UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

IMS HEALTH INCORPORATED; VERISPAN, LLC; and SOURCE HEALTH CARE ANALYTICS, INC., a Subsidiary of WOLTERS KLUWER, HEALTH INC., Plaintiffs, vs. WILLIAM H. SORRELL, as Attorney General of the State of Vermont, Defendant.	Civil Action No. 1:07-cv-00188
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, vs. WILLIAM H. SORRELL, in his official capacity as Attorney General of the State of Vermont, JIM DOUGLAS, in his official capacity as Governor of the State of Vermont, and CYNTHIA D. LAWARE, in her official capacity as the Secretary of the Agency of Human Services of the State of Vermont, Defendants.	Civil Action No. 1:07-cv-220

PLAINTIFF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA'S TRIAL MEMORANDUM

Vermont Acts No. 80 (2007) as amended by Vermont Acts No. 89 (2008) (collectively "the Vermont Act") infringes on the First Amendment rights of PhRMA's members, pharmaceutical companies that sell prescription drugs in Vermont. The Act also seeks to

regulate conduct outside Vermont, violating the Commerce Clause, and it interferes with the Food and Drug Administration's ("FDA") regulatory objectives. In this Trial Memorandum, PhRMA describes the claims in this case, the factual and legal issues to be determined, and the evidence that will be presented.

I. NATURE OF THE CASE

Plaintiff PhRMA asks this Court to declare certain provisions of the Vermont Act unconstitutional and to enjoin enforcement of those provisions. PhRMA's Amended Complaint alleges that: (1) Section 17(d) of the Vermont Act restricts the speech of pharmaceutical companies in violation of the First and Fourteenth Amendments; (2) Section 21(c) of the Vermont Act is preempted by federal law because it obstructs the ability of FDA to achieve its regulatory objectives; (3) Section 21(c) of the Vermont Act violates the Commerce Clause of the U.S. Constitution by regulating almost exclusively out-of-state commerce; and (4) Section 20 of the Vermont Act violates the First and Fourteenth Amendments by forcing pharmaceutical companies to subsidize speech favoring competitors' products.

Section 17(d) of the Vermont Act prohibits, absent prior consent by prescribers, communications to them by pharmaceutical companies that use prescriber-identifiable data for marketing or promotional purposes. *See* Act § 17(d), codified at 18 V.S.A. § 4631(d). The First Amendment prevents this type of restriction on speech, subjecting Section 17(d) to strict or intermediate scrutiny. It can withstand neither.

Section 21(c) of the Vermont Act, which creates a cause of action under the Vermont State Consumer Fraud Act for pharmaceutical advertisements deemed in violation of federal law, is also unconstitutional both because it is preempted by federal law and because it violates the Commerce Clause. *See* Act § 21(c), codified at 9 V.S.A. § 2466a(c). Section 21(c) obstructs the

Congressionally-mandated objectives of FDA by allowing Vermont courts to interpret and enforce FDA regulations on pharmaceutical advertising. Because pharmaceutical companies are located outside of Vermont, and their national advertisements are sensitive to potential divergences in interpretation of FDA regulations, Section 21(c) has an extraterritorial reach that renders the provision *per se* invalid.

Finally, Section 20 of the Vermont Act violates the First and Fourteenth Amendments to the U.S. Constitution because it imposes a fee on pharmaceutical manufacturers to subsidize speech in favor of competitors' products, namely, generic pharmaceuticals. This compelled speech directly violates the First Amendment to the U.S. Constitution. Furthermore, pharmaceutical companies play no role in creating the messages that their funds will subsidize, which will instead be established by Vermont's Blueprint for Health ("Blueprint"). The Blueprint is composed largely of private interests, and those private interests control the content of the messages that the Blueprint creates. Therefore, the messages that the Manufacturer Fee subsidizes are not government speech.

II. ISSUES OF LAW TO BE DETERMINED

1. Whether Section 17(d) of the Vermont Act restricts the speech of PhRMA members.
2. Whether the restriction of speech in Section 17(d) of the Vermont Act is subject to strict scrutiny or intermediate scrutiny under the First and Fourteenth Amendments.
3. Whether Section 17(d) of the Vermont Act violates the First and Fourteenth Amendments under either the strict scrutiny or intermediate scrutiny test by restricting communications to prescribers by pharmaceutical companies using prescriber-identifiable data.

4. Whether protecting the "privacy" of health care providers' prescribing practices is a substantial state interest cognizable under the First and Fourteenth Amendments.
5. Whether Section 21(c) of the Vermont Act is preempted by federal law, violating the Supremacy Clause of the U.S. Constitution, by obstructing the accomplishment and execution of the full purposes and objectives of FDA.
6. Whether Section 21(c) of the Vermont Act violates the Commerce Clause of the U.S. Constitution by directly regulating extraterritorial conduct.
7. Whether Section 20 of the Vermont Act violates the First and Fourteenth Amendments by forcing pharmaceutical companies to subsidize nongovernmental speech about competitors' products.

III. ISSUES OF FACT TO BE DETERMINED

The Court could decide this case as a matter of law, without need for findings of fact. In PhRMA's view, such issues as whether the Vermont Act directly serves a substantial state interest are predominantly legal rather than factual in nature. If the Court disagrees, or determines that it should make factual findings, PhRMA submits that the Court should consider the following issues:

1. Whether Section 17(d) of the Vermont Act restricts PhRMA members' speech.
2. Whether Defendants have established that the restriction on speech in Section 17(d) of the Vermont Act is narrowly tailored to advance a compelling state interest.
3. Whether Defendants have established that the restriction on speech in Section 17(d) directly advances substantial interests of the State of Vermont.

4. Whether Defendants have established that no alternatives less restrictive of speech than Section 17(d) could further the interests Vermont has identified.

5. In the alternative to issues two through four, whether Defendants have established that the restriction on speech by Section 17(d) directly serves substantial state interests in a manner no more restrictive than necessary to further those interests.

6. Whether the potential divergence between FDA and the Vermont courts in the interpretation and enforcement of FDA regulations under Section 21(c) of the Vermont Act will cause PhRMA members to modify, or refrain from, national advertising campaigns.

7. Whether the chilling effect created by Section 21(c) will obstruct FDA's efforts to fulfill its statutory objectives.

8. Whether the regulation of advertising under Section 21(c) directly regulates extraterritorial conduct.

9. Whether Section 20 of the Vermont Act forces PhRMA members to subsidize speech about competitors' products.

10. Whether Vermont's Blueprint for Health is controlled predominantly by private interests.

11. Whether the State of Vermont has ceded to private interests effective control over communications by the Blueprint for Health.

IV. PhRMA's CONTENTIONS AND THEORIES OF RECOVERY

Section 17(d) of the Vermont Act violates the First and Fourteenth Amendments because it restricts the speech of pharmaceutical manufacturers without adequate justification. It purportedly seeks to protect the privacy of physicians' prescribing information, but allows that

information to be widely disseminated. It purports to lower health care costs and protect public health, but, at best, pursues a circuitous route toward those objectives. It burdens speech as a first -- not a last -- resort, with no evidence that this approach will work, or that other, less restrictive measures will not work.

Section 21(c) of the Vermont Act is preempted by federal law, violating the Supremacy Clause of the U.S. Constitution. It interjects Vermont state courts into the business of interpreting and enforcing FDA regulations on the advertising of prescription drugs, creating a potential for discord that will affect the advertising of pharmaceutical manufacturers. This effect will occur outside Vermont, violating the Commerce Clause, and will disrupt the careful balance FDA has struck in its comprehensive regulation in this area.

Section 20 of the Vermont Act violates the First and Fourteenth Amendments because it imposes a fee on pharmaceutical manufacturers designed to subsidize speech that is shaped by private interests and benefits PhRMA members' competitors.

A. Section 17(d) Violates The First and Fourteenth Amendments

Section 17(d) of the Vermont Act violates the First and Fourteenth Amendments because it restricts communications to prescribers by pharmaceutical companies that use prescriber-identifiable data for marketing or promotional purposes, absent prescriber consent. *See* Act § 17(d), codified at 18 V.S.A. § 4631(d).[1] This provision impermissibly seeks to tip a perceived "imbalance" in the "marketplace for ideas" toward the viewpoint preferred by the State. *See* Act §§ 1(4), (6). Section 17(d) restricts truthful, non-misleading speech by speakers that the

[1] PhRMA's contention that Section 17(d) violates the First and Fourteenth Amendments is discussed in more detail in PhRMA's Amended Memorandum of Law in Support of Its Cross-Motion for Partial Summary Judgment at 5-13 (Dk. 177) and PhRMA's Reply in Support of Part I of Its Cross-Motion for Partial Summary Judgment at 1-9 (Dk. 299). PhRMA does not repeat that briefing here, but respectfully incorporates by reference the arguments presented in those filings.

Vermont Legislature disfavors -- brand-name pharmaceutical companies -- and forces them, if they use prescriber-identifiable data, either to remain silent or deliver a message shaped by Section 17(d). Under the First and Fourteenth Amendments, Section 17(d) must, but cannot, survive either strict or intermediate scrutiny. It is, therefore, unconstitutional.

Strict scrutiny applies here because the Vermont Act defines "marketing" and "promotion" broadly, encompassing virtually any communication designed to "publicize" a prescription drug. *See id.* § 17(b)(5), codified at 18 V.S.A. § 4631(b)(5); *Id.* § 17(b)(8), codified at 18 V.S.A. § 4631(b)(8).[2] Because pharmaceutical companies often "publicize" a drug to communicate scientific or health related information, to conduct research, and to disseminate information on risks and recalls, Section 17(d) restricts more than just "commercial speech" designed to sell a product. The provision, specifically its intrusion on free speech, is therefore subject to strict scrutiny.

Section 17(d) cannot survive strict scrutiny because it is not narrowly tailored to promote a compelling government interest and because less restrictive alternatives are available. Indeed, as discussed below, Section 17(d) cannot meet even the less stringent intermediate scrutiny standard, and thus, *a fortiori*, it cannot come close to satisfying the strict scrutiny standard.

Even if Section 17(d) only restricted commercial speech, it could not survive intermediate First Amendment scrutiny under *Central Hudson Gas & Electric Corp. v. Public Service Commission of N.Y.*, 447 U.S. 557 (1980). Under *Central Hudson*, Defendants bear the burden of proving that the provision directly advances substantial state interests. They cannot

[2] PhRMA maintained that the Vermont Act is subject to strict scrutiny in its Memorandum of Law in Support of Its Motion for Preliminary Injunction at 16-20, 23, 42-43 (Civil Action No. 1:07-cv-220-jgm, Dk. 7), its Reply in Support of Its Motion for Preliminary Injunction at 1 (Dk. 111), its Amended Memorandum of Law in Support of Its Cross-Motion for Partial Summary Judgment at n.1 (Dk. 177), and its Reply in Support of Part I of Its Cross-Motion for Partial Summary Judgment at n.6 (Dk. 299).

carry this burden, nor can they show that Section 17(d) intrudes on free speech no more than necessary.

The first of the interests identified in the Vermont Act -- protecting the privacy of physicians' prescribing practices -- is not a substantial state interest. *See IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007); *IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2007). Identifying the drugs that health care providers prescribe as part of their jobs, in the workplace, does not involve personal or financial information about their private lives. Even if this identified interest were substantial, Section 17(d) does not directly further it because the provision allows third parties, including insurers, the State, academics, and pharmaceutical companies, to continue receiving and using prescriber-identifiable data for many different purposes, except one. Pharmaceutical companies cannot use it to market or promote drugs. Nor does the provision, like the Federal Trade Commission and Federal Communications Commission's Do Not Call regulations, prevent unwarranted intrusions on health care providers' time. The provision does not keep pharmaceutical sales representatives from visiting Vermont prescribers. And it does not directly address the alleged problem of overly aggressive marketing tactics. Sales representatives who do not use prescriber-identifiable data are free, at least insofar as this provision is concerned, to market however they please.

Lowering health care costs could be a substantial state interest only insofar as it would not diminish public health, and the Vermont Act links the two purported objectives. The Act, however, serves neither interest directly. Section 17(d) does not control, limit, or even address the cost of prescription drugs. It addresses only marketing communications, leaving prescribers free to prescribe whatever products they choose. Nor does Section 17(d) address public health. It does not control the information provided to physicians, nor does it dictate, limit, or even

suggest the drugs physicians should prescribe. Indeed, it does not even purport to reach pharmaceutical marketing or promotion unconnected with prescriber-identifiable data.

Even if the Vermont Act were directly to address its stated interests, Defendants can provide no evidence that the Act will in fact lower health care costs or further public health. Defendants' own experts admit that not a single empirical study links prescriber-identifiable data to increased costs or increased health risks. *See* Dep. Tr. of Prof. Meredith Rosenthal at 180, 242 (May 16, 2008), attached as Ex. J to PhRMA's Reply in Support of Part I of Its Cross-Motion for Partial Summary Judgment (Dk. 299) ("PhRMA Part I Sum. J. Reply") (stating that because of the absence of empirical data on prescriber-identifiable data, she has no opinion as to whether Section 17(d) would increase or decrease health care costs or improve public health); Dep. Tr. of Dr. Aaron Kesselheim at 21-22, 26-27 (May 20, 2008), attached as Ex. A to PhRMA Part I Sum. J. Reply (admitting that he is not aware of a single study on prescriber-identifiable data); Dep. Tr. of Dr. David Grande at 319-20 (May 8, 2008), attached as Ex. E to PhRMA Part I Sum. J. Reply (acknowledging that there has been no empirical assessment of limits on the use of prescriber-identifiable data and impacts on prescribing). In the absence of scientifically valid evidence, Defendants' experts either disclaim any opinion or engage in patent speculation.

Even if the State could surmount this obstacle, Section 17(d) still would fail because it restricts free speech more than necessary. Vermont has available a wide variety of less restrictive alternatives, including many programs already in place in the State, such as generic substitution, generic vouchers, appropriately tailored state-sponsored detailing programs, notification to prescribers of the expiration of brand-name patents, best practices programs, and gift and price disclosure laws, among others.

That restrictions on speech by pharmaceutical companies using prescriber-identifiable data violate the First Amendment is well-established. Federal courts in both New Hampshire and Maine have invalidated state laws similar to Section 17(d) of the Vermont Act. *Ayotte*, 490 F. Supp. 2d 163; *Rowe*, 532 F. Supp. 2d 153. Nothing about the Vermont Act changes the analyses undertaken or the outcomes that those courts reached. In particular, the State's last-minute insertion of so-called legislative findings into the Vermont Act cannot save the Act from its constitutional infirmities, as the Court's analysis must look behind the conclusions of the Act. *See, e.g.*, *Landmark Commc'ns, Inc. v. Virginia*, 435 U.S. 829, 843 (1978) ("Deference to a legislative finding cannot limit judicial inquiry when First Amendment rights are at stake."); *Sable Commc'ns of Cal., Inc. v. FCC*, 492 U.S. 115, 129 (1989) ("[W]hatever deference is due legislative findings [could] not foreclose our independent judgment of the facts bearing on an issue of constitutional law"); *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 666 (1994) (noting that, when First Amendment rights are at stake, the legislature has a duty to show that it "has drawn reasonable inferences based on substantial evidence").

B. Section 21(c) Is Preempted[3]

Section 21(c) of the Vermont Act is preempted by federal law because it obstructs the accomplishment and execution of the full purposes and objectives of FDA. The provision makes it a violation of the Vermont Consumer Fraud Act "to present or cause to be presented in the state" a "regulated advertisement" that does not comply with federal law. *See* Act § 21(c),

[3] As requested in PhRMA's Opposition to Defendants' Motion for Summary Judgment -- Commerce Clause and Preemption Counts at 2-3 (Dk. 303), PhRMA respectfully submits that the Court should defer ruling on PhRMA's preemption challenge to Section 21(c) of the Vermont Act pending a decision in *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), *cert. granted*, 128 S. Ct. 1118 (Jan. 18, 2008), in which the Supreme Court will determine whether federal prescription drug labeling requirements preempt certain state law product liability claims challenging the adequacy of manufacturers' labeling.

codified at 9 V.S.A. § 2466a(c).[4] FDA comprehensively regulates pharmaceutical advertising. It has promulgated detailed regulations, issued extensive guidance documents, and developed a regulatory practice in decades of interactions with pharmaceutical manufacturers. FDA reviews pharmaceutical advertising, and has ample enforcement mechanisms available for violations of law or departures from accepted practice.

Section 21(c) interjects Vermont state courts into this comprehensive scheme of federal regulation. It allows Vermont courts to determine whether pharmaceutical advertising violates federal law, to put their own gloss on FDA regulations, and to impose penalties without regard to the balance FDA has struck to ensure dissemination of appropriate information. Indeed, even Defendants admit that state courts could interpret federal requirements differently than FDA. *See* Defs.' Mem. Supp. Mot. for Sum. J. (June 2, 2008), at 23 ("A state court could . . . engage in its own interpretation of the requirements of federal law.") (Dk. 257-2). That potential could affect the conduct of PhRMA members. It will create a chilling effect on PhRMA members' speech that may cause PhRMA members to modify or even refrain from national advertising campaigns to accommodate Vermont's requirements. Moreover, it inevitably will lead PhRMA members to increase the amount of advertising submitted to FDA for clearance before publication -- to get the FDA's blessing in the hope of avoiding liability in Vermont -- potentially overloading FDA and skewing its allocation of priorities. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 (2001) (stating that if pharmaceutical companies

[4] PhRMA's contention that Section 21(c) of the Vermont Act is preempted by federal law, violating the Supremacy Clause, is addressed in detail in PhRMA's Opposition to Defendants' Motion for Summary Judgment -- Commerce Clause and Preemption Counts at 1-2, 3-9 (Dk. 303). It is also discussed briefly in PhRMA's Memorandum of Law in Support of Its Consent Motion for Leave to Amend the Complaint and Opposition to Defendants' Partial Motion to Dismiss for Mootness at 5-6 (Dk. 172). PhRMA does not repeat that briefing here, but respectfully incorporates the arguments presented in those filings by reference.

anticipate that "their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court," manufacturers could "'submit a deluge of information that the Administration neither wants nor needs'").

C. Section 21(c) Violates The Commerce Clause

The effects of Section 21(c) will be entirely extraterritorial. In thus directly regulating the advertising practices of PhRMA members outside Vermont, Section 21(c) violates the Commerce Clause.[5] Specifically, Section 21(c) applies directly to advertisements created and distributed outside Vermont if those advertisements find their way to Vermont. *See* Act § 21(c), codified at 9 V.S.A. § 2466a(c) ("It shall be a prohibited practice under [the Vermont Consumer Fraud Act] 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 concerning drugs and devices and prescription drug advertising in federal law and regulations. . . .") (emphasis supplied). As a result, PhRMA members' advertising practices -- even when the relevant transactions occur entirely outside Vermont -- would have to account for state court interpretations of FDA regulations that diverge from FDA's approach. This extraterritorial reach renders Section 21(c) *per se* invalid.

[5] PhRMA's contention that Section 21(c) of the Vermont Act violates the Commerce Clause is discussed in more detail in PhRMA's Opposition to Defendants' Motion for Summary Judgment -- Commerce Clause and Preemption Counts at 9-13 (Dk. 303). The extraterritorial reach of Section 21(c) is also discussed in PhRMA's Memorandum of Law in Support of Its Motion for Preliminary Injunction at 38-40 (Civil Action No. 1:07-cv-220-jgm, Dk. 7). PhRMA does not repeat that briefing here, but respectfully incorporates the arguments presented in those filings by reference.

D. Section 20 Violates The First and Fourteenth Amendments

Section 20 of the Vermont Act compels PhRMA members to subsidize speech that is in large part developed by and that serves the interest of other private parties.[6] The provision forces PhRMA members to pay a fee that will fund an evidence-based education program. Both the intent and the effect of that program are to promote the products of generic drug manufacturers, who are competitors of PhRMA members, and to serve the interests of insurers that prefer generic products. This attempt, through compelled subsidies, to rectify a purported "imbalance" in the "marketplace for ideas" regarding pharmaceutical products and to control speech for the benefit of some participants over others is antithetical to the First Amendment. *See* Act §§ 1(4), (6).

Vermont's Blueprint for Health develops these communications. *See* Act § 14, codified at 18 V.S.A. § 4622(a)(1). The Blueprint is comprised mostly of private interests, including hospitals and insurers. The State Department of Health exercises no practical control over the communications -- it never has and provides no reason to believe it will in the future. *See, e.g.,* Dep. Tr. of Sharon Moffatt at 190-91 (Jan. 21, 2008), attached as Ex. C to PhRMA's Reply in Support of Part II of Its Cross-Motion for Partial Summary Judgment (Dk. 231) (explaining that the Executive Committee of the Blueprint has never rejected a proposal created by the working group or even suggested the working group amend or modify a proposal). The standards developed by the Blueprint therefore do not constitute government speech.

[6] PhRMA's contention that Section 20 violates the First and Fourteenth Amendments is addressed in more detail in PhRMA's Amended Memorandum of Law in Support of Its Cross-Motion for Partial Summary Judgment at 13-15 (Dk. 177), PhRMA's Reply in Support of Part II of Its Cross-Motion for Partial Summary Judgment and Response in Opposition to Defendants' Cross-Motion for Partial Summary Judgment -- Manufacturer Fee at 1-7 (Dk. 231), PhRMA's Memorandum of Law in Support of Its Motion for Preliminary Injunction at 40-42 (Civil Action No. 1:07-cv-220-jgm, Dk. 7), and PhRMA's Reply in Support of Its Motion for Preliminary Injunction at 13-15 (Dk. 111). PhRMA does not repeat that briefing here, but respectfully incorporates the arguments presented in those filings by reference.

V. PRESENTATION OF EVIDENCE AND ARGUMENT

PhRMA respectfully requests that the Court impose specific time limitations on the parties' respective presentations of evidence and argument, including direct- and cross-examinations, opening statements, closing arguments, and trial motion arguments. PhRMA submits that Plaintiffs and Defendants should each be provided with one-half of the allotted five trial days, and that PhRMA should be provided with 40 percent of Plaintiffs' time allocation.[7] These limitations will ensure both that the parties complete the hearing in the allotted five days and that the time is allocated equitably between them.

VI. PhRMA's WITNESSES AND ANTICIPATED TESTIMONY

PhRMA may or will ("will call" witnesses are indicated by italics) offer the following witnesses at trial to testify on the subjects indicated and other relevant topics:[8]

1. **Julie Corcoran**, PhRMA's Deputy Vice President of Government Affairs: (1) PhRMA's role as principal policy advocate for the brand-name pharmaceutical industry; and (2) PhRMA's testimony before the legislature relating to the Vermont Act.

2. **Lori Reilly**, PhRMA's Vice President for Policy and Research: (1) PhRMA's role as principal policy advocate for the brand-name pharmaceutical industry; and (2) pharmaceutical innovations.

3. ***Mick Kolassa***, Managing Partner and Chief Executive Officer of Medical Marketing Economics and PhRMA's designated expert witness on pharmaceutical marketing and the pharmaceutical industry: (1) the market for prescription drugs; (2) pharmaceutical marketing

[7] Defendants do not oppose PhRMA's application for a division of time.

[8] The parties are negotiating an agreement to protect sensitive testimony and other evidence from non-party PhRMA member companies. PhRMA anticipates that this agreement will soon be presented to the Court for consideration.

practices; (3) the uses of prescriber-identifiable data; (4) the diffusion of new scientific information about drugs through marketing practices; (5) the effect that the Vermont Act will have on pharmaceutical companies' advertising; and (6) the effect that the Vermont Act will have on pharmaceutical marketing practices, prescriber privacy, health care costs, and public health.

4. ***Peter Hutt***, Senior Counsel at Covington & Burling LLP and the Publisher Plaintiffs' designated expert on FDA issues: (1) the new drug approval process for patented and generic drugs; (2) drug innovation; (3) the role of patent term exclusivity in the drug development and approval process; (4) FDA regulation of pharmaceutical labeling and advertising and FDA's enforcement of those regulations; (5) the effect the Vermont Act will have on FDA's goals and enforcement; (6) the effect that the Vermont Act will have on health care costs and public health.

5. **James Short**, Director of Commercial Decision Support at GlaxoSmithKline ("GSK"): (1) how GSK uses prescriber-identifiable data; (2) GSK's policies regarding marketing to physicians and GSK's monitoring and enforcement of those policies; (3) GSK's advertising and marketing practices; and (4) the effect of the Vermont Act on GSK's advertising and marketing activities.

6. **Jeffrey Hurley**, Alliance Manager for Eli Lilly ("Lilly"): (1) how Lilly uses prescriber-identifiable data; (2) Lilly's policies regarding marketing to physicians and Lilly's monitoring and enforcement of those policies; (3) Lilly's advertising and marketing practices; and (4) the effect of the Vermont Act on Lilly's advertising and marketing activities.

7. **Joseph Bonaccorso**, Director of Sales for Novartis: (1) how Novartis uses prescriber-identifiable data; (2) Novartis's policies regarding marketing to physicians and

Novartis's monitoring and enforcement of those policies; (3) Novartis's advertising and marketing practices; and (4) the effect of the Vermont Act on Novartis's advertising and marketing activities.

8. **Paul Rabideau**, Director of Marketing Science for Novartis: how Novartis uses prescriber-identifiable data to issue drug safety alerts.

9. **Jeffrey Robertson**, Assistant Vice President of Sales Planning and Insight for Wyeth: (1) how Wyeth uses prescriber-identifiable data; (2) Wyeth's policies regarding marketing to physicians and Wyeth's monitoring and enforcement of those policies; (3) Wyeth's advertising and marketing practices; and (4) the effect of the Vermont Act on Wyeth's advertising and marketing activities.

10. **Sandra Pirao**, Manager for Global Pharmaceutical Business and Compliance for Schering-Plough: (1) how Schering-Plough uses prescriber-identifiable data; (2) Schering-Plough's policies regarding marketing to physicians and Schering-Plough's monitoring and enforcement of those policies; (3) Schering-Plough's advertising and marketing practices; and (4) the effect of the Vermont Act on Schering-Plough's advertising and marketing activities.

11. **Susan Silbermann**, Senior Vice President for Worldwide Commercial Development for Pfizer: (1) how Pfizer uses prescriber-identifiable data; (2) Pfizer's policies regarding marketing to physicians and Pfizer's monitoring and enforcement of those policies; (3) Pfizer's advertising and marketing practices; and (4) the effect of the Vermont Act on Pfizer's advertising and marketing activities.

12. **Paul Hawthorne**, Vice President of Sales and Commercial Effectiveness for sanofi-aventis: (1) how sanofi-aventis uses prescriber-identifiable data; (2) sanofi-aventis's policies regarding marketing to physicians and sanofi-aventis's monitoring and enforcement of

those policies; (3) sanofi-aventis's advertising and marketing practices; and (4) the effect of the Vermont Act on sanofi-aventis's advertising and marketing activities.

13. **Joshua Slen**, Director of the Office of Vermont Health Access ("OVHA"): (1) the goals, programs, and activities of OVHA; (2) any studies or analyses conducted by OVHA on the effects the Vermont Act may have on health care costs or quality in Vermont; (3) the Manufacturer Fee and the uses to which it will be put; (4) the goals, programs, and activities of the Blueprint for Health and its associated committees; (5) the State's Preferred Drug List and how decisions are made with respect to coverage of certain drugs and other expenses; and (6) Vermont's efforts to contain health care prices.

14. **Sharon Moffatt**, former Acting Commissioner of Vermont's Department of Health: (1) the goals, programs, activities of, and Offices under, the Vermont Department of Health; (2) the goals, programs, activities, and membership of the Blueprint for Health and its associated committees; (3) studies concerning the effects of prescriber-identifiable data; (4) the State's uses of prescriber-identifiable data; (5) the State's Preferred Drug List and how decisions are made with respect to coverage of certain drugs and other expenses; (6) the academic detailing program of the University of Vermont; and (7) the Vermont Act and health care costs.

15. **Robin Lunge**, former counsel of the Vermont Office of Legislative Council, and Policy Director for the National Legislative Association on Prescription Drug Prices ("NLARx"): (1) her involvement in drafting the Vermont Act while employed by the Vermont Legislative Council; (2) the involvement of Sean Flynn, Julie Brill, and other parties in the drafting of the Vermont Act; (3) studies regarding the effect of prescriber-identifiable data on health care costs; (4) Vermont's efforts to contain health care costs; and (5) the ways that Vermont uses prescriber-identifiable data.

16. **Paul Harrington**, Executive Vice President of the Vermont Medical Society: (1) the consideration and enactment of the Vermont Medical Society Resolution on prescriber-identifiable data; (2) the goals and operations of the Vermont Medical Society; (3) the research and drafting of the findings in the Vermont Act; (4) prescribers' experiences with pharmaceutical sales representatives; and (5) his testimony before the Legislature concerning the Vermont Act.

17. **Madeline Mongan**, Vice President for Policy for the Vermont Medical Society: (1) the consideration and enactment of the Vermont Medical Society Resolution on prescriber-identifiable data; (2) the goals and operations of the Vermont Medical Society; (3) the research and drafting of the findings in the Vermont Act; (4) prescribers' experiences with pharmaceutical sales representatives; and (5) her testimony before the Legislature concerning the Vermont Act.

18. **David Johnson**, an anesthesiologist with Fletcher Allen Health Care, and a former President of the Vermont Medical Society: (1) the consideration and enactment of the Vermont Medical Society Resolution on prescriber-identifiable data; and (2) his and other prescribers' experiences with pharmaceutical sales representatives.

19. **Sharon Treat**: (1) her background and employment at NLARx, including her role and responsibilities as Executive Director; (2) Robin Lunge's employment at NLARx; (3) Sean Flynn's role as counsel to NLARx and Prescription Policy Choices; and (4) the formation of NLARx, including its bylaws, purpose, membership, and locations, and the process by which it determines its goals and priorities.

20. **Sean Flynn**: (1) his testimony before the Vermont Legislature regarding the Vermont Act; (2) his communications with members of the Vermont Legislature or their staff, the Vermont Legislative Council, persons in the Vermont Attorney General's Office, and other third parties regarding the Vermont Act; (3) his knowledge of the pharmaceutical detailing

process, the regulations that apply to that process, and the use of prescriber-identifiable data; (4) the State's interests in enacting the Vermont Act; (5) the operation and effects of the Vermont Act on use of prescriber-identifiable data and pharmaceutical marketing in general; and (6) his contributions to the findings in the Vermont Act, including any research undertaken by him or students under his supervision.

21. **Craig Jones**: (1) the implementation of the Manufacturer Fee; and (2) the operations of the Vermont Blueprint for Health.

VII. PhRMA's EXHIBITS

The parties are negotiating to narrow disputes regarding the admissibility of exhibits. PhRMA's First Amended Exhibit List has been filed with the Court under seal at Docket No. 333.

VIII. STATEMENT OF DAMAGES

PhRMA seeks declaratory and injunctive relief. PhRMA also seeks reasonable attorneys' fees in connection with its challenges to the Vermont Act.

IX. ESTIMATED LENGTH OF TRIAL

The Court has allotted five days for this hearing. As noted above, PhRMA proposes that the Court impose time limits on each party during the hearing to ensure compliance with the five-day schedule.

Respectfully submitted,

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Dated: July 9, 2008

CERTIFICATE OF SERVICE

I, Linda J. Cohen, Esq., certify that on July 9, 2008, 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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A copy of the foregoing has also been served upon the following parties by mailing a copy thereof via U.S. first class, postage prepaid mail, to counsel of record at: None.

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