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SECOND CIRCUIT REVIEW

Expert Analysis

Court Declares Unconstitutional Law Banning Use of Prescriber Data

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This month we discuss *IMS Health Inc. v. Sorrell*,[1] in which the U.S. Court of Appeals for the Second Circuit struck down as unconstitutional a Vermont statute that banned the sale, transmission, or use of prescriber-identifiable data for marketing purposes by data mining companies and pharmaceutical manufacturers. The decision, written by District Judge John G. Koeltl (sitting by designation) and joined by Senior Circuit Judge Wilfred Feinberg, concluded that the Vermont statute placed an impermissible restriction on commercial speech under the First Amendment. The majority's decision was accompanied by a lengthy dissenting opinion, written by Circuit Judge Debra Ann Livingston, and is at odds with two recent decisions by the U.S. Court of Appeals for the First Circuit.

Background and History

In Vermont, pharmacies that fill prescriptions also collect prescriber-identifiable data (PI data), including the prescriber's name and address, the patient's age and gender, the drug name, dosage, quantity, and date and place the prescription is filled. Pharmacies then sell the PI data to data miners, which in turn aggregate the data and sell them to pharmaceutical manufacturers.

The manufacturers use PI data to identify marketing audiences and messages, including through a marketing process known as "detailing," by which pharmaceutical companies send pharmaceutical representatives ("detailers") to visit physicians to provide information on specific drugs. PI data also are used by law enforcement, scientific researchers, the Food and Drug Administration, the Center for Disease Control, the Drug Enforcement Administration, insurance companies, and state governments.

In 2007, Vermont enacted Vermont Acts No. 80, §17, legislation that prohibited the use, sale, and transfer of PI data for marketing purposes, unless a prescriber opts in to allow use of his or her PI data ("Section 17").[2] Section 17 expressly permits that PI data may be used and transferred for non-marketing purposes, including, but not limited to, patient care management, research, education, and law enforcement.[3] The Vermont legislative findings supporting Section 17 explicitly state the Legislature's concern that the "marketplace for ideas on medicine safety and effectiveness is frequently one-sided" and that "[p]ublic health is ill-served by the massive imbalance in information presented to doctors and other prescribers."[4]

> The decision concluded that the Vermont statute placed an impermissible restriction on commercial speech under the First Amendment.

Appellants are the data mining companies IMS Health Inc., Verispan, LLC, and Source Healthcare Analytics Inc., as well as the non-profit association Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the primary customers of data mining companies. Appellant data mining companies brought suit against the Vermont Attorney General in the District of Vermont to enjoin Section 17's enforcement prior to its effective date. The district court consolidated the action with a suit by PhRMA seeking declaratory and injunctive relief.

District Judge J. Garvan Murtha found that Section 17 was subject to intermediate scrutiny because it acted as a restriction on commercial speech. The district court concluded that the statute's restriction of commercial speech satisfied intermediate scrutiny under the First Amendment because Vermont had demonstrated substantial cost containment and public health interests, and the regulation was narrowly tailored because it allowed prescribers to determine how their PI data would be used.[5]

The Second Circuit Decision

The Second Circuit majority reversed the district court's decision and found that Section 17 did not withstand intermediate scrutiny, because the regulation did not directly advance the state's interests and was not sufficiently tailored.

The court began its analysis by recognizing that Vermont had adopted the regulation in the wake of similar enactments in New Hampshire and Maine, both of which subsequently had been subject to judicial review. The New Hampshire legislation, which prohibited the transmission of PI data for commercial purposes, had been struck down as an unconstitutional restriction on commercial speech by the District Court for the District of New Hampshire. Similarly, the District Court for the District of Maine had enjoined enforcement of a Maine statute that prohibited use of PI data for marketing purposes when the prescriber opts out of use.

Both decisions, however, had subsequently been reversed by the First Circuit on the basis that the legislation regulated only the conduct and not the speech of data miners, and thus was only subject to rational basis review.[6] Accordingly, the First Circuit found that the Maine and New Hampshire statutes did not violate the First Amendment.

Acknowledging these prior rulings, the Second Circuit turned to the issue of whether the Vermont statute restricted protected speech, as opposed to regulating conduct. The court agreed with the district court that Section 17 did not simply restrict commercial practice, explaining that "speech in a form that is sold for profit is entitled to First Amendment protection," even though it may be "dry information, devoid of advocacy, political relevance, or artistic expression."[7]

The court majority disagreed with the First Circuit, which had held that the similar New Hampshire and Maine statutes were species of economic regulation because they only affected data miners' activities. Noting the First Circuit's observation that it would be irrational to treat the regulation of information different from the regulation of beef jerky, the Second Circuit took

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issue with the First Circuit's "obscure distinction between speech and 'information assets,'" and characterized this approach as "declar[ing] new categories of speech outside the scope of the First Amendment."[8] The court emphasized that truthful commercial information, and restrictions on its availability, must be judged under heightened First Amendment standards.

The Second Circuit then addressed appellants' argument that the regulation restricts noncommercial speech, and thus should be subject to strict scrutiny. Whether speech is determined to be commercial or noncommercial dictates whether intermediate scrutiny or strict scrutiny, respectively, should be applied to review of a particular statute. Recognizing that the speech rights of two groups were affected—pharmaceutical manufacturers and data miners—the court separately examined the speech of each entity to determine the applicable level of scrutiny.

With respect to the pharmaceutical manufacturers, the court found that the statute affects manufacturers' ability to promote drugs to doctors through detailing, and that "[i]t cannot be seriously disputed that the primary purpose of detailing is to propose a commercial transaction—the sale of prescription drugs to patients."[9] Acknowledging that manufacturers simultaneously share other, noncommercial information with doctors in the process, the court nonetheless held that "the mere presence of non-commercial information in an otherwise commercial presentation does not transform the communication into fully protected speech."[10]

The court then turned to whether the data miners' speech should receive the same standard of scrutiny. Because data miners are in the business of aggregating and selling data to pharmaceutical manufacturers that later will be used for marketing purposes, their "regulated speech is…one step further removed from the marketing goals of the pharmaceutical manufacturers" and thus arguably could be subject to greater scrutiny than that of pharmaceutical manufacturers.[11] Because the court ultimately concluded that Section 17's restriction on data miners does not satisfy even intermediate scrutiny, however, the court expressly declined to decide whether the data miners' speech could be analyzed under the higher standards applicable to noncommercial speech.[12]

Having concluded that intermediate scrutiny applied, the court applied the Supreme Court's *Central Hudson* test governing commercial restrictions on speech, which provides that a government may regulate commercial speech when (1) the communication is not misleading or related to unlawful activity, (2) the government asserts a substantial interest to be achieved, (3) the restriction directly advances the state interest, and (4) the government interest cannot be served by a more limited restriction on commercial speech.[13]

Vermont advanced three state interests supporting the regulation: protecting public health, protecting "medical privacy," and containing health care costs. Neither appellants nor the court disputed the state's interest in protecting public health and containing health care costs. The court, however, did find that the asserted interest in medical privacy was too speculative to qualify as a substantial state interest because Vermont did not demonstrate that the harms it cited were real. In particular, the evidentiary record did not reflect that use of PI data in marketing had any effect on the integrity of the prescribing process or the trust patients place in their doctors.

The court then examined whether the regulation directly advanced Vermont's legitimate interests in protecting the public health and containing costs. The court found that the statute did not directly or materially advance these interests because it did not restrict either physicians' prescribing practices or detailers' marketing practices. Rather, the court found that it restricted the information available to detailers so that they would be less likely to influence the physicians' prescribing practices.

Citing the legislative history, the court explained that, in fact, the statutory purpose was to alter the marketplace of ideas by removing information that can be used too effectively. The court concluded that "[t]his approach is antithetical to a long line of Supreme Court cases stressing that courts must be very skeptical of government efforts to prevent the dissemination of information in order to affect conduct."[14]

The court found that the statute did not directly or materially advance Vermont's legitimate interests in protecting the public health and containing costs because it did not restrict either physicians' prescribing practices or detailers' marketing practices.

Finally, the court found that the Vermont statute also failed the final prong of *Central Hudson* because the state interest could be served by a more limited restriction on commercial speech. The court explained that, under intermediate scrutiny, the state must show that it carefully calculated the costs and benefits of burdening speech, and that, while the statute might not be a perfect fit, it could not have restricted less speech.

The court found the regulation to be a poor fit with the state's goal of regulating new and insufficiently tested brand name drugs because the statute applied to all brand name drugs, irrespective of efficacy or generic alternatives. Moreover, prohibiting PI data usage and transmission for marketing purposes for all prescription drugs, regardless of any problem with those drugs, acts as a categorical ban, and restricts speech beyond the purported interest in public health and health care costs.

The court thus held that the statute was unconstitutional, and reversed, because it failed the intermediate scrutiny review required for commercial speech under the First Amendment.

Judge Livingston wrote a spirited dissent, arguing that the regulation does not raise First Amendment concerns because the Constitution permits states to protect private PI data and restrict unfettered access to such data.[15] Noting that the majority's decision is the first circuit-level opinion to hold that data miners' sale of PI data constitutes First Amendment activity, Judge Livingston expressed concern that the majority has established precedent entitling the mere transfer of information to First Amendment protection.

The dissent further argued that, even if the statute is construed as a restriction on commercial speech, it satisfied *Central Hudson*. Stating that the level of scrutiny applied by the majority resembles strict scrutiny, rather than the reasonable proportionality standard that Central Hudson requires, Judge Livingston argued that all three of Vermont's stated interests (privacy, cost containment and public health) are substantial state interests that are directly advanced by the statute. Because Section 17 prevents pharmaceutical companies from using PI data, the effect of the statute is to make detailing less effective, therefore making it less likely that doctors will prescribe less cost effective drugs. Emphasizing that, in a heavily regulated field like pharmaceuticals, courts owe deference to state regulatory choices, the dissent concluded that the majority has inappropriately "second guessed" the decisions appropriately left to the legislature.

Conclusion

The Second Circuit's decision in *IMS Health* addresses significant issues of First Amendment law, including the distinction between speech and conduct, the parsing of mixed-purpose commercial and noncommercial speech, and the proper application of intermediate scrutiny to determine whether restrictions on commercial speech are permissible. On Dec. 13, 2010, Appellees filed a petition for certiorari with the United State Supreme Court. It will be interesting to see whether the Supreme Court grants review, in light of the split between the First and Second circuits on the proper construct for analyzing whether a state restriction on use and transmission of PI data encroaches on the First Amendment.

1. Docket No. 09-1913-cv, 2010 U.S. App. LEXIS 24053 (2d Cir. Nov. 23, 2010).
2. VT. STAT. ANN. TIT. 18, §§4631(a)-(d).
3. Id. at §4631(e)(1)-(7).
4. VT. ACTS NO. 80, §1(4)&(6).
5. *IMS Health Inc. v. Sorrell*, 631 F.Supp.2d 434, 447-50, 455, 456-49, 464 (D. Vt. 2009).
6. *IMS Health Inc. v. Sorrell*, 2010 U.S. App. LEXIS 24053, at *9-12 (2d Cir. Nov. 23, 2010) (citing *IMS Health Inc. v. Ayotte*, 490 F.Supp.2d 163, 170-71, 177 (D.N.H. 2007), rev'd, 550 F.3d 42, 50-54 (1st Cir. 2008)); see also *IMS Health Inc. v. Rowe*, 532 F.Supp.2d 153 (D. Me. 2007), rev'd, *IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010).
7. Id. at *17-19 (citations omitted).
8. Id. at *19-21 (citations omitted).
9. Id. at *25.
10. Id. at *26 (citing *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 68 (1983)).
11. Id. at *27.
12. Id. at *27-28.
13. Id. at *28 (citing *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 564 (1980)).
14. Id. at *36. The court further found that appellees' reliance on *Anderson v. Treadwell* was misplaced. 294 F.3d 453 (2d Cir. 2002). The statute at issue in *Anderson* banned in-person real estate solicitations of homeowners if the homeowner indicated that he or she did not want to receive such solicitations. The court determined that legitimate privacy interests were involved, as the statute sought to protect homeowners from in-person real estate solicitations and prevent homeowner harassment. Further, unlike the Vermont statute, the state interest was directly advanced by the statute and the opt-out provision sought to ensure that information available to homeowners was not unduly limited.
15. Id. at *49-98 (Livingston, J., dissenting).