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 *AMICI CURIAE* LOUIS W. SULLIVAN, M.D., TOMMY G. THOMPSON, AND THE HEALTHCARE LEADERSHIP COUNCIL IN SUPPORT OF RESPONDENTS

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INTEREST OF THE *AMICI CURIAE*[1]

Amici curiae are two former secretaries of the United States Department of Health and Human Services (HHS) and a nonprofit coalition of chief executives from all disciplines within the American health care industry.

As national leaders in efforts to improve health care delivery, *amici* have a strong and abiding interest in the availability and use of non-private health information. *Amici* believe that the delivery of quality and effective health care is materially advanced by the ready availability of robust data about the practices and performance of health care professionals. This data can reveal, among other useful information, considerable and measurable disparities in the delivery of health care services and health outcomes for patients. Accordingly, the collection, aggregation, and broad dissemination of non-private information about physician prescribing practices furthers these public policy goals.

Louis W. Sullivan, M.D.

As HHS secretary from 1989 to 1993, *amicus curiae* Louis W. Sullivan, M.D., led the federal department responsible for the major health, welfare, food and drug safety, medical research, and income security programs serving the American people.

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[1] Pursuant to Rule 37.2 and 37.6, counsel for the *amici* certifies that (1) counsel of record for all parties have consented to the timely filing of this *amicus* brief in letters lodged with the Clerk of the Court and (2) no counsel for a party authored this brief in whole or in part and no person other than the *amici* and their counsel made a monetary contribution to the preparation or submission of this brief.

Secretary Sullivan earned his medical degree, *cum laude*, from Boston University School of Medicine and received postgraduate training in internal medicine, pathology, and hematology. In 1975, after a distinguished career on the faculty of several prestigious medical schools, Secretary Sullivan became the founding dean and director of the Medical Education Program at Morehouse College, and he led the effort to establish that program as a fully accredited four-year medical school, now known as the Morehouse School of Medicine. With the exception of his tenure as HHS secretary, Secretary Sullivan was president of the Morehouse School of Medicine for more than two decades. Since 2002, he has served as the school's president *emeritus*.

Secretary Sullivan presently serves on numerous boards, panels, and committees. He is a member of the Health Disparities Technical Expert Panel of the Centers for Medicare and Medicaid Services of HHS, and he also is chairman of the board of the National Health Museum, the Sullivan Alliance to Transform America's Health Professions, and the Virginia-Nebraska Alliance (a unique partnership of academic health science centers and historically black colleges and universities).

Secretary Sullivan has written in opposition to constraints on the gathering and availability of non-private health care information, including in opposition to statutes that restrict the exchange and ready availability of physicians' prescription information like the one under review in this case. *See* Louis W. Sullivan, M.D., *Prescribing Records and the First Amendment*, 361 New Eng. J. Med. 209-10 (2009).

Tommy G. Thompson

As HHS secretary from 2001 to 2005, *amicus curiae* Tommy G. Thompson led efforts to modernize the department, add prescription drug coverage to Medicare, and expand services to seniors, disabled Americans, and low-income Americans.

Prior to his appointment as HHS secretary, Secretary Thompson had a long and distinguished career in public service in Wisconsin. He served for many years in the Wisconsin Assembly and was elected to an unprecedented four terms as the state's governor. As governor, he was known as a national leader on the issue of welfare reform as well as efforts to expand health care access across all segments of society.

Secretary Thompson also is well-known for his leadership in the fight against HIV/AIDS in the United States and abroad and is chairman *emeritus* of the Global Fund to Fight AIDS, Tuberculosis and Malaria. He presently is a partner in the law firm of Akin Gump Strauss Hauer & Feld LLP, where his practice focuses on developing solutions for clients in the health care industry, and he serves on numerous boards and committees, including as chairman of the board of Logistics Health, Inc.

Healthcare Leadership Council

Amicus curiae the Healthcare Leadership Council (HLC) is a coalition of chief executives from all disciplines within American health care—including hospitals, academic health centers, health plans, pharmacies, and medical and pharmaceutical manufacturers and distributors. HLC members advocate measures to increase the cost-effectiveness of American health care by emphasizing wellness and

prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to elevate value. HLC shares its members' vision for quality health care with members of Congress, the administration, the media, the research community, and the public through communications and educational programs.

Because of their strongly held belief that non-private information about physicians' prescribing practices should be readily available, *amici* submit this brief to relate their views on the question presented.

SUMMARY OF ARGUMENT

There is widespread agreement among practicing physicians, academics, and policymakers that the ready availability of comprehensive information about the practices and performance of health care professionals, including physicians' prescribing practices, is vital to identifying the substantial disparities in health care in the United States and improving the quality, affordability, and accessibility of health care.

The creation, maintenance, and utilization of statistically robust databases about health care practices and performance requires collaboration among numerous stakeholders in the public and private sectors and a careful balancing of public and private interests and incentives. That is why the federal government and numerous states have adopted policies designed to promote and expand the use of information technology throughout the health care system, including technology that facilitates the collection, aggregation, and analysis of physician-

specific data, with appropriate safeguards for patient privacy and confidentiality.

The Vermont statute in this case works against these express federal and state policies and initiatives and threatens to reduce the availability and use of statistically robust data about physicians' prescribing practices. The statute makes existing databases like those maintained by Publisher Respondents less current and complete and therefore less useful for commercial and noncommercial purposes. It also reduces incentives to create new databases and improve the analytical tools that are essential for utilizing and maximizing the value of health care data.

In that fashion, the statute directly and indirectly reduces the free flow of truthful information to everyone who has a stake in the performance of the health care system. The statute impairs not only commercial speech but also noncommercial research, public policy planning, continuing medical education initiatives, and efforts to improve the quality, affordability, and accessibility of patient care. The statute makes it harder, not easier, for health care professionals to identify and reduce the substantial variations that exist in the delivery of health care services and the considerable health disparities that affect the lives of many Americans.

The statute cannot fairly be justified on grounds of either patient or prescriber privacy. Federal and state regulations rigorously protect patient information and the data at issue here does not include any patient-specific information. The state's asserted interests in prescriber privacy also are

illusory, given the terms of the statute itself and this Court's jurisprudence.

ARGUMENT

I. Comprehensive Electronic Health Information About Physicians' Prescribing Practices Is A Valuable Tool For Identifying Disparities In The Delivery Of Health Services And Improving The Effectiveness And Accessibility Of Health Care.

Modern electronic information technology makes it possible to collect, aggregate, and analyze unprecedented amounts of information about health care services and practices, including information about physicians' practices prescribing medications and treatments for patients.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulates the collection, maintenance, use, and disclosure of "protected health information," including "electronic protected health information," that identifies individual patients. HIPAA expressly does not restrict the use or disclosure of "de-identified" health information—*i.e.*, health information that has been stripped of any patient identifiers. *See generally* 42 U.S.C. § 1320d, *et seq.*; 45 C.F.R. Pts. 160 & 164 (establishing standards and related requirements with respect to electronic protected health information, including standards for security and privacy).

Once individual patient privacy is protected, however, de-identified health information, including physician-specific information about prescribing

practices, can be collected, aggregated, and analyzed for multiple purposes that are vital to improving the quality, affordability, and accessibility of health care. These purposes include "epidemiological studies, comparisons of cost, quality or specific outcomes across providers or payers, studies of incidence or prevalence of disease across populations, areas or time, and studies of access to care or differing use patterns across populations, areas or time." *See* Secretary of the U.S. Department of Health and Human Services, *Proposed Rule: Standards for Privacy of Individually Identifiable Health Information*, 64 Fed. Reg. 59918, 59946 (Nov. 3, 1999).

De-identified health information is particularly valuable for identifying and measuring variations in the availability and utilization of health services and understanding how these variations contribute to health disparities that undermine quality of life, reduce productivity, and cause premature death in different communities and segments of our population.

Indeed, such variations in the availability and utilization of health care and related disparities in patient health are considerable. The National Committee for Quality Assurance, for example, has reported between 35,000 and 75,000 avoidable deaths, and $2.7 billion and $3.7 billion in avoidable hospital costs, in the year 2006 due to unexplained variations in quality of care. *See* NCQA, *The State of Health Care Quality 2007* at 12 (2007).

The need for statistically robust de-identified health information reflecting on the actual delivery of health care services is even more important when

one considers the country's changing demographics. There is ample evidence of measurable disparities in both health care service and health status among the growing population of ethnic and racial minorities in the United States.

In particular, it has been shown that ethnic and racial minorities tend to suffer disproportionately from the effects of chronic diseases (such as diabetes, heart disease, cancer, stroke, and asthma), mental health afflictions, and dental problems—conditions that generally are preventable and/or treatable with access to, and utilization of, state-of-the-art health care. *See generally Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (Brian D. Smedley, Adrienne Y. Stith, Alan R. Nelson, eds., Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Board on Health Sciences Policy, Institute of Medicine, 2003).

Yet, with the widespread availability of de-identified health information, it is possible to assess how variations in access to, and utilization of, health care services contribute to observed ethnic and racial health disparities and develop strategies and techniques to address these disparities.

For example, a considerable lag typically exists between advances in health science and the incorporation of new knowledge, techniques, and treatments into physicians' practices. *See* E.A. Balas and S.A. Boren, *Managing Clinical Knowledge for Health Care Improvement*, Yearbook of Medical Informatics 2000: Patient-Centered Systems, at 65-70 (2000) (estimating a lag of as much as fifteen to twenty years in some areas). This lag contributes to increased costs in health care, as well as losses in

productivity and quality of life and an increase in premature deaths.

Research consistently shows, however, that the collection and use of de-identified health information about physicians' practices can reduce this lag, benefit patients, and improve public health. *See, e.g.*, NCQA, *The State of Health Care Quality 2007* at 10, 26 (2007) (attributing the use of de-identified health information to a dramatic rise in the percentage of heart attack patients receiving inexpensive beta-blocker drugs to prevent second, often fatal, heart attacks—from 62% in 1996 to 97% in 2006, saving 4,400 to 5,600 lives over a six-year period and improving quality of health for tens of thousands).

In short, with ready access to comprehensive, de-identified health information about physicians' treatment practices, academics, policymakers, and practicing physicians can:

(1) see how individual physicians' decisions align with patterns of practice across communities and with state-of-the-art health care;

(2) engage in evidence-based discussions about how variations in treatments may contribute to systemic health disparities; and

(3) develop and adopt cost-effective practices and strategies that reduce or eliminate disparities, improve the prevention and treatment of chronic illnesses, enhance quality of life, boost productivity, and prolong lives in each segment of the population.

Such transparency in health information ultimately promotes efficiency, competition, and cost-effective personalized care and empowers consumers

about provider quality, choices, and prices. Without it, practicing physicians, researchers, and policymakers cannot see how individual practices shape patterns of health care and health outcomes.

That is why there is "widespread agreement"—even among academics and health care professionals who support state regulations like the one at issue in this case—that "physician-specific data," stripped of patient identifiers, is "an important tool for improving the quality and value of care" whose "use[] should be promoted and expanded." *See* David Grande & David A. Asch, *Commercial versus Social Goals of Tracking What Doctors Do*, 360 New Eng. J. Med. 747, 748 (2009).

II. The Aggregation And Dissemination Of Comprehensive Electronic Health Information About Physicians' Prescribing Practices Requires Public And Private Participation.

It should come as no surprise that the collection and maintenance of comprehensive, de-identified health information is complex, time-consuming, and expensive. Obtaining the data, as well as maintaining and improving its quality, requires participation by individuals and entities from both the public and private sectors, including public health officials, academics, practicing physicians, health insurers, self-insured employers, pharmacies, health information publishers, and other entities.

In order to be useful and reliable for statistical analyses, de-identified health information must be (1) representative of the entire population across time and geographic area and without regard to health care provider or payor, (2) gathered in large

amounts, (3) aggregated and compiled into comprehensive and customized databases, (4) updated in a timely fashion, and (5) supported by specialized services and analytics that help make the collected data understandable and useful—all while protecting the privacy and confidentiality of individual patients.

Databases such as those maintained by the Publisher Respondents are used extensively by academic researchers and public officials because they meet these requirements. The Publisher Respondents' databases, for example, include collections of prescription information relating to all prescriptions, without regard to the entity paying for the prescription. Other databases, such as those maintained by Medicare and Medicaid agencies or the claims databases of individual insurers, generally provide information that is less complete, less representative of the entire population, less current, and less well supported by services and analytics.

Moreover, numerous studies underscore the unique value of statistically robust databases for noncommercial research and policy planning. For example, the Publisher Respondents' databases and services have been used in research into physicians' prescribing practices in urban areas to determine patterns of under-treatment of asthma. This research showed, in turn, that asthma-controller medications were being under-utilized and that there was a need for improved physician education and public outreach concerning asthma treatments. The Publisher Respondents' databases and services also have been used in federally funded research on off-label prescribing practices. *See, e.g.*, Surrey M. Walton*, et al.*, *Prioritizing Future Research on Off-Label*

Prescribing: Results of a Quantitative Evaluation, 28 Pharmacotherapy 1443 (2008).

As these examples illustrate, when public and private interests are aligned and de-identified health information is transparent and readily available to all, the value of the aggregated data is maximized, costs are reduced, patient care and health improves, and the public benefits.

III. Federal And State Policies And Initiatives Related To Improving Health Care Delivery Strongly Support The Aggregation And Broad Dissemination Of The Prescribing Information At Issue In This Litigation.

Federal policies and initiatives strongly support the gathering and broad dissemination of de-identified health information, including information about specific physicians' prescribing practices.

As noted above, HIPAA requires that HHS establish national standards for the use and disclosure of protected health information that identifies individual patients, but does not restrict the use or disclosure of de-identified health information. *See supra* pp. 6-7.

With these patient privacy protections in hand, HIPAA's regulatory scheme expressly *encourages* the gathering and broad dissemination of de-identified health information—including information about specific physicians' prescribing practices. *See* 45 C.F.R. § 164.514 (providing a "safe harbor" for de-identified health information).

The notice of proposed rulemaking implementing HIPAA also explained (1) how de-identified health

information was "valuable" for both "public health activities (*e.g.*, to identify cost-effective interventions for a particular disease) as well as for commercial purposes (*e.g.*, to identify areas for marketing new health care services)" and (2) how HIPAA regulations were designed to encourage public-private collaboration in the gathering and broad dissemination of de-identified health information for commercial and non-commercial purposes. 64 Fed. Reg. at 59946-47. Consistent with these avowed goals, HHS expressly noted:

> [I]t would be our hope that covered entities, their business partners, and others would make greater use of de-identified health information than they do today, when it is sufficient for the research purpose. Such practice would reduce the confidentiality concerns that result from the use of individually identifiable health information for some of these purposes. The selective transfer of health information without identifiers into an analytic database would significantly reduce the potential for privacy violations while allowing broader access to information for analytic purposes, without the overhead of audit trails and IRB review. For example, providing de-identified information to a pharmaceutical manufacturer to use in determining patterns of use of a particular pharmaceutical by general geographic location would be appropriate, even if the information were sold to the manufacturer.

Id.

Following the enactment of HIPAA, a 2006 report indicated that the administration, both parties' congressional leaders, and nearly 40 states had begun to pursue major health information initiatives, to achieve greater value for health care spending. *See* eHealth Initiative, *States Getting Connected: State Policy-Makers Drive Improvements in Healthcare Quality and Safety Through IT* (2006). For example, the Centers for Medicare and Medicaid Services (CMS) also collects health care data related to Medicare, Medicaid, State Children's Health Insurance Program (SCHIP), and Medicare Current Beneficiary Survey (MCBS), and then disseminates it to academic and non-profit researchers, among others.

Other recent federal legislation likewise embraces policies and initiatives supporting the gathering and broad dissemination of statistically robust de-identified health information. *See American Recovery and Reinvestment Act of 2009*, Pub. L. No. 111-5 (2009) (appropriating $400 million to "accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies," including "the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data."); 42 U.S.C. § 300jj–11 (establishing an Office of the National Coordinator for Health Information Technology that supports the use and exchange of de-identified electronic health information that, among other things, improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized

exchange of de-identified health care information; promotes early detection, prevention, and management of chronic diseases; and supports greater and more effective competition, better systems analysis, increased consumer choice, improved outcomes in health care services, and efforts to reduce health disparities); 42 U.S.C. § 201 Note (providing immediate funding to strengthen the health information technology infrastructure and develop a state grant program to promote health information technology).

More recently, the Patient Protection and Affordable Care Act (PPACA) provides for a significant number of provisions related to the collection and dissemination of de-identified health information. *See* 42 U.S.C. § 280j-1 (mandating that "[t]he Secretary shall collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery" to implement the public reporting of performance information); 42 U.S.C. § 300kk (mandating that the HHS secretary collect demographic data for any federally conducted or supported health care or public health program, activity or survey in order to detect and monitor trends in health disparities, and permitting the secretary to make such data available for additional research, analyses, and dissemination to other Federal agencies, non-governmental entities, and the public, in accordance with any Federal agency's data user agreements); 42 U.S.C. § 1320e (establishing a private, non-profit Patient-Centered Outcomes Research Institute that has access to data collected by the Centers for Medicare & Medicaid Services and the data networks developed under section 937(f) of

the Public Health Service Act); 36 U.S.C. § 150303 Note (mandating the development of a Commission on Key National Indicators and Key National Indicator System that identifies and selects data to populate the key national indicators and designs, publishes, and maintains a public website that contains a freely accessible database allowing public access to the key national indicators).

Perhaps even more to the point, another HHS agency—the Agency for Healthcare Research and Quality (AHRQ)—has a specifically defined mission of supporting research that helps people make more informed decisions and improves the quality of health care services, including promoting the collection and broad dissemination of de-identified health care data. *See* 42 U.S.C. § 299; *see also* 42 U.S.C. § 299c-3.

There is still more. Consistent with congressional intent to create an environment to foster the gathering and dissemination of de-identified health care data, substantial multi-agency initiatives are underway to collaborate with industry and share de-identified health care data. For example, Community Health Data Initiative is "a major new public-private effort to catalyze the advent of a network of community … health data suppliers (starting with HHS) and data appliers …." *See About the Initiative: Open Government at HHS*, *available at* http://www.hhs.gov/open/datasets/about.html.
Indeed, in describing this plan, HHS states that a "cornerstone of Open Government at HHS is the ability to make high-value data available to the public and encourage innovative uses of it to advance the public good." *See Community Health Data*

Initiative: Open Government at HHS, *available at* http://www.hhs.gov/open/plan/opengovernment plan/initiatives/initiative.html.

Finally, the Public Heath Data Standards Consortium (PHDSC) is yet another public-private partnership among the Centers for Disease Control and Prevention (CDC) and its public health partners at the state and local levels, the eHealth Initiative (eHI) membership, and CMS. PHDSC works "together with health care providers, state and local public health agencies, and local coalitions to identify critical public health and quality-related data needs and develop strategies to rapidly, efficiently, and securely capture and transmit relevant health care information to and among public health partners," including information about "specific laboratory and pharmacy transactions, emergency room visits, hospital admission data, and data from out-patient visits." *See A Public-Private Sector Collaboration to Improve Public Health and Health Care Quality*, Foundations for eHealth (Feb. 28, 2002), *available at* http://www.phdsc.org/about/pdfs/ehi.pdf.

There is no debate about the purpose and goal of these regulations, policies, and initiatives. They all recognize the paramount importance of bringing public and private interests together to support the gathering and ready dissemination of de-identified health information to facilitate the more equitable and effective delivery of quality and affordable health care.

IV. Vermont's Prescription Information Law Has The Undesirable Effect Of Restricting The Availability Of Highly Beneficial Statistical Information.

The problem posed by Vermont's prescription information statute is plain enough. The statute unreasonably threatens to undermine the gathering and broad dissemination of de-identified health information concerning physicians' prescribing practices for all purposes.

Although the statute purports to regulate only the commercial exchange of de-identified, prescriber-specific information and the use of such information by pharmaceutical manufacturers for marketing and promoting prescription drugs, it plainly alters the balance of public and private interests that supports the creation, maintenance, and improvement of statistically robust databases like those provided by the Publisher Respondents and thus, of necessity, will have a considerable adverse impact on the availability and use of such databases—not only for marketing, but also for the noncommercial research and policy planning purposes described previously.

To begin with, the statute prohibits a health insurer, self-insured employer, pharmacy, electronic transmission intermediary, or other similar entity from selling de-identified, prescriber-specific health information without the express consent of the prescriber. 18 Vt. St. Ann. § 4631(d). This prohibition limits the incentives that these private entities have to make de-identified, prescriber-specific health information available to others and likewise limits the ability of private companies like the Publisher Respondents to collect de-identified, prescriber-

specific health information necessary to maintain, update, and improve existing databases and to create new databases that are statistically robust.

By prohibiting the commercial exchange of de-identified, prescriber-specific health information, the statute has a direct and immediate effect on the maintenance and improvement of existing databases and the creation of new databases, such as those of the Publisher Respondents, that may be used for both commercial and noncommercial purposes. If pharmacies, health insurers, and other entities are unable to sell, and health information publishers are unable to buy, de-identified, prescriber-specific health information, existing databases are certain to degrade, becoming less current, complete, and representative of the population over time. Furthermore, the development of new and improved databases will be stifled. And these consequences invariably will hurt the kind of noncommercial scientific research and policy planning described previously.[2]

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[2] There appears to be some disagreement between Petitioners and their *amicus curiae* the United States about the precise scope of the statutory restriction on the commercial exchange of de-identified prescription information. The United States reads the plain language of Section 4631(d) as restricting the sale of de-identified, prescriber-specific health information "without limitation." U.S. Brief at 12 n.1. Petitioners take a different tack, reading the same statutory language as prohibiting the sale of prescriber-identifiable data only when the exchange would "permit the use of such information for marketing or promoting a prescription drug." Pet. Br. at 10-11. Either way, Vermont's statute disrupts and chills the collection and broad dissemination of de-identified health information. The

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The statute also contains an additional prohibition on the use of de-identified, prescriber-specific health information by pharmaceutical manufacturers and marketers for the marketing and promotion of any prescription drug. *Id.* This restriction is certain to reduce the incentives that private health companies have to invest time and money in gathering, maintaining, supporting, and disseminating statistically robust databases of de-identified, prescriber-specific health information—and this too is an outcome that invariably will undermine noncommercial science and policy research.

From any perspective, therefore, the Vermont statute disrupts the balance of public and private interests established by HIPAA regulations and other federal policies and initiatives supporting the collection, aggregation, and broad dissemination of de-identified health information. As highlighted above, that disruption poses appreciable adverse consequences for important noncommercial research and policy planning. Concomitantly, without such restrictions, public and private interests would remain aligned to maximize the value of aggregated, de-identified health data for the benefit of patients and public health.

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disagreement among Petitioners and their *amicus* is only over the degree to which that undesirable result is accomplished.

V. The Privacy Interests Asserted By Petitioners To Justify The State's Restrictions On The Availability Of Critical Prescription Information Are Illusory.

Petitioners contend that Vermont's prescription information law is justified by the state's asserted interest in prescriber privacy. This contention is fully addressed by the briefs of the Respondents and other *amici*. However, it should be noted that what is definitely *not* at issue in this litigation is the privacy of patients and the confidentiality of patient-specific medical information. Patient privacy and confidentiality is rigorously protected under HIPAA, and Vermont's statutory restrictions are aimed directly at the commercial exchange and use of de-identified information about prescription practices that complies fully with HIPAA patient privacy standards and requirements.

Although Petitioners now seek to advance a state interest in "prescriber" privacy (and the *amicus* brief of the United States supports Petitioners on this point), it should be noted that, when Congress passed HIPAA and HHS proposed and adopted HIPAA regulations, a deliberate decision was made not to restrict the gathering and dissemination of de-identified health information based on any alleged "prescriber" privacy interests. Instead, the federal government adopted rules that both allow and encourage the gathering and broad dissemination of de-identified, prescriber-specific health information for both noncommercial and commercial interests.

Furthermore, it should be noted that the Vermont statute does not actually protect any privacy

interests that prescribing physicians arguably could have. The statute does not require that any de-identified, prescriber-specific health information be kept private or confidential, nor does it shield prescribing physicians from unwanted solicitation or marketing. The statute only purports to regulate the commercial exchange of de-identified, prescriber-specific information and the use of such undisputedly *truthful* information by pharmaceutical manufacturers for marketing and promoting prescription drugs.

Finally, the statute's default prohibitions expressly presume that prescribing physicians will make bad decisions about patient care if de-identified information about their prescribing practices is readily available to, and used by, pharmaceutical manufacturers and marketers. This premise is unfounded, deeply paternalistic in its treatment of prescribing physicians, and inconsistent with this Court's First Amendment jurisprudence. *See, e.g., Edenfield v. Fane*, 507 U.S. 761, 766 (1993) (striking down a state ban on in-person solicitation by certified accountants because the ban "threaten[ed] societal interests in broad access to complete and accurate commercial information").

CONCLUSION

When information about physicians' prescribing practices is stripped of patient identifiers and made transparent and available to all, public and private interests are closely aligned, and it is possible to maximize the value of that information to improve the quality, affordability, and accessibility of health care to all members of society. Federal statutes,

regulations, and policies have long recognized this. Vermont's prescription information law works against these profound interests and erroneously and unlawfully impairs public and private efforts to improve the quality, availability, and affordability of health care.

Respectfully Submitted,

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