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* MASSACHUSETTS BIOTECHNOLOGY COUNCIL, BIOTECHNOLOGY INDUSTRY ORGANIZATION ET AL. IN SUPPORT OF RESPONDENTS

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The Massachusetts Biotechnology Council ("MassBio"), Biotechnology Industry Organization ("BIO"), BIOCOM, BioForward, BioNJ, Colorado BioScience Association ("CBSA"), Connecticut United for Research Excellence, Inc. ("CURE"), Illinois Biotechnology Industry Organization, Iowa Biotechnology Association, Kansas Bioscience Organization, LifeScience Alley, Michigan BioSciences Industry Association ("MichBio"), Pennsylvania Bio, South Dakota Biotechnology Association, Texas Healthcare and Bioscience Institute ("THBI"), and Washington Biotechnology & Biomedical Association (collectively, the "Biotechnology Amici"), as *amici curiae*, urge the Court to affirm the decision of the Court of Appeals for the Second Circuit in *IMS Health Inc. et al. v. Sorrell*, 630 F.3d 263 (2d Cir. 2010), because Vermont's prohibition on the use of prescriber-identifiable information for the marketing and promotion of prescription drugs impairs not only Respondents' rights guaranteed by the First Amendment, but also those of our members, and will harm – rather than protect – the patients whom our members serve.[1]

[1] All parties to this appeal have consented to the Biotechnology Amici's filing of this *amici curiae* brief in support of Respondents by way of blanket consents on file with the Clerk of Court. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation and submission.

INTEREST OF *AMICI CURIAE*

The common mission of the Biotechnology Amici is to advocate policies that encourage biotechnological development, and to educate and aid local, state, and federal officials, as well as the general public, in making informed decisions about issues concerning biotechnology. MassBio is an association of more than 600 biotechnology companies, universities, and academic institutions, principally all based or active in the Commonwealth of Massachusetts. Its members include 370 companies directly engaged in the research, development, and manufacture of innovative biomedical products that bring great benefit to people around the world. Joining MassBio in this *amici curiae* brief are national and state biotechnology associations that advocate policies that encourage biotechnological development. BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,100 members worldwide. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. Corporate members range from entrepreneurial companies developing a first product to Fortune 500 multinationals. BIO also represents state and regional biotechnology associations, service providers to the industry, and academic centers and other research organizations. BIOCOM, based in Southern California, is the largest regional life science association in the world, representing more than 560 member companies in the life

science industry. BioForward represents bioscience companies, universities, non-profits, and governmental entities operating in Wisconsin. BioNJ represents the interests of biotechnology, pharmaceutical, and other life science industry participants in the State of New Jersey. CBSA represents 350 companies operating in Colorado in the biotechnology, pharmaceutical, medical device, and diagnostic fields, as well as educational institutions and research facilities. CURE is an educational and business support network for bioscience in Connecticut. CURE's membership includes emerging biotechnology companies, pharmaceutical companies and major research universities. The Illinois Biotechnology Industry Organization promotes the life sciences in Illinois and its members include large and small biotechnology companies developing medical solutions for human illnesses and injury types, as well as research organizations, including major universities, where research on innovative cures is conducted. The Iowa Biotechnology Association works to promote the biotechnology industry in Iowa on behalf of its member companies, research institutions, and state and federal associations. The Kansas Bioscience Organization represents bioscience companies and research institutions in Kansas and works to enhance that state's bioscience business and research climate. LifeScience Alley is a nonprofit organization that works on behalf of its member companies, educational institutions and government agencies to cultivate the bioscience industry in Minnesota. MichBio is a trade

association that represents biotechnology companies in the State of Michigan. MichBio members are bioscience-related companies, research institutions, hospitals, public universities and their technology transfer offices, service providers, and economic development organizations interested in furthering the expansion of the biosciences in Michigan. Pennsylvania Bio works on behalf of its member companies, research institutions, companies and nonprofits to promote the life science industry in the Commonwealth of Pennsylvania. The South Dakota Biotechnology Association is a non-profit association serving member organizations, businesses, universities and research institutions to advance the biosciences in South Dakota. THBI serves as the voice of the bioscience industry in Texas and promotes effective government legislation on industry's behalf at the state and federal level. Its members include biotechnology, medical device, and pharmaceutical companies, universities and private research institutions. The Washington Biotechnology & Biomedical Association serves the life sciences industry in the State of Washington and its members include organizations engaged in research, development and commercialization of life science technologies.

Biotechnology is essentially a small company industry. The significant majority of our member companies employ 50 or fewer workers. Accordingly, we are well-situated to inform the Court of how restrictions on the use of prescriber data would detrimentally affect small, innovative biotechnology firms and, more significantly, the public health.

In particular, many of our members are at the forefront of research and development trends that increasingly focus on personalized medicine for patient subpopulations, and on rare or orphan diseases and conditions – those that afflict only small populations of patients. To treat the specialized needs of these patients, biotechnology companies must be able to communicate vital information about their biopharmaceutical products to the doctors who treat these patients. To that end, many of our members use prescriber data as a means to identify and target physicians working with patients for whom their products would do the most good – a more efficient and effective use of these companies' limited financial and human resources. Vermont's statutory prohibition on such use is expressly intended to obstruct important communications by biotechnology companies to the medical community about their innovative, and often life-saving, drugs and biologics. Thus, the Biotechnology Amici have a significant interest in this Court's affirmation of the Second Circuit's decision in *Sorrell*, as it will discourage further infringements by the States on the free speech rights of our members.

SUMMARY OF ARGUMENT

Vermont's ban on the use of prescriber data in marketing or promoting prescription drugs violates the First Amendment rights of our members. Rather than directly advancing public health and lowering healthcare costs, this law actually does the opposite by impeding the ability of biotechnology firms to reach the patients that would benefit from the use of,

or information about, their products. Our members' experience in other states with similar prescriber data restriction laws illustrates how these restrictions, like the Vermont statute at issue in this appeal, reduce effectiveness and efficiency in the dissemination of important information concerning new or existing treatments available to patients. These restrictions also are unconstitutionally overbroad in that they ban use of prescriber information for promoting drugs and biologics even where there are no generic or less costly alternatives to "branded" products, and thus they represent the patients' only treatment option. While the states' asserted benefits from these prescriber data restrictions are speculative and unknown, the harms they cause are clear. Restricting biotechnology companies' right and ability to communicate important safety and effectiveness information regarding their innovative products to targeted physicians hinders quality of patient care and greatly increases the cost of physician identification and education.

ARGUMENT

I. THE EXPRESS PURPOSE OF THE VERMONT STATUTE IS TO RESTRICT SPEECH, RAISING A "CORE" FIRST AMENDMENT CONCERN.

The law at issue in this case, Vermont's Section 4631, Title 18 ("Act 80"), specifically prohibits "[p]harmaceutical manufacturers and pharmaceutical

marketers," like many of the biotechnology companies the Biotechnology Amici represent, from "us[ing] prescriber-identifiable information for marketing or promoting a prescription drug[.]" Vt. Stat. Ann. Tit. 18, § 4631(d). Vermont believes this restriction advances certain public policies:

> It is the intent of the general assembly 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, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

Id. at § 4631(a). Vermont further explained that it believed the restriction necessary to counterbalance the goals of pharmaceutical marketers, which, according to the state, are "often in conflict with the goals of the state." Vt. Acts No. 80, § 1(3). Under the assumption that the "marketplace for ideas on medicine safety and effectiveness is frequently one-sided," leading physicians to prescribe "drugs based on incomplete and biased information," Vermont concluded that "[p]ublic health is ill served by the massive imbalance in information presented to doctors and other prescribers." *Id.* at § 1(6). Vermont crafted Act 80 "to correct what it sees as an unbalanced marketplace of ideas that undermine the state's interests in promoting public health, protecting

prescriber privacy, and reducing health care costs." *Sorrell*, 630 F.3d at 270.

Thus, there is no question that the express purpose of Act 80 is to restrict speech – Act 80 itself concedes as much. It seeks to correct this "massive imbalance" not by encouraging or facilitating *more* speech, but by prohibiting "[p]harmaceutical manufacturers" from using prescriber data regarding prescriptions written and dispensed in Vermont to identify and communicate with physicians whose patients may benefit from use of information concerning their products. Vt. Stat. Ann. Tit. 18, § 4631(d). Indeed, the Vermont statute "is premised on limiting the information available to physicians as a means of impacting their conduct." *Sorrell*, 630 F.3d at 277. As the Second Circuit concluded, "[t]his approach is antithetical to a long line of Supreme Court cases stressing that courts must be very skeptical of government efforts to prevent the dissemination of information in order to affect conduct." *Id.* at 277-278 (citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503, 116 S. Ct. 1495, 134 L. Ed. 2d 711 (1996) ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770, 96 S. Ct. 1817, 48 L. Ed. 2d 346 (1976) (the alternative to a ban on pharmacist advertising "is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are

well enough informed, and that the best means to that end is to open the channels of communication rather than to close them.")). Thus, "[t]he statute is therefore clearly aimed at influencing the supply of information, a core First Amendment concern." *Id.* at 272.

The Second Circuit viewed the Vermont statute as a restriction on commercial speech, *id.* at 274,[2] and rightly concluded that Act 80 could not meet the demands of intermediate scrutiny required for regulation of commercial speech under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 564, 100 S. Ct. 2343, 65 L. Ed. 2d 341 (1980) (holding that the government may regulate commercial speech when (1) "the communication is neither misleading nor related to unlawful activity;" (2) the government "assert[s] a substantial interest to be achieved" by the regulation; (3) the restriction "must directly advance the state interest;" and finally (4) "if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive."). Based on the experience of our members in other states that have adopted similar

[2] The Court of Appeals for the Second Circuit concluded in its decision that intermediate scrutiny should apply to review of Act 80. *Sorrell*, 630 F.3d at 274. The Biotechnology Amici do not concede that intermediate scrutiny is the appropriate level of review. It may be that, as Respondents suggest, strict scrutiny of Act 80 is required.

prescriber data restrictions, the State of Vermont cannot establish that Act 80 directly advances the state's asserted interests, or that it does so in a manner that is not any more restrictive than is necessary to accomplish its interests. On both accounts, the law utterly fails constitutional scrutiny.

As illustrated in the case study described in Section II, *infra*, Vermont's sweeping conclusions lack adequate factual support, are overbroad, and are, indeed, contradicted by available evidence. Although Vermont's stated goals of protecting public health and lowering healthcare costs may be laudable, the restriction adopted to achieve these goals actually frustrates them instead. For these reasons, the law infringes the First Amendment rights of Respondents and our members.

II. EXPERIENCE SHOWS THAT PRESCRIBER DATA RESTRICTION LAWS ARE HARMFUL TO PUBLIC HEALTH AND INCREASE COSTS TO BIOTECHNOLOGY FIRMS AND, THUS, THE COSTS OF HEALTHCARE.

Vermont alleges that Act 80 advances the state's interests "in protecting the public health" and in containing healthcare costs in both the private and public sectors. Vt. Stat. Ann. Tit. 18, § 4631(a).[3] The

[3] The Biotechnology Amici do not specifically address Vermont's asserted interest in "protecting the privacy of prescribers and prescribing information." Vt. Stat. Ann. Tit. 18,

(Continued on following page)

third prong of *Central Hudson* requires that Vermont prove that the regulation "directly advance[s] the state interest involved." *Cent. Hudson*, 447 U.S. at 564; *see also Edenfield v. Fane*, 507 U.S. 761, 767, 113 S. Ct. 1792, 123 L. Ed. 2d 543 (1993) (describing the third prong of *Central Hudson* as "whether the challenged regulation advances these interests in a direct and material way," and holding that "the party seeking to uphold a restriction on commercial speech carries the burden of justifying it.") (internal quotations omitted) (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 71 n.20, 103 S. Ct. 2875, 77 L. Ed. 2d 469 (1983)). This prong is "critical," and requires invalidating a regulation that restricts commercial speech "if it provides only ineffective or remote support" for the government interests asserted. *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 188, 119 S. Ct. 1923, 144 L. Ed. 2d 161 (1999) (quoting *Cent. Hudson*, 447 U.S. at 564).

We agree with the Second Circuit's conclusion that "the Vermont statute cannot be said to advance the state's interests in public health and reducing costs in a direct and material way." *Sorrell*, 630 F.2d at 277. The Court of Appeals identified the shaky underpinnings of the relationship between the

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§ 4631(a). Rather, we agree with the Second Circuit's criticisms of this asserted interest, *Sorrell*, 630 F.3d at 275-276, and likewise conclude that the "state's asserted interest in medical privacy is too speculative to qualify as a substantial state interest under *Central Hudson*." *Id.* at 276.

Vermont statute and the asserted state interests. In fact, our members have observed these shortcomings in other states that have adopted similar prescriber data restrictions:

> Because section 17 [Act 80] is an attempt to influence the prescribing conduct of doctors by restricting the speech of others – namely data miners and pharmaceutical manufacturers – it does not directly advance the state's interests in protecting public health and reducing health care costs. Instead, the statute restricts protected speech when uttered for purposes the government does not approve of in order to reduce the effectiveness of marketing campaigns and, ultimately, alter the behavior of prescribers, who are not regulated by the statute. This route is too indirect to survive intermediate scrutiny.

Id. at 279.

Rather than directly advancing public health and lowering healthcare costs, data restriction laws actually impede the ability of biotechnology firms to reach the patients that would benefit from the use of, or information about, their products, increasing the already high level of risk associated with the development and launch of a new and innovative drug or biologic. MassBio and BIO member Eisai Inc.'s ("Eisai") experience with New Hampshire's similar prescriber data restriction law during the 2009 launch of its pharmaceutical product, BANZEL®, illustrates the perhaps unintended, but significant

and negative, consequences associated with prescriber data restrictions.[4] Encouraged by the Orphan Drug Act,[5] which Congress passed in 1983 to encourage drug manufacturers to develop drugs for diseases that affect smaller patient populations, Eisai, like many of our members, pursues new treatments for underserved patient communities. Using prescriber data, Eisai and other biotechnology companies can identify which physicians most frequently treat patients with the rare diseases their products are designed to combat. On the basis of that information, manufacturers are then able to reach out to these physicians, initially to identify patients who might be eligible to participate in clinical trials and, after approval by the Food and Drug Administration ("FDA"), to provide treatment information and post-treatment monitoring.

In November 2008, the FDA approved Eisai's BANZEL for adjunctive use in the treatment of seizures associated with Lennox-Gastaut Syndrome ("LGS") in children four years and older and adults.

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[4] N.H. Rev. Stat. Ann. § 318:47-f; *see also IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 170-171 (D.N.H. 2007), *rev'd* 550 F.3d 42 (1st Cir. 2008) (holding that New Hampshire's prescriber data restriction law regulated only the conduct of data mining companies, and therefore did not violate their First Amendment rights). *See* Brief of Respondents IMS Health Inc., Verispan, LLC, and Source Healthcare Analytics, Inc. at 19-20 (discussing the negative impact New Hampshire's prescriber data restriction law had on Eisai's launch of BANZEL in that state).

[5] *See* 21 U.S.C. § 360 (2011) *et seq*.

LGS is a rare and catastrophic form of childhood-onset epilepsy characterized by multiple types of seizures occurring many times a day (100 or more in some cases) and delayed intellectual development. Of approximately 300,000 children under the age of 14 who have epilepsy in the United States, only four percent or fewer have LGS. An LGS patient's long-term prognosis is usually bleak. Seizures are often resistant to therapy, which results in high rates of injury due to tonic and atonic seizures, also known as "drop attacks" or "drop seizures." It is often necessary for LGS patients to wear protective helmets with face guards to avert injury. Approximately 80 percent of patients continue to have seizures into adulthood. The mortality rate for LGS patients is approximately three percent, with death often resulting from seizure-related accidents and injuries.[6]

In treating LGS, physicians attempt to minimize seizures and adverse events with therapies that necessitate the fewest number of, and least severe, medical interventions, so that patients can enjoy the best quality of care possible. While antiepileptic drugs are considered first-line treatment, no one drug

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[6] *See, e.g., FDA Approves Reunamide in Lennox-Gastaut Syndrome*, Medscape Medical News, (Nov. 25, 2008), http://www.medscape.com/viewarticle/584170; Glauser, Kluger, Sachdeo, Krauss, Perdomo, and Arroyo, *Rufinamide for Generalized Seizures Associated with Lennox-Gastaut Syndrome*, Neurology, (2008), http://www.neurology.org/cgi/content/abstract/70/21/1950; Glauser and Morita, *Lennox-Gastaut Syndrome*, Emedicine from WebMD, http://emedicine.medscape.com/article/1176735.

has proven to be effective in managing LGS. Multiple drug therapy and invasive surgical approaches are often necessary – including catastrophic and costly surgery in which half the brain is removed or disabled.

In a pivotal clinical trial, BANZEL was shown to significantly reduce total seizures in patients with LGS. BANZEL accordingly received FDA approval under the Orphan Drug Act. But the potential for inappropriate use of BANZEL, and its possible impact on patient safety, made it imperative for Eisai to refine the target audience for the launch of its new drug. To identify physicians who treat the relatively small population of patients suffering from LGS, Eisai acquired market information, including prescriber data reports, from Respondent IMS Health, the nation's largest publisher of health information. The information IMS Health communicated to Eisai enabled the company to identify quickly and efficiently those physicians in the United States that prescribe other drugs used to treat LGS patients. Eisai then interviewed these physicians to determine whether treatment of LGS patients was a significant part of their practice. By this process, Eisai selected 1,300 child neurologists and epileptologists from a total universe of 10,000 to 12,000 general neurologists. This smaller universe of physicians included only those most knowledgeable about LGS and best suited to use and evaluate BANZEL in clinical practice.

Eisai understood it was critical for initial use of BANZEL to be carefully assessed by experts in LGS, since inappropriate use of the drug may result in

negative patient outcomes. Respondent IMS Health's organization, selection, and communication of relevant prescriber data and metrics to Eisai proved critical to Eisai's launch of BANZEL, not only in terms of communicating FDA-approved information about appropriate use, but also by allowing the most effective and efficient use of Eisai's resources. Without IMS Health's reports and data, the cost of identifying and communicating with the appropriate subset of physicians who treat LGS patients would have been exorbitant, and may have made a successful launch of this drug to treat this rare condition simply infeasible.

The BANZEL launch occurred in the shadow of New Hampshire's law restricting the commercial use of prescriber data, N.H. Rev. Stat. Ann. § 318:47-f, thus frustrating Eisai's efforts to identify quickly and efficiently physicians in that state who treat LGS patients. The data restriction law in New Hampshire obfuscated which neurologists in the state treated patients with LGS. As a result, Eisai was uncertain about which physicians to contact to enable treatment of LGS patients in New Hampshire. The New Hampshire restriction – which, like the Vermont restriction on prescriber data, was intended to advance the public health and lower healthcare costs – caused Eisai significant delay and inefficiency in locating and treating New Hampshire residents suffering from LGS.

Eisai's judicious and responsible use of data to launch BANZEL supports the critical role of prescriber data in bringing new, life-saving and life-enhancing

drugs and biologics to patients in the most effective and efficient manner. Eisai's experience in New Hampshire, however, illustrates how prescriber data restriction laws, like the Vermont statute at issue in this appeal, reduce effectiveness and efficiency in the dissemination of information concerning new treatments available to patients, particularly those suffering from a rare and serious illness like LGS. Although the purported benefits of these prescriber data restrictions are speculative and unknown, the harms they cause are clear. Restricting biotechnology companies' right and ability to communicate important safety and effectiveness information regarding their innovative products to targeted physicians hinders quality of patient care and greatly increases the cost of physician identification and education. As noted at the outset, the biotechnology industry is largely made up of small companies on the forefront of cutting-edge research and innovation in healthcare. Making it more difficult and more expensive for these companies to reach the patients that can benefit from their products is ***in no way*** beneficial to public health or to the reduction of healthcare costs.

III. THE VERMONT STATUTE IS AN EXCESSIVE RESTRICTION THAT CANNOT SURVIVE INTERMEDIATE SCRUTINY.

Act 80 "is a poor fit with the state's goal to regulate new and allegedly insufficiently tested brand-name drugs in cases where there are cheaper generic alternatives available," *Sorrell*, 630 F.3d at 279, and

therefore cannot survive intermediate scrutiny under this factor, either. To satisfy the final prong of *Central Hudson*, Vermont must do the near-impossible: demonstrate that Act 80 is narrowly tailored to serve the substantial state interests that it contends justify the speech restriction. *Id.* at 281; *Greater New Orleans Broad. Ass'n*, 527 U.S. at 188 (holding that the burden is on the government to show that it "carefully calculated" costs and benefits of burdening speech); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002) (stating that while the fit need not be perfect, "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so").

The professed purpose behind Act 80 is to stimulate the prescribing of generic pharmaceuticals and to weaken attempts by innovative biopharmaceutical manufacturers to promote "branded" medicines instead. But many biotechnology companies develop and market specialty medicines that address unmet or poorly met medical needs. Often, there are ***no generic or less costly alternatives*** to innovative treatments designed to meet the needs of underserved patient populations, such as the LGS patients who have benefited from Eisai's BANZEL. Yet the Vermont statute nevertheless restricts biotechnology companies from using prescriber data to promote even such novel products to physicians that treat patients with these unmet medical conditions. *See Sorrell*, 630 F.3d at 280 ("The statute prohibits the

transmission or use of PI data for marketing purposes for all prescription drugs regardless of any problem with the drug or whether there is a generic alternative. The statute bans speech beyond what the state's evidence purportedly addresses."). Thus, for many of our member companies, Act 80 sweeps beyond Vermont's stated interest in promoting less costly drugs, adopting a "remedy" that is decidedly *not* narrowly tailored. The law thereby unconstitutionally restricts the First Amendment rights of biopharmaceutical companies, while also – as discussed earlier – harming public health and increasing the cost of bringing new life-saving and life-enhancing drugs and biologics to market.

IV. VERMONT'S PRESCRIBER DATA RESTRICTION LAW FRUSTRATES THE ABILITY OF BIOTECHNOLOGY FIRMS TO MEET CERTAIN RISK MONITORING AND MITIGATION REQUIREMENTS.

Since the enactment of the Food and Drug Administration Amendments Act in 2007, mandatory Risk Evaluation and Mitigation Strategies ("REMS") have become integral to the launch of many new drugs and biologics as a means of assuring their benefits will outweigh their risks when used by patients. One element of a REMS that is frequently required by the FDA is a communication plan targeted at healthcare providers, in which risk information about the drug is provided to prescribing physicians. Access to prescribing data allows REMS communications to be targeted

at the appropriate providers. Complete and current prescribing data is critical to identifying new prescribers of a product for which a REMS is required, so that the manufacturer can promptly communicate product risks and safety information to a physician who begins prescribing the product to patients. Such data also is often necessary for required REMS assessments, a process under which companies must evaluate the effectiveness of these risk mitigation plans on a recurring basis. In the course of implementing risk mitigation programs, the biotechnology companies that we represent communicate important information about their products to all physicians who prescribe the product, and provide physician education to support optimal patient care. Because biologic treatments in particular are often administered directly by or in the physician's office, communication between such physicians and biopharmaceutical manufacturers is a critical component of proper patient care. Simply put, patient interests are well-served by a well-informed physician.

In a regulatory environment that relies on these risk mitigation programs to make new products safely available, access to prescriber information is critical both to regulatory compliance and the ongoing support of physicians managing patient care. Given its breadth and its language, however, Act 80 could be read to prohibit use of prescriber data for even these most salutary communications with physicians.[7]

[7] *See* Brief of Respondent Pharmaceutical Research and Manufacturers of America at 8-9 ("[Act 80's] prohibition against

(Continued on following page)

Further, to the extent that such restrictions in Vermont and other states end up limiting the availability of prescriber data generally, the ability of our member companies to meet their regulatory requirements in this regard would be undermined.

CONCLUSION

The Court should affirm the Second Circuit's decision in *IMS Health Inc. et al. v. Sorrell*, 630 F.3d 263.

Respectfully submitted,

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speech by pharmaceutical manufacturers is so overbroad that it potentially prohibits a manufacturer from using prescriber-identifiable data to convey to prescribers recent peer-reviewed scientific literature or to communicate to prescribers safety or risk information.").

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