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-00188
Plaintiffs,	)	**CONSOLIDATED WITH** 1:07-cv-00220
vs.	)	
WILLIAM H. SORRELL, as Attorney General of the State of Vermont,	)	
Defendant.	)	

DEFENDANTS' TRIAL MEMORANDUM

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INTRODUCTION

The principal question to be tried in these consolidated cases is the constitutionality of the Prescriber Confidentiality Law, 18 V.S.A. § 4631. Section 4631 was originally enacted as part of Act 80, a bill passed near the end of the 2007 legislative session. 2007, No. 80, sec. 17. (PhRMA also asserts facial challenges to two other parts of Act 80, which are discussed further below.)[1] Act 80 represents a concerted effort by the Legislature to address issues relating to the rising costs and sometimes inappropriate use of prescription drugs, as well as issues of medical privacy. The Act deals with, among other things, a pharmacy best practices program, pharmaceutical marketing, price disclosures for prescription drugs, pharmacy discount plans, pharmacy benefit managers, consumer fraud, and a state-run evidence-based education program. *Id.* secs. 1a, 3, 4, 6, 7, 8-10, 15, 21.

The Legislature found that spending on prescription drugs was the fastest-growing category of health care spending, with costs nearly doubling from 2000 to 2005. 2007, No. 80, sec. 1 ["Findings"], Finding 9. Costs increased rapidly notwithstanding strong efforts by the State to control them. Finding 10. Safety was also a concern for the Legislature, which noted as one example the experience with Vioxx, a drug that was heavily marketed and widely prescribed before it was removed from the market because of dangerous side effects. Findings 7, 8. Although drugs must be approved by the FDA before release, many drugs are

[1] This memorandum does not contain a detailed outline of the statute because the Court has asked the parties to file a separate document outlining the statute and comparing its provisions with those of similar statutes in Maine and New Hampshire.

recalled or subject to more serious "black box" warnings after their release. Finding 9.

An issue that drew the Legislature's particular attention, and resulted in 18 V.S.A. § 4631, was the practice of "physician identity data mining." Finding 18. The Legislature learned that pharmacies sell information about the drugs prescribed by physicians. The information is purchased by data mining companies and ultimately used by pharmaceutical manufacturers to "track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities." Finding 23. Pharmaceutical manufacturers use the information in their marketing programs to, among other things, "assess the impact of various gifts and messages," "tailor[] presentations," and "target" doctors. Findings 24-26. The use of prescriber-identifiable information thus "increases the effect of detailing programs." Finding 25.

The Legislature observed that the increased use of data mining in recent years was accompanied by a marked increase in spending on direct marketing to doctors. Pharmaceutical companies spend tens of billions of dollars a year marketing to physicians and use, on average, about one sales representative for every five office-based physicians. Findings 16, 17, 18. These expenditures on detailing pay off with more prescriptions for the newest and most expensive prescription drugs. Finding 15. While the marketing effort may succeed in selling more drugs, it does not succeed in providing doctors with complete and balanced information about prescription drugs. Findings 3-6, 13-15. And increased

prescribing of the newest drugs often runs counter to public health, because many new drugs have "little or no increased therapeutic value" over existing treatments – though they may have greater risk. Findings 7, 8, 14.

The Legislature also acknowledged the privacy interest at stake. Doctors and patients do not expect that prescription information will be used for marketing purposes. Rather, they expect the information to be used for filling the prescription and processing payment for it. They "do not consent to the trade of that information to third parties, and no such trade should take place without their consent." Finding 29.

For all of these reasons, the Legislature sought in Act 80 to restrict the commercial use of prescriber-identifiable data for marketing prescription drugs. Section 4631 allows such use only with the consent of the prescriber. The law had the strong support of the Vermont Medical Society, which adopted a unanimous resolution concluding that "the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine." Finding 20. The Legislature found that the new law was necessary to "protect prescriber privacy by limiting marketing to prescribers who choose to receive that type of information, to save money for the state, consumers, and businesses by promoting the use of less expensive drugs, and to protect public health by requiring evidence-based disclosures and promoting drugs with longer safety records." Finding 31.

That, in brief, is the beginning of the story of this case. The IMS plaintiffs and PhRMA challenged the statute on First Amendment grounds. The statute was

amended in some respects in 2008. 2007, No. 89 (Adj. Sess.). At trial, defendants will present evidence that supplements and confirms the findings and conclusions of the Legislature. The evidence principally comes from expert witnesses and documents from plaintiffs and pharmaceutical companies, as well as from documents in the public record. While plaintiffs argue that the Court should disregard the Legislature's findings, discovery has confirmed most of those findings and shown that the Legislature had a reasonable and – to the extent any First Amendment interests are implicated – constitutionally sufficient basis for passing 18 V.S.A. § 4631.

This pretrial memorandum is not intended to restate all the legal arguments of the parties, most of which are debated in the summary judgment filings. The memorandum instead provides a framework for the trial. Part I outlines the claims and defenses of the parties and notes which claims should be decided based on the pending summary judgment motions. Part II sets forth the broad framework for reviewing and considering the evidence at trial. It addresses the *Central Hudson* standard, the need for and degree of deference to the Legislature's findings and conclusions, and the scope of relevant evidence to be offered at trial. Part III, as requested by the Court, outlines defendants' plan for presenting witnesses and other evidence at trial.

Before moving on, defendants submit their observations about some names and terms used by the parties in this litigation. Both PhRMA and the IMS plaintiffs call the relevant state laws by names they made up. They call 18 V.S.A. §

4631 the "Prescription Restraint Law," a strange name indeed, as the statute places no restrictions whatsoever on the writing or filling of prescriptions. *See, e.g.,* PhRMA Amend. Compl. ¶¶ 49, 72; IMS Amend. Compl. ¶ 1. Similarly, PhRMA calls the consumer protection law, 9 V.S.A. § 2466a(c), the "advertising restraint provision." None of the plaintiffs have cited any precedent for a court identifying a state statute using an invented and prejudicial term coined by a party. Defendants use the statutory titles or appropriate short forms and respectfully ask the Court to do the same. See 2007, No. 80, sec. 17 (section titled "Prescription Drug Data Confidentiality"); *id.* (adding 18 V.S.A. § 4631, titled "Confidentiality of Prescription Information"); *id.* sec. 21 (section titled "Consumer Protection; False Advertising"); *id.* (adding 9 V.S.A. § 2466a, titled "Consumer Protections: Prescription Drugs").

Defendants also decline to adopt the name preferred by the IMS plaintiffs, who in their amended complaint claimed the label "publisher plaintiffs." Ordinarily, a party's chosen label would matter little. Here, however, the IMS plaintiffs are trying to distance themselves from their data mining work by adopting an inaccurate name. To "publish" means to disseminate to the public, to make generally known, or to print for public distribution or sale.[2] Plaintiffs' allegations do not in any way suggest that they are in the business of publishing prescriber-identifiable data. They describe their databases as "proprietary" and their work as offering "subscription services." *E.g.,* IMS Amend. Compl. ¶¶ 18, 22,

[2] *See, e.g.,* Merriam-Webster Online Dictionary, http://www.merriam-webster.com/dictionary/publish (accessed 7/9/08); American Heritage Dictionary 1075 (New College ed. 1975).

23, 24; Paper 307, ¶¶ 2, 13-15. Discovery has confirmed that the IMS plaintiffs and pharmaceutical manufacturers use prescriber-identifiable data for specific marketing purposes and do not publish the data. For obvious reasons, the IMS plaintiffs want to align themselves with newspapers and book publishers, but that is not what they do.

I. CLAIMS AND DEFENSES OF THE PARTIES

This section briefly outlines the claims and defenses of the parties and notes the motions that have been filed on each claim. The section is divided by statute, rather than complaint counts, because plaintiffs in some instances filed multiple counts challenging the same statute. The short summaries provided are not intended to set forth fully the arguments of the parties.

A. Consumer Protection – 9 V.S.A. § 2466a(c)

PhRMA's Count 1 contends that this statute is preempted by federal law. PhRMA Amend. Compl. ¶¶ 56-60. PhRMA seeks a declaration that the statute is invalid and an injunction barring Attorney General Sorrell from enforcing the statute. *Id.* Req. Relief ¶¶ A, D. Defendants argue that PhRMA's facial challenge to the statute fails, because the statute on its face does not conflict with any requirement of federal law. Defendants moved for summary judgment on this claim. *See* Papers 257, 303, 336.

PhRMA's Count 2 contends that this statute violates the dormant Commerce Clause because it excessively burdens interstate commerce. PhRMA Amend. Compl. ¶¶ 61-65. PhRMA seeks a declaration that the statute is invalid and an

injunction barring Attorney General Sorrell from enforcing the statute. *Id.* Req. Relief ¶¶ A, D. Defendants seek summary judgment, arguing that PhRMA's facial challenge fails. The statute on its face imposes no burdens on interstate commerce and the statute's regulation of advertising within Vermont has a plainly legitimate sweep. *See* Papers 257, 303, 336.

No factual development is required to rule on PhRMA's facial challenges to this statute.

B. Manufacturer Fee – 33 V.S.A. § 2004

PhRMA's Count 3 contends that the use of the manufacturer fee to fund the evidence-based education program violates the First Amendment. PhRMA Amend. Compl. ¶¶ 66-70; Papers 168, 169. PhRMA's complaint seeks a declaration that the fee is invalid and an injunction barring its enforcement. PhRMA Amend. Compl. Req. Relief ¶ E. PhRMA, however, has subsequently represented to the Court that it challenges only the use of the fee for the evidence-based education fund, not the collection of the fee or its use for other purposes. *See* Paper 264, at 9-10 & Attach. 5 (discussing and referencing PhRMA's statements at status conference). Defendants argue that the Court has no jurisdiction over this claim and, in any event, the use of the fee to fund government speech is constitutional. *See* Papers 82, 127, 205, 264.

PhRMA and defendants have cross-moved for summary judgment on this claim. *See* Papers 168, 169 (PhRMA's motion); Paper 205 (defendants' motion); Paper 231 (PhRMA's reply); Paper 264 (defendants' reply); *see also* Papers 82, 109, 127 (briefing on jurisdictional question); Paper 276 (Court's ruling on jurisdiction).

In defendants' view, no further factual development is required to rule on PhRMA's facial challenge to the use of the manufacturer fee for the evidence-based education program. Defendants may present a witness to rebut some of PhRMA's assertions, but it is defendants' position that PhRMA's speculative assertions are irrelevant to its facial challenge.

C. Prescription Confidentiality Law – 18 V.S.A. § 4631

Both PhRMA and the IMS plaintiffs challenge the constitutionality of 18 V.S.A. § 4631. PhRMA contends that the statute violates the First Amendment. PhRMA Amend. Compl. Count 4; Papers 168, 169. The IMS plaintiffs claim that the statute violates the First Amendment and the dormant Commerce Clause. IMS Amend. Compl. Counts I-IV.

1. Commerce Clause Claim

The IMS plaintiffs challenge 18 V.S.A. § 4631 under the dormant Commerce Clause, claiming that the statute regulates commerce outside Vermont. Defendants argue that this facial challenge to the statute fails, because the statute regulates Vermont transactions and businesses and does not regulate the conduct of data mining companies at all. Defendants also argue that the IMS plaintiffs lack standing. Defendants moved for summary judgment on this claim. *See* Papers 257, 300, 340.

No factual development is required to rule on this facial challenge by the IMS plaintiffs.

2. First Amendment Claims

There are three sets of First Amendment arguments. Defendants contend that two of these can potentially be resolved on summary judgment. If the Court reaches the issue, the application of the *Central Hudson* test should be addressed at trial.

a. *Level of First Amendment scrutiny*. Defendants argue, for several reasons, that the statute does not restrict speech and is not subject to any First Amendment scrutiny. In the alternative, defendants argue that the statute is at most a regulation of commercial speech subject to the *Central Hudson* test. *See* Papers 247, 339. PhRMA has argued for application of the *Central Hudson* test. PhRMA Amend. Compl. Count 4; Papers 168, 169. The IMS plaintiffs argue, in the alternative, for either the *Central Hudson* test or strict scrutiny. IMS Amend. Compl. Counts I, II; Paper 306.

Defendants moved for summary judgment on Count II of the IMS Amended Complaint, on the ground that strict scrutiny has no relevance here. *See* Papers 247, 306, 339. Defendants also seek summary judgment on plaintiffs' other First Amendment claims, on the ground that the statute does not restrict any speech protected by the First Amendment. *See* Papers 247, 299, 306, 339. If the Court agrees with defendants that the statute does not restrict speech protected by the First Amendment, then the Court should grant summary judgment to defendants on all plaintiffs' First Amendment claims. The Court could also reach this conclusion after hearing the evidence at trial. If the Court concludes that the

statute regulates commercial speech, then the Court should review the application of the *Central Hudson* test after trial. *See infra.*

b. *Application of the Central Hudson test.* The *Central Hudson* test is fact-specific and in this case should be applied based on the record developed at trial (together with the relevant legislative record). Although PhRMA sought summary judgment on this issue, *see* Papers 168, 169, its motion was unpersuasive and should not be granted, *see* Paper 245. Neither the IMS plaintiffs nor defendants have asked the Court to decide the *Central Hudson* issues on summary judgment. *See* Paper 245, at 22; Paper 306, at 24.

c. *Vagueness and overbreadth.* The IMS plaintiffs claim, in Count III, that the statute is vague and overbroad. Defendants have moved for summary judgment on these claims. *See* Papers 247, 306, 339. No factual development is required to rule on this facial challenge by the IMS plaintiffs.

* * * *

Based on the pretrial proceedings and filings of the parties, defendants assume that the trial will focus principally on whether § 4631 satisfies the *Central Hudson* test for restrictions on commercial speech. The other issues in the case call for little or no factual development and are likely to be decided based on the parties' summary judgment motions.

II. EVIDENTIARY FRAMEWORK FOR THE *CENTRAL HUDSON* TEST

The Court has a unique role in a case like this one, which involves a facial challenge to a statute not yet in force. The Court's principal role is not to find

historical or adjudicative "facts," but rather to review the legislative record, findings, evidence, and other relevant information to assess whether the legislative branch had a sufficient basis, under the appropriate constitutional standard, for making this policy choice. This memorandum explains this process in some detail, assuming solely for these purposes that the Court will apply the *Central Hudson* test as the appropriate constitutional standard.

Accordingly, this memorandum provides briefing on the following issues. First, defendants explain the intermediate scrutiny required under the *Central Hudson* test, showing, among other things, that plaintiffs exaggerate the scope of review under this standard. Second, defendants demonstrate that, consistent with intermediate scrutiny, the Court should afford a substantial degree of deference to the findings and conclusions of the Vermont Legislature. Third, defendants discuss the types of evidence that the Court should consider and argue that the Court should not accept plaintiffs' invitation to go beyond the official legislative history and make irrelevant findings that intrude on the legislative process. And last, defendants address the recent decisions from New Hampshire and Maine and explain both the flaws in the rulings and the reasons why this case is different.

A. The *Central Hudson* test calls for intermediate scrutiny.

The *Central Hudson* test applies to protected commercial speech that concerns lawful activity and is not misleading. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). The test has three parts. First, the government must assert a "substantial interest to be achieved by the restriction."

Anderson v. Treadwell, 294 F.3d 453, 461 (2d Cir. 2002). Next, the Court must determine "whether the regulation directly advances the governmental interest asserted." *Id.* (quotation omitted). Last, the Court must decide whether the regulation "is not more extensive than is necessary to serve that interest." *Id.* (quotation omitted).

Plaintiffs overstate the requirements of the *Central Hudson* test. Commercial speech is not a fundamental right. *Board of Trustees of State Univ. of N.Y. v. Fox,* 492 U.S. 469, 477 (1989). "Commercial speech [enjoys] a limited measure of protection, commensurate with its subordinate position in the scale of First Amendment values." *Id.* (quotation omitted). Consistent with the "limited" constitutional protection afforded to commercial speech, the *Central Hudson* standard is appropriately described as a form of intermediate scrutiny. *See, e.g., Florida Bar v. Went For It, Inc.,* 515 U.S. 618, 623 (1995); *Trans Union Corp. v. FTC,* 245 F.3d 809, 818 (D.C. Cir. 2001) (applying "reduced constitutional protection" to ban on sale of targeted marketing lists (quotation omitted)). In light of plaintiffs' prior arguments in this case, three points about the reduced scrutiny applied under *Central Hudson* are particularly relevant.

First, *Central Hudson* does not establish a "least restrictive means" standard. *See Florida Bar*, 515 U.S. at 632 (least restrictive means test "has no role in the commercial speech context"). 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). The Second Circuit also rejects the "least restrictive means" test in the commercial speech context. *Long Island Bd. of Realtors, Inc. v. Inc. Vill. of Massapequa Park,* 277 F.3d 622, 627 (2d Cir. 2002).

Plaintiffs nonetheless incorrectly advocate for a stringent "least intrusive" standard. *See, e.g.,* Paper 299, at 11 (claiming defendants must show statute "is no more intrusive than necessary"); Paper 169, at 6 (claiming that Prescription Confidentiality Law does not advance state's interests "in the least intrusive manner"); Paper 6, at 33 (claiming "if government can achieve its interests in a manner that restricts less speech, it must do so"). Courts have consistently rejected this standard. *See, e.g., Long Island Bd.,* 277 F.3d at 627; *Jim Gall Auctioneers, Inc. v. City of Coral Gables,* 210 F.3d 1331, 1333 (11th Cir. 2000) (commercial speech "regulations need not be the least restrictive or least intrusive means of serving the City's interest in order to qualify as narrowly tailored") (quotations omitted)); *Mastrovincenzo v. City of New York*, 435 F.3d 78, 98 (2d Cir. 2006) (applying intermediate First Amendment scrutiny to time, place, manner regulation

and noting that narrow tailoring requirement for intermediate scrutiny does not mean regulation must use least restrictive or least intrusive means).[3]

The State need not, as plaintiffs imply, address every conceivable alternative to establish the constitutionality of the challenged statute. *See Fox,* 492 U.S. at 481 ("reasonable fit" standard "take[s] account of the difficulty of establishing with precision the point at which restrictions become more extensive than their objective requires, and provide the Legislative and Executive Branches needed leeway in a field (commercial speech) traditionally subject to governmental regulation" (quotations omitted)). In a case that also involved professional regulation, the Second Circuit has cautioned that the *Central Hudson* test calls for more limited scrutiny. "[P]articularly 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 *Florida Bar*, 515 U.S. at 635)).

Second, plaintiffs' arguments about the speech that is *not* restricted by § 4631 are largely irrelevant. PhRMA, for example, provides a laundry list of things that Vermont has not restricted as supposed proof of the statute's unconstitutionality. *See* Paper 299, at 12-13 (noting that statute allows noncommercial uses of data, allows prescribers to consent to use of data, and does not limit other detailing or

[3] The Supreme Court has recognized the substantial similarity between the narrow tailoring requirement for regulations of commercial speech and the narrow tailoring requirement for content-neutral time, place and manner regulations of protected speech. *See Lorillard Tobacco Co. v. Reilly,* 533 U.S. 525, 554 (2001); *see also Fox,* 492 U.S. at 477-78 & n.3.

marketing tactics). PhRMA does not explain why the absence of other regulations means that this statute fails *Central Hudson*. *See id.* at 11-14 (providing list without explanation of relevance). But PhRMA seems to turn the narrow tailoring requirement on its head, suggesting that, to satisfy *Central Hudson,* the State should have enacted a much broader statute that restricted all forms of detailing and all uses of prescriber-identifiable data. The Second Circuit has rejected this sort of underinclusiveness argument before. "[I]n 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." *Anderson*, 294 F.3d at 463 (collecting cases and reversing district court for concluding that commercial speech regulation was "fatally underinclusive" because it only restricted real estate solicitations). In fact, *Central Hudson* calls for some degree of tailoring, not a broad-brush approach. Here, the Legislature reasonably "address[ed] itself to the phase of the problem which seem[ed] most acute to the legislative mind" and did so in a way that restricts less speech. *See McConnell v. FEC,* 540 U.S. 93, 207-08 (2003); *see also Anderson,* 294 F.3d at 463 ("[A] state is not required to 'make progress on every front before it can make progress on any front.'" (quoting *United States v. Edge Broadcasting Co.*, 509 U.S. 418, 434 (1993)). That approach is permissible even where courts apply strict scrutiny under the First Amendment. *See Republican Party of Minn. v. White,* 416 F.3d 738, 777 (8th Cir. 2005) ("*McConnell* confirms that the sort of underinclusiveness that is fatal in strict

scrutiny is arbitrary underinclusiveness, not underinclusiveness that results from attempting to focus the restriction on only the severest form of the threat").

Third, the Supreme Court's precedents do not require a specific quantum or type of empirical data to support a regulation of commercial speech. *See Lorillard Tobacco Co. v. Reilly,* 533 U.S. 525, 555 (2001). 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." *Florida Bar,* 515 U.S. at 628 (citations and internal quotations omitted); *see also Lorillard,* 533 U.S. at 555 (same). Although this language appears repeatedly in the Supreme Court's commercial speech cases, plaintiffs *never* quote it. Instead, plaintiffs misconstrue the Supreme Court's precedents when describing the State's burden in this case. PhRMA, for example, cites *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. A review of plantiffs' First Amendment filings, and those of plaintiffs' amici, shows that plaintiffs simply ignore the Supreme Court's standard.[4]

[4] The IMS plaintiffs and their amici rely upon *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996), but fail to acknowledge that the decision in the case is split and there is no majority opinion addressing the First Amendment issues. *See* Paper 337, at 10-11; Paper

The IMS Plaintiffs likewise claim 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 that the statute can only be justified by empirical studies that quantify the impact of the use of prescriber-identifiable data on physician prescribing practices, they are mistaken. *See* Paper 299, at 2 (claiming absence of studies); Paper 307, ¶¶ 34, 35, 37 (same). Neither the Supreme Court nor the Second Circuit has imposed such a rigid requirement – one that rarely could be met in advance of imposing an intended regulation – as part of the *Central Hudson* test. Plaintiffs' repeated efforts to turn the *Central Hudson* test into a form

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294, at 25. Also, *44 Liquormart* addressed a complete ban on price advertising for a legal product, *id.* at 516, and thus the issues discussed in that case have little to do with this one.

of strict scrutiny strongly suggest that, under the real standard, Vermont's law is constitutional.

B. Intermediate scrutiny allows for deference to the predictive judgments of the legislature.

The parties and the Court do not write on a blank slate in evaluating the need for and effectiveness of the statute's restriction on the use of prescriber-identifiable data. The Vermont Legislature considered these questions, held hearings, made findings, and reached a conclusion that is embodied in the Prescription Confidentiality Law. A critical issue in this case is whether, and to what extent, the Court should defer to the findings and conclusions of the Vermont Legislature. The parties disagree on this issue. In defendants' view, the Court's review under *Central Hudson* should include substantial deference to the Legislature's judgment in passing this statute.

The Supreme Court has held that deference to the Legislature is appropriate even where a statute regulates speech and is subject to First Amendment scrutiny. *See Turner Broadcasting Sys. v. FCC*, 512 U.S. 622, 665 (1994) (stating, in context of First Amendment challenge, that "courts must accord substantial deference to the predictive judgments of Congress"); *see also 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."). The Court's "obligation to exercise independent judgment when First Amendment rights are implicated is not a license to reweigh the

evidence *de novo*, or to replace [the Legislature's] factual predictions with [its] own." *Turner I*, 512 U.S. at 666.

The requirement that the Court exercise "independent judgment" coexists with the Court's call for deference to the Legislature – thus, 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."). Taken together, however, *Turner* and the commercial speech cases like *Fox* and *Lorillard* show that, in the regulation of commercial speech, 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 ("This 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' factual predictions with our own. Rather, it is to assure that, in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence."); *Fox,* 492 U.S. at 477 (noting "ample scope of regulatory authority" allowed under *Central Hudson*); *id.* at 479-80 (describing prior holdings as leaving certain decisions to legislatures, so long as legislative judgment was "reasonable"); *id.* at 480 (within bounds of "reasonable fit" requirement, Court "leave[s] it to governmental decisionmakers to judge what manner of regulation may best be employed"); *Lorillard,* 533 U.S. at 555-56 (noting wide range of

adequate justifications under *Central Hudson* standard and describing the "reasonable fit" requirement); *id.* at 561 (describing record and noting that Attorney General's decision to regulate tobacco advertising was not based on "speculation and conjecture"); *id.* at 561-62, 565-66 (striking down advertising regulations because Attorney General did not "carefully calculat[e] the costs and benefits" associated with burden imposed on speech (quotation omitted)).[5]

This case illustrates perfectly the need for, and basis for, 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. It is impossible for the Legislature to conduct, in advance, a valid empirical study that tests the impact of a law before it is implemented. Instead, the Legislature reviewed the evidence and concluded that marketing practices have an impact on physicians' prescribing practices; that marketing is designed to increase the sales of new and more expensive drugs, many of which have little or no therapeutic advantage over older drugs with established safety records; and that prescriber-identifiable data is a tool used with great efficiency to target doctors and persuade them to write more prescriptions for these new, more expensive, and possibly riskier drugs. *See*

[5] One of plaintiffs' amici argues unpersuasively that *Turner's* discussion of deference to the predictive judgments of legislatures does not apply to commercial speech and probably does not apply to state legislatures at all. *See* Paper 291, Amicus Brief of Washington Legal Foundation, at 14, 23; *see also* Paper 337, at 10 (similar argument from IMS plaintiffs). The brief's disdain for state legislatures is contrary to constitutional principles of federalism and has no support in Supreme Court case law. Its First Amendment argument is contrary to *Fox,* which acknowledges the place for legislative authority and policymaking under the *Central Hudson* test. 492 U.S. at 477-80. It is also contrary to *Lorillard,* which notes the substantial similarity between the type of intermediate scrutiny applied in *Turner* and the *Central Hudson* test for commercial speech. *See* 533 U.S. at 554.

generally Findings. 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. *See, e.g.,* Findings 31; 18 V.S.A. § 4631(a). If the Court re-weighs the evidence "de novo" and makes its own decision, the Court will simply be taking over the policymaking role of the Legislature and substituting its judgment for that of the representatives elected by the people of this State. Instead, 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.[6] *See, e.g., Turner I,* 512 U.S. at 666 (review means asking whether "in formulating its judgments, Congress has drawn reasonable inferences based on substantial evidence").

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., McConnell,* 540 U.S. at 137 (noting that *Buckley's* "closely drawn" test for campaign contribution limits "shows proper deference to Congress' ability to weigh competing constitutional interests in an area in which it enjoys particular expertise"); *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

[6] 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. *Tuan Anh Nguyen v. I.N.S.,* 533 U.S. 53, 77 (2001) (discussing rational basis review).

uncertainty."); *id.* at 1637-38 (noting deference given to congressional findings, though findings not dispositive, and upholding statute even though some findings were inaccurate). 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) (jettisoning the "substantially advances" prong of takings analysis). In short, the Supreme Court does not lightly call for the federal courts to usurp the role of the political branches – and such an approach is neither necessary nor appropriate here.

While plaintiffs argue against giving any deference to the Legislature, their arguments are unpersuasive. They point primarily to *IMS Health, Inc. v. Ayotte,* 490 F. Supp. 2d 163 (D.N.H. 2007), where the district court declined to afford deference to the New Hampshire Legislature. *See id*. at 177 n.12 (no deference to New Hampshire legislature in absence of express findings and extensive record); Paper 6, at 23-24 & n.17. The *Ayotte* court's approach should not be followed here, for two reasons.

First, the *Ayotte* court's rejection of the New Hampshire legislative process 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 relied upon two cases in which the Supreme Court declined to defer to legislative judgments, but neither of those cases involved commercial

speech. To the contrary, the Court in those cases was applying far more rigorous First Amendment review. *See Sable Communications of Cal., Inc. 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 Communications, Inc. v. Virginia,* 435 U.S. 829, 838, 845 (1978) (noting that "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). This stringent approach is not followed in the commercial speech cases. To the extent the *Ayotte* court substituted its judgment for that of the legislature, it erred.

Second, whatever the weaknesses of the New Hampshire legislative process, the Vermont Legislature engaged in substantial review of the matter before it and made detailed factual findings that are entitled to deference. The legislative record demonstrates that several committees of the Vermont Legislature amassed and reviewed information and testimony from a broad range of interested parties before it enacted Act 80 in a series of proceedings that spanned the entire 2007 session. In fact, there were 41 separate committee hearings on S.115: The Senate Health & Welfare Committee took up S.115 on nine occasions between January 17 and March 15, 2007. The Senate Finance Committee held fourteen hearings on S.115 from January 19 to March 27, 2007, and the House Health Care Committee addressed S.115 on thirteen separate dates from March 27 through May 3. The House Ways & Means Committee held three sessions on S.115 on April 25-27, 2007, and the House Judiciary Committee discussed it on April 27, 2007.

Significantly, 39 of those 41 sessions took place prior to April 30, 2007, the date the New Hampshire court issued *Ayotte*. The House Health Care Committee's May 2 and May 3 proceedings are the only ones that post-date the issuance of *Ayotte*. Thus, plaintiffs' contention that the Legislature "acted quickly," *see* Paper 6, at 24, in passing the bill after *Ayotte* is contradicted by the fact that the Legislature did the vast majority of its work on Act 80 before the New Hampshire decision issued.

The legislative proceedings that culminated in Act 80's passage encompassed oral testimony and written submissions from a robust cross-section of public and private interests. Not surprisingly, the three main committees (Senate Finance, Senate Health & Welfare, and House Health Care) each heard testimony from the Legislative Council and Joint Fiscal Office staff who were tasked with drafting and researching S.115, as well as representatives of the Vermont Department of Health, the Attorney General's Office, and other state agencies. They also heard from the full range of private-sector stakeholders—including plaintiffs—during these deliberations. Specifically, the committees took oral and written testimony 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.

In addition, the legislative record is replete with written submissions from across the entire spectrum of participants. *See, e.g.*, Readings & Handouts, House Health Care Committee, Documents pertaining to S.115 (LR000006-12). For example, the record includes articles authored by IMS, *see* LR000233-35 (article by Susan Neyhart, IMS manager of strategic programs, discussing "how one company used sophisticated 'data mining' techniques to . . . achieve effective results"); 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"); the PERC Report, LR 000369-415; and materials submitted by PhRMA, *see* Readings & Handouts, House Health Care Committee, Documents pertaining to S.115 (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 Legislature did precisely what the *Ayotte* court found lacking, by assembling 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 n.12.

The fact that the findings were drafted near the end of the legislative process means nothing, given the extensive legislative process that preceded the final drafting. Showing the weakness of their argument on this point, plaintiffs essentially contend that only a legislative process as lengthy as the one described in *Turner* provides an adequate basis for deference. *See* Paper 6, at 24; Paper 337, at 11. That is absurd. No part-time state legislature could possibly spend decades working on one subject and three years passing a single bill. *See id.* Here, the legislative record reflects that Act 80 resulted from a broadly inclusive and lengthy process of information-gathering, public discussion, and deliberation on the part of three separate committees of the Vermont Legislature. The work done by the Vermont Legislature, which spanned an entire session, is more than adequate to justify deference under the *Central Hudson* standard.

C. While the Court should consider the official legislative history and other relevant trial evidence, the Court should not consider irrelevant matters that are outside the scope of the official legislative record.

A review of First Amendment and other relevant case law shows that three broad categories of evidence and information are pertinent to the Court's review in a case like this one.

First, of course, the official legislative record, including legislative findings, are pertinent (and, as argued above, entitled to deference). The Supreme Court routinely looks to this legislative record in examining the justifications for a statute. *See, e.g., Turner Broadcasting Sys. v. FCC,* 520 U.S. 180, 195 (1997) (*Turner II*) (beginning review by examining evidence before Congress). As defendants have

previously briefed, the scope of the official legislative record is defined by statute, legislative rule, and the Legislature's practice of certifying the official legislative history. *See* Paper 275, at 8-9. Both Vermont and federal authorities confirm that judicial review is limited to the official record. *See id.*

Second, the parties may expand upon the legislative record by offering evidence at trial directly related to the findings and conclusions at issue. Again, the Supreme Court's decisions show that this type of post-enactment evidence is pertinent. *See, e.g., Crawford v. Marion County Election Bd.*, 128 S. Ct. 1610, 1618-19 (2008) (plurality) (reviewing evidence from other jurisdictions supporting legislature's concern for voter fraud); *Gonzales v. Carhart*, 127 S. Ct. 1610, 1637-38 (2007) (considering trial testimony that contravened Congress' findings as to abortion procedure); *Turner II*, 520 U.S. at 200 (considering declarations of expert witnesses to determine reasonableness of Congress' conclusion). Defendants intend to offer both expert and fact witnesses and documentary evidence, all of which will provide further support for the findings and conclusions of the Legislature.

Third, in a case like this one, the parties may submit at trial and the Court may consider on its own the kind of evidence or information generally referred to as "legislative facts." *See, e.g.,* John W. Strong et al., 2 McCormick on Evidence § 328, at 369 (5th ed. 1999) ("Judicial notice of [legislative] facts occurs when a judge is faced with the task of creating law, by deciding upon the constitutional validity of a statute, or the interpretation of a statute, or the extension or restriction of a common law rule, upon grounds of policy, and the policy is thought to hinge upon

social, economic, political, or scientific facts."); *id.* at 381 (contrasting "legislative facts," based on policy judgments, with "adjudicative facts," "which are historical facts pertaining to the incidents which give rise to lawsuits"). The Supreme Court often relies upon this type of information when it evaluates the constitutionality of statutes. *See, e.g., Lorillard,* 533 U.S. at 558-61 (reviewing numerous government and private reports, including FDA evidence and findings, to support Attorney General's conclusions about the link between advertising and youth tobacco use); *Edenfield v. Fane,* 507 U.S. at 772 (reviewing, among other things, "literature on the accounting profession"); *see also Carhart,* 127 S. Ct. at 1634 ("While we find no reliable data to measure the phenomenon, it seems unexceptionable to conclude some women come to regret their choice to abort the infant life they once created and sustained." (citing amicus brief)). Accordingly, defendants have asked the Court to take judicial notice of government reports and other publicly available documents that are relevant to the issues in this case and have further briefed this issue of judicial notice in their motion in limine. *See* Paper 290.

What plainly is not relevant is evidence about the workings and communications of lobbyists, legislative staff, and state employees during the weeks and months of the 2007 legislative session. Plaintiffs apparently believe that the Court should delve into the intricate workings of the legislative branch and make specific findings about the roles played by various staffers and lobbyists, including what documents they sent to each other and what they said to each other in emails. *See, e.g.,* Paper 259 (IMS plaintiffs' motion to compel); Paper 334 (opposition to

motion *in limine*). None of this material was certified by the Legislature as part of the official legislative history and none of it falls with the statutes and legislative rules that define legislative history in Vermont. *See* Paper 275, at 8-9. Defendants have previously explained why none of this "evidence" has any relevance to the constitutionality of the Prescription Confidentiality Law, and incorporate those arguments here. *See id.* at 5-13; Paper 301 (motion *in limine*).

D. This Court should not follow the decisions in *Ayotte* and *Rowe*.

As a last point, defendants acknowledge what colloquially might be called the "elephant in the room" in this case: that district courts in New Hampshire and Maine have invalidated laws restricting the use of prescriber-identifiable data. *See IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007), appeal docketed, No. 07-1945 (1st Cir. June 20, 2007); *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2007). These decisions of course are not controlling, but defendants recognize that given the proximity in time and subject matter, the Court may find them informative. Accordingly, defendants ask the Court to consider the following reasons why these rulings are not persuasive and should not be followed here.

First, both cases were expedited for trial and tried on limited factual records. For example, one glaring omission from both the New Hampshire and Maine trials was evidence about the actual practices of pharmaceutical companies. PhRMA was not a party in those cases and the states did not have time to obtain non-party discovery from pharmaceutical companies. In this case, defendants will present evidence about how pharmaceutical companies use prescriber-identifiable data and

other important information about the practice of detailing. Defendants also have access to evidence from the IMS plaintiffs that either was not available to the other states or not used by them.[7]

The *Ayotte* decision repeatedly points to the absence of evidence on certain points asserted by the New Hampshire Attorney General. *See, e.g.,* 490 F. Supp. 2d at 180, 181. Neither New Hamsphire nor Maine had much time to identify and work with experts, and their presentations were accordingly limited. Defendants in this case have identified a number of experts to address different aspects of the litigation and those experts will provide information that was not available to the *Ayotte* and *Rowe* courts. On a related point, after expert discovery in this case that included critiques of plaintiffs' experts, the IMS plaintiffs withdrew an expert witness who testified on their behalf in Maine and New Hampshire.

Second, both *Ayotte* and *Rowe* miss some critical issues that are relevant to the level of First Amendment scrutiny applied here. Defendants have addressed these issues previously. *See generally* Papers 247, 330. One problem shared by both decisions, and worth repeating here, is the failure to consider the right of the government to regulate the use of data in records, like prescription records, that are

[7] The evidence seriously undercuts some of plaintiffs' allegations. For example, in *Rowe,* the court noted that plaintiffs (there, only the data mining companies) supported making prescriber-identifiable data generally known, "so that their professional decision-making is better informed." 532 F. Supp. 2d at 177 n.36. Based on the evidence developed in this case, such an assertion by plaintiffs can only be described as bizarre. The IMS plaintiffs *restrict* public disclosure of prescriber-identifiable data and do not permit their clients (the pharmaceutical companies) to disclose the information even to individual prescribers. *See, e.g.,* Paper 307, ¶¶ 13, 14. Other statements in *Rowe* suggest that the court viewed the Maine statute as primarily preventing detailers from conveying prescriber information to prescribers, which is not generally how this information is used. *See* 532 F. Supp. 2d at 177.

kept at the government's behest and subject to extensive regulation – including other confidentiality requirements. *See Anderson*, 294 F.3d at 463 (explaining that speech regulations in highly regulated fields are subject to reduced scrutiny). The Vermont statute does not restrict the work of data mining companies. As challenged here, the statute prevents (regulated) pharmacies from selling or licensing information they obtain during the (regulated) dispensing of (regulated) prescription drugs.[8] Neither patients nor prescribers have any choice about providing this information to pharmacies – the *government* requires them to do so. The information is part of health care records that traditionally have been confidential. As defendants have consistently argued in this case, this type of regulation should not be analyzed under the First Amendment at all.

Third, these rulings offer only a cramped understanding of the government's interests. This is especially true with respect to the courts' observations about the privacy interest at stake. Both courts seemed skeptical that the state could articulate a substantial interest in privacy because prescriber information is disclosed in other parts of the health care system. *E.g., Ayotte,* 490 F. Supp. 2d at 179 n.13. As an initial matter, it proves too much to say that limited disclosures of information destroy a privacy interest. That would mean the patient has no privacy information either, because the patient's information is also disclosed to providers, staff, insurers, payment intermediaries, and occasionally even regulators investigating professional misconduct. Just as importantly, however, neither the

[8] The statute similarly restricts health insurers, but plaintiffs have not argued that they obtain any data from insurers and the restriction on insurers is not at issue here.

Ayotte nor the *Rowe* courts grasped the important difference between necessary disclosures of information to protect patients and arrange for health care, and the use of the data to try to influence the way doctors treat patients solely for the financial benefit of the pharmaceutical company. That is exactly why pharmaceutical companies use prescriber-identifiable data for marketing: to persuade prescribers to write new prescriptions for their patients (either for a new treatment or a change from one drug to a new one). It is an intrusion on the doctor-patient relationship to use information about a doctor's treatment of his or her patients in this way, particularly without the consent or even knowledge of the doctor.

Fourth, and in a similar vein, the *Rowe* court paid far too little attention to the Legislature's decision to allow doctors to control the use of their information for marketing purposes. In this way, the decision is somewhat of a contradiction, because the court relies upon the "professional training" of doctors and their ability to receive information from a wide range of sources, presumably to counter biased information presented by detailers. *See* 532 F. Supp. 2d at 177. Yet the court does not consider the fact that many doctors want to restrict the use of their prescribing information for marketing purposes. Presumably those doctors, based on their "extensive training and education" and "exercise [of] scientific judgment," *see id.,* have a valid concern about the influence of detailers on their prescribing practices. The Vermont Legislature reasonably concluded that doctors are in the best position

to decide whether the use of prescriber-identifiable data for marketing purposes is helpful or harmful.

As a final point, both courts embraced impractical or unworkable alternatives, which is not appropriate under the *Central Hudson* test. For example, the *Rowe* court suggests the Maine legislation is flawed because it did not prevent detailers from making slanted or "filtered" sales pitches. 532 F. Supp. 2d at 177. It is difficult to conceive of a state statute banning "slanted" sales pitches that would escape constitutional challenge – and indeed, a general and possibly discretionary standard like "not slanted" seems to raise far more constitutional concerns than a simple limitation on certain uses of specific data. *See also Ayotte,* 490 F. Supp. 2d at 182 (suggesting statute should "discriminate between beneficial detailing and harmful detailing" without indicating whether such a regulation would be constitutional). Both courts fault their respective statutes for allowing other noncommercial disclosures of prescriber-identifiable data. 532 F. Supp. 2d at 176; 490 F. Supp. 2d at 179 n.13. It makes little sense to suggest that the statute violates the First Amendment because it restricts too little speech. Again, the Second Circuit has reversed a trial court for striking a commercial speech regulation on this basis. *See Anderson,* 294 F.3d at 463. In any event, there is no evidence that other disclosures, like the use of prescription information to arrange insurance payments, posed any of the concerns identified by the state legislatures.

The *Ayotte* court was persuaded that the state's recourse was to compete with pharmaceutical companies by distributing practice guidelines and conducting

counter-detailing. 490 F. Supp. 2d at 182. That court entirely failed to consider, however, the impossible task faced by a small state trying to compete with billions of dollars in expenditures by pharmaceutical companies. *See id.* In short, neither court gave adequate deference to the legislative decision that restricting the use of prescriber-identifiable data directly served the governments' interests, and instead made their own judgments about other policies that might or might not be effective.

III. The Presentation of Evidence at Trial

The Court has asked the parties to use this memorandum to provide information on trial management issues. The parties have agreed that plaintiffs and defendants will split the 40 hours of trial time evenly, with defendants having 20 hours to present their case. All time used by a party will count against the party's time, including cross-examinations, extensive time arguing objections, and motions.

At trial, defendants intend to rely principally upon their expert witnesses. Those witnesses are identified in Part A, below, with a brief summary of their expected testimony. In Part B, below, defendants briefly sketch out the other trial evidence.

A. Trial Witnesses

Defendants will present five expert witnesses. Defendants may also present brief testimony from a few other witnesses, either to rebut certain assertions from plaintiffs or to clarify points not otherwise addressed by the evidence. The five experts are identified below, with brief summaries of their expected testimony. The

expert declarations cited below were previously filed in connection with the pending summary judgment motions. *See* Paper 245, Attachments 3-6.

1. Dr. Kesselheim. Dr. Kesselheim will testify in person at trial.

Dr. Kesselheim is a practicing medical doctor, board certified in internal medicine, and also a faculty member at Harvard Medical School. He has over thirty publications to his credit, including articles in the New England Journal of Medicine and the Journal of the American Medical Association. Kesselheim Decl. ¶¶ 1-5, 7, & Ex. A. In Dr. Kesselheim's opinion, the "use of prescriber-identifiable data in pharmaceutical marketing efforts contributes to inappropriate prescribing, including prescribing practices that increase risks to patient safety and health care costs." *Id*. ¶ 9. He will testify that the limitations imposed by 18 V.S.A. § 4631 on the use of prescriber-identifiable data will lead to more optimal prescribing practices. In his view, "[m]ore optimal prescribing practices will, in turn, reduce the health risks to Vermonters, including the risks caused by the overexpansion of use of newly approved patent-protected drugs that have limited safety records, and decrease the amount spent in Vermont on prescription drugs." Kesselheim Decl. ¶ 9. Dr. Kesselheim's testimony thus confirms the Legislature's conclusion that "the limitations imposed by the Statute on the use of prescriber-identifiable data will decrease the amounts spent in Vermont on prescription drugs while simultaneously decreasing the health risks to Vermonters posed by the accelerated adoption of newly approved patent-protected drugs." *Id*. ¶ 43.

In providing his opinion, Dr. Kesselheim will discuss several issues relevant to the legislation. He will explain that many newly approved drugs offer little or no therapeutic improvements over existing drugs, but are more expensive. Newly approved drugs also carry safety risks because a drug's risk profile may not be fully known until after the drug is approved and used in large numbers of patients. Serious warnings and safety-related recalls are much more likely to occur in the first few years a drug is on the market. Despite the expense and the safety risks, these new drugs are heavily marketed by the pharmaceutical companies and for that reason are often widely prescribed. Kesselheim Decl. ¶¶ 24, 28, 30.

Dr. Kesselheim will also testify about how physicians are influenced by marketing efforts and how those efforts, especially detailing practices, unnecessarily increase costs and risks to patient health. *Id.* ¶¶ 31, 32, 36-39. Detailers are trained to increase market share for their products, not to promote optimal prescribing practices. *Id.* ¶ 31. Prescriber-identifiable data plays a key role: "Detailing is conducted to increase sales of the drugs that are being promoted, with resulting negative consequences for both patient safety and health care costs, and it is the use of prescriber-identifiable data that permits effective targeted marketing leading to these consequences." *Id.* ¶ 40. Prescriber-identifiable data serves several purposes in pharmaceutical marketing – all of which contribute to the effectiveness of marketing campaigns without regard for cost or patient health: (1) the data allows marketers to identify the doctors most susceptible to marketing, and plan their detailing visits accordingly, *id.* ¶ 41; (2) the data "allow detailers to

tailor their advertising messages in an effort to increase the number of prescriptions written," such as by giving gifts to low prescribers, *id*. ¶ 42; (3) the data allow marketers to measure the effectiveness of detailing visits by tracking prescriptions, and to reinforce or adjust their marketing techniques as a result, *id*. ¶ 43; and (4) pharmaceutical companies use the data to "determine the overall effectiveness of particular detailers," promoting those who are most successful at gaining prescriptions and replacing those who are less effective, *id*. ¶ 44.

Dr. Kesselheim also refutes plaintiffs' suggested alternatives, pointing out that educational outreach efforts (such as academic detailing) are not sufficient and cannot be developed quickly enough to counter the billions of dollars spent on marketing each year by the pharmaceutical industry. *Id*. ¶¶ 48-50. Mandatory generic substitution only applies where a bioequivalent generic is available and thus does not does not address "those instances where it may be appropriate to substitute lower-cost therapeutically equivalent drugs – such as generic omeprazole for Nexium – or where it may be more effective to recommend a different type of treatment, such as a change in diet or lifestyle." *Id*. ¶ 51. In Dr. Kesselheim's view, the "relatively low generic drug utility rate in Vermont suggests that significant progress can still be made in expanding the appropriate use of generic drugs." *Id*.

2. Dr. Rosenthal. Dr. Rosenthal may testify in person or by video at trial.

Dr. Rosenthal has a PhD in health policy from Harvard University, where she teaches health economics and policy. Rosenthal Decl. ¶ 1. Her expertise is in the economics of the health care industry, including pharmaceuticals. *Id*. ¶ 2.

Among other things, Dr. Rosenthal provides expert testimony on the likely cost savings to Vermont if more prescriptions are written for generic drugs. She explains that generic drugs are significantly less expensive than brand-name drugs – on average, about 71% cheaper. *Id.* ¶ 9. She then points out that "additional cost savings are potentially available to Vermont through increased prescribing of generic drugs." *Id.* ¶ 14. While Vermont has a high rate of mandatory substitution of bioequivalent generic drugs, the State's overall utilization of generic drugs is substantially lower. *Id.* ¶¶ 12-14. In some cases, there are therapeutic (as opposed to bioequivalent) generic substitutes that could be prescribed for patients instead of more expensive branded drugs. *Id.*

Dr. Rosenthal also critiques several of the positions advanced by plaintiffs. Among other things, she shows that (1) the use of prescriber-identifiable data does not reduce drug prices, *id.* ¶¶ 19-22; (2) restricting the use of prescriber-identifiable data will not cause prescribers to spend more time with detailers, *id.* ¶¶ 23-26; and (3) there is no good evidence to support the claim that rapid, widespread adoption of new drugs improves life expectancy and health, or that it decreases the costs of health care, *id.* ¶¶ 29-34, 37-38.

3. Dr. Wazana. Dr. Wazana will testify in person at trial.

Dr. Wazana, a practicing psychiatrist and faculty member at McGill University, will testify about the influence of marketing on physicians. Wazana Decl. ¶¶ 2-4, 9. In his opinion, "most physicians do not perceive themselves to be unduly influenced by marketing messages delivered by pharmaceutical

representatives, but, contrary to this perception, physicians are negatively influenced by their interactions with the pharmaceutical industry." *Id.* ¶ 9.

4. Dr. Grande. Dr. Grande may testify in person or by video at trial.

Dr. Grande is a licensed physician who teaches at the University of Pennsylvania School of Medicine. Grande Decl. ¶¶ 1-4. Dr. Grande has researched "the influence that marketing of prescription drugs has on the medical profession, particularly clinical decision making" and has "analyzed the role that prescriber identifiable data plays in the marketing of prescription drugs and the influence it exerts on clinical practice." *Id.* ¶ 3. It is his "opinion, to a reasonable degree of medical certainty, that prescriber identifiable data allows marketers to influence prescribing practices of physicians and other prescribers in ways that threaten medical professionalism." *Id.* ¶ 9. He testifies, among other things, that "by reducing the use of prescriber-identifiable data for marketing purposes, pharmaceutical sales representatives will be less able to target prescribers and develop messages designed to place the economic interests of the pharmaceutical company over the interests of patients." *Id.* ¶ 11. Accordingly, in Dr. Grande's opinion, 18 V.S.A. § 4631 "will result in prescribing decisions that are less vulnerable to influence from profit centered marketers" and "prescribing practices that reflect a higher degree of professionalism and insulate the physician patient relationship from unwarranted intrusion." *Id.* ¶ 11.

5. Shahram Ahari. Shahram Ahari will testify in person at trial.

Shahram Ahari is a former sales representative for Eli Lilly. He has a master's degree in public health from the University of California and works as a consultant for Georgetown Medical School's PharmedOut Project. He will testify about his training and experience as a sales representative and talk about the marketing uses of prescriber-identifiable data. He confirms that sales representatives do not share prescriber-identifiable data with doctors and are trained to deflect any questions about its use. He also confirms that sales representatives are not trained to educate doctors but to persuade doctors to prescribe the company's products. Prescriber-identifiable data is used in this effort to maximize the company's market share, in part by identifying doctors that already prescribe large amounts of drugs and are susceptible to marketing tactics.

Other witnesses. Depending on the presentations made by plaintiffs, defendants may call a few other witnesses for brief testimony on certain other points. These witnesses include: Dr. Craig Jones, who is the director of the Blueprint for Health and whose testimony would address PhRMA's assertions about the manufacturer fee; and Madeleine Mongan, from the Vermont Medical Society, whose testimony would address the Medical Society's support for the legislation.

Defendants reserve the right to call any witness on defendants' witness list (Paper 269).

B. Other Evidence and Confidentiality Issues

The Court should consider the legislative record in ruling on the constitutionality of the Prescription Confidentiality Law. Defendants outlined the legislative record in section II.B., *supra.* The parties will submit the formal record to the Court at trial.

Defendants will present the deposition testimony of 8 witnesses who testified as representatives of pharmaceutical companies. The parties will address objections to any proposed testimony by deposition at the pretrial conference. Defendants do not intend to have the depositions read into the record at trial, but rather will submit the depositions for the Court's review.

Defendants will also rely upon documentary evidence as listed in the Exhibit List, including documentary evidence obtained from pharmaceutical companies.

The parties have agreed that documents and deposition testimony from pharmaceutical companies will be redacted to remove the identity of the companies. This measure is intended to avoid any alleged confidentiality concerns asserted by the companies. The companies will be referred to as "Company A," "B," etc.

* * * *

Dated: July 9, 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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