# 09-1913-cv(L), 09-2056-cv(CON)

# United States Court of Appeals

*for the*

# Second Circuit

IMS HEALTH INCORPORATED, VERISPAN, LLC, SOURCE HEALTHCARE ANALYTICS, INC., a subsidiary of Wolters Kluwer Health, Inc., and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

*Plaintiffs-Appellants,*

– v. –

WILLIAM H. SORRELL, as Attorney General of the State of Vermont, JIM DOUGLAS, in his official capacity as Governor of the State of Vermont, and ROBERT HOFMANN, in his capacity as Secretary of the Agency of Human Services of the State of Vermont,

*Defendants-Appellees.*

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

## BRIEF FOR *AMICI CURIAE* ASSOCIATION OF NATIONAL ADVERTISERS, CATO INSTITUTE, COALITION FOR HEALTHCARE COMMUNICATION, PACIFIC LEGAL FOUNDATION AND THE PROGRESS & FREEDOM FOUNDATION IN SUPPORT OF APPELLANTS

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# CORPORATE DISCLOSURE STATEMENTS

**Amicus Curiae Association of National Advertisers, Inc.** is incorporated as a nonprofit trade association, has no parent corporation, and has no stock or other interest owned by a publicly held company.

**Amicus Curiae Coalition for Healthcare Communication** is incorporated as a nonprofit trade association, has no parent corporation, and has no stock or other interest owned by a publicly held company.

**Amicus Curiae Cato Institute** is a nonprofit public policy research foundation, has no parent corporation, and has no stock or other interest owned by a publicly held company.

**Amicus Curiae Pacific Legal Foundation**, a nonprofit corporation organized under the laws of California, hereby states that it has no parent companies, subsidiaries, or affiliates that have issued shares to the public.

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## PRELIMINARY STATEMENT

The Vermont Prescription Restraint Law, and the similar laws enacted in New Hampshire and Maine, impose unprecedented paternalistic censorship on a broad swath of socially-important information. The speech these statutes suppresses is both truthful and of public concern. It is not invasive of privacy or within any other category of speech previously recognized as outside the protective umbrella of the First Amendment.

Vermont has nonetheless sought to constrain exchange of this valuable information because its Legislature hypothesized that, of its many legitimate uses, one ("detailing") induces doctors to alter their prescribing practices in a fashion that, it surmised, may impose additional costs on the State's budget. In fact, there appears to be little or no evidence supporting such hypothesis and surmise, and indeed there is other evidence in the record suggesting that health care costs could actually increase in the absence of comprehensive data on prescription practices.

More fundamentally, these amici, representing a range of businesses, healthcare organizations, policy analysts and others, are concerned that Vermont, in its haste to enact reforms without first studying their likely economic impact, has elected speech suppression as an expedient tool, in an area already fraught with political, economic and medical controversy, where more rather than less speech and debate is urgently needed.

There is another fundamental problem with the Vermont statute. The law purports to be narrowly targeted to only the use of prescriber-identifiable ("PI") data for marketing and promotion of pharmaceutical products in doctors' offices. In operation, however, its methodology intrudes into *all* aspects and *every* stage of PI data gathering, dissemination and use, reaching back to constrain the initial provision of raw data, and forward into the process of publication, dissemination and utilization of the data. The law thus sweeps up a broad range of non-commercial speech indisputably subject to protection under the First Amendment.

As a result, the statute's impact cannot be limited merely to PI data as it is used in "detailing," but it will adversely impact a broad range of speakers and listeners, including those represented by these amici. It will also undermine if not destroy the value of the prescription data, which has many other important uses in significant areas of scientific research, drug development and medical policy analysis. The data is only most useful if comprehensive. Yet, if upheld, the Vermont law will also eliminate a key part of the market, and thus the economic incentive to comprehensively gather the data in the first place.

But even beyond its adverse impact on the seemingly narrow subject of PI prescription data, the Vermont law and the other similar statutes are premised on an insupportable – indeed pernicious – theory that has broad and troubling

implications for the scope of permissible state regulation of information and the limits of free speech.

These statutes are premised on the dangerous notion that "data mining" – because it is a profitable, commercially-oriented form of information gathering and publication, and because it is heavily reliant on seemingly mechanical computer operations, rather than the toil of classical reporters and editors – is unlike other traditional journalistic activities that are subject to full First Amendment protection. The First Circuit went so far as to hold that gathering and publishing such data is actually conduct, not speech, and that the data is merely a "commodity," like "beef jerky," entirely unprotected by the First Amendment. This is an insupportable view that this Court must surely reject.

The Court below did not go that far, but it did broadly hold, following the First Circuit's alternative analysis, that data mining is "commercial speech," and therefore that it can be subjected to lesser First Amendment protection, notwithstanding that the operations of the plaintiff publishers cannot be meaningfully distinguished from those of any other traditional publisher. In so doing, the District Court also ignored this Court's narrower definition of what can be deemed commercial speech. And in assessing whether the Vermont law could pass constitutional muster, the Court below misapplied key elements of the Supreme Court's commercial speech doctrine, broadening its reach and limiting its

protective capacity at a time when many Supreme Court Justices have been questioning the fundamental wisdom of lesser protection for commercial speech altogether.

In sum, far from an innocuous or limited experiment that the State should be given latitude to pursue, the Vermont statute, properly understood, poses a serious danger to a wide array of important First Amendment interests and activities. The recrudescence of such outmoded and discredited paternalism by the State of Vermont, at the expense of broad freedom of expression in the marketplace of ideas and information, is precisely the wrong way to go in our 21st-century information age that is heavily and appropriately reliant on vast and useful bodies of computer-generated data.

This Court, centered in the home of the publishing and information industries, and long a thoughtful defender of First Amendment rights, should reject this dangerous narrowing of protection for free expression.

## INTERESTS OF THE AMICI

The Amici and their members are among those whose First Amendment interests have been adversely impacted by the Vermont law and whose speech will continue to be unjustifiably abridged if the law is upheld and if this Court accepts the reasoning of the Court below or of the First Circuit.

**Association of National Advertisers** includes over 350 companies with 9,000 brands that collectively spend over $200 billion in marketing communications and advertising annually in the United States. The ANA strives to communicate marketing best practices, to influence industry practices, and to advance, promote and protect advertisers and marketers. The ANA also serves its members by advocating clear and coherent legal standards governing advertising, including the "commercial speech" doctrine.

**Cato Institute** was established in 1977 as a nonpartisan public policy research foundation dedicated to advancing the principles of individual liberty, free markets, and limited government. Toward those ends, Cato's Center for Constitutional Studies publishes books, studies, and the annual *Cato Supreme Court Review*, and files amicus briefs. This case is of central concern to Cato because it addresses the collapse of constitutional protections for commercial speech and the attempt by government to impede the free flow of information.

**Coalition for Healthcare Communication** 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, including the American Association of Advertising Agencies and the Association of Medical Media, make extensive use of prescriber-identifiable data. The suppression of these 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 use of these data will effectively eliminate their availability for the non-commercial research, public policy planning, and safety uses in which CHC members participate.

**Pacific Legal Foundation** was founded more than 35 years ago and is widely recognized as the largest and most experienced nonprofit legal foundation of its kind. PLF litigates matters affecting the public interest at all levels of state and federal courts and represents the views of thousands of supporters nationwide, including in Vermont. The Foundation seeks to protect the free enterprise system from abusive regulation, including unconstitutional regulation of commercial speech. To that end, PLF has participated in several leading cases before the Supreme Court and other Courts on matters affecting the First Amendment and commercial speech.

**The Progress & Freedom Foundation** is a non-profit, non-partisan research and educational institution. Founded in 1993, PFF's principal mission is to study the impact of the digital and electronic revolution and its implications for public policy. PFF has published numerous papers and several books on the issues of privacy, data collection, and advertising.

The amici have obtained consent to file this amicus brief from both the State and the appellants.

## SUMMARY OF THE ARGUMENT

The Vermont law regulates speech, not conduct, and is therefore subject to protection under the First Amendment. (Point I)

The Vermont law regulates and abridges a broad range of expression that is clearly not commercial speech but that is fully protected by the First Amendment. Even "detailing," the supposedly targeted focus of the statute, is not commercial speech under this Court's appropriately narrow definition. (Point II)

Even if any commercial speech is regulated by the Vermont law, the District Court misapplied the "intermediate scrutiny" test of *Central Hudson,* relying on the First Circuit's erroneous analysis in determining whether the statute passes constitutional muster. (Point III).

## I.

## THE DISTRICT COURT CORRECTLY REJECTED THE FIRST CIRCUIT'S DEEPLY FLAWED VIEW THAT NO FIRST AMENDMENT INTEREST IS IMPLICATED BY THESE CONTENT-BASED, SPEECH-SUPPRESSIVE STATUTES

The District Court correctly held, citing and following Second Circuit and Supreme Court precedent, that the Vermont statute regulates speech that is protected under the First Amendment.

Applying *Universal City Studios v. Corley,* 273 F.3d 429, 446 (2d Cir. 2001), it recognized that "[e]ven dry information, devoid of advocacy, political relevance, or artistic expression" is protected speech under the First Amendment and that, in any event, the speech at issue here has social value.

Indeed, it can hardly be debated that the speech at issue – once it has been gathered, organized and analyzed by the "data miners" – possesses significant social value. In the aggregate this information may reveal large patterns and trends of interest to scientists, researchers and medical decision-makers, among the diverse professions that rely on it, and in the particular it may reveal similarly important information about specific actors or enterprises.

In recognizing that the Vermont statute does regulate protected speech, the District Court rejected a central element of the First Circuit's holding in *IMS Health Inc. v. Ayotte*, 550 F.3d 42 (1st Cir. 2008), *cert. denied*, 2009 U.S. LEXIS

4744 (2009), which was based on the erroneous view that the New Hampshire law regulates "conduct" rather than "speech," that any speech affected by this conduct regulation is of scant social value and that thus the law could be upheld on any rational justification.

But neither the New Hampshire nor the Vermont law is addressed to conduct. Rather the laws are aimed squarely at prohibiting the communication of information, and do so based solely on government's antipathy to its content. For example, neither law prohibits pharmaceutical companies from detailing, but both laws prohibit the acquisition, use or communication of certain information for the purpose of detailing. Therefore, rather than having to demonstrate merely a rational basis for their enactment, content-based restrictions on speech such as the Vermont statute are actually invalid unless they withstand "strict scrutiny,"[1] which they clearly cannot do.

[1] In order to survive a "strict scrutiny" review, a statute must be narrowly tailored to promote a compelling governmental interest and only "if it chooses the least restrictive means to further the articulated interest." *Sable Comm'ns of Cal., Inc. v. FCC*, 492 U.S. 115, 126 (1989). *See also United States v. Playboy Entm't Group*, 529 U.S. 803, 804 (2000); *Reno v. ACLU*, 521 U.S. 844, 874 (1997);

## II.

## THE DISTRICT COURT ERRED IN TREATING THE IMPACTED EXPRESSION AS ONLY "COMMERCIAL SPEECH;" A BROAD RANGE OF CLEARLY NON-COMMERCIAL SPEECH IS DIRECTLY REGULATED OR OTHERWISE INDIRECTLY ABRIDGED BY THE VERMONT STATUTE

Because the sale, licensing, and exchange for value of PI data does not itself propose a commercial transaction, it is fully protected under the First Amendment. This is so even if some of the acquirers of the information – e.g., manufacturers – may use the information, *inter alia,* in formulating their business plans. The information that traditional news reporters gather and report also is frequently used by subscribers for commercial purposes, but no law prohibiting the gathering or reporting of information subsequently used for marketing or promoting a product could be upheld as a mere commercial speech regulation.

It is a fundamental tenet of First Amendment theory that speech cannot be suppressed because of some alleged harm it may subsequently threaten unless that speech presents a "clear and present" or "imminent" danger of a harm the State is entitled to regulate.[2] The more attenuated is the relation between the speech regulated and the harm alleged, so the First Amendment teaches, the more

[2] See *Brandenburg v. Ohio*, 395 U.S. 444, 447 (1969) (adopting the "imminent danger" test).

opportunity there is for counter-speech, which is the preferred mechanism for self-correction in a democratic society that favors freedom over censorship.[3]

Although the Vermont law is flawed in numerous respects, perhaps its fundamental problem, for purposes of First Amendment analysis, is the attenuation – indeed the vast chasm – between initial collection of the truthful, public-interest PI data and the one limited transaction (end use of the data in "detailing" to doctors) that it seeks to regulate. Both logic and First Amendment theory cast a grave shadow over a regime that sweeps up so much fully-protected speech into the same dragnet simply in order to ban one aspect of its ultimate use long after the original expression.

In fact, amici submit that, properly understood, *every* aspect and *every* stage of the process the Vermont law seeks to regulate – from information gathering, to publication, and ultimately to the dissemination and use of the non-commercial data and analysis by a broad range of recipients, for a wide variety of legitimate purposes – actually implicates *non-commercial* speech entitled to *full* First Amendment protection.

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[3] As formulated by Justice Brandeis, "the remedy to be applied is more speech, not enforced silence. Only an emergency can justify repression." *Whitney v. California*, 274 U.S. 357 (1927). Even in the context of commercial speech analysis, the principles of *Whitney* and *Brandenburg* have been cited. See *Linmark Associates, Inc. v. Willingboro*, 431 U.S. 85, 97 (1977), *cited in 44 Liquormart v. Rhode Island*, 517 U.S. 484, 498 (1996).

### A. In the Gathering of Prescriber-Identifiable Data by the Plaintiff Publishers, Pharmacies are "Sources" of the Information, Not Commercial Speakers, And Are Fully Protected by the First Amendment

Under any definition of commercial speech, the provision of raw data of public interest by an information source to a publisher for analysis and publication – regardless of the profit-making motive of the source or the publisher[4] – is *not* commercial speech. This is so even if one (but hardly the only) end use of that disclosed data may ultimately be to assist in marketing or promoting the sale of prescription drugs to doctors.

If these pharmacies, as willing speakers who wish to communicate the PI data to the publisher plaintiffs, are directly censored by Vermont's ban on the content of their communication, and if they are deterred as sources by the threat that they will be punished for providing certain content should it later be used, after

[4] Although journalistic "sources" are often unpaid, it is also not unusual for certain kinds of sources to be paid for information – without ethical concern or loss of First Amendment protection. For example, polling is a costly operation that generates information of undeniable public importance. Yet polling frequently involves "mining" large bodies of data, organized and analyzed by computers, often performed by paid independent contractors. No one would argue that such polling, or the data it produces, is unprotected by the First Amendment or that it is commercial speech, no matter what end use is made of it. The profit motive of publishers, whether of data or other information of public importance, has also never been viewed as a bar to First Amendment protection. *See* Point II.F., *infra*.

organization, analysis and publication, for a prohibited end purpose, then they will surely be "chilled" and will not speak.[5]

Plain and simple, the ban on the provision of PI data by pharmacies and other similar sources to the plaintiff publishers under the Vermont statute is a clear breach of these parties' First Amendment rights.

### B. The Plaintiff Publishers Perform Information Gathering and Publishing Operations Indistinguishable From Those of Traditional Publishers And Are Engaged in Non-Commercial Speech Fully Protected by the First Amendment

The Vermont statute abridges the plaintiff publishers' protected non-commercial expression by proscribing and thus "chilling" the non-commercial speech of their sources *and* by proscribing and thus drying up the most economically significant market for their publications.

Whether or not pejoratively labeled as mere "data miners," for First Amendment purposes there is no principled difference between the plaintiff publishers and traditional news publications like the *Wall Street Journal* or *USA Today*. Indeed, for present purposes, the only difference is that the content of their specialized publications has come to be disfavored by the State of Vermont

[5] The Supreme Court, in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 428 U.S. 748, 753-54 (1976), noted that "[f]reedom of speech presupposes a willing speaker. But where a speaker exists, as is the case here, the protection afforded is to the communication, to its sources and to its recipients both …"

because their primary – but hardly exclusive – market is the pharmaceutical companies that use the data for, among other things, the "detailing" which Vermont seeks to suppress.

To separate out such data, based on its disfavored content, for special treatment, and to attack "data mining" on some theory that data is a mere commodity subject to no or lesser First Amendment protection, is to undermine development of a powerful and highly promising new and expanding source of information, research and analysis. The fact that, after its protected publication, such powerful data might ultimately be used for arguably "commercial" purposes by some recipients is irrelevant.

### C. A Prescription Restraint Law Has Already Impacted Use of PI Data By At Least One Traditional Publisher, Abridging The Exercise of Its First Amendment Rights as a Non-Commercial Speaker

The overbreadth of the Vermont statute has effectively turned the PI data into "contraband" for purposes far beyond "detailing." Even "traditional" publishers, not directly involved in the data mining of prescription information, will be limited in their attempt to publish legitimate news about medical matters that may fall afoul of these laws.

This is not speculation. It has already happened. Recently *USA Today*, the nation's largest circulation newspaper, and a publication otherwise clearly and fully covered by the First Amendment as a non-commercial speaker, entered into a

joint project with QForma, a medical research company which bills itself as "the leading provider of advanced analytics and predictive modeling technologies for the health sciences industry." The purpose of the project was to develop and publish a national "Most Influential Doctors" list.

According to an article about the project published in *USA Today*,[6] "[u]nlike standard best-doctor lists compiled by opinion-based surveys, the Qforma analysis represents a national effort to track subtle differences in doctors' practice patterns . . . . The project's goal is to offer consumers an innovative resource during the complex decision of how to choose a doctor."

As published, the list named doctors in all states – *except* New Hampshire. According to *USA Today*, "because of the ban, no New Hampshire doctors appear in the Qforma database." (Vermont doctors apparently were included because the article appeared before the Vermont statute went into effect on July 1.)

In sum, although the plaintiff publishers may be the targets of the abridgement of speech that is the central purpose of these restrictive laws, even traditional publishers like *USA Today* may be deterred from publishing information

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[6] *See* Steve Sternberg, Anthony DeBarros & Jack Gillum, *In Patient's Hunt for Care, Database 'A Place to Start,' -- National List of Specialists Has a Community Focus"* USA TODAY, May 14, 2009, at A1; *see also* www.influentialdoctors.usatoday.com. The list was compiled by Qforma, based on PI information provided by Wolters Kluwer Health (parent company of Appellant Source Healthcare). *See id.*

of public interest and concern for fear that their news publications may also fall afoul of these statutes.

### D. Communication of the Published Prescription Data for Research, Education, Policymaking and Other Legitimate Uses Is Clearly Non-Commercial Speech, Fully Protected By the First Amendment

The Vermont statute, evidently recognizing the importance of these clearly non-commercial uses, purports to exempt use of the PI data for certain educational or research purposes (Vt. Stat. Ann. tit. 18, §4631 (e)(1)).[7] The problem is that, although the statute does not directly ban such uses, it nonetheless severely restricts the development and communication of PI information, including for research or education, because the ability and incentive to gather and publish the data is proscribed and will inevitably be dried up or chilled by the statute, and the data thus rendered unavailable or at least substantially less useful, even for the supposedly exempt purposes.

Even the opt-in provision, presumably added as a saving safety-valve, is likely to leave huge holes in the data that is only fully useful if comprehensive. Moreover, the nature of those who do or do not opt-in, for whatever reasons, will also skew the sample and make it less useful or reliable for research purposes.

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[7] The First Circuit in *Ayotte* itself recognized that "[t]hese massive collections of information have great utility for certain non-profit entitites (e.g. educational institutions, public interests groups, and law enforcement agencies)," 550 F.3d at 46.

In sum, if comprehensive information cannot be gathered due to the ban on collection at the source from willing speakers, and if the economic incentive to gather, analyze and publish such comprehensive but costly data is permitted to be attacked and dried up, then the First Amendment right of access to such truthful, non-invasive information of public concern, even for exempt education and research uses, will also be adversely impacted by the Vermont statute.

### E. Communication of the Published PI Data to the Pharmaceutical Manufacturers Is Not Commercial Speech

The pharmaceutical manufacturers are surely entitled to solicit and pay for information of importance to their business that has many uses in addition to detailing. Communication by the plaintiff publishers of the PI data to the manufacturers is not commercial speech, even though one subsequent use of the data may be for marketing or promotional purposes.

Likewise, from the manufacturer's point of view, any such commercial speech by the manufacturer's for marketing and promotion of their products is inextricably intertwined with a range of vitally-important, fully-protected non-commercial speech. As noted in the manufacturers' brief on this appeal, in addition to any marketing or promotion of particular products, during "detailing":

> [P]harmaceutical sales representatives provide prescribers information regarding medical conditions the prescribers treat . . . . In addition, pharmaceutical manufacturers communicate with Vermont prescribers about scientific or safety related developments through "Dear Healthcare Professional" letters. When companies identify a new side

> effect or risk associated with a product or change the labeling of a prescription drug, they alert prescribers, including those in Vermont. Manufacturers use prescriber-identifiable data to assist in disseminating this safety information, ensuring that sales representatives reinforce with doctors who prescribe the product the information contained in the letter.

Such exchanges of important, health-related information, amici respectfully submit, are best understood as non-commercial speech under any standard – particularly the narrower definition of commercial speech followed in this Circuit – *see* Point II.F., *infra*.

### F. Even the Ultimate Use of the Publishers' PI Data In "Detailing" Is Best Seen as Non-Commercial Speech, Fully Protected By the First Amendment

Finally, even the "detailing" that is supposedly the commercial speech that is the sole focus of the Vermont law, is speech that proposes more than a mere commercial transaction. It is thus, properly analyzed, also not the kind of speech – or at least not exclusively the kind – that this Court has held would fit within a properly narrow definition of "commercial speech."

Detailers do not sell a product in doctors' office. They do not take orders. At most, their detailing will generate future prescriptions to be filled and sold by pharmacies. The undisputed record demonstrates – as does the very term "detailing" – that far more than the mere proposal of a commercial transaction occurs during a detailer's visit to a doctor's office. Although there is a commercial

motive[8] behind the process, which is doubtless related to the broad economic interests of the manufacturer, detailers provide a host of information regarding drug usage, efficacy, etc., and they discuss issues and answer questions not limited merely to sale of the product. Detailing is thus far more than an in-person "advertisement" for the detailer's drugs.

The Supreme Court has described "the test for identifying commercial speech," as "speech that does no more than propose a commercial transaction," *Discovery Network*, 507 U.S. at 423 (quoting *Board of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 473-74 (1989)). However, the Court has also on occasion referred more broadly to "expression related solely to the economic interests of the speaker and its audience." *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm.*, 447 U.S. 557, 561 (1980).

This Court, in *Commodity Futures Trading Comm'n v. Vartuli*, 228 F.3d 94 (2d Cir. 2000), stated its preference for the narrower construction of what

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[8] Commercial motive has never been viewed as a basis for denying First Amendment protection to what is otherwise non-commercial speech. *See Harte-Hanks Communications, Inc. v. Connaughton*, 491 U.S. 657, 667 (1989) ("If a profit motive could somehow strip communications of the otherwise available constitutional protection, our cases . . . would be little more than empty vessels."); *Joseph Burstyn, Inc. v. Wilson*, 343 U.S. 495, 501–02 (1952) ("[that] books, newspapers, and magazines are published and sold for profit does not prevent them from being a form of expression whose liberty is safeguarded by the First Amendment. We fail to see why operation for profit should have any different effect in the case of motion pictures.")

constitutes speech that is subject to full First Amendment protection). As explained by Judge Sack:

> That description [from *Central Hudson*] is overbroad for the purposes of this analysis. Speech may be related solely to economic interests and not share the 'commonsense differences' from other communications, Virginia Pharmacy, 425 U.S. at 771 n.24, upon which the lesser protection for commercial speech is based. Use of the Central Hudson description as a definition of commercial speech might, for example, permit lessened First Amendment protection and increased governmental regulation for most financial journalism and much consumer journalism simply because they are economically motivated, a notion entirely without support in the case law. See e.g., Thornhill v. Alabama, 310 U.S. 88, 102-03, 84 L. Ed. 1093, 60 S. Ct. 736 (1940) (speech about labor dispute protected even though economically motivated); see also Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc., 472 U.S. 749, 787, 86 L. Ed. 2d 593, 105 S. Ct. 2939 (1985) (Brennan, J., dissenting) ("This Court has consistently rejected the argument that speech is entitled to diminished First Amendment protection simply because it concerns economic matters or is in the economic interest of the speaker or the audience.") (additional citations omitted) *Id*. at 110 n.8.

Moreover, a majority of Justices on the Supreme Court – Justices Stevens, Kennedy, Ginsburg, Scalia, and Thomas – have in recent pronouncements suggested that *all* speech be subjected to "strict scrutiny" – even when the speech could be classified as "commercial." See *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554-55 (2001) (collecting opinions).

In sum, because the Vermont statute abridges a broad range of clearly protected expression, it surely cannot survive the requisite "strict scrutiny" accorded to non-commercial speech and must be overturned.

## III.

## TO THE EXTENT ANY COMMERCIAL SPEECH IS REGULATED BY THE VERMONT LAW, THE DISTRICT COURT MISAPPLIED THE "INTERMEDIATE SCRUTINY" TEST OF *CENTRAL HUDSON,* RELYING ON THE FIRST CIRCUIT'S ERRONEOUS ANALYSIS

Even if it is assumed that some speech regulated by the Vermont law could properly be labeled "commercial speech," it is still necessary to determine whether the statute passes constitutional muster under the First Amendment. Indeed, it is well-settled that commercial speech is an integral component of modern communications that must be accorded sensitive First Amendment protection.[9]

In *Central Hudson Gas & Electric Corp. v. Public Serv. Commission*, 447 U.S. 557 (1980), the Supreme Court established four criteria under which a reviewing court is to determine whether commercial speech is constitutionally-protected: (1) whether the speech concerns lawful activity and is not misleading, (2) whether or not the regulation abridging the speech supports a substantial or important government interest, (3) whether or not the regulation "directly advances

[9] For more than three decades, the Supreme Court has recognized that "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." *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 763 (1976). See also *Bigelow v. Virginia*, 421 U.S. 809, 818-20 (1975). In addition to the interests of particular individuals, "society also may have a strong interest in the free flow of commercial information," and a particular advertisement, "though entirely 'commercial,' may be of general public interest." *Virginia State Bd. of Pharmacy*, 425 U.S. at 764.

the governmental interest asserted," and (4) whether or not the regulation is "more extensive than is necessary" to the purpose for which it was enacted. 447 U.S. at 566.

Vermont, as the party seeking to uphold a restriction on commercial speech, bears the burden of proof with respect to all four elements. *See Thompson v. W. States Medical Ctr.*, 535 U.S. 357, 371-73 (2002).

### A. The District Court Erred By Deferring to the Legislative Judgment

Amici agree with the plaintiff publishers that the Court below fundamentally erred in the manner that it deferred to the judgment of the Vermont Legislature in its consideration of the *Central Hudson* test. The so-called "intermediate scrutiny" standard itself incorporates all of the deference to which a legislative body is entitled. There is no basis for further enhancing that deference by allowing a regulation of commercial speech to be upheld as long as the court finds that the legislature reasonably could have concluded that the law would advance its objectives or that the law is properly tailored to serve those objectives. Federal courts may not surrender their constitutional duty, as independent fact finders, in evaluating whether the *Central Hudson* standards have in fact been met.

The District Court purported to justify its deference, and its refusal to "reweigh the evidence de novo," under *Turner Broadcasting Systems, Inc. v. FCC*, 512 U.S. 622 (1994). But its reliance on *Turner* was misplaced. In *Turner*, as the

Supreme Court took pains to note, Congress had thirty years of experience regulating commercial broadcasting. Moreover, it found, the regulatory scheme in question was "content-neutral." Here, by contrast, the Vermont statute is admittedly new and experimental and the Legislature has had no experience attempting to regulate pharmaceutical "detailing." Moreover, it cannot reasonably be maintained that the Vermont law is content-neutral.

### B. The First Circuit Erred in its Application of *Central Hudson* and the District Court Repeated those Errors

Putting aside the issue of whether the District Court applied the correct standard in deferring to the Legislature's judgment, rather than independently evaluating the evidence, it plainly misapplied *Central Hudson* in reliance on the First Circuit's misapplication of the test in *Ayotte.*[10]

#### 1. The District Court Misapplied *Central Hudson* Prong Two

It is not contended that the Vermont law regulates or censors anything other than lawful activity involving speech that is truthful and not misleading. Therefore, the legislation must be examined and justified under the three remaining criteria of *Central Hudson*. Prong two requires proof of a substantial or important

[10] This Court must review these findings by the District Court, *de novo,* because the Court below *denied* First Amendment protection and the Appellants are asserting that the ruling they are appealing from violated their First Amendment rights. *See Bose Corp. v. Consumers Union of United States, Inc.*, 466 U.S. 485, 514 (1984).

government interest.

The First Circuit found cost containment to be an important government interest only if the costs contained were not "conferring any corresponding public health benefit." *Ayotte,* 550 F. 3d at 55. Amici agree that a state may have a substantial or important interest in preventing wasteful or unnecessary prescribing practices. If, however, that is the interest the state identifies, then it bears the burden of showing (under *Central Hudson* prong three) that the measure adopted will *directly* advance that important interest, not that it simply will lower costs in one category while raising them as much or more in another. The State did not meet this burden – *see* Point III.B.2, *infra*.

Vermont also claimed an interest in preventing the use of PI information to coerce and harass prescribers. But no evidence in the record supported this contention and the District Court's decision found no harassment. Nor was there evidence that the law would stop harassment of prescribers even if it did occur. The law does not target the "conduct" of harassment[11]; rather, it bans publication of truthful speech by pharmacies and others about prescribing practices that ultimately may be used in marketing, and it bars pharmaceutical companies from marketing with PI data whether or not the marketers are unfailingly truthful and

[11] See discussion of the District Court's misapplication of this Court's decision in *Anderson v. Treadwell*, 294 F.3d 453 (2d Cir. 2002), *infra* Point III.B.3.

polite in their interactions with doctors. Thus, it unavoidably abridges speech that has nothing to do with intimidation or harassment – speech that may be useful to the companies, the prescribers and a range of other interests.[12]

### 2. The First Circuit Misapplied *Central Hudson* Prong Three

As previously noted, the Court below took the same approach to deference as the First Circuit took in *Ayotte*. Instead of reviewing the evidence to determine whether prong three of the *Central Hudson* test had been met, with proof that the statute would "directly advance" an important or substantial interest of the State, it acknowledged, as had the First Circuit, that "we defer to the [] legislature on . . . whether it is sensible to conclude (hypothetically) that net medical outlays will decrease as a result of the withdrawal of prescribing histories from detailers." *Ayotte*, 550 F.3d at 59. This misapplication of *Central Hudson,* and the improper borrowing of "deference" from *Turner* by the First Circuit, plainly influenced the Court below to disregard the bulk of the contrary evidence offered by plaintiffs in

[12] The evidence also demonstrated that prescriber-identifiable data are not private and that Vermont law permits broad disclosure in other contexts. Researchers, insurers, and pharmacy benefit managers use the data for commercial purposes, including marketing to prescribers, and can continue to do so under the Vermont Law. The federal government and Vermont use the data for multiple purposes, including management of the preferred drug list and prior authorization process. Academics, insurers, and state agencies all use the data to urge doctors to change their prescribing habits. Even pharmaceutical manufacturers could continue to use the information, except for purposes of detailing. It is an odd and selectively porous concept of privacy that turns solely on the content of the speech of selected disfavored third parties in one selected context.

the Court below. At the very least, if properly reviewed *de novo*, that evidence could have supported a conclusion that the Vermont law was as likely to produce the opposite result of what was intended – higher healthcare costs and harm to public health.

On the basis of its improper deference, the Court below affirmed the Legislature's hypothesis that the statute would directly advance the goal of lower costs, yet it failed to cite any evidence that a single doctor had written a prescription for a drug that was unnecessarily expensive. This alone should have been fatal to the State's case because it cannot credibly assert that a legislative measure suppressing speech would advance the State's interest in optimizing prescribing without first offering evidence that doctors are not presently prescribing the proper medicines for their patients. Nor did Vermont offer the District Court any definition of "optimal prescribing." Without stating its goal, a court has no means to decide whether the law *directly* will advance the goal – a *sine qua non* of the *Central Hudson* test.

Doubtless, articulating such an objective is not easy. Doctors make prescribing decisions on the basis of the patients they face. They evaluate a complex biological organism that has a unique array of qualities. The patient may be old or young, suffering from an array of maladies or just one, averse to certain treatments, predisposed to prefer one drug over another, wealthy or poor, or

advised by others about the best course to proceed. In authorizing doctors and others to prescribe medications, Vermont, like other states, recognizes, that these "learned intermediaries" are the individuals in our society best suited to make prescribing decisions – far better suited than even the individual or a government agency. So, Vermont, like New Hampshire, in asserting that it was justified in adopting a speech-suppression law in order to improve prescribing practices was assigning itself a task that was impossible to perform. It could not show that the law advanced its interest in optimizing prescriber decisions because it had no way to define optimal prescribing for any one doctor, let alone for all of its doctors and their myriad diverse patients.

But in the end, of course, what all of this proves is not that deference should be given to the difficult task at hand for the State. What it proves is that the flawed methodology of the State's regulation – electing to suppress the *content* of pertinent expression where the State neither has nor can have any formulaic answers to the interests it is purportedly seeking to protect – represents an effort to paternalistically dictate answers to questions best left to professionals to determine, in an environment where full and complete information, rather than censored data, should be available to the prescribers who must make such individualized decisions.

This, in fact, is also the fundamental lesson of long-established First

Amendment doctrine – that *more* speech, not less, is the preferred answer in such situations and in our market-based democracy.[13]

### 3. The District Court Misapplied *Central Hudson* Prong Four

In concluding that the Vermont statute is sufficiently narrowly tailored, the fourth prong of the *Central Hudson* analysis, the Court below purported to rely on this Circuit's decision in *Anderson v. Treadwell*, 294 F.3d 453 (2d Cir. 2002). This reliance was wholly misplaced. The statute at issue in *Anderson* placed restrictions on in-home real estate solicitations by allowing home owners to be placed on a list that would prohibit such solicitations. In upholding the statute against a First Amendment challenge, the Second Circuit held that the "regulation can hardly be accused of being 'more extensive than necessary'; it is precisely co-extensive with those who are experiencing the particular harm that it is designed to alleviate." 294 F.3d at 462.

In stark contrast to *Anderson*, the Vermont statute burdens far more speech

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[13] As the Supreme Court held in *Virginia State Board. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976): "There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them. * * * But the choice among these alternative approaches is not ours to make or the Virginia General Assembly's. It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us."

than the narrow category the Vermont Legislature has arbitrarily deemed to be harmful – namely, the use of PI information by detailers. Moreover, most of the speech that it is censoring cannot reasonably be characterized as "commercial." Under the statute, information possessed of significant value to scientists, researchers and medical decision-makers as well as government bodies – information that is clearly non-commercial – is also effectively silenced. *See generally Point II, supra.*

Moreover, the District Court's attempt to analogize the silencing of real estate agents who might otherwise communicate with unwilling listeners to the censoring of information about physicians who may not wish to have their prescribing histories included in publications cannot withstand even the most cursory scrutiny. Whereas preventing unwanted in-home communications was a substantial state interest identified in *Anderson* with respect to private home owners, the substantial state interests identified in the case at bar are limited to "cost containment" and "promoting public health;" nowhere does the District Court identify as a substantial state interest providing "prescribers the ability to allow use of their PI data."

Finally, the Court below refused to consider, under prong four, whether alternative measures could achieve the law's objective with far less burden on constitutionally-protected speech. While it did not – as did the Vermont Attorney

General – declare such alternatives "irrelevant," it completely failed to address the alternatives propounded by the plaintiffs. The judgment should be reversed for this reason as well because the law was not carefully tailored to restrict no more speech than is necessary to achieve the State's objectives.

## CONCLUSION

For all of the foregoing reasons, the judgment of the District Court should be reversed and the Vermont Prescription Restraint Law overturned, because it violates the First Amendment rights of the parties, these amici, and the public at large.

Dated: July 13, 2009

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