No. 10-779

IN THE

Supreme Court of the United States

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

Petitioners,

v.

IMS HEALTH INC., et al.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR GENETIC ALLIANCE AND THE NATIONAL ORGANIZATION FOR RARE DISORDERS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*

Genetic Alliance is a not-for-profit health advocacy organization committed to using genetics research and the robust exchange of healthcare information to improve patient health. Founded in 1986, Genetic Alliance serves as a network for more than 10,000 health-related organizations, including 1,200 disease-specific advocacy organizations as well as universities, private companies, government agencies, and public policy organizations. The network enables diverse organizations to share resources and information to accelerate the development and availability of breakthrough medical treatments and to improve individualized patient treatment decisions by facilitating information access concerning available treatments.[1]

The National Organization for Rare Disorders ("NORD") is a not-for-profit federation of voluntary health organizations dedicated to helping people with rare "orphan" diseases – affecting fewer than 200,000 people in the United States – and assisting the organizations that serve them. There are an estimated 7,000 rare disorders that, taken together, affect approximately one out of ten men, women, and children in the United States. Founded in 1983, NORD serves as the primary non-governmental clearinghouse for information on rare disorders. NORD is committed to the identification, treatment, and cure of

1. This brief is filed with the written consent of all parties. Consent letters are on file with the Clerk of the Court. Sup. Ct. R. 37.3. No counsel for a party authored this brief in whole or in part, nor did any person or entity, other than *amici* or their counsel, make a monetary contribution to the preparation or submission of this brief. *Id.* 37.6.

rare disorders through programs of education, advocacy, research, and service.

Genetic Alliance and NORD ("Patient *Amici*") advocate unencumbered access to information, within the bounds of existing federal patient privacy laws, regarding all current and developing treatment options to assist future research efforts and to ensure that patients receive the best possible care based on fully informed prescriber decisions concerning available options. Patient *Amici* believe that restricting the free flow of such information could lead to sub-optimal patient care and may also drive up overall healthcare costs by inhibiting the development and use of more effective new products that shorten the course of treatment and avoid the need for costly medical procedures. Such restrictions also could adversely affect the development of new breakthrough treatments for rare, genetic, and other disorders – harming future patient care – by slowing post-approval recovery on the research investment necessary to develop these products and thus undermining the financial incentives that prompt pharmaceutical and biotechnology companies to bear the risks and costs of such research.

Patient *Amici* believe that the Vermont statute at issue in this case would, if upheld, have precisely these adverse effects on patient health. We respectfully submit this brief to ensure that the interests of patients are fully considered by the Court.

SUMMARY OF ARGUMENT

The Vermont statute at issue, Vt. Stat. Ann. tit. 18, § 4631 ("Act 80"), violates the First Amendment because its purpose and effect is to suppress speech that can benefit patients. By hindering patients' ability, through their doctors, to receive the full benefit of information that would otherwise be made available to them about their treatment options, Vermont seeks to tilt individual consumer decisions toward allegedly cost-reducing government preferences. This approach repeatedly has been condemned by this Court as an unjustified infringement on First Amendment rights.

None of Vermont's asserted governmental interests in restricting the speech at issue is valid. Act 80's speech prohibition runs counter to this Court's First Amendment jurisprudence because it paternalistically seeks to keep prescribers and patients in the dark about available treatment options to prevent them from making what the State has preemptively determined to be poor treatment choices. Moreover, it is no answer that Act 80 bans use of a tool for making speech effective rather than the speech itself – both forms of restriction are offensive to the First Amendment.

Vermont has failed to identify a single legitimate interest that would justify its restriction of the flow of information to prescribers and their patients even under the Court's intermediate scrutiny test for commercial speech set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557, 566 (1980). Its asserted interest in prescriber privacy is pretextual. The practice of medicine is highly regulated,

and prescribers must involuntarily subject themselves to extensive public disclosures under Vermont law in order to practice medicine in that State. Moreover, the very same information that Vermont purports to suppress from pharmaceutical companies for marketing purposes is freely permitted by Act 80 to be disclosed to anyone for any other use (and may even be used for marketing by entities other than pharmaceutical companies), thus negating any supposed privacy-protective effect.

Vermont's attempt to justify Act 80 on the basis of its interests in promoting the public health and controlling costs is equally suspect. Vermont presupposes that older, cheaper drugs are uniformly superior to newer treatments despite evidence that older drugs often provide less cost-effective or less safe treatment and drive up overall healthcare costs for a particular condition by lengthening the course of treatment or necessitating expensive medical procedures that newer drugs would render unnecessary. Vermont also assumes that these newer drugs are generally unsafe, but this directly collides with federal law, which requires the Food and Drug Administration ("FDA") to determine that such products are safe and effective for labeled uses before permitting them to be distributed in interstate commerce. *See* 21 U.S.C. § 355(d). Further, Vermont paternalistically assumes that prescribers will make inferior treatment choices for their patients when presented with truthful, non-misleading information in detailing, but this is an assumption that it is not entitled to make under this Court's First Amendment jurisprudence, as articulated in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 756-57 (1976), and numerous other cases.

The very notion that Vermont should be permitted to employ censorship to usurp patients' rights to participate in well-informed treatment consultations with their doctors, with full access to the most recent and pertinent information about new medicines, is offensive not only to First Amendment principles but to the very operation of a free enterprise system. When private funds finance prescription drug purchases, Vermont has no more of an interest in pressuring doctors to prescribe cheaper, and often less effective, generic drugs in place of newer therapies than it does in inducing citizens to buy cheaper consumer goods. And when public funds finance those purchases, the State already has in place extensive measures designed to control its costs.

Most alarming for patients are the real-world health consequences that arise from this constitutionally infirm statute if it operates as intended. Under Act 80, detailing would become less focused, less useful to doctors and their patients, and potentially economically unsustainable, and the production of prescriber-identifiable ("PI") information itself may become uneconomic. In the short-term, these effects would lead to sub-optimal patient treatment decisions, as physicians are inhibited from learning about potentially superior new drug treatments from the source best positioned to educate them. More perniciously, the operation of Act 80 would adversely decrease and deteriorate treatments available to patients over the long haul. Research and development of a new product requires a massive investment of resources, and the effort must be compensated through sales of that product. Slowed dissemination of information, however, would retard the adoption of these new drug treatments and could cause pharmaceutical companies to rethink

their research investment in future treatments. Sadly, this will disproportionately harm the patient populations that Patient *Amici* represent, who suffer from rare genetic and other diseases for which treatments are limited or nonexistent. Patient *Amici* urge the Court to affirm the United States Court of Appeals for the Second Circuit's invalidation of this constitutionally deficient Vermont law.

ARGUMENT

I. VERMONT'S ACT 80 INFRINGES PATIENTS' FIRST AMENDMENT RIGHTS BY SEEKING TO LIMIT THE FLOW OF TRUTHFUL AND NON-DECEPTIVE INFORMATION TO PRESCRIBERS AND PATIENTS.

Patients have a critical interest in ensuring that their doctors are fully informed about all current treatment options that could save or meaningfully improve their lives. The principal objective of Act 80, however – which is part of a chapter of Vermont's Health Code entitled "Prescription Drug Cost Containment" – is to reduce expenditures on pharmaceutical products by limiting the effectiveness of a key communication medium for promoting new products – pharmaceutical marketing ("detailing"). Pet. Br. 49-50 (Feb. 22, 2011) (describing goal of statute as "reduc[ing] the inappropriate influence of pharmaceutical marketing on doctors' prescribing decisions"). Vermont believes that suppressing detailing will expand the use of lower-cost generic alternatives vis-a-vis new branded drugs. Act 80 impermissibly discriminates against one type of speech – marketing – by one class of speakers – pharmaceutical companies – by banning the use of PI data by pharmaceutical companies "for marketing or promoting

a prescription drug." The law permits, however, unlimited use of the same data by all other speakers for a wide variety of purposes (including marketing by entities other than pharmaceutical companies and "counter-detailing" by the State itself). *See* Vt. Stat. Ann. tit. 18, § 4631(d); Br. of Resp'ts IMS Health Inc. *et al.* 3-4, 16-17, 35-38 (Mar. 24, 2011) ("Resp. Br.").[2]

Patients benefit directly from the use of prescriber-specific information in pharmaceutical detailing, as it allows pharmaceutical companies to determine which prescribers treat patient populations most likely to benefit from new treatments. It also helps identify prescribers who might be unaware of the existence of newer cutting-edge therapies and thus not offer them to their patients. With this information, pharmaceutical companies are better equipped to decide which prescribers to visit and how to tailor the content of their communications during those visits. They can thus most efficiently convey information about new treatments to prescribers best positioned to translate that information into better-informed prescription decisions and treatments for their patients. In other words, patients are the ultimate audience for the information that Act 80 seeks to inhibit.

Act 80, however, infringes upon the First Amendment right of prescribing physicians and, ultimately, patients, to have meaningful access to voluntarily supplied information

2. Notably, the law does not merely target false or misleading speech, which is regulated through multiple other avenues. Rather, the law targets *all* speech from a particular source, including truthful, non-misleading speech. Patient *Amici*'s concern with the law is its suppressive effect on truthful, non-misleading speech regarding new treatments.

about promising new drug treatments. *See*, *e.g.*, *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 565 (2001) ("[A] speech regulation cannot unduly impinge on … the adult listener's opportunity to obtain information about products."); *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 8 (1986) (observing that First Amendment "protects the public's interest in receiving information" (citations omitted)); *Kleindienst v. Mandel*, 408 U.S. 753, 762 (1972) ("[I] t is now well established that the Constitution protects the right to receive information and ideas." (quotation marks and citations omitted); *Va. State Bd. of Pharmacy*, 425 U.S. at 756-57 ("[T]he protection afforded is to the communication, to its source and to its recipients both."); *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir. 1999) ("Effective speech has two components: a speaker and an audience. A restriction on either of these components is a restriction on speech."); *see also Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 366-67 (2002) ("[T]he free flow of commercial information is indispensable' ... [and] a 'particular consumer's interest in the free flow of commercial information ... may be as keen, if not keener by far, than his interest in the day's most urgent political debate.'" (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 763, 765)).

If allowed to stand, Act 80 would permit the State of Vermont to interfere with the ability of prescribers, in consultation with their patients, to decide whether new branded drugs or older, less expensive drugs are the best treatment option. Restricting the flow of truthful and non-deceptive information as a means of tilting individual consumer decisions toward government preferences has repeatedly been condemned by this Court as an unjustified infringement on First Amendment rights. *See*, *e.g.*, *Va.*

State Bd. of Pharmacy, 425 U.S. at 767-69 ("This casts the Board's justifications in a different light, for on close inspection it is seen that the State's protectiveness of its citizens rests in large measure on the advantages of their being kept in ignorance."); *W. States Med. Ctr.*, 535 U.S. at 374 ("We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (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.").

It is no defense that Act 80 does not directly ban detailing itself but relies on depriving pharmaceutical companies of a tool – PI data – that makes detailing more effective and justifies the considerable cost of individualized marketing. Depriving speakers of the tools needed to make their communications effective is as suspect as direct suppression under the First Amendment. *See, e.g.*, *Saia v. New York*, 334 U.S. 558, 561 (1948) (invalidating law requiring permit for use of sound amplification equipment, explaining that "[l]oud-speakers are today indispensable instruments of effective public speech"); *City of Ladue v. Gilleo*, 512 U.S. 43, 54 (1994) (invalidating sign ordinance because government had "almost completely foreclosed a venerable means of communication that is both unique and important"); *Davis v. FEC*, 554 U.S. 724, 736, 744 (2008) (invalidating campaign finance law that was not direct speech ban but "has the effect of enabling [an] opponent to raise more money and to use that money to finance speech that counteracts and thus diminishes the

effectiveness of [candidate's] own speech"); *Boos v. Barry*, 485 U.S. 312, 321 (1988) (explaining that "[r]egulations that focus on the direct impact of speech on its audience" are subject to First Amendment scrutiny); *Grosjean v. Am. Press Co.*, 297 U.S. 233, 249 (1936) (observing that Court has been "careful not to limit the protection of the right [to free speech and press] to any particular way of abridging it"); *U.S. West*, 182 F.3d at 1239-40 (striking down on First Amendment grounds FCC's restriction on communications carriers' ability to use a customer's information to target market services to that customer).

Given Act 80's intended inhibition on communicating new drug information to prescribers who need it to make sound treatment decisions for their patients, Act 80 cannot withstand First Amendment scrutiny unless Vermont can at least demonstrate that it directly advances a substantial state interest and is narrowly tailored to further that interest.[3] *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980).

3. The parties dispute the level of scrutiny that should apply to Act 80. Because that law does not satisfy even the intermediate scrutiny standard articulated in *Central Hudson*, and thus would inevitably fail under the strict scrutiny standard, Patient *Amici* analyze the provision under the *Central Hudson* standard.

II. VERMONT CANNOT IDENTIFY A STATE INTEREST SUFFICIENT TO JUSTIFY LIMITING THE FLOW OF TRUTHFUL AND NON-DECEPTIVE INFORMATION TO PRESCRIBERS AND THEIR PATIENTS.

Vermont asserts three governmental interests in support of Act 80: (1) "protecting the privacy of prescribers and prescribing information"; (2) "protecting the public health of Vermonters"; and (3) "ensur[ing] costs are contained in the private health care sector, as well as for state purchasers of prescription drugs." Vt. Stat. Ann. tit. 18, § 4631(a). None of these interests justifies Vermont's attempt to keep prescribers and patients in the dark about valuable new treatments.

A. Vermont's Alleged Interest in Prescriber Privacy Is Pretextual.

Vermont's attempt to justify Act 80 by asserting an interest in protecting prescriber privacy is an obvious makeweight. In the first place, the information allegedly held private by Act 80 relates to the professional activity of prescribers, not to their personal lives. Prescribers are members of a highly regulated profession subject to scrutiny by federal and state government, licensing boards, and the general public. Thus, the prescriber-specific information at issue is not "private" in any meaningful sense.[4]

4. The United States – while supporting Vermont – acknowledges that "physicians' privacy interest in their prescribing practices is diminished – especially as against the government itself – by the extensive regulation of those practices under federal and state law." Br. for the United States as *Amicus*

Vermont physicians are regulated by the state board of medical practice, which is authorized to investigate complaints and to "reprimand the person complained against, as it deems appropriate; condition, limit, suspend or revoke the license or practice of the person complained against; or take such other action relating to discipline or practice as the board determines is proper." Vt. Stat. Ann. tit. 26, §§ 1353, 1361. Moreover, further contradicting Vermont's claimed interest in prescriber privacy, the State has decided to accumulate a wide repository of information about licensed prescribing physicians and make it "available for dissemination to the public." Vt. Stat. Ann. tit. 26, § 1368(a). The repository consists of seventeen specific types of information, including information of far greater personal and professional sensitivity to physicians than aggregated data on their prescribing practices. For example, the repository discloses, for the most recent ten years, "any criminal convictions for felonies and serious misdemeanors," "any charges to which a health care professional [pled] nolo contendere," "any formal charges served, findings, conclusions, and orders of the licensing authority, and final disposition of matters by the courts," any due-process-based "revocation or involuntary restriction of hospital privileges for reasons related to competence or character," and "the resignation from, or nonrenewal of, medical staff membership or the restriction

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Curiae Supporting Pet'rs 29 (Mar. 1, 2011); *see also* Center for Democracy & Technology, *Memo on Sorrell v. IMS Health Inc.: Supreme Court Case Requires Nuanced Understanding of Privacy* 5 (Mar. 22, 2011) ("CDT Memo") *available at* http://www.cdt.org/files/pdfs/20110324_SorrellvIMS.pdf ("The behavior of physicians and other health care professionals is routinely scrutinized by federal and state regulators, accrediting organizations, licensing boards, and health care plans, among others.").

of privileges at a hospital taken in lieu of, or in settlement of, a pending disciplinary case related to competence or character in that hospital." *Id.*

The repository also discloses, for the most recent ten years, "[a]ll medical malpractice court judgments," "all medical malpractice arbitration awards," and "all settlements of medical malpractice claims" where "a payment is made to a complaining party." *Id.*[5] The database further includes information concerning a doctor's professional credentials, including the medical schools attended, graduation dates, years in practice, graduate medical education, specialty board certifications, hospitals where the doctor has privileges, the doctor's primary practice setting, and whether the doctor participates in Medicaid and accepts new patients. *Id.* Prescribers are unable to prevent the public dissemination of any of the disclosures listed above. *Id.* § 1368(b).

Further, Act 80 itself belies Vermont's asserted interest in prescriber privacy by expressly permitting PI information to be disclosed to and used by a wide variety of entities, such as insurers, pharmacy benefits managers, academic researchers, public health officials, and law enforcement officers. Resp. Br. 35-38. In fact, the PI information may even be disclosed to pharmaceutical

5. Disposition of these paid claims must "be reported in a minimum of three graduated categories, indicating the level of significance of the award or settlement," and they must "be put in context by comparing an individual health care professional's medical malpractice judgment awards and settlements to the experience of other health care professionals within the same specialty within the New England region or nationally." Vt. Stat. Ann. tit. 26, § 1368(a).

companies so long as they do not use it for marketing. Vt. Stat. Ann. tit. 18, § 4631(d), (e). As the lower court aptly found, the law "plainly does not protect physician privacy." Pet. App. 22a.[6]

Not only does the law not protect physician privacy, but Patient *Amici* are troubled by any assertion that it *should* do so. Creating a constitutionally cognizable privacy interest in physician professional conduct, including prescribing history, would undermine a number of broad federal and state health reform efforts. Initiatives to increase the effectiveness of our health care system, improve patient care quality and safety, and lower health care costs depend on heightened health data fluidity and sophisticated statistical analysis of data at unprecedented levels. If prescriber records could be declared off-limits to oversight and analysis under a new right of prescriber privacy, nascent trends toward greater accountability and objective quality-improvement initiatives would be undercut, with corresponding harm to patients' (and taxpayers') interests.[7]

Vermont also attempts to bolster its professed *prescriber* privacy interest by suggesting that the law protects *patient* privacy, citing various provisions of Vermont law restricting the disclosure of patient-identifiable information in support of this argument. Pet. Br. 5-6, 36-37. Patient *Amici* fully endorse protection of

6. If, as Vermont hints, the real interest here is not "privacy" but rather doctors' desire not to be "targeted" by drug company sales representatives, Pet. Br. 46-47, the solution is simple and does not require any legislative action – individual doctors can simply refuse to accept detailing visits by drug company representatives.

7. *See* CDT Memo, *supra* note 4.

patient privacy, but the statute at issue itself safeguards no such interest. Vt. Stat. Ann. tit. 18, § 4631(a). The information that is collected and sold by the publisher respondents consists of data sets that meet the rigorous and detailed de-identification standard established by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") for removing patient-identifiable information. *See* Resp. Br. 2.[8]

Petitioners and some supporting *amici* cite an article that recommends fundamental changes in privacy laws, almost all of which are based on some distinction between personally identifiable and non-personally identifiable data, on the ground that data intended to be anonymous may be increasingly vulnerable to re-identification attacks. Pet. Br. 37 n.11 (citing Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. Rev. 1701, 1701 (2010)); Br. for the Vt. Med. Soc'y *et al.* as *Amici Curiae* Supporting Pet'rs 26 (Mar. 1, 2011) (citing same); Br. of *Amicus Curiae* Electronic Frontier Foundation in Supp. of Pet'rs 10 (Mar. 1, 2011) (same). But the only successful re-identification attack discussed in that article involving health information – a re-identification by a computer scientist of a pre-HIPAA data set that included former Massachusetts Governor Weld's health records – was performed from data that included "nearly one hundred attributes per patient and hospital visit, … including the critical trio of ZIP codes,

8. If – as has never been shown to occur with PI data – such information were not properly de-identified as to patient identities under the HIPAA standard, federal law has extensive penalties and remedies available, enforceable both by the Department of Health and Human Services and the state Attorneys General. *See* 42 U.S.C. §§ 1320d-5, 1320d-6; 45 C.F.R. § 164.512.

birth date, and sex." Ohm, *supra*, at 1719 (quotation marks omitted). Significantly, publishing this information could not have even approached compliance with the HIPAA de-identification standard, as HIPAA regulations require the removal of birthdates and five-digit zip codes. 45 C.F.R. § 164.514(b). Indeed, this successful re-identification of an insufficiently anonymized data set actually influenced the final HIPAA drafters to require the removal of dates of birth and five-digit zip codes in the final HIPAA de-identification standard. Ohm, *supra*, at 1737, 1742.

In short, Vermont's attempted reliance on prescriber privacy in support of Act 80 is neither based on any meaningful privacy interest nor linked to any meaningful – let alone direct – advancement of the interest that Vermont asserts.

B. The Legitimacy of Vermont's Alleged Interests in Promoting the Public Health and Controlling Costs Hinges on Unwarranted Assumptions.

Vermont's asserted public health and cost-containment interests, while more indicative of the real purpose of Act 80, are just as unfounded as its illusory interest in prescriber privacy.

In order to link these interests to Act 80, Vermont must establish that: older, cheaper drugs are as effective as, and cost less than, newer drugs; newer drugs approved as safe and effective by FDA are actually "unsafe"; and detailers relying on PI data will influence prescribers to make treatment decisions not in the best interest of their patients. None of these premises can be sustained.

1. Older, Cheaper Drugs Are Not Categorically Superior to Newer Treatments.

It is by no means the case that older drugs consistently provide better patient treatment options on balance than newer drugs. The scope of medical, pharmacological, and genetic knowledge is constantly expanding. Newer therapies represent the frontier of such knowledge and may treat disease conditions with greater efficacy, or equal efficacy with fewer side effects, than older treatments. *See infra* Part III.A. Nor are newer drugs necessarily more expensive over the course of treatment than older therapies. Even if a drug itself costs more than an older alternative on a dose-by-dose basis, it may shorten the treatment time or avoid the need for expensive future medical procedures, which reduces overall patient healthcare costs. *See infra* Part III.A. Most importantly, every patient is different. The best course of treatment for one person may not be best for another. Factors such as age, race, gender, concomitant health conditions, other medications being taken, and increasingly a patient's personal genetic profile affect a patient's response to a particular product. Vermont simply cannot categorically declare that older, cheaper generic products are superior treatments – or even more cost-effective – than newer therapies.

2. Newer FDA-Approved Drugs Are Not Unsafe for Patients.

Vermont's related assumption that newer products are needlessly unsafe is similarly flawed, as it directly conflicts with FDA's determination – required under federal law as a prerequisite to selling any new drug in commerce

– that any approved product *is* safe and effective for its labeled uses. *See* 21 U.S.C. § 355(d) (requiring FDA to refuse to approve a new drug application if, *inter alia*, the application fails to include adequate information to demonstrate that the drug is safe and effective for labeled uses). Even the United States – while generally supporting Vermont's position – specifically disavowed Vermont's claim that Act 80 advances the public health, observing that it "depends on the unwarranted view that the dangers of such new drugs outweigh their benefits to patients." Br. for the United States as *Amicus Curiae* Supporting Pet'rs 24 n.4 (Mar. 1, 2011) ("United States Br."). Because FDA's determination of safety necessarily signifies the opposite – *i.e.*, a drug's benefits outweigh its risks – Vermont's assumption improperly disregards FDA's congressionally mandated role as the nationwide guardian of drug safety. *See* FDA, *Guidance for Industry: Development and Use of Risk Minimization Action Plans* 4 (Mar. 2005), *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126830.pdf (observing that "a product is considered to be safe if the clinical significance and probability of its beneficial effects outweigh the likelihood and medical importance of its harmful or undesirable effects").[9]

9. While Vermont cites isolated examples of drugs that were ultimately withdrawn for safety reasons, such as Vioxx and Baycol, and drugs that are allegedly "widely over-prescribed" compared to allegedly comparable alternatives, purportedly including Nexium and Lipitor, these are the exception, not the rule. As the United States observed, merely because on occasion, "unanticipated side effects" may be discovered, "it does not follow that categorically reducing the volume of prescriptions for newly approved drugs materially advances public health." United States Br. 24 n.4.

3. Prescribers Receiving Truthful and Non-Misleading Information About Newer Drugs Cannot Be Presumed To Make Bad Choices for Their Patients.

Vermont also cannot justify limiting the flow of information by assuming that prescribers, when presented with truthful prescription drug information from pharmaceutical manufacturers, will be induced to make inferior treatment choices. Rather, prescribers and their patients have a First Amendment right to determine the usefulness of manufacturer communications without state censorship. As the Court observed over three decades ago in striking down an advertising restraint in which both cost-control and protecting the public health were identified as interests advanced by the measure, States must constitutionally "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." *Va. State Bd. of Pharmacy*, 425 U.S. at 767-70 (rejecting Virginia's "highly paternalistic approach" and making clear that the choice "between the dangers of suppressing information" and "the dangers of its misuse if it is freely available" is not the Court's or Virginia's to make but one "that the First Amendment makes for us"); *W. States Med. Ctr.*, 535 U.S. at 374 (explaining that the fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway "rests on the questionable assumption that doctors would prescribe unnecessary medications" (citing *Va. State Bd. of Pharmacy*, 425 U.S. at 769); *cf. Hill v. Colorado*, 530 U.S. 703, 716 (2000)

("The right to free speech, of course, includes the right to attempt to persuade others to change their views, and may not be curtailed simply because the speaker's message may be offensive to his audience."). Indeed, if there is any protected individual interest at stake in this case, it is the personal right of patients and prescribers to exercise their autonomy by having free access to the information needed to select the treatment option that best suits their needs.

C. Vermont's Act 80 Could Impair the Right of Patients and Their Doctors To Make Fully Informed Healthcare Decisions in Their Own Best Interest.

If Vermont's law is upheld, it would enable the State to use censorship to interfere with individual health treatment decisions that should properly be made by patients in consultation with their doctors.

By Act 80, Vermont seeks to force upon private citizens particular, state-favored, choices among alternative FDA-approved treatments. Where private choices do not impact public funds, a State simply has no substantial interest in imposing cost savings by tilting the flow of information toward what it considers more cost-effective treatment. Vermont has no more of a legitimate interest in restricting speech as a means to favor older, and often less effective, drugs than it would have in restricting speech to favor Timex® instead of Rolex® watches, standard definition over high-definition televisions, or Mrs. Butterworth's® pancake syrup over certified Vermont Maple syrup.[10]

10. Ironically, with respect to maple syrup, Vermont expends state funds to support private syrup marketing efforts using tactics that sound very similar to the pharmaceutical marketing

Recognizing the cost reduction "interest" put forward by Vermont as substantial would set a pernicious, paternalistic precedent that would enable States to justify all manner of restrictions on the free flow of information to consumers in the interest of preventing them from making "bad" economic choices with that information. That is anathema to this Court's First Amendment jurisprudence. *See Va. State Bd. of Pharmacy*, 425 U.S. at 765 ("So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable." (citation omitted)).

To be clear, Patient *Amici* do not question Vermont's right to protect the State fisc by selecting the drug treatments that it will cover under Medicaid or other State assistance programs. Nor do Patient *Amici* oppose the use of State funds to "counter-detail" by disseminating truthful, non-misleading, and non-coercive information

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tactics derided by the state. Vermont law declares that due to "the inability of individual producers to develop new and larger markets for agricultural commodities,…. It is therefore declared the legislative purpose and the policy of this state…to enable agricultural producers of this state, with the aid of the state, to more effectively correlate the marketing of their agricultural commodities with market demands…." Vt. Stat. Ann. tit. 6, § 250; *see also id.* § 251 (defining "agricultural commodity" to include maple syrup). In other words, Vermont actively seeks to impose higher food costs on in-state and out-of-state consumers by promoting the purchase of more expensive Vermont Maple syrup instead of lower-cost alternatives.

about older drugs to prescribers. Indeed, Vermont already directly controls prescription drug costs paid by the State. It has in place an extensive "cost control program designed to reduce the cost of providing prescription drugs," which includes a number of specific measures such as use of a "preferred list of covered prescription drugs," "a prior authorization review process," and "consideration of using maximum allowable cost pricing for generic and other prescription drugs." Vt. Stat. Ann. tit. 33, § 1998; *see also* Br. for Resp't Pharm. Research & Mfrs. of Am. 54 (Mar. 24, 2011) (identifying other Vermont cost-control measures and observing that "[g]eneric drugs are dispensed to Vermont Medicaid patients 97.7% of the time when the doctor prescribed their bioequivalent brand"). But Vermont's ability to protect its own financial interest does not legitimate Act 80's intrusion into privately funded healthcare decisions. Similarly, Vermont's ability to counter-detail does not legitimate Act 80's speech restraint. Vermont can protect its own interest directly, without resorting to indirect speech-restrictive options.

III. VERMONT'S ACT 80 ADVERSELY AFFECTS PATIENTS' IMMEDIATE AND ONGOING INTERESTS.

The constitutional infirmities in Act 80 reflect the practical difficulties arising when the golden calf of cost saving and the demonization of pharmaceutical marketers overcome our national confidence that maximizing available truthful and non-deceptive information will optimize prescription choices. If Act 80 operates as intended, direct pharmaceutical marketing will become less focused and less useful. Moreover, if pharmaceutical companies are precluded from purchasing PI information

for marketing purposes, production of this information likely will become economically unsustainable. While PI information has value to a large community of users, as acknowledged in the permitted use categories in Act 80, it is highly likely that those users would not be capable of covering the costs of creating the PI database. In fact, the academic medicine, government, and public health users of the PI data today regularly obtain it at low prices that are heavily subsidized by commercial customers (or even obtain it for free). Eliminating the financial support of pharmaceutical marketing departments would have detrimental consequences for other PI data users – and for the patients and taxpayers who obtain the benefits of the socially valuable uses of the data.[11]

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11. One important public health program that could be threatened is the use of PI data in connection with FDA-mandated Risk Evaluation and Mitigation Strategies ("REMS"). REMS programs are required for many new drugs to ensure that prescribers are fully informed of the potential risks of a drug and that their patients receive the most effective, safe, and up-to-date treatment possible based on current knowledge. Many such REMS require a drug company to provide educational safety information directly to specific physicians who prescribe the drug. For example, the REMS for the drug FORTEO® (teriparatide rDNA origin) requires the manufacturer to send a letter to "any [healthcare professional] who has prescribed FORTEO in the last 12 months." Eli Lilly & Co., *Proposed Risk Evaluation and Mitigation Strategy (REMS): FORTEO®* NDA: 21-318/S-012, at 2 (approved by FDA on July 22, 2009), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM173371.pdf. Similarly, FDA requires the sponsor of the drug Tasigna® (nilotinib) to hand deliver educational materials to "likely Tasigna prescribers; that is, the approximately 6,900 U.S. prescribers who treat patients for chronic myelogenous leukemia (CML)," a rare and deadly form of

A. Detailing Creates Important Patient Benefits, and Its Degradation or Unavailability Would Result in Sub-Optimal Prescribing Decisions.

Act 80's inhibition of detailing is detrimental to the patient populations served by the Genetic Alliance and NORD. Busy prescribers may well be unaware of beneficial new drugs, particularly if those drugs are effective for only a limited share of their patient populations. In addition, detailing often includes important information on recognition of disease conditions, including rare disorders, which may otherwise go unnoticed or be wrongly diagnosed. In the very limited time that prescribers have to familiarize themselves with new drug developments, it is essential that information be conveyed in a narrowly tailored manner. Blocking pharmaceutical companies from using PI data to determine which new drug information is most relevant to particular prescribers, or suppressing

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cancer. Novartis Pharms., *Risk Evaluation & Mitigation Strategy (REMS) for Tasigna*, at 2 (approved by FDA on Mar. 15, 2010; modified on June 17, 2010 and Jan. 14, 2011), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM217737.pdf. A similar REMS program is also in the works for the diabetes drug Symlin® pramlintide acetate injection). *See generally* BIOCOM, *Safety First: The Role of Physician Level Data in Supporting Risk Evaluation & Mitigation Strategies (REMS) for Optimal Patient Care – A Case Study* 3-6, *available at* http://www.biocom.org/?m=sp_view_doc&file=Shared%20Documents/Public%20Policy/MD_level_data_rpt.pdf (last visited Mar. 31, 2011). If the PI information is not developed to begin with, it will be far more difficult for companies to identify the prescribers with whom FDA has required them to communicate, thus thwarting compliance with this federally mandated safety program.

detailing altogether, will inevitably degrade prescribing decisions to the detriment of patients.

To be sure, Patient *Amici* recognize that detailing could be used to convey unauthorized or misleading information. Patient *Amici* fully support government efforts to attack such abuses and legal violations directly and forcefully. But Patient *Amici* cannot support invoking these abuses to foreclose an important channel of critical and highly beneficial medical information. *See Va. State Bd. of Pharmacy*, 425 U.S. at 765 (recognizing that "the free flow of commercial information is indispensable " to ensuring that purchase decisions "be intelligent and well informed" (citation omitted)).

Indeed, one need only look at the news headlines to perceive the value of such new products and the importance of ensuring that physicians are promptly and fully informed about them – particularly from the very entity that created the products and thus is in the best position to provide such information. For example, FDA recently approved Xenazine® (tetrabenazine) tablets, the first drug ever approved to treat chorea (involuntary movements) caused by Huntington's Disease. Prior to approval of Xenazine, common, unapproved treatments for Huntington's chorea included generic antipsychotic drugs such as haloperidol or tranquilizers such as clonazepam. Possible side effects of Xenazine include insomnia, drowsiness, nausea, and restlessness, but the side effects of the generic alternatives include sedation and increased muscle stiffness and rigidity. *See* Mayo Clinic, *Huntington's Disease: Treatments and Drugs*, *available at* http://www.mayoclinic.com/health/huntingtons-disease/DS00401/DSECTION=treatments-and-drugs (last visited Mar. 28, 2011).

Another drug, Xolair, is already approved to treat asthma triggered by allergies, but recent tests reveal that it shows promise to reduce children's milk allergies more quickly than the current standard of care. Adam Cole, *Pricey Asthma Drug Shows Potential in Easing Children's Milk Allergies* (Mar. 24, 2011), *available at* http://www.npr.org/blogs/health/2011/03/24/134793831/pricey-asthma-drug-shows-potential-in-easing-childrens-milk-allergies?ft=1&f=1001.

In 2010, FDA approved Provenge to treat prostate cancer. The drug is "the first therapy to train the body's immune system to destroy tumors," and its approval was described by one investment analyst as "truly a landmark event." Catherine Larkin, *Dendreon Approval Sparks New Era for Cancer Vaccines (Update 2)*, Bloomberg Businessweek, Apr. 30, 2010, *available at* http://www.businessweek.com/news/2010-04-30/dendreon-approval-sparks-new-era-for-cancer-vaccines-update2-.html. "The therapy involves extracting white blood cells from a patient, mixing them with vaccine components and injecting the combination back into the person" and "is designed to be given earlier in treatment of the cancer and pose fewer side effects than chemotherapy." *Id.* The drug has been so popular with prescribers and patients that FDA recently approved a four-fold increase in production of this drug. *FDA Approves Increased Availability of Prostate-Cancer Drug Provenge*, ABC News Radio, Mar. 11, 2011, *available at* http://abcnewsradioonline.com/health-news/fda-approves-increased-availability-of-prostate-cancer-drug.html#. While the drug is costly – $93,000 for a four-month, three-dose course of treatment – "to those men who have benefited from this revolutionary new therapy, it's worth every penny." Courtney Hutchison, *Provenge Cancer*

Vaccine: Can You Put a Price on Delaying Death?, ABC News, July 29, 2010, *available at* http://abcnews.go.com/Health/ProstateCancerNews/provenge-cancer-vaccine-months-life-worth-100k/story?id=11269159. As one patient said, "to survive is worth anything." *Id.* Another said that if the drug "keeps you alive," it's "absolutely worth the cost." *Id.*

On March 25, 2011, FDA approved Yervoy for late-stage melanoma, which is "the first drug shown to prolong the lives of patients with the skin cancer melanoma." Andrew Pollack, *Approval for Drug that Treats Melanoma*, N.Y. Times, Mar. 26, 2011, at B1, *available at* http://www.nytimes.com/2011/03/26/business/26drug.html?_r=2&scp=1&sq=approval%20for%20drug%20that%20treats%20melanoma&st=cse. The drug "is a novel type of cancer drug that works by unleashing the body's own immune system to fight tumors." *Id.* One medical professor involved in a clinical trial for the drug observed that it "is really the first time in the melanoma field that there is a drug that extended survival in a meaningful way." *Id.* The most recently approved drug for this condition was approved 13 years ago, "is so toxic it is rarely used," and did not "clearly demonstrate[] improved survival." *Id.* Benefits to patients from this drug can be life-altering. Indeed, one patient diagnosed with late-stage melanoma in 2008 who had been treated with this product said that it was "the first time in two years [he] had a sense that anything was going in the right direction." *Skin Cancer Drug from Bristol-Myers Extends Life; Is First Approved by FDA in 13 Years*, Wash. Post, Mar. 25, 2011, *available at* http://www.washingtonpost.com/business/skin-cancer-drug-from-bristol-myers-extends-life-is-first-approved-by-fda-in-13-years/2011/03/25/AFAkRNWB_story.html.

Drugs such as these offer clear and immediate public health benefits, and PI information is essential to enable drug companies to identify the doctors who treat patients with such conditions quickly and accurately and inform them about these breakthrough treatments so that patients can more quickly benefit from them. This holds particularly true for new treatments for rare, or "orphan," diseases, which are some of our most challenging and deadly diseases and for which no adequate treatment has been approved by FDA. Orphan diseases are often treated by small numbers of physicians who are listed in medical directories and other public sources as having other, more generalized practices, such as internal medicine, cardiology, or oncology. Effectively identifying practitioners with rare disease patient populations and informing them about treatment breakthroughs for the relevant orphan conditions is significantly facilitated by PI information. The sub-optimal information that these doctors would receive if Act 80 operates as intended would directly thwart this effort, causing patients to endure unnecessary and dangerous health risks by treating them with outdated and less effective medicines instead of cutting-edge new drugs.

Nor would curtailed detailing necessarily reduce healthcare costs, as Vermont claims. Pet. Br. 49. While a non-equivalent generic drug may appear less costly on a prescription-by-prescription basis, the most expensive drug is not necessarily the most expensive treatment over the course of a patient's care. More expensive breakthrough treatments often have therapeutic benefits not available from older, cheaper drugs. For example, they may work faster (reducing the amount of drug that must be purchased, and allowing the patient to resume work

and normal life activities sooner). They also are often more effective and avoid the need for future expensive medical procedures. They may have fewer or less serious side effects (reducing the cost of ancillary care). And they may work in a larger proportion of patients (reducing the cost of sequential treatment efforts with different older products). Thus, in the long run, inducing doctors to prescribe older, cheaper drugs may risk increasing overall costs, as health conditions are not cured as quickly or managed as efficiently.

B. Slowing Dissemination of Information Generating Rapid Adoption of New Drug Therapies Will Adversely Affect Research and Development of Vital New Drug Therapies.

The consequences arising from the intended operation of Act 80 would not be limited to affecting the prescribing mix of currently available drugs. Today's treatment decisions predict the financial value of future discoveries and are thus central to allocating pharmaceutical dollars to research and development. Discovering new breakthrough treatments is extraordinarily expensive, and these costs must be recovered through sales of new products. The slowed uptake of such products will lengthen the time necessary for companies to recover their massive investment of resources, time, and effort in research and development. This, in turn, will disincentivize those companies from researching and developing future products, resulting in the delayed discovery, development, and availability of new treatments or, in some cases, no discovery of breakthrough treatments at all.

This consequence is particularly troubling to Patient *Amici*, whose constituencies include many patients suffering from rare and other diseases for which there are no existing cures. While federal law provides exclusivity incentives to develop drugs to treat orphan diseases, *see* 21 U.S.C. §§ 360aa-360ee, the patient populations for these diseases are so small that any adverse effect on realizing income from these incentives could significantly discourage future research.

It is one thing to encourage the use of a chemically identical bioequivalent and cheaper generic drug in place of an innovator drug whose patents have expired. It is quite another, however, to enact a law that has the perverse effect of discouraging the development of new treatments for diseases for which no effective treatments are available at all. To protect and promote patient health in a market economy, manufacturers must have an incentive to bear the cost and risk of developing new products. Doctors must then be made aware of these treatments as quickly and efficiently as possible, both to ensure optimal patient healthcare decisions based on knowledge of all available treatment options and to encourage the development of future treatments. The Vermont law, however, would discourage these efforts and impair the interests of the very patients whose interests Vermont purports to advance.

CONCLUSION

The decision of the U.S. Court of Appeals for the Second Circuit should be affirmed.

Respectfully submitted,

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