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

REPLY BRIEF FOR PLAINTIFF-APPELLANT PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

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SUMMARY OF THE ARGUMENT

The State of Vermont has sought to restrict truthful speech by pharmaceutical companies regarding the use of prescription drugs to cure and ameliorate illness, because the State fears that medical professionals will respond with inappropriate prescribing decisions. The approach disregards First Amendment principles that have protected speech of incomparably less social value.

The First Amendment shields even the most false and repugnant speech from government regulation because we as a Nation believe that the "best test of truth is the power of the thought to get itself accepted in the competition of the market." *Abrams v. United States*, 250 U.S. 616, 630 (1919) (Holmes, J. dissenting). The cornerstone of our approach is the *freedom* of that market from governmental stricture, reflecting the premise that in "an *uninhibited* marketplace of ideas . . . truth will ultimately prevail." *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 390 (1969) (emphasis added); *see also Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 765 (1976) ("It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end, the *free flow* of commercial information is indispensable.") (emphasis added). As Judge Learned Hand restated this fundamental tenet, the First Amendment "presupposes that right conclusions are more likely to be

gathered out of a multitude of tongues, than through any kind of authoritative selection." *United States v. Associated Press*, 52 F. Supp. 362, 372 (D.C.N.Y. 1943).

Nevertheless, in this case involving truthful communications on medical issues, the State of Vermont has abandoned this bedrock First Amendment precept. Instead, the State has embraced "the offensive assumption that the public will respond 'irrationally' to the truth." *44 Liquormart, Inc. v. Rhode Island,* 517 U.S. 484, 503 (1996). Deeming the marketplace of ideas for prescription drugs "one-sided," A-4040 (Act 80, § 1(4)), Vermont made just the kind of "authoritative selection" that Judge Hand found objectionable. The State sought to restrict the marketing of pharmaceuticals to doctors because it perceives that those communications are effective. No matter how benign the State's intentions, the suppositions underlying this legislation and pervading the briefs of the State and its amici – that government knows best, that medical professionals cannot handle the truth, that certain disfavored speech by certain disfavored speakers has scant social value – cannot justify the abridgment of free speech.

The State's failure to grapple with this central issue is apparent in its relegation of the controlling case, *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), to one cursory reference devoid of analysis. The District Court, too, in its 61 page opinion, cited this important case only once, also without

discussion. Nonetheless, in reaffirming the centrality of a free marketplace of ideas, *Thompson* disposes of this case. The Supreme Court held that a restriction on drug advertising could not rest on the "questionable assumption that doctors would prescribe unnecessary medications." 535 U.S. at 374. Further, the Court found, the government does not have a valid "interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information." *Id.* That assumption is central to the State's case here. Perhaps most critically, the Court in *Thompson* dismissed the justification that the advertising could confuse patients, because the Government did not argue that the ads were misleading. So, too, here, the record contains no evidence that marketing with prescriber-identifiable data is anything other than truthful and non-misleading, *cf.*, *e.g.*, A-213-14 (explaining restrictions on sales representatives' speech to doctors), and the State makes no argument to the contrary.

The State and the District Court likewise disregarded the Supreme Court's decision in *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173 (1999). There the Supreme Court ruled that a government seeking to restrict speech must rule out possible "non-speech" alternatives. Here, far from ruling out such alternatives, the State deems it sufficient to label them "a list of

possible ways to improve health care outcomes and reduce health care spending." Vt. Br. at 108.

Finally, the District Court deferred to the Legislature's judgments insofar as they were reasonable and based on substantial evidence. The Supreme Court's most recent cases on commercial speech, however, inquire not whether the legislature was reasonable, but whether it "carefully calculate[d] the costs and benefits associated with the burden on speech." *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 561 (2001) (quotations omitted); *Greater New Orleans*, 527 U.S. at 188. Moreover, in determining whether the government exercised the requisite care to avoid unduly impairing First Amendment rights, the Supreme Court in *Lorillard* specifically focused on the "process by which" the government reached its judgments. 533 U.S. at 562. Here, the District Court excluded precisely such evidence offered to show that the process by which the Vermont Legislature reached its judgments cast their reliability and reasonableness into doubt.

In short, if the Vermont Legislature believed that the speech of pharmaceutical manufacturers had achieved undue predominance in the marketplace of ideas, the remedy was to promote more speech, not to obstruct the speech the State disfavored.

ARGUMENT

I. Vermont Improperly Constrains the Free Marketplace of Ideas

A. The Vermont Legislature Abridged the Speech of Pharmaceutical Manufacturers

Throughout its brief, the State downplays the express purpose of Act 80 – to restrict the speech of pharmaceutical manufacturers. The Legislature, by contrast, was not so reticent. It unabashedly proclaimed its goal of regulating the "marketplace for ideas on medical safety and effectiveness," A-4040 (Act 80, § 1(4)), imposing what it viewed as "balance" by limiting the speech of disfavored speakers – pharmaceutical manufacturers. *See also* A-4062-63 (Act 80, § 17(a)). Indeed, according to the State's own expert, the way Act 80 would achieve the State's asserted goals was by reducing the advertising component, but not the educational component, of sales representatives' messages to doctors, A-354 – in other words, by changing the speech of detailers. Another witness for the State likewise admitted the intended impact on communications, noting that Act 80 would have affected his discussions with doctors when he was a sales representative. A-336.

The District Court took the Legislature's articulated goal at face value and found that Act 80 restricted the speech of pharmaceutical manufacturers. *See* SPA-14-16 ("Plainly, the whole point of section 17 is to control detailers' commercial message to prescribers."). Every judge who has addressed similar restrictions on

the use of prescriber-identifiable data has agreed that they constrain the speech of pharmaceutical companies. *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 53 (1st Cir. 2008); *id.* at 65 (Lipez, J., dissenting); *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163, 175 (D.N.H. 2007); *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153, 167 (D. Me. 2008). Even the Court in *Ayotte* agreed, notwithstanding that the law, unlike Act 80, addressed only upstream transactions between pharmacies and publisher plaintiffs. *Compare* 18 V.S.A. § 4631(d) *with* N.H. Rev. Stat. Ann. § 318:47-f.

Vermont and its amici can neither validate the acknowledged objective of Act 80 nor evade First Amendment scrutiny by characterizing prescriber-identifiable information as simply a "marketing tool." *See* Vt. Br. at 9, 54; AARP Br. at 18, 21; NEJM Br. at 26-27. In evaluating governmental efforts to regulate the content of private speech, courts have focused on the substance of the regulation, not its form. And the issue of substance under the First Amendment is whether the restriction the State imposed was designed to regulate the "communicative impact" of speech. *See Lorillard*, 533 U.S. at 567 (striking down law that restricted the height at which indoor tobacco advertising could be placed); *see also U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir. 1999) (restriction on use of data to target customers is a restriction on speech).[1] Here, regulating the

[1] Nor would it be appropriate to analyze Act 80 under the intermediate scrutiny designed for content-neutral time, place, and manner restrictions, as the restrictions

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"communicative impact" of detailers' discussions with doctors – making the communications less effective by, among other things, preventing use of prescriber data to tailor marketing messages to individual prescribers – was, as the District Court found, SPA-16, precisely what the Legislature sought to do. *See* A-4062-63 (Act 80, § 17(a)) ("It is the intent of the general assembly . . . to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.")

Indeed, the State's brief echoes this rationale, justifying the restriction on the ground that "detailing works." Vt. Br. at 88. The implication is unmistakable. Vermont curtailed the use of prescriber-identifiable data because the State believed the data helped to make marketing of disfavored pharmaceuticals more effective, requiring the intervention of the State to shield doctors from these persuasive forces.

B. Vermont's Abridgement of Free Speech Improperly Hinged on the Content of the Speech and the Identity of the Speaker

One fact leaps from Act 80 and the State's brief supporting it – the State disapproves of pharmaceutical marketing. Act 80 specifically states that "The

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here are content-based. *See Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 429-30 (1993).

goals of marketing programs are often in conflict with the goals of the state." A-4040 (Act 80, § 1(3)). It charges further that, "Public health is ill served by the massive imbalance in information presented to doctors and other prescribers." *Id.* (Act 80, § 1(6)). The State's brief cites the ostensibly "disproportionate role" of "commercial forces . . . in shaping [doctors'] knowledge and prescribing decisions," Vt. Br. at 89, and asserts that manufacturers "'over-influence' physicians' prescribing practices and accelerate a new drug's uptake." *Id.* at 99. Thus, Act 80 prohibits the use of prescriber-identifiable data only by pharmaceutical manufacturers seeking to promote their products, and not by other speakers in the marketplace pursuing other commercial or noncommercial objectives. *See* 18 V.S.A. § 4631.

In conflict with Act 80, the core of the First Amendment is the "neutrality" principle, requiring the government to avoid favoritism in the marketplace of ideas. *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 505 (1984). As the Court held in *Police Department v. Mosley*, 408 U.S. 92, 95 (1972), "[a]bove all else, the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter, or its content." *See also Greater New Orleans*, 527 U.S. at 194 ("[D]ecisions that select among speakers conveying virtually identical messages are in serious tension with the principles undergirding the First Amendment."); *Rosenberger v. Rector & Visitors*

of Univ. of Va., 515 U.S. 819, 829 (1995) ("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."). Content-based restrictions are "presumed to be unconstitutional," and courts routinely strike them down. *Rosenberger*, 515 U.S. at 828.

Although Act 80 targets only those who engage in speech with which the State disagrees, the State argues that the law is not viewpoint-based because it restricts generic manufacturers as well as brand-name pharmaceutical manufacturers. Vt. Br. at 66-67. But the Act is predicated on the economic reality that generic manufacturers do not detail or use prescriber-identifiable data. A-188; A-336. Nor is the State correct that any regulation of commercial speech – assuming, for now, the correctness of that designation here – inherently differentiates it from non-commercial speech. *See* Vt. Br. at 67. Entirely within the realm of commercial speech, Act 80 distinguishes among commercial speakers, based on the content of their messages. *See* A-4064-65 (Act 80, § 17(e)); *cf.*, *e.g.*, A-123 (insurance companies pressure doctors to prescribe cheaper generic medications); A-188 (insurance companies use prescriber-identifiable data); A-298-99 (pharmacy benefit managers and HMOs use prescriber-identifiable data). Even makers of dietary supplements and homeopathic remedies could use

prescriber-identifiable information if they so chose in marketing their products to doctors.

The Act, in short, seeks to counteract the perceived "imbalance" in the marketplace of ideas by impeding the communications of one set of participants. First Amendment precedent has consistently taught, however, that the remedy for disfavored speech is more speech, not suppression, and that the First Amendment promotes discussion, not coercion. *See Va. State Bd. of Pharmacy*, 425 U.S. at 770. Vermont failed to heed those lessons.

C. Vermont's Abridgement of Free Speech Cannot Survive Constitutional Scrutiny Under *Central Hudson*

To sustain such a restriction of speech based on the viewpoint and identity of the speaker, Vermont, at the very least, had to satisfy the standard set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). In ruling that Vermont had met that test, the District Court not only misunderstood *Central Hudson*, but also overlooked the most recent decisions of the Supreme Court applying it. In the last 10 years, the Supreme Court has decided three cases involving restrictions on commercial speech. *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); *Greater New Orleans Broadcasting Ass'n, Inc. v. United States*, 527 U.S. 173 (1999). In each, the Court struck down the restriction. In each, the Court noted the inclination of several Justices – including four of the

current members of the Court – to repudiate the *Central Hudson* standard in favor of a "more straightforward and stringent test for assessing the validity of governmental restrictions on commercial speech." *Greater New Orleans*, 527 U.S. at 184; *see Thompson*, 535 U.S. at 367-68; *Lorillard*, 533 U.S. at 554. And in each, the Court found it unnecessary to take that step because, "*Central Hudson*, as applied in our more recent commercial speech cases, provides an adequate basis of decision." *Greater New Orleans*, 527 U.S. at 184 (emphasis added); *see Thompson*, 535 U.S. at 368 (quoting *Greater New Orleans*); *Lorillard*, 533 U.S. at 554-55 (same);.

The District Court, the State, and the State's amici essentially ignore these "more recent commercial speech cases," relying instead on the older decisions that the Court implied of late do not adequately protect First Amendment rights. *See, e.g.*, Vt. Br. at 68-74, 105-06. But where, as here, the speech at issue is not false or misleading, the Supreme Court, while leaving open the prospect of a stricter test, has required the government to prove at a minimum that any restriction on that speech directly advances a substantial state interest and is no "more extensive than is necessary to serve that interest." *Thompson*, 535 U.S. at 367 (quoting *Central Hudson*, 447 U.S. at 566).[2]

[2] Amicus AARP contends that Supreme Court precedent breaks down into categories depending on whether the speech involves private or public communications and whether the impact of the speech is private or public. AARP

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1. Act 80 Does Not Directly Advance Substantial State Interests

The State does not contend that Act 80 only addresses false or misleading pharmaceutical marketing. Nor does the State carry its burden of showing that its asserted interests in restricting truthful and non-misleading marketing are substantial. *See* PhRMA Br. at 43-49. Rather, by design or misapprehension, the State's brief proffers the notion of medical privacy as a justification for Act 80. The concept is an blurred amalgam encompassing the privacy of patient records – which is irrelevant given that the data pharmaceutical companies receive is stripped of information identifying patients – and the ostensible privacy of doctors' prescribing patterns.

No court, including the court below, has held that a physician or other health care provider has a protected privacy interest in the prescribing decisions that he or she makes in the workplace. *See* SPA-23. And even if there were such an interest, Act 80 fails to protect it. The Act allows wide use of doctors' prescribing histories, A-4064-65 (Act 80, § 17(e)), including by pharmaceutical companies for purposes other than marketing their drugs. Under the Act, moreover, *Consumer Reports* or

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Br. at 16. The Court has never adopted such categories. Instead, as noted above, the Supreme Court's precedent relies squarely on the *Central Hudson* analysis for all commercial speech restrictions. There is no logical reason, moreover, to distinguish between a regulation restricting a company's conversations with 1,000 doctors, and a regulation restricting a single communication by the company – an email, a broadcast, a brochure – that reaches 1,000 doctors.

equivalent periodicals could reprint this information in articles rating doctors. Groups opposed to the use of certain drugs could publish doctors' prescribing histories in the newspaper. And pharmacies could post prescribing histories to inform their customers where to find doctors experienced with particular products. In short, medical privacy is merely a different label, a misnomer, for the express inclination against one set of participants in the marketplace of ideas – brand-name pharmaceutical companies.

Even assuming the State's other asserted interests – reducing medical costs and protecting public health – are substantial, Act 80 still fails *Central Hudson* because, as a matter of logic and fact, the State cannot prove that Act 80 *directly* advances those interests. If, as the State asserts, over-prescription of brand name drugs raises costs and undermines safety, then, logically, the *direct* way to advance the State's interests would be to regulate doctors' prescribing decisions *directly*. Act 80 does not do that. Rather,

→ it limits the information pharmaceutical companies can use,

→ in order to affect the information doctors receive,

→ in order to affect, in turn, doctors' prescribing decisions.

Even the District Court below recognized that the Act pursues its goals only indirectly. SPA-16 ("The Court strains to understand how section 17 would control cost and protect health without the '*indirect*' effect on detailers' speech."

(emphasis added)). In *Thompson*, the Supreme Court found that a similar provision preventing pharmacists from advertising compounded drugs did not directly advance the government's interest in keeping those drugs from people who did not need them. Though the restriction was far less circuitous than Act 80, the Court still found it deficient because it did "not directly forbid such sales." 535 U.S. at 376.

Between the restriction Act 80 imposes on communications to doctors and the prescription of a drug to patients, there is interposed, necessarily, the doctors' independent medical judgment. By definition, this intermediate step renders the regulation of communications to doctors an indirect route to the State's objectives. But the infirmity and unwieldiness of the State's reasoning runs deeper still. To establish, as required, that restricting speech is effective in achieving the legislative goals, *see Central Hudson*, 447 U.S. at 566, 569, the State must show that marketing with prescriber-identifiable data leads doctors to exercise their independent judgment incorrectly, to over-prescribe brand name drugs. In *Thompson*, the Court addressed the directly parallel argument that the restrictions on speech there "were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway." 535 U.S. at 374. The Court branded the rationale "paternalistic," deemed "questionable" the "assumption that doctors

would prescribe unnecessary medications," and "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." *Id.* Moreover, in a ruling that is dispositive here, the Court disallowed the Government's asserted "interest in banning the advertising of compounded drugs because patients who see such advertisements will be confused about the drugs' risks." *Id.* at 376. The Government's proffered justification, closely parallel to the one the State advances here, was "*precluded . . . by the fact that the Government does not argue that the advertisements are misleading*." *Id.* (emphasis supplied).

The State sidesteps this holding and asserts that Act 80 is not paternalistic because doctors can consent to being marketed with prescriber-identifiable data. Vt. Br. at 67-68. This response, however, misses the point. *Thompson* and other modern commercial speech cases disallow the central premise underlying Act 80, that doctors will prescribe drugs improperly unless the State insulates them from communications by pharmaceutical companies. That some doctors can elect to receive communications from detailers using prescriber data does not nullify or even ameliorate that paternalistic premise. In *Thompson*, the doctors (and patients, for that matter) also could have opted in – they could have gone to the pharmacist and asked for information on available compounded drugs. Indeed, with regard to nearly every limitation of commercial speech, potential listeners can take their own

affirmative steps to obtain the information suppressed. That does not negate the paternalistic predicate of the restriction on speech, which the Supreme Court rejected in *Thompson*. 535 U.S. at 374; *see 44 Liquormart*, 517 U.S. at 503 ("[B]ans against truthful, nonmisleading commercial speech [cannot] rest solely on the offensive assumption the public will respond 'irrationally' to the truth.").

Nor does the State's repeated disparagement of the use of prescriber-identifiable data as "covert" have significance under the First Amendment. Doctors know that sales representatives addressing them are employed by pharmaceutical companies to promote prescription drugs the companies manufacture.[3] Whether doctors know that the sales representatives are relying on prescriber-identifiable data is irrelevant, so long as the information conveyed is truthful. Here, there is no evidence in the record, and the State does not contend, that detailing with prescriber-identifiable data makes the communications false or misleading.[4]

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[3] Indeed, doctors can opt out of having any discussion with sales representatives if they do not believe the detailer is providing valuable information or if they believe that they are being unduly influenced by the speech. A-125; A-173; A-299; A-3058.

[4] In fact, the record shows the contrary – that pharmaceutical manufacturers have comprehensive policies and procedures to ensure that communications to physicians are truthful and not misleading. *See* A-3156-57; A-3159; A-3161; A-3282-90; A-3336-37; A-3409-10; A-3441; A-3479-81; A-3633; A-3649-50; A-3657.

In fact, characterizing the use of prescriber-identifiable data as "covert" is not only irrelevant, but disingenuous. The use of prescriber-identifiable data for pharmaceutical marketing is well-known and widely publicized. In normal discourse, speakers do not relate what underlies their speech. Advertisers do not disclose to their audiences the market research that shaped the ads. And sales representatives do not disclose to customers their educational background or training. This argument, too, cannot excuse the State from establishing that its restriction on the use of prescriber-identifiable data directly advances the State's interests.

2. Act 80 Is Not Narrowly Tailored

The State also fails to cite *Greater New Orleans Broadcasting*, another of the trilogy of recent commercial speech cases. 527 U.S. 173. That case disposes of the arguments concerning the fourth factor under *Central Hudson* – the fit between the State's objectives and the means chosen to advance them. The Supreme Court in *Greater New Orleans* struck down statutes barring advertising of casino gambling in jurisdictions that allowed such gambling. A central constitutional flaw the Court found in those statutes was that they intruded on speech more than was necessary to advance the Government's interests. The statutes failed this test in two ways.

First, they "sacrifice[d] an intolerable amount of truthful speech," and "distinguishe[d] among the indistinct, permitting a variety of speech that poses the same risks the Government purports to fear, while banning messages unlikely to cause any harm at all." 527 U.S. at 195. In other words, the statutes were both over- and under-inclusive. The same is true here. Act 80 does not reach detailing that induces over-prescribing, so long as the detailer eschews use of prescriber-identifiable data in the process. At the same time, Act 80 does reach, and constrains, detailing that does *not* induce over-prescribing, where, for example, the brand-name drug is the appropriate product to prescribe, or where there is no generic substitute. A-182.

Second, the Court in *Greater New Orleans* found that there "surely are practical and nonspeech-related forms of regulation . . . that could more directly and effectively alleviate some of the social costs of casino gambling." 527 U.S. at 192. The Supreme Court listed a number of hypothetical alternatives as a basis for finding that the government could not satisfy this prong of the *Central Hudson* test. *Id.* at 193. The Court took a similar approach in *Thompson*. In fact, after proffering several "non-speech related means of drawing a line between compounding and large-scale manufacturing [that] *might be possible here*," the Court faulted the Government for not offering "any reason why these *possibilities*,

alone or in combination would be insufficient" to satisfy the Government's interests. 535 U.S. at 373 (emphasis supplied).

By contrast, in this case, far from imposing the burden on the Government to rule out less restrictive alternatives, the State, as well as the District Court, brushed off the multiple, direct, non-speech-related alternatives to influence doctors' prescribing habits, which plaintiffs had identified. The State dismisses those alternatives with the *non sequitur* that they are "nothing more than a list of possible ways to improve health care outcomes and reduce health care spending." Vt. Br. at 108; *see also* Vt. Br. at 86 (asserting "substantial interests in reducing health care costs and protecting public health"). In fact, the alternatives identified by plaintiffs were far more specific and concrete than the "possibilities" that the Supreme Court in *Thompson* required the Government to rebut. Nevertheless, the State here does not even attempt to rebut plaintiffs' evidence that each of those alternatives would address the State's articulated goals of reducing health care costs and protecting public health more directly, while intruding on speech less, than Act 80 does. *See* PhRMA Br. at 52-55.[5] This treatment of these less restrictive alternatives seriously

[5] For example, Joshua Slen, then Director of the Office of Vermont Health Access, testified that including a drug on Vermont's preferred drug list directly affected the amount of the drug prescribed in Vermont. A-3052 (adding Lunesta to list increased its market share and decreased that of competitor products). Mr. Slen also explained that Nexium, a drug the State highlights in its brief, was removed from the preferred drug list. A-3054. Subsequently, the market share of Nexium dropped from 39% in the first quarter to 8% in the third quarter of 2006, saving the State $272,277. A-2458.

misreads the Supreme Court precedent. It interprets a test that excuses the State from eliminating *every* alternative approach as excusing the State from eliminating *any* of them. *See Thompson*, 535 U.S. at 373; *see also* PhRMA Br. at 49 n.13.

In *Lorillard Tobacco Co. v. Reilly*, one of the Supreme Court's most recent commercial speech cases, the Court again emphasized the requirement of a reasonable fit. Even though the Court found that the State's interest there in preventing underage use of tobacco was "substantial, and even compelling," the decision invalidated a ban on outdoor advertisements of tobacco products within 1000 feet of a school. In the Court's judgment, this restriction swept more broadly than necessary to advance that interest, infringing on manufacturers' "interest in conveying truthful information about their products to adults, and adults['] . . . corresponding interest in receiving truthful information about tobacco products." 533 U.S. at 564. In this case, too, Act 80 curtails much speech by detailers that does not, even under the State's rationale, raise costs or undermine public health. A-148-49; A-179-83.

The Court in *Lorillard* also reversed the First Circuit's determination that a five foot height restriction for point-of-sale tobacco – based on the assumption that minors under five feet tall would not raise their view above eye level – fell "within the range of reasonableness in which the Attorney General is best suited to pass judgment." *Id.* at 566. Exhibiting no deference and carving out no "zone of

reasonableness," the Supreme Court held that while Massachusetts "may wish to target tobacco advertisements and displays that entice children. . . , the blanket height restriction does not constitute a reasonable fit with that goal." *Id*. at 567. By contrast, the District Court here improperly relieved the State of its burden of proof on this critical issue. In so doing, the Court turned on its head the Supreme Court's definitive declaration in *Thompson* that, "[i]f the First Amendment means anything, it means that regulating speech must be a last – not first – resort." 535 U.S. at 373.

II. Constitutional Facts Require *De Novo* Review

A. The Standard of Review in First Amendment Cases is *De Novo*, Not Clear Error

Despite acknowledging the "more rigorous standard of review for First Amendment cases" generally established by the Supreme Court, Vt. Br. at 33, the State suggests that, at most, some weakened strain of *de novo* review should apply, addressing only what the State deems "crucial facts." As an initial matter, the "crucial facts" selected by the State are not facts at all. Rather, the issues of whether "the law directly advances the State's interests and is narrowly tailored for those purposes," Vt. Br. at 34, are the core *questions of law* that the Court must decide to determine whether a restriction on commercial speech can survive intermediate scrutiny. Moreover, *Hurley v. Irish-Am. Gay, Lesbian and Bi-Sexual Group of Boston*, 515 U.S. 557, 567 (1995), on which the State relies, makes no

such distinction, instead requiring independent review, without deference to the trial court, of all factual findings "where a conclusion of law as to a Federal right and a finding of fact are so intermingled as to make it necessary, in order to pass upon the Federal question, to analyze the facts." *Id.* (citations omitted). Therefore, the Court must review *de novo* any findings of fact that underlay the District Court's ultimate conclusions of law.

Any lesser standard would jettison two decades of First Amendment jurisprudence. The Supreme Court has emphasized that appellate courts have an "obligation to 'make an independent examination of the whole record' in order to make sure that 'the judgment does not constitute a forbidden intrusion on the field of free expression.'" *Bose*, 466 U.S. at 499 (internal citations omitted). This requirement reflects the Supreme Court's "deeply held conviction that judges . . . must exercise such review in order to preserve the precious liberties established and ordained by the Constitution." *Id.* at 510-11.[6] This Court should therefore "make an independent and searching inquiry of the entire record." *Guiles ex rel. Guiles v. Marineau*, 461 F.3d 320, 324 (2d Cir. 2006) (explaining need for *de novo*

[6] Amicus New England Journal of Medicine musters unintended irony in its claim that it is "remarkably anti-democratic," NEJM Br. at 32, for a court to protect the central liberties on which our society is based, such as freedom of speech. The proposition would be surprising to Justice Holmes and Judge Hand. Indeed, long before even they discerned the primacy of the First Amendment to the preservation of our democracy, s*ee* pp. 1-2, *supra*, the courts had stepped forward as guardians against legislative abridgment of free speech and other constitutional rights. *See, e.g.*, *Terrett v. Taylor*, 13 U.S. (9 Cranch.) 43 (1815).

review of entire record in First Amendment cases); *accord O'Connor v. Washburn University*, 416 F.3d 1216, 1223 (10th Cir. 2005) ("In cases arising under the First Amendment of the United States Constitution, this court reviews a District Court's decision *de novo*. In doing so, this court has an obligation to make an independent examination of the whole record."); *Christ's Bride Ministries, Inc. v. SEPTA*, 148 F.3d 242, 247 (3d Cir. 1998) (court must "draw [its] own inferences from the factual evidence presented").

The State also contends that commercial speech restrictions are not entitled to *de novo* review because of the "subordinate position [of such speech] in the scale of First Amendment values." *See* Vt. Br. at 33-34 (quoting *Bd. of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 477 (1989). But however subordinate commercial speech was in 1989 in *Fox*, it was far less so in the Supreme Court's more recent trilogy of decisions on the subject. *See* pp. 10-11, *supra*. The Court has been clear in those cases that for commercial speech, no less than for other varieties, there is a "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." *Greater New Orleans*, 527 U.S. at 195. In line with this presumption, no Supreme Court or Second Circuit decision has limited

the *Bose* standard of review to cases not involving commercial speech.[7] The courts addressing the issue have applied the *Bose* standard to review of restrictions on commercial speech. *See Falanga v. State Bar of Georgia*, 150 F.3d 1333, 1336 (11th Cir. 1998); *Lindsay v. San Antonio*, 821 F.2d 1103, 1107-08 (5th Cir. 1987) ("[O]ur role as the reviewing court is not so limited [to the "'clearly erroneous' standard"] . . . [I]n deciding whether restrictions on speech are justified, appellate courts do not rely heavily on findings of fact made by trial courts."). Accordingly, this Court should review *de novo* the District Court's findings of both law and fact.

B. *Turner* Deference Is Inapplicable to Content-Based Restrictions on Commercial Speech

1. *Central Hudson* Requires Rigorous Analysis, Not Deference

The Supreme Court has recognized that not every governmental action involving speech is created equal. The most susceptible to abuse, the most corrosive to the free marketplace of ideas, is discrimination based on the content of speech. *Simon & Schuster v. Members of New York State Crime Victims Bd.*, 502 U.S. 105, 116 (1991); *Members of City Council v. Taxpayers for Vincent*, 466 U.S.

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[7] In *Commodity Futures Trading Commission v. Vartuli*, 228 F.3d 94 (2d Cir. 2000), cited by the State, Vt. Br. at 33, the Court noted in a footnote that "[i]t is arguable that we are required to review the district court's findings underlying its determination of the constitutional aspects of its judgment *de novo* rather than for clear error." *Id.* at 108 n.107. The State asserts that the Court was referring to "the commercial speech context," Vt. Br. at 33, but the text surrounding the footnote addresses the false and misleading nature of the speech, which places it outside the bounds of constitutionally protected commercial speech. *See Vartuli*, 228 F.3d at 108.

789, 804 (1984) ("[T]he first amendment forbids the government to regulate speech in ways that favor some viewpoints or ideas at the expense of others."). The premise of the First Amendment is that the speaker and the listener are in a better position to determine the value, veracity, and propriety of speech than is the Government. *Edenfield v. Fane*, 507 U.S. 761, 767 (1993); *see* Thomas I. Emerson, *Toward a General Theory of the First Amendment*, 72 Yale L.J. 877, 882 (1963) ("The only justification for suppressing an opinion is that those who seek to suppress it are infallible in their judgment of the truth."). Such issues are generally not implicated by content-neutral time, place, and manner restrictions, such as those analyzed in *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622 (1994). *See Discovery Network, Inc.*, 507 U.S. at 429-30. The deference to the Legislature urged by the State and practiced by the District Court has never been part of the *Central Hudson* analysis. To the contrary, the requirement that the State bear the burden of justifying content-based restrictions on speech, *Central Hudson*, 447 U.S. at 566, is incompatible with such deference to the Legislature. Consistent with this principle, Supreme Court cases since *Turner* have refused to defer to the Legislature when assessing restrictions on commercial speech such as this one. *See Thompson*, 535 U.S. at 376-66; *Greater New Orleans* 527 U.S. at 189; *44 Liquormart*, 517 U.S. at 509-10 (1996); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 482 n.2 (1995).

Nevertheless, invoking a deferential approach, the Court below inquired only whether the State's judgments regarding its restrictions on speech were reasonable and based on substantial evidence. SPA-22. This was the wrong standard. The Supreme Court in *Greater New Orleans* and *Lorillard* required not that the state act reasonably, but rather insisted that the government show it had "'carefully calculated' the costs and benefits associated with the burden on speech imposed by its prohibition." *Greater New Orleans*, 527 U.S. at 18 (quoting *Discovery Network*, 507 U.S. at 417); *Lorillard*, 533 U.S. at 561 (same).

Such careful calibration ensures that a regulation of speech does not "unduly impinge" on First Amendment rights. *Lorillard*, 533 U.S. at 565. In contrast, the Legislature's actions here could meet the District Court's "reasonableness" standard and still be wrong. *See, e.g.*, *44 Liquormart, Inc.*, 517 U.S. at 505 (striking down restrictions that exhibited "common sense" but no actual proof). The propriety of an abridgement of free speech turns not merely on whether the State *believed* the restriction was justified nor on whether the Legislature accumulated substantial evidence, but on whether the restriction *actually was* justified and whether at least a preponderance of the evidence actually established that it was appropriate. In other words, the State must satisfy its burden of *proving* that its belief is borne out in fact, *i.e.*, that the restriction does indeed directly advance the asserted interest and is not more extensive than necessary to serve it.

Central Hudson, 447 U.S. at 566. In deferring to the Legislature, the District Court accorded it the benefit of any doubt – the equivalent of presuming that its actions were appropriate. This approach overturns prevailing First Amendment law. The District Court should have analyzed not just whether the Legislature *thought* it was doing the right thing, but whether it in fact *did* do the right thing.

2. The District Court Compounded Its Error By Refusing to Admit Facts Demonstrating the Unreliability of the Legislative Process for Act 80

The District Court compounded this error of focusing on the reasonableness of the Legislature's judgments by barring PhRMA from presenting evidence that the process by which the Legislature reached its conclusions undermined their reliability. On the State's motion, the Court excluded evidence that the legislative "findings" were rushed, made up, and gerrymandered by interested outsiders who did not have access to evidence or testimony before the Legislature and who prepared the "findings" overnight.[8] SPA-64-66. This evidence was both admissible and probative. The Court excluded, among other things, deposition testimony of the outsider who drafted the "findings" and provided "support" for them, as well as the deposition or trial testimony of the legislative staff members

[8] The State's assertion that PhRMA has not adequately briefed this issue is specious. The exclusion of evidence regarding the legislative process was fully briefed in the opening brief, *see* PhRMA Br. at 41-43, and the order excluding the evidence was separately noted as an issue on appeal. *See* SPA-64-66.

tasked with creating and promoting those "findings." *Id.* (The Court also excluded the draft "findings" themselves.)

In *Lorillard*, the Supreme Court explicitly focused on the process by which the restrictions on speech were formulated in determining whether the State had satisfied the constitutional standard. The Court noted that "the breadth and scope of the regulations, *and the process by which the Attorney General adopted the regulations*, do not demonstrate a careful calculation of the speech interests involved." 533 U.S. at 562 (emphasis added). The District Court here refused to undertake a similar inquiry. SPA-64 ("I don't think the legislative process is a relevant consideration in this hearing.").

PhRMA does not dispute that an ostensible "legislative record," as defined and limited by the State, was admitted at trial for the limited purpose of demonstrating what evidence and testimony was before the Legislature (but not for the truth of its contents). Nor does PhRMA dispute that it was permitted to, and did, present evidence at trial demonstrating the inaccuracy of specific legislative "findings." *See, e.g.*, PhRMA Br. at 20-22 (laying out some of the pervasive errors). But these issues are distinct from the error raised here, where the District Court, even while granting special weight to the predictive judgments of the Legislature, excluded evidence challenging the trustworthiness and regularity of the process by which the Legislature reached those judgments. The District Court

thus erred in prohibiting PhRMA from introducing evidence about the legislative process, as distinct from the "legislative record" cherry-picked by the State. SPA-64.[9]

Contrary to the State's assertion, this evidence was not limited to questioning "legislative witnesses at trial about whether they believed that their testimony at committee hearings supported legislative findings." Vt. Br. at 80. Evidence developed during discovery demonstrated that the legislative process for Act 80 was so flawed that, under any standard, deference to legislative judgments was not appropriate. For example, a legislative counsel, Robin Lunge, was responsible for shepherding the "findings" – prepared from start to finish in three days – through the Legislature. In her deposition, she confirmed that it was not her job to ensure that findings were accurate or based on any testimony or evidence before the Legislature, stating that if she were told to write "the moon is made of cheese," she would write "the moon is made of cheese." Deposition of Robin Lunge, at 112-13 (4/18/08). Indeed, no one on the legislative staff had responsibility for ensuring the accuracy of the findings. *Id.* at 113-14. Ms. Lunge's testimony was among the materials excluded from the trial record.

[9] The State's assertion that the Legislature held "dozens of hearings over four months" is misleading. Vt. Br. at 80. Only a small portion of those hearings related to restrictions on prescriber-identifiable data, the State's asserted interests in controlling healthcare costs or protecting public health, or the "findings" developed by the Legislature. *See* PhRMA Br. at 19-20, 41-42.

This problem was compounded here because the drafting of the findings was not even done by the Legislature or legislative staff, but outsourced to Sean Flynn, an interested outsider who had attended no legislative hearings in Vermont and did not have access to the transcripts or evidence presented to the Legislature. A-4746-66. In his deposition, Mr. Flynn (who authored an amicus brief in support of the State in this appeal) admitted that he had drafted the document on which the findings are based overnight, in a matter of hours, after the New Hampshire district court decision was released. A-4762; Deposition of Sean Flynn, at 138-139 (4/25/08). He conceded further that many of the citations did not in fact support the findings. *See*, *e.g.*, A-4762-63. These flaws in the process resulted in "findings" that were unsupported by the actual testimony or evidence before the Legislature and that were factually inaccurate. More fundamentally, if a court looks to a legislative record to determine whether the Legislature "carefully calculated" the costs and burdens of a restriction on speech, as the Supreme Court requires, it matters whether the Legislature *actually made* such a calculation. The District Court barred that inquiry – the very type of inquiry the Court undertook in *Lorillard* – and excluded Mr. Flynn's testimony. Moreover, the District Court found – and the State still argues – that the Legislature did not have to rely on empirical evidence to support its predictive judgments. This approach compounded the Court's error and precluded meaningful constitutional review.

CONCLUSION

For the reasons set forth above and in PhRMA's initial brief, 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 in violation of their rights under the First and Fourteenth Amendments of the U.S. Constitution.

Respectfully submitted,

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Dated: September 29, 2009

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September 29, 2009

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