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Supreme Court Strikes Down Vermont Prescriber Data-Restriction Law

By William S. Bernstein | Susan R. Ingargiola | Anne Karl

On June 23, 2011, the United States Supreme Court struck down Vermont's law restricting the sale, disclosure, and use of pharmacy records that reveal the prescribing patterns of individual physicians. Vermont and other states with similar laws argue that these laws both protect physician privacy and curtail growth in health care spending. But others, including pharmaceutical manufacturers, argue that they place undue restrictions on freedom of speech.

Vermont pharmacies collect and store information about the prescriber and prescription when filling prescriptions. Pharmacies retain information including the prescriber's name and address, as well as the type and quantity of drug prescribed. Many pharmacies then sell the prescriber information to "data miner" firms that analyze the prescriber information and produce reports on prescriber behavior. The data miners then lease these reports to pharmaceutical manufacturers. Pharmaceutical marketers called "detailers" use these reports to tailor their marketing efforts.

In 2007, Vermont enacted the Prescription Confidentiality Law to restrict the use of prescriber-identified data for marketing purposes.[1] First, the Prescription Confidentiality Law prohibits pharmacies, health insurers, and similar entities

from selling prescriber-identified data without the prescriber's consent. Second, the law bars pharmacies, health insurers, and similar entities from allowing prescriber-identified information to be used for marketing purposes. Finally, the law prohibits pharmaceutical marketers and manufacturers from using prescriber-identified information for marketing without the prescriber's consent. Prescriber-identified data may, however, be used without the prescriber's consent for the following activities:

- Health care research,
- To enforce compliance with a health insurance plan's formulary,
- Patient care management educational communications,
- Law enforcement operations, and
- Any other purpose permitted by law.

IMS Health, Inc., Verispan, LLC, and Source Healthcare Analytics, Inc., three data-mining companies, filed suit in August 2007 to prevent the enforcement of the Prescription Confidentiality Law. An association of pharmaceutical manufacturers separately filed suit, and the two suits were later consolidated. The data miners and manufacturers argue that the law violates their freedom of speech under the First Amendment and that it restricts commercial activities outside Vermont in violation of the Commerce Clause.

The United States District Court for the District of Vermont upheld the law, finding that it was a permissible restriction on commercial speech and did not violate the Commerce Clause.[2] In November 2010, the United States Court of Appeals for the Second Circuit reversed the District Court's decision and struck down the law, finding that the law violates the First Amendment by burdening the speech of pharmaceutical manufacturers and data miners without adequate justification.[3] The Second Circuit's decision conflicted with decisions of the United States Court of Appeals for the First Circuit addressing similar legislation in New Hampshire

and Maine. To resolve the conflict among the Circuits, the Supreme Court agreed to hear the case.

The Supreme Court affirmed the Second Circuit's decision striking down Vermont's Prescription Confidentiality Law by a vote of 6-3. In an opinion by Justice Kennedy, the Court held that burdens placed on the protected speech of pharmaceutical manufacturers and data miners do not directly advance a substantial interest of the State and that the measure is not tailored to achieve that interest. Specifically, the Court found that the law fails to protect prescriber privacy, since the law permits the use of prescriber-identified information in an array of circumstances. Additionally, the Court found that the law only indirectly advances the State's interest in controlling health care costs by limiting a certain speech by certain speakers, noting that other efforts, such as counter-detailing (*i.e.*, promoting lower-cost generic drugs when effective), might be equally effective in curtailing costs while protecting the rights of pharmaceutical manufacturers and data miners.

As this case proceeded through the federal courts, health care quality advocates argued that the Vermont law and others like it could impede the potential of emerging health information technology ("health IT") tools to improve patient care and public health. With the advent of health IT tools like electronic health records that enable the collection, exchange, aggregation, and analysis of health information, experts can analyze health care providers' performance and suggest paths for improvement. Quality advocates argue that data-restriction laws like Vermont's could create enough uncertainty about the legality of certain activities that pharmacies and data miners would be reluctant to make available any prescriber data, including for permissible quality-improvement efforts. Manatt filed amicus curiae briefs on behalf of several stakeholders in the Vermont and New Hampshire cases, making this and other arguments.

With the Supreme Court's decision, states will no longer be able to create sweeping restrictions on the use of prescriber-identified information for use in

pharmaceutical marketing. Health care stakeholders will now be watching closely to see whether states seek to enact new laws that are similar to Vermont's but that are tailored not to run afoul of the First Amendment or whether states seek to combat growth in health care costs in other ways.

For questions or for more information, contact William Bernstein at 212-830-7282, Susan Ingargiola at 212-790-4639, or Anne Karl at 212-790-4578.