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

BRIEF FOR PLAINTIFF-APPELLANT PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, plaintiff-appellant Pharmaceutical Research and Manufacturers of America discloses that it has no parent corporation and no publicly held company owns 10% or more of its stock.

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PRELIMINARY STATEMENT

This is an appeal from a final judgment entered on April 24, 2009, by the United States District Court for the District of Vermont, the Honorable J. Garvan Murtha, presiding, and from interlocutory orders merged into the judgment. The decision is reported at *IMS Health Inc. v. Sorrell*, -- F. Supp. 2d ---, 2009 WL 1098474 (D. Vt. Apr. 23, 2009).

JURISDICTIONAL STATEMENT

The District Court had subject matter jurisdiction pursuant to 28 U.S.C. § 1331. This Court has jurisdiction over the appeal pursuant to 28 U.S.C. § 1291 because it arises from the final judgment of the District Court, which disposed of all parties' claims. This Court also may review on appeal any interlocutory rulings that merge into the final judgment. *Shannon v. Gen. Elec. Co.*, 186 F.3d 186, 192 (2d Cir. 1999).

The District Court entered final judgment on April 24, 2009. Pharmaceutical Research and Manufacturers of America ("PhRMA") filed a timely notice of appeal on May 5, 2009. *See* Fed R. App. P. 4(a)(1)(A); A-5146-48.

ISSUES PRESENTED FOR REVIEW

1. Whether Vermont Act 80, which has the stated goal of rectifying an imbalance in the "marketplace of ideas," restricts non-commercial speech and does not survive strict scrutiny.

2. Whether Vermont Act 80, which at a minimum restricts commercial speech, fails intermediate scrutiny under *Central Hudson* because it does not directly advance the state's asserted interests and is no more restrictive of speech than necessary.

STATEMENT OF THE CASE

With the express, but constitutionally impermissible, goal of rectifying a perceived "imbalance" favoring brand-name pharmaceutical manufacturers in the "marketplace for ideas," the Vermont Legislature barred those manufacturers from using information about doctors' prescribing histories ("prescriber-identifiable data") for "marketing or promoting a prescription drug." A-4064; A-4074-75 (Vermont Act No. 80, as amended by Vermont Act 89, Section 17(d), codified at 18 V.S.A. § 4631(d)).[1]

[1] Vermont Act 89 repealed several of the provisions of Vermont Act 80 that had been challenged by PhRMA, including Section 17(f), which compelled pharmaceutical manufacturers who used prescriber-identifiable data to also make certain disclosures that would be drafted by the state. A-4065; A-4075.

The First and Fourteenth Amendments to the United States Constitution preclude both this stated goal of leveling speech and the means Vermont chose to achieve it. Those authorities command that the marketplace for ideas be a *free* market. It was Justice Oliver Wendell Holmes who invoked the analogy of the "marketplace" under the First Amendment almost 90 years ago. He credited the Framers for recognizing that "the ultimate good desired is better reached by free trade in ideas – that the best test of truth is the power of the thought to get itself accepted in the competition of the market, and that truth is the only ground upon which their wishes safely can be carried out." *Abrams v. United States*, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting); *see Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 390 (1969) (First Amendment assures "an uninhibited marketplace of ideas."). In curtailing the speech of pharmaceutical companies, the Vermont Act violates this fundamental constitutional tenet.

The Vermont Act is entitled "An Act Relating to Increasing Transparency of Prescription Drug Pricing and Information." The legislature's stated purpose in enacting Act 80, however, was to rectify the perceived "one-sided nature" of the "marketplace for ideas on medicine safety and effectiveness." A-4040 (Act 80, § 1(4)). Although identifying the reduction of healthcare costs and the promotion of public health as objectives, the Act in Section 17(d) does not impose any direct controls on costs or prescribing practices. It also does not mandate continuing

medical education for doctors. And it does not address other potential cost-saving or safety measures. Instead, it curtails the speech of pharmaceutical manufacturers, including a great deal of speech that has nothing to do with the State's asserted objectives.

On October 22, 2007, plaintiff-appellant PhRMA sued for declaratory and injunctive relief on the ground that Section 17(d) violated the First and Fourteenth Amendments. Doc. 1 (07-cv-220). IMS Health Incorporated, Verispan, LLC, and Source Healthcare Analytics, Inc. (the "publisher plaintiffs") had previously filed a similar complaint, Doc. 1, and the court consolidated the cases. Doc. 60. On April 29, 2008, after Vermont Act 89 repealed some of the challenged offending provisions of the law, PhRMA amended its complaint to address the revised statute.[2] Doc. 221.

After the close of discovery, Defendants moved *in limine* to exclude testimony of "legislative witnesses," including the legislative staffers and outside lobbyists who had drafted Act 80. Doc. 301. Defendants' motion in particular sought to preclude Plaintiffs from introducing evidence regarding the preparation of the legislative findings – including the rushed consideration by the Legislature,

[2] PhRMA's Amended Complaint focused on Section 17(d), while maintaining its challenge to Section 20 under the First Amendment and to Section 21 under the Supremacy and Commerce Clauses. The District Court held that PhRMA's claims regarding Sections 20 and 21 were not subject to a facial challenge, SPA-54; SPA-57, and PhRMA does not appeal that aspect of the judgment.

the pervasive errors and omissions, the role of interested third parties as authors, and the *post hoc* search for evidence to fit prefabricated findings. The District Court excluded this evidence. SPA-64-66; Doc. 375.

The trial was held from July 28, 2008 to August 1, 2008. On November 18, 2009, before the District Court had ruled, the Court of Appeals for the First Circuit in *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), a case to which PhRMA was not a party, reversed the New Hampshire District Court and upheld a similar statute in that state. On April 23, 2009, the District Court here denied Plaintiffs' motions for declaratory and injunctive relief. SPA-1-61. Finding that the Vermont law restricted the speech of both pharmaceutical manufacturers and the publisher plaintiffs, the court nonetheless held that the law survived intermediate scrutiny under the First Amendment. SPA-16. In so ruling, the court did not independently review, or in its words, "reweigh," the evidence ostensibly justifying the abridgement of free speech. SPA-22. Rather, the court "defer[red] to the legislative findings, predictions, and judgments to the extent they are reasonable and based on substantial evidence." *Id.* One consequence of this deference was that the court conducted no meaningful evaluation of the unnecessary breadth of the statute, encompassing speech unrelated to the State's objective, or of the availability of less intrusive means by which the State could have achieved those objectives without restricting speech.

The District Court entered judgment on April 24, 2009. Doc. 431. PhRMA filed a timely notice of appeal, Doc. 434, and joined the publisher plaintiffs' motion for an injunction pending appeal. Doc.435. The District Court denied an injunction. Doc. 443. This Court also denied the publisher plaintiffs' motion for injunction pending appeal.

STATEMENT OF FACTS

I. PhRMA

PhRMA is a non-profit association of the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's members develop and manufacture life-saving and life-enhancing new medicines, which are promoted, prescribed, and sold in Vermont. A-155-58; A-2511-13; A-2742. PhRMA is the pharmaceutical industry's principal policy advocate, representing the interests of its members in matters before Congress, the executive branch, state regulatory agencies and legislatures, and the courts. A-153-54; A-166. Among other objectives, PhRMA seeks to advance public policies that foster continued medical innovation and to educate the public about how new drugs are discovered and developed. A-155-58; A-2742. PhRMA also leads industry efforts to develop responsible self-regulation of companies' marketing and research activities through ethical codes and guidelines. A-160-61; A-2341-96; A-2706-41.

II. Development, Marketing, and Prescription of Pharmaceutical Products

A. Development, Innovation, and Approval of Life-Saving and Life-Enhancing New Products

Research-based pharmaceutical and biotechnology companies – that is, brand-name manufacturers – are responsible for almost all the innovation in prescription drugs. A-149; A-157. These companies invest billions in research and development every year – more than $58 billion in 2007 – as they strive to develop new life-saving products.[3] A-141; A-159. New drugs were responsible for 40% of the increase in the human life span between 1986 and 2000. A-2624. Breakthroughs by the pharmaceutical industry have extended the life expectancy of Americans by two years between 1986 and 2000, advancing the treatment of diseases such as HIV/AIDS, diabetes, and hypertension. A-156-57; A-2624.

The Food and Drug Administration ("FDA") oversees development and marketing of prescription drugs. *See* 21 U.S.C. § 355; A-135. Sponsors of new drugs must submit a New Drug Application ("NDA") reflecting all evidence of safety and effectiveness, developed through testing in animals and then humans. *Id.* FDA will approve a new drug only if the NDA provides "substantial evidence that the drug will have the effect it purports or is represented to have under the

[3] In 2008 alone, PhRMA members invested an estimated $50.3 billion in discovering and developing new medicines; industry-wide investment reached a record $65.2 billion in 2008. *See* http://www.phrma.org/about_phrma.

conditions of use prescribed, recommended, or suggested in the proposed labeling" and includes sufficient evidence that "such drug is safe for use under such conditions." 21 U.S.C. § 355(d)(4), (5).

Evidence not cited by the District Court showed that only 1 in 5000 chemical entities tested by pharmaceutical companies survives this process. A-134-35. Those that do often require fourteen to sixteen years to come on the market. A-135-36. The average investment required to develop a new drug is approximately $2 billion. A-137.

B. Development and Introduction of Generic Drugs

Generic manufacturers do not conduct independent research or development of new drugs, but rather produce unbranded versions of brand-name drugs once the sponsor's patent protection expires. A-119; A-157. FDA may approve a generic version of a pioneer prescription drug based on an Abbreviated New Drug Application ("ANDA") that need not contain full non-clinical and clinical data to establish the drug's safety and effectiveness. A-120; A-136; A-140. Instead, generic manufacturers only have to show that their drug is the "same as" and "bioequivalent to" the pioneer drug, that the method of manufacture is adequate to produce the bioequivalent drug, and that the labeling is the same as the pioneer's. A-120; A-136; A-140. Developing and obtaining approval of a generic drug generally costs between $100,000 and $500,000, compared with the billions spent

by innovator companies. A-140; A-149. As a result, generic drugs usually cost less than brand-name counterparts. A-149.

Sales of generic drugs have skyrocketed in recent years. In 2000, for example, 51% of prescriptions written in the United States were for generic drugs. A-159. By 2007, the generic share had increased to 67%, and it has continued to rise. *Id.* There are several reasons for this trend, including the growing number of medicines not protected by patents and the introduction (in January 2006) of Medicare Part D, extending prescription drug insurance to an additional 14 million Americans. *Id.* The health insurance industry, including the companies administering the Part D program, has thus exerted pressure in favor of generics in order to reduce its own costs. A-123; A-159. The District Court's opinion nowhere discusses this trend or recognizes that data regarding the share of generics prior to Medicare Part D is outdated.

C. FDA Oversight of the Marketing of Prescription Drugs

Although the District Court did not acknowledge the breadth of FDA's oversight, the Agency intensely regulates pharmaceutical products both before and after approval of an NDA. In particular, FDA examines communications by pharmaceutical companies to prescribers, including oral statements by sales representatives, to ensure that the information provided is truthful and not misleading. 21 U.S.C. §§ 321(m), 352, 355(n); 21 C.F.R. § 202.1. If FDA finds

any communication, including those by detailers, to be "false or misleading in any particular," the Agency deems the drug misbranded, potentially a criminal offense. 21 U.S.C. § 352(a); A-138-39.

Evidence not cited by the District Court showed that pharmaceutical companies prohibit sales representatives from making statements inconsistent with the FDA-approved labeling and only allow use of materials pre-approved by appropriate company staff. A-213; A-3158-59; A-3410. Pharmaceutical companies adopt and enforce internal policies – none of which are mentioned in the District Court's opinion – to ensure appropriate interactions with prescribers and intensively train sales representatives to comply with those policies. A-213-14; A-2606; A-2861; A-2954; A-3156-59; A-3288-90; A-3336; A-3409-10; A-3479-81; A-3633; A-3756-63.

In 2002, PhRMA issued a "Code on Interactions with Healthcare Professionals." A-2341-96. An updated version of this Code was announced in July 2008 and took effect in January 2009. A-160-61; A-165-66; A-2706-41. To comply with the PhRMA Code, signatories must establish policies on use of prescriber data and honor any request by a prescriber not to make his or her data available to sales representatives. A-2720. The Code further provides that companies should not give health care professionals entertainment, recreational items, or other materials, regardless of value, unless the materials help in treatment

of disease or are educational. A-2711-12. As of the time of trial on August 1, 2008, more than thirty PhRMA members had publicly committed to follow the new Code. A-161.[4]

D. Marketing of Brand-Name Prescription Drugs

Pharmaceutical manufacturers promote their drugs to prescribers, including those in Vermont, through detailing, advertising, and other means. A-2701. "Detailing" refers to communications by individual pharmaceutical company representatives with prescribers focusing on specific prescription drugs. Trained to a high level of expertise, detailers generally provide prescribers with relevant information regarding the drug being promoted, including, as found by the District Court, "'details' regarding the use, side effects and risk of interactions of the drug." SPA-4. That information often consists of published, peer-reviewed medical studies and guidelines on disease management. A-125; A-197; A-210-11; A-2701-03; A-3410; A-3489-91. Some prescribers find detailing useful. A-123; A-125; A-173; A-196-97. Evidence not cited by the District Court showed that

[4] The American Medical Association also has ethical guidelines for prescribers regarding gifts from pharmaceutical companies, which also were not discussed in the opinion below. A-213; A-2606. And in 2003, the Office of Inspector General of Health and Human Services issued guidelines – not cited by the District Court – regarding promotional practices of pharmaceutical manufacturers. Under these guidelines, companies cannot give health care providers "anything of value" or an "offer of payment" in exchange for prescriptions or referrals of business if federal health care programs provide reimbursement for those services or prescriptions. HHS Office of Inspector General, "OIG Compliance Guidelines for Pharmaceutical Manufacturers," 68 Fed. Reg. 23,731-23,743, at 23-734; A-254.

prescribers who do not find detailing useful can and do choose not to interact with sales representatives. A-125; A-173; A-299; A-3057; A-3561.

E. Prescribing Decisions Rest with the Physician, But Insurers Increasingly Limit Those Choices

"Prescription" drugs bear that name because consumers cannot legally obtain them without a prescription from a licensed healthcare provider. A-143. The evidence, not discussed in the District Court's opinion, showed that each patient responds differently to drugs. The same drug may work for one patient but not for another who has the same condition. A patient's unique characteristics also may make a particular drug more or less risky for him or her than other drugs in the same class. Thus, choosing the appropriate drug for a particular patient is often a highly individualized decision. The physician must take into account the patient's condition, age, size, other medications, prior responses to drugs, severity of illness, kidney and liver function, allergies, and many other factors. A-192-95; A-351-52. The physician must integrate this information with knowledge regarding the treatment options, including not only the side effect profiles of drugs but their potential interactions with other medications, as well as medical guidelines for appropriate treatment of specific disorders, the evolving medical literature, and other new developments. A-122-23; A-161-62; A-192-95. Evidence not cited by the District Court showed that physicians draw this information from multiple sources, such as medical journals, scientific meetings,

and colleagues, as well as from sales representatives. A-16-62: A-192-95; A-391. Indeed, Act 80 specifically found that "physicians frequently rely on information provided by pharmaceutical representatives" in determining "which drugs are the best treatments for particular conditions." A-4041 (Act 80, § 1(13)).

Evidence not cited by the District Court showed in addition that physicians no longer have full discretion in making many prescribing decisions. Their medical decisions are limited by the efforts of private insurers and government programs. A-123; A-159; A-287. The vast majority of patients have coverage from private insurance or government-sponsored healthcare programs, such as Medicare or Medicaid. A-159: A-282. These third-party payers go to great and ever-increasing lengths to induce physicians to prescribe generic drugs. They adopt preferred drug lists of the medications for which they will reimburse the patient or provider.[5] A-286; A-3032; A-3043. They also use incentive-based (tiered) formularies, offering lower co-payments for generic or lower cost treatment options, thereby creating financial pressure for patients to request and prescribers to select those preferred drugs. A-123; A-265-69. They bar prescriptions of a brand-name drug for which there is a generic or lower cost alternative, unless the company or program consents in advance. A-123; A-267-

[5] Insurers usually manage these "formularies" in a way that encourages prescribers to prescribe the least expensive drugs for the insurer that are also medically appropriate for the patient. A-267; A-286.

68. And they dictate "step therapy," requiring prescribers to initiate treatment with a generic or lower cost alternative and to use brand-name treatments only if the initial therapy fails, or "prior authorization," requiring special approval before a brand drug can be prescribed. A-267-68; A-353; A-3051-52. Prescriber-identifiable data plays an important role – one not discussed by the District Court – in implementing these mandated preferences for generic drugs. Insurers and state Medicaid agencies use the information to police the prescribing practices of physicians and to pressure them to prescribe drugs that cost the payers less money and increase profits of private insurers. A-179; A-268; A-287; A-3032-33; A-3051-52.

III. Uses of Prescriber-Identifiable Data

A. Pharmaceutical Manufacturers Use Prescriber-Identifiable Data for a Wide Variety of Purposes

Pharmaceutical manufacturers purchase prescriber-identifiable data from the publisher plaintiffs. A-78; A-211. The manufacturers use the data both to identify specific audiences for marketing efforts and to focus their marketing messages to the needs of particular prescribers. A-172-73; A-182-83; A-211-12; A-3146-47; A-3312; A-3322; A-3337; A-3386-87; A-3516-18; A-3566; A-3645; A-3673-77; A-3726. Pharmaceutical manufacturers also use prescriber-identifiable data to direct scientific and safety messages regarding particular drugs to physicians who are more likely to need such information, to track disease progression, to assist law

enforcement, to implement risk mitigation programs, and to conduct clinical trials and post-marketing surveillance, as required by FDA. A-178; A-182-83; A-3153-54; A-3159-60; A-3271-72; A-3370; A-3402-04; A-3448-49; A-3471-72; A-3747; A-3754-55. The District Court discussed none of these uses.

B. Many Other Organizations, Though Not Subject to Act 80, Also Use Prescriber-Identifiable Data

Many other entities not covered by Act 80 also use prescriber-identifiable data. Researchers for academic and other institutions analyze the information to identify and remedy overuse of a particular medication in a specific population. A-79. Federal agencies, such as the Drug Enforcement Agency, the Center for Disease Control, and FDA use the data to track inappropriate use of controlled substances and to identify prescribers who may need time-sensitive information. A-80; A-103-04; A-178. Insurance companies and pharmacy benefit managers also employ prescriber-identifiable data to process patient claims, manage formulary compliance, and encourage the use of cheaper, generic drugs. A-123; A-188-89; A-298-99; A-3032-33; A-3051-52. Vermont itself draws on prescriber-identifiable data in law enforcement and various state programs. A-283; A-286-87; A-3031-33; A-3039-41; A-3050; A-3054; A-3056-57; A3097; A-3106. Although Act 80 does not explicitly restrict these uses, evidence not mentioned by the District Court showed that the sales barred under the Act are essential to the

publisher-plaintiffs' ability to gather and provide the data for these other purposes. A-82-83; A-88; A-97; A-100; A-111.

IV. Section 17(d) – The Prescription Restraint Provision

A. Restriction on the Use of Prescriber-Identifiable Data by Pharmaceutical Manufacturers for Marketing

As amended by Act 89, Section 17(d) of the Vermont Act is intended to regulate the speech of "[p]harmaceutical manufacturers and pharmaceutical marketers." A-4075. Unabashedly directed at rectifying what the Legislature adjudged the "one-sided nature" of the free "marketplace for ideas on medical safety and effectiveness," A-4040 (Act 80, § 1(4)), the Act restricts the speech of one set of disfavored participants in that marketplace and stifles one set of disfavored messages. Specifically, the Act cuts off the flow of communications from pharmaceutical sales representatives to Vermont prescribers if the company "use[s] prescriber-identifiable data for marketing or promoting a prescription drug," unless the prescriber has granted advance permission in his or her biannual license renewal. A-4074-75 (Act 89, § 3(d), codified at 18 V.S.A. § 4631(d)).

The "marketing" covered by the Vermont Act extends to communications far beyond those proposing a commercial transaction, encompassing, as noted, the entire "marketplace of ideas" on drug safety and effectiveness. The Act defines "marketing" to include "promotion," and it defines "promotion" broadly to include "any activity or product the intention of which is to advertise or *publicize* a

prescription drug, including a brochure, media advertisement or announcement, poster, free sample, *detailing visit*, or personal appearance." A-4063 (Act 80, §§ 17(b)(5), (8), codified at 18 V.S.A. §§ 4631(b)(5), (8)) (emphasis supplied). Any visit by a sales representative of a company using prescriber-identifiable data, even to convey recent peer-reviewed literature or to provide safety or risk information, thus can fall within the ambit of "marketing and promotion" and potentially violate the State Consumer Fraud Act. A-4076-77 (Act 89, § 5(a), codified at 9 V.S.A. § 2466a(a)).

While imposing these restrictions on pharmaceutical manufacturers, Section 17(d) carves out broad exceptions that allow all other health care sector participants virtually free rein to use prescriber-identifiable data. Thus, for example, a health insurer can employ the data for "prescription drug formulary compliance." A-4064 (Act 80, § 17(e)(1), codified at 18 V.S.A. § 4631(e)(1)). This euphemism masks the operative principle: an insurer, for commercial reasons, can use the data to tell a physician, "Do not prescribe this drug," while a pharmaceutical company, with no greater commercial motive, cannot use the same data to tell the same physician, "Consider prescribing this drug."

B. Rushed and Biased Process Underlying Enactment of Section 17

Although the State cited the legislative findings in the Act, and the District Court deferred to them, evidence excluded below shows that they were drafted

hurriedly, mostly overnight, and tailored to support preconceived conclusions and to justify, after the fact, a deliberate intrusion on free speech. Indeed, the excluded evidence showed that, far from reflecting the care and discipline required when legislatures abridge the right of free speech, the process here was hasty, yielding findings with significant substantive errors.

The precursor of the Vermont Act, introduced in February 2007, proposed a ban on the licensing, transfer, use, or sale of prescriber-identifiable data for commercial purposes. A-1506-09. The Legislature closely modeled the ban after a similar New Hampshire law enacted in 2006. *See* 2006 N.H. Laws § 328, codified at N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, 318-B:12(IV) (2006). In hearings on the Vermont bill, no witness presented evidence that the law was likely to reduce costs. In fact, witnesses testified that, to the contrary, the spillover effect of the bill would undermine the marketing of cost-effective drugs. A-802. As regards alternatives less restrictive of speech, the Legislature did not hear evidence as to whether direct limits on prescribing, continuing medical education, mandatory disclosure of patent expiration, "dear doctor letters" from the State to Vermont physicians, or industry marketing codes could achieve the State's objectives. The Legislature did hear evidence from a witness the State promotes as an expert that one such alternative approach, "academic detailing" (*i.e.*, having the State or academics educate physicians about less costly treatment options), could

reduce prescription drug spending by two dollars for every one dollar invested by the State. A-1255.

Despite these legal and factual gaps, the House Healthcare Committee approved a New Hampshire-style prohibition on April 24, 2007. A-1655-59. The House scheduled a vote for May 3, 2007. A-4125. On April 30, 2007, however, the United States District Court in New Hampshire struck down that State's prototype law. *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 183 (D.N.H. 2007). Analyzing the law as a restriction on commercial speech, the court found that it could not withstand intermediate scrutiny. *Id.* The court held the state to its burden of justifying its restriction of speech and thus refused to defer to the state's legislative judgments. *Id.* at 177 n.12. In fact, the court found such deference particularly unwarranted because the legislature had "acted quickly after the bill was introduced, received hearing testimony by numerous individuals who had yet to review proposed amendments, made no express findings either on the record or incorporated into the statute, failed to discuss alternative measures that would not restrict speech, and cited no evidence as to how effective the restriction might prove to be." *Id.*

Confronting this setback in the waning days of the legislative session, the Vermont House Committee on Healthcare did not pause to review its policy choices. Rather, as evidence excluded by the District Court showed, the

Committee scrambled to fashion legislative findings that rationalized the preconceptions already reflected in the bill. A-4743-45; A-4760-61.[6] The "findings" tacked on to the legislation reflected no facts developed through testimony or investigation. Indeed, the responsible legislative aide could not substantiate the findings when legislators asked, A-1462-63, reflecting the rushed turnaround by outside drafters who had their own agenda.[7] A-4739-45. One such outsider, Sean Flynn, a lecturer at American University, A-4742-44, had attended no legislative hearings in Vermont, A-4764, but nonetheless provided the responsible staffer proposed findings to support the law, along with citations ostensibly documenting the findings. A-4764-71. Under oath, Mr. Flynn later conceded that many citations in fact did not support the proposed findings, *see, e.g.*, A-4762-63 ("Q. And the document you cited doesn't support the proposition for which it was cited, does it? A. No, it doesn't."). As a result of the passing of legislative fact-finding and drafting obligations to interested outsiders, the errors – though not mentioned by the District Court – were pervasive. For example:

> - Finding (5) states that FDA has limited legal ability to enforce the requirement that marketing be fair and balanced. In reality, Congress has

[6] In addition to these unfounded "findings," the Committee also gave prescribers a pro forma right to agree in advance, every other year, that companies could use their data. A-1682.

[7] Those outside drafters included lobbyists from the AARP and the National Legislative Association on Prescription Drug Prices.

conferred FDA with legal authority to enforce its marketing rules, including through criminal proceedings. *See* 21 U.S.C. §§ 352, 355(n); A-138; A-140.

- Finding (8) states that 50% of all drug withdrawals and black box warnings were within the first two years a drug comes on the market In fact, the percentages cited apply to less than a third of new drugs on the market. A-355.

- Finding (14) states that nearly one-third of the increase "in spending on drugs in the last decade" is attributable to marketing induced shifts from generic drugs. In fact, the study in question was from 2001, six years out of date, and could not support the statement regarding spending after the study was published. A-180.

- Finding (17) states that pharmaceutical manufacturers spend twice as much on marketing as on research and development. In fact, this statement counts as marketing expenses the general administrative costs to run companies, *e.g.*, computer operations, maintenance, and bookkeeping. In fact, the evidence at trial showed that the pharmaceutical industry spends nearly five times as much on research and development as on marketing. A-162; A-2624.

- Finding (18) reports that companies have doubled their sales forces. In fact, the record showed that more recent trends are in the opposite direction. A-181.

- Finding (21) cites a study purportedly stating that distribution of drug samples causes physicians to change prescribing habits. In fact, the study disclaims any generalized conclusions. Chew, et al., *A Physician Survey of the Effect of Drug*

Sample Availability on Physician's Behavior, J. of Gen. Internal Med. (July 2000), at 482-83.

- Finding (26) asserts that "[p]rescriber identified databases of prescribing habits encourage pharmaceutical companies to increase the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers." There was, however, no evidence before the Legislature of such "quid pro quo" relationships, which would be a crime under federal law if they existed. A-181; *see also* 42 U.S.C. § 1320a-7b (2006).

On May 3, 2007, just three days after the New Hampshire District Court's *Ayotte* decision had prompted wholesale revision of the Act, the House adopted the new version.[8] The Senate promptly concurred, and the Governor signed the law on June 9, 2007. A-1873.

As originally adopted, Act 80 not only restricted marketing (expansively defined) with prescriber-identifiable data, but also dictated the information that detailers had to tell doctors they visited. Specifically, Section 17(f) of the Act required detailers to promote competitors' products and other alternative treatment options whenever discussing their own. A-4065. Finding 31 of the Act, in

[8] Committee members recognized the First Amendment infirmities of the hastily revised bill and objected to the findings. *See*, *e.g.*, A-1437 ("I almost felt like it was flaunting the free speech."); A-1424 ("[I]s there any rhyme or reason for the – ordering which these findings are placed?"); A-1481 ("[A]nd I don't feel I even know what's in this bill. It's being pushed past us way too fast. There's been way too many changes made and for us to be voting on a bill that they're going to take up on the floor in ten minutes is something I've never seen before."); A-1480 ("I felt as if I was trying to write legislation to get around a decision that was made by a judge as opposed to writing legislation to solve a problem.").

summarizing the purposes of the Act, thus focused only on this provision as furthering the goals of reducing healthcare costs and protecting public health and linked the limitation on prescriber data to the goal of protecting physicians' privacy:

> This act is necessary to protect prescriber privacy by limiting marketing to prescribers who choose to receive that type of information, to save money for the state, consumers, and businesses by promoting the use of less expensive drugs, and to protect public health by requiring evidence-based disclosures and promoting drugs with longer safety records.

A-4044.

In the wake of this lawsuit, the Legislature repealed Section 17(f), but did not revisit Finding 31 to identify any other provision that "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." *Id.* In particular, although the Legislature left in place the provisions on prescriber-identifiable data, it did not change the justification for that provision in Finding 31, linking the limitation only to "prescriber privacy." Nor did the Legislature supplement, alter, or delete any other findings in Act 80. In fact, the Legislature made no discernible effort to ascertain whether, once the statute was amended, the findings still supported the law, the Act still served the articulated purposes, or the infringement of First Amendment rights was still justified.

Overall, the legislative history does not reflect – and the District Court did not independently determine – that the cost of this legislation was "carefully calculated," *Bd. of Trustees of the State Univ. of New York v. Fox,* 492 U.S. 469, 480 (1989); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371-73 (2002), that the abridgment of the speech of pharmaceutical companies would achieve the State's objectives, or that the Legislature had analyzed alternatives less intrusive on First Amendment rights.

SUMMARY OF THE ARGUMENT

The District Court committed several errors in its ruling that the Vermont Act is constitutional. First, as described below, the District Court applied the wrong standard. While correctly noting that the Act restricts speech, the court improperly analyzed the law as a restriction of commercial speech. By its terms, the Vermont Act not only restricts speech that proposes a commercial transaction, but also restricts all promotion as defined by the Act – encompassing any activities to publicize a drug – if the pharmaceutical manufacturer uses prescriber identifiable data. The broad definitions in the Act sweep in communications about drug risks, drug safety, and disease management – non-commercial speech that "publicizes" a drug. The Vermont Act cannot survive the strict scrutiny that applies to restrictions on non-commercial speech.

Second, even if Act 80 did abridge only commercial speech, the District Court misapplied the test for those communications. The court erred in relieving the State of its burden of proof, imposed under *Central Hudson*, to demonstrate that the Act directly and materially advances substantial state interests in a manner no more restrictive of speech than necessary. Rather than putting the State to its proof and independently weighing the evidence to determine whether the Act was justified or not, the District Court deferred to the legislative findings, even to those that were demonstrably incorrect. In following this deferential approach, the court did not require the State to prove how a restriction of truthful communications from detailers to highly-trained physicians – who make independent prescribing decisions – *directly* furthers the State's asserted interests in cost reduction and public health. Instead, the court uncritically accepted an elongated and indirect causal chain proffered without any empirical support. The court's approach abdicated any responsibility to determine whether the Act swept in speech that did not in fact raise costs or undermine public health or to consider less restrictive alternatives. Instead of the careful review of this issue dictated by the Supreme Court, the court here dismissed as "irrelevant" the "laundry list of alternative ways the Legislature could have advanced its substantial interest in protecting public health." SPA-34.

In short, the Vermont Act is a content-based, viewpoint-based restriction of speech, which discriminates against a particular set of speakers and messages disfavored by the State. Accordingly, the State, at a minimum, had to prove that the Act advanced its asserted interests directly and materially, that the abridgement of speech did not extend farther than necessary, and that less restrictive alternatives could not do the job. The State did not meet this burden. The District Court therefore erred in upholding the Vermont Act.

ARGUMENT

I. Standard of Review

The District Court committed an error of law when it determined that Section 17 only restricts commercial speech. The District Court also committed an error law when, in assessing Act 80 as a restriction on commercial speech, the court deferred to the Legislature's findings and predictive judgments and thereby diluted the intermediate scrutiny test set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). This Court reviews such issues *de novo*. *United States v. Gayle*, 342 F.3d 89, 91 (2d Cir. 2003). Findings of fact predicated on an erroneous legal standard are also reviewed *de novo*. *Weissmann v. Freeman*, 868 F.2d 1313, 1317 (2d Cir. 1989) (citing *United States v. Parke, Davis & Co.*, 362 U.S. 29, 44 (1960)).

Moreover, particularly when First Amendment rights are at issue, an appellate court has a "constitutional duty to conduct an independent examination of the record as a whole, without deference to the trial court." *See Hurley v. Irish-Am. Gay, Lesbian and 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)). This duty dictates "an independent examination of the whole record" for any "intrusion on the field of free expression." *Hurley*, 515 U.S. at 567-68 (citing *New York Times Co. v. Sullivan*, 376 U.S. 254, 285 (1964)). Because "the reaches of the First Amendment are ultimately defined by the facts it is held to embrace," courts must "decide for [them]selves whether a given course of conduct falls on the near or far side of the line of constitutional protection." *Id.* at 567.

Within this framework, this Court reviews evidentiary rulings for abuse of discretion. *United States v. Tin Yat Chin*, 371 F.3d 31, 40 (2d Cir. 2004). "The abuse of discretion standard includes review to determine that the discretion was not guided by erroneous legal conclusions." *Koon v. United States*, 518 U.S. 81, 100 (1996).

II. Section 17 of Vermont Act 80 Restricts Non-Commercial Speech and Cannot Withstand Strict Scrutiny

Because of its all-encompassing definitions of "marketing" and "promotion," Vermont Act 80 extends to communications between pharmaceutical manufacturers and prescribers beyond the mere proposal of a commercial

transaction. For example, pharmaceutical sales representatives provide prescribers information regarding medical conditions the prescribers treat and their company's innovative treatments for those conditions. In addition, pharmaceutical manufacturers communicate with Vermont prescribers about scientific or safety-related developments through "Dear Healthcare Professional" letters. When companies identify a new side effect or risk associated with a product or change the labeling of a prescription drug, they alert prescribers, including those in Vermont. Manufacturers use prescriber-identifiable data to assist in disseminating this safety information, ensuring that sales representatives reinforce with doctors who prescribe the product the information contained in the letter. A-215; A-3153-54; A-3159-60; A-3402-03; A-3754-55.

These activities fall within the statutory definition of "promotion." Vermont Act 80 is therefore subject to strict scrutiny. *See generally R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992). Moreover, given that commercial speech by pharmaceutical manufacturers is "inextricably intertwined with otherwise fully protected speech," it is not appropriate to parse the communications by category. *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988). Rather, the communications as a whole are subject to strict scrutiny. *See id.*

A law subject to strict scrutiny must be narrowly tailored to promote a compelling government interest, and if a less restrictive alternative would serve the

government's purpose, the legislature must use that alternative. *United States v. Playboy Entm't Group*, 529 U.S. 803, 804 (2000); *see also Reno v. Am. Civil Liberties Union*, 521 U.S. 844, 874 (1997); *Sable Commc'ns of Cal., Inc. v. FCC*, 492 U.S. 115, 129 (1989). As is true of challenges to laws regulating purely commercial speech, the government also bears the burden of proof in challenges to laws regulating non-commercial speech. *Playboy*, 529 U.S. at 816-17; *see also Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 428 (2006); *Ashcroft v. ACLU*, 542 U.S. 656, 666 (2004). Because, as discussed below, Section 17 fails to satisfy the *Central Hudson* intermediate scrutiny test, it follows *a fortiori* that it cannot satisfy the more stringent strict scrutiny standard.

III. Insofar as Vermont Act 80 Restricts Commercial Speech, It Fails Intermediate Scrutiny Under *Central Hudson*

Vermont has imposed a content-based restriction of speech, predicated on the Legislature's disapproval of the message conveyed by brand-name pharmaceutical companies. The State has curtailed the freedom that defines the very marketplace of ideas it cites and has ignored the central maxim of First Amendment law that the appropriate governmental response to disfavored speech is more speech, not prior restraint.

Central Hudson reflects these fundamental principles. The Supreme Court there identified four constitutional prerequisites for governmental restrictions of commercial speech. *First*, the speech at issue must concern a lawful activity and

cannot be misleading. 447 U.S. at 564, 566. *Second*, the regulation of speech must promote a substantial government interest. *Id.* at 566. *Third*, the law must "directly advance[] the governmental interest asserted." *Id.* *Fourth*, the regulation must not be "more extensive than is necessary" to serve the substantial interest. *Id.* The State, as the party seeking to uphold a restriction on commercial speech, bears the burden of proof with respect to all four elements. *See Thompson*, 535 U.S. at 371-73; *Edenfield v. Fane*, 507 U.S. 761, 770 (1990) ("It is well established that '[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it.'"); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 561 (2001) ("Whatever the strength of the Attorney General's evidence to justify the outdoor advertising regulations, however, we conclude that the regulations do not satisfy the fourth step of the *Central Hudson* analysis."). The State cannot meet this burden by demanding judicial deference to its legislature's conclusions. Such deference would abdicate judicial review.

A. Section 17 Restricts Truthful Speech Based on the Viewpoint Expressed and the Speaker Expressing It

The State presented no evidence that communications by pharmaceutical company representatives to prescribers are anything but truthful and not misleading. SPA-22. As to this truthful and nonmisleading speech, the District Court acknowledged that "the whole point of section 17" is to restrict it, "to control detailers' commercial message to prescribers." SPA-16; *cf. Ayotte*, 550 F.3d at 65

(Lipez, J., concurring in part, dissenting in part) ("[T]he New Hampshire Legislature chose to regulate the upstream transactions because it wanted to alter the message used by pharmaceutical detailers in pursuing a downstream transaction with health care professionals. In other words, the Act was designed to limit the speech of those detailers.").

The restriction of speech in Section 17(d) overtly discriminates based both on the viewpoint expressed and the identity of the speaker expressing it. The prohibition on the use of prescriber-identifiable data does not turn on commercial motive, but rather the disfavored content of the message and the disfavored status of the speaker. As regards discrimination based on viewpoint, Section 17, as noted, bars a pharmaceutical manufacturer from using prescriber-identifiable data if it urges a doctor to consider prescribing the drug, but permits an insurance company to use that same information, with no less commercial purpose, to urge the same doctor not to prescribe the drug. As regards the identity of the speaker, the Act prohibits pharmaceutical companies from using prescriber-identifiable data in advocating use of prescription drugs, but allows other entities, for example, government health programs or academic institutions, to do so. *See* 18 V.SA. § 4631(d), (e). The First Amendment does not countenance the government's promotion of speech it prefers and obstruction of speech it disapproves. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996) ("[O]ur commerical

speech cases have recognized the dangers that attend governmental attempts to single out certain messages for suppression."); *Hurley*, 515 U.S. at 579 ("While the law is free to promote all sorts of conduct in place of harmful behavior, it is not free to interfere with speech for no better reason than promoting an approved message or discouraging a disfavored one, however enlightened either purpose may strike the government."). Nor does the First Amendment permit the government to play favorites, silencing the speakers it dislikes, but blessing speech by a privileged few. *See Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 193-94 (1999) ("Even under the degree of scrutiny we have applied in commercial speech cases, decisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment.").

The Legislature determined that views with which it disagreed – views favoring brand-name drugs – had gained ascendancy in the marketplace of ideas. A-4040 (Act 80, § 1(4), (6)). Rather than promote its own views in the marketplace, the Legislature sought to suppress the ideas and constrain the speakers it opposed – to bar speech by pharmaceutical companies.[9] But a state

[9] At trial, counsel for Defendants argued that "this is about tailoring the message" conveyed to prescribers by pharmaceutical companies. A-382. Defendants' own expert witnesses focused on the marketing messages of pharmaceutical companies and explicitly stated that the purpose of the law was to change those messages. A-354.

cannot ban speech, including commercial speech, simply because it is effective. As Justice Brandeis recognized, the essential feature of the marketplace for ideas is that if one viewpoint is prevailing, "the remedy to be applied is more speech, not enforced silence." *Whitney v. California*, 274 U.S. 357, 377 (1927) (Brandeis, J., concurring).

In particular, the government may not impede the dissemination of truthful information based on a paternalistic prediction that the speech may lead others – in this case, highly trained medical professionals – to make decisions the State does not like. *Thompson*, 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*, 517 U.S. at 503 ("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."); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976) ("It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if freely available, that the First Amendment makes for us."); *Edenfield*, 507 U.S. 761, 767 (1993) ("[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented."); *Greater New Orleans*, 527 U.S. at 195 (noting

"presumption that the speaker and the audience, not the Government, should be left to assess the value of accurate and nonmisleading information about lawful conduct"). When First Amendment rights are at stake, the default must be to protect truthful and non-misleading speech.

B. Deference to Legislative Findings Cannot Displace Independent Judicial Scrutiny under *Central Hudson*

The District Court diluted its review of Vermont's restriction here by deferring to the legislative findings in the Act. As noted, however, the Supreme Court has made clear that the State bears the burden of establishing that a restriction on speech "directly" advances "substantial" state interests in a manner "not more extensive than is necessary to serve that interest." *Central Hudson*, 447 U.S. at 566; *see also 44 Liquormart*, 517 U.S. at 500, 508-12; *Thompson*, 535 U.S. at 367, 371-73. Deferring to the State's determination means that when a court is unable to determine whether a restriction on free speech is justified, the restriction will stand. The tie goes to the State. But since the State bears the burden of proof, the State cannot prevail unless it establishes its justification by at least a preponderance of the evidence. *See 44 Liquormart*, 517 U.S. at 508-12 (rejecting argument that courts must defer to a legislative judgment because expert opinions as to the effectiveness of the price advertising ban at issue "go both ways"); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 482 n.2 (1995). Consistent with that allocation of the burden of proof, the Supreme Court has repeatedly confirmed that

laws infringing First Amendment rights demand no deferential acquiescence, but rigorous inquiry into the reliability and substantiality of the evidence supporting the restriction on speech. *See, e.g.*, *Gonzales v. Carhart*, 550 U.S. 124, 165 (2007) ("The Court retains an independent constitutional duty to review factual findings where constitutional rights are at stake."); *Sable*, 492 U.S. at 129 ("Deference to a legislative finding cannot limit judicial inquiry when First Amendment rights are at stake."). A searching and independent review is required.

By deferring to the Legislature's findings insofar as they were "reasonable and based on substantial evidence," SPA-22, the District Court did not fulfill that obligation. A justification could be reasonable yet still be wrong. When the Court knows the justification is invalid, it cannot sustain a governmental restriction on speech, particularly a content-based restriction. In *44 Liquormart*, the Supreme Court expressly held that "reasonable" was not good enough to justify an infringement of commercial speech. *See* 517 U.S. at 505. The Court acknowledged that common sense supported the government's position and that it was "reasonable to assume" that efforts to raise the price of alcohol would promote temperance, but that assumption could not substitute for evidence. *Id.* Nor is the District Court's view that the State had "substantial evidence" for the restriction equivalent to a finding that the State *proved* the restriction is justified. It is hard to see how a party could meet its burden of proving a proposition if it has not

established by a preponderance of the evidence that the proposition is true. The District Court had to find, but did not, that Vermont actually had established the truth of its assertion that restricting the speech of pharmaceutical companies would advance its asserted interests.

1. *Turner* Deference Is Inapplicable To Content-Based Restrictions on Commercial Speech

In deferring to the Legislature's findings, the District Court relied on *Turner Broadcasting System, Inc. v. FCC* ("*Turner I*"), 512 U.S. 622 (1994), which involved a content-neutral time, place, and manner restriction, not a commercial speech restriction. Indeed, the entire focus of discussion in *Turner I* was on why the requirement that cable operators carry local broadcast signals was content-neutral, explaining that "laws that confer benefits or impose burdens on speech without reference to the ideas or views expressed are in most instances content neutral." *Id.* at 643. In contrast, "laws that by their terms distinguish favored speech from disfavored speech on the basis of the ideas or views expressed are content based" and are particularly invidious under the First Amendment. *Id.* The Court concluded that "[n]othing in the [must-carry provisions] imposes a restriction, penalty, or burden by reason of the views, programs, or stations the cable operator has selected or will select." *Id.* at 644. The Court used the descriptions "content-neutrality" and "content-based" at least 13 times to limit its holding. Justice Stevens, whose vote provided a five-judge majority, made clear

that content neutrality was determinative. *Id.* at 671 n.2 ("[F]actual findings accompanying economic measures . . . that have only incidental effects on speech merit greater deference than those supporting content-based restrictions on speech."); *see also Turner Broad. Sys., Inc. v. FCC* ("*Turner II*"), 520 U.S. 180, 225 (1997) (Stevens, J., concurring) ("If this statute regulated the content of speech rather than the structure of the market, our task would be quite different.").

Not all restrictions on commercial speech are content-based, but, as demonstrated above, this one is. The burden the law imposes on speech is thus not incidental to a regulation of commercial activity, but a direct regulation of the content of the speech itself. The Supreme Court's commercial speech cases after *Turner* dealt with content-based restrictions, and they neither cited that case nor extend deference as the District Court did here. To the contrary, they held the government to its burden of showing "the harms it recites are real and that its restriction will in fact alleviate them." *Edenfield*, 507 U.S. at 762. In *44 Liquormart,* the plurality opinion overruled the holding in *Posadas de Puerto Rico Associates v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986), that it was "up to the legislature" to choose to reduce gambling by suppressing advertising of casinos or engaging in educational speech. *See* 517 U.S. at 509-10 ("Because the 5-to-4 decision in *Posadas* marked such a sharp break from our prior precedent, and because it concerned a constitutional question about which this Court is the final

arbiter, we decline to give force to its highly deferential approach."). Moreover, Justice O'Connor, writing for an additional four Justices in *44 Liquormart*, also concluded that the deference in *Posadas* was not representative of the burden placed on the state by *Central Hudson*. *See id.* at 531-32 ("The closer look that we have required since *Posadas* comports better with the purpose of the analysis set out in *Central Hudson*, by requiring the State to show that the speech restriction directly advances its interest and is narrowly tailored."). That opinion noted that the Court had adopted a more rigorous approach since *Posadas* and had "declined to accept at face value the proffered justification for the State's regulation, but examined carefully the relationship between the asserted goal and the speech restriction used to reach that goal." *Id.* at 531. Eight justices therefore rejected the "highly deferential approach" of *Posadas,* holding instead that "a state legislature does not have the broad discretion to suppress truthful, nonmisleading information for paternalistic purposes that the *Posadas* majority was willing to tolerate." *Id.* at 510.

Similarly, in *Greater New Orleans Broadcasting Assoc., Inc. v. United States*, the Court showed no signs of *Turner* deference in striking down a similar ban on advertising of casinos as a means of reducing gambling, even though it was "no doubt fair to assume that more advertising would have some impact on overall demand for gambling." 527 U.S. at 189; *see also Thompson*, 535 U.S. 357

(striking down a federal law prohibiting advertisements of certain compounded drugs); *Lorillard*, 533 U.S. 525 (striking down ban on advertising for tobacco products). Nothing in *Turner* suggests that the deference afforded congressional findings made in connection with content-neutral time, place, and manner restrictions should extend to legislative findings made in connection with statutes, such as Vermont Act 80, that are content-based restrictions on commercial speech.

Board of Trustees of State University of New York v. Fox, does not suggest otherwise. *Fox* predated both *Turner* and *44 Liquormart*. It addressed whether government restrictions must be the least restrictive means available in commercial speech cases. 492 U.S. at 471. While holding that the state need not choose "necessarily the single best disposition" or that "distinguishment is 100% complete," *id.* at 480, the Court afforded governmental decision-makers discretion only "*within th[e] bounds*" of narrowly tailored options. *Id.* (emphasis supplied). Even in that regard, the Court predicated its holding on the subsequently discredited opinion in *Posadas*. And the Court made clear that even the outer, and subsequently redrawn, boundary of acceptable fit outlined in *Fox* did not excuse *independent* review by the courts. The courts themselves had to assess the evidence supporting the restriction on speech, not merely acquiesce in the State's assessment. Thus, the Court stated, the cost of any restriction had "to be carefully

calculated," and the State had to "affirmatively establish the reasonable fit we require." *Id.*[10]

2. Even If *Turner* Applied to Content-Based Restrictions on Commercial Speech, Deference Is Inappropriate Here

Even in assessing a content-neutral provision in *Turner*, the Supreme Court scrutinized the process by which Congress reached its legislative findings before according deference. *Turner I*, 512 U.S. at 665-66. The Court noted that Congress had acquired considerable experience in broadcast and cable regulation over decades and had developed, over three years, tens of thousands of pages of evidence, including not only anecdotal testimony but also extensive studies, on which it based its legislative findings. In those limited circumstances, Justice Kennedy, writing for the majority on this issue, concluded that deference to the predictive judgments of Congress as to future events and the likely impact of these events was appropriate. *Id.* In this case, the Vermont Legislature does not have the same type of institutional expertise in regulating pharmaceutical marketing,

[10] The Court in *Fox* noted its previous suggestion in *San Francisco Arts & Athletics, Inc. v. United States Olympic Committee*, 483 U.S. 522, 537 n.16 (1987), that the First Amendment test for time, place, and manner restrictions and the *Central Hudson* test were "substantially similar." 492 U.S. at 477. The *San Francisco Arts* case, however, made clear that in that case, the "application to these facts is substantially similar." 483 U.S. at 537 n.16. The Court recognized in *Fox*, 492 U.S. at 478, and in subsequent cases, *see*, *e.g.*, *44 Liquormart*, 517 U.S. at 501 (explaining need to review commercial speech bans, which are "particularly dangerous," more carefully than content-neutral time, place, and manner restrictions), that the two lines of authority are distinct.

particularly the use of prescriber-identifiable data, as the FCC and Congress had in regulating the cable and broadcast industry in *Turner*.

Moreover, in the commercial speech context, case after case has emphasized the point the Court made in *Fox*, that the state must be "careful" in imposing a restriction on speech. *Fox*, 492 U.S. at 480; *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 (1993); *Lorillard*, 533 U.S. at 561. In this case, the Court excluded evidence regarding the legislative process, refusing to assess whether the Legislature exercised such care. SPA-64-66. As noted previously, that evidence showed a flimsy process compared to the years of Congressional and administrative study in *Turner*. The legislative record reflects that the Vermont Legislature first considered the matter in February 2007. After just three months, the Legislature was prepared to adopt a law similar to the New Hampshire law without any findings as to whether it would achieve important or compelling objectives. Moreover, during this time frame, testimony and evidence regarding the restriction on the use of prescriber-identifiable data focused on its connection to maintaining prescriber privacy, rather than reducing healthcare costs or improving public health. After the New Hampshire law was invalidated on April 30, 2007, the Vermont Legislature made material changes to its law (including adding the mandatory disclosures in Section 17(f) and an opt-in provision) and created findings over three days, allowing the legislature only hours

to review drafts that changed dramatically between each short committee session. A-1666-67; A-1674-80; A-1682; A-1688-94; A-1700-01; A-1719-26; A-1728-36; A-1746-54. Because the New Hampshire court had determined that prescriber privacy was not a substantial governmental interest, the focus of the findings switched to the State's other asserted interests, even though they had not been fully addressed in the prior hearings. As discussed previously, the findings were largely drafted not by legislative staff, but by outsiders with a stake in the legislation. And, as observed above, *see* pp. 17-24, they contained significant, substantive mistakes.

It was error for the District Court to exclude this evidence showing the flawed and abbreviated evolution of the legislative findings. PhRMA was entitled to show that the feverish, reverse-engineered drafting of the findings cast doubt not only on the reliability, but also on the substantiality of many of the statutory predicates for the legislature's action. PhRMA was entitled to show that the legislative process was not the careful weighing of interests mandated by the Supreme Court. And it was entitled to attack the legislative record on which the State relied, without being barred from inquiring into portions of the record – deemed "unofficial" – that undermine or subtract from the evidence advanced. The court should not have declined review of the deficiencies that mar the State's evidence.

All these issues aside, deference to the findings in Act 80 is inappropriate because those findings did not focus on the provision at issue in this case. The findings applied to *all* of Act 80, *including Section 17(f)* mandating that detailers who promoted their own company's products had to inform doctors about their competitors' products as well. The summary finding, Finding 31, appears on its face to connect this mandate to the goals of reducing healthcare costs and improving public health and to link prescriber-data restrictions *only* to the protection of physicians' privacy. *See* pp. 22-23, above. When the Legislature repealed Section 17(f), it neither made new findings, nor affirmed the continued applicability of the old ones in light of the amendment, nor provided the slightest indication that it had considered that issue. Thus, even if *Turner* controlled here, this court could not identify the "reasonable inferences" the Legislature drew nor the "substantial evidence" on which it relied with regard specifically to the restriction on prescriber-identifiable data. *Turner I*, 512 U.S. at 666. Under the circumstances, deference is not warranted.

C. Section 17 Does Not Directly Advance Substantial Governmental Interests

Under *Central Hudson*, limitations on commercial speech "must be designed carefully to achieve the State's goal" and "be in proportion to that interest." 447 U.S. at 564. Toward this end, "the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective

or remote support for the government's purpose." *Id.* It is decidedly the State's burden to "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. The State cannot carry this burden with "mere speculation or conjecture." *Id.*

1. Section 17 Does Not "Directly" Further the State's Objectives

In this case, the State itself argued that Section 17 was an "indirect" limitation on detailers' speech. SPA-15-16. And the speech of detailers, on the State's theory, predisposes doctors, when they make their independent decisions on what to prescribe, to specify brand-name drugs. And, the State contends, because brand-name drugs are usually more expensive and sometimes riskier than generic alternatives, these decisions, when honored by insurers and health programs, raise the cost of healthcare and undercut public health. There are many appropriate descriptions of this elongated chain of reasoning. "Direct" is not one of them. A law that *directly* advanced the State's interest in controlling costs would directly control costs. Section 17 does not mention costs. A law that *directly* advanced the State's interest in stemming perceived over-prescription of expensive drugs would directly regulate over-prescription of expensive drugs. Section 17 does not address prescribing practices.[11]

[11] The Vermont Legislature passed H.441 on May 9, 2009, which has two provisions that directly address prescribing practices for patients covered by state-

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Under *Central Hudson*, the Supreme Court has invalidated far more linear justifications than this one as "only indirectly advanc[ing] the state interest involved." 447 U.S. at 564; *see, e.g.*, *Va. State Bd. of Pharm.*, 425 U.S. at 766-68 (ban on advertising drug prices did not directly advance goals of professionalism among pharmacists and protection of patient health); *Bates v. State Bar of Ariz.*, 433 U.S. 350, 368, 377 (1977) (advertising ban did not directly protect quality of attorneys' work); *Rubin*, 514 U.S. at 477, 489-90 (prohibiting disclosure of alcohol content on beer labels did not directly further interest in reducing alcohol consumption); *44 Liquormart*, 517 U.S. at 505 ("[P]rice advertising ban will [not] significantly advance the State's interest in promoting temperance."). Section 17(d) cannot satisfy this branch of the *Central Hudson* test.

2. Section 17 Does Not "Materially" Further the State's Objectives

At trial, the State defended the constitutionality of Section 17 mainly through the testimony of five expert witnesses. None of these experts, however, supplied the missing link between a restriction on the use of prescriber-identifiable data for marketing and the State's asserted interests. The State's experts each

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funded insurance programs. First, Sec. E.307 "limit[s] payment for select drugs used as maintenance treatment to increments of 90-day supplies." Second, Sec. E.309.9 implements a therapeutic equivalency pilot program, which requires the use of over-the-counter or generic drugs for the treatment of certain conditions. The explicit purpose of this section is "to maximize the use of over-the-counter (OTC) and generic drugs."

acknowledged that they had not conducted any studies of the likely effects of restricting the use of prescriber-identifiable data for marketing. Nor were any of them aware of any such studies. A-257; A-294-95; A-351. In fact, all of the State's experts agreed that there is no empirical evidence available on the effects of prescriber-identifiable data. While two of the State's experts nonetheless speculated on the effects of the law, they admitted that they could not know from an empirical or evidentiary basis that the law would in fact reduce healthcare costs for the State without harming patient health. A-294-95; A-351. At trial, the State neither pointed to nor adduced any empirical evidence, anecdotal evidence, or even logical argument that restricting marketing with prescriber-identifiable data would lower drug costs. In place of that missing link, the District Court deduced that pharmaceutical companies would not use prescriber identifiable data if they did not increase sales, which increased costs because brand-name drugs are more expensive and increased risk, because new drugs are more dangerous. SPA-33. Even if the assumptions were correct, the Supreme Court again and again has held this precise rationale inadequate to justify a restriction on speech. *See, e.g.*, *Va. State Bd. of Pharm.*, 425 U.S. at 770 (restriction on speech cannot be justified by desire to suppress the flow of truthful information); *Thompson*, 535 at 374 (rejecting paternalistic desire to protect consumers from truthful information); *44*

Liquormart, 517 U.S. at 503 (protecting consumers from truthful speech is not a substantial government interest).[12]

Thompson v. Western States is directly on point. The government there offered a similar rationale for a ban on advertising of compounded drugs, 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. The Court rejected the rationale. It noted that the concern rested first "on the questionable assumption that doctors would prescribe unnecessary medications," and second, on a "fear that people would make bad decisions if given truthful commercial information about compounded drugs." *Id.* The Court underscored that it had repeatedly "rejected the notion that the Government has an interest in preventing the dissemination of truthful information in order to prevent members of the public from making bad decisions with the information." *Id.* Further, absent any allegation that the advertisements were misleading, the Court disallowed the argument that people seeing them would be "confused about the drugs' risks." *Id.* at 376.

[12] Even if the State's expert opinions were not mere speculation, the other evidence presented outweighed them. Experts with far greater experience and qualifications in the fields of medicine, economics, and pharmaceutical marketing gave testimony expressly contradicting the opinions of the State's experts or otherwise called their opinions into doubt. *See*, *e.g.*, A-141; A-148; A-174-80; A-183-84. The District Court did not cite at all to PhRMA's experts.

Here, as in *Thompson*, the State cannot substitute paternalism for empirical evidence. Yet paternalism – the notion that highly-trained physicians cannot be trusted to make the appropriate decisions for their patients – is, at bottom, the only connection the State offers between prescriber-identifiable data and the costs of healthcare and the protection of public health. The State's implicit assumption that it knows best what doctors should hear and prescribe is particularly untenable here. It would turn the First Amendment on its head to allow a ban on truthful speech on the ground that it is persuasive.

The State's alternative theory for upholding the law is that it directly and materially advances the privacy interests of prescribers. Protection of prescriber privacy is not a substantial state interest. *Ayotte*, 490 F. Supp. 2d at 179-80; *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 172 (2008). But even if it were, Section 17 does not directly and materially advance it. Section 17 allows disclosure of prescriber information for a whole host of purposes, commercial and non-commercial, including pharmacy reimbursement, formulary compliance, patient care management, utilization review by a health care professional, the patient's health insurer, or the agent of either, health care research, the dispensing of prescription medications to a patient or the patient's authorized representative, and certain pharmacy file transfers. A-4064-65; A-4075. The statute is not "part of a substantial effort to advance a valid interest;" rather, the most it accomplishes

is "the removal of a few grains of [non-private] sand from a beach of" unfettered disclosure of prescriber-specific information. *See Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 100 (2d Cir. 1998).

D. The Restrictions on the Use of Prescriber-Identifiable Data Do Not Present a Reasonable Fit with the State's Asserted Interests

The fourth step in the *Central Hudson* test requires the State to demonstrate a reasonable fit between the Legislature's ends and the means chosen to accomplish them; in other words, that the means are narrowly tailored to achieve the desired objective. *Lorillard*, 533 U.S. at 528; *Bad Frog*, 134 F.3d at 100-01. In applying this prong, the Supreme Court has made clear that if the state can achieve its interests in a manner that restricts less speech, it must do so.[13] *Thompson*, 535 U.S. at 373 ("If the First Amendment means anything, it means that regulating speech must be the last – not first – resort.").

[13] *See Rubin*, 514 U.S. at 490-91 (invalidating law prohibiting beer labels from displaying alcohol content in view of available alternatives "such as directly limiting the alcohol content of beers, prohibiting marketing efforts emphasizing high alcohol strength . . ., or limiting the labeling ban only to malt liquors."); *44 Liquormart*, 517 U.S. at 507, 530 (invalidating ban on advertising price of alcoholic beverages in part because alternatives that would not restrict speech, such as increased taxation, limits on purchases, and education campaigns, would be more likely to achieve the state's goal of promoting temperance); *Bad Frog*, 134 F.3d at 101 (enjoining rejection of application for beer label depicting a frog extending its finger, because label prohibition was broader than necessary to serve state's goal of shielding minors from vulgarity; alternatives included restrictions on placement of beer advertisements in places where children were likely to see them); *N.Y. State Ass'n of Realtors, Inc. v. Shaffer*, 27 F.3d 834, 844 (2d Cir. 1994) (enjoining regulation against solicitation of real estate listings, intended to prevent "blockbusting," where Secretary failed to show that use of cease and desist orders on an individualized basis would be inadequate).

In *Central Hudson*, the Supreme Court characterized this as the "critical inquiry in the case: whether the Commission's complete suppression of speech ordinarily protected by the First Amendment is no more extensive than necessary to further the State's interest in energy conservation." 447 U.S. at 569-70. In that case, the Commission's order banned "all promotional advertising, regardless of the impact of the touted service on overall energy use." *Id.* at 570. Even though the state's interest in energy conservation was substantial, it could not "justify suppressing information about electric devices or services that would cause no net increase in total energy use." *Id.* The Court further explained why the challenged order did not sufficiently "fit" the state's asserted interest:

> The Commission's order prevents appellant from promoting electric services that would reduce energy use by diverting demand from less efficient sources, or that would consume roughly the same amount of energy as do alternative sources. In neither situation would the utility's advertising endanger conservation or mislead the public. *To the extent that the Commission's order suppresses speech that in no way impairs the State's interest in energy conservation, the Commission's order violates the First and Fourteenth Amendments and must be invalidated. See First National Bank of Boston v. Bellotti*, 435 U.S. 765 (1978).

Id. (emphasis supplied).

Vermont's restrictions on the use of prescriber-identifiable data by pharmaceutical manufacturers for marketing purposes presents a similarly poor fit with the State's asserted interests. Marketing with prescriber-identifiable data is a

subset of all marketing undertaken by the pharmaceutical industry. The law's restriction on the use of prescriber-identifiable data is a poor fit because it is both over- and under-inclusive. It sweeps in detailing that is appropriate and useful, thereby suppressing speech that is broader than required to accomplish the State's purported interests. The Act applies even when there is no generic available for the condition that the brand-name drug treats, even when the brand-name drug is not the most expensive treatment, even when the brand-name drug is a medical breakthrough or the only, or most effective, treatment for a particular disease, and even when the use of a brand-name drug would reduce overall medical costs. A-175; A-177; A-182. But it also fails to restrict any detailing that is not undertaken with prescriber-identifiable data, even if that detailing would lead to the prescription of newer, more expensive brand-name drugs. Although the State's experts identified the marketing of new drugs in general (and a handful of specific drugs in particular) as a concern, the law bans the use of prescriber-identifiable data in connection with the marketing of all prescription drugs, both new and old.

The Supreme Court in *Thompson* found just this sort of imprecision to be a fatal constitutional flaw. For one, the Court noted, "Forbidding the advertisement of compounded drugs would affect pharmacists other than those interested in producing drugs on a large scale," who were the source of concern. 535 U.S. at 376. Moreover, much as a detailer in this case who used prescriber data could not

tell a doctor about a new development, the Court worried in *Thompson* that "a pharmacist serving a children's hospital where many patients are unable to swallow pills would be prevented from telling the children's doctors about a new development in compounding that allowed a drug that was previously available only in pill form to be administered another way." *Id.* at 377.

This flaw, this overreaching to restrict speech that is unobjectionable even on the State's theories, is exacerbated by the availability of obvious alternatives that would more directly address the State's asserted interests and that the Vermont Legislature itself recognized were available and untested. In the very same bill that contained the Vermont Law, the Legislature voted to fund an academic detailing program that it created years ago. This program, through the University of Vermont College of Medicine, would serve to educate doctors about the State's views on the appropriate prescription of brand-name and generic drugs. A-191; A-268-69; A-282-83; A-3123. This alternative is consistent with the admonition that "the remedy to be applied is more speech, not enforced silence." *Whitney*, 274 U.S. at 377. Yet, Vermont has not given this program a chance to work before enacting a restriction on speech. The Legislature heard testimony while considering Vermont Act 80 that academic detailing could reduce prescription

drug spending by two dollars for every one dollar invested.[14] A-1255. Academic detailing thus would directly and materially advance both the State's asserted interests in protecting public health and in reducing healthcare costs.

Vermont Act 80 also established a program to distribute vouchers for samples of generic drugs equivalent to frequently prescribed prescription drugs that are used to treat common health conditions. The House Ways and Means Committee estimated that spending $270,000 on generic vouchers could save the State more than $27 million annually. A-4351. This program is just getting underway and, if effective, may obviate entirely the need for imposing restrictions on speech. Moreover, providing vouchers for generic drugs would more directly and materially advance the State's asserted interests in reducing healthcare costs and protecting the public health.

Vermont has in place already several other laws and programs aimed at reducing healthcare costs that have not been shown to be ineffective at further reducing costs if properly managed or funded. Generic substitution laws enacted by a number of states, including Vermont, limit the instances in which brand-name drugs can be prescribed and dispensed. The law in Vermont, for example,

[14] The State's excuse for not relying on academic detailing was that the State could not afford it. This rationale does not hold up given the testimony of the State's own witness that the return on the State's investment would be 100%. But even if the State itself could not fund such a program, insurers have both the resources and the economic incentives to finance such programs.

provides that when a drug is available in both brand-name and bioequivalent generic form, the pharmacist must fill the prescription with the lowest cost drug, unless the prescriber specifies otherwise. 18 V.S.A. § 4605. As a consequence, when a bioequivalent generic is available, the generic is prescribed to Vermont Medicaid patients 97.7% of the time. A-310.

Vermont has in place a pharmacy best practices program that operates to lower healthcare costs in the state, and which includes establishment of a Preferred Drug List for Medicaid recipients by the Vermont Drug Utilization Review Board. 33 V.S.A. § 1998; A-283; A-286-87; A-3031-33: A-3043; A-3065; A-3071. The Drug Utilization Review Board also approves automated step therapies to encourage the use of first-line therapies, which often require the use of generic drugs. A-2454-55; A-3051-52. Vermont also utilizes prior approval processes to reduce drug costs. A-2503-07; A-3065.

Vermont participates in the Sovereign States Drug Consortium with other states in order to negotiate favorable supplemental rebates with pharmaceutical companies. 33 V.S.A. § 1998; A-3066-67. A Vermont law requires that prescribers of prescription drugs be alerted when the patent of a particular drug has recently expired or is due to expire. *See* 18 V.S.A. § 4622(a)(2). Vermont also has a best practices program that prepares and distributes best practice guidelines that educate healthcare providers about the appropriate use of generic drugs. A-3123.

The State also could address its concern that targeted marketing has an undue influence on prescribers by, for example, requiring prescribers to receive training about marketing as a continuing medical education requirement; using "Dear Doctor" letters to educate prescribers; using more comprehensive drug formulary tools; and supporting industry ethical codes, among existing alternatives. Even the State's own expert, Dr. Kesselheim, admitted that these alternatives constituted more direct ways to influence a doctor to prescribe more generic drugs. A-353-54. And if the State was concerned, as the District Court noted, about the *covert* use of prescriber data in marketing, SPA-29-31, the State could have required disclosure to a physician if the detailer was relying on such data. The State never considered that option. This, and the other examples, are all more direct, less restrictive of speech, and more likely to be an effective means of ensuring prescribers are prescribing the appropriate medications for their patients.

The District Court failed to analyze any of these less restrictive alternatives, brushing aside the inquiry with the observation that "Plaintiffs' laundry list of alternative ways the Legislature could have advanced its substantial interest in protecting public health is irrelevant." SPA-34. The court stated that the restriction on use of prescriber-identifiable data for marketing was "a targeted response to the harm of overprescription caused by detailers' use of [prescriber-identifiable] data." SPA-37. This reasoning is circular. The objectives defined in

Act 80 are lowering health care costs and protecting public health, not curbing "overprescription caused by detailers' use" of prescriber-identifiable data. If it were permissible to redefine the statutory objective by reference to the target of the restriction on speech, every restriction would be narrowly tailored. The restriction on outdoor advertising of tobacco struck down in *Lorillard* would be a targeted response to tobacco use caused by outdoor advertising. The restriction on the advertising of the price of alcohol struck down in *44 Liquormart* would be a targeted response to alcohol use caused by advertisements of pricing.

The District Court's circular reasoning evaded the inquiry, the availability of other means of meeting a state's goals, that the Supreme Court has regarded as not merely relevant, but critical. *Thompson*, 535 U.S. at 373. The last four Supreme Court cases on commercial speech have each struck down restrictions on speech precisely because of the poor fit and availability of alternative means of regulation. *See Thompson*, 535 U.S. at 376-77; *Lorillard*, 533 U.S. at 561, 567; *Greater New Orleans*, 527 U.S. at 189-90; *44 Liquormart*, 517 U.S. at 507.

The failure to undertake this "critical inquiry" into fit required by *Central Hudson* is an error of law. The clear and ready availability of options that would further the State's interests while not suppressing speech dictates reversal of the decision and entry of an injunction. At a minimum, this Court should remand to

the District Court with instructions to undertake the "critical inquiry" as instructed by *Central Hudson* and its progeny.

CONCLUSION

For the reasons set forth above, the judgment of the District Court should be reversed. Section 17 of Vermont Act 80, as amended by Vermont Act 89, should be permanently enjoined because it restricts the speech of pharmaceutical manufacturers and fails intermediate scrutiny under *Central Hudson*.

Respectfully submitted,

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