

IN THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF NEW HAMPSHIRE

IMS HEALTH INCORPORATED, a Delaware)
Corporation, and VERISPAN, LLC, a Delaware)
Limited Liability Company,)
)
Plaintiffs,)
)
V.) CASE NO. 06-CV-280-PB
)
KELLY A. AYOTTE, as Attorney General of)
The State Of New Hampshire,)
)
Defendant.)
_____)

BRIEF OF *AMICUS CURIAE* THE NATIONAL LEGISLATIVE ASSOCIATION ON
PRESCRIPTION DRUG PRICES, THE NEW HAMPSHIRE MEDICAL SOCIETY, AND
PRESCRIPTION POLICY CHOICES IN SUPPORT OF DEFENDANT'S OBJECTION TO
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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STATEMENT OF INTEREST

Amici represent the interests of legislators, doctors and patients in New Hampshire and throughout the nation. *Amici's* primary concern is with providing patients in the United States the best possible care through a socially and economically sustainable health system. The trading of prescriber-identities in prescription records for use in drug marketing to physicians threatens this goal by facilitating highly individualized and coercive promotional environments that override physician autonomy and contribute to rising prescription drug spending. *Amici* support the policy objectives of the New Hampshire Prescription Confidentiality Act, N.H. Rev. Stat. Ann. § 318:47-f, in prohibiting such conduct and have a strong interest in defending its constitutionality.

The National Legislative Association on Prescription Drug Prices (NLARx) is a nonpartisan, nonprofit organization of state legislators from across the country who advocate for lowering prescription drug costs and increasing access to affordable medicines. NLARx acts as a clearinghouse for legislation and information, assists state legislators and other policymakers in developing appropriate prescription drug and related legislation, and works with academics, other policymakers and consumer organizations to support prescription-drug related policy efforts. The New Hampshire Legislature is a member of NLARx and Rep. Cindy Rosenwald, sponsor of HB 1346 which is challenged in this action, has been appointed by the Speaker of the New Hampshire House of Representatives to serve on the NLARx Board of Directors. Bills similar to the New Hampshire statute at issue in this case were sponsored by NLARx members and are currently pending in member states West Virginia, Maine, Arizona and Hawaii.

The New Hampshire Medical Society (NHMS) is the largest physician membership organization in New Hampshire. Since 1791 NHMS has worked to promote the art and science

of medicine for the betterment of public health. The NHMS represents the concerns of all medical specialties and regions across the state as well as patient interests through advocacy, education and commonality. NHMS supported HB 1346 in the New Hampshire Legislature, and its member physicians testified on the impact of identity data mining on physician privacy and prescribing patterns.

Prescription Policy Choices (PPC) is a nonprofit, nonpartisan educational and charitable organization which provides educational and research materials to state legislators, academics, policymakers, and the general public to assist them to reduce prescription drug prices and thereby increase access to affordable prescription drugs in the United States. PPC's primary focus is promoting and preserving innovative and effective policies aimed at reducing the cost of prescription drugs in the United States.

SUMMARY

Plaintiffs in this case, IMS Health Inc. and Verispan, LLC, seek a preliminary injunction to prevent the enforcement of the New Hampshire Prescription Confidentiality Act, N.H. Rev. Stat. Ann. § 318:47-f ("New Hampshire Act" or "Act"). That Act protects consumers and the privacy interests of doctors by banning the increasingly common practice of using doctor-identifying information in prescription records to facilitate targeting of pharmaceutical marketing and gifts toward doctors who prescribe the most expensive drugs for their patients. This practice raises drug costs for all New Hampshire residents and compromises the professional autonomy of doctors.

Plaintiffs ask this Court for the extraordinary relief of enjoining the enforcement of an Act, passed with nearly unanimous support in the New Hampshire Legislature and by the governor, absent any actual application of the Act against an infringing party. This brief

addresses the failure of the plaintiffs to show that they are likely to succeed on the merits of either their First Amendment or Commerce Clause claim.

In regard to the First Amendment, plaintiffs assert a radical and unprecedented argument that heightened, even strict, scrutiny must be applied to every state regulation that has the effect of limiting the sales of information products between private contracting parties. The Supreme Court has never held that the regulation of any information exchanged between contracting parties for commercial purposes is subject to First Amendment scrutiny, rather than the lenient rational-basis Due Process standard that has been applied to social and economic regulation since the downfall of *Lochner v. New York*, 198 U.S. 45 (1905). See *Nebbia v. New York*, 291 U.S. 502, 537 (1934) (“[T]here can be no doubt that upon proper occasion and by appropriate measures the state may regulate a business in any of its aspects.”). Indeed, the most recent Supreme Court case to address a law restricting the use of the content of a record for secondary purposes instructed that such laws are “a regulation of conduct,” not of speech. *Bartnicki v. Vopper*, 532 U.S. 513, 526-27 (2001). The plaintiffs’ argument would revive *Lochner’s* ghost, forcing courts to apply heightened scrutiny to interrogate the means and ends of every regulation of contract, antitrust conspiracy, confidentiality protection, corporate reporting, consumer product safety labeling, and other regulation of business practices that involve exchanges of data or information between private parties. The Supreme Court has admonished against such “reliance on the First Amendment as a basis for reviewing economic regulations.” *Glickman v. Wileman Brothers & Elliot, Inc.*, 521 U.S. 457, 476 (1997); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 591, 589 (1980) (Rehnquist, J., dissenting) (warning against using the commercial speech doctrine “to resurrect the discredited doctrine of cases such as

Lochner” to strike economic regulations “based on the Court’s own notions of the most appropriate means for the State to implement its considered policies”).

Should this Court find that the First Amendment is applicable to New Hampshire’s regulation, then the most lenient standard of First Amendment review should be applied, i.e. that reserved for “speech solely in the individual interest of the speaker and its specific business audience.” *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 762 (1985). Under this deferential standard, the Act must be upheld if it is reasonably tailored to a substantial government interest. The Act undoubtedly meets this standard. It directly and narrowly serves the substantial interests of the state assuring the health and welfare of its citizens and reducing costs that must be borne by the state, by protecting doctors (and thus their patients) from inappropriate individualized targeting. And it does so without burdening the ability of pharmaceutical companies to craft and deliver any message they wish to inform doctors and patients about their products.

Plaintiffs also urge this court to accept an expansive and radical view of the deregulatory reach of the dormant Commerce Clause, claiming that the Clause’s infamous “great silences”¹ may be used as a basis to strike down, on a facial challenge, legislation which unquestionably can be applied to in-state conduct and interpreted to regulate transactions that take place with persons in New Hampshire. Because plaintiffs cannot show that every instance of the Act necessarily regulates commercial activity undertaken wholly outside of the State of New Hampshire, their facial challenge must fail.

¹ *H.P. Hood & Sons, Inc. v. Du Mond*, 336 U.S. 525, 534-535 (1949); *cf. Wardair Canada Inc. v. Florida Dept. of Revenue*, 477 U.S. 1, 17 (1986) (Burger, C. J., concurring in part and concurring in judgment) (referring to “the cloudy waters of this Courts’ dormant Commerce Clause doctrine”).

This brief adopts, and thus does not repeat, the State of New Hampshire’s response to the Plaintiffs’ third argument – that the detailed and well-defined terms of the Act are unconstitutionally vague.

BACKGROUND

Nearly a third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to the increased efficacy of pharmaceutical marketing efforts that shift doctors’ prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments.² In 2004, the industry spent \$27 billion on drug marketing (more than any other sector in the U.S. on its sales force or media advertising),³ over 85 percent of which was targeted at doctors.⁴

Direct marketing of drugs to doctors through sales representatives, called “detailers,” has been a staple of pharmaceutical marketing practices since the mid-nineteenth century.⁵ But the practice of detailing has changed radically over the last decade (paralleling the propulsion of the industry to the position of the most profitable in the world, with the ten largest pharmaceutical companies garnering profits equivalent to the other 490 Fortune 500 companies combined).⁶ Coincident with the rise of physician identity data mining, the pharmaceutical industry increased

² National Institute for Health Care Management (NIHCM), *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs*, 2-3 (revised May 6, 2002).

³ Puneet Manchanda & Elisabeth Hokna, *Pharmaceutical Innovation and Cost: The Effects and Role of Direct-to-Physician Marketing in the Pharmaceutical Industry: An Integrative Review*, 5 *Yale J. of Health Pol’y L. & Ethics* 785, 785 (2005).

⁴ Kaiser Family Foundation, *Trends and Indicators in the Changing Health Care Marketplace*, <http://www.kff.org/insurance/7031/print-sec1.cfm>, exhibit 1.20 (2005).

⁵ Carl Elliott, *The Drug Pushers*, *Atlantic Monthly* (April 2006), available at www.theatlantic.com/doc/print/200604/drug-reps.

⁶ Public Citizen Congress Watch, *Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries* (June 2003).

its spending on direct marketing to doctors by more than 275 percent⁷ and doubled its sales force to over 90,000 drug representatives.⁸ There is now a pharmaceutical sales representative for every five office-based physicians in the United States.⁹

Physician identity data mining began in the late 1980s and became a common component of pharmaceutical marketing tactics by the mid-1990s. The practice began with IMS Health Inc., and other pharmaceutical marketing firms, collecting prescription data from pharmacies and other intermediaries in the prescription processing chain and selling it to pharmaceutical companies in increasingly sophisticated formats. The practice was dramatically facilitated by automation of prescription processing by pharmacy benefit managers and other intermediaries, who were then in a position to sell the information to third parties.¹⁰ The data miners also spend tens of millions of dollars a year leasing the “physician masterfile” from the American Medical Association, which allows matching of physician identities to Drug Enforcement Agency numbers for each physician included on every prescription. This information is compiled into proprietary databases and sold to pharmaceutical companies, who use the databases to provide their sales force with up-to-the minute information on the prescribing behaviors of every doctor in a given sales territory.¹¹

⁷ Kaiser, *Trends and Indicators*, exhibit 1.20.

⁸ Manchanda & Hokna, *Pharmaceutical Innovation and Cost*, 5 Yale J. of Health Pol’y L. & Ethics at 788.

⁹ Center for Policy Alternatives, *Prescription Drug Marketing*, www.stateaction.org/issues.cfm/issue/prescriptiondrugmarketing.xml

¹⁰ See PricewaterhouseCoopers, *HCFA Study of the Pharmaceutical Benefit Management Industry*, HCFA Contract No. 500-97-0399/0097, 5 (June 2001) (describing rapid growth of PBM industry in 1990s).

¹¹ See Leg. Hist. at 94-97 (Liz Kowalczyk, *Drug Companies’ Secret Reports Outrage Doctors*, The Boston Globe, A1 (May 25, 2003)); *id.* at 104-114 (Emily Clayton, *‘Tis Always the Season for Giving: A White Paper on the Practice and Problems of Pharmaceutical Detailing*, CALPIRG (September 2004)); see also Jake Whitney, *Big (Brother) Pharma: How Drug Reps*

Physician identity data mining facilitates coercive pharmaceutical marketing efforts in several key ways. First, armed with data about prescribing habits, the sales representatives focus their resources on high volume prescribers, brand-loyal doctors, “cowboys” who are the first to prescribe new medicines, and doctors who have recently switched away from the brand or otherwise changed their prescribing behavior in a way that makes them look susceptible to a sales call.¹²

Second, they use the information to target and tailor rewards to their best-prescribing “customers,” thus heightening the *quid pro quo* attributes of drug representative gift-giving. While low-value targets receive the routine gifts – small meals, pens, notepads, etc. – the high value targets can receive weekly, even daily, meals for their entire staff, luxury vacations in the guise of educational seminars, and can earn thousands – even hundreds of thousands – of dollars a year as speakers and “consultants” on drug company junkets.¹³

Third, monitoring of prescribing practices also allows the sales representative to assess the impact of various gifts and messages on a particular physician to help them select the most

Know Which Doctors to Target, The New Republic, TNR Online, www.tnr.com/doc.mhtml?i=w060828&s=whitney082906 (August 29, 2006); Elliott, *The Drug Pushers*, *supra*; Robert Steinbrook, *For Sale: Physicians’ Prescribing Data*, 354 *New Eng. J. Med.* 2745 (2006); Stephanie Saul, *Doctors Object to Gathering of Drug Data*, *N.Y. Times* (May 4, 2006), available at <http://www.nytimes.com/2006/05/04/business/04prescribe.html?ex=1304395200&en=bf193ef7c92f2476&ei=5088&partner=rssnyt&emc=rss>; Shannon Brownlee & Jeanne Lenzer, *Spin Doctored: How Drug Companies Keep Tabs on Physicians*, *Slate* (May 31, 2005), available at www.slate.com/id/2119712/

¹² See Saul, *Doctors Object*, *supra* at * 2; Elliott, *The Drug Pushers*, *supra* at *7.

¹³ See Leg. Hist. at 108-109 (Clayton, *’Tis Always the Season for Giving*) (describing “five and even six figure checks” given to doctors to induce prescription writing); Elliott, *The Drug Pushers*, *supra* at *7-8.; Stephanie Saul, *Drug Makers Pay for Lunch as the Pitch*, *N.Y. Times* (July 28, 2006), available at www.nytimes.com/2006/07/28/business/28lunch.html?ex=1311739200&en=704a144090f77cda&ei=5088&partner=rssnyt&emc=rss; Whitney, *Big (Brother) Pharma*, *supra* at *2.

effective set of rewards. A doctor who did not respond to a meal for the staff may next time receive an invitation to a steak dinner or a ball game; the doctor that did not respond to the flirtatious former cheerleader may next time receive a solicitation from a representative with a science background and a briefcase full of studies.¹⁴

Fourth, doctors are informed that they are being monitored – through messages of appreciation for writing prescriptions,¹⁵ or messages of disappointment that they are not prescribing what was implicitly promised.¹⁶ This awareness of being monitored (and the pressure to conform thereby exerted) is internalized by physicians as each prescription is written with knowledge that the action is subject to the watchful eye of the drug representative.¹⁷

The combination of identity data mining and targeted detailing is extremely effective at prompting physicians to alter their prescribing behavior, often in ways that have no or negative therapeutic benefit to the patient while raising drug costs. Numerous studies demonstrate that “[p]hysicians’ use of targeted prescriptions increases substantially after visits with sales

¹⁴ See Elliott, *The Drug Pushers*, *supra* at *7-8; Leg. Hist at 95-96 (Kowalczyk, *Drug Companies’ Secret Reports*).

¹⁵ See Saul, *Doctors Object*, *supra* (reporting that “Dr. Brad Wexler . . . was surprised four years ago when pharmaceutical representatives began thanking him for writing prescriptions – the first time he realized that the drug representatives had information he assumed was private”).

¹⁶ See Elliott, *The Drug Pushers*, *supra* at *7 (reporting that with data mining reports “drug reps could detect deception immediately”); Leg. Hist. at 33 (Testimony of Ms. Finocchiaro, Director of Cholesterol Management Center, Catholic Medical Center) (describing sales representative promise of breakfast for staff every week if she will “write me two prescriptions every week,” which the sales representative checked through mining data and returned complaining that “you didn’t write my two prescriptions”).

¹⁷ Cf. Michel Foucault, *The Eye of Power*, in *Power/Knowledge* (1974) (discussing the exertion of power over individual behavior through a “system of surveillance,” an “inspecting gaze, a gaze which each individual under its weight will end by interiorisation to the point that he is his own overseer”); Tal Z. Zarsky, *Mine your Own Business!: Making the Case for the Implications of the Data Mining of Personal Information in the Forum of Public Opinion*, 5 *Y. J. L. & Tech.* 1, 38-40 (2003) (discussing potential for an “autonomy trap” created by the use of data mining to alter preferences of targeted purchasers).

representatives.”¹⁸ Other studies show that the industry investments of tens of billions of dollars every year on direct marketing of drugs to doctors yield returns of over \$10 for every dollar spent.¹⁹

Sellers of more cost-effective drugs with lower profit margins often have no incentive to undertake the large investment necessary for physician marketing, and therefore the practice of detailing is highly biased in favor of promoting the most expensive products.²⁰ One study showed, for example, that marketing branded calcium channel blockers for high blood pressure treatment instead of the less expensive therapies recommended by national treatment guidelines increased U.S. health expenditures by \$3 billion in 1996 alone.²¹

It is in this context that New Hampshire passed the Prescription Confidentiality Act, which regulates only the conduct of how prescription data is sold and used. The Act requires

¹⁸ Declaration of Avorn and Kesselheim at 6 (citing N Lurie, E.C. Rich, D.E. Simpson, *et. al.*, *Pharmaceutical Representatives in Academic Medical Centers*, 5 J. Gen. Intern. Med. 240-43 (1990). *See also* Declaration of Jerry Avorn, M.D. and Aaron S. Kesselheim, M.D., J.D., pp. 3-5 (discussing studies demonstrating the “powerful effect [of gifts and detailing] on driving drug utilization”); Abigail Caplovitz, *Turning Medicine Into Snake Oil: How Pharmaceutical Marketers Put Patients at Risk*, NJPIRG Law and Policy Center, 5 (2006) (reviewing studies); Manchanda & Hokna, *Pharmaceutical Innovation and Cost*, 5 Yale J. Health Pol’y L. & Ethics at 797-808 (reviewing studies). *See, e.g.* H. Prosser, S. Almond & T. Walley, *Influences on GPs Decisions to Prescribe New Drugs – the Importance of Who Says What*, 20 Family Practice 61 (2003); Dana J, Loewenstein G. *A social science perspective on gifts to physicians from industry*, 290 JAMA 252 (2003).

¹⁹ Elliott, *The Drug Pushers*, *supra* at *1.

²⁰ *See* Declaration of Avorn and Kesselheim at 6 (noting that “[t]here is virtually no economic incentive for the manufacturers of generic drugs to send sales representatives”); Caplovitz, *Turning Medicine Into Snake Oil*, *supra* (discussing incentives and practices of sales representatives misrepresenting therapeutic value and indications for medicines to increase sales).

²¹ Declaration of Avorn & Kesselheim at 7, discussing Cardarelli R, Licciardone JC, Taylor LG, *A cross-sectional evidence-based review of pharmaceutical promotional marketing brochures and their underlying studies: Is what they tell us important and true?* 7 BMC Fam Pract 13 (2006). *Cf.* Leg. Hist. at 14 (testimony that the least and most expensive calcium channel blocker on the New Hampshire Medicaid formulary is \$13.50 vs. \$87.30 per month

that certain persons in custody of prescription records keep individualized patient and prescriber information in the records confidential, so that it cannot be used to facilitate inappropriate targeting for pharmaceutical marketing.

ARGUMENT

“[A] preliminary injunction is an extraordinary remedy that may be granted only by a clear demonstration by a plaintiff of the merits of such a request.” 13 Moore's Fed. Prac. § 65.20, at 65-29 (3d ed.1998) (footnotes omitted). To succeed in their effort to enjoin the enforcement of the New Hampshire Act, plaintiffs must show that: (1) they are likely to succeed on the merits; (2) absent the injunction they will suffer irreparable harm; (3) their injury outweighs any harm the granting of the injunction would inflict upon the State; and (4) the public interest will not be adversely affected by the injunction. *Langlois v. Abington Hous. Auth.*, 207 F.3d 43, 47 (1st Cir. 2000) (citations omitted). This brief focuses on the first prong of the analysis: whether plaintiffs are likely to succeed on the merits of their First Amendment and Commerce Clause Claims.

I. THERE IS NO LIKELIHOOD THAT PLAINTIFFS WILL SUCCEED ON THE MERITS.

In this case, the plaintiffs' burden is especially high because they seek to enjoin the Act on a facial challenge, before it is ever enforced. In part to protect the safeguards inherent in the adversarial system, the facial challenge is “the most difficult challenge to mount successfully, since the challenger must establish that no set of circumstances exists under which the Act would be valid.” *United States v. Salerno*, 481 U.S. 739, 745 (1987).

respectively).

A. *The Act Does Not Regulate Speech Protected by the First Amendment.*

Plaintiffs' attempt to enjoin enforcement of the New Hampshire Act on First Amendment grounds must be rejected because the Act regulates only the commercialization of prescription drug records, not any "speech" protected by the First Amendment.

The First Amendment, as applied to the states through the Fourteenth Amendment, limits the abilities of states to regulate speech, not conduct. "[I]t has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Rumsfeld v. Forum for Academic and Institutional Rights, Inc.*, __ U.S. __, 126 S.Ct. 1297, 1308 (2006) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)).

The New Hampshire Act regulates only certain conduct performed with prescription records by those that come into their possession in the course of their business. Specifically, it states that records containing patient- or prescriber-identifiable data "shall not be licensed, transferred, used, or sold . . . for any commercial purpose" not related to the filling of the prescription or obtaining reimbursement for it. N.H. Rev. Stat. Ann. § 318:47-f. By narrowly restraining the *use* of prescription records, the New Hampshire Act is substantively similar to the aspects of the Electronic Communications Privacy Act of 1986 approved of by the Supreme Court in *Bartnicki v. Vopper*, 532 U.S. 513 (2001).

In *Bartnicki*, the Court struck down a section of the statute that constituted a "naked prohibition against disclosures" of information obtained through a wiretap, but approved of the section of the law that penalized any person who "uses . . . the contents of" a wiretapped communication. 18 U.S.C. § 2511(1)(d). The court recognized cases holding that the use prohibition made it unlawful to "use an illegally intercepted communication . . . to create a competing product," "in trading in securities," "to prepare strategy for contract negotiations," or

“to discipline a subordinate.” *Bartnicki*, 532 U.S. at 527 n.10. These prohibitions did not implicate the First Amendment, the Court explained, because “the prohibition against the ‘use’ of the contents of an illegal intraception” is “a regulation of conduct.” 532 U.S. at 526-27.

Like the section of the Electronic Communications Privacy Act approved of by the court in *Bartnicki*, the New Hampshire Act regulates certain uses of the content of a record and thereby regulates conduct, not speech. The Act is substantially similar to the many “secondary use” regulations that inhibit information provided for one purpose from being used for other purposes, which are “unproblematic from a First Amendment perspective.” Neil M. Richards, *Reconciling Data Privacy and the First Amendment*, 52 UCLA L. Rev. 1149, 1190 (2005).

Federal and state laws contain numerous secondary use regulations that are similar in nature to the New Hampshire Act. For example, federal law: prohibits information furnished to the Census from being “used to the detriment of any respondent,” 13 U.S.C. §8(c); prohibits release of individually identifiable health information, Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936; prohibits disclosures of “personally identifiable information concerning any consumer” of a video rental establishment, Video Privacy Protection Act, 18 U.S.C. §2710-2711, or of a cable operator, Cable Communications Policy Act, 47 U.S.C. §551(c)(1); requires that internet service providers “not knowingly divulge” subscriber information and communications except for certain public purposes, 18 U.S.C.A. §2702; and requires states to limit the disclosure of drivers’ personal identifying information without their consent, Driver’s Privacy Protection Act, 18 U.S.C. §§ 2721-25. *See Reno v. Condon*, 528 U.S. 141 (2000) (upholding Driver’s Privacy Protection Act as valid regulation of commerce). Similarly, states: prohibit divulging, publishing or receiving social security numbers in certain forms, Cal. Civ. Code § 1798.85(a); regulate the use and

disclosure of information “obtained in connection with a motor vehicle record,” Ohio Rev. Code § 4501.27(A); require that a news-gathering organization “shall not use or distribute” accident reports “for a commercial purpose other than the news-gathering organization's publication or broadcasting of the information,” Ky. Rev. Stat. § 189.635, *see Amelkin v. McClure*, 330 F.3d 822, 827 (2003) (holding that § 189.635 “does not restrict or even regulate expression”); and declare that “prescription records, physician orders and other records related to any patient care or medical condition(s) of a patient that are maintained by a pharmacy . . . shall be considered confidential,” 20 Mo. Code of State Regulations 2220-2. Such laws regulate the use of data and other information and thus constitute “a regulation of conduct,” not speech. *Bartnicki*, 532 U.S. at 526-27. This is true without regard to how much more (or less) speech might occur if the uses of the data were not regulated. Otherwise, *Bartnicki* could not have held as it did.

The Act does not restrict corporations from advertising to customers or doctors, or otherwise selecting and transmitting sales messages that would fall within the definition of “commercial speech”. *See Glickman v. Wileman Brothers & Elliot, Inc.*, 521 U.S. 457, 476 (1997) (holding “the standard appropriate for the review of economic regulation,” not the First Amendment, applicable where there is “no restraint on the freedom of any producer to communicate any message to any audience”).²² Under the Act, there is no limit on any prescribing pharmaceutical company’s ability to communicate “vital information about the market” through “accurate information about the availability of goods and services.” *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 495-96 (1996). Unlike the state regulations in any of the Supreme Court cases involving unconstitutional regulations of advertising, the Act does not ban any industry from engaging in commercial advertising, *cf. Cent. Hudson Gas &*

²² *Cf. Dun & Bradstreet*, 472 U.S. at 762 n.8 (“We do not hold [that a credit report is]

Elec. v. Pub. Serv. Comm'n of New York, 447 U.S. 557 (1980) (striking down ban on promotional advertising by electric utilities), does not limit the substance of messages that may be disseminated, *cf. 44 Liquormart, Inc.*, 517 U.S. at 495-96 (striking down ban on advertisement of liquor prices), and does not limit the forums available for commercial advertising, *cf. Metromedia, Inc. v. City of San Diego*, 453 U.S. 490 (1981) (striking down ban on certain outdoor advertising display signs); *City of Cincinnati v. Discovery Network*, 507 U.S. 410 (1993) (striking down ban of commercial handbills on public property); *Edenfield v. Fane*, 507 U.S. 761 (1993) (striking down ban on in-person solicitation by certified public accountants). Rather, the Act simply prevents companies from using prescribing data to target doctors to receive commercial speech.

At bottom, this Court is reviewing one of the “[n]umerous examples” where the regulation of exchanges of information between private firms does not trigger First Amendment scrutiny. *Ohralik v. Ohio State Bar Assn.*, 436 U.S. 447, 456 (1978). *See id.* (noting the lack of First Amendment scrutiny for regulation of “the exchange of information about securities, corporate proxy statements, the exchange of price and production information among competitors, and employers’ threats of retaliation for the labor activities of employees”) (citations omitted).²³ Accordingly, the Act “is a species of economic regulation that should

commercial speech”).

²³ *See also* Frederick Schauer, *Commercial Speech and the Architecture of the First Amendment*, 56 U. Cin. L. Rev. 1181, 1183-84 (1988) (noting “a vast range” of exchanges of information between companies the regulation of which does not implicate the First Amendment, including “communications to offerees, stockholders, and investors now regulated by various state and federal securities laws, including the Securities Act of 1933 and the Securities Exchange Act of 1934; numerous communications among business executives about prices and business practices now regulated by the Sherman Antitrust Act; communications about working conditions and the like now regulated by the National Labor Relations Act; representations about products and services now regulated by the Federal Trade Commission and the Food and Drug Administration; representations about products now regulated by various consumer protection

enjoy the same strong presumption of validity that [the court must] accord to other policy judgments made by [a state].” *Glickman*, 521 U.S. at 477.

The plaintiffs do not argue that the New Hampshire Act lacks a rational basis and do not contend that the law cannot survive the deferential scrutiny reserved for constitutional review of economic regulations. See *FCC v. Beach Communications, Inc.*, 508 U.S. 307, 313-314 (1993); *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483 (1955). Accordingly, they have failed to show that they are likely to succeed on the merits of their substantive challenge to the means and ends of the Act.

B. If the First Amendment Were to Apply, the Act Would Nevertheless be a Valid Regulation of Commercial Speech.

Assuming *arguendo* that the Court finds that the New Hampshire Act is a regulation of speech protected by the First Amendment, the plaintiffs have nonetheless failed to show that the Act is unconstitutional under what would be the applicable (and most lenient) standard of First Amendment review.

The Supreme Court has instructed that commercial speech must be afforded First Amendment protection “commensurate with its position in relation to other constitutionally protected expression.” *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 555 (2001). Thus blanket bans on commercial advertising to the general public, which “not only hinder consumer choice, but also impede debate over central issues of public policy,” *44 Liquormart, Inc.*, 517 U.S. at 503, are subject to more exacting scrutiny and “rarely survive constitutional review.” *Id.* at 504;

laws, by the Uniform Commercial Code, and by the common law of warranty and contract; statements about willingness to enter into a contract now regulated by the common law of contract; and so on and on”) (internal citations omitted); Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA Law. Rev. 1, 20-25 (2000) (listing examples); Frederick Schauer, *The Boundaries of the First Amendment: A Preliminary Exploration of Constitutional Salience*, 117 Harv. L. Rev. 1765, 1777-787 (2004) (same).

see id. at 505, 507 (requiring that the law banning all price advertising by liquor sellers “significantly” advance a substantial state interest and be “no more extensive than necessary”). Where the state restricts one type of advertising to the public, e.g. in-person solicitations, but leaves other channels of communication available, a less strict form of constitutional scrutiny has been applied. *See Edenfield*, 507 U.S. 767 (explaining that ban on in-person solicitation by public accountants “need only be tailored in a reasonable manner to serve a substantial state interest”). Finally, in a related context, the Court has explained that the least demanding form of constitutional protection is warranted for “speech solely in the individual interest of the speaker and its specific business audience.” *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 762 (1985) (holding that credit report delivered to five business subscribers was entitled to “reduced constitutional protection” and could be subject to state defamation damages without showing of actual malice).

The New Hampshire Act does not ban all pharmaceutical advertising, or even one type of such advertising (e.g. in-person solicitations), and therefore, as we argue above, the commercial speech doctrine is inapplicable. If it is applied, it is clear that its most deferential form must be used. Thus, citing *Dun & Bradstreet*, the D.C. Circuit held that “targeted marketing lists” sold to clients by credit reporting agencies “are private speech warranting only qualified constitutional protection.” *Trans Union Corp. v. Fed. Trade Comm’n*, 267 F.3d 1138, 1140-41 (D.C. Cir. 2001). The D.C. Circuit therefore applied a deferential form of intermediate scrutiny to the FTC’s regulation of the sale of the marketing lists, upholding their use despite arguments that it was possible to meet the ends of the legislation in a manner less invasive to the regulated corporations’ interests. *See id.* at 1143 (holding that the First Amendment “does not obligate

courts to invalidate a remedial scheme because some alternative solution is marginally less intrusive”) (internal quotation marks omitted).

The New Hampshire Act was designed to serve two related goals: (1) to protect the privacy interests of patients and doctors in prescription records; and (2) to save the state, consumers and businesses money on prescription drug spending.²⁴ The Act substantially advances each goal without unduly limiting First Amendment protected speech, and thereby survives constitutional scrutiny.

The Act’s relation to the legitimate state interest in controlling drug prices and promoting public health objectives is well canvassed by the *amicus* brief of AARP *et. al.* and *Amici* adopt those arguments in total. In addition, it is important to acknowledge the second objective of the Act implicated by this suit – protecting the privacy interests of doctors and the records they create when they write prescriptions.²⁵ As in *Trans Union Corp.*, this interest is directly advanced by the Act because “the government cannot promote its interest (protection of personal financial data) except by regulating speech because the speech itself (disseminating of financial data) causes the very harm the government seeks to prevent.” 267 F.3d at 1142.

The Supreme Court and lower courts have frequently recognized that governments have a legitimate interest in protecting individuals against particularly invasive and coercive solicitation practices. *See Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 624-25 (1995) (recognizing substantial interest in protecting privacy of personal injury victims by prohibiting solicitation by lawyers); *Mainstream Mktg. Serv., Inc v. Fed. Trade Comm’n*, 358 F.3d 1228, 1238 (10th Cir. 2004) (recognizing substantial government interest in preventing “coercive sales practices”); *Van*

²⁴ *See* Leg. Hist. at 9-11 (statement of Representative Rosenwald).

²⁵ Plaintiffs do not challenge the State’s interests in protecting the privacy interests of patients.

Bergen v. State of Minnesota, 59 F.3d 1541, 1555 (8th Cir.1995) (recognizing substantial interest, motivated by protecting consumer privacy, in limiting use of unsolicited sales calls by auto-dialing/announcing devices); *Lanphere & Urbaniak v. State of Colorado*, 21 F.3d 1508, 1514-15 (10th Cir.1994) (recognizing substantial interest in protecting privacy of persons charged with misdemeanor traffic offenses and DUI).

Plaintiffs do not challenge *patients'* interests in not being targeted for direct-to-consumer advertising based on prescription data monitoring. Rather, they suggest that there is no substantial interest in protecting doctors from targeted advertising. But even if doctors' interests in being free from such targeting were not alone sufficient, with prescription medications doctors act as patients' agents. With medicines, it is the doctors, not the patients, who decide what medicines to prescribe and therefore make the choices about what medicines will be consumed. As Director of Pharmacy Services at New Hampshire Community Hospital explained to the New Hampshire Legislature:

Writing a prescription is unlike any other form of purchase. A physician makes a decision that not only influences, but "prescribes" what his patient needs to purchase. Think of the financial stability that General Motors would experience if one person could decide which cars others must purchase!

Leg. Hist. at 62.

It is because doctors prescribe patients' pharmaceutical consumption choices that doctors are the target of over 85 percent of all marketing expenditures by pharmaceutical companies and are thus most likely to be subjected to harassing solicitations facilitated by commercial trading of prescription data. As with consumers in other contexts, New Hampshire has a substantial interest in protecting the privacy and autonomy interests of doctors in not being subjected to coercive marketing practices based on the release and monitoring of their prescribing behavior.

The New Hampshire Act is narrowly tailored to restrict no more speech than necessary to meet its goals – indeed, it restricts no speech at all. The Act does not regulate the practice of pharmaceutical detailing in New Hampshire, which is undoubtedly commercial speech afforded some measure of protection under the First Amendment. Nor does it prohibit the use or sale of prescription information coded by geographical area or other format that does not divulge the identity of individual prescribers, as is the common practice in Europe, Canada and much of the rest of the world.²⁶ In this way, is it a narrowly tailored to prevent the data from being used to facilitate the most abusive practices in pharmaceutical marketing.

C. Plaintiffs are not Likely to Succeed on their Facial Challenge Based on the Commerce Clause.

Plaintiffs’ attempt to enjoin enforcement of the New Hampshire Act based on the argument that it may be applied to commerce taking place wholly outside of the state must be rejected because they fail to establish “that no set of circumstances exists under which the Act would be valid.” *Salerno*, 481 U.S. at 745.

The plaintiffs’ Commerce Clause argument is based on the Supreme Court’s line of cases holding that the “Commerce Clause . . . precludes the application of a state statute to commerce that takes place wholly outside of the State’s Borders.” *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982). Under this doctrine, the Court struck down an Illinois “blue sky” law that regulated corporate takeovers “which would not affect a single Illinois shareholder,” *id.* at 642, as well as price affirmation statutes (requiring prices in one state to be no higher than in another state) the necessary effect of which was to control product prices outside of the regulating state.

²⁶ See Steve Niles, *No Way to Fill in the Blanks*, 25 *Euromoney Institutional Investor* 1 (May 1, 2006) (noting that “in Europe, Canada, and many other parts of the world” prescription data is available only in a “brick” – “a statistical group put together in such a way that you’re not supposed to be able to work out which doctor is writing what”).

See Healy v. Beer Institute, 491 U.S. 324, 337-38 (1989) (explaining that “the interaction of the Connecticut affirmation statute with the Massachusetts beer-pricing statute . . . has the practical effect of controlling Massachusetts prices”). The Commerce Clause does not, however, ban all state regulation that reaches out-of-state parties doing in-state business. A state law may reach out-of-state conduct where the regulated transactions “wind up within their borders,” *K-S Pharmacies, Inc. v. Am. Home Prod., Corp.*, 962 F.2d 728, 731 (7th Cir. 1992); *see also PhRMA v. Walsh*, 538 U.S. 644, 669 (2003) (rejecting Commerce Clause challenge based on allegation that “Maine’s regulation of the terms of transactions that occur elsewhere”); *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 612 (7th Cir. 1997) (upholding application of state price fixing prohibition to an interstate scheme of manufacturers and wholesalers even though “it is doubtful that any of the price-fixed sales attacked in the suit took place in intrastate rather than interstate commerce”) or otherwise involve an in-state party, *Goldmen & Co., Inc. v. New Jersey Bureau of Securities*, 163 F.3d 780, 787 (3rd Cir. 1998) (“contracts formed between citizens in different states implicate the regulatory interests of both states”).

It is not disputed that sales and transfers of prescriber-identified prescription drug records take place in New Hampshire, “wind up within” New Hampshire, *K-S Pharmacies*, 962 F.2d at 731, or otherwise involve New Hampshire contracting parties, *Goldmen*, 163 F.3d at 787. Accordingly, the Act is clearly constitutional in at least some of its applications and therefore the plaintiffs cannot show they are likely to prevail on a facial Commerce Clause claim.

Plaintiffs cannot succeed on their Commerce Clause challenge based solely on their argument that ambiguous language in the Act could be interpreted to apply to out-of-state conduct. Plaintiffs base their claim in large part on the argument that the ban on certain sales or transfers of “records relative to prescriber identifiable data” is not explicitly restricted to sales or

transfers of records in or from New Hampshire. Plaintiffs' Brief at 59. A similar claim was rejected by the 7th Circuit in *K-S Pharmacies*, 962 F.2d at 730-31. There, the plaintiffs argued that a statute violated the Commerce Clause by banning pharmaceutical prices in Wisconsin higher than those given to its "most favored purchaser," without specifying that the most favored purchaser must also be in Wisconsin. The Court rejected the challenge, explaining that "[i]t is all but certain that the Supreme Court of Wisconsin, if given the chance, would interpret 'most favored purchaser' to mean 'most favored purchaser in Wisconsin'" to "conform the legislation to the limits of state power." *Id.*²⁷ New Hampshire courts can be similarly expected to conform the language of the Act to the limits of its power.

Finally, the degree to which any particular enforcement of the Act may transgress the State's authority under the Commerce Clause is not appropriate to review on a facial challenge. Determining the scope of the in-state nexus in a particular transaction is a highly fact-intensive process that is not appropriate for summary resolution absent an actual enforcement of the Act. *See Country Classic Dairies v. Milk Control Bureau*, 847 F.2d 593 (9th Cir. 1988) (remanding commerce clause claim for trial to develop facts "detailing each step in the interstate commerce"); *Farmland Dairies v. McGuire*, 789 F. Supp. 1243, 1255-57 (S.D.N.Y. 1992) (denying summary judgment on Commerce Clause challenge to New York regulation of milk claimed to be destined for New Jersey); *Mississippi ex. rel. Patterson v. Pure Vac Dairy Prod. Corp.*, 251 Miss. 457, 469 (1964) (applying Mississippi law to out-of-state contract found to be a "fiction of duality" erected to evade Mississippi regulation).

²⁷ *Cf. Taylor v. Rodale, Inc.* 2004 WL 1196145, *2 (E.D. Pa. 2004) (construing Pennsylvania law to avoid extraterritorial application); *cf. EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244, 248 (1991) (expressing "longstanding principle" that federal legislation is interpreted to "apply only within the jurisdiction of the United States").

CONCLUSION

For the foregoing reasons, the Plaintiffs' motion for a preliminary injunction should be denied.

Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that I have on this 15th day of December, 2006, caused the foregoing brief to be served electronically by operation of the Court's electronic filing system.

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