plaintiffs' argument that *Cruzan v. Dir. Mo. Dep't of Health*[19] – which held that a state can require clear and convincing evidence of an incompetent patient's wishes, articulated when she was competent, regarding the withdrawal of life-sustaining treatment – compelled the Court to invalidate the Policy because the Policy did not take into account the wishes of a patient who has never had the mental capacity to make medical decisions.[20] The Court agreed with the Second Circuit in *Blouin v. Spitzer*[21] that nothing in *Cruzan* supports the view that a patient who has always lacked the mental capacity to make medical decisions has a constitutional right to have his or her wishes considered.[22] The Court furthermore observed that the plaintiffs were unable to demonstrate that the consideration of the wishes of a patient who has always lacked the mental capacity to make medical decisions is "deeply rooted in this Nation's history and tradition," such that "neither liberty nor justice would exist if [the asserted right] were sacrificed."[23]

Tarlow is evidence of a slowly growing consensus among the circuit courts that the rights of a patient who once possessed the mental capacity to make medical decisions are distinct from the rights of a patient who has never had such capacity.

Jonathan Amar

Prescription Privacy: Federal Court Strikes Down New Hampshire Law Limiting Use of Prescription Data in Pharmaceutical Marketing - *IMS Health, Inc. v. Ayotte*[1] - The United States District Court for the District of New Hampshire recently held that a state law restricting the license, transfer, use, or sale of prescription data is unconstitutional under the First Amendment because it regulates constitutionally-protected, commercial speech without directly serving a substantial State interest.[2] The Prescription Information Law,[3] enacted by the New Hampshire Legislature in 2006, prohibits pharmacies and other similar entities from transmitting or using prescription records containing patient-identifiable or prescriber-identifiable information for commercial purposes.[4] The statute defines "commercial purpose" to include advertising, marketing, and "any activity that could be used to influence sales or market share of a pharmaceutical product."[5]

This prohibition directly impacts the "data-mining" business. Data-mining companies purchase prescription data from pharmacies, match it with detailed information about individual prescribers, and sell the resulting prescriber "profiles" to interested parties. Their revenue derives nearly exclusively from sales to pharmaceutical companies which use the prescriber

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19 497 U.S. 261 (1990).
20 Tarlow, 489 F.3d at 383.
21 356 F.3d 348, 360 (2d Cir. 2004).
22 Tarlow, 489 F.3d at 383.
23 *Id.*
1 490 F. Supp. 2d 163 (D.N.H. 2007).
2 *Id.*
3 N.H. REV. STAT. ANN. §§ 318:47-f, 318:47-g, 318-B:12(IV) (Supp. 2007).
4 The statute's prohibition on the use of patient-identifiable data is not at issue in the case. *IMS Health*, 490 F. Supp. 2d at 170 n.6.
5 §§ 318:47-f, 318-B:12(IV).

profiles to tailor their drug marketing efforts to individual physicians. In 2006, two leading data-mining companies, IMS Health, Inc. and Verispan, L.L.C., sued the State of New Hampshire challenging the constitutionality of the statute and seeking declaratory judgment to bar its enforcement. The plaintiffs claimed the law impermissibly restricted their right to free speech under the First Amendment. The court agreed.

In its opinion, the court first detailed the ways in which the use of prescriber-identifiable prescription data facilitates pharmaceutical marketing. The court then discussed the language of the New Hampshire statute and the legislative history establishing the State's purpose in passing the bill: to protect patient and physician privacy and to contain health care costs. The court subjected the statute to intermediate scrutiny by analyzing the nexus between the legislation and this asserted purpose. The defendant, the Attorney General of New Hampshire, bore the burden of proof in seeking to uphold the statute; therefore, the court structured its opinion around her arguments, rejecting each.

As an initial matter, the court discarded the Attorney General's contention that the plaintiffs lacked standing to sue, reasoning that the plaintiffs could be prosecuted for their resale of prescriber-identifiable information as "other similar entities" or conspirators under the Prescription Information Law, and, in any case, suffered sufficient economic injury from the law to procure standing.[6]

Substantively, the Attorney General first argued that the law does not regulate speech and is not, therefore, in violation of the First Amendment. She contended that prescription data constitutes "factual information" rather than speech, and that, even if it does constitute speech, a law that restricts its use and not its disclosure does not regulate speech for the purposes of the First Amendment. The court held that the Prescription Information Law does not escape First Amendment review "merely because it targets factual information rather than viewpoints, beliefs, emotions, or other types of expression."[7] The court stated that "transfer" of prescription information is a form of disclosure, and that the statute's prohibition on the transfer and use of prescription data directly regulates speech.[8] Furthermore, the court noted that laws that only indirectly regulate speech may nonetheless be subject to the First Amendment when they "affect . . . the speaker's ability to communicate with his intended audience."[9]

The Attorney General next argued that, even if the law regulates speech, it survives intermediate scrutiny because it directly serves substantial State interests. The court applied intermediate scrutiny, following the rule for commercial speech restrictions in the First Circuit and rejecting the plaintiffs' contention that the restricted prescription information falls outside the definition of commercial speech, thereby requiring strict scrutiny of the statute.[10] The court held that the law qualifies as a commercial speech

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6 IMS Health, 490 F. Supp. 2d at 174 n.9.

7 *Id.* at 174-175.

8 *Id.* at 175.

9 *Id.* (citing U.S. West, Inc. v. Fed. Commc'n Comm'n, 182 F.3d 1224, 1232 (10th Cir. 1999)).

10 *Id.* at 176.

restriction because it explicitly restricts the transmission of prescription information data for commercial purposes alone and is "squarely aimed" at commercial transactions.[11]

The court applied a three-prong intermediate scrutiny test assessing whether the law "is in support of a substantial government interest, directly advances the government interest asserted, and is not more extensive than necessary to serve that interest."[12] Accordingly, the Attorney General articulated the State's interest in protecting prescriber privacy, promoting public health by reducing industry influence on prescribing decisions, and containing health care costs by reducing brand name prescriptions. The State characterized its interest on behalf of prescribers not as protecting private information or intellectual property, but rather as protecting physicians from "unwarranted intrusions into their decision-making process" by pharmaceutical companies.[13] The court disagreed that this constitutes a substantial interest, observing that there was no evidence on the record that pharmaceutical companies use prescription data to "coerce or harass" in an effort to truly infringe upon a prescriber's professional privacy.[14] The court concluded that the State's concern that drug companies use prescription data to affect "inadvisable prescribing decisions" among physicians was merely a "restatement" of its other proffered public health interests.[15]

The court then held that the Prescription Information Law failed to directly advance the State's legitimate interests in public health and cost containment.[16] The court agreed with the Attorney General that the availability of prescription information renders pharmaceutical marketing more persuasive to prescribers and leads to increased prescribing of brand name drugs.[17] The court, however, rejected the idea that increased brand name prescribing is necessarily "injurious to public health" and expensive to the health care system as a whole.[18] The court noted that although some brand name drugs, particularly those without generic equivalents, are the most appropriate medication for certain conditions, the law restricts the promotion of helpful and harmful brand name drugs equally.[19] The law, therefore, failed the second prong of the intermediate scrutiny test because the Attorney General did not demonstrate that the restriction of prescription data for use in marketing would directly promote public health and reduce costs without "compromising patient care."[20] The court also pointed out that the Attorney General did not argue that drug marketers use prescription data to send "false or misleading" messages, only that they are highly persuasive and manipulative in their use of truthful information.[21] The State, the court

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[11] *Id.*

[12] *Id.* at 177 (quoting El Dia, Inc. v. P.R. Dep't of Consumer Affairs, 413 F.3d 110, 113 (1st Cir. 2005)).

[13] *Id.* at 178-179.

[14] *Id.* at 179.

[15] *Id.*

[16] *Id.* at 180-181.

[17] *Id.* at 180.

[18] *Id.* at 180-181.

[19] *Id.* at 181.

[20] *Id.*

[21] *Id.*

said, "simply does not have a substantial interest in shielding [prescribers] from sales techniques that enhance the effectiveness of truthful and non-misleading marketing information."[22]

Finally, the court assessed whether the law was "more extensive than necessary" to serve the State's interests and concluded that it was.[23] In so doing, the court offered several alternative methods for the State to further its interests, including a ban on gifts from pharmaceutical marketing representatives to prescribers, strategies for the State to equip prescribers with information on the efficacy of generic drugs to counter industry marketing efforts, and a Medicaid pharmacy program that would allow cost to be considered before a prescription is authorized.

The *IMS Health* decision will impact the health care industry in several ways. Primarily, it will reinstate the status quo in New Hampshire; that is, barring a reversal on appeal, pharmaceutical companies will be able to use prescriber-identifiable prescription data in their marketing efforts. Pharmaceutical sales is a robust industry.[24] As the court itself noted, large pharmaceutical companies spend thirty percent of their revenue on marketing, compared with thirteen percent on research and development.[25] Studies have demonstrated that physicians are highly responsive to these expensive marketing techniques.[26] The *IMS Health* decision will allow these effective efforts to continue unfettered.

Although the *IMS Health* court dismissed this argument, if a data-mining prohibition in fact increases the safe use of generic equivalents, it could result in substantial cost savings for the state. Research shows that generic substitution dramatically reduces pharmaceutical expenditures.[27] Because the court found the Prescription Information Law to be too broadly drawn for the purpose of cost containment, New Hampshire will not provide the forum to test this hypothesis.

At the time it was passed, New Hampshire's law was the only one of its kind in the United States.[28] Now both Vermont and Maine have data-mining statutes in effect, and thirteen other states have proposed similar legislation.[29] The *IMS Health* decision will likely dampen legislative efforts in other states because of the threat of litigation and resulting social costs. At the same time, it will caution legislators to craft prescription information laws that are narrowly drawn around the State's considerable interest in improving public health and mitigating health care costs.

Adaline R. Strumolo

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22 *Id.*

23 *Id.* at 182-183.

24 Ashley Wazana, *Physicians and the Pharmaceutical Industry*, 283 JAMA 373, 373 (2000).

25 IMS Health, 490 F. Supp. 2d at 167.

26 *See* Wazana, *supra* note 24.

27 *See, e.g.*, Jennifer S. Haas, *Potential Savings from Substituting Generic Drugs for Brand-Name Drugs*, 142 ANNALS INTERNAL MED. 891 (2005).

28 Rachel Brand, *Doc's Data—A Privacy Question*, STATE LEGISLATURES, June 2007 at 46.

29 *Id.*