No. 10-779

IN THE
Supreme Court of the United States

WILLIAM H. SORRELL, 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 ACADEMIC RESEARCH SCIENTISTS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Amici are scientists at leading universities who perform research in numerous fields related to public health. Their work relies on basic data obtained from many different sources, including data from databases that are created for commercial purposes but are made available to academic researchers at little or no cost because the database owners recognize the value inherent in such research. *Amici* include researchers who have utilized the specific commercial databases containing prescriber-identifiable data produced by one of the respondents, IMS Health Inc. ("IMS Health"), for the purposes of conducting research and publishing results analyzing pharmaceutical practices in the United States. A list of *amici* and their credentials appears in the Appendix.

While the Vermont legislation at issue in this case, Vt. Stat. Ann. tit. 18, § 4631 ("Act 80"), specifically exempts from its scope the publication of data for health care research, *id.* § 4631(e)(1), *amici* have an overarching interest in ensuring the continued publication of basic data regarding medical prescription practices and health care that is essential to scientific research and vital to society. By reducing the economic incentive to engage in the labor-intensive and costly task of gathering and

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[1] Petitioners and Respondents have filed with this Court blanket consents to *amici* participation. No counsel for a party authored this brief in whole or in part and no person other than *amici* and their counsel made a monetary contribution to its preparation or submission.

organizing such information and making it available in databases for sale in the marketplace, Act 80 strongly diminishes the likelihood that such databases will continue to exist in the future.

This data is of enormous value to academic researchers, authors, policymakers, journalists and the public. A large part of contemporary research in virtually all fields of intellectual endeavor—including science, technology, economics, business, law, education, sociology and politics—involves the gathering, synthesizing, organizing and analyzing of thousands, millions or even billions of discrete transactions and events. This data is "crunched" for what it may illuminate or reveal, thereby advancing creativity and innovation in all realms of learning.

The analysis of such data is valuable in the aggregate, for what it may reveal about large patterns and trends and, in the particular, for what it may reveal about specific actors or enterprises. The production and use of such data serves all of the worthy purposes that animate the First Amendment's protection of the free flow of information, including the advancement of discovery and invention, the free play of the marketplace of ideas and the service of transparency and accountability. This data has particular significance to health care policy because it is crucial that researchers and policy makers have access to *comprehensive* data that enables them to develop a complete picture of prescribing patterns, something that is exceedingly challenging given the fragmented nature of health care delivery in the United States.

SUMMARY OF ARGUMENT

Act 80 prohibits the sale, license or exchange for value of regulated records that include "prescriber-identifiable" ("PI") data and the use of such records for the purposes of marketing or promoting a prescription drug without the consent of the prescriber. Vt. Stat. Ann. tit. 18, § 4631(d). The statute's stated rationale is "to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs . . . ." *Id.* § 4631(a).

PI data, published by companies like IMS Health, Verispan, LLC and Source Healthcare Analytics, Inc. (the "Publisher Respondents"), is prescription-history information that contains the identity of the prescriber. (As required by Federal law, information that identifies the patient is removed when PI data is distributed.) Chief among the concerns cited by Vermont is the practice of "detailing," by which employees of pharmaceutical companies use PI data "as a targeting tool, to identify and target the most valuable doctors with potential to drive market share . . . [and] to push the physician's behavior toward their product." Pet. Br. 9-10 (internal quotation marks omitted) (noting that pharmaceutical companies spend close to $8 billion per year marketing their drugs to doctors, excluding the value of free samples).

The basic flaw in the State's argument is that it fails to recognize that the publication of data by

companies like the Publisher Respondents is speech worthy of full First Amendment protection. Instead, it views publication of this data, first, as commercial conduct (not speech) and, alternatively, as commercial speech, worthy only of decreased First Amendment protection.

The State effectively ignores that the data at issue in this case, which no doubt is used by many in service of commercial ends, is also used by academic researchers like *amici*. *Amici* and other researchers use this data to study a range of issues relevant to public health and health care policy. *See infra* Section I.A. Viewed in the research context, there can be no doubt that the publication of this data is protected speech. And the fundamental nature of this data is not changed—whether to "commercial conduct" or to "commercial speech"—when it is published in identical form but in a different context or for a different purpose. *See infra* Section I.B-C. Furthermore, even if this Court were to review Act 80 under its commercial speech doctrine, it would not pass constitutional muster because it does not directly advance the asserted governmental interests in privacy, cost containment and protection of public health. *See infra* Section II.

ARGUMENT

I. THE PUBLISHER RESPONDENTS' DATA IS VALUABLE INFORMATION DESERVING OF FULL FIRST AMENDMENT PROTECTION

A. The Publisher Respondents' Data is Relied Upon by Academic Researchers in Studies of Significant Scientific and Public Concern.

Academic researchers such as *amici* have a powerful interest in fighting any regulation that empowers the government to restrict the dissemination of accurate information that can be used to inform cutting edge public health issues. Vermont's position is that the Court should allow it and other states to do exactly that. By targeting information related to medical prescriptions and health care practices, such regulation menaces the free flow of basic data relevant to a vast array of subjects, thereby exerting a chilling effect on research.

To academic researchers, authors and journalists, the data gathered, processed and distributed by information providers such as the Publisher Respondents—including PI data—is not a "commodity." Nor is it "commercial speech." It is data describing real-world events and practices; data that forms the basis of invaluable information for researchers as they study and evaluate medical practices and health care policies—issues of vital interest to society, and information squarely within the core of constitutionally protected speech.

Commercial databases such as those compiled by the Publisher Respondents often have unique value to the academic world because they provide a broad, unbiased view of data that is not available from smaller or noncommercial databases. Unlike databases maintained, for example, by insurance companies, the IMS Health databases include collections of prescription information relating to prescriptions without regard to the identity of the entity paying for the prescription.

Academic researchers like *amici* rely on data made available by the Publisher Respondents, including PI data, in their studies and critical analyses of numerous public health topics. The contribution of this data in the academic arena underscores the importance of this protected speech to public discourse and scientific progress. *See* IMS Br. 37-38. In fact, among the topics that academic researchers can and do use this data to study are health care cost containment and the impact of pharmaceutical marketing—the very issues that purportedly animated Vermont in passing Act 80. *See Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 758-59 (1985) (plurality opinion) (noting that speech concerning matters of public concern "is at the heart of the First Amendment's protection" (internal quotation marks omitted)).

For example, a team of researchers has used IMS Health's National Prescription Audit, National Sales Perspectives and MIDAS databases to study recent trends in pharmaceutical costs. These researchers concluded that, contrary to most projections, the annual increase in prescription drug spending slowed between 2003 and 2007 to rates not

seen in over 30 years. During this period, the researchers found, the pharmaceutical industry saw a reduction in the number of "blockbuster" drugs (those that create annual revenues in excess of $1 billion) and a decline in the sales of primary care medicines. As the authors recognized, these results have significant policy implications, including for the Food and Drug Administration ("FDA"), which must consider whether it can or should take steps to encourage innovation in light of slowing revenues in the pharmaceutical industry. *See* Murray Aitken, et al., *Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point*, 28 Health Affairs 151 (2009) (co-authored by *amicus* Ernst R. Berndt, Louis E. Seley Professor in Applied Economics at the MIT Sloan School of Management); *see also* Mark R. Trusheim, et al., *Characterizing Markets for Biopharmaceutical Innovations: Do Biologics Differ from Small Molecules?*, 13 Forum for Health Econ. & Pol'y art. 4 (2010), *available at* http://www.bepress.com/fhep/13/1/4 (co-authored by *amicus* Berndt).

Other researchers have used IMS Health's National Disease and Therapeutic Index and National Prescription Audit databases to identify the costs associated with an increasingly prevalent disease, Type 2 diabetes. Using the IMS Health data, these researchers identified the complex treatments being applied to treat this disease, and noted that drug expenditures for diabetes increased by 87% between 2001 and 2007. The researchers left for another day the question whether these high treatment costs are associated with improved outcomes, which would require the generation of

additional data measuring "effectiveness and cost-effectiveness across treatment classes." *See* G. Caleb Alexander, et al., *National Trends in Treatment of Type 2 Diabetes Mellitus, 1994-2007*, 168 Archives of Internal Medicine 2088 (2008), *available at* http://archinte.ama-assn.org/cgi/reprint/168/19/2088.

Researchers have also used IMS Health data to explore the effects of pharmaceutical marketing efforts on prescribing behavior—an issue that the instant litigation makes clear is the subject of much public interest and disagreement. One group of researchers has examined the impact of "direct-to-consumer" advertising, detailing to physicians and providing free samples of antidepressants on treatment patterns for patients suffering from depression. The researchers concluded that direct-to-consumer advertising—which is not regulated by Act 80—had the effect of increasing the likelihood of the initiation of drug therapy and its duration while, notably, direct promotion to physicians did not. *See* Julie M. Donohue, et al., *Effects of Pharmaceutical Promotion on Adherence to the Treatment Guidelines for Depression*, 42 Medical Care 1176 (2004), *available at* http://depts.washington.edu/drugmyth/cme/freeSamples/Donohue%20Medical%20Care%2004%2042%2012%201176.pdf (co-authored by *amicus* Berndt).

IMS Health data has also been used by academic researchers to study numerous other questions of great import to public health—including the impact of regulatory warnings on prescriber behavior. One team of researchers has used data provided by IMS Health to study the effect of FDA suicidality warnings on the prescription rates for

antidepressant and antipsychotic drugs. These researchers used this data to study antidepressant prescription rates and to conclude that FDA warnings led to a 22% reduction in the number of children and adolescents taking these drugs and this reduction was associated with a 14% increase in the youth suicide rate in 2003 and 2004. Robert D. Gibbons, et al., *Early Evidence on the Effects of Regulators' Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents*, 164 Am. J. Psychiatry 1356 (2007).

Databases that contain PI data as part of their prescription data provide an additional avenue of analysis for research scientists. With this robust data, researchers can follow up with physicians to understand their prescribing behavior beyond what might be discerned from raw numbers. They can learn, for example, not merely *that* certain physicians respond differently to FDA warnings but also *why*. Furthermore, studies based on PI data can enable targeted education—by researchers, pharmaceutical companies or the government—of physicians whose practice may be out of line with the most recent medical evidence and guidance.

For example, researchers at the Centers for Disease Control and Prevention ("CDC"), together with a researcher from IMS Health itself, have relied on IMS Health's Xponent database to investigate geographic variation with regard to antibiotic treatment throughout the United States. *See* Lauri A. Hicks, et al., *Antimicrobial Prescription Data Reveal Wide Geographic Variability in Antimicrobial Use in the United States, 2009*, Presentation to Infectious Diseases Society of America, *available at*

http://www.imshealth.com/deployedfiles/imshealth/global/content/staticfile/Antimicrobial_Prescription_Data_2009.pdf. Unlike previous studies that have been conducted at the national level, the CDC-led team used the data obtained from IMS Health to map regional variations in prescribing practices at the level of individual zip code. Their results revealed significant regional variations and suggested that inappropriate use of antibiotics could be reduced by increased attention to cultural and demographic influences on prescribing behavior and targeted interventions with individual physicians.

In addition, some researchers have used PI data to consider how prescriber-specific characteristics can predict prescribing behavior. One team recently used IMS Health's Xponent database to examine the impact of a doctor's gender, training and proximity to retirement, among other characteristics, on his or her propensity to prescribe antipsychotic drugs. The study, which relied on the identifying information of 17,652 physicians and focused on prescriptions of antipsychotic drugs, concluded, among other things, that prescribers with greater total volumes of prescriptions written, prescribers with training in psychiatry, male prescribers and those not approaching retirement age exhibit less-concentrated prescribing patterns. *See* Anna A. Levine Taub, et al., *The Diversity of Concentrated Prescribing Behavior: An Application to Antipsychotics* (Nat'l Bureau of Econ. Research, Working Paper No. 16823, 2011), *available at* http://www.nber.org/papers/w16823.pdf (co-authored by *amicus* Berndt).

B. Publication of the Data at Issue in This Case is Not Commercial Conduct.

The underlying data at issue in this case—which is at the heart of significant research studies, such as the ones described above—is entitled to the full protection of the First Amendment, protection that is routinely extended to a wide range of information on matters relating to science, politics, economics, religion or culture. The protections of the First Amendment "are not confined to any field of human interest." *United Mine Workers of Am., Dist. 12 v. Ill. State Bar Ass'n*, 389 U.S. 217, 223 (1967). This Court has recognized that "[f]reedom of discussion, if it would fulfill its historic function in this nation, must embrace all issues about which information is needed or appropriate to enable the members of society to cope with the exigencies of their period." *Thornhill v. Alabama*, 310 U.S. 88, 102 (1940).

1. The State contends that the data at issue in this case is maintained by pharmacies only pursuant to government recordkeeping requirements, and thus, that the government's subsequent restriction on the commercial use of this nonpublic information "is better described as [a restriction on] commercial conduct than commercial speech." Pet. Br. 26. As an initial matter, this argument fails on its assumption that pharmacies would not otherwise collect this data were it not for government regulation. *See* IMS Br. 23-24; PhRMA Br. 57-58. If anything, the value of this data for commercial uses—and as demonstrated above, *supra* Section I.A, non-commercial uses—makes clear that pharmacies have a strong incentive to maintain this data, regardless of government requirements to do so.

Moreover, even if the Publisher Respondents' data were kept by pharmacies only pursuant to government regulation, that would not suffice to strip the data of all First Amendment protection. *See* IMS Br. 23-27; PhRMA Br. 55-59. A ruling to that effect would cast a long shadow on free speech, especially in the field of public health research, where crucial records are often maintained pursuant to government regulation or in connection with government programs.

For example, in connection with its approval of pharmaceutical products, the FDA has the authority to require manufacturers to provide a Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the drug's benefits outweigh its risks. *See* 21 U.S.C. §§ 355(p), 355-1; *see also* Food & Drug Admin., *Draft Guidance on Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications* (2009), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM184128.pdf. As part of its REMS program, a pharmaceutical company will often be required to conduct studies and collect data in support of its risk assessment.

An example of a company that has gone through this process is Amylin Pharmaceuticals. As a condition of FDA approval for its drug, Symlin, the company was required by the FDA in 2005 to identify those physicians (roughly 22,000) who were most likely to prescribe the drug, to monitor their prescribing patterns, to conduct a survey to gauge their understanding of the risks associated with the drug and to provide the results to the FDA. *See*

BIOCOM, *Safety First: The Role of Physician Level Data in Supporting Risk Evaluation & Mitigation Strategies (REMS) for Optimal Patient Care—A Case Study* (2011), *available at* http://www.biocom.org/?m=sp_view_doc&file=Shared%20Documents/Public%20Policy/MD_level_data_rpt.pdf. The mere fact that a company is required by the FDA to collect this data does not undercut the value of this data to the company, researchers and other third parties; nor does it provide the government with a greater basis to restrict who receives the data or how it is used.

In a similar program, the Centers for Medicare and Medicaid Services ("CMS") provides what is known as "coverage with evidence development." This coverage is for promising drugs that would not otherwise meet CMS's standards for being "reasonable and necessary," and is provided subject to a condition that the manufacturer maintain a registry and/or participate in a clinical research trial. *See* 42 U.S.C. §§ 1395y(a)(1)(E),1320b-12; *see also* Ctrs. for Medicare & Medicaid Servs., *Guidance on National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development* (2006), *available at* https://www.cms.gov/CoverageGenInfo/03_CED.asp (follow "National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development" hyperlink). Like information collected pursuant to the FDA's REMS program, such information will have lasting value for the company and researchers generally, well beyond CMS's decision whether to allow reimbursement for patients who use these drugs. Again, that this information was initially collected pursuant to

government regulation provides no basis to allow the government to deprive this privately collected data of First Amendment protection.

In a similar vein, adoption of the State's position would have significant implications for data that is not simply kept pursuant to government regulation but is actually collected by the government itself—which also provides the basis for a substantial amount of public health research. For example, the Dartmouth Atlas Project (with which *amicus* William B. Weeks, Associate Professor of Psychiatry and of Community and Family Medicine at Dartmouth Medical School, is associated) has spent over 20 years studying how medical resources are distributed and used across the United States, and relies on Medicare data to do so. *See* The Dartmouth Atlas of Health Care, http://www.dartmouthatlas.org (last visited Mar. 30, 2011).

Academic researchers also use Medicare and Medicaid data to study nationwide variations in medical treatment. For example, *amicus* Frank R. Lichtenberg, Courtney C. Brown Professor of Business at the Columbia University Graduate School of Business and a Research Associate of the National Bureau of Economic Research, has used this data in an attempt to explain the considerable regional variation in longevity growth within the United States. Using this state-by-state data, he has considered the effects of medical innovation (including drug vintage), behavioral risk factors and other variables on longevity. *See* Frank Lichtenberg, *The Quality of Medical Care, Behavioral Risk Factors, and Longevity Growth*, 11 Int'l J. Health Care Fin. & Econ. 1 (2011).

A ruling that treated prescription records in the possession of private parties as outside the scope of the First Amendment would likewise apply to this government data. Such a ruling would allow the government to dole out this valuable data based on the viewpoint of the entities who would use it—much as Vermont has sought to do here through Act 80, which favors the use of PI data to further its own viewpoint over those of pharmaceutical companies. *See* IMS Br. 49-56; PhRMA Br. 28-39. The First Amendment cannot tolerate such a result, whether the data at issue is collected pursuant to government regulation or by the government itself.

2. The mere fact that the data at issue in this case is used by some for commercial purposes is not sufficient, as the State would have it, Pet. Br. 26-27, to strip it of First Amendment protection. The importance of this data to a wide range of scientific research relevant to public health and health care policy confirms that the publication of this information is speech clearly worthy of full First Amendment protection. There can be no doubt of that proposition when considered in the context of the scholarly research work that depends on this data. Nothing changes the essential character of this data—as speech, as opposed to conduct—if the data is sold to a pharmaceutical company for marketing purposes, rather than provided at a reduced rate to an academic institution for research. Either way, the process and act of distributing the data—*i.e.*, the speech—is the same.

As this Court held in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, a state could not prohibit pharmacists from

publishing prescription drug prices on the grounds that this activity "merely reports a fact." 425 U.S. 748, 762-64 (1976). Even though the information may be communicated for a commercial purpose, "[a]s to the particular consumer's interest in the free flow of commercial information, that interest may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Id.* at 763; *see also Rubin v. Coors Brewing Co.*, 514 U.S. 476, 491 (1995) (finding that a ban on the publication of alcohol content on beer labels violates the First Amendment).

The attempt by the State to convert information into a commodity, and in turn to convert the publication of speech into mere conduct, cannot be squared with established First Amendment doctrine. As the Publisher Respondents point out, the "contributions to expression" inherent in disseminating the data at issue in this case fit at least as comfortably within the category of speech as the choice of what floats to include in a parade or which stations are made available on a cable television network. *See* IMS Br. 13 (citing *Hurley v. Irish-American Gay, Lesbian, and Bisexual Group of Boston*, 515 U.S. 557 (1995); *Turner Broad. Sys. v. FCC*, 512 U.S. 622 (1994)). The clear content-based application of Act 80 underscores that it is speech that is being regulated. *See Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989) (regulation is content-neutral only if it is "*justified* without reference to the content of the regulated speech" (internal quotation marks omitted)); *see also Clark v. Cmty. for Creative Non-Violence*, 468 U.S. 288, 295 (1984).

The gathering and analysis of basic data contributes significantly to the marketplace of ideas, as evidenced by the myriad uses made of it by academic researchers. The production and use of such data serves the vital purposes that animate the First Amendment's protection of the free flow of information, including the advancement of discovery and invention, the free exchange of ideas and the service of transparency and accountability. There is no merit to the position that it does not constitute speech.

C. Publication of the Data at Issue in This Case is Not Commercial Speech.

The State argues that, at most, publication of the information at issue in this case is "commercial speech," deserving only the intermediate scrutiny applicable under *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980), and its progeny. That position, too, fails.

This Court has generally confined "commercial speech" to advertising or marketing activity, speech "that does no more than propose a commercial transaction." *United States v. United Foods, Inc.*, 533 U.S. 405, 409 (2001); *Bd. of Trustees v. Fox,* 492 U.S. 469, 473-74 (1989). The Court has at times suggested a modestly broader definition, treating "commercial speech" as "expression related solely to the economic interests of the speaker and its audience." *Cent. Hudson*, 447 U.S. at 561.

Regardless of whether this Court eventually decides that the appropriate definition of commercial speech should be narrower or broader than

advertising and marketing in the classic sense, the treatment of the data at issue here as commercial speech would work great mischief for all of First Amendment law, reversing the settled principle that the mere existence of a commercial motive or the use of speech for a commercial purpose does not render the speech itself "commercial speech." Companies such as the Publisher Respondents serve as information middlemen. They advance the free flow of information by gathering and synthesizing data and then selling that data to those who find it valuable—both commercially and otherwise. As such, they are not conceptually different from mainstream media companies that gather raw data and package it, enterprises that operate for profit but that have always been understood as falling within the core purpose and protection of the First Amendment.

There is no loophole in the First Amendment relieving government of its constitutional obligations to avoid the abridgment of speech merely because the information is pure data. *See Dun & Bradstreet*, 472 U.S. at 762 n.8; *see also Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446-47 (2d Cir. 2001) (the First Amendment protects "[e]ven dry information"). The information used by academic research scientists clearly relates to matters of public concern and emphatically cannot be equated to speech that is "solely in the individual interest of the speaker and its specific business audience [or is] . . . wholly false and clearly damaging to [a] victim's business reputation." *Dun & Bradstreet*, 472 U.S. at 758-59, 762.

A law preventing the *Wall Street Journal* from harvesting raw data from corporate reports and packaging that data to sell it for "commercial purposes," for example, would plainly violate the First Amendment. The stock transactions reported by the *Wall Street Journal*, whether reported in aggregate form to present conclusions about large economic trends or presented in highly specific form to analyze the past performance of particular economic players, is understood as speech *about commerce*, but not itself *commercial speech*. The fact that data has value in the marketplace and can be bought and sold does not render it a "commodity" that is something less than speech. And the fact that the speech might be exploitable for a "commercial purpose" by investors, stock advisors, marketers and advertisers does not render publication of the data "commercial speech."

What is true of the the *Wall Street Journal* reporting on economic transactions, *Sports Illustrated* reporting on baseball or *USA Today* reporting on presidential politics is also true of the information providers who sell information to willing buyers with specialized interests and needs. In all of these examples, the Constitution is agnostic as to whether the motivation to gather and disseminate the speech is driven in whole or in part by profit.

This Court has repeatedly admonished that constitutional protection of speech is not diminished merely because the speech is sold for commercial gain. "Speech . . . is protected even though it is carried in a form that is 'sold' for profit." *Va. State Bd. of Pharmacy*, 425 U.S. at 761; *see also Buckley v. Valeo*, 424 U.S. 1 (1976); *Pittsburgh Press Co. v.*

Pittsburgh Comm'n on Human Relations, 413 U.S. 376 (1973); *N.Y. Times Co. v. Sullivan*, 376 U.S. 254 (1964); *Smith v. California*, 361 U.S. 147 (1959); *Joseph Burstyn, Inc. v. Wilson*, 343 U.S. 495 (1952); *Murdock v. Pennsylvania*, 319 U.S. 105 (1943). Further, as is clear from the many valuable research uses to which the dissemination of basic data is put, it cannot be equated to speech that is "so removed from any exposition of ideas, and from truth, science, morality, and arts in general, in its diffusion of liberal sentiments on the administration of Government, that it lacks all protection." *Va. State Bd. of Pharmacy*, 425 U.S. at 762 (internal citations and quotation marks omitted).

II. THE VERMONT LEGISLATION CANNOT WITHSTAND SCRUTINY UNDER THIS COURT'S COMMERCIAL SPEECH DOCTRINE.

The substantial amount of academic research made possible by the Publisher Respondents' data—research that is clearly not "related solely to the economic interests of the speaker and its audience"—underscores why this basic data should be entitled to the full protection of the First Amendment. But even if this Court determines that publication of this data is commercial speech, Act 80 cannot withstand intermediate scrutiny, as the Act does not "directly advance[] the governmental interest asserted." *Cent. Hudson*, 447 U.S. at 566.

Vermont's asserted governmental interest in prescriber privacy does not justify Act 80's restriction on speech. The respondents have shown that Vermont actually authorizes widespread use of PI data—for example, by the State itself as part of its

counter-detailing program, by insurers and other third parties who use the data to promote the use of generics, and by pharmaceutical companies to assist in their development of new drugs. IMS Br. 35-38; PhRMA Br. 11-13. In addition, Act 80 allows for the use of PI data in the extensive academic research in which *amici* are engaged. *See* Vt. Stat. Ann. tit. 18, § 4631(e)(1) ("The prohibitions . . . shall not apply to . . . the sale, license, exchange for value, or use, of regulated records for the limited purposes of . . . health care research.").

Nor does Vermont's purported interest in controlling medical costs and protecting public health provide support for Act 80's restriction on speech. Regulation of the availability of PI data itself sweeps far too broadly because, as the State notes, it is "marketing [that] has a proven effect on prescribing decisions, and that . . . 'over-accelerates' the prescribing of newly approved brand-name drugs." Pet. Br. 49. As respondents show, Vermont's approach of paternalistically restricting the dissemination of valuable data does not regulate detailing itself, does not distinguish between speech that promotes the use of therapeutically superior drugs and that which does not, does not identify which drugs are over-prescribed and does not show that doctors subjected to detailing do not make informed prescription decisions. *See* IMS Br. 57-62; PhRMA Br. 49-55.

Moreover, the State's purported interests would be *undermined* by any restrictions that decrease the commercial incentive to develop the sorts of databases that the Publisher Respondents offer, as Act 80 no doubt would. As discussed above, *supra*

Section I.A, academic researchers use this very data to study and illuminate important public health issues, including the effectiveness of warnings mandated by regulators, the impact of physicians' characteristics and location on prescribing behavior, the cost impacts of recent trends in the pharmaceuticals industry and the effects of marketing on prescribing behavior. To the extent the work of academics and researchers is hampered by restrictions on the databases on which they rely, the public discourse on these important issues would be seriously chilled.

In light of the significant amount of scientific research with applicability to health care policy issues made possible by the use of prescriber-identifiable information, it cannot be said that Act 80 advances governmental interests of cost containment and protecting public health, much less that it *directly* does so.

CONCLUSION

For the foregoing reasons, *amici curiae* respectfully submit that this Court should affirm the result reached below by the United States Court of Appeals for the Second Circuit.

Respectfully submitted,

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APPENDIX

The *amici curiae* are as follows[1]:

Ernst R. Berndt, Ph.D., is the Louis E. Seley Professor in Applied Economics at the MIT Sloan School of Management and Co-Director of the Harvard-MIT Biomedical Enterprise Program. In the last decade, much of Professor Berndt's research has focused on economic issues in health care, with a strong emphasis on measurement of costs, outcomes and prices. From 1999 to 2010, he served as Director of the National Bureau of Economic Research Program on Technological Progress and Productivity Measurement, and until recently was Chair of the Federal Economic Statistics Advisory Committee, an interagency committee formed by the Bureau of Labor Statistics, the Bureau of Economic Analysis and the U.S. Census Bureau. He also served as a member of the National Science Foundation Panel on Measurement, Methodology and Statistics. Currently he serves on the Editorial Board of *Health Affairs*. Professor Berndt's health care research has been published in peer-reviewed journals such as the *New England Journal of Medicine, American Journal of Psychiatry, Journal of Mental Health*

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[1] This brief reflects the views of the *amici* professors as individuals, and may or may not reflect the views of their institutions. The names of their institutions are included only for identification purposes. The *amici* have joined in this brief due to their concern that important information that is made available to them by commercial data providers such as the Publisher Respondents may no longer be available if prohibitions on commercial use of the information are allowed to stand. The legal analysis herein is that of their counsel.

Policy and Economics, Journal of Health Economics and *Health Affairs*. Professor Berndt received his Ph.D. in economics from the University of Wisconsin-Madison in 1972, and was awarded an honorary doctorate from Uppsala University in Sweden in 1991. He is an elected Fellow of the Econometric Society.

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