

# Companies Challenge New Hampshire Data Law

Two major health information companies filed a lawsuit challenging the constitutionality of a recently enacted New Hampshire law (HB 1346) that prohibits the sale of prescribing data for any commercial purposes (see “New Hampshire Bill Could Ban Prescribing Data Sale,” June 2006, p. 4). The intention of the law is to lower the state’s health care costs by limiting access to information about physician prescribing patterns that drug companies can use to better guide detailing efforts. However, “by denying access to vital prescribing information, the new law will violate plaintiffs’ First Amendment rights and have significant unintended consequences,” according to a lawsuit filed by IMS Health and Verispan LLC on July 28 in the U.S. District Court in Concord, N.H.

The final version of the law bans “records relative to prescription information containing patient-identifiable and prescriber-identifiable data” from being licensed, transferred or sold for any commercial purposes. However, under the New Hampshire law, sharing prescribing data is permitted for purposes of pharmacy reimbursement, formulary compliance, health care research and other limited purposes. It also does not prohibit the collection or sale of prescribing data stripped of all identifying information about the prescriber.

The New Hampshire law provides for criminal and civil penalties including fines and imprisonment. IMS states in the complaint that company representatives met with New Hampshire’s senior assistant attorney general to discuss how the state would interpret and enforce the new law. He said the state would enforce the law and defend its constitutionality should it be questioned, and was “unable to provide any assurance that the health information companies could not or would not be prosecuted if they continued their existing business practices,” the complaint states.

## **A Matter of Public Health?**

New Hampshire hopes the law will reduce health care costs by lessening the influence of marketing on doctors’ prescribing habits by limiting the data pharmaceutical companies and others can collect about their prescribing history. IMS and Verispan argue that the law will not reduce health care costs but will in fact harm public health and cause “irreparable injury” to their businesses, to pharmacies that sell prescriber data and to patients who “benefited from the licensing, sale and transfer of the patient-de-identified information” that is the subject of the New Hampshire law. IMS and Verispan argue that the data they cull and sell is a vital part of monitoring the safety of new medications.

Not all of the companies’ dealings are commercial — IMS claims that it frequently provides its data at no cost to academic and medical researchers, humanitarian organizations (such as the Red Cross), law enforcement organizations, regulatory authorities and clinical trial investigators. The data allows these organizations to “track patterns of disease and treatment, conduct outcomes research, implement best practices and apply health economic analyses,” the complaint states. It notes that IMS’ doctor-identifying data has been used to: examine prescribing patterns in areas where childhood asthma is undertreated; study overuse of antibiotics in children; and evaluate the regional impact of bioterrorist threats on prescribing. Verispan’s data is used by the FDA and for recruitment purposes in clinical trials, according to the company. None of the data is sold with identifying patient information.

## **First Amendment Considerations**

The plaintiffs object to what they view as the open-ended language of the New Hampshire law. It criminalizes the sale, use and transfer of information containing identifiable prescriber data for “commercial purposes,” which “includes but is not limited to advertising, marketing, promotion, or any activity that could be used to influence sales or market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, or evaluate the effectiveness of a professional pharmaceutical detailing sales force” (emphasis added). “This definition sweeps within its ambit, substantial non-commercial speech in which the plaintiffs engage that would not be regarded as ‘commercial speech.’

“The fact that information may be sold for a profit does not transform the speech into ‘commercial speech,’” the complaint states. For example, it notes that newspapers and magazines also sell information for a profit, which still is considered non-commercial because it serves an important public purpose unrelated to commercial transactions. “Commercial speech is speech that does no more than propose a commercial transaction,” the plaintiffs argue.

Likewise, when pharmacies and other entities sell data to companies like IMS and Verispan, they are not proposing a commercial transaction — “they are conveying truthful information that lawfully is in their possession to a third party that is interested in learning the information and using the information for a myriad of purposes,” both commercial and non-commercial. Although a substantial amount of the commercial purchases for which this data is obtained are for profit, not all are, the plaintiffs argue.

The Supreme Court case *Central Hudson Gas & Electric Corp. v. Pub. Service Comm’n of New York* (447 U.S. 557, (1980)) articulates a four-part test to evaluate the constitutionality of government restriction of commercial speech, which is defined in the case as “expression related solely to the economic interests of the speaker and its audience.” One of the requirements under *Central Hudson* is that the government must assert a “substantial” interest before restricting truthful, commercial speech — a level of interest that New Hampshire lacks, according to the plaintiffs.

For restriction of commercial speech to be constitutional under *Central Hudson*, the proposed solution also must directly advance the substantial government interest. The New Hampshire law not only does not directly advance the state’s interest but “appears to be taking the most indirect route that it possibly could take to achieve its objectives,” the complaint states. “Instead of imposing direct regulations on the manner in which pharmaceutical companies market their products or the pricing of the products, the statute aims to prevent the information that pharmaceutical companies would like to consider in deciding how to market their products from being licensed, sold, used or transferred for any of a broad range of commercial purposes, many of which may be unrelated to advertising.” New Hampshire has the right to regulate drug marketing and pricing but not by violating the First Amendment, the plaintiffs argue.

In their eyes, the New Hampshire law also fails another part of the *Central Hudson* test — that the government use the least restrictive means of achieving its interests.

For example, if the state contends that doctors are being misled with false and misleading information from drug companies, it can impose penalties on the manufacturers for doing so, the complaint states. Or, if New Hampshire is concerned that doctors lack information about suitable generic drugs not marketed by drug companies, the state could provide additional information to prescribers as a condition of renewing their licenses. Such measures would not “require the suppression of constitutionally protected speech in order to achieve the State’s objectives,” according to the plaintiffs.

### **Vague and Overbroad**

IMS and Verispan also allege in the lawsuit that the statutory language of the New Hampshire law is “vague and overbroad.” For example, section 3 of the law lists covered entities such as pharmacies, insurance companies and electronic transfer intermediaries and other “similar” entities. The plaintiffs assert that this “forces companies, such as plaintiff health information companies, to speculate about whether they will be treated as falling within the direct application of the statute.”

Furthermore, the suit alleges that section 4 of the New Hampshire law prohibits the licensing, transfer, use or sale of specific information for certain purposes but it does not spell out exactly what determines the purpose of the transfer: the purpose of the entity acquiring the information; the provider of the information; the ultimate consumer of the data; or some combination of all these. The suit also states that the New Hampshire law inadequately defines terms important to its execution, such as “care management,” “health care research” and “as otherwise provided by law.” Similarly, the lawsuit asks whether the license, transfer, use, or sale of covered data by a covered entity that merely “could be used” for a prohibited commercial purpose, but which would not be used for such a purpose, would violate the statute.

This alleged lack of clarity in the law “fails to give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he or she may act accordingly” and also “creates a risk of arbitrary and discriminatory enforcement,” the complaint states. Additionally, the plaintiffs state that the New Hampshire statute is of greater concern because it is vague but content-based regulation of speech that “raises special First Amendment concerns because of its obvious chilling effect on free speech” and because it is a criminal statute.

“As a practical matter, this increased deterrent effect, coupled with the ‘risk of discriminatory enforcement’ of vague regulations, poses greater First Amendment concerns than those implicated by civil regulation,” the complaint states.

Finally, IMS and Verispan also allege that the New Hampshire law violates the Dormant Commerce Clause of the Constitution because it regulates conduct occurring wholly outside of the state. The plaintiffs are seeking a preliminary and permanent injunction against the enforcement of the New Hampshire law and a declaration from the court that the law is unconstitutional as written and as applied to the non-commercial speech in which the companies engage.

### **For More Information**

See the final version of the New Hampshire law at:  
<http://www.gencourt.state.nh.us/legislation/2006/HB1346.html>.

IMS and Verispan's complaint, press release, position paper and other information are available online at: <http://www.imshealth.com/newhampshire>.

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