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,	)	**Case No. 06-280-PB**
vs.	)	
KELLY A. AYOTTE, as Attorney General of the State of New Hampshire,	)	
Defendant.	)	

Brief of *Amici Curiae* AARP, AFL-CIO, AFSCME, Center for Medical Consumers, Community Catalyst, National Women's Health Network, and New Hampshire Citizens Alliance in Support of Defendant

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STATEMENTS OF INTEREST

AARP is a nonpartisan, nonprofit membership organization of over 37 million persons, age 50 or older, dedicated to addressing the needs and interests of older persons. Approximately 220,000 AARP members live in New Hampshire. AARP conducts research and engages in educational activities and advocacy to increase access to affordable prescription drugs since older persons who have the highest rate of prescription drug use. *See e.g.* AARP, Rx Watchdog Report, *available at* http://www.aarp.org/issues/rx_watchdog; Families USA, *Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010*, at 2 (July 2000), *available at* http://www.familiesusa.org/assets/pdfs/drugod852b.pdf. Because prescription drug spending has skyrocketed over the last fifteen years, thereby limiting access to medically necessary medicines, AARP advocates for policies that can broaden access to prescription drugs, such as adding prescription drug coverage to the Medicare program (Part D), and for policies that lower the cost of prescriptions for consumers. AARP has worked at the state and national levels to increase access to lower cost generic versions of drugs. AARP supported passage of the law challenged in this case, 2006 N.H. Laws 328, codified as N.H. Rev. Stat. Ann. §§ 318:47-f, 318:47-g, and 318-B:12, IV (2006), in the New Hampshire legislature. AARP has also supported other state efforts to contain pharmaceutical costs and recently filed briefs as *amici curiae* in litigation concerning Pharmacy Benefit Manager (PBM) transparency laws in Maine and the District of Columbia. *Pharmaceutical Care Management Ass'n v. Rowe*, 429 F.3d 294 (1st Cir. 2005), *cert. denied,* 126 S. Ct. 2360 (2006), and *Pharmaceutical Care Management Ass'n v. District of Columbia,* No. 04cv01082 (D. D.C., motion for preliminary injunction granted December 21, 2004), *remanded*, No. 05-7707 (D.C. Cir. January 31, 2005).

The American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) is the largest organization of working people in the United States, consisting of 54 affiliated national and international labor organizations representing 10 million workers. Unions affiliated with the AFL-CIO represent doctors and many other health care professionals and workers. In addition, all of the unions in the AFL-CIO negotiate contracts with employers that provide for healthcare benefits, including coverage of necessary prescription drugs. The skyrocketing cost of such drugs has, in many cases, frustrated labor and management's efforts to reach agreements and presents a mounting obstacle to their common objective of providing quality healthcare to American workers. For these reasons, the AFL-CIO has taken an active role in shaping creative legislative solutions to the problem of high drug costs, such as the New Hampshire law at issue in this case.

American Federation of State, County and Municipal Employees (AFSCME) is a labor organization with its principal office in Washington, D.C. AFSCME represents approximately 1.5 million public and private sector employees throughout the United States. AFSCME represents the interests of its members in bettering the terms and conditions of employment, including the provision of quality health care and prescription drug coverage at an affordable price.

The Center for Medical Consumers, a nonprofit 501(c) 3 advocacy organization, was founded in 1976 to promote informed decision-making. Staff members have written numerous articles about prescription drugs and direct-to-consumer advertising that are available at the Center's Web site www.medicalconsumers.org. Its director Arthur A. Levin recently co-authored an article for Archives of Internal Medicine calling for sweeping reforms of the FDA's process for determining drug safety. He serves as a consumer representative on an FDA Safety and Risk

Management Advisory Committee.

Community Catalyst is a nonprofit, nonpartisan organization that builds consumer and community participation in the shaping of the U.S. health system to ensure quality, affordable health care for all. One of its key initiatives is the Prescription Access Litigation Project (PAL). PAL uses class action litigation and consumer education to challenge illegal drug industry tactics. Its mission is to make prescription drugs more affordable and reform the drug industry. PAL is a coalition of over 125 state, local and national organizations, including senior citizen groups, consumer advocates, health care advocates, legal services offices, women's health groups, non-profit health plans, labor unions and union benefit funds. The members of the PAL coalition have a combined membership of over 14 million. Community Catalyst and PAL have examined the effects of the drug industry's marketing to consumers and doctors of expensive brand-name drugs and are actively engaged in activities that seek to counter those effects while also promoting the use of generic drugs.

New Hampshire Citizen's Alliance (NHCA) is a statewide 501(c)(3) organization working toward social, political, and economic justice for all. Health care is one of NHCA's primary issues, and during the last year it been actively working to remove the provision in the Medicare Modernization Act that prevents Medicare from negotiating prices with the drug companies. NHCA believes strongly in transparency in drug pricing and reducing drug costs, and believes that New Hampshire residents should have access to affordable prescription medications.

The National Women's Health Network is a member-supported, non-profit organization that works to improve the health of all women. The NWHN has a three decade history of monitoring the way drug companies market their products to women, building market share by

promoting unnecessary spending on unneeded prescriptions. The NWHN has identified reining in marketing by drug companies as a critical step in the effort to control health care costs and make it possible to expand access to care. Put simply, NWHN believes this country will have to stop pharmaceutical industry profiteering to make it possible to get comprehensive health care for everyone.

SUMMARY OF ARGUMENT

Amici support New Hampshire's objections to plaintiffs' motion for a preliminary injunction to enjoin enforcement of the Prescription Confidentiality Act ("Act" or "PCA") RSA 318:47-f, 318:47-g, and 318-B:12, and urges the Court to deny the motion since plaintiffs fail to meet the heavy burden of proof needed for such extraordinary relief.

First, plaintiffs fail to meet the first threshold factor courts consider when determining whether to grant a preliminary injunction – they are unlikely to succeed on the merits in this case. Notwithstanding plaintiffs' contentions, the Act does not violate the First Amendment of the U.S. Constitution since it does not affect speech. The Act only restricts the use of prescriber-identified data for commercial purposes, i.e., marketing or advertising to influence the prescribing behavior of individual health care providers.

However, assuming *arguendo* that it does regulate "speech", the PCA does not violate the First Amendment since the law, evaluated under intermediate scrutiny used for content neutral commercial speech analysis, furthers a substantial government interest, and does so directly without affecting more speech than necessary. Moreover, since the Act's restriction does not involve communications to the public at large, the Act has "reduced constitutional protection". Alternatively, the Act fits within the category of content-based statutes analyzed under the same framework more commonly associated with time, place and manner, content-

neutral restrictions on speech because the State's objective is not to cut off speech because of the speech itself.

The State's substantial interest in passing the PCA cannot be overstated. The State enacted the PCA in order to promote consumer protection, and limit pharmaceutical expenditures by consumers, insurers and the State. The legislature enacted the PCA after hearing ample evidence that physicians are more likely to prescribe more expensive medications, i.e., brand name pharmaceuticals, as opposed to less expensive generic versions, when pharmaceutical company sales representatives known as "detailers" make sales pitches armed with the knowledge of the health care provider's individual prescribing records, and that such prescribing practices increased spending for publicly funded health insurance programs. Hence, the public interest will be adversely affected should the Court enjoin the PCA.

ARGUMENT

I. Plaintiffs Are Unlikely to Succeed on the Merits and Therefore Their Motion for a Preliminary Injunction Must Be Denied.

In order to obtain a preliminary injunction to enjoin enforcement of the PCA, plaintiffs must demonstrate that: (1) they are likely to succeed on the merits; (2) they will suffer irreparable harm if the injunction is not granted; (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). Amici's brief supporting New Hampshire's opposition focuses on the first threshold factor, namely that the plaintiffs are not likely to succeed on the merits since the PCA does not violate the First Amendment.

A. The PCA Does Not Violate the First Amendment Because It Regulates Economic Conduct, Not Speech.

The Act regulates behavior that falls outside the scope of the First Amendment. Since the First Amendment's purpose is "to ensure that debate on public issues will be uninhibited, robust, and wide-open," the Act's limited prohibitions leaves this concern untouched and undisturbed. *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 762 (quoting *N.Y. Times v. Sullivan*, 376 U.S. 254, 270 (1964)). The PCA restricts the sale of doctor-identified prescription records when such records will be used to market prescription drugs to doctors and other medical personnel who write prescriptions for pharmaceutical drugs. Though plaintiffs' characterization of the prescription records in this case as "speech" is superficially appealing, a more careful analysis reveals that their argument is without merit since the Act restricts and regulates only economic conduct (i.e. the *use* of such information).

Even if, as plaintiffs' imply, New Hampshire's right to regulate a corporation's sales is restricted to tangible objects (e.g. consumer goods), plaintiffs' position leads to an unreasonable result. That is, in today's modern economy where information and data is increasingly a "manufactured" good for sale, the State's ability to regulate commerce would be intolerably restricted under the First Amendment. For example, the State's ability to regulate how businesses *use* collected personal data or information always would be undermined by the First Amendment. Thus, Plaintiffs attempt to evade permissible state regulatory oversight by inappropriately shielding themselves with the First Amendment, is, quite simply, overreaching. *See Dun & Bradstreet*, 472 U.S. at 759, n.5 (1985) (citing *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978)).

The Supreme Court recognizes a sharp distinction between prohibitions of the disclosure of information (subject to First Amendment review) from prohibitions on the use of information

(which are not subject to First Amendment review). *See Bartnicki v. Vopper,* 532 U.S. 514, 526-27 (2001). Unlike the statute struck down in *Bartnicki* that banned the transfer of information, the PCA allows the transfer of prescription records for a variety of uses other than marketing, so it is not the "naked prohibition against disclosures" contemplated in *Bartnicki*. *Id.* at 526. Also, the Act's prohibition of sales or transfers of prescription records used "for any commercial purpose" is, effectively, a ban on the *use* of such information for commercial purposes, and should therefore be analyzed as such. N.H. Rev. Stat. Ann. § 318:47-f. The Act restricts only the commercial *use* of prescription records, whereas the sale or transfer of prescription records to be used for health care research, patient care management, pharmacy reimbursement, formulary compliance, and a variety of other purposes, are all explicitly permitted. *Id.*

B. Even If the Act Regulates Speech, It Does Not Violate the First Amendment Where the Restricted Data is Content-Neutral, Not of Public Concern and Warrants Reduced Constitutional Protection.

Assuming *arguendo* that the Court determines the PCA falls within the scope of the First Amendment, the Act passes constitutional muster. Almost all commercial speech cases involve statutes that inhibit communication between a company and the public via a prohibition or restriction on advertising. *See, e.g., 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996); *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980); *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618 (1995); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); *Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457 (1997); *El Dia, Inc. v. P.R. Dep't of Consumer Affairs*, 413 F.3d 110 (1st Cir. 2005). In these cases, the Court subjects the challenged statute to a form of intermediate scrutiny because of its recognition that the public is being deprived of information.

The PCA, regulating only a corporation's transfer of its product, a prescription record

database, to another corporation, does not trigger the same level of public concern as the advertising ban cases. Since the Act involves "speech only in the interest of the speaker and its specific business audience", and does not relate to matters of public concern, the Act's prescription data restriction warrants at best reduced constitutional protection. *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc*. 472 U.S. 749, 762 (1985).

In a similar case involving a federal ban on the selling of "target marketing lists," the D.C. Circuit dismissed the industry's First Amendment challenge. *See Trans Union Corp. v. Fed. Trade Comm'n*, 245 F.3d 809 (D.C. Cir. 2001)*, petition for rehearing denied*, 267 F.3d 1138 (D.C. Cir. 2001), *cert denied*, 536 U.S. 915 (2002). The D.C. Circuit found that lists of consumers' credit information (the purported banned speech) was only of interest to the company and its business customers, and that the state's interest in protecting consumer privacy was undoubtedly substantial. As such, the court held that the statute in question merited only "reduced constitutional protection" under *Dun & Bradstreet*. *Trans Union*, 245 F.3d at 818. Likewise, the statute in this case only bans the transmission of data between IMS and *some* of its potential business customers (those who would use it for care management, for example, can still legally purchase it), and the state's interest in protecting its citizens' health is undoubtedly great.

In addition, the Act is a "content-neutral" statute, as the restriction is "*justified* without reference to the content of the regulated speech" but only its commercial purpose. *Renton v. Playtime Theatres, Inc*., 475 U.S. 41, 48 (1986) (emphasis in original). A complete content-based ban on commercial speech is subject to stricter scrutiny than content-neutral regulation of such speech. *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 499 (1996) (holding "the State retains less regulatory authority when its commercial speech restrictions strike at the substance of the information communicated rather than the commercial aspect of [it]-with offerors

communicating offers to offerees.") (internal quotations omitted).

1. Alternatively, the PCA's Restrictions Are Aimed Not at the Content of the Provider Identified Prescription Data, but at the Secondary Effects of Its Use for Targeted Marketing of Prescription Drugs.

The Supreme Court's analysis in *Renton* reveals another appropriate course for this Court to follow should it conclude that the PCA falls within the scope of the First Amendment. *See Renton*, 475 U.S. 41. In *Renton*, the Court upheld a zoning ordinance that disallowed adult movie theaters from locating within 1,000 feet of any residential zone, church, park, school, etc. *Id.* at 44-45. The Court upheld the ordinance because it was "aimed not at the *content* of the films..., but rather at the *secondary effects* of such theaters on the surrounding community." *Id.* at 47 (internal quotations omitted) (emphasis in original). Stated a different way, the city's "*predominate* concerns" were with the secondary effects of the speech, not the contents of the speech itself. *Id.* (emphasis in original). Because the city was principally concerned with the secondary effects of the speech, and not the speech itself, the ordinance at issue in *Renton* is analogous to a content-neutral regulation since both "are *justified* without reference to the content of the regulated speech." *Id.* at 48 (citation omitted) (emphasis in original). Thus, the fundamental principle behind the First Amendment – that "government may not grant the use of a forum to people whose views it finds acceptable, but deny use to those wishing to express less favored or more controversial views" – is left undisturbed. *Id.* at 48-49 (internal quotation omitted).

Similar to the ordinance in *Renton*, the PCA does not involve a total ban of "speech". The Act does not ban the sharing of prescription records; it allows the "data" (i.e. prescription record) to be shared once the doctor-identifying portion has been severed from it. Alternatively, if the doctor-identifying portion is the "speech" in question, it has not been banned for it may

still be sold, licensed or shared for health care research purposes, and several commercial purposes as well (e.g. pharmacy reimbursement, formulary compliance, etc.) N.H. Rev. Stat. Ann. § 318:47-f. Like the ordinance in *Renton*, the PCA can be analyzed under a traditional time, place, or manner analysis which is generally reserved for content-neutral statutes.

In *Renton*, the city was concerned with the problems that are associated with adult movie theaters (i.e. the diminution of surrounding property values, the prevention of crime, etc.). *Id.* at 48. New Hampshire is also not seeking to restrict the data's use because of its content. Most importantly, the sale of doctor-identified prescription records was not restricted because the state or some portion of the population views them unfavorably; the sale was restricted only because of an undesirable secondary effect – sales representatives were using this information to apply *individualized* pressure to doctors to change their prescription practice in a way that needlessly raised expenditures on brand-name drugs. If the state was really concerned with suppressing the speech regulated, the legislature would not have allowed the sale of this information in so many other situations. N.H. Rev. Stat. Ann. § 318:47-f . In this sense, the fundamental concern or principle behind the First Amendment cited above - that the government not favor or provide a forum for some views over others - is left undisturbed and undamaged by the PCA.

Similarly, the justification for the regulation in this case – minimizing needless expenditures on more expensive brand name drugs prescribed as a result of pharmaceutical companies' high pressure, personalized sales "presentations" – has nothing to do with the actual doctor-identified prescription record that is regulated by the PCA.

Plaintiffs' suggestion that the legislature might have been concerned with the direct effect of the prescription records on doctors themselves is nonsensical because doctors are already aware of their prescription records – they wrote the prescriptions! Nonetheless, this is what

plaintiffs' seem to argue. *See* Plaintiffs' Br. at 27 (stating "all conceivable justifications of the statute are based on the primary effect that the speech supposedly has on the listener [the doctor]....") Furthermore, plaintiffs go on to cite a variety of cases that would only be applicable to this case if the "speech" the Legislature sought to regulate was the pharmaceutical companies' sales pitch. *Id.* (e.g., "Listener's reaction to speech is not a content neutral basis for regulation," and citing *Forsyth County v. Nationalist Movement*, 505 U.S. 123, 134 (1992)). The plain words of the statute prevent this from being true, however. This illustrates plaintiffs' misunderstanding and or obfuscation of the difference between what the PCA regulates, i.e. the doctor-identified prescription record, and the purpose and effect of the Act, i.e. to insulate the health care providers from the pressure pharmaceutical sales representatives put on them through their sales pitches. Even if both can be termed "speech," there is no ignoring the glaring differences.

C. Even if the PCA Affects Commercial Speech, It Survives Intermediate Scrutiny Because It Serves a Substantial Governmental Interest and Allows for Reasonable Alternative Avenues of Communication.

A state may restrict commercial speech when it demonstrates 1) a substantial state interest, 2) a direct connection between the state interest and the speech restricted, and 3) that the state's goal could not have been accomplished through a more limited speech regulation. *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980).

One of the state's principal responsibilities is to protect the health and life of its citizens. *See Bill Johnson's Rests., Inc. v. NLRB*, 461 U.S. 731, 742 (1983) (noting "the substantial state interest 'in protecting the health and well-being of its citizens.'") (quoting *Farmer v. United Bhd. of Carpenters and Joiners of Am., Local 25*, 430 U.S. 290, 302-03 (1977); *see also Regents of Univ. of Cal. v. Bakke*, 438 U.S. 265, 310 (1978) (Powell, J.) (illustrating the gravity of this state interest by observing "It may be assumed that in some situations a State's interest in facilitating

the health care of its citizens is sufficiently compelling to support the use of a suspect classification.") The amount of money the state or its citizens can spend on health care is not infinite so every dollar spent on brand-name drugs is a dollar less for primary care, disease prevention, education, medical devices, etc. Each dollar spent, or not spent, on healthcare, in turn, has real effects on the health and quality of life of New Hampshire's citizens. The State, therefore, has an important general interest in keeping the overall amount spent on prescription drugs at a reasonable and affordable level, but most importantly, a substantial and real interest in ensuring that the finite amount of money available to be spent on prescription drugs is spent wisely, and not frittered away on brand-name drugs that are far more expensive than equally appropriate and efficacious generic counterparts.

1. High Prices for Prescription Drugs Have Serious, Harmful Consequences.

High prices for prescription drugs have serious, harmful consequences for millions of consumers. From 2000 to 2003, brand name, retail prescription drug prices increased an average of 6% per year, more than double the average inflation rate of 2.5%. David Gross et al., *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000-2003*, at vi, *available at* http://assets.aarp.org/rgcenter/post-import/2004_06_drugprices.pdf; Heather Won Tesoriero, *Drug Firms Raised Prices 5.5% in First Half of Year*, Wall St. J., Aug. 2, 2005, at D4 (reporting that from January to June of 2005 alone, pharmaceutical companies raised prices of top-selling drugs by 5.53%, more than doubling the pace of inflation during the same period). Updates show that brand name, retail prescription drug prices increased by 7.1% and 6.0% in 2004 and 2005, respectively, well out-pacing the rate of inflation. David Gross et al., *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older*

Americans, 2004 Year-End Update and *2005 Year-End Update*, respectively, at 3, *available at* http://assets.aarp.org/ rgcenter/post-import/dd112_brand_drugs.pdf, and http://assets.aarp.org/rgcenter/health/ dd134_drugprices.pdf, respectively.

The effects on consumers of high prescription drug prices are well understood--consumers forego their medicines when costs become too high. A study of older adults found that eighteen percent of persons with chronic conditions such as heart disease and depression skip some of their prescription medicines because of out-of-pocket cost pressure, and fourteen percent do so at least every month. John D. Piette et al., *Cost Related Medication Underuse Among Chronically Ill Adults: the Treatments People Forego, How Often, and Who is at Risk*, 94 Am. J. Pub. Health 1782 (2004). "The consequences of cost-related medication underuse include increased emergency department visits, psychiatric admissions and nursing home admissions, as well as decreased health status." *Id.* at 1782.

Numerous other studies of Medicare beneficiaries age 65 and older, done prior to passage of amendments to the Medicare Act providing prescription drug coverage, showed the same pattern-people foregoing prescription medications because of cost. *See* Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings From a 2003 National Survey*, Health Aff. (2005), *available at* http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.152v1; Jan Blustein, *Drug Coverage and Drug Purchases By Medicare Beneficiaries with Hypertension*, 19 Health Aff. 219, 228 (2000). In a national survey of Americans aged 50 or older, one in four reported that they did not fill at least one prescription written by their doctor. AARP, *Prescription Drug Use Among Midlife and Older Americans* 6 (January 2005), *available at* http://assets.aarp.org/rgcenter/ health/rx_midlife_plus.pdf; *The NewsHour with Jim Lehrer*, Kaiser Family Foundation, Harvard School of Public Health, *National Survey on Prescription*

Drugs 4 (Sept. 2000), *available at*

http://www.pbs.org/newshour/health/prescriptions/summaryandchartpack.pdf.

The amount of money Americans spend on health care in general and prescription drugs in particular, is enormous, and growing every year. In 2004, almost $2 trillion ($1,877,600,000,000) was spent on health care in the U.S. *See* Centers for Medicare and Medicaid Services, National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1980-2004, tbl2, http://www.cms.hhs.gov/NationalHealth ExpendData/downloads/tables.pdf. Since 1990 domestic spending for prescription drugs has more than quadrupled to $188.5 billion in 2004. *Id.* In that time, prescription drugs grew to command twice the share of total health care expenditures as they did in 1990. *Id.* (growing from 5.62% of total health care expenditures in 1990 to 10.04% in 2004).

The legislative history of HB 1346 shows that New Hampshire legislators were well aware of the linkage between high drugs costs caused in part by the practices they sought to proscribe and strains on the state budget.[1] *See* Rep. Cindy Rosenwald's testimony, Sen. Comm. on Executive Dep'ts and Admin. Hearing on HB 1346 at 11 (observing that the pharmaceutical industry focuses dollars and sales force time to convince prescribers to write more prescriptions for their brand drugs which leads to high prescription drug utilization and a significant burden on the health care system.); Rep. Pamela Price's testimony, Sen. Comm. on Executive Dep'ts and Admin. Hearing on HB 1346 at 14 (comparing drugs in similar therapeutic categories and noting the impact of higher costs drugs to the state Medicaid program); Gregory Moore's testimony,

[1] References to the Legislative History are in accordance with the page designations as submitted by the Plaintiffs.

Sen. Comm. on Executive Dep'ts and Admin. Hearing on HB 1346 at 16 (data mining companies tell pharmaceutical companies to use prescription profiles to target doctors and convince them to switch medications in order to raise the pharmaceutical companies' revenue, and which ultimately drives up the cost of prescription drugs and the cost of health care in the aggregate). *Accord* Dr. Janet Monahan's testimony, Sen. Comm. on Executive Dep'ts and Admin. Hearing on HB 1346 at 35.

There can be no doubt that the State has a substantial interest in ensuring this rapid growth in expenditures on prescription drugs is not further fueled by health care providers who, unconsciously or not, prescribe more expensive prescription drugs because of the pressure put on them by a pharmaceutical sales force equipped with doctor-specific prescription habits and a mandate to increase the sales of their companies drugs.

2. As a Result of the PCA, Providers Are Less Likely to Prescribe Expensive Brand-Name Drugs When Equally Efficacious and Cheaper Generic Drugs Exist.

As the plaintiffs' brief states, "the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose." *Central Hudson Gas. & Elec. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 564 (1980). The government, however, is not limited in the evidence that it may use to meet its burden, and can rely upon anecdotes, history, consensus or simple common sense. *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 628 (1995) (observing that the Court has upheld speech restrictions, even in cases applying strict scrutiny, justified by "history, consensus and simple common sense.") (citation omitted). In addition, the legislative findings should be given deference because the Act so closely resembles a time, place and manner restriction as already shown, *supra*, despite some amici's urging to the contrary. *See* Washington Legal Foundation Br. 16 (adopting an extreme position when it argues "extending

judicial deference to any fact-finding by the New Hampshire legislature is unwarranted....") But even if legislative fact-finding is not given any deference, a plethora of anecdotes and plain common sense, much of which is conveniently located in the legislative history, provide more than enough evidence that the PCA will further the limited state purpose in this case.

3. New Hampshire's Purpose Is Narrow, and Seeks to Eliminate Only the Most Pernicious Form of Pressure Put on Doctors and Nurse-Practitioners.

In passing the PCA, New Hampshire is attempting to prevent pharmaceutical sales representatives from placing undue pressure upon doctors by using practitioner-specific prescription data to persuade them, unconsciously or not, to prescribe a brand-name drug when an equally safe and efficacious, but cheaper, generic drug exists. That is a quite limited purpose. It is important to note a crucial, but reasonable, assumption lies behind the PCA – that a sales representative can be more effective in changing a doctor's prescription practices when the representative makes it known, inconspicuously or not, that the doctor's personal prescription habit is being monitored and judged less than satisfactory, when compared to a situation (which the PCA will bring about) where the sales representative provides information to the doctor regarding prescription drugs, but the doctor or nurse-practitioner knows that their prescription habits are unknown to the pharmaceutical company. This assumption, moreover, is amply supported by evidence contained in the legislative history and wider anecdotal reports.

4. Legislative History, Common Sense, and Anecdotal Evidence All Support the State's Reasonable Belief That the PCA is the Best Way to Accomplish this Limited Goal.

The PCA's legislative history amply demonstrates that the law is an appropriate, reasonable, and effective method of furthering the states' narrow purpose to lower the spiraling costs of prescription drugs. Dr. Seddon Savage explains "So we [i.e. doctors] like to think we're

objective and we always base our decision making on science and on clinical considerations. Numerous studies have shown that in fact our decision making can be and sometimes is shaped by marketing efforts, skilled marketing efforts." Dr. Seddon Savage's testimony, President-elect of N.H. Medical Soc'y, Sen. Comm. on Executive Dep'ts and Admin. Hearing on HB 1346 at 24.

In addition it is well-known that pharmaceutical sales representatives provide doctors and their staff with meals, coffees, free drug samples, and a range of other gifts in addition to providing information about their products. One way a doctor and nurse-practitioner can feel pressured to change their prescribing habits, unconsciously or not, is that the same figures bestowing gifts and information to them are also in the position to withdraw these enticements, even if this threat is most often left unstated. *See, e.g.*, Carolyn Finocciaro's prepared testimony, Assoc. Clinical Dir. of the Cholesterol Mgm't Ctr. at Catholic Medical Ctr., Sen. Comm. on Executive Dep'ts and Admin. Hearing on HB 1346 at 117 ("We feel pressure from her to prescribe her product even though we have never asked her to bring coffee. …, but I feel that since she knows exactly how many prescriptions I write each week for her drug versus the competitors, she is expecting a quid pro quo."). *But see* Carolyn Finocciaro's testimony at 41 (for example of conspicuous linking of gifts to prescriber's compliance with pharmaceutical sales force's wishes, stating "I had one rep come in. She brought coffee and bagels on Tuesday and said, 'I will bring you these things every Tuesday if you write me two prescriptions every week.'... Does she have a right to know that and do I have to deal with that?") The rational pharmaceutical representative would only withdraw these incentives if the doctor's performance is individually monitored, and the PCA makes this impossible.

A New York Times article quotes a district manager's email to pharmaceutical sales

staff:

> Our goal is 50 or more scripts per week for each territory…. If you are not achieving this goal, ask yourself if those doctors that you have such great relationships with are being fair to you. Hold them accountable for all of the time, samples, lunches, dinners, programs and past preceptorships that you have provided or paid for and get the business!! You can do it!

Sen. Comm. on Executive Dep'ts and Admin. Hearing on HB 1346 at 101; *see* Gardiner Harris & Robert Pear, *Drug Maker's Efforts to Compete in Lucrative Insulin Market Are Under Scrutiny*, N.Y. Times, Jan. 28, 2006, at A14. The PCA would halt this practice because the technique is made possible only if the compliance with the desired behavior can be monitored.

But the granting of gifts paired with the implicit threat of their withdrawal is only the most obvious manner in which doctors can be pressured to change their prescription practice to favor more expensive brand-name drugs. The sales representative's informational visit may also include the creation of a period of discomfort when the doctor or nurse is questioned as to why their personal prescription practice remains unchanged, or simply questioned as to why they are not prescribing more of the sales representative's preferred drug. *See* Dr. Marc Sadowsky's testimony, President of N.H. Medical Soc'y, House Comm. on Health, Human Servs. & the Environment Hearing on HB 1346 at 130 (stating "At times I have been asked why I prescribe more of drug A last month instead of the salespersons drug B."); *see also* Carolyn Finocciaro's prepared testimony, Assoc. Clinical Dir. of the Cholesterol Mgm't Ctr. at Catholic Medical Ctr., Sen. Comm. on Executive Dep'ts and Admin. Hearing on HB 1346 at 117 (stating "Recently another drug rep from a different pharmaceutical company said to me. 'Your patients would have better outcomes if you used more Niaspan.'").

While drug sales representative will still be able to say anything they want to doctors about their products, they will be unable to create the type of pressure that is possible only when

the sales representative has access to data showing whether the target is complying with their wish or recommendation. Undoubtedly, pharmaceutical sales representatives will still visit offices, bestow gifts, and seek to persuade a doctor to prescribe the favored brand-name drug in greater quantities. The State, however, is simply seeking to immunize doctors from the most pernicious form of pressure exerted by pharmaceutical sales representatives that is only possible with doctor-specific prescription data.

5. The PCA's Restriction is Narrow and Does Not Impact Any More Speech than Necessary.

Again, assuming the Court finds that the Act is subject to First Amendment scrutiny, the State's goal of lowering the cost of prescription drugs could not have been accomplished through a more limited regulation. *Central Hudson Gas. & Elec. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 564 (1980). *But see Trans Union Corp. v. Fed. Trade Comm'n*, 267 F.3d 1138, 1143 (2001) (holding "a regulation is not invalid simply because a court concludes that the government's interest could be adequately served by some less-speech-restrictive alternative.") (citing *Turner Broad. Sys., Inc. v. Fed. Commc'n Comm'n*, 520 U.S. 180, 218 (1997)). Plaintiffs' argument that the PCA is too broad a restriction fails on three levels. First, plaintiffs allege that the Act prevents a variety of uses of doctor-identified prescription data that are, in fact, *not* prohibited by this statute. *See* Plaintiffs' Br. at 7 (alleging that the PCA would prohibit or prevent "prescription drug recall programs" among other things). Second, plaintiffs mischaracterize the breadth of the existing statute by comparing it to a complete ban on speech. *See* Plaintiffs' Br. at 52-53 (comparing the statute at issue in *Central Hudson*, 447 U.S. 557, which completely banned any promotional advertising by an electric utility, to the PCA.) The PCA is not a complete ban for two reasons. First, it only disallows the sale, transfer, etc., of

doctor-identifiable data when it is to be used for a commercial purpose, as evidenced by the exceptions to the sale ban. N.H. Rev. Stat. Ann. § 318:47-f. Second, this same data can be sold for commercial purposes when sorted by zip code, medical specialty, etc. *Id.*

Finally, plaintiffs misconstrue the purpose behind the Act. Plaintiffs' characterize the State's interest as "ensuring prescribers are prescribing the appropriate medications for their patients". Plaintiffs' Br. at 54. From this erroneous assumption, they point to the availability of a more speech-friendly solution (that the State simply provide "counter" informational presentations to doctors) as evidence that the PCA is too broad a restriction. But as established earlier, New Hampshire's interest, and the goal of the PCA, is to eliminate a particularly effective, if hidden, form of personalized pressure applied to doctors by pharmaceutical sales representatives which can only be applied if the sales force has access to the prescription practice of a particular provider. This law leaves sales representatives unrestricted in speaking to doctors, and in no way diminishes their freedom of speech. This law also allows them to measure, by zipcode or medical specialty, the effectiveness of their sales presentations. But the Act immunizes an individual doctor from the pressure that comes with knowing that the doctor's compliance with sales representative's suggestion is being monitored and examined, perhaps with negative consequences.

Assuming *arguendo* the State was to attempt to counter the pharmaceutical companies overwhelming effort to advertise their brand-name drugs to doctors with personal informational visits of its own, it would be impossible. Pharmaceutical companies employ upwards of 100,000 people in their sales force. *See* "Generic Detailing", Pharma Marketing Blog, March 19, 2006, http://pharmamkting.blogspot.com/2006/03/generic-detailing.html. If those representatives make only 5 visits a day, doctors in the U.S. are visited somewhere in range of 100 million times per

year. Promoting "counter-detailing" as an alternative, therefore, seems unrealistic at best.

CONCLUSION

For the foregoing reasons, Amici urges the Court to uphold the Prescription Confidentiality Act.

Respectfully submitted,

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