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Court Upholds Drug Data Law, Dismissing Free Speech Concerns

Until recently, trying to sell a new drug did not also require expertise in First Amendment free-speech law.

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Pharmaceutical sales representatives walk into New Hampshire physicians' offices armed with facts about their companies' products and data about physicians' patient prescribing habits. Until recently, however, pitching a new drug did not also require expertise in First Amendment free-speech law.

That may change due to New Hampshire's Prescription Information Law—the nation's first prohibition on the use or sale of a physician's prescribing history for pharmaceutical marketing or other commercial purposes. In a precedent-setting decision, the 1st Circuit in November upheld the law's restrictions on data-mining companies that provide such information to drug companies.

Vermont and Maine have adopted laws similar to New Hampshire's (see "State BroadSides") raising red flags over the threat of copycat restrictions spreading across the country and hindering free speech in commercial endeavors.

"My concern is that the 1st Circuit ruling paves the way for state restrictions on the use of patient de-identified data, which hampers the development of the health-information exchange marketplace. That's a really unfortunate result of the ruling," says William Bernstein, chair of the health care practice at Manatt, Phelps & Phillips.

The court's action "strikes at the heart of protected commercial speech," adds Craig Donais, a Bostock Donais partner.

Lost in the 'Details'

Pharmaceutical sales representatives, or "detailers," tailor their pitches by using physicians' prescribing histories. New Hampshire legislators contend that when successful, this technique induces physicians to prescribe expensive brand-name drugs in place of equally effective but less costly generic drugs.

New Hampshire Attorney General Kelly A. Ayotte says state legislature passed the Prescription Information Law in 2006 to help offset the spiraling cost of health care. And because of the law, "Consumers can be assured that when they fill a prescription at their local pharmacy, the

State BroadSides

New Hampshire was the first state to pass a prescription information law in 2006, with Vermont and Maine quick to follow. Just as quickly, data-mining company IMS Health filed separate suits in Vermont and Maine, alleging violations of First Amendment speech rights. The district court in Vermont requested additional briefings in *IMS Health Inc. v. Sorrell* before making a decision. In the Maine case, *IMS Health Inc. v. Rowe*, attorneys expect a preliminary injunction blocking enforcement of that state's law to be reversed in light of the 1st Circuit's action in *IMS v. Ayotte*.

Experts predict this is only the beginning of the legal tussle over prescription-information laws.

"The 1st Circuit's decision is going to encourage other states to revisit adopting such laws," says **Richard Samp of the Washington Legal Foundation**. "A lot of states were dissuaded from this by the New Hampshire [district court] ruling, but now you may find more states willing to pass these laws and take on the burden of being sued."

information contained in that prescription will not subsequently be sold to data-mining companies for commercial purposes," Ayotte says.

Data-mining companies IMS Health and Verispan, both headquartered in Pennsylvania, immediately filed suit alleging the statute violated the free speech clause of the First Amendment and the Commerce Clause of the U.S. Constitution. A district court blocked enforcement of the law in April 2007.

The 1st Circuit reversed the lower court ruling and remanded the Commerce Clause claim, noting: "In combating this novel threat to the cost-effective delivery of health care, New Hampshire has acted with as much forethought and precision as the circumstances permit and the Constitution demands."

Sean Fiil-Flynn, counsel for the public interest amici in the case, argues, "The First Amendment does not protect every exchange of information from traditional social and economic regulation." The court agreed. "The portions of the law at issue here regulate conduct, not speech," Judge Bruce Selya wrote for the majority. "The societal benefits flowing from the prohibited transactions pale in comparison to the negative externalities produced. This unusual combination of features removes the challenged portions of the statute from the proscriptions of the First Amendment."

But Thomas Julin, a Hunton & Williams partner who represented the plaintiffs, says the court's view of the law as a restriction on conduct rather than speech is "an unusual way of analyzing a statute that is clearly designed to control the use of information."

Selya countered that notion in his opinion: "Even if the Prescription Information Law amounts to a regulation of protected speech—a proposition with which we disagree—it passes constitutional muster."

Righting a Wrong

Judge Kermit Lipez, in his dissent, tried to accommodate both sides of the argument. "The very elimination of the detailers' ability to use 'a particular informational asset' restricts the message they are allowed to disseminate and implicates the free speech concerns of the First Amendment," he wrote. But Lipez saw the restriction as permissible since it aims to lower drug costs.

Bernstein believes both New Hampshire and the 1st Circuit simply "got it wrong" and that the decision will be reversed. IMS filed an appeal Dec. 15 for an en banc rehearing by the 1st Circuit. "Regulation of de-identified data is using a blunt instrument to try to solve spiraling health care costs," Bernstein says. "I see a law that imposes civil and criminal penalties on the commercial uses of de-identifiable patient data. If the real public purpose [of this law] is to protect the physicians from detailing, you [don't] have to let a detailer into your office to try to influence you." The concern is that this action could lead to even more restrictive rulings.

"This particular law is narrow and tailored for a specific potential harm, which is drug companies using [the information] to push higher-end drugs," says Kirk Nahra, a partner at Wiley Rein. "The question is, what's the next step? What else will states try to do in the guise of controlling health care costs? The next law might have privacy issues or affect broader behavior."

And Julin says the implications extend to other industries as well.

"There's no way to limit the rationale of this decision to pharmaceutical cases," Julin says. "What this court says is that there's no First Amendment protection whatsoever for the gathering and dissemination of information. It's giving a green light to legislators to regulate speech."