Food & Drug

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First Circuit Upholds New Hampshire Law Banning Sale of Prescriber Information

A New Hampshire statute prohibiting the sale of prescriber-identifiable data for use in pharmaceutical detailing was upheld by a divided panel of the United States Court of Appeals for the First Circuit in an opinion issued on November 18, 2008.[1] The decision reversed an April 2007 ruling by the New Hampshire district court that had enjoined implementation of the law on First Amendment grounds.[2] The lawsuit was brought by two companies that purchase prescription data from pharmacies and process and sell the data to pharmaceutical companies for marketing uses.

The First Circuit, in an opinion written by Judge Selya and joined by visiting Judge Siler, held that the statute did not violate either the First Amendment or the Commerce Clause. Judge Lipez, concurring in part and dissenting in part, agreed with the result of the majority's First Amendment analysis but would have remanded the plaintiffs' Commerce Clause claims for further proceedings. The First Circuit's opinion is the first by an appellate court with respect to the constitutionality of statutory restrictions on the sale of prescriber-identifiable data.

I. Background

New Hampshire enacted the challenged statute in 2006 to curb the use of information related to individual physicians' prescribing histories in the course of "detailing," or face-to-face marketing communications between pharmaceutical representatives and physicians. The statute was primarily intended to contain rising prescription drug costs. Although New Hampshire was the first state to enact such a law, Maine and Vermont have since enacted prescriber-data legislation, and similar bills are pending in other states.

The New Hampshire statute provides, among other things: "Records relative to prescription information containing patient-identifiable and prescriber-identifiable data shall not be licensed, transferred, used, or sold by any pharmacy benefits manager, insurance company, electronic transmission intermediary, retail, mail order, or Internet pharmacy or other similar entity, for any commercial purpose," except for certain limited purposes.[3] "Commercial purpose 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."[4]

[1] *IMS Health Inc. v. Ayotte*, No. 07-1945 (1st Cir. Nov. 18, 2008).
[2] *See IMS Health Inc. v. Ayotte*, 490 F. Supp. 2d 163 (D.N.H. 2007).
[3] N.H. Rev. Stat. Ann. § 318:47-f. The acceptable commercial purposes listed in the statute are: "pharmacy reimbursement; formulary compliance; care management; utilization review by a health care provider, the patient's insurance provider or the agent of either; health care research; or as otherwise provided by law." *Id.*
[4] *Id.*

II. The First Circuit's Opinion

A. Standing

The court's opinion began with a discussion of standing. More specifically, the court addressed whether the plaintiffs, both "data miners" in the court's parlance, had standing to assert the First Amendment rights of pharmaceutical sales representatives or physicians.[5] The court observed that plaintiffs generally may not assert the rights of third parties unless they can demonstrate that the third party suffered a constitutional injury in fact, the plaintiff enjoys a close relationship with the third party, and an obstacle exists as to the third party's assertion of his or her own rights.[6] This exception to the third-party standing doctrine was not applicable here, the court held, because the record contained no evidence that either detailers or physicians were hindered from asserting their own rights. The court therefore restricted its analysis to whether New Hampshire's regulation of data miners' activities, i.e., "the acquisition, aggregation, and sale of prescriber-identifiable data," was constitutional.[7]

B. Speech or Conduct

With its analysis thus narrowed, the court considered whether the regulated activity qualified as speech protected by the First Amendment. The court held that the New Hampshire statute principally regulates conduct, not speech. In its view, the "challenged provisions serve only to restrict the ability of data miners to aggregate, compile, and transfer" a commodity, and it is of no First Amendment significance that the commodity is in the form of information.[8] Because the court determined that the challenged provisions fell outside the ambit of the First Amendment,[9] they were subject only to rational-basis review. Given the plaintiffs' concession that the statute satisfied that low level of scrutiny, the court held that their First Amendment challenge must fail.

C. Commercial Speech

Although it could have ended its analysis there, the court also decided the First Amendment claims on an "alternative ground."[10] Assuming that "the acquisition, manipulation, and sale of prescriber-identifiable data comes within the compass of the First Amendment," the court undertook the "intermediate scrutiny" applicable to regulation of commercial speech.[11] Under this type of review, "so long as the speech in question concerns an otherwise lawful activity and is not misleading[,] . . . statutory regulation of that speech is constitutionally permissible only if the statute is enacted in the service of a substantial governmental interest, directly advances that interest, and restricts speech no more than is necessary to further that interest."[12]

The court first agreed with New Hampshire that cost containment qualified as a "substantial" government interest under the commercial-speech doctrine.[13] The court also found that the state met its burden of demonstrating that its regulation of prescriber-identifiable data directly advanced that interest. In the court's view, New Hampshire

[5] The court characterized those First Amendment rights as "the rights of detailers to use prescriber-identifiable information in communicating face-to-face with physicians" and the "rights of physicians to receive that information during such interactions." *Ayotte*, slip op. at 14.
[6] *Id.* at 14-15 (citing *Craig v. Boren*, 429 U.S. 190, 194-95 (1976)).
[7] *Id.* at 16.
[8] *Id.* at 22-23.
[9] Although the majority acknowledged that "certain information exchanges are foreclosed" by the statute, it observed that those exchanges "are not . . . the sorts of exchanges valued by the Supreme Court's First Amendment jurisprudence but, rather, are exchanges undertaken to increase one party's bargaining power in negotiations." *Id.* at 26; *see also id.* at 22 ("[T]o the extent that the challenged portions impinge at all upon speech, that speech is of scant societal value.").
[10] *Id.* at 27.
[11] *Id.*
[12] *Id.* at 28 (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980)).
[13] The court did not address the other government interests cited by the state, "maintaining patient and prescriber privacy" and "protecting citizen's health from the adverse effects of skewed prescribing practices." *Id.*

presented sufficient evidence to the district court to support its contentions that detailing increases the number of prescription drugs prescribed by physicians, that the success of detailing is enhanced by use of prescriber information, and that detailing escalates drug costs without contributing to improved patient health. The court also determined that the state appropriately used this evidence to reason that restrictions on the use of prescriber information would decrease the number of brand-name drugs dispensed and, correspondingly, decrease drug costs.

Finding the first two prongs of the commercial speech doctrine satisfied, the court then considered whether the state "'could achieve its interests in a manner that does not restrict speech, or that restricts less speech.'"[14] The majority evaluated and rejected each of the district court's suggested alternatives to regulation and observed that the plaintiffs had also failed to identify an alternative that would "achieve the goals of the law without restricting speech."[15] The court therefore held that the challenged portions of the law satisfied intermediate scrutiny and were permissible under the First Amendment.

D. Additional Constitutional Challenges

The court rejected the plaintiffs' challenge to the New Hampshire statute as void for vagueness under the First Amendment. In a portion of the opinion joined by Judge Lipez, the court held that the statute was sufficiently clear when read in light of the legislature's manifest intent.

The majority of the court also rejected the plaintiffs' dormant Commerce Clause claims. Although the plaintiffs argued that the statute impermissibly regulated transactions taking place outside of New Hampshire, the state had expressed its view that the law would "'relate only to activity that takes place domestically.'"[16] The court found that the state's narrow interpretation of the law was reasonable and, therefore, that the statute survived a facial challenge under the Commerce Clause.

E. Judge Lipez's Opinion

Judge Lipez concurred in part and dissented in part. With respect to standing, Judge Lipez acknowledged that the plaintiffs could not satisfy the exception to the third-party standing doctrine described above. He noted, however, that the third-party standing doctrine is prudential, rather than constitutional, in nature, and that overriding pragmatic reasons warranted consideration of the primary First Amendment challenges in the case. Judge Lipez also rejected the majority's characterization of the regulated activity as conduct. He noted that the legislation was intended to modify the content of the marketing messages communicated by detailers, and "where the goal of a regulation relates to suppression of expression, even a restriction that indirectly achieves that objective may run afoul of the First Amendment."[17]

Judge Lipez therefore conducted his own analysis of the New Hampshire law under the commercial-speech doctrine. In addressing whether the statute directly advanced the goal of cost containment, Judge Lipez deferred to the state's determination that detailing leads to an increased tendency to prescribe unnecessary brand-name drugs. In particular, he noted: "The regulation was the first of its kind in the country, and it had been in effect for less than a year when the district court invalidated it. It is unreasonable in these circumstances to expect the Attorney General to provide extensive quantifiable data that might only become available after the statute has been in place for some time."[18] Judge Lipez further found that the restriction on speech was sufficiently limited in scope to pass the narrow-tailoring requirement of the commercial-speech doctrine.

[14] *Id.* at 38 (quoting *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 371 (2002)).
[15] *Id.* at 42.
[16] *Id.* at 49 (quoting Appellant's Reply Br. at 13).
[17] *Id.* at 87-91.
[18] *Id.* at 119.

Judge Lipez also dissented from the majority's Commerce Clause holding. He noted that the state's narrow reading of the law was not reasonable insofar as "the statute's impact in New Hampshire appears negligible if it truly governs only transactions that occur within the state."[19] Judge Lipez would have instead remanded the claims to the district court for further fact-finding regarding the flow of prescriber-identifiable data between pharmacies, data miners, and detailers.

III. Implications

The First Circuit's opinion will affect legal challenges currently pending against similar legislation enacted by Maine and Vermont. The Maine statute, which incorporates an opt-out requirement but is otherwise similar to the New Hampshire law, was struck down by a federal district court last year and is now the subject of a First Circuit appeal.[20] The appellate proceedings were stayed pending resolution of *Ayotte*, which will now be binding precedent.[21] The challenge to the Vermont law, which uses an opt-in structure, is awaiting a decision by the federal district court.[22] In addition, the Vermont Attorney General has postponed implementation of the law until July 1, 2009.

The opinion may also have implications in other states. In 2008, legislation that would limit or prohibit the sale or use of prescriber-identifiable data was introduced in more than a dozen states.[23] The First Circuit's opinion upholding this type of law could lead to renewed activity in these and other states.

With respect to the New Hampshire statute, unless the plaintiffs seek rehearing en banc, the district court's injunction will be lifted and the law will take effect on December 9, 2008. The First Circuit left the door open, however, to future First Amendment challenges by detailers or physicians. The majority opinion noted that "[b]ecause no pharmaceutical company is a party to this litigation, we decline to address whether an action could be maintained under the Prescription Information Law against a pharmaceutical company that uses data properly acquired for one purpose to target physicians for detailing."[24] The majority also observed that "[a]lthough speech, protected or not, is implicated by the [statute], it consists primarily of communications between detailers and doctors," and "an adjudication of that aspect of the law must await a proper plaintiff."[25]

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[19] *Id.* at 145.
[20] *See IMS Health Corp. v. Rowe*, 532 F. Supp. 2d 153 (D. Me. 2007) (invalidating P.L. 2007, Ch. 460, § 1711-E(2-A)).
[21] *See IMS Health Inc. v. Rowe*, No. 08-1248 (1st Cir. filed Mar. 4, 2008).
[22] *See IMS Health Inc. v. Sorrell*, No. 07-cv-188-JGM (D. Vt. filed Aug. 29, 2007).
[23] Legislation is currently pending in Arizona (SB 1251) and Illinois (SB 2893 and HB 1459).
[24] *Ayotte*, slip op. at 46 n.10.
[25] *Id.* at 24.