

Health Law Advisory: Federal Court Upholds Vermont Law Restricting the Sale and Use of Prescriber-Identifiable Data

5/4/2009

On April 23, 2009, the United States District Court for the District of Vermont dealt another blow to pharmaceutical manufacturers and the data mining companies that sell prescriber-identifiable data to them by upholding a Vermont law prohibiting various entities from selling or using such data for marketing purposes without prescriber consent. *IMS Health Inc. v. Sorrell*, No. 07-cv-188 (D. Vt. Apr. 23, 2009). The ruling follows the recent ruling by the U.S. Court of Appeals for the First Circuit upholding a similar New Hampshire law. A full summary and analysis of the First Circuit's decision is available [here](#).

The Vermont legislature enacted the law, codified at [Vt. Stat. Ann. Tit. 18, § 4622](#), to curb the state's prescription drug costs, which it believed had increased in large part due to the provision of promotional and educational information by pharmaceutical sales representatives to prescribers during face-to-face meetings — a practice commonly known as “detailing.” To increase the effectiveness of detailing activities, pharmaceutical companies analyze prescriber-identifiable data to understand the habits of specific prescribers and then tailor their marketing message to the individual prescriber. Pharmaceutical sales representatives only detail branded drugs, which typically are more expensive than the generic alternatives.

The Vermont law prohibits data mining companies from selling, and pharmaceutical manufacturers and marketers from using, prescriber-identifiable data for marketing purposes without the prescriber's consent. Prescriber consent may be provided via an “opt-in” provision on licensing applications and renewal forms and may be revoked by the prescriber. The pharmaceutical and data mining companies asserted that the law restricted speech in violation of the First Amendment. The data mining companies also argued that the law affected interstate commerce in violation of the dormant Commerce Clause.

The First Amendment Analysis

Unlike the majority in the First Circuit case, the District Court of Vermont held that prescriber-identifiable data is protected “speech” under the First Amendment. The court then held that the law satisfied all three elements of the test used to analyze commercial speech. With respect to the first element, the court found that the law was sustainable on the state's cost containment and public health interests, which it found to be substantial. The court stated that, because it had accepted cost containment and the protection of public health as substantial government interests, it did not need to address the Vermont Attorney General's assertion that the protection of prescriber privacy also was a substantial government interest. Next, the court noted that the Vermont legislature had chosen to counter the over-prescription of “detailed” drugs by restricting

the use of prescriber-identifiable data in marketing activities, and found that the Attorney General had presented “ample evidence” that a shift in prescribing practices from detailed drugs to generics would result in a significant cost savings to the state. Finally, the court found that the law’s marketing restriction was a “targeted response” to the harms caused by the over-prescription of detailed drugs, noting that the law did not prohibit the practice of detailing and that sales representatives remained free to distribute medical literature about the detailed drugs.

The Dormant Commerce Clause Analysis

The data mining company plaintiffs also asserted that the statute improperly restricted interstate commerce in violation of the dormant Commerce Clause because it allowed Vermont pharmacies to transfer prescriber-identifiable data to their out-of-state parent entities but then prevented those out-of-state parent entities from contracting with out-of-state data mining companies to sell the data. The data mining companies also argued that, because the statute imposed penalties on pharmacies and similar entities that permit the use of prescriber-identifiable data for marketing, those entities must place contractual limitations on purchasers’ downstream uses, thus imposing Vermont’s laws on contracts executed outside of Vermont.

The court recognized that the Vermont statute would impact data companies located outside of Vermont by eliminating their ability to sell prescriber-identifiable data originating in Vermont for use in marketing activities directed at Vermont prescribers. But the court also noted that data companies were free to conduct this business in connection with all other states because the Vermont statute did not regulate the sale or use of data originating in any other state. The court stated that Vermont pharmacies “[could] not avoid compliance simply by routing data through a parent company’s server on its way to data vendors,” and noted that the Second Circuit had made it clear that “state regulations are not rendered unconstitutional simply because a business uses the Internet to conduct transactions.”

The court’s holding is significant because it answers a question the First Circuit declined to address. In its decision, the First Circuit held that the New Hampshire statute, which was similar in scope to the Vermont statute, was constitutional under the dormant Commerce Clause. The court based its holding on the New Hampshire Attorney General’s interpretation of the law, which she asserted was not intended to reach activities outside of New Hampshire. The First Circuit conceded that the Attorney General’s interpretation of the law would permit the routine transfer of data out-of-state where it then could be aggregated and legally sold to others and thus “may not accomplish very much.” In a footnote to this concession, the court withheld judgment on a key issue, stating that, “the question remains, however, whether the purchasers could subsequently make use of the aggregated data in New Hampshire. That question is not before us.” *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 64 (1st Cir. 2008). The District Court of Vermont addressed this question head-on, and held that purchasers could not subsequently make use of such aggregated data. This holding may embolden other states considering similar legislation and create a trend towards increased regulation of data sales.

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