients with the disease that a given medicine or treatment is designed to address and the physicians who treat them. Researchers can then approach this targeted set of physicians to learn more about the efficacy of existing therapies and, if appropriate, invite their patients to participate in clinical trials. The more quickly researchers can locate clinically appropriate subjects, the more quickly the safety and efficacy of a new compound can be determined, the more quickly the FDA can approve a new drug application, and the medicine can be available to the public.

A recent study from the non-profit Massachusetts Biotechnology Council highlights how pharmaceutical and biotech companies use PI data to quickly identify individuals who could potentially benefit from a new life-enhancing (if not life-saving) medicine. *See* Mass. Biotech. Council, *Treatment Delay is Treatment Denied – The Unintended Consequences of State Laws to Ban the Use of Physician Level Data* (2010), *available at* http://www.massbio.org/writable/editor_files/banzel_case_study_2.1.10.pdf. In 2008, the FDA approved BANZEL, a breakthrough therapy for the treatment of Lennox-Gastaut Syndrome ("LGS"), a rare and catastrophic form of epilepsy in children that may produce more than 100 seizures a day. These uncontrollable seizures and associated behavior problems severely limit common everyday activities for those with the disease and many become wheelchair

bound or are forced to wear protective helmets with face guards to protect them from frequent falls. Because LGS is so rare—affecting less than 5% of children with epilepsy—and the company (Eisai) that developed BANZEL had a relatively small U.S. presence, it would have been extremely inefficient (and the costs potentially exorbitant) to identify which physicians among the 10,000-12,000 general neurologists in the United States were the most likely to treat LGS without using PI data. Indeed, in every state where Eisai could readily access PI data it was able to promptly identify the appropriate subset of physicians whose patients would most benefit from BANZEL, but who would also be the most knowledgeable about how to use and evaluate its efficacy in clinical practice. It was only in New Hampshire, which had enacted legislation similar to Vermont's restricting the use of PI data by pharmaceutical companies, that Eisai confronted significant difficulties in promptly identifying the right physicians to discuss the benefits and risks of BANZEL.

PI data are also used to monitor the safety of medicines and identify usage trends (and, accordingly, develop and refine the best standards for clinical practice) after those medicines have received FDA approval. For example, in one recent study, physicians used PI data (obtained from IMS) to determine that the need for a certain type of highly-invasive surgery declined after the introduction and widespread adoption of proton pump inhibitors. *See* Naline M. Guda, M.D. & Nimish Vakil, M.D., *Proton Pump Inhibitors and the Time Trends for Esophageal Dilation*, 99 Am. J. Gastroenterol. 797 (2004). Identifying such trends can be extremely beneficial to

patient care by leading to fewer invasive procedures, shorter recovery times, and overall reduced costs. A study such as Guda and Vakil's would be, however, virtually impossible to conduct without PI data.

Moreover, the FDA requires new drug applications to include a Risk Minimization Action Plan ("Risk MAP"). Risk MAPs explain how a manufacturer intends to study the health effects of a new medicine on patients after the drug has been approved and entered the market. Pharmaceutical companies must be able to identify which physicians are prescribing the medicine in question in order to learn about its health effects. Without PI data, the task of identifying the appropriate patient pool and executing the Risk MAP would be an exceedingly difficult and inefficient process.

The availability of PI data not only advances drug discovery, development, and public health, but in addition, law enforcement agencies, for example, routinely use PI data to identify physicians who may be unlawfully prescribing controlled substances. By examining prescribing patterns, law enforcement can identify such physicians by looking for those with patterns that vary excessively from their peers. In a recent investigation, for example, investigators were able to use Medicaid PI data—data similar to that at issue here—to identify the top 10 prescribers nationwide for eight prescription drugs (some with high street value among abusers). Christian Davenport, *Doctors Who Prescribe Oft-abused Drugs Face Scrutiny*, Wash. Post, Jan. 1, 2011, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2011/01/01/AR2011010102801.html. This data, which was also provided by state regulators to Senator

Charles Grassley, revealed a number of instances in which doctors had prescribed drugs vastly in excess of what their practices should have required—including, one case where a Florida physician wrote nearly 97,000 prescriptions for controlled mental health medications in a 21-month period. In response to such findings, state medical boards, local police, and the federal Drug Enforcement Administration have taken actions to prosecute doctors who abuse their prescribing privileges, and to revoke their licenses to practice medicine. As Senator Grassley observed, these enforcement efforts not only further public health, they also help control Medicaid and other health care costs by rooting out "overutilization or even health-care fraud." *Id.*

There is therefore no question that PI data are critical to serving public health needs—such data not only expedite the development of potentially lifesaving new medicines, but also identify those who are most likely to benefit from these medicines. These data also improve the ability of regulators and pharmaceutical manufacturers to more efficiently monitor drug safety. At the same time, PI data facilitate the marketing efforts of pharmaceutical companies (i.e., detailing). And although Vermont seeks to make such marketing less efficient and therefore to some degree curtail it, this practice serves a crucial function by educating physicians about the safety and efficacy of new medicines, information that they may not otherwise have become aware but for the marketing communications.

The fact that the statute does not directly forbid the use of PI data for these unquestionably beneficial purposes is not the issue. The restriction on the use of

the data for marketing will severely curtail the economic incentive to gather the data in the first instance. Were the data not gathered, its many inarguably beneficial uses would be lost, all to the detriment of public health.

Privacy. Vermont notably does not contend that § 4631 protects *patient* privacy. Nor could it because the data at issue is de-identified PI data, which under the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 ("HIPAA"), must not contain any patient-identifying information. Contrary to the position of certain *amici*, the distribution of de-identified HIPAA data does not threaten to endanger patient privacy. *See* Douglas Peddicord, et al., *A Proposal To Protect Privacy Of Health Information While Accelerating Comparative Effectiveness Research*, 29 Health Affairs 2082, 2085 (2010) (noting that, to date, there has been no instance in which a HIPAA de-identified data set has been successfully re-identified).

Vermont instead asserts that § 4631 directly advances the "real and substantial privacy interest" that a doctor has in her prescription decisions. Pet. Br. at 46 (characterizing a doctor who writes a prescription as "essentially a customer" who is making "'purchasing' decisions that are relevant to pharmaceutical manufacturers").

Physicians do not have—and should not have—a cognizable privacy interest in data about the medications they prescribe. The practice of medicine is heavily regulated, and the transparent flow of physician-identifiable information about prescribing practices is essential for appropriate oversight,

regulation, licensing, and accreditation to occur. Vermont, both as a regulator and as a payor, surely has a *significant* interest in knowing what its doctors are prescribing—§ 4613 does not in the least directly advance this interest. *See also* U.S. Br. at 29 ("To be sure, physicians' privacy interest in their prescribing practices is diminished . . . by the extensive regulation of those practices under federal and state law."). Indeed, the statute permits (if not encourages) the distribution of PI data to virtually every interested party for numerous other purposes, regardless of whether the doctor consents, thereby not protecting whatever physician privacy interest that allegedly could exist. *See, e.g.*, *United Reporting*, 528 U.S. at 46 (Stevens, J., dissenting) ("By allowing such widespread access to the information, the State has eviscerated any rational basis for believing that the Amendment will truly protect the privacy of these persons.") (citing *Cox Broad. Corp. v. Cohn*, 420 U.S. 469, 493-95 (1975)).

Cost Containment. Cost containment is the stated goal of § 4613. In essence, the statute sets up a somewhat bizarre construct whereby the state has agreed to pay for medicines, or mandated that others do so, while at the same time seeking to discourage certain medicines from being prescribed in the first place. Vermont's stated goal of cost containment rests on several unproven assumptions: that new medicines are always more expensive than established medicines, that use of new (even if more expensive) medicines never saves health care dollars in other ways, and that blocking PI data-based detailing will make physicians less likely to prescribe new medicines.

Even if these unproven assumptions were to be established, § 4613 would serve the interest of controlling costs in only the most indirect sense. Section 4613 does not forbid physicians from prescribing any medicines or require the use of less expensive medicines. It does not forbid detailing or require physicians to perform a cost benefit analysis of various treatment options. It does not impose price caps on medicines. Rather, it simply seeks indirectly to influence physician behavior by depriving them of truthful information about the safety and efficacy of new treatments, information which is clearly relevant to a physician's treatment decision.

Even accepting the dubious logic that less-efficiently-targeted detailing will lead to fewer prescriptions for certain medicines, such a result does not even imply lower costs. For example, when a new medicine replaces an invasive surgical procedure or results in shortened hospital stays, the new medicine, while expensive, may be far more cost effective.

Moreover, because PI data are used to make clinical trials and other research more effective, not having it available would increase health care costs. Indeed, the costs of clinical trials ultimately are reflected in the costs of medicines. Increasing the costs of clinical trials can therefore only increase the costs of health care.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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