IN THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

IMS HEALTH INCORPORATED; VERISPAN, LLC; and SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of WOLTERS KLUWER, HEALTH INC.,	)	Civil Action No. 1:07-cv-188
Plaintiffs,	)	**CONSOLIDATED WITH** 1:07-cv-00220
vs.	)	
WILLIAM H. SORRELL, as Attorney General of the State of Vermont,	)	
Defendant.	)	

DEFENDANTS' POST-TRIAL BRIEF

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INTRODUCTION

Over the course of the 2007 session, the Vermont Legislature devoted substantial time to investigating the relationship between health care costs, prescription drug marketing, and the safety of Vermont's citizens. The Vermont Medical Society and numerous doctors, among others, expressed concern over a particular marketing practice of the pharmaceutical industry, and the influence of the industry in steering physicians' prescribing practices towards the newest and most expensive drugs. At their request, the Legislature studied the use and sale of prescription drug data – without the consent of the doctor or patient – for the purpose of highly-targeted marketing of prescription drugs to doctors. After 20 days of hearings and debate, the Legislature passed a narrowly tailored statute that provides health care professionals the right to choose whether or not to disclose their identifying information in prescription records for use in marketing prescription drugs.

Plaintiffs – data-vendor companies that buy and sell prescription drug data, and PhRMA, the trade organization of the pharmaceutical industry – seek to permanently enjoin the law. Their opposition is understandable. Data-vendors and pharmaceutical manufacturers make an enormous amount of money from the use of this data as a marketing tool. These companies sent lobbyists, economists, and other experts to the Vermont Legislature to make the case for unfettered commercial use of doctors' prescription information. The Legislature listened, but was not swayed. The Legislature was persuaded instead by doctors who called the practice "spying" and "outrageous" and found no possible "public good" from the use of data for marketing. Defs. Annotated Leg. Findings, Findings 27, 29. The Legislature was also persuaded by medical scholars who explained how marketing practices influence doctors to prescribe expensive new drugs that are no more effective than cheaper treatments and also carry

unknown safety risks that can harm patients. *E.g., id.* Findings 7, 8, 15. The Legislature concluded that use of the data for marketing without doctors' consent invades a substantial privacy interest, contributes to rising health care costs, and threatens public health and safety. *E.g., id.* Findings 1-3, 6-9, 15, 20, 27-29, 31. The Legislature weighed the evidence before it and decided that doctors should be given the right to decide whether their prescribing information may be used for marketing prescription drugs.

This Court should not disturb the policy judgment reached by the Legislature. Applying the *Central Hudson* test to strike down this law would turn the commercial speech doctrine on its head, taking a doctrine intended to protect the flow of information to interested consumers and using it to protect the rights of companies to use people's nonpublic information without permission. Giving doctors the right to choose whether or not to disclose their prescribing practices for marketing is a natural outgrowth of the existing privacy protections for health care information. Affording doctors this right also directly advances Vermont's interests in controlling health care costs and protecting public health. The Prescription Confidentiality Law is constitutional.

Plaintiffs' arguments under the dormant Commerce Clause and their challenges to a planned educational program on prescribing practices and to a law that protects consumers from illegal drug advertising should also be rejected.

SUMMARY OF ARGUMENT

The Court advised the parties that it intends to treat the Prescription Confidentiality Law, 18 V.S.A. § 4631, as a restriction on commercial speech subject to intermediate scrutiny under the *Central Hudson* test. *E.g.,* Tr. 1253; *see Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). This post-trial brief accordingly limits the First Amendment

argument to showing why the Law satisfies *Central Hudson.* Defendants emphasize, however, that they continue to press, and do not waive, the other First Amendment arguments set forth in defendants' summary judgment papers. Papers 245, 246, 247, 248, 251, 339. Defendants maintain that recognition of plaintiffs' asserted First Amendment rights in this case would mark a significant expansion of existing commercial speech rights under Supreme Court and Second Circuit case law. *See id.*

The *Central Hudson* test requires the government to provide some justification for a restriction on commercial speech. In defendants' view, this case has a different starting point. Plaintiffs should explain why regulated pharmacies have any First Amendment right to sell nonpublic information from the confidential health care records they are required to maintain – especially when pharmacies have the information only because the government requires doctors and patients to provide it. This data is not protected speech and restricting the use of the data for marketing is at most a regulation of commercial conduct. *See generally id.* The Court queried, at the end of the trial, "who is the speaker" affected by this Law? Tr. 1247-48. In fact, there is no "speaker" other than the doctor who should get to decide how her information is used.

Turning to *Central Hudson,* the application of the test here is informed by at least two aspects of the Law that distinguish this case from the New Hampshire statute invalidated in *IMS Health, Inc. v. Ayotte,* 490 F. Supp. 2d 163 (D.N.H. 2007), *appeal docketed,* No. 07-1945 (1st Cir. June 20, 2007). The first is that the Vermont Legislature acted on the basis of a substantial legislative record and made detailed, well-supported statutory findings. This Court, accordingly, should afford deference, consistent with First Amendment review, to the Legislature's findings and its reasoned, predictive judgment about the effects of the Law. Second, Vermont's Law fittingly allows doctors to decide whether their information may be used for marketing purposes.

The consent provision brings the Law in line with other privacy laws. It also means that doctors, the people we trust to write prescriptions, are the people who evaluate their experience with marketing fueled by prescriber-identifiable data and decide whether or not to allow the practice.

Against this background, and in light of both the legislative record and the trial record, the Court should hold that the Prescription Confidentiality Law meets the requirements of *Central Hudson*. The Law directly advances three substantial state interests: it protects privacy, controls costs by reducing unnecessary spending on prescription drugs, and protects the public health by limiting the over-prescription of new drugs that lack established safety records. The evidence supports each of these interests. Prescriber-identifiable data is used as a tool for aggressive, targeted marketing campaigns that influence doctors to prescribe new, expensive drugs. New drugs are not necessarily better than old drugs; often new drugs offer little or no therapeutic advantages over existing treatments, but they are always more expensive and sometimes more risky. Use of the data gives pharmaceutical sales representatives a powerful advantage in trying to sway doctors' prescribing practices. It allows them to target doctors, target messages, and monitor the success of sales techniques – all in an effort to increase the number of prescriptions doctors write for their drugs. And these techniques work, to the advantage of pharmaceutical companies (and sales representatives, who get paid for making their sales quotas) but to the disadvantage of doctors, the patients they treat, and the State of Vermont. Allowing doctors to prevent the use of their data for marketing will improve doctors' prescribing practices and that, in turn, will reduce unnecessary spending on prescription drugs and protect against possible harm to patients who need not be exposed to unknown side effects and risks of new drugs. It will reduce Vermont's spending and give Vermonters greater access to affordable health care.

The Law is also narrowly tailored, with the requisite "reasonable" fit between the State's interests and the statute. *See Greater New Orleans Broadcasting Ass'n v. United States*, 527 U.S. 173, 188 (1999). Vermont has not barred detailing or prevented pharmaceutical companies from distributing information about their products. The Law only applies to the use of prescriber-identifiable data for marketing and it allows doctors (not the government and not pharmaceutical companies) to decide whether to allow that use. Because of the consent provision, the Law is similar to privacy regulations upheld by courts, including the Second Circuit. *See, e.g., Anderson v. Treadwell*, 294 F.3d 453, 462 (2d Cir. 2002).

While plaintiffs' First Amendment challenge to the Prescription Confidentiality Law was the focus of the trial, plaintiffs also raise other constitutional claims. Each of these claims was fully briefed on summary judgment and defendants preserve the arguments made in those filings. *See* Papers 257, 258, 340 (Commerce Clause and preemption claims); 205, 206, 264, 265, 379 (manufacturer's fee). For the Court's convenience, defendants have incorporated those arguments into Parts II-IV of this brief. The Court should reject plaintiffs' Commerce Clause arguments and further hold that the other statutes challenged by PhRMA are constitutional.

STATUTORY FRAMEWORK

This case centers on the Prescription Confidentiality Law, codified at 18 V.S.A. § 4631; *see* 2007, No. 80, sec. 17; 2007, No. 89, sec. 3 (Adj. Sess.). Both the IMS plaintiffs and PhRMA challenge it under the First Amendment. PhRMA Am. Compl., Paper 174, Count 4; IMS Pls. Am. Compl., Paper 220, Counts I-III. As discussed in Section II, below, the IMS plaintiffs also challenge the Law under the dormant Commerce Clause. IMS Pls. Am. Compl., Paper 220, Count IV.

This section outlines the elements of the Prescription Confidentiality Law. The other provisions of Act 80 challenged by PhRMA – the manufacturer's fee and the consumer fraud provision – are discussed in Sections III and IV, below.

1. Restriction on the nonconsensual sale or use of prescriber-identifiable data for marketing prescription drugs

The Prescription Confidentiality Law applies to "regulated records," 18 V.S.A. § 4631(d), which are "information or documentation from a prescription dispensed in Vermont and written by a prescriber doing business in Vermont" – put briefly, Vermont prescription records. *Id.* § 4631(b)(9). The law creates two restrictions regarding prescriber-identifiable data (i.e., information that identifies a prescriber) in prescription records. First, covered entities (discussed below) "shall not sell, license, or exchange for value regulated records containing prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents as provided in subsection (c) of this section." *Id.* § 4631(d). Second, "pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents as provided in subsection (c) of this section." *Id.* Thus, the law prohibits the sale or use of prescriber-identifiable data for the purpose of marketing prescription drugs, unless the prescriber consents.

"Marketing" and "promotion" are both defined. 18 V.S.A. § 4631(b)(5), (b)(8). They are, essentially, advertising. Marketing also includes the use of the data to "evaluate the effectiveness of a professional pharmaceutical detailing sales force." *Id.* § 4631(b)(5).

2. Exceptions

The statute restricts the use of prescriber-identifiable data only "for marketing or promoting a prescription drug." 18 V.S.A. § 4631(d). Numerous noncommercial uses of the data are

permitted. *Id.* § 4631(e). For instance, the statute does not apply to the "license, transfer, use, or sale of regulated records for" health care research, patient care management, formulary compliance, and utilization review. *Id.* § 4631(e)(1). It does not apply to dispensing drugs, pharmacy reimbursement, and communications between prescribers and pharmacies are expressly exempted. *Id.* § 4631(e)(1),(2),(3). The data may also be used for treatment and safety-related purposes, including communications to patients about treatment options, recall or patient safety notices, and clinical trials. *Id.* § 4631(e)(4). The statute also permits the commercial use of prescriber data so long as the data does not identify the prescriber. *Id.* § 4631(e)(7).

3. Covered entities

The statute regulates health insurers, self-insured employers, electronic transmission intermediaries, pharmacies, and similar entities. *Id.* § 4631(d). A pharmacy is "any individual or entity" who must register under the State's pharmacy licensing laws. *Id.* § 4631(b)(6). The definition of "health insurer" incorporates the definitions used in the health administration statutes. *Id.* § 4631(b)(4). An electronic transmission intermediary is:

> an entity that provides the infrastructure that connects the computer systems or other electronic devices used by health care professionals, prescribers, pharmacies, health care facilities and pharmacy benefit managers, health insurers, third-party administrators, and agents and contractors of those persons in order to facilitate the secure transmission of an individual's prescription drug order, refill, authorization request, claim, payment, or other prescription drug information.

Id. § 4631(b)(1).

Of the covered entities listed above, pharmacies are the businesses that supply plaintiffs with prescriber-identifiable data. *E.g.*, Tr. 83, 616. The statute does not regulate data-vendor companies like the IMS plaintiffs. *See* 18 V.S.A. § 4631(d), (b).

4. The consent process

The Legislature designed a simple system to allow prescribers to consent to the use of their prescription information for marketing prescription drugs: the "prescriber data-sharing program." 18 V.S.A. § 4631(c)(1). All prescribers (including physicians, dentists, nurse practitioners, and physicians' assistants) are health care professionals who are licensed by the State of Vermont. They must apply for, and regularly renew, their licenses. The Office of Professional Regulation and the Department of Health "shall solicit the prescriber's consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent." *Id.* That is, prescribers will be asked whether they consent on forms they already complete for their professional licenses. The Office and the Department will collect this information and "make available the list of prescribers who have consented to sharing their information." *Id.* § 4631(c)(2). Entities seeking to use it must review the list at least every six months. *Id.*

ARGUMENT

I. The Prescription Confidentiality Law satisfies *Central Hudson.*

The Court should uphold the Law under the *Central Hudson* standard. As explained below, the Court's review should be tempered by deference to the Legislature. The Court's review should also recognize that a Law allowing doctors to control the use of nonpublic information as a marketing tool has little effect on the values of free expression protected by the First Amendment. The evidence from both the Legislature and the trial record show that the Law directly advances each of the State's interests and its consent provision is narrowly tailored. Indeed, the Law's restriction is quite narrow: it allows doctors to decide whether they want their information used for drug marketing and it places no limit on the ability of drug companies to convey information about their products. None of the arguments or evidence advanced by

plaintiffs is sufficient to change this analysis. Much of their evidence is irrelevant or unpersuasive and their speculative assertions about unknown future events cannot support a facial challenge to the Law before it is implemented.

A. The Court's review under *Central Hudson* should be informed by deference to the Legislature's findings and predictive judgment.

The Vermont Legislature engaged in substantial review of the matter before it and made detailed factual findings that are entitled to deference. Plaintiffs contend that the legislative findings essentially do not matter and the Court's role is to review the evidence and decide, in the first instance, whether the Legislature identified substantial interests and whether the Law in fact serves those interests. That is not correct. The Court should not take over the policymaking role of the Legislature and substitute its judgment for that of the representatives elected by the people of this State. Instead, the Court should evaluate the evidence in the legislative and trial records and decide whether there was a *reasonable basis* for the Legislature to decide that the statute would directly advance the State's interests.[1] *See, e.g., Turner Broadcasting Sys. v. FCC, (Turner I)*, 512 U.S. 622, 666 (1994) (review asks if "in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence").

1. The legislative record shows a lengthy process that included all stakeholders.

The legislative record demonstrates that several committees of the Vermont Legislature amassed and reviewed information and testimony from a broad range of interested parties in a series of proceedings that spanned the entire 2007 session. In fact, there were 41 separate committee hearings on S.115 by five separate committees. Defs. Proposed Findings 2-3. The legislative proceedings that culminated in Act 80's passage encompassed oral testimony and

[1] This is not the same as rational basis review, which asks only whether a statute could conceivably serve *any* legitimate government interest, including interests only "hypothesize[d]" by the Court. *See Tuan Anh Nguyen v. I.N.S.*, 533 U.S. 53, 77 (2001) (discussing rational basis review).

written submissions from numerous public and private interests. This included a full range of private-sector stakeholders. The committees took oral and written testimony and reviewed documents from witnesses including the Vermont Medical Society; several Vermont practitioners and prescribers; AARP; Drs. Jerry Avorn and Aaron Kesselheim; Sean Flynn; a former FTC official; IMS's in-house counsel, IMS's Vice-President, External Affairs, and IMS lobbyists; lobbyists for PhRMA, as well as for PhRMA members Eisai, Inc. and Glaxo SmithKline; a lobbyist for the Vermont Pharmacists Association; Medco, Express Scripts, and other Prescription Benefit Managers ("PBMs"); CVS/Caremark; Mylan Pharmaceuticals; Burlington Drug Company; and MVP Healthcare. Defs. Proposed Findings 3; *see, e.g.*, Readings & Handouts, House Health Care Committee, Documents pertaining to S.115 (LR000006-12).

As part of this process, the Legislature took evidence from plaintiffs and heard the views now advanced by them in this lawsuit. In addition to the testimony cited above, the record includes articles authored by IMS, *see* LR000233-35 (article by Susan Neyhart, IMS manager of strategic programs); LC001520-28 (article by IMS employees entitled "Data Mining at IMS HEALTH: How we turned a mountain of data into a few information-rich molehills"); Mr. Turner's PERC Report, LR 000369-415; and materials submitted by PhRMA, *see* LR000008 (entries attributing documents to Julie Corcoran, PhRMA). Indeed, the list of citations in support of the findings specifically references IMS documents and testimony. *See* LR000817-20, Finding 4(h), (i) (referencing IMS 2005 Annual Report and Neyhart article); Finding 22 (referencing testimony of Randy Frankel and Steve Kimbell).

In short, the General Assembly did precisely what the *Ayotte* court found lacking in New Hampshire: it assembled a "quality record" which "establishes that the Legislature conducted an

extensive investigation, acquired considerable expertise in the regulated area, and incorporated express findings into the approved statute." *Ayotte,* 490 F. Supp. 2d at 177 n.12.

2. The Legislature's findings are supported by substantial evidence.

After engaging in this process, the Legislature identified three primary problems with the current use of prescriber-identified prescription information. Those problems are outlined in the Legislature's 31 Findings (Findings). With some minor exceptions, these findings are supported by substantial evidence in the legislative record. To aid in the Court's review, defendants are filing a separate document, Defendants' Annotated Legislative Findings, which sets forth the evidence in support of each of the Findings. The following discussion highlights some of the findings and evidence, organized around the Legislature's three interests.

First, many physicians view the practice of marketing using their prescribing formation as intrusive and unhelpful. Findings 20, 26, 27. The Vermont Medical Society adopted a unanimous resolution that "the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine." Finding 20. Some of the doctors who testified used stronger language, calling the practice "spying," "outrageous," and "nasty." Defs. Annotated Leg. Findings, Finding 29. Dr. Landry told the Legislature "no public good" could come from pharmaceutical companies using this information for marketing. *Id.* Dr. Boerner urged that "it's a wonderful . . . idea to not be spying on doctors and having the reps come back and make us feel guilty for not doing what they want us to do." *Id.* She complained that "[i]t is disgusting and really demeaning when a drug rep can say, well, you say nice things to my face but I know you're not using my product. . . . They're in my office and they're accusing me of lying." *Id.* The Legislature accordingly found the nonconsensual use of prescriber-identifiable data in marketing to be an invasion of prescriber privacy. It found that when a doctor writes a

script, and the patient fills it at a local pharmacy, neither the doctor nor the patient consents to the pharmacy trading the information to data vendors and other third parties to be used for advertising and marketing purposes. *Id*. 29.

Second, because pharmaceutical manufacturers use detailing to expand the market share of new and expensive drugs, the use of prescriber-identifiable data for advertising and marketing purposes drives up the cost of prescription drugs. Findings 15, 31. The Legislature noted the extraordinary amount of money spent on marketing by pharmaceutical companies. Finding 17 (industry spent $27 billion on marketing in 2004). Because of these marketing campaigns, the Legislature found, "'the work of pharmaceutical sales representatives drives drug use toward the most expensive products . . . , and contributes to the strain on health care budgets.'" *Id*. 15 (quoting testimony of Dr. Jerry Avorn).

Unfortunately, the new drugs that are the subject of these marketing campaigns are often no more effective than existing, less expensive treatments. Findings 7, 14. But the industry's heavily funded marketing efforts may not provide this information to doctors. Findings 3-6. Sales representatives have no incentive to encourage physicians to research and determine the best and most cost-effective treatments for their patients. Sales representatives want doctors to write more prescriptions for their products. "Marketing programs are designed to increase sales, income, and profit." Finding 3. One of the articles in the legislative record explains in detail how sales representatives befriend doctors and use prescribing data to monitor doctors' practices and develop the best sales pitches. Defs. Annotated Leg. Findings 4, 6. Because the use of prescriber-identified data makes detailing efforts more successful, Finding 25, it causes unnecessary increases in the cost of prescription drugs.

Third, the Legislature made findings about possible risks to patient health caused by aggressive detailing efforts. New drugs are disproportionately likely to be recalled or relabeled because of serious safety concerns. Finding 8. Although drugs are tested before being approved by the FDA, drug trials do not reveal all risks. Thus, new drugs may not only be more expensive than existing treatments; they may also carry greater risks than existing drugs with established safety records. The Legislature looked at experiences like that of Vioxx and other "COX-2 inhibitors" – heavily marketed drugs which later proved to have serious safety concerns – and concluded that "[m]arketing which results in prescribers using the newest drugs will also result in prescribing drugs that are more likely to be subject" to safety warnings and recalls. Finding 8; Defs. Annotated Leg. Findings, Findings 3, 7, 8 (evidence about safety risks of new drugs).

Based on these well-supported findings, the Legislature decided to allow doctors to choose whether to share their identifying information for purposes of marketing prescription drugs in an effort to address each of these three real problems: (1) the invasion of privacy caused by this intrusive marketing method; (2) increased health care costs; and (3) a concern for safety in the newest, most marketed prescription drugs.

3. The Legislature's findings and predictive judgment are entitled to deference.

The Legislature's findings and predictive judgment are entitled to deference under any intermediate standard of review, including *Central Hudson*. The requirement that courts leave room for the reasoned judgments and predictions of the political branches under *Central Hudson* is not a novel argument – it is a built-in feature of intermediate scrutiny recognized in existing case law. The *Central Hudson* standard gives the political branches "leeway" to shape regulations on commercial speech that satisfy the "reasonable fit" requirement. *Bd. of Trs., State Univ. of NY v. Fox*, 492 U.S. 469, 481 (1989). This standard is no different than the deference

to reasoned, predictive judgments of legislatures outlined by the Supreme Court in its *Turner* decisions: *Turner Broadcasting Sys. v. FCC, (Turner I),* 512 U.S. 622, 665 (1994); *Turner Broadcasting Sys. v. FCC, (Turner II),* 520 U.S. 180, 199 (1997).[2]

The *Turner* cases provide the starting point for this analysis because the decisions explain the role of deference and legislative decision-making in First Amendment cases. In both cases, the Supreme Court considered the constitutionality of a federal law that requires cable television operators to carry a certain number of local broadcast television channels on their systems. *Turner I,* 512 U.S. at 630. Over dissent, the Court concluded that these "must-carry" rules were not content-based and thus were subject only to intermediate scrutiny under the First Amendment. *Id.* at 621-22. In conducting its review under this intermediate standard, the Supreme Court acknowledged that "courts must accord substantial deference to the predictive judgments of Congress." *Turner I,* 512 U.S. at 665. The Court stressed a combination of "independent judgment" with deference to legislative decision-making. It held that the "obligation to exercise independent judgment when First Amendment rights are implicated is not a license to reweigh the evidence *de novo*, or to replace Congress's factual predictions with [the Court's] own. Rather, it is to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence." *Turner I,* 512 U.S. at 666. As phrased in *Turner II,* the question for the court is not whether the legislative determination is "correct" as "an objective matter." "Rather, the *question is whether the legislative conclusion was*

[2] The district court in *Ayotte* afforded no deference to the New Hampshire Legislature. *IMS Health, Inc. v. Ayotte,* 490 F. Supp. 2d 163, 177 n.12 (D.N.H. 2007). That approach should not be followed here, for at least two reasons. First, the Vermont Legislature made express findings based upon an extensive record – thus addressing any weaknesses identified in the New Hampshire process. Second, the *Ayotte* court's reasoning is questionable in light of the Supreme Court precedents (discussed above) that acknowledge the role for the political branches in regulating commercial speech. The *Ayotte* court erroneously relied upon two cases that did not involve commercial speech. *See Sable Commc'ns of Cal. v. FCC*, 492 U.S. 115, 126 (1989) (applying strict scrutiny and "least restrictive means" requirement to ban on indecent dial-a-porn messages); *Landmark Commc'ns v. Virginia,* 435 U.S. 829, 838, 845 (1978) (noting "the publication Virginia seeks to punish under its statute lies near the core of the First Amendment" and finding "clear and present danger" test not satisfied).

reasonable and supported by substantial evidence in the record." *Turner II*, 520 U.S. at 211. (emphasis added).

Plaintiffs' argument that *Turner's* call for deference does not apply to a regulation of commercial speech has no support in Supreme Court case law. In *Turner*, as in the commercial speech cases, the Supreme Court applied intermediate scrutiny under the First Amendment. It is true that *Central Hudson's* "intermediate scrutiny" is not precisely the same as the standard applied in *Turner* to a content-neutral "time, place, and manner" regulation of speech. The Supreme Court has, however, recognized that these two forms of intermediate scrutiny under the First Amendment are substantially similar: "In recognition of the distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech, we developed a framework for analyzing regulations of commercial speech that is substantially similar to the test for time, place, and manner restrictions." *Lorillard*, 533 U.S. at 554. The Court has never limited *Turner* to time, place, and manner regulations. *Cf. Columbia Broadcasting Sys. v. DNC*, 412 U.S. 94, 103 (1973) ("The judgment of the Legislative Branch cannot be ignored or undervalued simply because [a plaintiff] casts its claims under the umbrella of the First Amendment.").

Moreover, plaintiffs' argument on this point disregards *Fox*, a commercial speech case that also considered the relationship between the *Central Hudson* standard and the intermediate scrutiny that applies to time, place, and manner regulations. The issue in *Fox* was whether *Central Hudson's* "narrow tailoring" requirement equated with the "least restrictive means" requirement used in other First Amendment cases. 492 U.S. at 477-78. The Court observed that its review of time, place, and manner regulations, which apply even to "core political speech," did not include the least restrictive means requirement. The Court concluded that, "it would be

incompatible with the asserted subordinate position [of commercial speech] in the scale of First Amendment values to apply a more rigid standard" under *Central Hudson*. *Id.* at 478 (quotation omitted). That is, the *Central Hudson* standard for commercial speech cannot be more difficult to satisfy than the standard that applies to time, place, and manner regulations, because "commercial speech [enjoys] a limited measure of protection" under the First Amendment. *Id.* at 477; *see also United States v. Edge Broadcasting Co.*, 509 U.S. 418, 429-30 (1993) (same).[3]

As this discussion illustrates, plaintiffs get this point exactly backwards. They advocate for a stricter standard under *Central Hudson*, one without any deference to legislative judgments. Put concretely, plaintiffs say that a law that requires consent for the use of a marketing tool is subject to stricter scrutiny than a law that dictates which channels a cable company must provide. That is not the Supreme Court's view. *See, e.g., Edge Broadcasting*, 509 U.S. at 429 ("validity of restrictions on commercial speech should not be judged by standards more stringent than those applied to . . . time, place, or manner restrictions").

Fox rebuts plaintiffs' position for another reason: it confirms the "ample scope of regulatory authority" for the political branches to restrict commercial speech. *Id.* at 477. The *Fox* Court rejected the least restrictive means standard because commercial speech "is subject to 'modes of regulation that might be impermissible in the realm of noncommercial expression.'" *Id.* (quoting *Ohralik v. Ohio State Bar Ass'n,* 436 U.S. 447, 456 (1978)). Thus, the "reasonable fit" standard of *Central Hudson* takes "account of the difficulty of establishing with precision the point at which restrictions become more extensive than their objective requires, and provide[s] the

[3] Plaintiffs may also be arguing that because the Prescription Confidentiality Law restricts only the commercial use of prescriber-identifiable data, the law is "content-based" for purposes of the First Amendment. *See, e.g.*, Tr. 1193-94. Regulations that focus on commercial speech are inherently content-based, like the tobacco advertising limits at issue in *Lorillard*, *see* 533 U.S. at 561, and the restrictions on real estate solicitations at issue in *Anderson*, 294 F.3d at 453. As the Second Circuit held in *Anderson*, the fact that a commercial speech restriction is content-based does not change the level of scrutiny applied to it. 294 F.3d at 460. The *Central Hudson* test still applies, *see id.*, and that test affords "ample . . . regulatory authority" and "needed leeway" in the regulation of commercial speech. *Fox*, 492 U.S. at 477, 481.

Legislative and Executive Branches needed leeway in a field (commercial speech) traditionally subject to governmental regulation." *Fox*, 492 U.S. at 481 (quotations omitted). The Second Circuit has likewise observed that "particularly where the standards and conduct of professionals have traditionally been subject to extensive regulation by the States, 'it is all the more appropriate that we limit our scrutiny of state regulations to a level commensurate with the subordinate position of commercial speech.'" *Anderson,* 294 F.3d at 463 (quoting *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 635 (1995)) (upholding real estate agent solicitation law).

Taken together, then, *Turner* and the commercial speech cases like *Fox* and *Lorillard* show that there is room for the political branches to make policy judgments based on deliberation, the weighing of competing evidence, and reasoned factual predictions. *See, e.g.*, *Turner I,* 512 U.S. at 666; *Turner II*, 520 U.S. at 211, 213 ("question is not whether Congress, as an objective matter, was correct" and "Congress is not obligated, when enacting its statutes, to make a record of the type that an administrative agency or court does to accommodate judicial review" (quotation omitted)); *Fox,* 492 U.S. at 477 (noting "ample scope of regulatory authority" allowed under *Central Hudson*); *id.* at 479-80 (prior holdings leave certain decisions to legislatures, so long as legislative judgment was "reasonable"); *id.* at 480 (within bounds of *Central Hudson's* "reasonable fit" requirement, Court "leave[s] it to governmental decision-makers to judge what manner of regulation may best be employed"); *Lorillard,* 533 U.S. at 555-56, 561 (noting wide range of adequate justifications under *Central Hudson* standard; upholding finding as not based on "mere speculation and conjecture").

This case illustrates the importance of deference to the predictive judgments of the Legislature. When making policy, the Legislature must evaluate the facts before it and predict the effects of a proposed law. Here, the Legislature looked at the evidence, heard competing

views, and concluded that the Prescription Confidentiality Law will be effective in advancing the State's goals of protecting public health, reducing costs, and protecting prescriber privacy. Defendants do not suggest that the Court must simply accept uncritically the Legislature's decision that the statute directly advances the State's interests. *See Turner I,* 512 U.S. at 666 ("That Congress' predictive judgments are entitled to substantial deference does not mean, however, that they are insulated from meaningful judicial review altogether."). If the Court re-weighs the evidence "de novo" and makes its own decision, however, the Court will be substituting its judgment for that of the legislative branch. Instead, as described above, the Court should evaluate the evidence in the legislative record and the trial record and decide whether there was a *reasonable basis* for the Legislature to decide that the statute would directly advance the State's interests. *E.g., Turner I,* 512 U.S. at 666; *Turner II,* 520 U.S. at 211-13.

This approach finds support in cases across the legal spectrum, from First Amendment cases addressing core political speech to the Court's recent decision upholding restrictions on certain late-term abortions. *See, e.g., Gonzales v. Carhart,* 127 S. Ct. 1610, 1636 (2007) ("The Court has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty."); *id.* at 1637-38 (upholding statute even though some findings inaccurate); *McConnell v. Fed. Election Comm'n,* 540 U.S. 93, 137 (2003) (noting *Buckley's* "closely drawn" test for contribution limits "shows proper deference to Congress' ability to weigh competing constitutional interests in an area in which it enjoys particular expertise"). The Supreme Court recently abandoned part of its Fifth Amendment takings test because "it would empower – and might often require – courts to substitute their predictive judgments for those of elected legislatures and expert agencies." *Lingle v. Chevron USA Inc.*,

544 U.S. 528, 544-45 (2005). Plaintiffs' insistence that this Court disregard the findings and judgment of the Legislature contravenes these precedents.[4]

B. Allowing doctors to control the use of identifying information in confidential health care records amounts, at most, to a minimal intrusion on First Amendment interests.

The Prescription Confidentiality Law is a limited statute that restricts the *nonconsensual* commercial use of doctors' identifying information in prescription drug records. The Law is remarkably narrow in scope and forms part of a web of regulation around privacy for health care records. Vermont prescription records, like all medical records, are highly regulated and presumed to be private. Interactions among a doctor, patient, and pharmacist[5] are regulated to protect public health and welfare. *See, e.g.*, 26 V.S.A. §§ 1311-1449 (regulating physicians); *id.* §§ 2021-2079 (regulating pharmacists); Vermont Board of Pharmacy Administrative Rules (eff. Aug. 15, 2003), *available at* http://vtprofessionals.org/opr1/pharmacists/forms/rxrules.pdf ("Pharmacy Board Rules"). Among other things, these regulations protect the privacy and integrity of the doctor-patient relationship and the confidentiality of health information generally. *See, e.g.*, 42 U.S.C. § 1320d-6 (prohibiting disclosure of individually identifiable health information); 45 C.F.R. § 164.502 (same); 12 V.S.A. § 1612 (patients' privilege); 18 V.S.A. § 4211 (protecting confidentiality of prescription information for regulated drugs); Pharmacy Board Rules Pt. C, §§ 5.3, 18.1.2.8, 19.3.1.9 (requiring confidentiality of "[p]rescription and

[4] Plaintiffs at times rely upon *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996), but there is no binding majority opinion in that case addressing the commercial speech analysis. The Court's later opinions, like *Lorillard*, acknowledge the various opinions in *44 Liquormart* but continue to hold that the *Central Hudson* standard applies to commercial speech regulations. *Lorillard*, 533 U.S. at 554. Also, *44 Liquormart* addressed a complete ban on price advertising for a product, 517 U.S. at 516, and thus the issues discussed in that case have little to do with this one.

[5] This brief often refers to "doctors" and "physicians" in place of the statutory term "prescriber." While most prescribers are medical doctors, other health care professionals may also prescribe prescription drugs and are covered by the statute. Covered prescribers include dentists, optometrists, physician assistants, anesthesiologist assistants, podiatrists, nurse practitioners, osteopaths, and naturopaths. The brief also refers primarily to pharmacies as the covered entities in possession of prescriber-identifiable data, though the law applies to other entities. 18 V.S.A. § 4631(d). Plaintiffs generally have identified pharmacies as the source of the data they purchase. IMS Pls Am. Compl., Paper 220 at ¶¶ 30, 36; Tr. 83, 616.

other patient health care information" and mandating policies and procedures for "maintaining the integrity and confidentiality" of the information). These federal and state statutes and rules reflect the *presumption* of confidentiality that attaches to health care information.

Because of the sensitive nature of health care, pharmacists must reasonably expect – and licensing laws require – restrictions on the freedom to use or disclose information obtained as part of their practice. *See, e.g.*, Pharmacy Board Rules Pt. C, §§ 5.3, 18.1.2.8, 19.3.1.9. The limited nature of a First Amendment right to sell data in this context, if any, is supported by Supreme Court cases law showing greater deference to regulations of communications in highly-regulated fields. *See, e.g., Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 620 (1995) (upholding ban on targeted direct-mail solicitation of clients by lawyers within thirty days of accident); *Friedman v. Rogers*, 440 U.S. 1, 15 (1979) (upholding ban on practice of optometry under a trade name); *Ohralik v. Ohio State Bar Ass'n,* 436 U.S. 447, 468 (1978) (upholding state bar disciplinary rule); *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 399-401 (1969) (upholding regulation of broadcasters, noting extensive regulation of broadcasting).

This context shows that the Law represents, at most, a minimal intrusion on First Amendment interests in a field that is already highly regulated. Neither the *Ayotte* court nor the Maine district court in *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2007), fully grasped this point because both focused on the commercial speech rights of data vendors. Vermont's law, however, directly regulates the *pharmacies* that obtain prescription drug information under the terms of their licenses from the State. Data vendors are not even covered under the law. The Law does not regulate the ability of data vendors to buy and sell information available on the public market. It regulates the ability of pharmacists to sell (or allow the

commercial use of) information contained in their confidential records. This aspect of the Law should inform the Court's review under *Central Hudson.*

The Court should also consider, as part of the *Central Hudson* analysis, that the consent provision of this Law makes it nothing like an advertising restriction that prevents the flow of information from a business to an interested consumer. The commercial speech doctrine has its origins in a case about the rights of consumers to receive information. *See Va. State Bd. v. Va. Citizens Consumer Council*, 425 U.S. 748, 756, 763-64 (1976) (allowing consumers standing and noting "keen" interest of consumers in learning information about the prices of prescription drugs). The interests of consumers still animate the Supreme Court's rulings in this area. *See Lorillard,* 533 U.S. at 564 (emphasizing interests of adult consumers in receiving information about tobacco products). This Law takes nothing away from a willing consumer. A doctor is free to consent to the use of her data for marketing, and pharmaceutical companies can still convey their chosen advertising messages to any doctor. What plaintiffs say, however, is that they have a right to use doctors' information without permission for targeted marketing techniques that doctors object to. It turns the commercial speech doctrine on its head to say that it protects a business's right to make nonconsensual use of consumer information for unwanted marketing tactics.

C. The *Central Hudson* standard is a form of intermediate scrutiny and should not be equated with rigorous First Amendment review of core protected speech.

Under *Central Hudson,* a state may restrict commercial speech that concerns lawful activity and is not misleading[6] if (1) "the asserted governmental interest is substantial," (2) "the regulation directly advances the governmental interest asserted," and (3) the regulation "is not more extensive than is necessary to serve that interest." *Central Hudson,* 447 U.S. at 566.

[6] If the commercial speech is misleading or concerns unlawful activity, it lacks constitutional protection. *Central Hudson,* 447 U.S. at 563-64.

Plaintiffs equate *Central Hudson* with rigorous constitutional scrutiny, but the Supreme Court does not. Commercial speech is not a fundamental right, *Fox*, 492 U.S. at 477, and it is "traditionally subject to government regulation," *Lorillard*, 533 U.S. at 554. "Commercial speech [enjoys] a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values." *Id.* (quotation omitted); *see also Edge Broadcasting*, 509 U.S. at 426 (commercial speech afforded "lesser protection"). In prior argument to the Court, plaintiffs have overstated the government's burden under the test in at least two significant ways.

First, *Central Hudson* does not establish a "least restrictive means" or "least intrusive means" standard. *Fla. Bar*, 515 U.S. at 632 ("the 'least restrictive means' test has no role in the commercial speech context" (quoting *Fox*, 492 U.S. at 480)); *Long Is. Bd. of Realtors, Inc. v. Inc. Vill. of Massapequa Park*, 277 F.3d 622, 627 (2d Cir. 2002) (rejecting "least restrictive means" for commercial speech); *see also Ward v. Rock Against Racism*, 491 U.S. 781, 798-99 & n.6 (1989) (equating "least restrictive" and "least intrusive means," holding neither apply to intermediate scrutiny of time, place, manner laws); *Jim Gall Auctioneers, Inc. v. City of Coral Gables*, 210 F.3d 1331, 1333 (11th Cir. 2000) (*Central Hudson* does not require "the least restrictive or least intrusive means" (quoting, in part, *Ward*, 491 U.S. at 788-89)).

As the Supreme Court has explained, the pertinent question is "whether the speech restriction is not more extensive than necessary to serve the interests that support it." *Greater New Orleans Broadcasting Ass'n v. United States*, 527 U.S. 173, 188 (1999). The government need not "employ the least restrictive means conceivable, but it must demonstrate narrow tailoring of the challenged regulation to the asserted interest – 'a fit that is not necessarily perfect, but *reasonable*; that represents not necessarily the single best disposition but one whose scope is in

proportion to the interest served.'" *Id.* (quoting *Fox*, 492 U.S. at 480) (emphasis added).[7] Contrary to plaintiffs' contentions, the State need not address every conceivable alternative to establish the constitutionality of the challenged statute; to the contrary, within the bounds of the "reasonable" fit requirement, it is left "to governmental decisionmakers to judge what manner of regulation may best be employed." *Fox*, 492 U.S. at 480. Additionally, the "imperfect" fit allowed under *Central Hudson* means that underinclusiveness of a regulation is not fatal. *Anderson*, 294 F.3d at 463 (rejecting claim that law was fatally underinclusive, stating "in the commercial speech context, the Supreme Court has made clear that underinclusiveness will not necessarily defeat a claim that a state interest has been materially advanced").

Second, the Supreme Court's precedents do not require a specific quantum of empirical data to support a regulation of commercial speech. *See Lorillard*, 533 U.S. at 555. To the contrary, the Court has "permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and simple common sense." *Fla. Bar*, 515 U.S. at 628 (citations and quotations omitted); *see also Lorillard*, 533 U.S. at 555 (same). Plaintiffs misconstrue the Supreme Court's precedents when describing the State's burden. PhRMA, for example, has cited *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993), as requiring the State to demonstrate its position by "empirical evidence." Paper 169 at 5. That phrase does not appear in *Edenfield*, and indeed the *Edenfield* decision acknowledges the relevance not just of studies, but of anecdotal evidence, experience from other states, and various kinds of publications. *See* 507 U.S. at 771-72.

[7] *Fox* acknowledges that the Court sometimes uses language in commercial speech cases that suggests a standard akin to a least restrictive means requirement. 492 U.S. at 476. But *Fox* expressly rejects that requirement, holding that the *Central Hudson* test has a "more flexible meaning" and affords an "ample scope of regulatory authority." *Id.* at 477.

The IMS plaintiffs have likewise claimed that the State must "marshal 'empirical evidence to support its assumptions.'" Paper 6 at 29. Plaintiffs cite that point to *Bad Frog Brewery, Inc. v. New York State Liquor Authority*, 134 F.3d 87, 100 (2d Cir. 1998), but their citation is incomplete. The Second Circuit in *Bad Frog* reviewed New York's claim that a "raised finger gesture" and accompanying slogan on a beer bottle encouraged consumers to defy authority, including the Surgeon General's warning, and also appealed to children who could not legally buy alcohol. The Second Circuit observed that the "truth of these propositions is not so self-evident as to relieve the state of the burden of marshalling some empirical evidence to support its assumptions." *Id.* at 100. The *Bad Frog* court thus did not create a substantial new burden to justify commercial speech regulation, but merely adhered to *Edenfield's* requirement that the State demonstrate that the "harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Bad Frog,* 134 F.3d at 98; *Edenfield*, 507 U.S. at 771.

To the extent plaintiffs contend the statute can only be justified by empirical studies quantifying the impact of the use of prescriber-identifiable data on physician prescribing practices, they are mistaken. Neither the Supreme Court nor the Second Circuit has imposed such a rigid requirement – one that rarely could be met in advance of imposing a regulation – under *Central Hudson*. *See* Defs. Proposed Findings 55 (impossibility of conducting empirical study). Plaintiffs' efforts to turn *Central Hudson* into a form of strict scrutiny suggest that, under the real standard, Vermont's law is constitutional. *See, e.g.*, Tr. 1173 (PhRMA, arguing State must show, under *Central Hudson*, that "statute's no more restrictive than necessary"); Tr. 1159, 1171, 1210-12 (similar; IMS and PhRMA).

D. The Law directly advances Vermont's three substantial interests: protecting privacy, controlling health care costs, and protecting public health.

The Law directly advances each of the interests identified by the Legislature. First, the Legislature recognized a real and substantial interest in protecting the privacy of doctors and the integrity of the doctor-patient relationship. The Law's consent provision serves that interest by allowing doctors to control the use of their information for marketing purposes. Second, the Law directly advances the State's interests in controlling health care costs and protecting public health because it will reduce the over-prescription of expensive new drugs, promote better and safer prescribing practices, and encourage marketing that is more educational and informative.

1. The Prescription Confidentiality Law directly protects prescriber privacy and the integrity of the doctor-patient relationship.

The Legislature intended the Prescription Confidentiality Law to protect a real and substantial interest: the privacy of doctors and their prescribing information. Findings 20, 22-29. As discussed above, the Legislature's findings on this issue are supported by the views of the Vermont Medical Society and by the testimony of doctors who asked for this Law. *See also* Defs. Annotated Leg. Findings, Findings 4, 6, 20, 27-29.

In contending this interest is not substantial, plaintiffs offer a cramped view of the privacy interests at stake. The prescription data that pharmacies sell to the data-vendor plaintiffs contains extraordinarily detailed information about doctors and the patients they treat. The records purchased by the data-vendor plaintiffs include the identity of the prescriber, the address of the prescriber, the specialty area of the prescriber, the medication being prescribed, the quantity, date, and duration of the prescription, the payor (the entity paying for the prescription), and the name and location of the pharmacy filling the prescription. The records also include the patient's age and gender, geographic information for the patient (including the location of

patient's doctor and pharmacy), and details about drugs prescribed to the patient over time. Defs. Proposed Findings 6-7. Plaintiffs seek to use this information solely for marketing and advertising purposes – that is, they want to use the information to convince doctors to write more prescriptions for the drugs they sell. Defs. Proposed Findings 8-32.

The State has a substantial interest in allowing doctors – not sales people – to decide whether nonpublic prescribing information should be used for these purposes. Doctors understand the practice of detailing and the problems associated with aggressive marketing strategies that use prescriber-identifiable data. To the extent doctors agree with plaintiffs, and view detailing as a helpful, educational practice that improves patient health, they will consent to the use of their information for marketing purposes. Plaintiffs apparently concede that most doctors do not hold that view, given their own belief that few doctors will consent. Tr. 777. That fact alone proves the point: doctors view the marketing use of their nonpublic information as unwanted and intrusive. *See also* Defs. Annotated Leg. Findings, Findings 4, 6, 24-26, 27-29 (collecting evidence in legislative record).

The fact that doctors are professionals does not undercut their privacy interests. In *Edenfield v. Fane,* the Court recognized that there is a substantial state interest in "the protection of potential [CPA] clients' privacy." *Edenfield*, 507 U.S. at 769. *Edenfield* dealt with solicitation of potential clients "in the business context." *Id*. at 763. Thus, the Court recognized the government's substantial interest in protecting the privacy of a business or place of business against intrusive solicitations. *See also Missouri ex rel. Nixon v. Am. Blast Fax, Inc.*, 323 F.3d 649, 654-55 (8th Cir. 2003) (upholding limits on unsolicited faxes based in part on evidence of harm to businesses receiving unwanted faxes).

Plaintiffs misinterpret *Edenfield*, citing out of context the Court's conclusion that "invasion of privacy is not a significant concern." *Edenfield*, 507 U.S. at 776. The Court's statement referred not to the level of privacy afforded to a place of business, but to the *type* of solicitation at issue – a telephone call attempting to set up a meeting with a potential client. 507 U.S. at 776. Here, the challenged statute does not bar the solicitation but the use of nonpublic information for marketing and advertising purposes. What plaintiffs seek to do is akin to – using the *Edenfield* CPA analogy – a CPA soliciting potential business clients *using* the businesses' nonpublic financial information. That use of nonpublic data is a far more intrusive practice than a mere phone call and request for a meeting.[8] In fact, Mr. Frankel from IMS implicitly recognized this when, asked at trial about the likelihood of doctors consenting, he responded "would you check a box if the IRS sent you something and said just check this so we can use all your financial data to evaluate your personal life?" Tr. 836-37. Mr. Frankel is correct. Not many people or businesses want detailed information about their practices used as a marketing tool. That is why doctors have a substantial privacy interest.

The use of information for marketing is particularly troubling in this context, where marketers seek to use nonpublic data to influence the way doctors treat their patients. Dr. Grande's testimony confirmed that the Law reduces undue commercial influence on the doctor-patient relationship. The greater the influence of marketing, including marketing with the advantage conferred by this extremely detailed information, the more likely that the patient's interests may not be put first. This matters not only because patient care can be compromised

[8] While the *Ayotte* court found no substantial interest in protecting prescriber privacy, its decision is of limited value here, for at least two reasons. First, the New Hampshire statute imposed a flat prohibition on the license, transfer, use or sale of prescriber-identifiable data for commercial purposes. The statute was not designed to recognize the privacy interest of doctors and allow doctors to control the commercial use of their nonpublic information. Second, the *Ayotte* court noted weaknesses in the factual record, observing that New Hampshire did not "even attempt to prove . . . that [pharmaceutical companies] use the data to improperly coerce or harass health care providers." *Ayotte*, 490 F. Supp. 2d at 179. The Vermont Legislature found otherwise, *see* Leg. Findings 20, 27, 28, and this Court's decision must be based on deference to those findings and the evidence presented at trial.

but because patient trust in the health care system is undermined. Patients need to know that their interests are put first. By reducing undue commercial influence, the Prescription Confidentiality Law will enhance medical professionalism, *see* Defs. Proposed Findings 49-50, and prevent an unwarranted intrusion on doctors' practice of medicine, *see* Defs. Annotated Leg. Findings, Finding 20.

The Court should also not discount the privacy interests of patients. At trial, plaintiffs defended their practices as consistent with federal rules for protecting patient privacy. Tr. 619. Yet the evidence casts some doubt on whether plaintiffs' interpretation of those rules fully protects patients. For example, the rules restrict geographical information to a partial zip code for most people. 45 C.F.R. § 164.514(b)(2)(i)(B). But prescription information includes the identity of the doctor and the pharmacy, which taken together could easily reveal the small Vermont town that a patient lives in. The rules also restrict dates about a patient to the year only, *id*. § 164.514(b)(2)(i)(C), but the data includes the date of the *prescription* – again, very specific information. Most importantly, nothing in this federal rule contemplates that de-identified patient information will be combined with specific identifying information (full name, address, and specialty) for the patient's doctors. The issue is not whether a person looking at a Verispan chart could match that information to a random name in a phone book. The issue is whether a sales representative who lives and works in a town might be able to connect the de-identified information with other information he or she has about friends or family members. It is hard to reconcile the extraordinary level of detail in these records with plaintiffs' confident assertions that patient privacy could never be compromised. *See* Paper 319 at 10-12 (Amicus Brief of AARP, Vermont Medical Society, et al.).

Once the Court recognizes the State's substantial interest in protecting privacy, the Court should readily find that the Law directly advances that interest. The harm identified by Vermont is the use of prescriber-identifiable data for marketing purposes without the doctor's consent. *Cf. Individual Reference Servs. v. FTC*, 145 F. Supp. 2d 6, 43 (D.D.C. 2001) (identifying harm as "use and disclosure of [customer data] without the consent of the consumer"), *aff'd sub nom*. *Trans Union LLC*, 295 F.3d 42 (D.C. Cir. 2002). The Prescription Confidentiality Law allows doctors to choose whether or not their prescribing information is used in this manner. Accordingly, the law directly advances the State's interest and is "precisely co-extensive with those who are experiencing the particular harm that it is designed to alleviate." *Anderson*, 294 F.3d at 462 (upholding statute that allowed homeowners to choose not to receive certain real estate solicitations).

Plaintiffs contend that the Law cannot protect privacy because other kinds of uses are permitted, including use to fill the prescription and uses related to health insurance. If plaintiffs are correct on this point, then no privacy protection could ever withstand review. Any statute like this one must balance privacy concerns with the need for certain disclosures. HIPAA does not fail as a privacy statute because doctors may transmit health care information to insurance carriers. *See* Defs. Proposed Findings 51. This statute targets precisely the harm identified by the Legislature: the invasion of privacy when nonpublic prescribing information is used for marketing purposes. Plaintiffs appear to suggest that the statute should be broader and restrict *more* speech than necessary to achieve the State's interest. That reasoning has no place in the *Central Hudson* analysis. *Cf. Trans Union*, 245 F.3d at 819 ("regulation is not fatally underinclusive simply because an alternative regulation, which would restrict *more* speech or the

speech of *more* people, could be more effective" (quotation and citation omitted)); *Anderson*, 294 F.3d at 463 (similar).

2. The Law directly advances the State's interests in controlling health care costs and protecting public health.

The other two interests identified by the Legislature, controlling costs and protecting public health, are best discussed together, because the Law achieves these goals in much the same way: by reducing the influence of marketing designed to increase the number of prescriptions written for new drugs and thus promoting better prescribing practices. The evidence shows that the Law will directly advance these interests.

a. Both interests are substantial.

Plaintiffs do not appear to seriously dispute that the State has substantial interests in controlling the ever-rising costs of health care and protecting the public health and safety. The evidence shows that spending on prescription drugs skyrocketed in recent years and continues to grow every year. Defs. Proposed Findings 5-6. The health care dollar is not infinitely elastic. Unnecessary spending on prescription drugs means cutbacks somewhere else, perhaps in access to health care or the type of care available. Defs. Proposed Findings 6. Consistent with Vermont's role as a "pioneer" in trying to control health care costs, *see* Tr. 798-99, 844 (Mr. Frankel), this Law represents a further effort to make health care affordable.

Likewise, the evidence shows that new drugs come with safety concerns and unknown risks. In the first few years a drug is on the market, its side effects and risks are not fully understood. An FDA "badly crippled by underfunding," Tr. 351 (Mr. Hutt), may exacerbate these concerns. Over-prescribing of newly approved drugs exposes more people to unknown risks and at times cause serious harm, as happened with two drugs discussed at trial, Vioxx and Baycol. Defs. Proposed Findings 37-39, 47-49.

b. The Law directly advances these interests.

The Law advances these goals to a material degree by limiting a marketing technique – the use of prescriber-identifiable data – that allows pharmaceutical manufacturers to aggressively market the most expensive, newest, and least understood drugs. The Law limits the use of a specific form of targeted marketing – marketing using prescriber-identifiable data – that influences prescribing decisions in favor of newer, more expensive drugs. No one disputes that pharmaceutical manufacturers use prescriber-identifiable data to promote the sales of newer, more expensive drugs – and no one can credibly dispute that the practice is successful.

i. New drugs are not necessarily better than older drugs, but are more expensive and carry risks

Before addressing these marketing techniques, however, the first step in understanding how the Law works is recognizing that often doctors should *not* be prescribing new drugs. The Legislature found that "[n]ewer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects." Finding 7. As it turns out, plaintiffs cannot credibly dispute this critical Finding.[9] Dr. Wharton, one of their own witnesses, testified that he generally waits before prescribing new drugs, in part because of possible side effects and risks. Tr. 563-65. Dr. Kolassa agreed that new drugs do not necessarily offer therapeutic benefits over existing drugs, Tr. 498-99, and Mr. Frankel agreed that for most patients, a generic drug is equally effective as other drugs in a therapeutic class, Tr. 840. Defendants' witness Dr. Kesselheim explained the point further. To gain approval by the FDA, a drug manufacturer does not have to show that the drug is better than or even equivalent to other

[9] To the extent plaintiffs rely on Dr. Kolassa's testimony to argue that newly approved drugs are generally better than older drugs, the Court should discount that testimony as unpersuasive. Dr. Kolassa's expertise, tellingly, is in pharmaceutical *marketing*, not in health care or medical treatment. Defs. Proposed Findings 64-65. Dr. Rosenthal effectively rebutted his views, demonstrating that there is no good evidence that rapid, widespread adoption of new drugs improves life expectancy and health or decreases the cost of health care. Tr. 962-64; Defs. Proposed Findings 37.

drugs on the market. All they have to do is show that it is more effective than placebo in a small trial of a limited number of patients. So, many newly approved drugs offer little or no benefit over existing drugs, but are more expensive. Defs. Proposed Findings 33-37. New drugs are substantially more expensive than drugs available in generic form, and generic drugs are often just as effective. *Id.* at 36. Dr. Kesselheim testified that there are many examples of new drugs that offered little benefit and other drugs that, after coming on the market, turned out to have much less value than was previously believed. *Id.* at 33.

As noted above, the problem is not just unnecessary cost, although that alone is significant. New drugs have risks because their use and their side effects are not fully understood. Because of the way drugs are tested – that is, in small sets of patients who are generally healthier than the patients who may later take the drug -- new drugs enter the market with unknown safety concerns. These concerns may not be fully understood until after the drug is approved and used in substantial numbers of patients. In fact, serious warnings and safety-related recalls are much more likely to occur in the first few years a drug is on the market. Defs. Proposed Findings 37-40. By the time a drug loses its patent protection and is available in generic form – typically after ten to fourteen years on the market – the medical community generally has accrued enough knowledge of and experience with the drug to fully understand its risks and benefits. *Id.* at 38.

There is, in short, no good evidence that rapid, widespread adoption of new drugs improves life expectancy and health or decreases the cost of health care. Tr. 962-64. And so the evidence shows a laundry list of widely prescribed new drugs that offered little benefit over cheaper, generic drugs (the proton-pump inhibitor Nexium; calcium channel blockers for blood pressure; Vytorin for cholesterol) and, even worse, new drugs that were expensive, over-prescribed without reason, and actually dangerous to the patients who took them (the pain reliever Vioxx

and the cholesterol drug Baycol, both removed from the market for serious side effects). Defs. Proposed Findings 33-39. The over-prescription of these drugs added untold millions to health care budgets and harmed patients. *Id*.

ii. Targeted marketing campaigns using prescriber-identifiable data lead to the over-prescription of new drugs.

It is this problem of over-prescribing that is addressed by the Prescription Confidentiality Law. Targeted marketing campaigns using prescriber-identifiable data focus on aggressively promoting the widespread use of new drugs as soon as they are available. There is no question that the data is used in this way. The evidence details this marketing practice, showing how pharmaceutical companies use the data to target "valuable" doctors (meaning those who prescribe a lot of drugs) and target messages based on doctors' prescribing practices. Defs. Proposed Findings 10. The data is used not just to develop marketing strategies, but to monitor the success of those strategies. *Id.* 23-29. The ability to monitor doctors – the "spying" complained of in the Vermont Legislature – is part of what makes the practice so effective. Sales representatives can track the prescribing practices of the doctors they visit and carefully note how doctors respond to different strategies – to gifts of food, to a particular message, to samples, or other tactics. Sales representatives get to see the results, in prescriptions written or not written, and adjust their tactics accordingly. *Id*. Mr. Fisher, from Verispan, looks at the marketplace for prescription drugs as a game and prescriber-identifiable data as the scoreboard. Tr. 168. That analogy is troubling enough for the health care industry. But the evidence shows that prescriber-identifiable data is *not* just a scoreboard. It is the tool that companies use to win the game. Dx 246[10] at 7481 (aim of purchasing data is to reap "big returns").

[10] As is clear from the transcript of the proceedings before the Court, the document admitted into evidence as Defendants' exhibit 246 is an IMS document authored, in part, by Mr. Sadek entitled *It's All in the Details*. Because exhibit 246 was identified on a pre-trial submission as exhibit 245, however, the reporter's exhibit list reflects a

Plaintiffs may argue, as they did throughout the trial, that detailing to doctors is educational and provides information that doctors need. The industry's own documents, however, show that detailing is about increasing the number of prescriptions written for the drugs being promoted.[11] Defs. Proposed Findings 8-15. Mr. Ahari, the former sales representative for Eli Lilly, was unequivocal on this point: his goal as a sales representative was not to educate doctors, but to get them to prescribe the drugs he promoted. *Id.* at 12. The substantial evidence compiled over the course of the trial confirms this. Detailers are given quotas and compensated for reaching them; they are not trained to educate doctors; they are told to focus their efforts on the doctors that can "drive market share" and to use the resources available to them to get results. Defs. Proposed Findings 8-13, 29-32. If plaintiffs truly view this marketing practice as a valuable educational process, one wonders why the relevant industry documents – those that discuss targeted marketing using prescriber-identifiable data – were submitted to the Court by defendants, not by plaintiffs. Indeed, the documents tell the story. IMS tells its customers that prescriber-identifiable data can be used to "maximize the revenue per sales call and the scripts per detail." Tr. 130; Dx 71 at 2110. As one company explains the practice, its sales force uses prescriber-identifiable data to "find top potential physicians that can help move share" and "identify physicians within a zip code for performance and potential." Dx 1213 at 30, 32, 33. The instructions for how to target physicians illustrate how little education has to do with any of this. Sales representatives use the data to sort physicians, transfer the list "to a new spreadsheet for further manipulation" and then "delete" physicians who do not make the "market share cutoff." The list should include "only those top physicians that can help move share." Dx 1213

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different document for exhibit 246. Defendants will file a motion to correct the record. When referring to defendants' exhibit 246 in this memorandum, the document referenced is the IMS article written by Mr. Sadek.

[11] To the extent plaintiffs' rely on Dr. Kolassa, again, the Court should find his testimony unpersuasive. Any claim that marketing is not used to increase demand or that doctors cannot be influenced by marketing is contradicted not just by defendants' highly qualified experts, but by the industry's own documents. *See generally id.*

at 34, 35, 37. Over and over again, the industry documents make the same point: prescriber-identifiable data is used to target the "right" physicians, with the "right" message, to maximize sales and increase market share. *See generally* Defs. Proposed Findings 14-32; *see also* Defs. Annotated Leg. Findings, Findings 4, 6 (Dr. Landry; "To say that the pharmaceutical representatives are providing doctors with education on drugs is . . . pathetic").

The secrecy surrounding the use of prescriber-identifiable data for marketing also illustrates its use as a sales tool and lack of educational value. By contract, the data-vendor plaintiffs prohibit pharmaceutical companies from disclosing the data to anyone, even doctors. Defs. Proposed Findings 32-33. While sales representatives are expected to study the data to prepare for sales calls, they are warned that the reports are "not for use in detail." Co. B Dep. 49, 52-54. Mr. Ahari explained that he was trained not to bring his computer with the data into a doctor's office, to dismiss or deflect questions about the use of the data, and to understate the value of the data to the company's marketing practices. Tr. 991. As he explained, sales representatives use the data to tailor messages without letting on that the message is based on prescribing information, because "physicians usually regard this information as confidential; they don't really wish to tell the drug rep about this. So we pretend that we don't know and again make all our comparisons seemingly coincidental." Tr. 1007.

The data is also used to compensate sales representatives for meeting or exceeding sales quotas, and here again the industry documents show sales representatives are motivated to move product, not educate doctors. *See* Defs. Proposed Findings 29-32. Using the data, managers provide advice like: "These are important doctors in your territory, but they are really dragging down your share. If you move 10 of these doctors by 5 percentage points, you will hit your goal easily." Dx 1204 at 321. Mr. Sadek from IMS describes the two most important questions

facing a pharmaceutical sales representative as one, how much am I getting paid, and two, what do I need to do to make more money. Tr. 135; Dx 246 at 7483. Prescribe-identifiable data gives sales representatives the tools to answer these questions and motivate sales. They get "payout calculators" that provide regular, quick updates on how much money a sales representative will earn based on current trends, and what they need to accomplish to make more money. Defs. Proposed Findings 31-32. These come with directions like: "Plug in your desired payout and the calculator will show what volume or share you will need to achieve to get there." Dx 1202 at 6.

Plaintiffs may also return to their claim that doctors are not influenced by marketing, so the use of the data cannot have a negative influence on prescribing practices. Defendants' experts, all scholars in this area, effectively rebutted this argument. Dr. Wazana, the author of a widely cited study in the Journal of the American Medical Association, explained that while doctors tend to believe they are immune from marketing influences, in fact the evidence shows that they are influenced. Dr. Kesselheim and Dr. Grande agree. Defs. Proposed Findings 40-42. As Dr. Kesselheim testified – testimony supported by numerous concrete examples – many new drugs that come on the market are over-prescribed without reason. *Id.* at 43-45. Even Dr. Wharton's testimony implicitly confirms the influence of marketing on doctors. Dr. Wharton testified that he has not prescribed the cholesterol drug Vytorin, even though it was heavily marketed. But it has had billions of dollars in sales – until recently, when studies showed that it did not provide the expected benefit, a benefit provided by other drugs already on the market. Tr. 562, 566-68. Indeed, nothing can explain the tremendous sales of other drugs like Vioxx and Nexium except marketing – because the science was not there.

Dr. Grande explained how the use of prescriber-identifiable data amplifies the influence of marketing, and his testimony was entirely consistent with the industry's own marketing

documents. Sales representatives use their knowledge of the drugs prescribed by a particular physician to develop and tailor messages that present information in a selective fashion. As one example, when a sales representative knows that a physician is prescribing a competitor's product, the representative can focus the message on a side effect where the representative's product compares favorably to the competitor's product. Defs. Proposed Findings 42. Mr. Ahari confirmed that sales representatives tailor messages in this way without ever mentioning the competitor's product, and described it as delivering a "very skewed perspective" of what should be objective information. *Id.* at 22. Prescriber-identifiable data also allows sales representatives to measure the response to their practices, in terms of prescriptions written, and very carefully decide how to use them – for example how many samples to bring and how many lunches to provide. *Id.* at 25-26. Without question, pharmaceutical marketing practices have a very strong impact on physicians' prescribing habits and the use of prescriber-identifiable data is key. It helps pharmaceutical sales representatives attune their messages for the highest advertising and promotional effect. *Id*. at 14-29.

The evidence is thus overwhelming that marketing using prescriber-identifiable data influences doctors. To argue otherwise, plaintiffs have to convince the Court that their multibillion dollar targeted marketing campaigns do not work – that is, they do not influence doctors to prescribe the advertised drugs. That is not possible.

iii. The Law directly advances the State's interests by limiting this marketing technique.

The Law directly advances the State's goals by limiting a marketing technique – the use of prescriber-identifiable data – that allows pharmaceutical manufacturers to market new drugs aggressively. The use of prescriber-identifiable data leads to the over-prescription of new drugs and over-accelerates the uptake of a new drug when it comes on the market. Defs. Proposed

Findings 40-45. Limiting the "sales pitch" tactics facilitated by prescriber-identifiable data will help prevent inappropriate use and over-prescription of drugs in patients for whom the drugs are not indicated or for conditions where the data might not support their use. Because the law will limit the impact of marketing, it will lead to more optimal prescribing practices. *Id*. at 45-47.

With respect to cost, the overuse of newly-approved, more expensive products can lead to substantial overcharges for the government health care budget and other health care payors. Those budgets are already tight and unnecessary expenses hurt the health care system. Recent past examples show tremendous opportunities for savings. Vioxx was widely overprescribed and cost multiple dollars per pill, the same as a whole bottle of generic ibuprofen that would have served most patients equally well. *Id.* at 44. The use of calcium channel blockers instead of less expensive medications for controlling blood pressure cost government programs billions of dollars. *Id.* at 44-45. Another study by Dr. Kesselheim showed that states could have saved $800 million from 2001 to 2005 if doctors prescribed a generic proton pump inhibitor instead of Nexium. *Id*. at 43.

Indeed, Vermont can save substantial sums through increased appropriate prescribing of generic drugs. At present, Vermont's overall utilization of generic drugs is only about 62%. Based on Dr. Rosenthal's calculations, which no party has disputed, Vermont would save about $2 million annually by increasing utilization of generic drugs by just 1%. *Id*. at 45-48. Taken together, the testimony of Dr. Kesselheim and Dr. Rosenthal shows that restricting the use of prescriber-identifiable data for marketing purposes will lower health care costs by decreasing the amount spent in Vermont on prescription drugs. *Id.* at 46.

The benefit in terms of patient safety cannot be quantified, but it is real. Patients are harmed when doctors prescribe new drugs unnecessarily, because they are exposed to uncertain risks and

side effects. *Id*. at 47-49. The Law will limit those risks by making detailing more educational and promoting better prescribing practices. *Id.*

E. The Law is narrowly tailored.

1. The Law satisfies the "reasonable fit" requirement.

The Law satisfies *Central Hudson's* requirement of narrow tailoring because it focuses solely on the particular problem of targeted marketing using nonpublic prescribing information. The requisite "reasonable" fit between the State's interests and the Law's limited restriction is shown by at least two salient factors.

First, the Law only restricts the use of nonpublic information as a marketing technique for doctors who do not want to participate in this kind of marketing program. Courts consistently uphold laws that afford an individual the ability to choose whether or not to receive a commercial message. In *Anderson*, the Second Circuit held that a statute allowing homeowners to choose whether or not to receive certain solicitations satisfied the reasonable fit requirement because the restriction was "precisely co-extensive" with the harm. *See* 294 F.3d at 462-63; *see also Rowan v. United States*, 397 U.S. 728, 729-30, 737 (1970) (upholding statute allowing individuals to remove names from mailers' list; mailers' First Amendment rights were subject to "an affirmative act of the addressee giving notice that he wishes no further mailings from that mailer"); *United States v. Playboy Enter. Group*, 529 U.S. 803, 815 (2000) (upholding law allowing "targeted blocking" of unwanted television in individual households); *Trans Union LLC v. FTC*, 295 F.3d 42, 53 (D.C. Cir. 2002) (upholding opt-in financial privacy protections under Gramm-Leach-Bliley); *Trans Union Corp. v. FTC*, 267 F.3d 1138, 1143 (D.C. Cir. 2001) (upholding opt-in financial privacy protections under Fair Credit Reporting Act); *ACLI v. Vermont*, 2004 WL 578737, at *6-7 (Vt. Super. Ct. Feb. 12, 2004) (upholding opt-in protections

against disclosure of nonpublic financial and personal health information by insurance companies). "Do not call" registries, which allow consumers to block unwanted telephone solicitations, have also been widely upheld. *See, e.g.*, *Mainstream Marketing Servs. v. FTC*, 358 F.3d 1228 (10th Cir. 2004). Indeed, this Law is similar to, but even narrower than, a do-not-call registry. By declining consent, doctors – not the State – control the commercial use of their nonpublic identifying data in prescription records.

Laws that protect the privacy of identifying information and restrict commercial use of the information are increasingly common. *See, e.g.*, Driver's Privacy Protection Act, 18 U.S.C. § 2721(d) (restricting disclosure of driver information without consent); Video Privacy Protection Act, 18 U.S.C. § 2710-2711 (prohibiting disclosure of "personally identifiable information concerning any consumer" of a video rental establishment without consent); Cable Communications Policy Act, 47 U.S.C. § 551(c)(1) (prohibiting disclosure of "personally identifiable information concerning any subscriber without the prior written or electronic consent of the subscriber"); Gramm-Leech Bliley Act, 15 U.S.C. § 6802(b) (providing customers of financial institutions the right to "opt-out" of disclosure of their personal information to third parties); Stored Communications Act, 18 U.S.C. § 2702(c) (restricting use of internet subscriber information without customer's consent); 8 V.S.A. §§ 10201-10205 (financial privacy); 9 V.S.A. § 2480e (credit reports). Although plaintiffs may claim that these laws protect individuals but not businesses or professionals, in fact business customers have rights under these laws as well. The Prescription Confidentiality Law's restriction is similar to numerous other state and federal laws in less private fields than health care, which further shows that the Law is narrowly tailored.

The *Ayotte* court relied upon *U.S. West, Inc. v. FCC*, 182 F.3d 1224 (10th Cir. 1999) and plaintiffs may cite this case as well. *See Ayotte*, 490 F. Supp. 2d at 175. There, the Tenth Circuit

held, over dissent, that an FCC rule requiring phone companies to get consent from their customers before using records of their customers' phone calls for targeted marketing did not have enough evidentiary support to satisfy *Central Hudson*. *See U.S. West*, 182 F.3d at 1239. The *U.S. West* court's analysis of consumer privacy interests is mistaken and should not be followed here. (It bears noting that the two D.C. Circuit cases cited above, both of which uphold information privacy laws, do not discuss *U.S. West*, much less follow its reasoning.). The suggestion that consumers may not have a privacy interest in the detailed records of their phone calls, or in avoiding unwanted solicitations based on those records, is hard to credit. *See id.* at 1235-36. In fact, the court dismissed evidence showing that customers did value the privacy of their information. The record showed that when a phone company called customers to ask for consent, the vast majority did not give it. *Id.* at 1239. In any event, the analysis in *U.S. West* is not relevant here, because the court focused on FCC's alleged failure to consider an "opt-out" rule instead of requiring affirmative customer consent. *See id.* at 1238-39. Plaintiffs here do not argue that a consent requirement could be implemented in another fashion. Rather, they argue that doctors do not have a right to control the use of their prescribing information for marketing.

Second, the State has not prohibited detailing, restricted the content of advertising, or curtailed the industry's ability to convey truthful, nonmisleading information about prescription drugs to doctors. Prescriber-identifiable data is not part of the "message" conveyed to doctors; to the contrary, sales representatives try to keep doctors from knowing they have the information. Defs. Proposed Findings 32-33. The fact that the law does not restrict the advertising message distinguishes this case from those in which the Supreme Court has struck down bans on particular kinds of advertising or solicitation. *See, e.g., Va. State Bd.*, 425 U.S. at 773 (striking flat ban on pharmacists' advertising of price of prescription drugs); *Bates v. State Bar of Ariz.*,

433 U.S. 350, 383 (1977) (striking flat ban on lawyer advertising); *Edenfield v. Fane*, 507 U.S. 761, 777 (1993) (striking flat ban on in-person solicitation of potential clients by CPAs); *Rubin v. Coors Brewing Co*., 514 U.S. 476, 491 (1995) (striking flat ban on disclosure of alcohol content on beer labels); *44 Liquormart v. Rhode Island*, 517 U.S. 484, 489 (1996) (plurality opinion) (striking ban on advertising price of alcohol, except for placement of price on or near product); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 562, 571 (2001) (striking law prohibiting placement of smokeless tobacco ads within 1000 feet of schools, noting "in some geographic areas, these regulations would constitute nearly a complete ban" on advertising of smokeless tobacco); *Thompson v. W. States Med. Ctr*., 535 U.S. 357, 377 (2002) (striking flat ban on pharmacists' advertising of compounded drugs).

2. Plaintiffs' suggested alternatives are irrelevant and inadequate.

Instead of acknowledging the narrowness of the restriction in this Law, plaintiffs focus their arguments on a changing list of programs or laws they claim would also serve Vermont's interests. As argued above, *Central Hudson* does not impose a "least restrictive means" test, although plaintiffs keep trying to inject that requirement. Defendants nonetheless briefly address the two alternatives discussed by plaintiffs at trial.

Academic detailing. While academic detailing (also known as counterdetailing) is a good practice that can provide unbiased information to doctors, it is not a realistic alternative to the Prescription Confidentiality Law. For one thing, it does not address doctors' privacy interests. Moreover, academic detailing is expensive and a difficult process to manage. Tr. 845 (Mr. Frankel). The programs cannot be developed quickly enough or employed widely enough to counter the billions of dollars spent on marketing to doctors each year by the pharmaceutical industry. It is not realistic to expect states or academic institutions to match the resources

expended by the pharmaceutical industry. Defs. Proposed Findings 63. It also bears noting that the Legislature's efforts to expand academic detailing in Vermont are at risk because of PhRMA's claims in this lawsuit. *See infra* (discussing manufacturing fee). The industry should not be allowed to endorse academic detailing as an alternative while simultaneously opposing funding for the practice.

Prior authorization and formularies. These are practices that make it more difficult for doctors to prescribe certain drugs or for patients to obtain them. A doctor may need to get special permission to prescribe the drug or the patient may have to pay substantially more money for it. Vermont already has these programs and while helpful at controlling costs, they have not been sufficient to prevent over-prescription of new drugs. Moreover, plaintiffs' description of these programs as "less restrictive" is not quite right. The programs may not restrict the data vendors' acquisition of data, but they impose burdens on doctors and patients. The Prescription Confidentiality Law does not prevent a prescriber from prescribing any drug. Defs. Proposed Findings 62-63.

F. No other arguments asserted by plaintiffs are sufficient to overcome the deference afforded the Legislature and much of their evidence amounts to speculation that is not relevant to a facial challenge.

Plaintiffs devoted a substantial amount of trial time to discussing issues that have, at most, tangential relevance to this case. These topics included federal regulation of drug advertising, voluntary codes of conduct like the PhRMA code, and uses of prescriber-identifiable data, like health care research, that are not restricted by the statute. They make sweeping policy arguments about funding pharmaceutical research. To the extent plaintiffs rely on this type of evidence to suggest that the Prescription Confidentiality Law is unconstitutional, they are mistaken. And the speculative evidence they cite is not sufficient to support a facial challenge.

1. Federal regulation of drug advertising does not serve the same purposes.

Federal regulation of marketing is not sufficient to prevent marketing strategies that promote over-prescription of new drugs. *See* Defs. Proposed Findings 59 (describing current practices that are generally consistent with federal law). While certain conduct by sales representatives would violate federal law, there is a range of conduct that is not illegal under federal law but serves to make sales pitches more effective and move product. The Prescription Confidentiality Law addresses the latter type of detailing. The Law also addresses the privacy interests of doctors, a subject not touched upon by FDA advertising restrictions. This Law will work in conjunction with existing federal requirements to help improve healthcare outcomes and reduce financial stresses on the health care system. *Id.*

In addition, federal enforcement is not sufficient even to guard against violations of federal law. Mr. Hutt, a witness for PhRMA, testified about his view that the FDA has been badly crippled by underfunding in recent years. Tr. 351. As one example, in recent years, the FDA has greatly reduced the number of warning letters it has sent out about advertising that violates federal rules. In 1992, there were 1,712 warning letters and 1,788 in 1993. In 2007, the year the Law was passed, there were 467 warning letters. Defs. Proposed Findings 48, 58. Mr. Hutt concluded, with respect to the decreased number of warning letters, that a "weakened FDA inevitably leads to weak compliance with the law." And he testified at trial that "there is no question about that." Tr. 356.

2. The PhRMA Code and other voluntary codes of conduct are likewise irrelevant.

As with federal regulation, the PhRMA code and other voluntary codes of conduct neither stop the targeted marketing practices at issue nor protect doctors' privacy. Moreover, the

evidence casts doubt on the effectiveness of the PhRMA Code. Company E, for example, instructs its sales representatives to make sure their call notes, which are detailed notes about meetings with physicians, "reflect compliance." The advice is quite specific: "you cannot put in things like; spouse came to dinner, loaned my proxima to the doctor, brought a gift for xxx, etc." Dx 1200 at 92. And there should be "[n]o mention of off label uses even if it was the doctor that brought it up." Dx 1200 at 92. (Companies may not market products for off-label uses.). The Court should infer that the language used in this material shows that Company E is aware of conduct that is not compliant and does not want sales representatives to make a record of it. PhRMA's own internal documents discuss "persistent anecdotal reports of sales representatives using prescriber-identifiable information in ways that physicians find inappropriate or offensive, ways which we believe are inconsistent with the PhRMA Code on Interactions with Healthcare Professionals." Dx 108. *See also* Defs. Proposed Findings 57-58.

3. The Law does not restrict other uses of the data, and the evidence shows that pharmaceutical companies use prescriber-identifiable data principally for marketing.

Plaintiffs also argued at trial that the Law will undermine beneficial uses of the data, such as health care research and safety alerts. These claims are irrelevant because the Law allows these uses of the data. 18 V.S.A. § 4631(e). The claims also lack factual support in the record. Prescriber-identifiable data is not necessary to conduct clinical trials, drug recalls, and drug safety alerts. Some companies do not use the data for these purposes at all and others make only limited use, conceding that the data is not necessary. Defs. Proposed Findings 60-62. Prescriber-identifiable data is not used by pharmaceutical companies to track patterns of disease and treatment for scientific or health research. *Id.* at 62. In general, pharmaceutical companies either use the data only for marketing purposes or principally for marketing purposes. *Id.*

4. Speculation about funding research in the pharmaceutical industry is irrelevant.

Plaintiffs seem to argue that efforts to control spending on prescription drugs are misguided because the pharmaceutical industry needs the money to fund its future research efforts. Mr. Hutt expressed opposition to the Law based on his view that the country "must have high enough drug prices" to fund research and development for the world. Tr. 347-48; Tr. 344-46 (expressing similar concerns about any program that increases use of generic drugs and decreases spending on newly approved drugs). This kind of testimony is neither fact nor relevant opinion; it is nothing more than an expression of a policy preference that favors spending over cost control. Moreover, any link between Vermont's Law and funding for drug research is entirely speculative, and thus has no bearing on the Law's facial constitutionality, as discussed below.

5. Speculative evidence about future events is irrelevant to a facial challenge.

One of the reasons the Supreme Court cautions against enjoining state laws before they are implemented is that such claims are speculative and risk premature interpretation of statutes without necessary facts. *Wash. State Grange v. Wash. State Republican Party*, 128 S. Ct. 1184, 1995 (2008). Facial challenges are properly addressed only to the "facial requirements" of the statute and courts may not "speculate about 'hypothetical' or 'imaginary' cases." *Id*. at 1190. Plaintiffs ask the Court to engage in just this kind of speculation, however. They contend that future events like a new PhRMA Code that takes effect next year and changes to FDA funding that may improve federal enforcement are somehow relevant to the constitutionality of this Law. They ask the Court to accept as fact that the data-vendor plaintiffs will stop acquiring prescriber-identifiable data for any purpose, including purposes permitted under the Law, for financial reasons. And they argue that if pharmaceutical companies do not make enough money, it may

affect future drug development. None of these predictions about future events can be tested and none are relevant to a facial challenge. This is precisely the sort of "premature interpretation of statutes on the basis of factually barebones records" that the Supreme Court discourages, even in the First Amendment context. *Id*. at 1195 (quotations omitted). The Court should accordingly disregard arguments based on speculation and possible future events.

G. The evidence at trial confirms that the Law is not vague.

Defendants have previously addressed plaintiffs' claim that the Law is vague, *see* Papers 247, 339, and do not repeat that briefing here, given the Court's request for the First Amendment briefing to focus on *Central Hudson*.[12] The trial evidence confirms, however, that the statute is not vague. Specifically, the evidence confirms two points that show that plaintiffs could easily comply with the Law.

First, data vending is already organized around contractual relationships and licensing agreements, including agreements that restrict the use of the data by pharmaceutical companies. Defs. Proposed Findings 32 (data-vendor plaintiffs restrict use of data); Tr. 629 (CVS puts restrictions on data vendors' use of data). Data vendors routinely encrypt data as well. Tr. 151, 159-60. The data-vendor plaintiffs' assertion that they could not acquire prescriber-identifiable data while restricting its use for marketing is contradicted by this evidence.

Second, both the data-vendor plaintiffs and pharmaceutical companies readily understand the concept of using prescriber-identifiable data for marketing and promoting prescription drugs. That is what they do. The information is sold to pharmaceutical companies who use it for their market research and sales force. In fact, it was often difficult to get a pharmaceutical company to identify any non-marketing use of the data. At least one company said they expressly limit the

[12] Defendants' prior briefing addresses the prior restraint, vagueness, overbreadth, and strict scrutiny arguments asserted by plaintiffs. *See* Papers 247, 339. Defendants rely upon their prior briefing of these issues and incorporate those arguments here.

use of the data to marketing and do not allow its use by medical divisions. Plaintiffs' self-serving assertions they could not understand and implement a restriction on the use of data for marketing and promoting prescription drugs should not be credited.

II. The Prescription Confidentiality Law does not violate the dormant Commerce Clause.

The data-vendor plaintiffs' claim that the Prescription Confidentiality Law violates the dormant Commerce Clause is no more successful than their First Amendment claims. A dormant Commerce Clause challenge may be premised on one of three assertions: the state law "discriminates on its face against interstate commerce," *United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth*., 127 S. Ct. 1786, 1793 (2007); the law impermissibly burdens interstate commerce, *Pike v. Bruce Church, Inc*., 397 U.S. 137, 142 (1970); or the law regulates commerce entirely outside the State's borders, *Healy v. Beer Inst*., 491 U.S. 324, 332 (1989). The data-vendor plaintiffs' claim falls into the last category. They contend that the Prescription Confidentiality Law "impermissibly regulates conduct occurring wholly outside of Vermont." IMS Pls. Am. Compl., Paper 220 ¶ 97. They are mistaken, and their claim fails, for the following reasons: (1) the data-vendor plaintiffs lack standing to assert this claim; (2) the Law has no extraterritorial reach; (3) Supreme Court and Second Circuit precedent show the Law is constitutional; and (4) plaintiffs have not shown that the Law violates the dormant Commerce Clause in all of its applications, as required with a facial challenge.

A. Plaintiffs do not have standing to challenge a law that does not regulate their conduct and they cannot raise the dormant Commerce Clause rights of pharmacies.

Plaintiffs face a threshold obstacle to their dormant Commerce Clause claim: they are not the proper plaintiffs to bring it. A "plaintiff must demonstrate standing for each claim he seeks to press," *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006), and the data-vendor plaintiffs have not made an adequate showing of their standing for this claim. The Prescription

Confidentiality Law does not regulate transactions by data vendors. Plaintiffs' extraterritoriality argument is instead premised on the idea that the Law "makes it illegal for *pharmacies* and other similar entities to continue providing prescriber identifiable data to the publisher plaintiffs." IMS Pls Am. Compl., Paper 220 ¶ 98 (emphasis added). The data vendors are not the proper parties to litigate whether Vermont may regulate the pharmacies that do business in this State. It is the conduct of pharmacies that is at issue, and no pharmacy has chosen to sue.

The Supreme Court has acknowledged its "general reluctance to permit a litigant to assert the rights of a third party." *Campbell v. Louisiana*, 523 U.S. 392, 397 (1998); *see also Singleton v. Wulff*, 428 U.S. 106, 113 (1976) ("courts must hesitate before resolving a controversy . . . on the basis of the rights of third persons not parties to the litigation"). A "plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Warth v. Seldin*, 422 U.S. 490, 499 (1975). So-called third-party standing is permitted only where "three preconditions [are] satisfied: (1) the [party asserting the claim] suffered an injury in fact; (2) he had a close relationship to the [third parties]; and (3) there was some hindrance to the [third parties] asserting their own rights." *Campbell*, 523 U.S. at 397 (quotation omitted). The Second Circuit applies the same test. *See, e.g., Mid-Hudson Catskill Rural Migrant Ministry, Inc. v. Fine Host Corp.*, 418 F.3d 168, 174 (2d Cir. 2005) (plaintiff seeking third-party standing in federal court must satisfy prudential requirements, including demonstrating a hindrance to other party's ability to protect its own interests).

Applying this test, even if the data-vendor plaintiffs can show an injury-in-fact, they lack standing unless they can show some obstacle to pharmacies asserting their own rights under the Commerce Clause. Pharmacies are established businesses with substantial revenues – indeed, many pharmacies in Vermont are operated by major national corporations like Rite Aid and

CVS. They also have a financial interest in this issue. Defs. Proposed Finding 68. Pharmacies are not like prospective jurors, *see Campbell*, 523 U.S. at 400 (criminal defendant may raise equal protection rights of venirepersons, who have "economic disincentives to assert their own rights"), or newborn children, *see Lewis v. Thompson*, 252 F.3d 567, 585 (2d Cir. 2001) ("few individuals less able to protect their own interests than newborn children"). Nothing stops these corporations from litigating their own claims, so the data-vendor plaintiffs cannot meet the requirements for third-party standing. *See Mid-Hudson Catskill*, 418 F.3d at 174 (organization lacked standing to litigate members' rights without demonstrated hindrance to members' ability to protect own interests).

The one case on which plaintiffs have relied for standing, *Government Suppliers Consolidating Services, Inc. v Bayh*, 975 F.2d 1267 (7th Cir. 1992), is not persuasive in light of the Supreme Court and Second Circuit precedent above, and its own sparse analysis. The *Bayh* court, in a few sentences, found that the plaintiffs had standing for a dormant Commerce Clause challenge given their economic injury, despite the fact that they did not engage in the regulated activity (backhauling). 957 F.2d at 1274. The court did not give sufficient consideration to the limits on parties raising the legal rights of others. The *Bayh* court also relied on *Association of Data Processing Services Organizations v. Camp*, 397 U.S. 150 (1970), which the Second Circuit, like other circuits, has expressly limited to the context of administrative actions under the Administrative Procedure Act. *Conn. Action Now, Inc. v. Roberts Plating Co.*, 457 F.2d 81, 89 (2d Cir. 1972). *Bayh* is not persuasive, and it does not afford plaintiffs standing here.

The Court should avoid unnecessary constitutional adjudication where no direct party in interest has litigated the Law's alleged extraterritorial reach. *See Valley Forge Christian Coll. v. Ams. United for the Separation of Church and State, Inc.*, 454 U.S. 464, 474 (1982).

B. Properly construed, the Prescription Confidentiality Law has no extraterritorial reach.

Even if plaintiffs have standing, their claim fails on the merits. The Prescription Confidentiality Law does not regulate commerce occurring entirely outside of Vermont. Rather, it regulates the use of data from a regulated Vermont transaction. The entities regulated by the Prescription Confidentiality Law – health insurers, self-insured employers, electronic transmission intermediaries, pharmacies, and similar entities, 18 V.S.A. § 4631(d) – all conduct business in Vermont. Pharmacies and health insurers are licensed by Vermont. *See id*. § 4631(b)(6) (defining pharmacy), (b)(4) (defining health insurer). The statute governs the use of prescriber-identifiable data in "regulated records," which are prescription drug records for prescriptions dispensed in Vermont or written by Vermont prescribers. *Id.* § 4631(b)(9),(d). The Law restricts certain uses of the data by covered entities unless the prescriber has consented or the use is permitted by an exception. *Id.* § 4631(d), (e). [13]

As this description shows, the statute has no extraterritorial application. The covered entities are located in or have a nexus to Vermont: they are principally pharmacies doing business in and licensed by Vermont.[14] The prescription drug information at issue is from prescriptions written by Vermont prescribers and prescriptions dispensed by pharmacies licensed by and located in Vermont or having a nexus to Vermont. Vermont pharmacies acquire the data in Vermont and enter it into computers physically located in Vermont. Defs. Proposed Findings 68.

The data-vendor plaintiffs nonetheless mistakenly assert that the Law violates the dormant Commerce Clause because it regulates a transaction by two businesses located outside Vermont – that is, the sale of data by a pharmacy chain like CVS to a data mining company like IMS.

[13] PhRMA does not assert a Commerce Clause challenge to § 4631(d), so the Commerce Clause claim does not extend to the portion of the statute that regulates pharmaceutical companies and pharmaceutical marketers.
[14] The IMS plaintiffs' allegations about their purchase of data apply only to pharmacies, so the restrictions on other covered entities are not at issue in this case. The analysis is the same in any event.

Vermont may, however, regulate the practices of a business like CVS that has a physical presence in and conducts substantial business in the State. The fact CVS may transfer data from its Vermont stores to a computer in another state before selling the data to IMS is of no importance. CVS does business in Vermont, its pharmacies are licensed in Vermont, and it is subject to all Vermont laws that govern the dispensing of prescription drugs in the State, including the collection and security of prescription records. *See, e.g.*, 26 V.S.A. §§ 2021-2064 (pharmacy licensing statutes); Vt. Pharmacy Board Rules, Part C, §§ 5.3, 18.1.2.8, 19.1, 19.8. It cannot avoid that regulation by claiming to conduct a transaction in a different state using data from Vermont records.[15]

C. Supreme Court and Second Circuit precedent support the constitutionality of the Prescription Confidentiality Law under the dormant Commerce Clause.

An analysis of relevant precedent shows that the Prescription Confidentiality Law does not offend the dormant Commerce Clause. The Second Circuit looks at "extraterritoriality" challenges by asking whether a state law "has the practical effect of requiring out-of-state commerce to be conducted at the regulating state's direction." *SPGGC, LLC v. Blumenthal*, 505 F.3d 183, 193 (2d Cir. 2007) (quotation omitted); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 110 (2d Cir. 2001). The burden on a plaintiff making such a challenge is high. The plaintiff must show that the law in question "inescapably" or "undeniably" controls transactions outside of the state. *See SPGGC*, 505 F.3d at 193-95 (upholding state law prohibiting the expiration of gift certificates against extraterritoriality challenge; distinguishing previous laws struck by the Supreme Court which "had the undeniable effect of controlling commercial activity

[15] An analogy to regulation of the legal profession illustrates this point. Vermont attorneys may be disciplined by the state for wrongful disclosure of confidential client information. *See* Vermont Rules of Professional Conduct, Rule 1.6. In the information age, it takes little imagination to see how a breach of Rule 1.6 could occur outside Vermont. For example, an attorney traveling out of state could breach a client confidence by communicating information via email to another person outside Vermont. The fact that the electronic disclosure took place outside Vermont does not prevent the state from disciplining the attorney.

occurring wholly outside the boundary of the State" (quotation omitted)); *Nat'l Elec.*, 272 F.3d at 110 (concluding that Vermont's mercury-labeling law does not violate Commerce Clause "because the statute does not inescapably require manufacturers to label all lamps wherever distributed"). This approach is consistent with the general presumption that legislation applies only within the territorial jurisdiction of the governmental body enacting it. *See Small v. United States*, 544 U.S. 385, 389 (2005) (recognizing general "presumption against extraterritorial application" of statutes); *K-S Pharmacies, Inc. v. Am. Home Prods. Corp.*, 962 F.2d 728, 730 (7th Cir. 1992) (recognizing strong "presumption of exclusive domestic application" of state statutes and declining to interpret state law as having invalid extraterritorial reach).

The Second Circuit's ruling in *SPGGC* is directly relevant and shows that the IMS plaintiffs' arguments are mistaken. The *SPGGC* decision addresses the constitutionality of a Connecticut consumer protection law regulating gift cards. The plaintiff claimed the Gift Card Law could not apply to gift cards sold on the internet because that would be "inherently extraterritorial." 505 F.3d at 195. The court of appeals rejected the argument, noting that the seller of gift cards had a "readily available" means of distinguishing between consumers protected by the law and those outside its scope – billing addresses. *Id.* Likewise, pharmacies may readily separate identifying information for Vermont prescribers from unregulated data from other states and conduct their business transactions accordingly.

The Prescription Confidentiality Law is readily distinguished from laws struck down by the Supreme Court in the cases cited by plaintiffs. Those decisions instruct that state statutes that directly link in-state prices to prices charged in other states have an impermissible extraterritorial reach. *See Healy*, 491 U.S. at 335-36 (striking Connecticut law requiring out-of-state liquor producers to affirm their prices were no higher than those of bordering states); *Brown-Forman*

Distillers Corp. v. N.Y. State Liquor Auth., 476 U.S. 573, 575-76 (1986) (striking similar New York law); *Baldwin v. G.A.F. Seelig, Inc*., 294 U.S. 511, 526 (1935) (striking New York law setting minimum prices for milk and banning resale within New York of milk purchased for a lower price). Here, by contrast, the statute "makes no mention of other states for any purpose." *Nat'l Elec.*, 272 F.3d at 110. None of these decisions provides a basis for invalidating the Prescription Confidentiality Law.

Moreover, both the Supreme Court and the Second Circuit have cautioned against expansive use of the Commerce Clause to limit state consumer protection laws. Consumer protection is a traditional field of state regulation and courts therefore "'should be particularly hesitant to interfere with the [State's] efforts under the guise of the Commerce Clause'" in this context. *SPGGC*, 505 F.3d at 194 (quoting *United Haulers*, 127 S. Ct. at 1796). This reasoning applies with special force to this case, because plaintiffs' novel Commerce Clause theory has consequences far beyond this case. Plaintiffs contend that Vermont simply cannot regulate any use of identifying or personal information for Vermont residents once that data is transferred to an out-of-state computer – even though the data is acquired by a Vermont business in the course of a Vermont transaction. Tr. 1216-17. Under that reasoning, the State is powerless to protect the personal, financial, or health information privacy of its residents, because any Vermont business could simply transfer its data out of state and avoid state regulation. Not surprisingly, plaintiffs do not identify any legal support for such a narrow view of a state's regulatory and police powers. The Court should reject their invitation to employ the "dormant Commerce Clause [as] a roving license for federal courts to decide what activities are appropriate for state

and local government to undertake, and what activities must be the province of private market competition." *United Haulers*, 127 S. Ct. at 1796.[16]

D. Plaintiffs' facial challenge is speculative and premature.

Because this is a facial challenge, the Court must look only to the "facial requirements" of the statute and may not "speculate about 'hypothetical' or 'imaginary' cases." *Wash. State Grange*, 128 S. Ct. at 1190; *see also Field Day, LLC v. County of Suffolk*, 463 F.3d 167, 174 (2d Cir. 2006) ("A 'facial challenge' to a statute considers only the text of the statute itself, not its application to the particular circumstances of an individual."). On its face, 18 V.S.A. § 4631 regulates the actions of entities that do business in Vermont and restricts certain uses of information obtained from Vermont transactions. Speculation about the law's potential application to out-of-state commerce is irrelevant to a pre-enforcement facial challenge. Moreover, plaintiffs must show that the law *necessarily* regulates out-of-state commerce in all of its applications to sustain their pre-implementation facial challenge. *See United States v. Salerno*, 481 U.S. 739, 745 (1987); *United States v. Sage*, 92 F.3d 101, 106 (2d Cir. 1996) (applying *Salerno* standard to facial Commerce Clause challenge); s*ee also United States v. Lopez*, 215 Fed. Appx. 863, 864 n.3 (11th Cir. 2007) (same); *Nebraska v. EPA*, 331 F.3d 995, 998 (D.C. Cir. 2003) (same); *S.D. Myers, Inc. v. City & County of San Francisco*, 253 F.3d 461, 467 (9th Cir. 2001) (same for dormant Commerce Clause); *Am. Booksellers Found. for Free*

[16] Plaintiffs may also be suggesting that the Prescription Confidentiality Law violates the Commerce Clause because it affects their businesses, which are located out of state. The fact that a state law may have some effect on out-of-state commerce does not make it unconstitutional. The Supreme Court "has never suggested that the dormant Commerce Clause requires Balkanization, with each state's law stopping at the border." *Instructional Sys., Inc. v. Computer Curriculum Corp.*, 35 F.3d 813, 825 (3d Cir. 1994) (upholding law regulating franchise agreements, despite extraterritorial effect); s*ee also, e.g., Pharm. Research and Mfrs. of Am. v. Walsh*, 538 U.S. 644, 668-70 (2003) (summarily rejecting Commerce Clause challenge under *Baldwin* and *Healy*, despite extraterritorial effects of Maine prescription drug rebate program, because law did not tie in-state and out-of-state prices). Plaintiffs' businesses may be marginally less profitable if Vermont pharmacies no longer sell data about Vermont prescribers to them. That type of incidental consequence does not amount to a Commerce Clause violation, however.

Expression v. Strickland, 512 F. Supp. 2d 1082, 1102 (S.D. Ohio 2007) (same). Plaintiffs cannot meet this heavy burden, entitling defendants to judgment on this basis alone.[17]

III. The manufacturer's fee does not violate PhRMA's First Amendment right against compelled speech.

Besides addressing the use of prescriber-identifiable data in marketing, Act 80 also established a fee on pharmaceutical manufacturers, known as the manufacturer's fee. 2007, No. 80, sec. 20 (codified at 33 V.S.A. § 2004). The fee funds several state programs, including a state program designed to educate doctors about the "therapeutic and cost-effective utilization of prescription drugs." 18 V.S.A. § 4622(a)(1). PhRMA challenges this proposed use of the manufacturer's fee as a violation of its First Amendment right against compelled speech. PhRMA Am. Compl., Paper 174, Count 3. Because the State may spend its tax revenues on its own programs without violating the First Amendment, the fee is constitutional.

The parties cross-moved for summary judgment on this count and subsequently agreed that the Court's resolution of the count shall be based solely on the summary judgment papers. *See* Stipulation, Paper 363. For the convenience of the Court, defendants and PhRMA agreed to incorporate the summary judgment arguments into the post-trial briefs. The Stipulation still controls on this count and the Court should not consider any facts or arguments not contained in the summary judgment papers. *See* Papers 168-70, 205, 206, 231, 233, 264, 265, 363, 369, 376, 379. Because this issue is to be resolved on the papers, defendants incorporate by reference their statement of undisputed facts and related filings and attachments. Papers 204, 206, 264, 265, and PhRMA Paper 376-1 (deposition of Dr. Craig Jones).

[17] Plaintiffs claim that they have not brought a facial challenge, but a pre-implementation as-applied challenge "to the extent [the law] applies to transactions occurring wholly outside the state of Vermont." Paper 300 at 10. Only facial challenges can be considered before a statute is applied. *Bowen v. Kendrick*, 487 U.S. 589, 600 (1988). Facial challenges are based solely on the facial requirements of a statute – not on speculation, assumptions, or hypotheticals as to how the law may be applied. *Wash. State Grange*, 128 S. Ct. at 1190-91. Plaintiffs' effort to re-characterize their claim as a pre-implementation challenge to how the law *could be* applied to out-of-state transactions is inconsistent with the doctrine of facial challenges.

A. The Manufacturer's Fee: Basic Framework

The manufacturer's fee is calculated as a percentage (0.5%) of the State's spending on a particular manufacturer's products each year. 33 V.S.A. § 2004; 2007, No. 89, sec. 4 (Adj. Sess.) (technical correction). Pharmaceutical manufacturers pay the manufacturer fee to the Agency of Human Services. 33 V.S.A. § 2004(a). The revenues are deposited in the evidence-based education and advertising fund. *Id.* § 2004(b); *see also id.* § 2004a(a) (creating the evidence-based education and advertising fund).

By statute, the revenues from the manufacturer fee are to be used for three purposes: (1) collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18; (2) analysis of prescription drug data needed by the attorney general's office for enforcement activities; and (3) the evidence-based education program established by 18 V.S.A. §§ 4621-4622. *See* 33 V.S.A. § 2004(b); *id.* § 2004a(a). The evidence-based education program is also created by Act 80. *See* 2007, No. 80, sec. 14 (codified at 18 V.S.A. §§ 4621, 4622). It includes a pilot program for the distribution of vouchers for generic drugs. *Id.* sec. 15 (generic drug voucher pilot project). The vouchers will be funded by revenues from the manufacturer fee. *Id.* sec. 15(b); 2007, No. 89, sec. 1 (technical correction).

PhRMA's challenge to the fee is directed at only one of its intended uses: the evidence-based education program. Paper 172 at 13. The Legislature directed the Department of Health, in collaboration with other agencies and the University of Vermont, to "establish an evidence-based prescription drug education program for health care professionals." 18 V.S.A. § 4622(a)(1). The statute defines "evidence-based" as "based on criteria and guidelines that reflect high-quality, cost-effective care." *Id.* § 4621(2). The methodology used to develop guidelines "shall meet recognized standards for systematic evaluation of all available research and shall be free from

conflicts of interest." *Id.* Consideration of certain "experimental or investigational treatment" is not precluded. *Id.* The evidence-based education program is "designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals." *Id.* § 4622(a)(1).

The fee has not yet been collected and neither the evidence-based education program nor the generic voucher program has been implemented. Defs. Facts, Paper 206 ¶¶ 12-14.

The statute creating the evidence-based education program also provides that, "[t]o the extent practicable," the evidence-based education program "shall use the evidence-based standards developed by the blueprint for health." 18 V.S.A. § 4622(a)(1). PhRMA focuses on this provision, *e.g.*, Paper 169 at 14-15, so some additional detail about the Blueprint is useful.

The Blueprint for Health is "the state's plan for chronic care infrastructure, prevention of chronic conditions, and chronic care management program." 18 V.S.A. § 701(1). The goals, benchmarks, and purposes of the Blueprint are spelled out in some detail in statute. *Id.* §§ 701-702; Defs. Facts, Paper 206 ¶¶ 1, 11. The director of the Blueprint for Health oversees its development and implementation. Defs. Facts, Paper 206 ¶¶ 3, 11. The director is an appointed state official, Craig Jones, M.D., *id.* ¶ 2, and his duties, again, are spelled out in statute. 18 V.S.A. § 702. Among other things, the director makes final decisions about the implementation of the Blueprint and gives final approval to the clinical quality and performance measures adopted by the Blueprint. Defs. Facts, Paper 206 ¶¶ 6, 10.

The director is advised by an executive committee. Defs. Facts, Paper 206 ¶¶ 5, 6. The members of the executive committee are appointed by the Secretary of the Agency of Human Services and include several state officials as well as a consumer, representatives from the Vermont Medical Society and from private insurers, and other persons drawn from the private

and nonprofit health care sectors. 18 V.S.A. § 702(c)(1); Defs. Facts, Paper 206 ¶ 5; Jones Aff., Paper 206-2, 206-3 Attach. A. The statute does not require a representative of a pharmaceutical manufacturer to be included on the executive committee. 18 V.S.A. § 702(c)(1).

Dr. Jones explained in his deposition that the Blueprint has not developed any standards for the evidence-based education program and also pointed out that the Blueprint's standards generally do not recommend the use of particular prescription drugs. Jones Dep., Paper 376-1 at 97-98, 100-02, 138-39.

B. The manufacturer's fee is constitutional.

The Court should reject PhRMA's First Amendment challenge to the manufacturer fee for three reasons: (1) the fee funds a government program, which is permissible under the First Amendment; (2) PhRMA's speculation about how the program will be developed lacks factual support and is irrelevant to a facial challenge; and (3) PhRMA's facial challenge serves no purpose since PhRMA is not challenging the collection of the fee, only its potential future use.

1. The manufacturer fee funds a government program, which is permissible under the First Amendment.

The State of Vermont may constitutionally tax PhRMA's members to fund the State's own policies and programs, including speech and advertising by the State, whether or not PhRMA's members agree with the message conveyed. *See generally Johanns v. Livestock Marketing Ass'n*, 544 U.S. 550 (2005) (upholding compelled support of beef marketing campaign by beef producers, where government controls advertising message). PhRMA contends that the evidence-based education program "will be shaped in large measure by . . . private interests" and that private parties will "determine the content" of the program. Paper 169 at 15. Those statements are not accurate, but even if they were, the program is constitutional so long as the State has the final say in approving the content of the program. *See Johanns*, 544 U.S. at 560-61.

As argued below, the State may consult with and rely upon persons outside state government in creating its programs, so long as state officials control the programs and have final authority over their content. Applying the *Johanns* standard, there is no question that the evidence-based education program is a state program run by state officials.

a. *Johanns* allows compelled subsidies for government speech.

The starting point for the First Amendment analysis is *Johanns*. *Johanns* holds that compelled subsidy of government speech does not violate the First Amendment. *Id.* at 559, 560-62. The Court in that case analyzed the federal government's mandatory fee to support advertising and promotion of beef. *Id.* at 553-54. The Court upheld the assessment because the "message of the promotional campaigns is effectively controlled by the Federal Government itself." *Id.* at 560. Vermont's planned evidence-based education program, like the beef promotional campaign, is controlled by the government, not by private parties. To the extent PhRMA argues to the contrary, it is wrong.

Instead of accepting that *Johanns*[18] controls this case, PhRMA cites frequently to an earlier case about compelled subsidies, *United States v. United Foods*, 533 U.S. 405 (2001), which was effectively reversed by *Johanns*. *See* Paper 169 at 14-15. A more detailed explanation of the cases is necessary to place PhRMA's First Amendment claim in the proper context.

The First Amendment claims asserted in *United Foods* and *Johanns* were quite similar. In both cases, farmers and producers contested the mandatory assessments imposed on them by the Department of Agriculture to subsidize generic advertisements promoting their particular

[18] PhRMA's description of the holding in *Johanns* requires clarification. PhRMA describes the case as "allowing financial levies used to subsidize government speech on behalf of the livestock industry, but distinguishing such levies where the speech was *shaped even in part by private interests*." Paper 169 at 15 (emphasis added). In fact, the Court in *Johanns* held that, so long as the government sets the "overall message" and approves the wording, the government is "not precluded from relying on the government-speech doctrine merely because it solicits assistance from nongovernmental sources in developing specific messages." 544 U.S. at 562.

commodity (mushrooms in *United Foods* and beef in *Johanns*). *See United Foods*, 533 U.S. at 408-09; *Johanns*, 544 U.S. at 555-56. The farmers objected to subsidizing speech that, in effect, benefitted their competitors. The objecting mushroom grower sought to "convey the message that its brand of mushrooms is superior to those being grown by other producers," 533 U.S. at 411, and the beef ranchers believed the beef promotions "impede[d] their efforts to promote the superiority of" specific kinds of beef like American beef or Angus beef, 544 U.S. at 556.

United Foods was decided first and the Supreme Court held the mushroom marketing program to be unconstitutional. *See* 533 U.S. at 413. The Court reached this conclusion, however, on the assumption that the mandatory assessment for the marketing program was a compelled subsidy of private speech, not unlike the use of compelled union dues for political speech. *See id.* at 413-14 (analogizing advertising program to union dues and attorney bar membership fees). The Court declined to consider whether the advertising program was government speech, because the government did not raise the issue until the case reached the Supreme Court and the opposing parties had no opportunity to address it. *See id.* at 416-17.

Just a few years later, however, the Court effectively reversed itself in *Johanns*, where it upheld the constitutionality of the Department of Agriculture's beef marketing program. The Court acknowledged that the beef program was "very similar" to the mushroom program struck down in *United Foods* and treated the programs as indistinguishable for First Amendment purposes. *See id.* at 555 n.2 (describing "similar" programs overseen by Department of Agriculture for various commodities); *id.* at 558 (describing programs as "very similar," and quoting court of appeals as saying programs were identical in "all material respects"); *id.* at 569 (Breyer, J., concurring) (programs "virtually identical"). The Court reached different conclusions in the two cases only because the federal government waived the government speech

argument in *United Foods. Johanns,* 544 U.S. at 558-59 & n.3; *United Foods,* 533 U.S. at 416-17 (deeming government speech argument waived). In *Johanns,* the federal government argued persuasively that the advertising programs, which are controlled by the Secretary of Agriculture, are government speech. *See id.* at 560. The Court agreed. *Id.* at 563-64.

The Court's reasoning in *Johanns* thus governs the analysis of whether a particular program is government speech for First Amendment purposes. PhRMA's reliance on *United Foods* is misplaced. *See* Paper 169 at 14. The Court's disapproval of compelled subsidies in *United Foods* was premised on the assumption that the subsidies funded the speech of private persons. *See Johanns,* 544 U.S. at 558. Where taxes or fees subsidize the government's own speech, the compelled subsidy is permissible. *See id.* at 559 ("Our compelled-subsidy cases have consistently respected the principle that '[c]ompelled support of a private association is fundamentally different from compelled support of government.'" (quoting *Abood v. Detroit Bd. of Educ.,* 431 U.S. 209, 259 (1977)).

b. The fee is constitutional under *Johanns.*

PhRMA cannot succeed under the standard set out in *Johanns.* PhRMA attempts to draw a line from the evidence-based education program to the Blueprint for Health, and then to the Blueprint's "provider practice work groups" – all to argue that the Blueprint's work groups are composed of persons from outside state government. *See* Paper 169 at 15. But the "speech" to which PhRMA objects is not the Blueprint, it is the intended message of the evidence-based education program. That message has been set by the Legislature and entrusted to the state Department of Health to carry out. *See* 18 V.S.A. §§ 4621, 4622. The fact that the Legislature directed the Department of Health to possibly use standards developed by another program does not affect its constitutionality. The evidence-based education program is still a government

program under the control of government officials. So long as that is the case – that the government sets the message and approves the wording – the government may, under *Johanns,* "solicit[] assistance from nongovernmental sources in developing specific messages." 544 U.S. at 562; *see also id.* at 560 n.4 (governmental or nongovernmental status of committee that designed promotional campaigns was not at issue, given role of Secretary of Agriculture and Board appointed by Secretary).

PhRMA attempts to distinguish this case from *Johanns,* but it cannot plausibly do so. The differences either do not exist or were not relevant to the Supreme Court's reasoning in *Johanns.*

1. PhRMA claims that this case is different because in *Johanns,* the assessments supported generic industry advertising, while here the fee will be used to, in PhRMA's words, "advance a viewpoint favoring products sold by only some pharmaceutical manufacturers and *competitive to the products of other manufacturers.*" Paper 232 at 5-6; Paper 169 at 13. (That is, PhRMA apparently believes that "criteria and guidelines that reflect high-quality, cost-effective care," 18 V.S.A. § 4621(2), will inevitably encourage doctors to prescribe generic drugs.) The critical flaw in this reasoning is that the *Johanns* plaintiffs made the same unsuccessful argument. The objecting beef producers in *Johanns* contended that the generic advertising "impede[d] their efforts to promote the superiority of" their products. 544 U.S. at 556. They said that the beef program was controlled by a "narrow interest group" that paid "no heed to [their] dissenting views" and claimed the generic advertising limited their ability to promote their specific products. *Id.* at 562. The dissenting opinion highlighted the plaintiffs' disagreement with the generic advertising. *See id.* at 570-71 (noting that objecting ranchers believed generic advertising did not distinguish between the American beef they sold and imported beef they

considered inferior). There is no difference between this case and *Johanns*: in both, the objecting parties believe that the government's speech is contrary to their financial interests.

Contrary to PhRMA's suggestion, the Court's holding in *Johanns* did not turn on a view that the beef marketing program purported to benefit the entire beef industry. Rather, the Court upheld the marketing program because its content was controlled by the federal government. *See* 544 U.S. at 560. Likewise, here, the State may constitutionally require PhRMA's members to fund a program that educates doctors about generic drugs.

It bears noting, however, that PhRMA's argument relies on mistaken premises. The statute does not, in fact, call for the evidence-based education program to uniformly promote the use of generic drugs. The program is intended to "provide information and education on the therapeutic and cost-effective utilization of prescription drugs." 18 V.S.A. § 4622(a)(1). It may well be that "criteria and guidelines that reflect high-quality, cost-effective care" will support the medically appropriate use of many generic drugs. *See* 18 V.S.A. § 4621(2) (defining "evidence-based"). If PhRMA's views about the benefits of branded drugs are correct, however, the program may at times recommend the use of name-brand drugs. At this point, PhRMA's position is based on speculation.[19] Moreover, PhRMA's members sell both brand-name drugs and generic drugs. *See* IMS Consulting, Assessment of Authorized Generics, Paper 264-4; Berndt et al., Authorized Generic Drugs – Working Paper, Paper 264-5; PhRMA's Responses Req. Admit, Paper 264-7 ¶ 50. So even if the program recommends the use of generic drugs, the program may well be supporting the products of PhRMA's members.

[19] The same is true of PhRMA's claim that the evidence-based education program is "inaccurate and unbalanced." Paper 232 at 7. PhRMA cannot have support for this claim, since the program does not exist yet. The statutory direction is exactly the opposite: "'Evidence-based' means based on criteria and guidelines that reflect high-quality, cost-effective care. The methodology used to determine such guidelines shall meet recognized standards for systematic evaluation of all available research and shall be free from conflicts of interest." 18 V.S.A. § 4621(2).

2. PhRMA's disagreement with the stated purposes of the evidence-based education program is irrelevant. It is not clear why PhRMA and its members would object to educating doctors about "high quality, cost-effective care" including "the therapeutic and cost-effective utilization of prescription drugs." 18 V.S.A. §§ 4621(2), 4622(a)(1). But regardless, their objections have no bearing on the First Amendment analysis. The beef producers who challenged the beef marketing program in *Johanns* did so because they disagreed with the program's content. They objected to "advertising [that] promotes beef as a generic commodity" because such advertising "impede[d] their efforts to promote the superiority of, *inter alia,* American beef, grain-fed beef, or certified Angus or Hereford beef." *Johanns,* 544 U.S. at 556. As the decision in *Johanns* shows, the government may require persons to provide financial support for the government's speech, even over protests or objections. *Id.* at 559-60, 564 n.7.

3. PhRMA complains, too, that its members will have no role in developing the evidence-based education program because the pharmaceutical industry is not presently represented on the executive committee for the Blueprint for Health. PhRMA also argues that the Blueprint has not done a good enough job of publicizing its meetings. *See* Jones Dep., Paper 376-1 at 78-81, 137 (Dr. Jones was not personally involved in publishing notice of the meetings, because the matter was handled by staff within the Agency of Administration). This is not the appropriate forum to review the requirements of the State's public meeting laws. Even assuming PhRMA and its members have no say in shaping the content of the evidence-based education program, the program may still constitutionally be funded by the manufacturer fee. The objecting beef producers in *Johanns* believed they had no meaningful voice on the Beef Board's Operating Committee, which designed the promotional campaigns for approval by the Secretary of Agriculture. *See Johanns,* 544 U.S. at 560-61 & n.4, 562. The Court found the composition and

role of the Committee irrelevant to the First Amendment analysis, because "the message set out in the beef promotions is from beginning to end the message established by the Federal Government." *Id.* at 560 & n.4. The same is true here.

2. PhRMA's speculation about how the program will be developed lacks factual support and is irrelevant to a facial challenge.

PhRMA's arguments have another weakness, one PhRMA does not adequately address. This case is a facial challenge to the collection of the fee and its use to fund the evidence-based education program. The fee has not yet been collected and, without funding, the program has not been developed. *See* Defs. Facts, Paper 206 ¶¶ 12-14. PhRMA's claims are thus limited to the provisions of the statute, not its application or implementation. *See, e.g., Field Day, LLC v. County of Suffolk*, 463 F.3d 167, 174 (2d Cir. 2006) ("A 'facial challenge' to a statute considers only the text of the statute itself, not its application to the particular circumstances of an individual."). "In determining whether a law is facially invalid, [the Court] must be careful not to go beyond the statute's facial requirements and speculate about 'hypothetical' or 'imaginary' cases." *Wash. State Grange*, 128 S. Ct. at 1190.

"Facial challenges are disfavored," even in the First Amendment context, and the Supreme Court has recently cautioned about the importance of exercising "judicial restraint" in this area. *See id.* at 1191. To succeed at this early stage, PhRMA must show "that the challenged law either could never be applied in a valid manner or that even though it may be validly applied to the plaintiff and others, it nevertheless is so broad that it may inhibit the constitutionally protected speech of third parties." *Marchi v. Bd. of Coop. Educ. Servs.*, 173 F.3d 469, 479-80 (2d Cir. 1999) (describing facial challenges under the First Amendment) (quotations omitted). PhRMA does not suggest that the evidence-based education program inhibits speech, so the premise of its facial challenge must be that the "law. . . could never be applied in a valid

manner." *Id.* Put another way, PhRMA must demonstrate "'that no set of circumstances exists under which the Act would be valid,' i.e., that the law is unconstitutional in all of its applications." *Wash. State Grange*, 128 S. Ct. at 1190 (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)).

Instead of trying to satisfy this standard, which would be impossible, PhRMA bases its argument on mistaken assumptions about how the evidence-based education program will be run. PhRMA's first mistaken assumption is that "the Blueprint for Health's 'provider practice working group' will develop the standards" for the evidence-based education program. Paper 232 at 3. The statute says nothing of the kind. It makes no mention of the provider practice working group and does not even call for the Blueprint to develop standards for the evidence-based education program. The statute merely directs the evidence-based education program to use Blueprint standards "[t]o the extent practicable." 18 V.S.A. § 4622(a)(1). The evidence-based education program has not yet been implemented, so no one knows to what extent the program will draw upon the Blueprint. Speculation about how the program may or may not be run is not relevant to PhRMA's facial challenge. *See Wash. State Grange*, 128 S. Ct. at 1191 (cautioning that facial challenges "often rest on speculation" and "raise the risk of 'premature interpretation of statutes on the basis of factually barebones records'" (quoting *Sabri v. United States*, 541 U.S. 600, 609 (2004)).

Moreover, the evidence does not support PhRMA's assertions about the relationship between the Blueprint and the evidence-based education program. Contrary to PhRMA's representation, Joshua Slen did not testify that the Blueprint's provider practice work group would develop standards for use by the evidence-based education program. Paper 232 at 3. In the cited testimony, Mr. Slen was asked about the workings of the Blueprint for Health. He was not asked

about the relationship between the Blueprint and the evidence-based education program and did not testify that the provider practice work group would develop any standards or programming for the evidence-based education program. *See* Slen Dep., Paper 264-1 at 185-197.[20]

Surprisingly, PhRMA continues to advance the same argument even after taking the deposition of Blueprint director Dr. Jones. Dr. Jones was questioned at some length about the relationship between the Blueprint and the evidence-based education program. *See* Jones Dep., Paper 376-1 at 97-102, 113. His testimony confirms that the Blueprint program is not developing programs or standards for the evidence-based education program. Among other things, Dr. Jones testified as follows:

> Q: Has the Blueprint for Health, and you'll notice the Legislature used the term developed, has the Blueprint for Health developed any evidence-based standards that would be applicable or relevant to this particular aspect of the statute [referring to section 4622(a)(1)]?
> A. Not that I'm aware of.
> *******
> Q. Okay. So are you aware that the Blueprint has developed any standards that would be, or on which this evidence-based education program with respect to prescription drugs could be based?
> [Objection.]
> A. Not since I've been here.

Id. at 100-02. Dr. Jones also testified that the standards adopted and used by the Blueprint do *not* include recommendations for specific pharmaceuticals nor do they encourage the use of generic

[20] Mr. Slen's testimony confirms several points that PhRMA either disputes or disregards: (1) the evidence-based education program has not yet been implemented; (2) in the Blueprint, the work of the provider practice group is reviewed first by the Executive Committee and then by the Executive Director; (3) the Blueprint is a state program run by state officials; and (4) the Blueprint does not adopt standards that recommend the use of particular prescription drugs. *See, e.g.,* Slen Dep., Paper 264-1 at 185 ("The Vermont Blueprint for Health was originally started by Governor Douglas, and it was formalized in legislation and State law by the State Legislature."); *id.* at 187 ("In general terms, the . . . Executive Committee is responsible for advising the Executive Director of the Blueprint for Health on appropriate actions to move forward the chronic care management system in the state."); *id.* at 188 ("In the last few months those work groups have not been meeting; the Executive Committee has been taking a more active role in actual implementation pieces and the new Executive Director of the Blueprint who started in August is really shaping direction for this year."); *id.* at 191 ("I am unaware of the standards of care identifying individual pharmaceuticals."); *id.* at 197 (evidence-based education program not yet implemented).

drugs instead of branded drugs. Jones Dep., Paper 376-1 at 97-98, 138-39; *see also* Jones Aff., Paper 206-3, ¶ 9; Slen Dep., Paper 264-1 at 191.

PhRMA thus has no evidence to show that the "message of the evidence-based education program" is developed by the Blueprint's workgroups and the workgroups are "design[ing] the evidence-based education program." *See* Paper 376 at 2, 4-5. The evidence is to the contrary. Dr. Jones' testimony certainly provides no support, since he repeatedly said that the Blueprint had done nothing in connection with the evidence-based education program. Jones Dep., Paper 376-1 at 97-102, 113.

PhRMA also makes a number of unsupported assertions about the workings of the Blueprint. As defendants have consistently pointed out, this case is not about the Blueprint, but about the evidence-based education program, so much of this irrelevant. But given the emphasis PhRMA places on its description of the Blueprint, some correction is required. The Blueprint is not run by a provider practice work group consisting of private individuals. All of the evidence – including the evidence cited by PhRMA – shows that the Blueprint is run by state officials, with an advisory committee *entirely appointed* by the Secretary of the Administration. *See* Jones Aff. ¶¶ 2-7, 10-11; Moffat Dep., Paper 264-2 at 117 ("Our role is in determining the *certification* of the standards of care that are drawn on." (emphasis added)); Slen Dep., Paper 264-1 at 193 (Executive Committee "adopts, or *recommends to the Executive Director the Blueprint adoption*" of recommendations made by the provider practice work group (emphasis added)). The statute confirms this point. *See* 18 V.S.A. § 702.[21] The advisory role of the provider

[21] PhRMA cites the January 2007 Blueprint Strategic Plan for its membership lists for the Blueprint's Executive Committee and working groups. The 2007 Plan does not reflect the current organizational structure of the Blueprint. The Legislature amended the Blueprint statute in 2007 to create a Director and locate the Blueprint in the Agency of Administration. *See* 2007, No. 71, § 4. The same statute also made other significant changes to the Blueprint. *See generally id.* This exercise of legislative control further confirms that the Blueprint is a state program.

practice work group shows that the Blueprint is wisely seeking input from clinicians in fulfilling its statutory mission. Indeed, no one disputes that the Blueprint seeks input from a range of stakeholders in the private, public, and nonprofit health care sectors. The Blueprint is nonetheless controlled by state officials. Dr. Jones' testimony confirms that he is the director of the Blueprint and that the Blueprint's committees provide advice and recommendations to him and his staff. Jones Dep., Paper 376-1 at 18-19, 21-22, 45-46.

In this vein, PhRMA's description of the State as a "rubber stamp" for the work group is rhetoric unsupported by any evidence. *See* Paper 232 at 4. PhRMA conveniently disregards Mr. Slen's description of the current efforts of the Blueprint, which downplays the role of the work group: "In the last few months those work groups have not been meeting; the Executive Committee has been taking a more active role in actual implementation pieces and the new Executive Director of the Blueprint who started in August is really shaping direction for this year." Slen. Dep., Paper 264-1 at 188. PhRMA also disregards the evidence from the person best informed about the running of the Blueprint, its executive director, Dr. Craig Jones. *See, e.g.*, Jones Aff. ¶ 10 ("It is my role as Director, in collaboration with the Commissioner of Health, to give final approval to the clinical quality and performance measures for chronic conditions."). Continuing with this rhetoric, PhRMA makes the unfounded charge that Dr. Jones, the Blueprint Director, acts as a "rubber stamp" because Blueprint officials have not rejected any clinical recommendations from the provider practice work group. As Dr. Jones explained in his deposition, the Blueprint uses "well established and nationally recognized standards of care" in its efforts to improve the way health care is delivered. Jones Dep., Paper 376-1 at 10-11; *see id.* at 13-17, 26-32 (discussing at length how the Blueprint adopts and uses national standards, such as those promulgated by the National Institutes of Health). It is not

surprising that there is little disagreement on the adoption of these standards. And it would be a strange result indeed if the Blueprint staff had to reject "well established and nationally recognized standards of care" for the State's education program to be constitutional. PhRMA's bizarre allegation that members of the work group are "accountable to no one," Paper 232 at 4, has no evidentiary or statutory support. The discussion above illustrates that PhRMA's facial challenge is inadequate and premature. PhRMA's entire case rests on the following assumption: The Blueprint's provider practice work group will develop evidence-based standards for use by the evidence-based education program, and no state official will review and adopt those standards before they are used. *See* Paper 232 at 2-4. There is no factual or legal basis for this assumption. The statute merely provides a general direction to the Department of Health to use the Blueprint's standards "[t]o the extent practicable." 18 V.S.A. § 4622(a)(1). The statute does not specify which standards should be used, how those standards may have been developed or approved by the Blueprint, or how the Department should mesh the Blueprint's standards with a program intended to convey information about the use of prescription drugs. The Department will address these issues as it develops and implements the evidence-based education program.

For these reasons, PhRMA's facial challenge fails. The State "has had no opportunity to implement" the statute, *Wash. State Grange*, 128 S. Ct. at 1190, and the Court should not presume that the State will develop the program in a manner that violates the First Amendment. Even if PhRMA could prove that some Blueprint standards are "private speech" – something it has not done – the Department of Health could design its program to ensure that its presentations "are reviewed by Department officials both for substance and for wording" and are "from beginning to end" messages adopted by the State of Vermont. *See Johanns*, 544 U.S. at 560-61. Indeed, there are many options available to the Department of Health in designing the evidence-

based education program that would avoid any constitutional concerns. PhRMA cannot demonstrate that there is "no set of circumstances . . . under which the Act would be valid." *Wash. State Grange*, 125 S. Ct. at 1190 (quotation omitted). The Court, therefore, should not "short circuit the democratic process by preventing laws embodying the will of the people from being implemented in a manner consistent with the Constitution." *Id.*

3. PhRMA has conceded that the Court cannot enjoin collection of the fee, so its facial challenge serves no purpose.

At the April 29, 2008 status conference, PhRMA conceded that it is not asking the Court to enjoin the collection of the manufacturer fee. PhRMA's counsel advised the Court "we are not seeking to enjoin collection of a tax, of a tax or of a fee. We are seeking to enjoin its use for one of the three purposes that the state has articulated." Tr. 04/29/08, Paper 264-6 at 39. PhRMA then expressly conceded that it does not object to the use of the fee for other statutory purposes. *Id.* ("We don't have a problem with that."). Although PhRMA's complaint appeared to seek an injunction against the fee, *see* PhRMA Am. Compl. Request for Relief, ¶ E, PhRMA has now abandoned any such request for relief. *See* Tr. 04/29/08 at 40 ("And it is that use, not the collection, the use that we seek to enjoin.").

In light of this, PhRMA's facial challenge serves no purpose. PhRMA's claim is not directed to avoiding the obligation to pay the fee. It is too early to challenge the "use" of the fee, because the program PhRMA is challenging does not exist. The Court should not entertain PhRMA's facial challenge.

IV. The consumer fraud provision is constitutional.

PhRMA also challenges the constitutionality of a third section of Act 80 – the section creating a cause of action under Vermont's Consumer Fraud Act for certain regulated advertisements that violate federal requirements for prescription drug advertising. 9 V.S.A.

§ 2466a(c). This statute provides that "[i]t shall be a prohibited practice under [9 V.S.A. § 2453] for a manufacturer of prescription drugs to present or cause to be presented in the state a regulated advertisement if that advertisement does not comply with the requirements" of federal law. 9 V.S.A. § 2466a(c)(1). The relevant provisions of federal law are identified: "the requirements concerning drugs and devices and prescription drug advertising in federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202." *Id.*

A "regulated advertisement" is only advertising within Vermont. It is defined as:

> (i) the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is broadcast on television, cable, or radio from a station or cable company that is *physically located in the state, broadcast over the internet from a location in the state, or printed in magazines or newspapers that are printed, distributed, or sold in the state*; or
>
> (ii) a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs or its representative that is conveyed:
> (I) to the office of a health care professional doing business in Vermont, including statements by representatives or employees of the manufacturer and materials mailed or delivered to the office; or
> (II) at a conference or other professional meeting occurring in Vermont.

9 V.S.A. § 2466a(c)(2)(B) (emphasis added).

PhRMA claims that 9 V.S.A. § 2466a(c) is preempted or, in the alternative, that it violates the Commerce Clause. PhRMA Am. Compl., Paper 174, Counts 1, 2. PhRMA's facial challenges are premature and based on mistaken understandings of the statute and the governing law. The Court should dismiss both counts.

A. The consumer fraud provision is not preempted and PhRMA's facial challenge fails.

PhRMA alleges that 9 V.S.A. § 2466a(c)(1), which only applies to advertising that violates federal requirements, somehow conflicts with federal regulation of prescription drug advertising.

PhRMA Am. Compl., Paper 174, ¶ 60. Its only support for this claim is its speculative allegation that Vermont courts will "adjudicat[e] . . . pharmaceutical manufacturers' compliance with federal law" and this, in turn, will "interfere with" FDA regulation. *Id.* ¶ 59. This kind of speculation is not sufficient to show a conflict with federal law. The Court should be particularly wary of finding a state statute facially preempted, because the Supreme Court recognizes a strong presumption against federal preemption of state law and state-law causes of action. *See, e.g., Medtronic v. Lohr,* 518 U.S. 470, 485 (1996) ("because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action"); *Madeira v. Affordable Housing Found.*, 469 F.3d 219, 238 (2d Cir. 2006) (absent "compelling congressional direction, courts will not infer that Congress ha[s] deprived the States of the power to act" (quotation omitted)). PhRMA has not and cannot establish the requisite "clear and manifest" intent for federal law to displace this state-law cause of action for consumer protection. *Medtronic v. Lohr*, 518 U.S. at 485.

The Supreme Court has in any event repeatedly rejected the same type of preemption argument advanced by PhRMA. On its face, § 2466a(c)(1) creates additional state-law remedies for prescription drug advertising that violates federal law. *See* 9 V.S.A. §§ 2458, 2461 (remedies available under the Consumer Fraud Act). The Supreme Court has consistently held that state-law causes of action may provide different or additional remedies for conduct that also violates federal law. In *Medtronic v. Lohr*, for example, the Court found no preemption of state-law causes of action that provided a damages remedy for actions that violated federal regulations. 518 U.S. at 495. Other cases similarly hold that additional state remedies neither conflict with nor frustrate the purposes of federal law, and thus are not preempted. *See Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 257 (1984) (award of punitive damages against operator of nuclear

facility not preempted by federal laws providing for civil penalties for safety violations; "exposure to punitive damages" does not "frustrate any purpose of the federal remedial scheme"); *California v. ARC Am. Corp.*, 490 U.S. 93, 102-03 (1989) (state antitrust remedies for indirect purchasers not preempted by federal antitrust law, which limits remedies to direct purchasers; state laws consistent with broad purposes of federal law); *Hayfield N. R.R. Co. v. Chicago & N.W. Transp. Co.*, 467 U.S. 622, 636 (1984) (state condemnation proceedings not preempted by federal regulatory scheme for abandonment of railroad lines; "second opportunity" to litigate "does not frustrate the purpose of the federal valuation scheme"); *cf. Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1011 (2008) (preemption provision for medical devices, 21 U.S.C. § 360k(a), "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case parallel, rather than add to, federal requirements").

The Court's decision in *Medtronic v. Lohr* is particularly relevant, because the Court there rejected a stronger argument for preemption than PhRMA presents here. In *Medtronic* the Court interpreted the scope of a statute that expressly preempted "additional" or "different" state-law requirements for certain FDA-approved medical devices. 518 U.S. at 495. Yet the Court had no trouble concluding that a state-law cause of action for damages was not preempted. "The presence of a damages remedy does not amount to the additional or different 'requirement' that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id.*

Here, PhRMA argues for implied conflict preemption, not express preemption as in *Medtronic v. Lohr*. *See* PhRMA Am. Compl., Paper 174 ¶ 60. It can prevail only by showing that the state-law remedies afforded by § 2466a(c) conflict with federal law. *Madeira*, 469 F.3d

at 238 (explaining test for conflict preemption). "The conflict standard for preemption is strict" and requires a "clear demonstration" of conflict. *Id.*

In light of this strict standard, and the Supreme Court's reasoning in *Medtronic v. Lohr*, PhRMA's conflict preemption argument cannot succeed. A state-law cause of action that affords additional remedies for violations of federal law creates no actual conflict for regulated parties, because the substantive requirements are the same. *See Medtronic v. Lohr*, 518 U.S. at 495; *Riegel v. Medtronic, Inc.*, 128 S. Ct. at 1011; *Madeira*, 469 F.3d at 238. Nor does the availability of state-law remedies create an "obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Madeira*, 469 F.3d at 238 (quotation omitted). "Ordinarily, state causes of action are not pre-empted solely because they impose liability over and above that authorized by federal law . . . ." *California v. ARC*, 490 U.S. at 105. As the Supreme Court observed in *Medtronic v. Lohr*, the state-law remedies merely provide "another reason" for regulated parties to comply with federal law. 518 U.S. at 495.

PhRMA relies on *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), *see, e.g.*, Paper 111 at 8-9, but that decision does not control the outcome of this case. In *Buckman*, the Supreme Court held preempted a state-law cause of action alleging fraud on a federal agency, namely the Food and Drug Administration. The *Buckman* plaintiffs sought damages solely on the theory that the manufacturer of a medical device had defrauded the FDA and, absent that fraud, the device would not have been approved and the plaintiffs not injured. *Id.* at 343. The Court began its analysis by noting that states play no traditional role in "[p]olicing fraud against federal agencies." *Id.* at 347. The Court then found a conflict between the state-law cause of action and the federal regulatory scheme, because "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and . . . this authority is used by

the Administration to achieve a somewhat delicate balance of statutory objectives." *Id*. at 348. The Court concluded that allowing the plaintiffs to pursue a "fraud on the agency" theory under state law would "skew[]" the FDA's objectives and create an "extraneous pull on the scheme established by Congress." *Id.* at 348, 353.

The consumer protection cause of action authorized by 9 V.S.A. § 2466a(c) is not comparable to a "fraud on the agency" claim, and the statute raises none of the concerns present in *Buckman*. *See* 531 U.S. at 349-52 (describing possible undesirable consequences of allowing private plaintiffs and state courts to interfere with FDA's authority to police fraud). Section 2466a(c) does not require state courts to police the relationship between the FDA and the companies the FDA regulates. *Cf. Buckman*, 531 U.S. at 347 ("relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law"). Congress and the FDA have created certain standards for advertising for prescription drugs. *See, e.g.*, 21 C.F.R. § 202.1 (prescription drug advertisements). Section 2466a(c) merely allows parties to recover under state law for violations of those requirements. The state statute does not change the requirements, nor does it "inevitably conflict" with the responsibilities assigned to the FDA under federal law. *See Buckman*, 531 U.S. at 350 (state law "fraud on the agency" claims "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives").[22] The plain language of the statute does exactly

[22] *Pennsylvania Emp. Benefit Trust Fund v. Zeneca, Inc*. is a case in which the Third Circuit, in a split decision, found that federal law preempted a state consumer fraud action for false advertising. 499 F.3d 239 (3d Cir. 2007). Defendants disagree with the reasoning in *Zeneca* and submit that the dissenting judge's analysis is more consistent with the Supreme Court's preemption rulings. *See id.* at 253-59 (Cowen, J., dissenting). In any event, *Zeneca* did not address a statute like § 2466a(c). The *Zeneca* court "generalized state consumer fraud laws" could not "dictate the parameters of false and misleading advertising in the prescription drug context." *Id.* at 253. Section 2466a(c) is not a general consumer fraud law, but a specific statute that applies only to advertising that violates federal requirements.

what the Supreme Court has repeatedly said is permissible: it creates additional remedies under state law for conduct that violates federal law.

In light of the Supreme Court's decisions approving of additional state-law remedies for violations of FDA regulations, *see Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, and *Medtronic v. Lohr*, 518 U.S. 470, PhRMA's discussion of the scope of FDA regulation adds nothing to its preemption argument. No one involved in this litigation disputes that the FDA regulates prescription drug advertising. The views of Mr. Hutt, PhRMA's lawyer and lobbyist, *see* Tr. 320, are not relevant because the question of conflict preemption is for the Court to decide as a matter of law. In any event, Mr. Hutt agreed that a state court's ruling enforcing a federal determination would not conflict with federal law. Tr. 340-341.

Mr. Hutt's testimony illustrates that PhRMA's preemption argument is premised on the *possibility* that a state court will impose requirements for pharmaceutical advertising that differ from the requirements of federal law. *See, e.g.*, Tr. 320; Paper 303 at 2, 4, 8, 14. And that is why PhRMA's facial challenge cannot succeed. The Supreme Court's precedents could not be clearer on this point: facial challenges must be based solely on the facial requirements of the statute, not on speculation, assumptions, or "predictions" about how the statute may be applied. *See Wash. State Grange*, 128 S. Ct. at 1190-91 (for facial challenge, court must look only to "facial requirements" of the statute and may not "speculate about "hypothetical" or "imaginary" cases; facial challenges are "disfavored" because they are often based on speculation). PhRMA cannot prevail on a theory that state courts *may* apply the statute in a way that conflicts with federal law. To the contrary, state courts should be given the opportunity to interpret the statute consistent with federal law. *See Wash. State. Grange*, 128 S. Ct. at 1190-91.

The statute does not on its face require a state court to decide, in the first instance, whether an advertisement violated federal law. A state court could interpret § 2466a(c) in any one of several different ways: the court might allow a claim to proceed only if the FDA had already determined the advertising violated federal law; the court might allow the claim only if the violation of federal law is clear and unambiguous; or the court might engage in its own interpretation of the requirements of federal law. In deciding how the statute should be interpreted, the Vermont court is likely to be guided by constitutional requirements and "accord the law a limiting construction to avoid constitutional questions." *Wash. State Grange*, 128 S. Ct. at 1190.

This Court, accordingly, should exercise the "judicial restraint" counseled in *Washington State Grange*. *See id*. at 1191 ("Exercising judicial restraint in a facial challenge frees the Court not only from unnecessary pronouncement on constitutional issues, but also from premature interpretations of statutes in areas where their constitutional application might be cloudy." (quotations omitted)). PhRMA's members are free to raise their preemption arguments in any lawsuits brought under § 2466a(c). That is, in fact, the context in which most preemption claims of this kind are litigated. *See, e.g., Riegel*, 128 S. Ct. at 1005-06 (successful preemption claim raised as defense to injured plaintiffs' suit); *Buckman*, 531 U.S. at 343 (state law cause of action found preempted in lawsuit brought by injured plaintiffs); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 865-67 (2000) (injured plaintiff's tort claims preempted by federal law); *Medtronic*, 518 U.S. at 495 (plaintiffs' suit not preempted by federal law); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 88 (2d Cir. 2006) (injured plaintiffs' tort claims not preempted by federal law), *aff'd by equally divided court sub nom. Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (per curiam); *Penn. Emp. Benefit Trust Fund v. Zeneca, Inc.*, 499 F.3d 239, 241 (3d Cir. 2007) (federal preemption raised as defense to state consumer fraud claims); *Levine v. Wyeth*, 944 A.2d

179 (Vt. 2007) (injured plaintiffs' suit not preempted by federal law), *cert. granted*, 128 S. Ct. 1118 (2008). Uncertainty as to how state courts may interpret and apply § 2466a(c) means that PhRMA's facial challenge must fail.[23]

B. The statute is constitutional under the dormant Commerce Clause.

PhRMA has advanced two Commerce Clause theories. The allegations in PhRMA's complaint rely on the *Pike* balancing test. *See Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); PhRMA Am. Compl., Paper 174 ¶¶ 63, 64 (statute "excessively burdens interstate commerce" with "minimal" local benefit). PhRMA's summary judgment filings appear to abandon this approach in favor of an argument that a statute that regulates advertising in Vermont has an extraterritorial reach. Neither argument has merit and neither is sufficient to sustain a facial challenge.

1. The statute should not be invalidated under *Pike*.

The statute easily survives review under *Pike*. "The fundamental objective of the dormant Commerce Clause is to 'preserv[e] a national market for competition undisturbed by preferential advantages conferred by a State upon its residents or resident competitors.'" *Brown &*

[23] PhRMA has suggested that the Court should defer ruling on this claim until the Supreme Court issues its decision in *Wyeth v. Levine*. Paper 169 at 1 n.2. Defendants disagree, and ask the Court to instead enter judgment for defendants on this claim at this time. Waiting for *Wyeth* is impractical for several reasons. First, a decision could be issued as late as June 2009, meaning that final resolution of this litigation could be delayed for another year. Second, the issue in Wyeth is not the same as the issue in this case. In *Wyeth*, the defendant pharmaceutical company argues that the plaintiff's state law failure to warn claim is preempted by FDA approval of the product labeling. The defendant contends that state law cannot impose liability for failure to provide a warning not required by the FDA. As discussed in the text, § 2466a(c) does not impose different requirements, but merely creates a remedy for a violation of FDA requirements. Third, to the extent PhRMA expects a broad statement from the Supreme Court regarding federal preemption of state laws in this area, such expectations have been dashed in previous cases. *See, e.g., Desiano v. Warner-Lambert & Co*., 467 F.3d 85, 88 (2d Cir. 2006), *aff'd by equally divided court sub nom. Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008) (per curiam). And lastly, because preemption is matter of congressional intent, the Supreme Court does not have the last word in this area. Congress could amend federal law to clarify the limited scope of federal preemption. All of these reasons further confirm that PhRMA's facial challenge is untimely. Instead of staying its consideration of the facial challenge, the Court should find that the facial challenge is premature, and allow these issues to be resolved in the context of actual disputes arising under § 2466a(c).

Williamson, 320 F.3d at 208 (quoting *Gen. Motors Corp. v. Tracy*, 519 U.S. 278, 299 (1997)). In dormant Commerce Clause jurisprudence, the *Pike* test is used to evaluate state laws that, like 9 V.S.A. § 2466a(c), serve a "legitimate local purpose" and do not "evince" an intent to discriminate in favor of local interests and against interstate commerce. *Id*. at 209. "The *Pike* test evaluates whether the statute's burdens on interstate commerce are 'clearly excessive in relation to the putative local benefits.'" *Id*. (quoting *Pike*, 397 U.S. at 142).

The purpose of the balancing test is not to allow courts to "to second-guess legislatures by estimating the probable costs and benefits of the statute." *Id*. Rather, the question for the Court is whether the statute imposes "a burden on interstate commerce that is '*different from*' the burden imposed on intrastate commerce." *Id*. (quoting *Nat'l Elec. Mfrs*., 272 F.3d at 109). A statute "survives *Pike* as long as it affects intrastate and interstate interests similarly – the similar effect on interstate and intrastate interests assuaging the concern that the statute is designed to favor local interests." *Id*.

This explanation of the dormant Commerce Clause and the *Pike* test illustrates the initial flaw in PhRMA's reasoning: PhRMA has not alleged, nor could it, that 9 V.S.A. § 2466a(c) is in any way designed to favor local interests. *See* PhRMA Am. Compl., Paper 174 ¶¶ 61-65 (Commerce Clause allegations). PhRMA's complaint is that it is difficult for advertisers to "differentiate among jurisdictions" and thus PhRMA members may have to change national advertising practices to comply with § 2466a(c). *Id*. ¶ 63. Even if this were true, the burden imposed on PhRMA's members is no different from the burden imposed on any pharmaceutical manufacturer, whether based in Vermont or elsewhere. *Nat'l Elec. Mfrs*., 272 F.3d at 109 ("if no such unequal burden be shown, a reviewing court need not proceed further").

PhRMA is also wrong about the effects of the statute on its members' advertising practices. The statute creates a cause of action under the Consumer Fraud Act only for advertising that violates the requirements of federal law. *See* 9 V.S.A. § 2466a(c)(1). There is no basis for PhRMA's claim that its members will need to "change their detailing, marketing, advertising, and scientific communication practices outside the state of Vermont." PhRMA Am. Compl., Paper 174 ¶ 63. PhRMA's members are already required to comply with federal law in all jurisdictions. The Vermont statute provides additional state remedies for violations of federal law but does not create any new substantive standards. Thus, PhRMA's members need not change their practices either outside Vermont or within the State. Applying the *Pike* test, any burden imposed on PhRMA's members is minimal or nonexistent. On the other hand, the local benefits are substantial, because both the Vermont Attorney General and Vermont consumers may seek remedies in state court for illegal advertising practices by pharmaceutical manufacturers. The statute should be upheld under *Pike*. *See, e.g., Brown*, 320 F.3d at 216-17 (statute constitutional under *Pike* in part because effects on interstate commerce "de minimis").

2. PhRMA's Commerce Clause theory of "extraterritorial" reach conflicts with *NEMA v. Sorrell* and makes no sense in light of the statute's plain language.

PhRMA's alternate theory of extraterritorial reach is foreclosed by *National Electric Manufacturers Association v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) ("*NEMA*"). PhRMA's argument also makes no sense in light of the statute's plain language. This second point is the necessary starting point for opposing PhRMA's argument. PhRMA asserts that its members will have to "change their advertisements to comport with Vermont-created standards" and "tailor their advertisements in advance." Paper 303 at 12, 13. That cannot be so, as a matter of law, because the statute creates no "Vermont" standards for prescription drug advertising. PhRMA

never explains what new requirements its members will have to satisfy in Vermont. There are none.

Turning to the law, the weakness of PhRMA's position is perhaps best illustrated by its assertion that the case "most directly on point," Paper 303 at 10, is the Supreme Court's 1935 holding in *Baldwin v. G.A.F. Seeling, Inc.*, 294 U.S. 511 (1935). *Baldwin* invalidated a New York statute that regulated wholesale milk prices in other states. It is certainly true that New York cannot regulate Vermont's wholesale milk prices, *see id.* at 521, but that says nothing about whether Vermont can regulate advertising presented within Vermont. PhRMA has not cited a single case that restricts a state's ability to regulate advertising presented within that state.

In fact, it bears noting that PhRMA's Commerce Clause theory is remarkably broad and would undermine state consumer fraud laws regulating false and misleading advertising for all types of consumer products. PhRMA's members are no different from auto manufacturers, airlines, and other companies that advertise in national publications and on television. Under PhRMA's theory, a Vermont consumer has no cause of action for consumer fraud if one of these national companies presents a false and misleading advertisement in Vermont. If the Commerce Clause requires this result, one would expect PhRMA to cite some precedent for it. It has not.

Although PhRMA claims otherwise, its "extraterritoriality" argument is foreclosed by *NEMA*. *NEMA* involved a dormant Commerce Clause challenge to Vermont's labeling requirement for lamps containing mercury. The plaintiff in *NEMA* made the same type of argument PhRMA makes here: that Vermont was legislating outside its own boundaries because lamp manufacturers would "be forced as a practical matter to label lamps sold in every other state." 272 F.3d at 110 (discussing NEMA's "extraterritoriality contention"). The Second Circuit found this argument unpersuasive, observing that the Vermont statute was "indifferent"

to whether lamps sold in other states were labeled or not. *Id.* The same is true here. The Vermont law regulates only advertising presented in this State. It is "indifferent" to advertising presented in other states. PhRMA's assertions about the practical difficulties of tailoring its members' advertising do not establish a Commerce Clause violation – and particularly cannot support a facial challenge to the statute.

The fact is that the statute at issue in this case poses even less of a burden on interstate commerce than the mercury labeling statute because this law imposes no substantive requirements at all. It only creates a state-law remedy for a violation of federal law. A state cannot possibly contravene the dormant Commerce Clause with a statute that adheres to the requirements of federal law; all regulated parties must already comply with federal law.

3. PhRMA's dormant Commerce Clause claim is premature as a facial challenge.

Vermont "has had no opportunity to implement [the statute], and its courts have had no occasion to construe the law in the context of actual disputes." *Wash. State Grange*, 128 S. Ct. at 1190. If any one of PhRMA's members is sued for a violation of § 2466a(c), the company may then litigate the constitutionality of the statute as part of its defense. That would allow the Vermont courts to evaluate the constitutionality of the statute as applied to a concrete dispute. PhRMA instead asks the Court to take the extraordinary step of invalidating the statute in its entirety, before it is ever interpreted or enforced by the state courts. The Court should decline to do so, for at least three reasons.

First, as discussed above with respect to PhRMA's preemption claim, PhRMA's Commerce Clause arguments are likewise based on speculation about how the law will be interpreted and the impact it may have on PhRMA's members. That is not permissible. *Wash. State Grange*, 128 S. Ct. at 1191 ("[c]laims of facial invalidity often rest on speculation" and are "disfavored").

Second, PhRMA's allegations go well beyond the plain language of the statute. Again, in reviewing a facial challenge, the Court "must be careful not to go beyond the statute's facial requirements and speculate about hypothetical or imaginary cases." *Id*. at 1190; *see also Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d 200, 210, 211-12 (2d Cir. 2003) (district court erred in concluding that statute discriminated on its face against interstate commerce, where court's determination was based on "its interpretation of the Statute's operation, or effect, rather than [the statute's] terms"). Nothing in the statute's plain language suggests that Vermont will impose requirements on pharmaceutical advertising that are different from or in addition to the requirements of federal law. 9 V.S.A. § 2466a(c)(1).

Third, PhRMA's arguments disregard the statute's "plainly legitimate sweep." *Wash. State Grange*, 128 S. Ct. at 1190. Even if PhRMA were correct about the supposed burdens on national advertising – and it is not – the statute nonetheless regulates a broad range of advertising that is conducted solely or principally in Vermont. This category includes print advertisements in Vermont newspapers, magazines, and other periodicals; advertisements broadcast on Vermont stations; and commercial messages conveyed in doctors' offices and at professional meetings within Vermont. *See* 9 V.S.A. § 2466a(c)(2)(B). PhRMA cannot demonstrate that there is "no set of circumstances . . . under which the Act would be valid," *Wash. State Grange*, 125 S. Ct. at 1190 (quotation omitted). Vermont may regulate advertisements in the Vermont media. PhRMA's facial challenge fails.

CONCLUSION

For the reasons given here and in defendants' prior briefing, plaintiffs' request to permanently enjoin these three state laws should be denied and judgment should be entered on all counts for defendants.

Dated: September 29, 2008

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CERTIFICATE OF SERVICE

I hereby certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system. The CM/ECF system will provide service of such filing via Notice of Electronic Filing (NEF) to all attorneys of record, the following NEF parties:

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