

# Client Alert

FDA & Life Sciences Practice Group

June 24, 2011

## **U.S. Supreme Court Issues Opinion in *Sorrell v. IMS Health, Inc.*, Striking Down Vermont Prescription Confidentiality Law (Vt. Stat. Ann., Tit. 18, § 4631(d), amended by H. 750)**

For more information, contact:

**Seth H. Lundy**  
+1 202 626 2924  
slundy@kslaw.com

**Patrick Morrissey**  
+1 202 626 3740  
pmorrissey@kslaw.com

**Nikki Reeves**  
+ 1 202 661 7850  
nreeves@kslaw.com

**Brian Bohnenkamp**  
+1 202 626 5413  
bbohenkamp@kslaw.com

**Ami Patel**  
+1 202 626 9257  
appatel@kslaw.com

**King & Spalding**  
**Washington, D.C.**  
1700 Pennsylvania Avenue, NW  
Washington, D.C. 20006-4707  
Tel: + 1 202 737 0500  
Fax: +1 202 626 3737

[www.kslaw.com](http://www.kslaw.com)

The United States Supreme Court issued its decision in *Sorrell v. IMS Health, Inc., et al.* on June 23, 2011. The 6-3 decision, authored by Justice Anthony Kennedy, struck down the Vermont Prescription Confidentiality Law (Vt. Stat. Ann., Tit. 18, § 4613(d), amended by H. 750) as unconstitutional restriction of First Amendment commercial speech.

A summary of this case and the related prescriber data privacy cases, authored by King & Spalding attorneys Edward Basile and Marian Lee, appeared as chapter 13, “IMS Health Inc. v. Sorrell,” in *Top 20 Food and Drug Cases, 2010 & Cases to Watch, 2011*, edited by John B. Reiss (FDLI 2011).

### **Background and Procedural History**

The Vermont Prescription Confidentiality Law was originally enacted in 2007. The law restricts the sale or use of prescriber-identifiable prescription information for marketing or promoting a prescription drug, unless the prescriber has consented to such use. The law additionally states that pharmaceutical manufacturers and marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents. There are several exceptions to the general restriction, including the use of prescriber-identifiable information for “health care research,” “pharmacy reimbursement,” “prescription drug formulary compliance,” and for purposes that are “otherwise provided by law.”

The constitutionality of the law was challenged in the U.S. District Court for the District of Vermont almost immediately by three data mining companies, IMS Health, Source Healthcare Analytics, Inc., and Verispan LLC, and separately by the Pharmaceutical Research and Manufacturers of America (PhRMA). In an April 2009 decision combining the two challenges, the District Court upheld the law as constitutional. The Court held that the Vermont law is a “limited restraint” on protected commercial speech and that the restrictions are reasonably proportioned to the Vermont’s stated interests, which include protecting prescriber privacy and cost containment.

# Client Alert

FDA & Life Sciences Practice Group

The three companies and PhRMA appealed the District Court decision to the United States Court of Appeals for the Second Circuit (Second Circuit). The Second Circuit reversed the District Court decision in November 2010, holding that the Vermont Prescription Confidentiality Law is an unconstitutional regulation of commercial speech because it “does not directly advance the substantial state interests asserted by Vermont and is not narrowly tailored to serve those interests.”

Prior to the Second Circuit’s decision, the First Circuit Court of Appeals had upheld the constitutionality of similar prescriber data privacy laws in New Hampshire in November 2008 and Maine in August 2010. The Supreme Court had denied *certiorari* of the appeals from the First Circuit (*IMS Health, Inc. v. Ayotte* (New Hampshire), *IMS Health, Inc. v. Mills* (Maine)); however, the Second Circuit’s decision presented a “circuit split” with two Circuit Courts reaching different conclusions regarding the constitutionality of prescriber data privacy laws. Following the Second Circuit’s decision, Vermont Attorney General William Sorrell petitioned the U.S. Supreme Court to review the case and in effect resolve the circuit split. The U.S. Supreme Court granted the request for review in January 2011 and heard arguments in April 2011.

## ***Sorrell v. IMS Health, Inc. Decision***

In its June 23, 2011 decision, the U.S. Supreme Court held that the Vermont Prescription Confidentiality Law is subject to heightened judicial scrutiny and the State’s justifications for the law do not withstand that scrutiny.

The Court found that the Vermont law, on its face, enacts content-based and speaker-based restrictions on the sale, disclosure, and use of prescriber-identifiable information by limiting the marketing of pharmaceutical products by pharmaceutical manufacturers. The exceptions to the law allows prescribed-identifiable information to be purchased and used for other forms of speech (*i.e.*, research) by other speakers. In its application, the Vermont law “goes even beyond mere content discrimination, to actual viewpoint discrimination.” The Court did not agree with Vermont’s argument that the law is a restriction of conduct and not commercial speech. The Court stated, the “creation and dissemination of information are speech within the meaning of the First Amendment.” For these reasons, the restrictions in the Vermont law are subject to heightened judicial scrutiny.

The Court held that Vermont’s justifications for the law do not withstand heightened judicial scrutiny. To withstand heightened judicial scrutiny, the State’s interests must be proportional to the burdens imposed by the law. Vermont argued that the law advanced the State’s goal of protecting medical privacy, which includes maintaining physician confidentiality, avoiding harassment from pharmaceutical marketers and preserving the integrity of the patient-physician relationship. The Court found that the law was not designed to address those interests, particularly in light of the exceptions to the law that allow for “widespread availability and many permissible uses” of the information. The Court was critical of the opt-in provision of the Vermont law, which allows prescribers to consent to the use of the prescribing information for marketing purposes. The Court called this a “contrived choice,” by which prescribers may either consent to having their information used for marketing purposes, or withhold consent, allowing their information to be used by “speakers whose message the State supports.”

Vermont’s other justification for the Prescription Confidentiality Law is related to policy objectives, namely improved public health and reduced healthcare costs. The State indicated that with the aid of prescriber-identifiable information, detailers are more effective at promoting brand-name pharmaceutical products and prescribers may be less likely to

# Client Alert

FDA & Life Sciences Practice Group

prescribe generic alternatives. The Court found that the State's impression that brand-name pharmaceutical detailers are too effective or persuasive does not justify content-based restrictions on speech. The Court held that the law was an indirect means that did not appropriately advance Vermont's policy objectives.

## ***Sorrell v. IMS Health, Inc. Dissent***

Justice Stephen Breyer wrote a dissenting opinion in *Sorrell*, and was joined in the opinion by Justices Ruth Bader Ginsburg and Elena Kagan. In the dissent, Justice Breyer wrote that the Vermont Prescription Confidentiality Law is a permissible regulation of a commercial enterprise and should not be reviewed under the heightened standard reserved for First Amendment issues. Moreover, the dissent stated that the law meets the First Amendment standard as it "meaningfully furthers substantial state interests," related to privacy and public health.

## **Ramifications**

The *Sorrell* case invalidates the current Vermont Law and allows companies, such as IMS Health, Source Healthcare Analytics, Inc., and Verispan LLC, to resume the sale and distribution of Vermont prescriber-identifiable data. Although the *Sorrell* case was decided on the unique facts and arguments presented in Vermont, the result is likely to raise further challenges to the similar prescriber data privacy laws in New Hampshire and Maine, which are now likely to be similarly struck down.

*Celebrating 125 years of service, King & Spalding is an international law firm with more than 800 lawyers in Abu Dhabi, Atlanta, Austin, Charlotte, Dubai, Frankfurt, Geneva, Houston, London, New York, Paris, Riyadh (affiliated office), San Francisco, Silicon Valley, Singapore and Washington, D.C.. The firm represents half of the Fortune 100 and, according to a Corporate Counsel survey in August 2009, ranks fifth in its total number of representations of those companies. For additional information, visit [www.kslaw.com](http://www.kslaw.com).*

*This alert provides a general summary of recent legal developments. It is not intended to be and should not be relied upon as legal advice.*