

FDA Law Update

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Vermont Data Mining Law Under Review By 2nd Circuit Appeals Court

We reported recently that Vermont's data mining law (i.e. Vermont's Prescription Confidentiality Law), which is to take effect on July 1, was upheld by the U.S. District Court for the District of Vermont. The law will ban all use of prescriber data for marketing purposes unless a physician explicitly agrees to a waiver. On June 23, 2009, the 2nd Circuit was petitioned to prevent enactment of the law in an appeal from a district court holding that although prescriber data is protected speech under the First Amendment, the law itself is not unconstitutional because it satisfies the three-prong test used by courts to analyze statutory limitations of commercial speech.

The companies appealing the lower court decision are known as health information organizations ("HIOs"). HIOs create prescriber profiles by purchasing doctors' prescribing information from pharmacies. Such prescribing information includes the physician's name, specialty, practice site, and which and how many prescriptions the physician writes. HIOs sell this information to pharmaceutical companies who use the information to tailor marketing strategies to individual physicians.

Attorneys representing IMS Health Inc., Verispan LLC, and Source Healthcare Analytics Inc., argued to the 2nd Circuit that Vermont's data mining law would violate the First Amendment rights of HOIs because information collected is noncommercial speech protected by the First Amendment. Since the parties are expected to follow up with written arguments within the next two months, the attorneys for the HIOS have argued that implementation of the law be stayed until the 2nd Circuit issues its ruling.

Proponents for the Vermont data mining law argued the ban on use of prescriber data for marketing purposes promotes public health, medical privacy and will contain health care costs. Attorneys for proponents further argue the state has proven that data mining by companies leads to higher health care costs and contributes to inappropriate prescribing decisions. The HIOs strongly opposed these statements, responding that the state could not prove that the law will result in lower health care costs, and, in fact, that the law likely will drive up health care costs.

We await the 2nd Circuit's decision.

As noted in our previous post, the U.S. Supreme Court also has been asked to review the data

mining issue, specifically the 1st Circuit Court of Appeals decision to uphold New Hampshire's Prescription Privacy Law. The Supreme Court has not indicated whether it will take up this issue.

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