BNA

Pharmaceutical Law & Industry Report

VOL. 0, NO. 0 JULY 15, 2011

Does *Sorrell v. IMS Health* Mark the End of Off-Label Promotion Prosecution?




BY LISA BLATT, JEFFREY HANDWERKER, JOHN NASSIKAS, AND KIRK OGROSKY

On June 23, 2011, the U.S. Supreme Court held in *Sorrell v. IMS Health Inc.*, No. 10-779, that Vermont violated the First Amendment by banning pharmaceutical manufacturers from marketing or promoting their drugs to physicians based on a physician's prescription history. The Court held 6-3, in an opinion authored by Justice Kennedy, that Vermont law's was subject to ''heightened scrutiny'' because it prohibited pharmaceutical manufacturers from ''communicat[ing] with physicians in an effective and informative manner.''[1] The Court also held that the law violated intermediate scrutiny under *Central Hudson & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), applicable to restrictions on commercial speech.

In holding that the law was subject to heightened scrutiny, the Court reasoned that the law selectively burdened a manufacturer's ability to disseminate truthful and non-misleading information about life-saving medicine while permitting other participants in the marketplace, such as the government and insurers, to disseminate such information without restriction. This article addresses the impact of the *Sorrell* decision on the debate over the constitutional validity of ''off-label'' promotion prohibitions. The Food and Drug Administration's (FDA) prohibitions may unconstitutionally prevent pharmaceutical and medical device manufac-

Blatt, Handwerker, Nassikas, and Ogrosky are partners at Arnold & Porter LLP in its Washington office. They may be reached at (202) 942-5000. All express their gratitude to firm associates Robert Katerberg and Murad Hussain for their assistance with this article. The firm represented the Pharmaceutical Research and Manufacturers of America in the Sorrell *case before the U.S. Supreme Court.*

[1] *Sorrell*, Slip Op. (Majority Op.) at 9 (9 PLIR 771, 6/24/11).

 ISSN 1542-9547

turers from providing physicians with truthful and nonmisleading information about medically accepted uses for FDA-approved pharmaceuticals and devices. The implications of *Sorrell* for the FDA's off-label promotion regulatory regime may be tested in litigation, as well as in new regulations, in the months ahead. In addition, the Department of Justice (DOJ) will undoubtedly be troubled by *Sorrell* because their enforcement efforts have rested on a narrow interpretation of the First Amendment.

Lower Court Proceedings

At issue in *Sorrell* was the pharmaceutical manufacturers' practice of marketing branded drugs through one-on-one ''detailing'' visits by sales representatives to physician' offices using data summarizing physician prescribing histories. Manufacturers use this information about physician prescribing histories to target sales visits and the message they communicate to physicians. Manufacturers purchase this data from data aggregation companies, which in turn acquire the data from pharmacies. By using prescribing pattern data, manufacturers focus their commercial marketing practices in ways that provide useful information to physicians based on the types of disease for which physicians most frequently prescribe medication.

Three states banned the manufacturers' use of prescriber data to thwart detailers' efforts to persuade doctors to prescribe branded or newer drugs over generic or older drugs. States also cited the need to protect a purported privacy interest in the doctor's prescription history, even though the information contained no patient-specific information. In 2007, Vermont enacted its ''Prescription Confidentiality Law,'' or Act 80, prohibiting pharmacies, health insurers, and similar entities from selling prescriber data, absent a prescriber's consent, subject to a wide range of statutory exceptions.[2] The law also barred pharmaceutical companies from using prescriber data for promotional purposes unless the prescriber had consented to the use. The statute permitted, however, insurance companies, the state, academic detailers, and anyone else other than a pharmaceutical company to use prescriber data for promotional purposes without obtaining prescriber consent.

The Pharmaceutical Research and Manufacturers of America, as well as IMS Health Inc. and other data aggregators, challenged Vermont's law under the First Amendment. A federal district court held that the law was constitutional under the intermediate scrutiny standard set forth in *Central Hudson Gas*.[3] Under *Central Hudson*, commercial speech receives First Amendment protection if it ''concern[s] lawful activity'' and is not ''misleading.''[4] If those criteria are met, any commercial speech restriction must ''directly advance'' a ''substantial'' governmental interest and may not be ''more extensive than is necessary to serve that interest.''[5] The district court concluded that the law directly advanced Vermont's asserted interests in cost containment and protecting public health.

In November 2010, the U.S. Court of Appeals for the Second Circuit reversed, holding Act 80 unconstitutional. Applying the *Central Hudson* test, the Second Circuit found that although Vermont had asserted substantial state interests, Act 80 did not directly advance those interests, nor was it sufficiently tailored. For example, the court of appeals reasoned that the law did not ''directly restrict the prescribing practices of doctors,'' nor did it ''directly restrict the marketing practices of detailers. Rather, the law was designed to ''restrict[] the information available to detailers so that their marketing practices will be less effective and less likely to influence the prescribing practices of physicians.''[6] In addition, the law was not adequately tailored to fit Vermont's asserted interests because the law applied ''to *all* brand name prescription drugs, irrespective, for example, of whether there is a generic alternative or whether an individual drug is effective or ineffective.''[7]

The Second Circuit's decision created a circuit split with the First Circuit's prior decisions in *IMS Health Inc. v. Ayotte*[8] and *IMS Health Inc. v. Mills*.[9] The First Circuit decisions had upheld similar laws enacted in New Hampshire and Maine. Although the Supreme Court had previously declined to review the First Circuit's *Ayotte* decision, it granted the *Sorrell* petition for writ of *certiorari* in January 2011.

The Supreme Court Decision

Justice Kennedy's opinion for the Court began by reviewing the two key sentences of Act 80. The first sentence barred pharmacies from disclosing information about a physician's past prescribing practices without the prescriber's consent. The second sentence prohibited pharmaceutical manufacturers and marketers from using a physician's prescription history for marketing without the physician's consent. Act 80 defined ''marketing'' broadly to include '' 'advertising, promotion, or any activity' that is 'used to influence sales or the market share of a prescription drug.' ''[10]

The Court observed that the law contained a number of statutory exceptions to the prohibitions on using and disseminating prescriber-identifying information. These exceptions allowed prescriber-identifiable data to be used for: (a) health care research, (b) enforcing compliance with health insurance formularies, (c) caregivers' communications with patients about treatment options, and (d) law enforcement operations. In addition, Act 80 authorized funding for state-sponsored ''counter-detailing'' efforts in which health care personnel would visit prescribers to educate them about availability of lower cost or generic substitutes for branded prescription drugs.

Next, the Court examined Act 80's findings and discriminatory purpose. The legislature enacted statutory ''findings'' that, among other things, asserted that the ''marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name

[2] Vt. Stat. Ann., Tit. 18, § 4631.

[3] *IMS Health Inc. v. Sorrell*, 631 F. Supp. 2d 434 (D. Vt. 2009).

[4] *Id.* at 566.

[5] *Id.*

[6] *IMS Health Inc. v. Sorrell*, 630 F.3d 263, 277 (2d Cir. 2010).

[7] *Id.* at 279.

[8] 550 F.3d 42 (1st Cir. 2008).

[9] 616 F.3d 7 (1st Cir. 2010), *vac'd and remanded sub. nom IMS Health Inc. v. Schneider*, No. 10-984 (June 28, 2011) (remanding for consideration in light of *Sorrell*).

[10] *Sorrell*, Slip Op. (Majority Op.) at 3 (quoting statute).

  PLIR ISSN 1542-9547

companies invest in expensive pharmaceutical marketing campaigns to doctors.''[11] The Vermont legislature also found that detailing causes busy doctors to rely too heavily and too soon upon biased information provided by pharmaceutical representatives; that it increases the cost of health care and insurance; and that the use of physician prescription histories makes detailing more effective by helping marketers target specific doctors and tailor their presentations accordingly.

The Supreme Court held that Act 80 imposed a content-based, speaker-based, and viewpoint-based burden on pharmaceutical companies' speech. The Court explained that the law prohibited sales of prescription histories to pharmaceutical companies for promotional purposes, but allowed speakers who promoted the state's preferred message, such as insurance companies and academic detailers, to purchase and freely use that information. In the Court's words: the law ''disfavors specific speakers, namely pharmaceutical manufacturers'' and ''has the effect of preventing detailers – and only detailers – from communicating with physicians in an effective and informative manner.''[12] The Court concluded that the law's ''express purpose and practical effect are to diminish the effectiveness of marketing by manufacturers of brand-name drugs.''[13]

Because the law is content and viewpoint-based, the Court found it subject to ''heightened judicial scrutiny.''[14] Significantly, *Sorrell* represents the first occasion in which the Court has held that a commercial speech restriction is subject to heightened review. Indeed, the Court rejected the State's arguments against this more stringent standard of review. The Court rejected the State's argument that the law was merely a commercial regulation that imposed only ''an incidental burden on protected expression.''[15] And in response to Vermont's argument that the law regulated only ''access to information,'' the Court explained that the law burdened speech based on both content and speaker.[16] Vermont also maintained that the initial sale of prescriber data is conduct outside the First Amendment's reach, likening the raw data regarding which physicians prescribe which medicines to a ''mere 'commodity.' ''[17] The Court expressed skepticism about this argument too, observing that ''the creation and dissemination of information is speech.''[18] In the end, however, the Court declined to reach this issue because Vermont's statute, like ''a law prohibiting trade magazines from purchasing or using ink.'' ''impose[d] a speaker- and content-based burden on the availability and use of prescriber-identifying information'' by pharmaceutical manufacturers.[19]

In addition to finding the law invalid under ''heightened judicial scrutiny,'' the Court also invalidated the Act under *Central Hudson*, which the Court explained required Vermont to ''show at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest.''[20] The Court rejected Vermont's reliance on two justifications for the law: (1) protecting ''medical privacy, including physician confidentiality, avoidance of harassment, and the integrity of the doctor-patient relationship;'' and (2) achieving ''policy objectives'' of ''improved public health and reduced healthcare costs.''[21]

The Court explained the asserted privacy interest was belied by the fact that the law made prescriber data ''available to an almost limitless audience,'' other than the manufacturers whose speech the government disfavored.[22] And in rejecting Vermont's reliance that the law allowed physicians to consent to the use of the data, the Court stated: ''Vermont has given its doctors a contrived choice: Either consent, which will allow your prescriber-identifying information to be disseminated and used without constraint; or, withhold consent, which will allow your information to be used by those speakers whose message the State supports.''[23] The Court reasoned that ''if pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive. The fear that speech might persuade provides no lawful basis for quieting it.''[24] While Vermont was free to disseminate its messages about pharmaceuticals through counter-detailing programs, the government's inability to persuade ''does not allow it to hamstring the opposition'' or to ''burden the speech of others in order to tilt public debate in a preferred direction.''[25] The Court similarly stated that the law impermissibly ''burdened a form of protected expression that [the state] found too persuasive'' while leaving ''unburdened those speakers whose messages are in accord with [the state's] own views.''[26]

Impact on Truthful and Non-Misleading Promotion

Sorrell provides strong support for challenging FDA's efforts to regulate what the government calls the off-label promotion of drugs for medical uses that are not approved by the FDA. Broadly construed, *Sorrell* stands for the proposition that absent compelling circumstances, the government cannot consistent with the First Amendment criminalize truthful and non-misleading speech about lawful conduct, particularly when that lawful conduct concerns a physician's prescription of an FDA-approved medication for a medically accepted off-label use. Despite the vigor of recent government enforcement efforts against pharmaceutical manufacturers, no statute forbids the promotion of FDA-approved drugs for uses that are unapproved. Quite to the contrary, federal law *prevents* the FDA from interfering with a physician's decision to prescribe drugs for off-label use as an exercise of his or her medical judgment.[27]

Notwithstanding the prevalent, medically accepted, and lawful use of off-label drugs, the government pro-

[11] *Id.* at 25 (quoting statute).
[12] *Id.* at 8-9.
[13] *Id.* at 9.
[14] *Id.* at 11.
[15] *Id.*
[16] *See id.* at 12-14.
[17] *Id.* at 14.
[18] *Id.* at 15.
[19] *Id.*
[20] *Id.* at 16.
[21] *Id.* at 17.
[22] *Id.* at 18.
[23] *Id.*
[24] *Id.* at 21.
[25] *Id.* at 23.
[26] *Id.* at 25.
[27] *See* 21 U.S.C. § 396 (''Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally mar-

hibits manufacturers from speaking about the subject in obtuse FDA regulations that purport to define the meanings of ''misbranded'' drugs.[28] Similar to the law the Court invalidated in *Sorrell*, FDA regulations singularly criminalize pharmaceutical companies' efforts to ''communicat[e] with physicians in an effective and informative manner,''[29] *e.g.*, by discussing off-label uses for their drugs that physicians routinely prescribe in a course of accepted medical practice. Unlike drug manufacturers, other speakers may, without fear of prosecution, freely discuss off-label uses of FDA-approved drugs.

For example, a pharmaceutical sales representative would not be allowed to inform a doctor – truthfully and accurately – of the fact that a drug compendium lists a product for a certain use, if that use is not already on the product's FDA-approved label. The same sales representative cannot describe the contents of a *New England Journal of Medicine* article that describes a clinical trial unrelated to a drug's FDA-approved label indication (unless compliant with the Good Reprint Practices). But doctors, public health organizations, insurance companies, academics, the media, or anyone else may freely communicate that same information to physicians without restrictions. Thus, the exact same conversation that one doctor can freely have with another doctor is a crime when the speaker works for a pharmaceutical or medical device manufacturer.

Sorrell builds on prior Supreme Court precedent in establishing a strong foundation to argue that a pharmaceutical company's truthful, non-misleading information about its products cannot be subjected to content-based and speaker-based restrictions.[30] First, the Supreme Court repeatedly emphasized in *Sorrell* that the ''dissemination of information [is] speech,'' and noted that ''[f]acts . . . 'are the beginning point for much of the speech that is most essential to advance human knowledge and conduct human affairs.' ''[31] As a result, there is little doubt that discussions of off-label uses trigger First Amendment analysis, as opposed to being deemed mere ''conduct.''

The FDA's regulation of off-label promotion may be even *more* vulnerable to First Amendment scrutiny than the Vermont law struck down in *Sorrell*. FDA's regulations make speech a crime. By contrast, Act 80 did not directly censor any message by pharmaceutical companies; it simply deprived them of using a prescriber's history to identify the physicians who would be most interested in a particular message or drug. The Court noted that Vermont's law nonetheless violated the First Amendment because ''the distinction between laws burdening and laws banning speech is but a matter of degree'' and ''[l]awmakers may no more silence unwanted speech by burdening their utterance than by censoring its content.''[32] FDA's regulations criminalizing speech about off-label promotion is a much more direct and punitive burden on truthful speech.

Indeed, in dissent, Justice Breyer specifically offered FDA regulation as a leading example of the type of ''widely accepted regulatory activity'' that was ''threaten[ed]'' by the *Sorrell* decision.[33] According to Justice Breyer, ''the same First Amendment standards that apply to [Act 80] would apply to similar regulatory actions taken by . . . the Federal Government acting, for example, through [FDA] regulation.''[34] For example, ''the FDA oversees the form and content of labeling, advertising, and sales proposals of drugs, but not of furniture.''[35] In addition, ''[t]he FDA might control in detail just what a pharmaceutical firm can, and cannot, tell potential purchasers about its products. Such a firm, for example, could not suggest to a potential purchaser (say, a doctor) that he or she might put a pharmaceutical drug to an 'off label' use, even if the manufacturer, in good faith and with considerable evidence, believes the drug will help. All the while, a third party (say, a researcher) is free to tell the doctor not to use the drug for that purpose.''[36] Justice Breyer's dissent supports use of *Sorrell* as support for a challenge to the FDA's off-label promotion regime in the proper context.

Sorrell confirms once again that the government cannot suppress information solely because of a fear that the information may be persuasive to its audience or influence the listeners' behavior. The Court explained that government cannot ''seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements'' simply because they are effective in shaping a physician's prescribing practices through ''impressive endorsements'' or other techniques.[37] This paternalistic view is especially inappropriate in the context of discussions with prescribing physicians, who are considerably more ''sophisticated and experienced consumers'' by virtue of their medical training and experience.[38] The principle that the laws may not suppress truthful speech (particularly to licensed professionals) about lawful conduct seriously undermines the government's public-safety justification for suppressing speech about medically accepted off-label use. And as far as the government's interest in encouraging manufacturers to seek FDA approval for new uses, the regulatory scheme has never employed the most obvious alternative of requiring manufacturers simply to inform doctors that off-label uses have not been approved by the FDA.

Relatedly, content-based restrictions on speech – commercial or otherwise – must reasonably and materially fit the government's asserted goal and ''may not be sustained when the options provided by the State are too narrow to advance legitimate interests or too broad to protect speech.''[39] As even *Central Hudson* held, content-based restrictions on commercial speech cannot indiscriminately ''suppress[] speech that in no way impairs the State's interest[s].''[40] In other words, restrictions on speech must be a scalpel, not a meat-axe. With respect to off-label promotion, the underlying statute that defines ''misbranded'' drugs does so largely by

keted device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.'').

[28] 21 C.F.R. Part 201; *see* 21 U.S.C. § 352.

[29] *Sorrell*, Slip Op. (Majority Op.) at 9.

[30] *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002); *Va. Pharmacy Bd. v. Va. Consumer Council*, 425 U.S. 748 (1976).

[31] *See Sorrell*, Slip Op. (Majority Op.) at 15.

[32] *Id.* at 10 (internal quotation marks omitted).

[33] *Sorrell*, Slip Op. (Breyer, J., dissenting) at 11.

[34] *Id.* at 6.

[35] *Id.* at 9-10.

[36] *Id.* at 10-11.

[37] *Sorrell*, Slip Op. (Majority Op.) at 22.

[38] *Id.*

[39] *Id.* at 19.

[40] 447 U.S. at 570.

  PLIR ISSN 1542-9547

reference to false or otherwise misleading labeling.[41] Indeed, the *Sorrell* majority attempted to respond to Justice Breyer's dissent by suggesting that the FDA's regulations could be defended as prohibitions on ''false or misleading'' commercial speech, which would receive less (or no) First Amendment protection.[42]

FDA's regulations, however, take a more expansive approach and prohibit a great deal of truthful, nonmisleading, and beneficial speech about potentially lifesaving medications. Specifically, the agency has interpreted federal law to forbid or severely limit sales representatives from even discussing truthful, nonmisleading, and often wholly factual information with doctors, such as notifying them of government reimbursement policies, reference materials, or published studies that propose or evaluate drugs for off-label uses. This variance between the text of the statute and the regulatory thicket that has grown up around it may renew questions about whether, in light of *Sorrell*, FDA's off-label promotion regulations, or at least some of the more extreme applications of them, can survive *ultra vires* and ''arbitrary and capricious'' review under the Administrative Procedure Act.[43] Although the dissenters in *Sorrell* would have upheld Vermont's *statute* against First Amendment attack, even they accepted that ''*regulatory* actions are subject to judicial review'' under the APA and ''such review might be informed by First Amendment considerations.''[44] A well-recognized principle of statutory interpretation holds that statutes will be construed wherever possible to avoid constitutional problems.[45] After *Sorrell*, courts may lean toward narrower interpretations of the statute and insist that FDA's enforcement program hew more closely to the letter of the statute as a way of obviating some of the First Amendment issues that would otherwise be posed. And to the extent that the government itself reimburses for medically accepted off-label prescriptions, it borders on absurd to impose criminal penalties when a person communicates truthful information about lawful conduct that the government subsidizes.

Almost a decade ago, the FDA solicited public comments on the First Amendment implications of its regulations governing off-label promotion.[46] Despite receiving ample feedback, the agency has shown little inclination to more narrowly tailor its approach. The Supreme Court's *Sorrell* decision and the increased prospect of judicial invalidation might encourage the FDA to voluntarily revise its position. In all events, *Sorrell* should give more leverage to pharmaceutical and medical device manufacturers in negotiations with DOJ in off-label promotion cases.

Conclusion

Given *Sorrell*'s defense of the First Amendment right of pharmaceutical manufacturers to communicate effectively about their products, the FDA and DOJ should revisit their enforcement regimes and implement changes that comply with the Court's decision in *Sorrell*. For over a decade, the threat of prosecution and exclusion from federal health care programs have placed manufacturers in the constitutionally dubious position of being nearly powerless to assert their rights to truthfully discuss their products. The *Sorrell* decision should embolden manufacturers to challenge DOJ's aggressive interpretations and enforcement actions. Drawing a line at the dissemination of untruthful or misleading information may be the new enforcement solution. Perhaps even more appropriate would be having FDA take on the exclusive enforcement role and remove these matters from DOJ's criminal enforcement arsenal. Ultimately, allowing physicians to have truthful and nonmisleading information to act in the best interest of patients is in everyone's interest.

---

[41] *See generally* 21 U.S.C. § 352.

[42] *See Sorrell*, Slip Op. (Majority Op.) at 24.

[43] 5 U.S.C. § 706(2)(A).

[44] *Sorrell*, Slip Op. (Breyer, J., dissenting) at 8 (emphasis added).

[45] *See, e.g., Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988).

[46] *See* Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942 (May 16, 2002).