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Ruling on Prescriber Data Law Creates Circuit Split

The 2nd Circuit upholds pharmacists' right to sell prescriber-identifiable data.

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Published on 3/1/2011

In 2007, Vermont passed a controversial new law known as section 17, banning the sale of prescriber-identifiable data (PI data) for marketing or promoting prescription drugs.

Pharmacies in Vermont and other states collect PI data when filling prescriptions. The information includes the prescriber's name and address; the name, dosage and quantity of the drug; the date and place the prescription is filled; and the patient's age and gender. Pharmacies sell PI data to data-mining companies, which aggregate it and strip it of patient information. The data miners sell the data mostly to pharmaceutical manufacturers, which use the trends revealed in the data to tailor their marketing to doctors.

By passing the law, state officials said they intended to protect public health and patient privacy and reduce health care costs. But several data-mining companies sued Vermont's attorney general, governor and secretary of human services, arguing section 17 unfairly restricts commercial speech. They said the law was unfair because PI data is widely used outside of marketing, and the law did not solve any of the problems it purportedly addressed.

After a district court judge upheld the law's validity, the companies appealed to the 2nd Circuit. On Nov. 23, 2010, a three-judge panel in *IMS Health v. Sorrell* overturned Vermont's law, reversing the lower court decision.

"We conclude that because section 17 is a commercial speech restriction that does not directly advance the substantial state interests asserted by Vermont, and is not narrowly tailored to serve those interests, the statute cannot survive intermediate scrutiny under *Central Hudson*," wrote Judge John Koeltl for the majority.

The decision creates a direct split with the 1st Circuit, which upheld a similar New Hampshire law in 2008. Some experts say *Sorrell* will likely end up before the Supreme Court.

"I see a pretty ripe issue for the Supreme Court to take up in the coming year," says Jonathan Weinrieb, a principal at Olsson Frank Weeda. "I don't see the Supreme Court letting this one rest."

Preventing Paternalism

For a variety of reasons, the court was unconvinced by Vermont's stated motives of protecting privacy, lowering health care costs and improving public health. In its analysis, the judges used the test outlined by the Supreme Court in *Central Hudson Gas & Electric v. Public Service Commission*, which states that the government may only regulate truthful commercial speech when restriction directly advances the state's interest.

"The court did a pretty rich analysis," says William Bernstein, the chair of Manatt, Phelps & Phillips' health care practice. It decided the Vermont law wasn't advancing those assertions, he says, and that there were less restrictive ways to accomplish the legislature's goals.

According to the ruling, PI data is used by the state of Vermont itself for law enforcement and other programs. Researchers use it to find drug overuse in specific populations, to develop new drugs and to find potential participants in clinical trials. The FDA, the Center for Disease Control and the Drug Enforcement Agency all use PI data to monitor usage of controlled substances and to help doctors who need time-sensitive safety information.

Insurance companies and pharmacy benefit managers use the data to process claims and manage formulary compliance. Moreover, insurance companies and state governments use PI data to encourage the use of cheaper, generic medications.

It didn't make sense to single out marketers from that long list, says James Beck, of counsel at Dechert.

"It was pretty poor to go and claim the right to privacy given how much privacy invasion was already allowed," says Beck, author of the Drug

Strikes at the Heart

In November 2008, the 1st Circuit upheld New Hampshire's Prescription Information Law in *IMS Health v. Ayotte*. The case was the same as *IMS Health v. Sorrell* in almost every way except for the result. Both suits were even filed by the same data-mining companies.

"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," Manatt, Phelps & Phillips Partner William Bernstein told InsideCounsel in a February 2009 story about the case.

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

and Device Law blog.

The underlying motivation behind the law was a reduction in "detailing," which refers to pharmaceutical representatives who visit doctors' offices to provide information about (and pitch) new pharmaceutical products. Critics say detailing leads doctors to prescribe more expensive name-brand drugs instead of cheaper, equally effective generic ones. Either way, section 17 ignored the fact that practitioners don't have to let the salespeople in the door to begin with, Bernstein says.

"[The law operates] on the theory that if drug companies were less persuasive, maybe doctors wouldn't be prescribing all these drugs," Beck says. "It assumes doctors are incapable of analyzing this information."

A Definitive Opinion

Resolving the split between *Sorrell* and the 1st Circuit's *IMS Health v. Ayotte* has national implications because many organizations use PI data for marketing or otherwise. Other states have introduced legislation that would restrict its use.

"A definitive statement from the Supreme Court is a good thing because it would add clarity to what is a very unclear area right now," Bernstein says.

For the time being, *Sorrell* should remind in-house counsel that the government generally may not regulate information like it would other products, Weinrieb says. The 2nd Circuit explicitly disagreed with the *Ayotte* court's opinion that information should be regulated the same way as beef jerky.

"[A]s the Supreme Court recently affirmed, courts do not have freewheeling authority to declare new categories of speech outside the scope of the First Amendment," Judge Koeltl wrote.

Regardless of *Sorrell's* final outcome, pharmaceutical companies may eventually have to deal with legislative distaste for detailing. But Bernstein says laws like section 17 are not the solution.

"It feels overly broad," Bernstein says. "I understand the concern with detailing. It just feels like this is using a meat ax to get at the problem."