09-1913-cv(L)
09-2056-cv(CON)

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

IMS HEALTH INCORPORATED, VERISPAN, LLC, SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of Wolters Kluwer Health, Inc., and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiffs-Appellants,

—against—

WILLIAM H. SORRELL, as Attorney General of the State of Vermont, JIM DOUGLAS, in his official Capacity as Governor of the State of Vermont, and ROBERT HOFMANN, in his capacity as Secretary of the Agency of Human Services of the State of Vermont,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT (BRATTLEBORO)

REPLY BRIEF FOR PLAINTIFFS-APPELLANTS IMS HEALTH INCORPORATED, VERISPAN LLC AND SOURCE HEALTHCARE ANALYTICS, INC.

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ARGUMENT

I.

The Prescription Restraint Law Restricts Appellants' Constitutionally Protected Speech

The district court correctly held that the Prescription Restraint Law is properly subject to First Amendment scrutiny because it restricts Appellants' speech. *See* (SPA 13-14). Although a divided panel of the First Circuit previously reached the contrary conclusion based on its view that prescription-history information receives no more First Amendment protection than the distribution of "beef jerky" (*IMS Health, Inc. v. Ayotte*, 550 F.3d 42, 52-53 (1st Cir. 2008), *cert. denied*, 129 S. Ct. 2864 (2009)), the district court properly rejected that conclusion.

In the first place, the Vermont law directly prohibits the dissemination of prescription-history information, which is speech. Settled precedent establishes that the distribution of lawfully acquired information of public concern may not be restrained. *Bartnicki v. Vopper*, 532 U.S. 514 (2001). It also is established that the First Amendment equally applies to "[e]ven dry information, devoid of advocacy, political relevance, or artistic expression." *Universal City Studios, Inc. v. Corley*, 273 F.3d 429, 446 (2d Cir. 2001); *see also, e.g., Nat'l Cable & Telecomms. Ass'n v. FCC*, 555 F.3d 996, 1000 (D.C. Cir. 2009); *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir. 1999).

This precedent is sound. Facts, statistics, data, bits of information in many

forms are the raw building blocks that are necessary to the discovery of truth and innovation. Every day researchers, scientists, sociologists, and the owners of business are unlocking insights into our existence by finding patterns in data and means to accomplish ends in new ways that improve the human condition. Further, "[t]he formal mechanisms that businesses have developed to transfer information about consumers, borrowers, and other businesses serve valuable economic and social purposes formerly served by person-to-person informal information networks." Solveig Singleton, *Privacy as Censorship*, CATO Policy Analysis No. 295 (Jan. 22, 1998), *quoted in* New Eng. Legal Found. Br. at 19. As this case illustrates, government control of information is no less dangerous to Our Democracy than government control of political advocacy. Attempts by the government to restrict the distribution of information carry with them an immense power to control not only speech but knowledge.

Vermont's contrary argument is implausible. The necessary implication of this position is that the government could prohibit the distribution of the *Wall Street Journal*'s stock reports or other information to protect unsophisticated investors for marketing purposes. Those reports, of course, are nothing more than information distributed for commercial purposes.

Wholly apart from its restrictions on the publishers' activities, the Vermont law is subject to First Amendment scrutiny because it is a transparent attempt to

circumvent the Constitution's protection of pharmaceutical companies' speech. Vermont believes that in-person pharmaceutical marketing – so-called "detailing" – inappropriately persuades prescribers to use brand-name drugs over alternatives preferred by the State. Vermont's Legislature thus made an explicit legislative determination to change the "one-sided nature" of the "marketplace of ideas." Vt. Act 80, § 1(4) (2009) (A 4040). But Vermont knows that the First Amendment precludes it from banning pharmaceutical detailing on such paternalistic grounds. *See, e.g.*, *Thompson v. W. States Med. Ctr.*, 5353 U.S. 357, 359 (2002); *Edenfield v. Fane*, 507 U.S. 761, 766 (1993).

So instead, Vermont enacted the statute to forbid the distribution and use of prescription history information to promote drugs without the prescriber's permission. Rather than outright prohibiting pharmaceutical companies from detailing, Vermont is attempting to make it much harder for those companies to find their audience – the prescribers who would be receptive to their marketing message.

Vermont analogizes the statute to "confidentiality rules," which "are common, not just for doctors and pharmacists but for lawyers, accountants, and other professionals." Vt. Br. 45. According to Vermont, if Appellants prevailed here, "[d]ata vendors could assert precisely the same argument to justify acquiring and selling data from credit card transactions, bank records, credit reports, video

rentals, school records, and even other patient health care records." *Id*. 63.

But even if a state may adopt regulations that are justified by a compelling privacy interest, it may not circumvent the First Amendment in this fashion by indirectly limiting communication. *See, e.g., Arkansas Writers' Project, Inc. v. Ragland*, 481 U.S. 221 (1987) (invalidating a sales tax targeted at a few journals that could be used for censorship indirectly); *Minneapolis Star & Tribune Co. v. Minn. Comm'r of Revenue*, 460 U.S. 575, 577, 592-93 (1983) (invalidating imposition of use tax on small segment of press that could be used indirectly to censor the press).

Vermont's reliance on the principle that the government may act to protect individual privacy thus only begs the First Amendment question presented by this case: is the Vermont Law in fact a genuine and coherent effort to protect confidentiality, or instead is a back-door effort to restrict Appellants' speech? It is transparently the latter, and it therefore is subject to First Amendment scrutiny.

Preliminarily, the statute does not promote patient confidentiality, which would most directly implicate personal privacy. The principal "private" fact implicated by the distribution of prescription history information – that a particular patient was prescribed a medication – is already separately protected from disclosure and therefore is not reflected in the patient-deidentified data that Appellants publish and use. *See* (SPA 68 & A 78, 98). Furthermore, the statute

does not give patients any control over whether their own prescription information is distributed. In determining whether to authorize use of their history information under the Vermont statute, prescribers are not required to make any judgment about patients' privacy.

Vermont therefore is reduced to arguing that at least the law "allows prescribers to control the use of their own identifying information for marketing purposes." Vt. Br. 49. But Vermont offers no support for the claim that such an interest is substantial. With respect to this information, forty-seven other states freely permit its distribution. Even within Vermont, the information may be disclosed by the patients themselves.

Even more telling, the Vermont Law is not actually intended to accomplish the goal of furthering prescriber privacy. If it were, it would be consistent: perhaps with rare exceptions, Vermont would forbid the involuntary disclosure of prescription-history information. But it does not. Instead, the statute explicitly exempts essentially every other known uses of prescription history information: pharmacy reimbursement; formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or their agent; health care research; dispensing medication; and pharmacy file transfers. (A 4064-65, 4075). As Vermont elsewhere emphasizes, "The law specifically exempts use of the data for other purposes, including health care research,

treatment, and safety-related uses such as 'recall or patient safety notices.'" Vt. Br. 30. Also, "[d]ata vendors may acquire prescriber-identifiable data from pharmacies and sell the data to pharmaceutical manufacturers, so long as the data is not used for marketing prescription drugs." *Id*. at 61. Indeed, the statute authorizes a pharmacy to distribute without charge any prescription history – indeed, all of the history information for every prescription it has ever filled – publicly on the Internet.

To illustrate the point, the exception for formulary compliance allows Vermont and generic drug companies to acquire and use the identical prescription-history information – without consent – to contact prescribers and discourage the use of brand name drugs, a process known as "counter-detailing." And that practice is common. *See* Part II-B, infra. That intrusion on prescribers' confidentiality is absolutely indistinguishable from the disclosure of prescription-history information for purposes of detailing.

The law thus infringes on the pharmaceutical companies' free speech rights because – like the tax in *Arkansas Writers*' *Project*, supra – it seeks to impose a burden on the publishers' speech with the specific purpose and effect of inhibiting the speech itself. Just as the First Amendment would apply to statutes that either prohibited contracts between a newspaper and its subscribers (though it might fall within the government's power over commercial transactions) or forbade the use of

newspaper delivery trucks (though otherwise authorized by the state's power to preserve the safety of the public roads), so too the First Amendment applies to a measure that prevents publishers from providing information to drug companies for use in identifying an audience for detailing and shaping their message to prescribers.

Vermont nonetheless urges this Court to recharacterize the statute and "hold that the law regulates commercial conduct, not speech." Vt. Br. 52. But the only "conduct" that the statute regulates is the act of communicating truthful factual information. The proscribed activities can no more be divorced from the speech itself than could a regulation forbidding the "conduct" of distributing newspapers, pamphleting, broadcasting, or mailing letters. Conduct regulations that burden speech are justified only "if the government interest is unrelated to the suppression of free expression" (*United States v. O'Brien*, 391 U.S. 367, 377 (1968)), which manifestly is not the case of the Prescription Restraint Law.

Vermont's remaining, passing contention that the law does not violate the First Amendment rights of the individual Appellants is equally lacking in merit. Vermont asserts that the statute does not restrict the publisher plaintiffs because it supposedly "does not regulate the data vendors." Vt. Br. 30. This is a semantic game. The law both restricts pharmacies from selling information to Appellants and also forbids pharmaceutical companies from acquiring prescription history

information from Appellants. To say that it does not regulate the publishers would be to say that a law banning anyone from placing newspaper advertisements or purchasing a newspaper at a newsstand does not regulate *The New York Times*. Vermont's position is substantively empty as a First Amendment matter.

The Vermont law does regulate the publisher plaintiffs, who collect, aggregate, analyze, and distribute prescriber-history information. They thus play a central role in the process that the Vermont legislature sought to eliminate. The statute, in turn, broadly prohibits publication by any "electronic transmission intermediary" or "similar entity." 18 Vt. Stat. Ann. § 4631(d); (SPA 68). Vermont never explains how this language can be construed not to apply to the publisher plaintiffs' activities.

The district court accordingly was correct to hold that the Prescription Restraint Law is a restriction on speech that is subject to the First Amendment.

II.

The Prescription Restraint Law is Subject to Rigorous Judicial Scrutiny

The district court erred in holding that the statute is subject only to intermediate scrutiny as a regulation of commercial speech. In fact, searching judicial review is required because the law restricts fully protected speech and discriminates on the basis of drug companies' viewpoint.

A. The Law Restricts Fully Protected, Non-Commercial Speech

Appellants' opening briefs, and those of their supporting amici, demonstrated that the district court erred in treating the Prescription Restraint Law as merely a regulation of commercial speech. *See* Initial Br. at 22-30; PhRMA Br. at 27-28; New England Legal Found. Br. at 9-18). The statute instead is properly regarded as a prohibition on fully protected speech on a matter of significant public importance.

In arguing to the contrary, Vermont conspicuously ignores the extensive precedent from both the Supreme Court and this Court drawing the line dividing commercial from non-commercial speech. That is a glaring, and telling, omission. The Supreme Court has repeatedly held that "'the test for identifying commercial speech'" is whether it "does no more than propose a commercial transaction." *Cincinnati v. Discovery Network*, 507 U.S. 410, 423 (1993) (emphasis added) (quoting *Board of Trustees of State Univ. of N.Y.* v. *Fox*, 492 U.S. 469, 473-74 (1989)). This Court's precedent is in accord. *See, e.g., CFTC v. Vartuli*, 228 F.3d 94, 110 (2d Cir. 2000); *Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 97 (2d Cir. 1998); *N.Y. Ass'n of Realtors, Inc. v. Shaffer*, 27 F.3d 834, 840 (2d Cir. 1994). That clear definitional line tracks the rationale undergirding the category of "commercial speech," which is "'linked' inextricably with the commercial arrangement that it proposes, so the State's interest in regulating the

underlying transaction may give it a concomitant interest in the expression itself." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993).

The district court and Vermont thus err in their assumption that it is enough to limit the First Amendment's protections that speech relates to "commerce." If it were, then the government could freely regulate virtually all discussion of business – whether stock reports or marketing methods – as "commercial speech." That obviously is not the law, and the district court's ruling would substantially expand the category of lesser-protected commercial speech.

Here, it is undisputed that prescription-history information – whether disseminated by pharmacies; aggregated, analyzed, and distributed by the publisher plaintiffs; or acquired and applied by the pharmaceutical plaintiffs – is not itself part of any commercial transaction. Vermont makes that very point in the language quoted in Part I, supra. Nor do Appellants' activities – all of which involve unquestionably truthful information that does not deceive prescribers – otherwise implicate the consumer-protection rationale of the commercial speech doctrine.

Vermont equally errs in arguing that "[t]here is no matter of 'public concern' here; the data is taken from non-public health records and used as a covert marketing tool." Vt. Br. 60. There is no free-floating exception under the First Amendment for matters that the State deems of insufficient "public concern."

Speech either falls within the commercial speech doctrine, or it does not. Here, it does not, and because it does not fall within any category excluded from the First Amendment's protections (such as obscenity), it is fully protected.

In any event, Vermont's characterization of Appellants' speech is simply wrong. Appellants collect, analyze, and distribute information of great public significance. An analogy drawn by amici Association of National Advertisers et al. at 12 n.4 illustrates the point: "polling is a costly operation that generates information of undeniable public importance. Yet polling frequently involves 'mining' large bodies of data, organized and analyzed by computers, often performed by paid independent contractors. No one would argue that such polling, or the data it produces, is unprotected by the First Amendment or that it is commercial speech, no matter what end use is made of it."

The same is true in this case. Particularly in the aggregate form in which it is compiled and distributed by the publisher plaintiffs, prescription-history data unquestionably addresses a matter of tremendous public importance. The extent to which physicians prescribe brand name drugs is the subject of significant study and (as this case illustrates) controversy. The further use to which the information is put by some in its audience does not deprive the information of its public significance.

Put another way, the public importance of prescription-history information

arises from all of its multitudinous uses, including for public health research and campaigns. *See* (A 79 "The use of prescriber-identifiable data in the pharmaceutical and biotechnology industry is widespread at multiple stages within the development and launch cycles" of drugs); (A 102-03 explaining that the Centers of Disease Control uses prescriber-identifiable data to track patterns of disease and treatment). There is no support for Vermont's effort to segregate and define as less worthy of free speech protection certain instances in which the information is acquired because of the audience's intended use for that information. The government cannot regulate the distribution of newspapers to businesses on the ground that it has identified a category of users who purchase the paper only to serve their private, commercial ends, rather than some broader public purpose.

Indeed, the Vermont law causes tremendous damage to the many other vital uses of prescription-history information. The opening briefs of Appellants and their amici explained (*See* Initial Br. at 4-5; Br. of New Engl. Legal Found. at 2) – and Vermont notably does not deny – that drug companies' purchases of information from the publishers effectively subsidizes a wide array of non-commercial uses of that information by, for example, health researchers attempting to detect patterns of disease, identify and understand treatment variability among physicians, and determine which education programs improve physicians

prescribing practices. The First Amendment is surely concerned with these concrete harms created by the Vermont's restrictions on Appellants' speech.

Vermont's only response is a failed attempt to shift attention to the fact that "detailing is unquestionably commercial speech." Vt. Br. 58-59 (emphasis added). That answer does not address the statute's antecedent regulation of the distribution, analysis, and publication of fully protected prescription-history information. The information published by Appellants is not in fact part of any commercial message nor is it advertising. Rather, when used by pharmaceutical companies, the information serves as a source for making decisions about operating their business. *Accord CFTC v. Vartuli*, 228 F.3d 94, 109 (2d Cir. 2000) (Sack, J.) (information that "guides [a] user in making investments" is not thereby reduced to the category of commercial speech).

Moreover, detailing itself is a matter of tremendous public importance. Though "[t]he purpose of detailing is to promote specific drugs and increase sales of those drugs" Vt. Br. 59, drug companies "market" their products to experienced and knowledgeable prescribers with substantive information. The detailers' message is heavily infused with non-commercial, medically valuable information regarding best practices, the health effects of multiple drugs being prescribed in combination, and the extent to which physicians' instructions on use are followed. Simultaneously, detailers collect information on, for example, side effects that

prescribers see in their patients. (A 99-101, 125, 195). Regulation of detailing thus has the potential to seriously obstruct the exchange of valuable information on matters of great public importance, which is a central concern of the First Amendment.

B. The Law Engages in Invidious Viewpoint Discrimination

The Vermont law is subject to strict scrutiny review for a second reason. Appellants demonstrated that the statute amounts to prohibited viewpoint discrimination because the Vermont law prohibits the use of information only for the purpose of "promoting" prescription drugs. (SPA 67). Indeed, Vermont's own asserted interest in passing the law was to change the "one-sided nature" of the "marketplace of ideas." Vt. Act 80, § 1(4) (2009) (A 4040).

Yet, the statute exempts uses of prescription-history information for "prescription drug formulary compliance" (18 Vt. Stat. Ann. § 4631(e)(1)). Thus, Vermont freely permits favored entities – including the government (as a Medicaid payor) and insurers – to use prescription-history information to discourage the use of particular drugs. It is uncontested that the government and insurers do in fact actively engage in such "counter" detailing. (A 123, 188, 283, 286-87, 298-99).

The statute, as measure that engages in viewpoint discrimination, accordingly violates the First Amendment. Suppressing speech that promotes brand name drug use but permitting identical speech that discourages the same

activity – is almost always invalid. "The government must abstain from regulating speech when the specific motivating ideology or the opinion or perspective of the speaker is the rationale for the restriction." *Rosenberger v. Rector & Visitors of the Univ. of Va.*, 515 U.S. 819, 829 (1995).

Vermont responds that "the statute by its terms is neutral and nondiscriminatory. It regulates the advertising and promotion of prescription drugs – all prescription drugs, brand-name or generic." Vt. Br. 66-67. This response misses entirely Appellants' point that the statute improperly forbids the use of prescription history data to promote a class of products (brand name drugs), but permits the identical data to be used to discourage the consumption of those very same products.

Vermont suggests that the First Amendment prohibition on viewpoint discrimination does not apply in the context of commercial speech. It cites no authority for that proposition, but hypothesizes that "[a] restriction on tobacco advertising does not discriminate on the basis of viewpoint merely because the restriction does not apply to non-commercial speech about smoking." Vt. Br. 67. That analogy is inapt. Vermont is not merely inhibiting price data and marketing puffery about a product (such as cigarettes). Instead, the Vermont law's viewpoint discrimination arises from the state's judgment about a broad social and economic dispute – the value and dangers of prescription drugs vis-à-vis generic drugs. The

avowed purpose of the statute is to mute the voice in one side of the debate, inhibiting speech (including speech on scientific questions) that favors the use of prescription drugs, thereby allowing the voices taking the opposite position to be heard more clearly. (Of note Vermont's viewpoint is shared by at most two states: only New Hampshire and Maine have adopted analogous measures.)

In such a context, courts apply the viewpoint discrimination doctrine to regulations of even commercial speech. *E.g., AIDS Action Comm. of Mass. v. Mass. Bay Transp. Auth.*, 42 F.3d 1 (1st Cir. 1994) (government may not refuse to display condom advertisement while displaying other sexually explicit advertisements). The Vermont is accordingly subject to strict judicial scrutiny.

III.

The Prescription Restraint Law Cannot Survive First Amendment Scrutiny

Whether subject to strict or intermediate scrutiny, the Vermont statute violates the First Amendment because it is not sufficiently tailored to further any of the interests invoked by Vermont. The district court's contrary view that it was required to defer to the judgment of the state legislature lacks merit.

A. The Law is not Sufficiently Tailored to Further any Substantial Governmental Interest

Vermont does not even attempt to argue that the statute survives strict First Amendment scrutiny. Even if this Court were to agree with the district court that

the statute is subject only to intermediate scrutiny, it is invalid because it fails to "directly advance[] the governmental interest" and is "more extensive than is necessary" to achieve that interest. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). *See* Initial Br. 34-56; PhRMA Br. 43-57.

1. Vermont's Statutory Scheme is Illogical

The Supreme Court has made clear that the First Amendment does not permit a regulation of commercial speech that is internally inconsistent, such that the government is not coherently advancing its asserted interests. Thus, *Greater New Orleans Broadcast Association v. United States*, 527 U.S. 173, 190 (1999), invalidated a prohibition on certain casino advertising, reasoning that "[t]he operation of [the statute] and its attendant regulatory regime is so pierced by exemptions and inconsistencies that the Government cannot hope to exonerate it." The Court cited *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 488 (1995), which invalidated a ban on disclosing alcohol content on containers while permitting the disclosure of the same information in ordinary advertising.

Most glaringly, the Vermont law does not attempt to forbid detailing, including through the use of prescription-history information. According to Vermont, drug companies "can easily call a doctor's office and ask if a doctor is interested or prescribes a particular drug – and do not need prescriber-identifiable data for that purpose." Vt. Br. 93. Even with respect to detailing that employs

prescription-history information, "doctors who endorse this marketing practice may consent." *Id*. at 104. The State provides no evidence that this opt-in mechanism will not substantially undercut the statute. The fact that brand-name drug companies willing to invest in detailing retain the ability to engage in precisely the practices that Vermont is attempting to target virtually guarantees that the statutory scheme will fail to advance the State's interests.

The Vermont law equally violates the First Amendment because it does not consistently pursue any of the three interests identified by the State:

First, as Appellants explained in Part I, *supra*, the statute does not genuinely protect prescriber confidentiality, given the vast number of exceptions to its prohibition. Vermont's only answer is to attempt to redefine its asserted interest and assert that "the statute targets precisely the harm identified by the Legislature: the invasion of privacy when non-public prescribing information is used for marketing purposes." Vt. Br. 85. But the First Amendment cannot be so facilely evaded. As explained in PhRMA's opening brief (at 56), if it could, then the tobacco advertising statute invalidated in *Lorillard Tobacco v. Reilly*, 533 U.S. 525 (2001), would have been sustained on the ground that it addresses outdoor tobacco advertising, and the bar on alcohol price advertising struck down in *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996), would have been upheld as a response to alcohol purchases driven by price advertising.

Second, the statute does not consistently attempt to advance patient health. Vermont maintains that "new" drugs are "not necessarily" better than older therapies. Vt. Br. 19. But because detailing is not limited to "new" drugs, neither is the Vermont law. The statute instead seeks to inhibit all detailing, including the promotion of the vast number of drugs that have been on the market for many years (but still retain their patent protection) and that are regularly promoted as alternatives to the newer therapies that Vermont disfavors.

Third, the identical flaw demonstrates the irrationality of the Vermont law as an attempt to lower the State's costs. The law equally inhibits marketing of older, less expensive drugs, as well as the many newer therapies that produce significant cost savings. Vermont is able to identify only five instances – out of many thousands of prescription drugs – in which detailing might promote a brand-name drug over another brand that has a generic alternative. Vt. Br. 95-99. Whatever the limited and hypothetical cost savings from those few cases, the relevant point is that the statute paints with a sweeping brush that equally inhibits treatments that will allegedly reduce the State's costs. Conversely, the statute fails to prohibit detailing undertaken without prescription-history information that favors expensive medications for which generic alternatives are readily available.

A further profound illogic in the statutory scheme lies in Vermont's reliance on the claim that it has an interest in expanding generic drug use. The State's

argument that "[s]hifting prescribing practices even slightly in favor of generic drugs would provide substantial savings for Vermonters," Vt. Br. 21, seriously misdescribes pharmaceutical marketing. Vermont elsewhere concedes that detailing has essentially no effect on prescribers' choice between brand-name drugs and their generic alternatives: detailing "is focused almost entirely on brand-name drugs that retain patent-protection. . . . Generic drugs cost far less money than brand-name drugs, so once a generic version is available, the original manufacturer's marketing efforts generally cease." *Id*. at 10.

Finally, the Vermont law is remarkably overbroad. Vermont asserts an interest in limiting in-person detailing, which it regards as an especially pernicious form of marketing. But the statute sweeps far more broadly. Prohibited "marketing" includes "any activity that is intended to be used or is used to influence sales or the market share of a prescription drug," including any "activity . . . to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement." 18 Vt. Stat. Ann. § 4631(b)(5), (8). Vermont does not even attempt to justify the law's application to ordinary print and television advertising, which are encompassed by the statute's broad terms.

2. Vermont Can Directly Advance its Asserted Interests Without Obstructing Free Speech

Vermont also has no persuasive answer to Appellants' showing that the law violates the principle that the "suppression of speech" must be "no more extensive

than necessary to further the State's interest." *Central Hudson*, 447 U.S. at 569-70. Despite the Supreme Court's admonition that, "[i]f the First Amendment means anything, it means that regulating speech must be the last – not first – resort," *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 373 (2002), Vermont has not attempted to show – and could not show – that measures other than restrictions on speech would fail to accomplish its asserted interests.

Vermont claims an interest in reducing its health care expenditures and ensuring that only safe drugs are prescribed. But the government has the power to pursue both of those goals directly, rather than incidentally by inhibiting detailing. It may set lower reimbursement rates and forbid the prescription of certain medications. Indeed, Vermont already requires pharmacists to fill prescriptions with available generic alternatives. 18 Vt. Stat. Ann. § 4605.

Vermont's only response is nonsensical: "The sheer number and variety of these policy proposals – everything from mandatory doctor education programs to drug vouchers to multi-state drug purchasing pools – suggests the flaw in plaintiffs' approach." Vt. Br. 105. To the contrary, the undisputed fact that Vermont has innumerable ways to achieve its asserted interests more directly establishes that the Prescription Restraint Law restricts more speech than is necessary and is therefore invalid under the First Amendment.

3. The Law Does Not Advance a Permissible Goal in Improving Public Health

Appellants' opening briefs demonstrated that the Vermont law does not directly or materially further a cognizable interest in improving public health. *See* Initial Br. at 34-45; PhRMA Br. at 43-49. The district court nonetheless held, and the State once again asserts, that detailing promotes new drugs, which "are not necessarily better than existing, older drugs in a therapeutic class." (Vt. Br. 19). *See also* (SPA 5, 27). That argument lacks merit.

First, as discussed above, the Vermont law does not coherently seek to advance a state interest in promoting public health because it is not directed to new drugs. The publishers' opening brief also explained (at 12), and the State does not deny, that no legislative witness or trial witness testified to even a single anecdotal instance in which detailing had led to an inappropriate prescribing decision. Vermont did not compile anything remotely like the record that would be required to support its wildly overbroad assertions and the blunderbuss approach of the Prescription Restraint Law. Prescription drugs are subject to an extensive federal regulatory regime. *See* Initial Br. 6; PhRMA Br. 7-11. The overwhelming majority of new therapies are safe and effective and advance modern health care. (A 193, 136, 141). Yet, the statute inhibits the detailing of all prescription drugs on the theory that "some" are unsafe.

Second, Vermont's asserted interest is impermissible under the First

Amendment because it is wholly paternalistic. Vermont's argument rests entirely on the premise that the truthful messages conveyed in pharmaceutical detailing persuade prescribers to make poor choices – *i.e.*, the State believes that by suppressing detailing, it will cause doctors to receive less information and make better treatment decisions. Vermont reasons: "Because the use of prescriber-identifiable data in marketing campaigns leads to inappropriate prescribing of new drugs, restricting its use will reduce both health care costs and unnecessary risks to patients." Vt. Br. 23. But the Supreme Court has held time and again – and Vermont does not deny – that the government may not obstruct speech in order to protect individuals from making choices based on accurate information. *See* Initial Br. 23, 34, 47; PhRMA Br. 33-34, 38, 46-47.

That is particularly true with respect to drug advertising and the marketing of services to professionals. In *Thompson*, the Supreme Court rejected the government's argument that it could restrain the advertising of compounded drugs on the theory that it "would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway." 535 U.S. at 374. *See also, e.g.*, *Edenfield,* 507 U.S. at 771-72 (upholding restriction on CPA solicitation where state presented "no studies that suggest personal solicitation of prospective business clients by CPA's creates the dangers of fraud, overreaching, or compromised independence that the Board claims to fear").

Vermont ignores that the interest it asserts is impermissible under the First Amendment because it is concededly paternalistic. Vermont's only answer to its obvious paternalism is that, "because of the consent provision, the law does not restrict any marketing to a willing audience." Vt. Br. 107. Preliminarily, that is false. A prescriber who does not opt-in will still receive detailing requests. Conversely, a prescriber who does consent will receive less accurate information, because the statute prevents drug companies from studying the marketing of their products with the benefit of information from those prescribers who do not consent. For example, Vermont forbids the use of prescription-history information absent consent if a drug company wants to study generally whether its marketing in Vermont is effective, or how medical practices in Vermont utilize various therapies in order to develop a marketing message.

Moreover, it makes no difference that the prescriber has the option to allow the use of his prescription-history information, because the statute does not further a legitimate goal. The Supreme Court has repeatedly "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." *Thompson*, 535 U.S. at 374 (emphasis added). Here, Vermont allows the prescriber to make an antecedent choice about the availability of prescription-history information, but the statute's purpose is the forbidden

paternalistic goal of preventing prescribers from receiving the truthful and valuable speech conveyed in detailing visits. The district court thus erred as a matter of law in holding that the statute furthers a substantial governmental interest in improving public health.

4. The Law Does not Further an Interest in Avoiding Marketing Visits

In Part I, *supra*, Appellants demonstrated that the Prescription Restraint Law is not genuinely and coherently designed to promote the privacy of patients or prescribers by preserving the confidentiality of prescriptions. The statute instead allows prescription-history information to be published for innumerable other purposes.

Vermont nonetheless advances a different form of privacy interest – limiting the intrusion of detailing visits – on the basis of *Anderson v. Treadwell*, 294 F.3d 453 (2d Cir. 2002), which "upheld an ordinance that allowed homeowners in certain neighborhoods to block real estate solicitations." Vt. Br. 38. According to Vermont, "Just as the homeowners in Anderson could choose whether or not to receive real estate solicitations, doctors may decide whether or not to allow the use of their information for marketing purposes." *Id*. at 84.

The analogy to *Anderson* is inapt, however. That case upheld a statute giving the audience the power not to receive a harassing message – *i.e*., it permitted the homeowner to refuse to receive real estate solicitations. *Anderson*,

294 F.3d at 461. Unlike homeowners, prescribers do not have a substantial privacy interest in their prescribing practices. No court has so held. Moreover, an analogous statute in this context would prohibit a drug company from calling on a prescriber who objected to seeing detailers. Prescribers already have the power to refuse detailing visits, which they may effectively exercise. The Vermont law in no way gives prescribers greater rights to limit detailing visits: as the State itself emphasizes, under the statute, drug companies remain free to contact prescribers.

Also, unlike *Anderson*, the Vermont law restrains speech by third-parties not involved in detailing (pharmacies and the publisher plaintiffs), which is fully protected (*see* Part II-A, *supra*) rather than a commercial solicitation. This Court in *Anderson* never suggested that the government could enact a measure analogous to the one at issue here – *i.e*., a prohibition on even acquiring information relating to real estate listings.

The Vermont law also lacks the "fit" of the statute in *Anderson*, which was tailored precisely to the individuals whose privacy interests were implicated. Vermont suggests that the statute allows prescribers to control whether their prescription history information will be used to market drugs to them. That is not accurate because Vermont's statute forbids the use of a non-participating prescriber's history information for any marketing-related purpose. (SPA 68).

B. There is No Merit to Vermont's Invocation of "Deference"

Appellants' brief and their supporting amici demonstrated that even if the Vermont law made logical sense, it would fail for lack of any substantial evidence demonstrating its effectiveness. The district court nonetheless sustained the statute on the ground that it was required to defer to the judgment of the Vermont Legislature. That ruling conflicts with settled First Amendment principles. *See* Initial Br. 34-38; PhRMA Brief 34-42.

Appellants' demonstrated that the record in this case overwhelmingly supports the conclusion that, as a matter of fact, the Vermont law does not directly or materially advance any substantial governmental interest. *See* Initial Br. 39-45; PhRMA Brief 20-23. Randy Frankel, for example, testified that the law will not reverse the growth of healthcare costs, but instead will cause harm to patients if its intended purpose of slowing the adoption new drugs actually works because the law purports to slow the adoption of all drugs – even life saving drugs – and keep doctors ignorant about new treatments. (A-284).

Peter Hutt, former chief counsel to the FDA, who is intimately familiar with the process of drug conception, development and approval, testified that the law will not drive the cost of prescription drugs down. Rather, the law, with its intent on shifting use away from brand name drugs to generic drugs, will result in higher healthcare costs. (A 141). He explained that manufacturers of generic drugs do

not invent new drugs or health treatments. (A 139-40). Rather, manufacturers of brand-name drugs are responsible for fueling all the drug innovation in the world. *Id*. These manufacturers, however, can only exist if they make a profit, and to the extent that the law tries to slow the introduction of new drugs and affect a shift in the consumption of older, generic drugs, either the prices of drugs will go up or the introduction of new drugs will go down as the industry will have less money to devote to research and development. (A 141). Mr. Hutt testified that the law will also harm patient health because aging patients, who need new drugs in order to treat common medical problems, will be denied those drugs. *Id*.

Dr. Wharton, a prominent New Hampshire cardiologist, testified that the introduction of new pharmaceutical products in the field of cardiology has vastly improved the quality of life and longevity of his patients. (A 193). For example, he explained that older drugs for cholesterol treatment were "poorly tolerated," "hard to take," "not very efficacious, and had high side effect profile." (*Id*.). This changed with the introduction of statins into the market. In his view, most new statins that entered the market "represented an improvement of the previous statin in terms of efficacy and lowering cholesterol, often at reducing side effects." (*Id.*). As part of the advancement in new product development, Dr. Wharton testified that it is common for cardiovascular patients to be on multiple medications at once. (*Id*.). It is therefore essential for doctors to understand how the various classes of

drugs interact with one another. (*Id*.). In his view, doctors should stay informed about how new drugs work and interact with one another from as many sources of information as possible, including information from drug representatives. (A 195-97).

Vermont provides no substantive answer. Instead, it contends that this issue is not within the appropriate scope of appellate review. Vermont believes it to be sufficient that "[t]he State canvassed the legislative record and submitted to the district court a document that summarizes the evidence in support of each finding" (Vt. Br. 29), because it asserts that the Court must "apply the clearly erroneous standard to the vast majority of the facts found below" (*Id*. at 34). In fact, this Court's "constitutional duty [is] to conduct an independent examination of the record as a whole, without deference to the trial court." *Hurley v. Irish-Am. Gay, Lesbian & Bi-Sexual Group of Boston*, 515 U.S. 557, 567 (1995) (citing *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 499 (1984)).

For its part, the district court did not genuinely assess the trial record. Instead, it erred as a matter of law when it limited itself to determining whether the "legislature has drawn reasonable inferences based on substantial evidence" and explicitly "deferr[ed] to legislative findings, predictions, and judgments" so long as they were merely reasonable. (SPA 22). The Supreme Court has repeatedly held that "a government body seeking to sustain a restriction on commercial speech

must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield*, 507 U.S. at 770-71. That burden is "not satisfied by mere speculation or conjecture," *id*. at 770, nor by "anecdotal evidence and educated guesses," *Rubin*, 514 U.S. at 490. Review of restrictions on fully protected speech is obviously still more searching.

It cannot be that a legislature satisfies the First Amendment merely by making reasonable-sounding pronouncements regarding a statute's efficacy, but that is at bottom what the district court held. Vermont argues (at 73) that the district court's ruling is nonetheless supported by the Supreme Court's decision in *Turner Broadcast System v. FCC*, 512 U.S. 622 (1994). But over the course of dozens of cases, neither the Supreme Court nor this Court has ever cited *Turner* as articulating the appropriate standard for evaluating a restriction on commercial speech, much less a regulation of fully protected communication. As discussed at length in Appellants' opening briefs (particularly the amicus brief of the Washington Legal Foundation), *Turner* involved a very different statute – a content-neutral measure involving a principally economic judgment that Congress had studied in tremendous depth while compiling an extensive record.

Furthermore, whatever the rule in an ordinary case, the findings underlying the Prescription Restraint Law are particularly suspect. As the publisher plaintiffs' opening brief demonstrated (at 8), the Legislature made these so-called "findings"

only after a parallel New Hampshire statute was invalidated. The "findings" were introduced and dramatically changed in three successive draft bills over the course of twenty-four hours without any study or explanation at all. Vermont backhandedly admits as much with its recognition that "[t]he House committee working on the bill reviewed the [New Hampshire district] court's ruling and changed the bill to respond to certain concerns raised by the court." Vt. Br. 26.

In addition, the critical finding that the statute "promot[ed] the use of less expensive drugs" and "protect[ed] public health by requiring evidence-based disclosures and promoting drugs with longer safety records" (A 4044, finding 31), rested on section 17(f) of the Act, which required detailers to promote competitors' products and other alternative treatments (A 4065). But in the wake of Appellants' suit, the Vermont Legislature repealed section 17(f), without revisiting the finding or otherwise providing any justification for it. Thus, there is simply no nexus even between the central finding and the statute as it now stands.

For the foregoing reasons, the Vermont law is invalid under the First Amendment.

IV.

The Prescription Restraint Law Violates the Commerce Clause

The statute is also invalid under the Commerce Clause as an unconstitutional regulation of extra-territorial conduct. Vermont is not merely regulating marketing

within its borders. Rather, it is undisputed that the law's regulation of pharmacy companies and the publisher plaintiffs occurs entirely outside of Vermont – both sets of entities are located in other states. Further, pharmaceutical companies acquire prescription-history information outside Vermont. Finally, and critically, the statute prohibits drug companies from using prescription-history information from Vermont – which is used to identify broad national trends, such patient reactions to drugs and overall patient compliance (A 99-101) – in marketing in other states. In turn, if the law is invalidated as a barrier against interstate trade, it no more can prohibit PhRMA members from using the information for marketing their products in interstate commerce than it can prohibit pharmacies from licensing, selling or exchanging for value information that is used for marketing those same products. Publisher plaintiffs have challenged both aspects of the law.

This case falls squarely within the principle that one state may not regulate conduct in another. A state law "directly regulat[ing]" commerce beyond its borders is per se invalid and "generally struck down . . . without further inquiry." *Brown-Forman Distillers Corp. v. N.Y. State Liquor Author.*, 476 U.S. 573, 579 (1986). "[T]he critical inquiry is whether the practical effect of the statute is to control conduct beyond the boundaries of the state." *Healy v. The Beer Inst.*, 491 U.S. 324, 336 (1989). The Prescription Restraint Law certainly offends the Commerce Clause more directly than the New York pricing law in *Baldwin v.*

G.A.F. Seelig, 294 U.S. 511 (1932), which itself only explicitly regulated in-state transactions, but had an extraterritorial effect.

Vermont's arguments to the contrary are not persuasive. First, it asserts that the Appellants are licensed to operate in Vermont and subject to that state's laws. But there is no exception to the Commerce Clause that permits a state to regulate in-state entities in their out-of-state activities. "Extraterritorial state regulation cannot be justified by the bare fact that a state has legal jurisdiction, strictly as a matter of due process to regulate a transaction." Laurence H. Tribe, 1 *American Constitutional Law* 1078 (3d ed. 2000). Courts thus consistently reject the claim that it is sufficient under the Commerce Clause that an entity has "minimum contacts" with the regulating state. *E.g., Quill Corp. v. North Dakota*, 504 U.S. 298, 312-13 (1992); *Carolina Trucks & Equip., Inc. v. Volvo Trucks of N. Am., Inc.*, 492 F.3d 484 (4th Cir. 2007). For example, *American Booksellers Foundation v. Dean*, 342 F.3d 96, 101 (2d Cir. 2003), invalidated a law prohibiting an out-of-state seller from selling sexually explicit materials inside Vermont, notwithstanding that the seller was subject to Vermont's jurisdiction.

Second, Vermont contends that an entity may not attempt to evade a state's laws by manipulating its operations so that some occur in another state. Even if that were correct, pharmacies and the publisher plaintiffs have transmitted information out of Vermont for decades in the ordinary course of business, not to

avoid the Prescription Restraint Law.

Third, Vermont invokes the holding of *SPGGC v. Blumenthal*, 505 F.3d 183 (2d Cir. 2007), that state regulation of activities by its citizens over the Internet does not violate the Commerce Clause. But *SPGGC* does not license every state to regulate every electronic transmission of information, wherever it happens. The relevant point is that the exchanges regulated by the Vermont law are occurring between entities located outside of Vermont. The fact that those exchanges involve computerized information, rather than physical volumes of paper, does not constitutionalize the state's regulation.

Fourth, Vermont contends that the implication of Appellants' position is that states lack the power to engage in consumer protection. That is not correct. States may exercise their police powers to enact consumer protection laws that directly advance the interest asserted, but they may not "regulate[] by indirection" by imposing trade barriers in the name of consumer protection. *Baldwin*, 294 U.S. at 524. State consumer protection laws that, for example, ensure that milk is safe by requiring appropriate certification, may be said to regulate milk manufacturers that sell their product wholly outside the state to milk dealers, but they have such a "direct and certain" impact on legitimate internal state interests that they do not violate the Commerce Clause. *Id.* Similarly, state laws that prohibit disclosure of a patient's private medical information or a consumer's financial information have

an extraterritorial effect, but they so directly and certainly advance legitimate internal state interests that this effect would not violate the Commerce Clause.

The Vermont law is a very different statute: in contrast to local regulation of drug costs and prescribing behavior, this statute regulates transactions with significant interstate economic consequences that occur entirely outside its borders. That point is best illustrated by the fact that the statute forbids marketing in other states that employs data derived from Vermont. The State's motivation to generally protect its citizens does not exempt the statute from the Commerce Clause. *See, e.g.*, *Pharm. Research & Mfrs. of Am. v. D.C.*, 406 F. Supp. 2d 56 (D.D.C. 2005), *aff'd sub nom Biotech. Indus. Org. v. D.C. on other grounds*, 496 F.3d 1362 (Fed. Cir. 2007) (invalidating law intended to lower drug costs measured by wholesale prices of transactions occurring in other jurisdictions).

Finally, this is not merely a facial challenge to the Prescription Restraint Law. Like the challenges in *Baldwin* and *PhRMA v. D.C.*, plaintiffs challenge the law as applied to commerce wholly outside of Vermont. Although it is far from clear that the law applies to any in-state transaction (no pharmaceutical manufacturers sell drugs solely in Vermont and no publishers sell information solely in Vermont), this lawsuit does not and need not challenge such hypothetical intrastate applications of the law.

CONCLUSION

The Court should reverse the district court's decision and direct entry of judgment for the plaintiffs.

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CERTIFICATE OF COMPLIANCE

This brief contains 7,963 words, excluding parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)B)(iii). An unopposed motion to file an oversized brief has been filed simultaneously with this brief.

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09-1913-cv(L) IMS Health v. Sorrell

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I, Natasha R. Monell, hereby certify that the Reply Brief submitted in PDF form as an e-mail attachment to **civilcases@ca2.uscourts.gov** in the above referenced case, was scanned using CA Software Anti-Virus Release 8.3.02 (with updated virus definition file as of 9/29/2009) and found to be VIRUS FREE.

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