

No. 07-1945

In The
United States Court of Appeals
For The First Circuit

**IMS HEALTH, INC., a Delaware Corporation;
VERISPAN, LLC, a Delaware Limited
Liability Company,**

Plaintiffs - Appellees,

v.

**KELLY A. AYOTTE, Attorney General for the
State of New Hampshire,**

Defendant - Appellant.

**ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE
AT CONCORD**

**BRIEF OF *AMICUS CURIAE* COALITION FOR
HEALTHCARE COMMUNICATIONS IN SUPPORT OF
PLAINTIFFS, URGING AFFIRMANCE**

**Bert W. Rein
Andrew M. Miller
Joshua S. Turner
WILEY REIN LLP
1776 K Street NW
Washington, DC 20006
(202) 719-7080**

Counsel for Amicus Curiae

**John Kamp
COALITION FOR HEALTHCARE
COMMUNICATION
405 Lexington Avenue, 18th Floor
New York, New York 10174
(212) 850- 0708**

Counsel for Amicus Curiae

CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 29(c) and 26.1, the Coalition for Healthcare Communications provides the following information concerning corporate affiliations.

The Coalition for Healthcare Communications (“CHC”) is an organization incorporated under the laws of New York that represents trade associations and their members who engage in medical education, publishing, and marketing of prescription products and services, including drugs, devices, and biologics. The CHC defends the right of health professionals and consumers to receive truthful information regarding pharmaceuticals and medical products. The CHC does not have a parent company or any publicly-traded stock.

TABLE OF CONTENTS

	<u>Page</u>
CORPORATE DISCLOSURE STATEMENT	i
TABLE OF AUTHORITIES	iv
STATEMENT OF INTEREST	1
SUMMARY OF ARGUMENT	2
STANDARD OF REVIEW	4
ARGUMENT	5
I. THE NEW LAW RESTRICTS SPEECH PROTECTED BY THE FIRST AMENDMENT	5
II. THE NEW LAW CANNOT SURVIVE SCRUTINY UNDER <i>CENTRAL HUDSON</i>	11
A. The Speech at Issue Is About Lawful Activity and Is Not Misleading	12
B. New Hampshire Has Not Demonstrated a Substantial Government Interest that Justifies the Restriction on Truthful Commercial Speech	13
1. The State Fails To Demonstrate a Substantial Government Interest in Protecting Prescriber and Patient Privacy	14
2. The State Fails To Demonstrate a Substantial Government Interest in Controlling Health Care Costs or Protecting Public Health	15

C. The State Cannot Demonstrate that Its New Law Directly and Materially Advances a Substantial Interest 18

The New Law Does Not Directly or Materially Advance the State’s Purported Interest in Controlling Health Care Costs or Promoting Public Health 19

D. The New Law Also Fails Under the “Narrow Tailoring” Prong of *Central Hudson* 22

CONCLUSION 29

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF FILING AND SERVICE

TABLE OF AUTHORITIES

	<u>Page(s)</u>
 <u>CASES</u>	
<i>44 Liquormart, Inc. v. Rhode Island</i> , 517 U.S. 484 (1996)	<i>passim</i>
<i>AIDS Action Comm. of Mass., Inc. v. Mass. Bay Tranp. Auth.</i> , 42 F.3d 1 (1st Cir. 1994)	4, 5
<i>Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.</i> , 134 F.3d 87 (2d Cir. 1998)	21
<i>Bartnicki v. Vopper</i> , 200 F.3d 109 (3d Cir. 1999), <i>aff'd</i> , 532 U.S. 514 (2001)	6, 7, 8, 27
<i>Bd. of Trs. of the State Univ. of N.Y. v. Fox</i> , 492 U.S. 469	23
<i>Bose Corp. v. Consumers Union of United States, Inc.</i> , 466 U.S. 485 (1984)	5
<i>Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n</i> , 447 U.S. 557 (1980)	<i>passim</i>
<i>City of Cincinnati v. Discovery Network, Inc.</i> , 507 U.S. 410 (1993)	23
<i>Edenfield v. Fane</i> , 507 U.S. 761 (1993)	<i>passim</i>
<i>El Día, Inc. v. Puerto Rico Dep't of Consumer Affairs</i> , 413 F.3d 110 (1st Cir. 2005)	11, 19, 23
<i>Greater New Orleans Broad. Ass'n, Inc. v. United States</i> , 527 U.S. 173 (1999)	3, 9, 14

<i>IMS Health, Inc. v. Ayotte</i> , 490 F. Supp. 2d 169 (D.N.H. 2007)	<i>passim</i>
<i>Linmark Assocs., Inc. v. Township of Willingboro</i> , 431 U.S. 85 (1977)	16
<i>Lorillard Tobacco Co. v. Reilly</i> , 533 U.S. 525 (2001)	3, 10
<i>Meyer v. Grant</i> , 486 U.S. 414 (1988)	16
<i>New Hampshire v. Moran</i> , 861 A.2d 763 (N.H. 2004)	12-13
<i>Pac. Frontier v. Pleasant Grove City</i> , 414 F.3d 1221 (10th Cir. 2005)	10
<i>Project 80's, Inc. v. City of Pocatello</i> , 942 F.2d 635 (9th Cir. 1991)	16, 25
<i>R.I. Ass'n of Realtors, Inc. v. Whitehouse</i> , 51 F. Supp. 2d 107 (D.R.I. 1999)	11
<i>Rubin v. Coors Brewing Co.</i> , 514 U.S. 476 (1995)	18
<i>Shapero v. Ky. Bar Ass'n</i> , 486 U.S. 466 (1988)	16, 24
<i>Speaks v. Kruse</i> , 445 F.3d 396 (5th Cir. 2006)	28
<i>Thompson v. W. States Med. Ctr.</i> , 535 U.S. 357 (2002)	<i>passim</i>
<i>United States v. Playboy Entm't Group, Inc.</i> , 529 U.S. 803 (2000)	25

U.S. West, Inc. v. FCC,
182 F.3d 1224 (10th Cir. 1999) 16, 25

Va. Bd. Of Pharmacy v. Va. Citizens Consumer Council, Inc.,
425 U.S. 748 (1976) 3, 9, 17, 18

Veilleux v. Nat’l Broad. Co.,
206 F.3d 92 (1st Cir. 2000) 5

Verizon Nw., Inc. v. Showalter,
282 F. Supp. 2d 1187 (W.D. Wash. 2003) 21, 25, 26

W. States Med. Ctr. v. Shalala,
238 F.3d 1090 (9th Cir. 2001) 21

CONSTITUTIONAL PROVISION

U.S. CONST. amend. I *passim*

STATUTES

15 U.S.C. §§ 41-58 12

21 U.S.C. § 353a(c) 10

N.H. REV. STAT. ANN. § 318:47-f *passim*

N.H. REV. STAT. ANN. § 318-B:12, IV (2006) 2, 24

OTHER AUTHORITIES

“Are the Benefits of Newer Drugs Worth Their Cost? Evidence from
the 1996 MEPS,” *Health Affairs* 20(5), September/October 2001 2

“Do (More and Better) Drugs Keep People Out of Hospitals?,”
American Economic Review 86, May 1996 2

Legislative History Packet HB 1346 *passim*

STATEMENT OF INTEREST

Amicus the Coalition for Healthcare Communications (“CHC”) comprises trade associations and their members who engage in medical education, publishing, and marketing of prescription products and services, including drugs, devices, and biologics. Trade association members include the American Association of Advertising Agencies, the Association of Medical Publications, the Healthcare Marketing and Communications Council, the Medical Marketing Association, and the Healthcare Businesswomen’s Association. These members make extensive use of prescriber data for a variety of marketing purposes that enable them to increase the effectiveness and efficiency of education and communication programs on behalf of the manufacturers of prescription products. The absence of this data would interfere substantially with the ability of member companies to meet their clients’ needs, educate prescribers, and improve patient care. Moreover, a ban on commercial use of this data raises the costs to other users that would effectively eliminate the availability of the data for the non-commercial research, public policy planning, and safety uses that are supported by commercial marketing and research revenues. Thus, the CHC has a considerable interest in the outcome of this case.

The CHC obtained consent to file this *amicus curiae* brief from both the State and Plaintiffs.

SUMMARY OF ARGUMENT

New Hampshire’s Prescription Restraint Law (or “new law”) prohibits, with important and discriminatory exceptions, the sale or use of prescriber-identifiable prescription data “for any commercial purpose” including “*advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product.*” N.H. Rev. Stat. Ann. §§ 318:47-f, 318-B:12, IV (2006) (emphasis added). The legislative intent behind the new law is ultimately to limit the efficiency and effectiveness of pharmaceutical marketing by innovator, branded companies. However, this intent masks a more critical public interest objective that no government or private sector entity has yet been able to demonstrate – *i.e.*, that a reduction of prescription drug costs will lead to an overall reduction in healthcare expenditures.¹ In its hope to achieve a speculative, fractional saving goal, New Hampshire’s new law strikes speech at its core—by suppressing the tools through which marketers communicate efficiently, rather than an outright ban on speech.

The State candidly acknowledges in its brief that the “new law” is not designed to completely safeguard prescriber privacy. Indeed, prescriber-identifiable data can

¹ In fact, a series of economic studies by Columbia University professor Frank Lichtenberg suggests an opposite effect, that is: for every \$1 increase in newer prescription drug expenditures, there is a corresponding *decrease* of nearly \$4 in overall health costs. “Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS,” *Health Affairs* 20(5), September/October 2001, 241-51; “Do (More and Better) Drugs Keep People Out of Hospitals?” *American Economic Review* 86, May 1996, 384-8.

continue to be sold and used in New Hampshire for all non-commercial purposes, including “public interest” publications that discuss an individual physician’s prescribing practices. The data also can be used for the excepted commercial purpose of “counter-detailing” by insurers who seek, through “formulary compliance,” to affect physician prescribing practices.

The State speculates that the new law might encourage New Hampshire physicians to prescribe older, generic drugs instead of newer, branded drugs and that this substitution might reduce total prescription drug costs. In other words, the State is attempting to regulate the prescribing conduct of its physicians for economic purposes by restraining the speech of politically disfavored commercial entities that provide truthful and non-misleading information to those physicians.

For four decades, the Supreme Court of the United States has repeatedly struck down, on First Amendment grounds, attempts to place restrictions on advertising, marketing, and commercial solicitation.² In doing so, the Court has explained that:

² See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (soliciting of compounded pharmaceutical drugs); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (tobacco and cigar advertisements near schools and playgrounds); *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173 (1999) (legal gambling advertisements); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (alcoholic beverage advertisements); *Edenfield v. Fane*, 507 U.S. 761 (1993) (in-person solicitation by accountants); *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976) (advertising and marketing of pharmaceutical drugs).

The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment.

Thompson v. W. States Med. Ctr., 535 U.S. 357, 367 (2002). New Hampshire's new law violates this fundamental constitutional tenet and thus must suffer a similar fate. By seeking to hobble speakers who wish to effectively introduce truthful communications into the marketplace of ideas, the new law strikes at the very heart of the First Amendment. *Id.* at 366-67 (“[T]he free flow of commercial information is indispensable . . . [and] a particular consumer’s interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day’s most urgent political debate.” (quotation and citation omitted)). Because the new law serves to effectively ban marketing speech, it cannot survive First Amendment scrutiny.

STANDARD OF REVIEW

The First Circuit has long accorded a significant amount of deference to a district court’s factual findings as well as most determinations of mixed law/fact issues, “letting them stand unless they are clearly erroneous.” *AIDS Action Comm. of Mass., Inc. v. Mass. Bay Transp. Auth.*, 42 F.3d 1, 7 (1st Cir. 1994). The Court of

Appeals, meanwhile, reviews *de novo* a district court’s application of a First Amendment standard to the facts in a particular case. *Id.* The Supreme Court has carved out an exception to this general standard of review, directing appellate courts to conduct an “independent review” of the facts where a *restraint* on First Amendment liberties has been *sustained* on a factual record. *Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 510-11, 514 (1984) (applying independent review rule where underlying judgment served to “strip the utterance of First Amendment protection”); *Veilleux v. Nat’l Broad. Co.*, 206 F.3d 92, 107 (1st Cir. 2000) (recognizing it is the duty of reviewing courts to conduct an independent review “to *safeguard* precious First Amendment liberties”) (emphasis added).

In this case, Plaintiffs’ constitutional liberties have been safeguarded by the permanent injunction granted by the district court, thus eliminating the need to apply a heightened scrutiny to the district court’s factual findings.

ARGUMENT

I. THE NEW LAW RESTRICTS SPEECH PROTECTED BY THE FIRST AMENDMENT.

The State argues the new law restricts only the *use* of prescriber-identifiable prescription data as opposed to the actual communication or expression of ideas and thus does not implicate the First Amendment. The State maintains that because Plaintiffs can freely obtain and transfer prescriber-identifiable prescription data as

long is that data is not used for a “commercial purpose,” the new law is strictly a regulation of non-expressive conduct. State Br. at 27-28. The State’s attempt to avoid the strictures of a First Amendment inquiry is unavailing.

In support of its contention that the new law does not abridge freedom of speech under the First Amendment, the State cites *Bartnicki v. Vopper*, 532 U.S. 514 (2001), for the proposition that prohibiting the *use* (as opposed to the disclosure) of information is a regulation of non-speech conduct. State Br. at 28-29. The State’s reliance on *Bartnicki* is distinguishable on several important grounds.

First, the regulation at issue in *Bartnicki* involved the *unlawful* gathering of information and the subsequent regulation prohibiting the further dissemination of that information by the party who illegally obtained it. 532 U.S. at 517-18. The policy underlying the regulation was premised on the desire to protect the privacy of wire, electronic, and oral communications by creating a disincentive for intercepting private communications and by minimizing the harm to persons whose communications were unlawfully intercepted. *Id.* at 529 (“[T]he communications at issue are singled out by virtue of the fact that they were illegally intercepted—by virtue of the source, rather than the subject matter.”). The Court was primarily concerned with restricting the ability of the person who illegally obtained the information from transmitting it further. *Id.* at 533. The Court ultimately concluded that the regulation precluding disclosure was unconstitutional under the First

Amendment when applied to a speaker who was a “stranger” to the underlying illegal conduct. *Id.* at 534-35. In contrast, it is undisputed that the prescriber-identifiable prescription data at issue here is *legally* gathered by Plaintiffs. Unlike the regulation in *Bartnicki*, nothing in the legislative history of the new law seeks to address any unlawful conduct on the part of Plaintiffs who initially gather the data or the pharmaceutical companies who legally obtain that data from Plaintiffs for use in their marketing activities.

Second, the State argues the Supreme Court drew a sharp distinction between regulating the *use* of information and regulating the *disclosure* of information. State Br. at 28. (citing *Bartnicki*, 532 U.S. at 526-27). According to the State, the *use* of information constitutes a regulation of non-speech conduct, not speech. *Id.* The Supreme Court’s holding in *Bartnicki* makes no such distinction. Instead, the Court equated the *transfer* of data to the *disclosure* of data—the prohibition of which was explicitly recognized as a “regulation of pure speech.” *Bartnicki*, 532 U.S. at 526 (“[I]f the acts of ‘disclosing’ and ‘publishing’ information do not constitute speech, it is hard to imagine what does fall within that category, as distinct from the category of expressive conduct.” (quoting *Bartnicki v. Vopper*, 200 F.3d 109, 120 (3d. Cir. 1999))).

The district court likewise determined that “[a] *transfer* of information to a third party is a form of *disclosure*.” *IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 169,

175 (D.N.H. 2007) (emphasis added). And, insofar as the new law provides that prescriber-identifiable prescription data “shall not be licensed, *transferred*, used or sold” for a commercial purpose, N.H. Rev. Stat. Ann. § 318:47-f, the holding in *Bartnicki* expressly validates Plaintiffs’ position that the transfer of prescriber-identifiable prescription data necessarily involves speech subject to First Amendment protection.

Plaintiffs have aptly explained why the new content-based law directly and indirectly restricts fully protected non-commercial speech and is subject to strict scrutiny under the First Amendment. Plaintiffs’ Br. at 47-52. We agree. Nonetheless, even if one were to focus only on the words of the statute, it is clear that, at the very least, the new law restricts commercial speech by banning the use of prescriber-identifiable data to tailor targeted commercial communications.

The new law provides that prescription records containing such data “shall not be licensed, transferred, used, or sold . . . for *any* commercial purpose,” where “commercial purpose” is defined to include, among other things, “*advertising, marketing, promotion*, or any activity that could be used to influence sales or market share of a pharmaceutical product . . . or evaluate the effectiveness of a professional pharmaceutical detailing sales force.” N.H. Rev. Stat. Ann. § 318:47-f (emphasis added). By its terms—“advertising,” “marketing,” and “promotion”—the new law

directly targets commercial speech and bans the use of prescriber-identifiable data to tailor marketing communications.

In any event, the State concedes that the purpose, design, and effect is to hamper targeted marketing to prescribers. State Br. at 25 (“[T]he Act directly advances [the State’s purported interest] by *preventing the use* of prescriber-identifiable prescription data to influence the prescribing behavior of physicians.” (emphasis added)); Legislative History Packet HB 1346 (“Legis. Hist.”) at 3 (Rep. Rosenwald noting that the legislation was necessary because, *inter alia*, “[i]t is a truism in marketing that you spend your money more efficiently by investing in the customers you already have rather than trying to gain new customers. That is why it is so important to drug companies to identify who their biggest volume prescribers are.”). Thus, as the text and legislative history of the new law demonstrate (and the State concedes), the provision is clearly not unrelated to “the speaker’s ability to propose a commercial transaction and the adult listener’s opportunity to obtain information about products”; it is a restriction focused on the content of commercial speech. See *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976) (singling out speech of a particular content (pharmacist price advertising) and explaining that seeking to prevent its dissemination completely cannot be given reduced scrutiny as a time, place, and matter restriction); *Greater New Orleans Broad. Ass’n, Inc. v. United States*, 527 U.S. 173 (1999) (legal

gambling broadcast advertisements); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (alcoholic beverage prices); *Edenfield v. Fane*, 507 U.S. 761 (1993) (in-person solicitation by accountants); *W. States*, 535 U.S. 357 (solicitation of compounded pharmaceutical drugs); *see also Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 565 (2001).

The First Amendment incontrovertibly protects the type of speech expressly targeted by the new law, including the right of pharmaceutical manufacturers to specially tailor direct-mail and in-person solicitations through detailers. *See W. States*, 535 U.S. at 365-66 (holding unconstitutional FDCA amendments requiring prescriptions for compounded drugs to be “unsolicited” and directing pharmacists to “not advertise or promote the compounding of any particular drugs, class of drug, or type of drug” (quoting 21 U.S.C. § 353a(c))); *Edenfield*, 507 U.S. at 765-67 (invalidating state’s attempt to ban personal solicitation of clients by accountants); *Pac. Frontier v. Pleasant Grove City*, 414 F.3d 1221, 1231 (10th Cir. 2005) (noting that “[t]he Supreme Court has recognized that personal solicitation is imbued with important First Amendment interests” and enjoining restriction on door-to-door solicitations (citations omitted)). The fact that the State has attacked the tools

through which marketers communicate efficiently, rather than deny access to its intended audience, does not remove it from constitutional scrutiny.³

II. THE NEW LAW CANNOT SURVIVE SCRUTINY UNDER *CENTRAL HUDSON*.

As explained above, *Amicus Curiae* the CHC supports Plaintiffs' position that the new law restrains fully protected non-commercial speech and should be subject to strict scrutiny. The CHC respectfully submits, however, that even under the constitutional standards applied to restraints on commercial speech as outlined in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), the new law cannot survive.

Under *Central Hudson*, if the regulated speech is not misleading and does not concern unlawful activity, "it can only be limited if the restriction (1) is in support of a substantial government interest, (2) 'directly advances the governmental interest asserted,' and (3) 'is not more extensive than is necessary to serve that interest.'" *El Día, Inc. v. Puerto Rico Dep't of Consumer Affairs*, 413 F.3d 110, 113 (1st Cir. 2005) (quoting *Central Hudson*, 447 U.S. at 566). The State bears the burden on each of these inquiries. *See 44 Liquormart*, 517 U.S. at 505; *Edenfield*, 507 U.S. at 771.

³ Indeed, New Hampshire's law is conceptually no different from denying an unpopular political group access to polling data. *See, e.g., R.I. Ass'n of Realtors, Inc. v. Whitehouse*, 51 F. Supp. 2d 107, 111 (D.R.I. 1999) (acknowledging that "[c]ommercial solicitation is a form of commercial speech protected by the First Amendment" and invalidating prohibition against use of information obtained from public records "to solicit for commercial purposes").

Thus, if the State cannot satisfy each of the three *Central Hudson* prongs, Plaintiffs will succeed on the merits.

A. The Speech at Issue Is About Lawful Activity and Is Not Misleading

Targeted detailing speech, and the other commercial communications that rely on prescriber-identifiable data, advocate a lawful activity—encouraging an authorized person to consider lawfully prescribing certain pharmaceutical products.⁴ Nowhere in the legislative history did the State suggest that such detailing is itself unlawful. Instead, it appears the conduct that may have troubled legislators was the offering of benefits to prescribers to induce them to prescribe drugs that may not be cost-effective for patients. *See, e.g.*, Legis. Hist. at 105 (White Paper, *'Tis Always the Season for Giving*, discussing such gifts in the record). Yet, New Hampshire did not enact a commercial anti-kickback or anti-inducement statute for this purpose; it chose instead to restrict truthful expression.

The General Court did not suggest that the law in any way is focused on false or misleading speech nor did the State assert on appeal that the new law is unlawful or misleading. Even if this were the case, existing law prohibits advertisers from engaging in false or misleading marketing, regardless of what underlying data they use to craft their message. *See, e.g.*, FTC Act, 15 U.S.C. §§ 41-58; *New Hampshire*

⁴ Similarly, the non-detailing and arguably commercial use of prescriber-identifiable data, such as to target market certain continuing medical education courses to physicians, is undoubtedly lawful.

v. Moran, 861 A.2d 763, 765-66 (N.H. 2004) (describing New Hampshire’s Consumer Protection Act and explaining that New Hampshire “look[s] to the Federal Trade Commission Act for guidance” regarding whether “actions are unfair or deceptive”); *see also* N.H. Rev. Stat. Ann. § 318:47-f (incorporating existing law: “[A] violation of this section is an unfair or deceptive act or practice within the meaning of *RSA 358-A:2*”).

In any event, *the very point of targeted marketing is to collect accurate prescriber-level data* in an effort to tailor the most appropriate and relevant communications to the prescriber. Manufacturers and detailers have every interest in being as useful and informative as possible, not misleading. Because the speech subject to the new law is neither false nor misleading, it is clearly subject to the three-part *Central Hudson* review.

B. New Hampshire Has Not Demonstrated a Substantial Government Interest that Justifies the Restriction on Truthful Commercial Speech.

On appeal, the State argues it has a substantial government interest in: (1) protecting the privacy of its citizens, including both physicians and patients; (2) controlling health care costs; and (3) protecting the health and safety of New Hampshire citizens. *See* State Br. at 35-39.

1. The State Fails To Demonstrate a Substantial Government Interest in Protecting Prescriber and Patient Privacy

The State fails to establish that it has a substantial government privacy interest. Importantly, the myriad exceptions permitting disclosure of precisely the same information in other contexts belies the State's assertion that the new law was designed to protect the privacy of its citizens. N.H. Rev. Stat. Ann. § 318:47-f (limiting the restriction to communications "for any commercial purpose" and expressly exempting transmission of records for numerous non-"commercial" purposes); *see also Greater New Orleans*, 527 U.S. at 190 (striking down under *Central Hudson* a statute where "[t]he operation of [the statute] and its attendant regulatory regime is so pierced by exemptions and inconsistencies that the Government cannot hope to exonerate it"). In other words, the new law cannot be justified on the basis that prescriber privacy is at issue unless the sale of prescriber-identifiable prescription data was foreclosed entirely. Clearly, such is not the case here.

In addition, the district court rejected the State's claimed privacy interest on the basis that the asserted interest was "nothing more than a restatement of [the State's] contentions" with regard to containing health care costs and protecting public health. *IMS Health*, 490 F. Supp. 2d at 179. For all of these reasons, the State has not alleged a substantial government interest in prescriber or patient privacy.

2. The State Fails To Demonstrate a Substantial Government Interest in Controlling Health Care Costs or Protecting Public Health

The State also asserts a government interest “in lowering health care costs and limiting unwarranted intrusions into the decision making process of prescribing physicians.” State Br. at 43; *see also id.* at 35. These “unwarranted intrusions” are not harmful because they offend any notion of privacy; they are harmful, by the State’s reasoning, because they are *persuasive*. On this point, the State is explicit: “[P]harmaceutical companies’ use of prescriber-identifiable prescription data for target marketing purposes *influences the prescribing practices of New Hampshire physicians in ways that serve the interests of the pharmaceutical companies and not necessarily the clinical needs of patients.*” *Id.* at 38-39 (emphasis added). It is, the State believes, “[t]his *marketing activity* [that] adds to the financial burden of New Hampshire’s health care system by increasing pharmaceutical costs for the state, consumers, and businesses.” *Id.* at 39 (emphasis added).

More specifically, the motivation behind the new law is its desire to make targeted marketing less effective. *Id.* (“Common sense dictates that pharmaceutical companies would not spend significant amounts of money purchasing prescriber-identifiable prescription data *if that data did not greatly assist them* in selling the high cost branded drugs they market.”) (emphasis added). This desire to remove truthful information from the marketplace of ideas simply because it is persuasive is not a

constitutionally legitimate one, regardless of whether the purpose is to eliminate effective drug “detailing” or to effectuate indirect cost controls. *44 Liquormart*, 517 U.S. at 501; *Meyer v. Grant*, 486 U.S. 414, 424 (1988) (“The First Amendment protects [the speaker’s] right not only to advocate their cause but also to select what they believe to be the most effective means for doing so.”); *Shapero v. Ky. Bar Ass’n*, 486 U.S. 466, 473-74 (1988) (“[T]he First Amendment does not permit a ban on certain speech merely because it is more efficient”); *U.S. West, Inc. v. FCC*, 182 F.3d 1224, 1232 (10th Cir. 1999) (“[A] restriction on speech tailored to a particular audience, ‘targeted speech,’ cannot be cured by the fact that a speaker can speak to a larger indiscriminate audience, ‘broadcast speech.’”); *Project 80’s, Inc. v. City of Pocatello*, 942 F.2d 635, 639 (9th Cir. 1991) (“[O]ptions that involve ‘more cost and less autonomy’ to the seller, that are less likely to reach those persons ‘not deliberately seeking sales information,’ and that may be less effective media for communication the message, ‘are not satisfactory substitutes for speech that is prohibited.’” (quoting *Linmark Assocs., Inc. v. Township of Willingboro*, 431 U.S. 85, 93-94 (1977))).

The Supreme Court has never recognized a valid state interest in restricting commercial speech simply because it is persuasive. To the contrary, the Supreme Court has repeatedly “rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent

members of the public from making bad decisions with the information,” including restrictions in the medical and pharmaceutical realm. *W. States*, 535 U.S. at 374 (discounting fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs because such a position “rests on the questionable assumption that doctors would prescribe unnecessary medications” (citing *Va. Bd. of Pharmacy*, 425 U.S. at 769 (rejecting restriction on pharmacist price advertising supported by purported interests in preventing people from choosing “the low-cost, low-quality service and driv[ing] the ‘professional’ pharmacist out of business” and preventing the destruction of the “pharmacist-customer relationship”))); *see also 44 Liquormart*, 517 U.S. at 503 (“The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”).

It is thus not surprising that the State has failed to cite a single case supporting the notion that a speech restriction can be upheld because the speech at issue was too effective at persuading a consumer—here an educated and licensed medical care provider—to engage in permissible activity. The desire to have consumers, let alone industry professionals, make different market choices among goods and services is not a substantial enough interest to warrant a restriction on First Amendment expression. As the Court explained three decades ago in striking down an advertising

measure in which cost-control was identified as an interest served, the significance of the proffered interest must not be judged in a vacuum but in light of the protections of the First Amendment. *Va. Bd. of Pharmacy*, 425 U.S. at 767-68 (“It is also claimed that . . . [i]f one pharmacist advertises, others must, and the resulting expense will inflate the cost of drugs.”). “This casts the Board’s justifications in a different light, for on close inspection it is seen that the State’s protectiveness of its citizens rests in large measure on the advantages of their being kept in ignorance.” *Id.* at 769. Because the thrust of the State’s interest is that it does not like the market choices consumers—here, licensed prescribers—are making and wants to shield those purchasers from certain information relating to the proposed commercial transaction to alter their market choices, the provision simply cannot stand under the First Amendment. *See id.* at 773 (holding that a state may not “completely suppress the dissemination of concededly truthful information about entirely lawful activity, fearful of that information’s effect upon its disseminators and its recipients”).

C. The State Cannot Demonstrate that Its New Law Directly and Materially Advances a Substantial Interest.

To meet the “direct advancement” requirement, the State must prove “that the challenged regulation advances the government’s interest ‘in a direct and material way.’” *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995). This burden “is not satisfied by mere speculation or conjecture; rather [the State] must demonstrate that

the harms it recites are real *and* that its restriction will in fact alleviate them to a material degree.” *Edenfield*, 507 U.S. at 770-71 (emphasis added); accord *El Día*, 413 F.3d at 115. Restrictions will fail this prong if they “provide[] only ineffective or remote support for the government’s purpose.” *Central Hudson*, 447 U.S. at 564.

The New Law Does Not Directly or Materially Advance the State’s
Purported Interest in Controlling Health Care Costs or Promoting
Public Health

The new law fares no better when analyzed in light of the stated goal of reducing total prescription drug costs in New Hampshire by causing doctors to prescribe, and patients to purchase, less costly generic drugs. New Hampshire clearly portrays its new restriction on speech as a measure that will reduce costs. Legis. Hist. at 126-27 (Rep. Rosenwald, introducer of the bill, explaining that “HB 1346 is about cost containment”). But the pursuit of “cost containment” under the new law is clearly not “direct”; the law does not attempt to regulate which drugs doctors prescribe or which drugs consumers purchase. It does not, therefore, “directly advance” the State’s interest in reducing drug costs. *See W. States*, 535 U.S. at 375-76 (explaining that a statute which does not directly forbid sales of compounded drugs but rather the advertising and soliciting of compounded drugs does not “directly advance” the purported interest). This Court need look no further than the many steps between the State’s end goal and the means chosen to advance that interest to hold that the new law violates the First Amendment.

Moreover, the State has failed to meet its burden to demonstrate any actual, non-speculative connection between the use of prescriber data to engage in targeted marketing and the reduction of prescription drugs costs in New Hampshire. *See Edenfield*, 507 U.S. at 771 (finding the restriction failed the direct advancement prong where the government “presents no studies that suggest personal solicitation of prospective business clients by CPA’s creates the dangers of fraud, overreaching, or compromised independence that the Board claims to fear”); *44 Liquormart*, 517 U.S. 484 (striking down marketing ban on liquor prices where there was no evidence demonstrating that a tenuous chain of events necessary to further the government interest would actually occur). As the district court observed, the State presented no evidence to support its essential propositions that: (1) curtailing targeted marketing will, in fact, change prescriber choices; (2) if so, prescribers will choose more generic drugs, as opposed to different branded drugs; and (3) if so, differences in effectiveness and length of treatment will not outweigh unit cost savings. *IMS Health*, 490 F. Supp. 2d at 180-81.

And, as further noted by the district court, even if the record were to reveal evidence of the new law’s impact on prescribing habits, the State failed to present evidence suggesting that its speech prohibition would significantly reduce marketwide purchases of non-generic drugs or that increased use of generic drugs will actually reduce total costs. *Id.*; *see also 44 Liquormart*, 517 U.S. at 506 (holding that

speculation and a record absent of evidence confirming significant marketwide reduction in the consumption of alcohol “does not suffice when the State takes aim at accurate commercial information for paternalistic ends”). Nor could it in light of the numerous other ways in which pharmaceutical manufacturers can continue to market prescription drugs to licensed healthcare professionals. *See, e.g.,* N.H. Rev. Stat. Ann. § 318:47-f (“Nothing in this section shall prohibit the collection, use, transfer, or sale of patient and prescriber de-identified data by zip code, geographic region, or medical specialty for commercial purposes.”). That is, a restriction on speech will also fail the direct advancement prong where it is underinclusive—such that it does not materially advance the government’s stated aim. *Verizon Nw.*, 282 F. Supp. 2d at 1193 (striking down speech restriction on use of customer information to market to that customer where it was “riddled with exceptions”); *see also W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1095 (9th Cir. 2001) (holding that restrictions were “so riddled with exceptions that it is unlikely that the speech restrictions would actually succeed in . . . directly advanc[ing] the government’s interest”); *see also Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 100 (2d Cir. 1998) (government “must demonstrate that its commercial speech limitation is part of a substantial effort to advance a valid state interest, not merely the removal of a few grains of offensive sand from a beach”).

The district court also found that “[n]on-bioequivalent generic drugs are not always as effective as brand-name alternatives” and that even assuming non-biogenetic drugs work as well or better than brand-name alternatives, there are nevertheless patients who will benefit by taking the brand-name medication. *IMS Health*, 490 F. Supp. 2d at 180 (stating that it is “counterintuitive” to suppose that the public health is necessarily undermined simply where detailing for brand-name drugs proves effective and explaining that to conclude otherwise would be to adopt the “unproven proposition” that brand name drugs “are more injurious to the public health than generic alternatives”). The district court also recognized that the new law would affect *both* helpful and harmful brand-name prescribing practices and, without any evidence to the contrary, the State failed to “prove that any reductions in health care costs that may result from a ban on the use of prescriber-identifiable data can be achieved without compromising patient care.” *Id.* at 181.

For each of these reasons, the new law cannot survive the direct advancement prong of *Central Hudson*.

D. The New Law Also Fails Under the “Narrow Tailoring” Prong of *Central Hudson*.

The final step of the *Central Hudson* analysis, the “critical inquiry in this case,” requires a reasonable fit between the means and ends of the regulatory scheme. 447 U.S. at 569. In the commercial speech context, “the First Amendment mandates that

speech restrictions be narrowly drawn.” *El Día*, 413 F.3d at 117 (quoting *Central Hudson*, 447 U.S. at 565). Accordingly, the restriction must signify a “careful calculat[ion of] the costs and benefits associated with the burden on speech imposed by its prohibition.” *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 (1993). And as the Supreme Court has recently reiterated, “[i]f the First Amendment means anything, it means that regulating speech must be a last—not first—resort.” *W. States*, 535 U.S. at 373. The new law, deemed a “sweeping ban” by the district court, *IMS Health*, 490 F. Supp. 2d at 182, fails this final prong of the *Central Hudson* inquiry.

It is clear that the General Court’s first step was to restrict truthful commercial speech. *See* Legis. Hist. at 26 (Dr. Savage expressing this sentiment by saying “I think it is generally better to start from the position of *more restrictive access to information* and to really specify what can be released rather than to work backwards as we are doing now” (emphasis added)). To the extent the interest the General Court sought to advance was legitimate and substantial—a proposition with which *amicus curiae* the CHC strongly disagrees—it had an obligation to explore and consider alternative means that would restrict substantially less speech than does the restriction it adopted. *See Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 479 (“[A]lmost all of the restrictions disallowed under *Central Hudson*’s fourth prong

have been substantially excessive, disregarding ‘far less restrictive and more precise means.’” (quoting *Shapero*, 486 U.S. at 476)). It did not do so.

First, the General Court failed to acknowledge the clearly less speech restrictive alternative of refraining from speech regulation and relying on the market and the marketplace of ideas to insure that doctors receive sufficient information to support their prescribing decisions. For example, any party that has an interest in the prescribing habits of New Hampshire doctors may seek to educate and inform the doctors (and their patients) about what they perceive to be the best prescribing behavior. This marketplace of ideas includes entities that seek to influence prescribing habits for reasons that are non-commercial, as well as commercial enterprises other than pharmaceutical manufacturers, such as insurance companies and HMOs that seek to influence prescribing habits for their own bottom line. Indeed, the new law recognizes that these forms of counter-speech exist; the express exemption for “formulary compliance” communications protects insurance companies’ right to communicate with physicians about their prescribing habits that affect insurance company costs and revenues. *See* N.H. Rev. Stat. Ann. § 318-B:12, IV.

Doctors are able to turn away commercial (or non-commercial) speech that they choose not to receive.⁵ Courts have consistently held that requiring prospective recipients of speech to take some affirmative action to request communications before they can receive speech violates the First Amendment. *See, e.g., Project 80's*, 942 F.2d at 639 (“The government’s imposition of affirmative obligations on the residents’ first amendment rights to receive speech is not permissible.”); *U.S. West*, 182 F.3d 1224 (striking down federal “opt-in” scheme that required a customer to affirmatively approve the carrier’s use of his or her information in target marketing to that customer); *Verizon Nw.*, 282 F. Supp. 2d at 1187 (same for state “opt-in” scheme); *see also United States v. Playboy Entm’t Group, Inc.*, 529 U.S. 803, 813 (2000) (“Where the designated benefit of a content-based speech restriction is to shield the sensibilities of listeners, the general rule is that the right of expression prevails, even where no less restrictive alternative exists.”).

This is particularly true where the market is already taking steps to address the perceived harm the State seeks to alleviate. For instance, the General Court was informed that the American Medical Association (“AMA”) has instituted a new “opt-

⁵ The legislative record included no suggestion that physicians are unable to reject office visits by detailers, or other forms of targeted commercial communications. Dr. Sadowsky, who spoke in support of the new law, did suggest that he feels an obligation to speak to sales persons because he has a desire to receive free samples from pharmaceutical companies that he can distribute to his patients. Legis. Hist. at 26-27. Not even the State suggests that the desire to receive free goods from a speaker, however, constitutes some form of compulsion that could justify restricting speech.

out” program whereby participating prescribers may choose to exclude their data from the pool of information that can be reviewed by detailers. Although it is not at all clear that such a program, if it were enacted by the government, would itself pass constitutional muster, it is relevant in its private form as an additional means of furthering the State’s alleged interest. *See also* Legis. Hist. at 24 (Dr. Savage identifying various guidelines and policies established by the Accreditation Council for Continuing Medical Association and “[m]ost hospitals, most clinics, and many individual providers” to address what he called the “risk of influence”). *Second*, to the extent the State believes there is some dysfunction in the marketplace of ideas that requires government intervention, the answer under the First Amendment is to encourage *more* speech, not less. Thus, New Hampshire could engage in its own campaign to educate prescribers about the specific drugs at issue or about what it believes to be shrewd marketing tactics more generally.⁶ *See, e.g., Verizon Nw.*, 282 F. Supp. 2d at 1194 (“This court finds that there are other means available [other than an opt-in regime] to achieve the same purpose that impact less speech. For instance the state could more stringently regulate the form and content of opt-out notices and

⁶ To the extent such a campaign would be costly, the State may as matter of policy determine that its interest in cost containment does not warrant the expense of an education campaign. The First Amendment for its part, however, forbids the State from adopting a restriction on speech merely because it may be a less costly means of achieving the State’s goal. *See W. States*, 535 U.S. at 373 (“Nowhere . . . is there any explanation of why the Government believed forbidding advertising was a necessary as opposed to merely convenient means of achieving its interests.”).

combine those regulations with educational campaigns to inform consumers of their rights.”); *see also 44 Liquormart*, 517 U.S. at 503; *W. States*, 535 U.S. at 375. As specifically detailed by Plaintiffs and recognized by the district court, the State has numerous options at its disposal whereby it may achieve its stated purpose while not offending First Amendment principles. *See* Plaintiffs’ Br. at 44-47 (noting that the state health department could be required to disclose to prescribers the availability of generic drugs, provide funding for programs designed to inform prescribers of the appropriate guidelines related to the prescribing of branded and generic drugs, or provide funding for continuing education programs for prescribers concerning generic drugs); *IMS Health*, 490 F. Supp. 2d at 182-83 (explaining the “number of ways in which the State can address the concerns that underlie the [new law] without restricting protected speech”).

Finally, to the extent that New Hampshire is concerned with deceptive trade practices, the most appropriate and effective way to eradicate such practices is to target them directly by penalizing or prosecuting those who engage in such practices. It is not appropriate under the First Amendment to attempt a prophylactic prohibition on certain truthful commercial communications. *See, e.g., Bartnicki*, 532 U.S. at 529-30; *W. States*, 535 U.S. at 371-73 (striking down a commercial speech restriction because the government could not demonstrate that it “was a necessary as opposed to merely convenient means of achieving its interests” in light of the numerous more

direct methods of attacking the bad behavior at issue); *Speaks v. Kruse*, 445 F.3d 396, 396 (5th Cir. 2006) (striking down prohibition against solicitation of potential medical patients who “are vulnerable to undue influence” because several alternatives would have been less speech restrictive, including prohibiting false or misleading advertising during a telephone call). Indeed, the legislative record demonstrates just a few such measures. *See, e.g.*, Legis. Hist. at 99 (noting *New York Times* article stating that “prosecutors are now investigating possible criminal violations” regarding payments made to encourage pharmacists to make certain drug switches); *id.* (“[F]ederal anti-kickback statutes prohibit [drug companies] from offering financial incentives to doctors or pharmacists to encourage or reward the prescribing of particular drugs, according to a 2003 guidance from [HHS].”).

What the State cannot do, particularly in light of all of these less speech restrict alternatives, is effectively ban certain forms of commercial speech and commercial messages based on prescriber-identifiable data. The Supreme Court’s decision in *Western States*, a case which the State systematically ignores in its brief, is particularly apt here. 535 U.S. 357. In *Western States*, the government’s stated interest was curtailing large-scale drug “compounding” at the pharmacy level that could circumvent the government’s restrictions on drug “manufacturing.” *Id.* at 365-66. Rather than simply enacting additional restrictions on drug compounding itself, Congress chose instead to try to decrease demand for, and utilization of, compounded

drugs by decreasing the effectiveness of commercial speech about drug compounding. *Id.* at 364-65. Specifically, the statute prohibited advertising by pharmacists who engaged in compounding of the availability of specific compounded drugs but permitted pharmacists to continue to advertise their compounding services generally. *Id.* The Supreme Court struck down this restriction on speech as not narrowly tailored, observing that “regulating speech” “seems to have been the first strategy the Government thought to try.” *Id.* at 373. If the government’s interest was in restricting certain drug compounding, the Court explained, the proper path was to adopt one or more regulations that targeted or restricted drug compounding directly. *Id.* at 372-73. What the government could not do was use the indirect means of restricting effective advertising to reduce demand or alter the underlying behavior of pharmacists. This is precisely what New Hampshire has sought to do here, and the new law fails under the last prong of *Central Hudson* for the same reason.

CONCLUSION

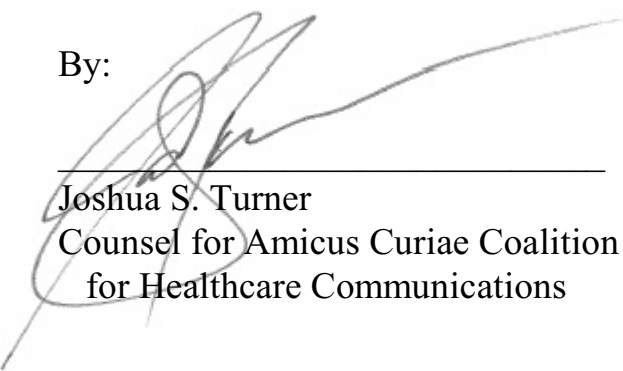
For all of the reasons herein, New Hampshire’s ban on using prescriber-identifiable data to tailor targeted commercial speech cannot survive First Amendment scrutiny under *Central Hudson*. *Amicus Curiae* the CHC respectfully requests that this Court affirm the judgment of the district court permanently enjoining the State from enforcing this new law.

Of Counsel:

Bert W. Rein, Esq.
Andrew M. Miller, Esq.
Joshua S. Turner, Esq.
First Circuit Bar No. 104265
Wiley Rein LLP
1776 K Street NW
Washington, DC 20006
TEL: 202.719.7080
brein@wileyrein.com

Respectfully submitted,

By:



Joshua S. Turner
Counsel for Amicus Curiae Coalition
for Healthcare Communications

John Kamp
Executive Director
Coalition for Healthcare Communication
405 Lexington Ave., 18th Floor
New York, NY 10174
212-850-0708
jkamp@cohealthcom.org

CERTIFICATE OF COMPLIANCE

This Brief of *Amicus Curiae* has been prepared using:

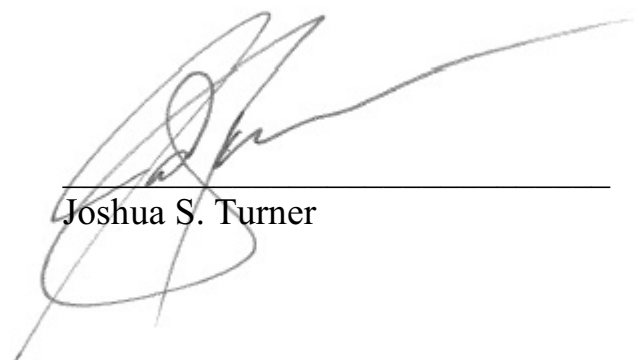
Corel Word Perfect;

Times New Roman;

14 Point Type Space.

EXCLUSIVE of the parts of the Brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), this Brief contains 6,917 words.

I understand that a material misrepresentation can result in the Court's striking the brief and imposing sanctions. If the Court so directs, I will provide an electronic version of the Brief and/or a copy of the word or line print-out.



Joshua S. Turner

CERTIFICATE OF FILING AND SERVICE

I hereby certify that on this 18th day of October, 2007, I filed with the Clerk's Office of the United States Court of Appeals for the First Circuit, via UPS Next Day Air Transportation, the required number of copies of this Brief of *Amicus Curiae*, and further certify that I served, via UPS Next Day Air Transportation, the required number of said Brief (in both paper and electronic format) to the following:

Richard W. Head
Laura E.B. Lombardi
OFFICE OF THE ATTORNEY GENERAL
33 Capitol Street
Concord, New Hampshire 03301

Counsel for Appellant

Mark S. Rotenberg
EPIC
1718 Connecticut Avenue, NW
Suite 200
Washington, DC 20009

Counsel for Appellant

James P. Bassett
ORR & RENO, P.A.
1 Eagle Square
Post Office Box 3550
Concord, New Hampshire 03302

Counsel for Appellees


Sean Fiil-Flynn
WASHINGTON COLLEGE OF LAW
AMERICAN UNIVERSITY
4801 Massachusetts Avenue, NW
Washington, DC 20016

Counsel for Appellant

Patricia Acosta
Thomas R. Julin
Michelle R. Milberg
HUNTON & WILLIAMS
1111 Brickhill Avenue, Suite 2500
Miami, Florida 33131

Counsel for Appellees

The necessary filing and service were performed in accordance with the instructions given me by counsel in this case.



The LEX Group^{VA}
1108 East Main Street, Suite 1400
Richmond, Virginia 23219