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SORRELL v. IMS HEALTH INC.: SOWING MISCHIEF IN COMMERCIAL SPEECH PROTECTION⁺

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I. INTRODUCTION

In *Sorrell v. IMS Health Inc.*,¹ the U.S. Supreme Court in a six to three decision ruled Vermont's Prescription Confidentiality Law ("PCL")² violated the First Amendment protections accorded commercial speech.³ PCL prohibited the sale, disclosure and use of pharmacy records that disclosed the prescription practices of individual physicians without their consent. PCL disrupted the practice of "detailing" used by pharmaceutical companies to ascertain and report the prescription practices of individual doctors and thereby tailor their marketing efforts to increase sales of prescription drugs. Equipped with the detailing information, drug samples, and clinical study results, pharmaceutical sales representatives visit physician offices and pitch certain drugs for patient illnesses. Denied access to detailing information, the detailers and drug manufactures sued for injunctive and declaratory relief. Vermont argued its prohibition "safeguarded medical privacy and diminished the likelihood that marketing will lead to prescription decisions not in the best interests of patients or the state."⁴ The U.S. Supreme Court disagreed and ruled PCL violated the detailers and drug manufacturers' First Amendment rights, "because of the imprecise fit between means and ends."⁵

Sorrell is the first venture of the U.S. Supreme Court into the First Amendment rights accorded commercial speech in several years and the first

⁺ Received the "Best Article Award" for Volume XXV of the *Southern Law Journal*.

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¹ *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (2011).

² Vt. Stat. Ann., tit. 18, § 4631 (Supp. 2010).

³ *Sorrell* at 2658-59. Justice Kennedy wrote the majority opinion, in which Chief Justice Roberts and Justices Scalia, Thomas, Alito and Sotomayor joined. Justice Breyer wrote the dissenting opinion in which Justices Ginsburg and Kagan joined.

⁴ Vikram D. Amar, *A First Amendment Feast, or Perhaps a Smorgasbord, During the 2010 Term*, 8 A.B.A. PREVIEW 325, 326 (2011).

⁵ *Id.*

attempt by the Court to evaluate restrictions on commercial speech in the context of health care information.⁶ Indeed, because the Court's most recent attempts to resolve commercial speech rights involved compelled commercial speech, it is refreshing to return to a mainstream commercial speech case and to the comfortable and well-worn *Central Hudson* test.⁷

II. VERMONT'S PRESCRIPTION CONFIDENTIALITY LAW

Vermont enacted PCL in 2007. PCL prohibits health insurers, pharmacies, and other similar entities from selling or licensing prescriber identified prescription records or disclosing prescriber identified prescription records for use in marketing drugs without the prescribers' consent, and bars pharmaceutical companies from using prescriber identified prescription records in marketing drugs without the prescriber's consent.⁸ In addition,

⁶ Elliott B. Pollack, *Prescription Data Collection: The Intersection of the First Amendment and Medical Confidentiality*, 7 A.B.A. PREVIEW 313, 315 (2011) ("Sorrell raises issues which go to the core of our modern health care system, including whether, in a so significantly regulated area, health care, the Supreme Court should defer to a state's decision as to additional regulatory regime designed to achieve legitimate and substantial state interests. Pharmaceutical companies can engage in unlimited commercial speech; it is their access to prescription data in the hands of pharmacists via the data miners that lies at the heart of this important case.").

⁷ *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 564 (1980) ("If the communication is neither misleading nor related to unlawful activity, the government's power is more circumscribed. The State must assert a substantial interest to be achieved by restrictions on commercial speech. Moreover, the regulatory technique must be in proportion to that interest. The limitation on expression must be designed carefully to achieve the State's goal. Compliance with this requirement may be measured by two criteria. First, the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose. Second, if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.") Under the four-part test, the speech must be lawful and not misleading, the government interest in regulating commercial speech must be substantial, the regulation must advance the government interest in a direct and material way, and the regulation must be narrowly tailored, i.e. there must be a reasonable fit between the regulation and its intended goals.

⁸ Section 4631(d) of PCL provides: "A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not sell, license, or exchange for value regulated records containing prescriber-identifiable information, nor permit the use of regulated records containing prescriber-identifiable information for marketing or promoting a prescription drug, unless the prescriber consents Pharmaceutical manufacturers and pharmaceutical marketers shall not use prescriber-identifiable information for marketing or promoting a prescription drug unless the prescriber consents" *Sorrell*, 131 S.Ct. at 2660. The information generated by data miners is both rich and highly useful. As noted by one commentator: "The reach of data collectors' activities is extensive. Using pharmacy-sold data, prescriptions and doctors apparently can be correlated to individual patients. The companies can 'track [a doctor] over time and determine behaviors' such as

PCL carves out a number of exceptions to its ban on prescriber identified prescription records: health care research, drug coverage formularies, patient treatment plans, and law enforcement requirements.⁹

Prior to PCL's enactment, pharmacies regularly sold prescriber identified prescription records, developed routinely in filling prescriptions, to "data miners"—companies that analyze prescriber identified prescription records to develop reports detailing the prescriber's practices in issuing prescriptions to patients—which in turn lease the reports to pharmaceutical manufactures. Pharmaceutical company sales representatives—"detailers"—use the reports to refine their marketing efforts to increase the sale of the pharmaceutical company's drugs. By better understanding the physician's prescription preferences, the detailer uses his office visit with the physician more effectively to recommend new or different drugs for patients, provide drug samples, and persuade the doctor on the advantages of the recommended drug. Because detailing is expensive, pharmaceutical companies and their detailers focus their attention on pitching higher-profit brand-name drugs protected by patents, rather than generic drugs.¹⁰

Three data mining companies, denied a lucrative source of income, and an association of pharmaceutical manufacturers of brand-name drugs, denied a valuable marketing tool, brought suit in Vermont contending PCL violated their First Amendment rights and requesting declaratory and injunctive relief.¹¹ The federal district court denied relief. The U.S. Court of Appeals for the Second Circuit, deciding PCL violates the data mining and pharmaceutical manufacturing companies' First Amendment commercial speech rights without sufficient justification, reversed and remanded, and the U.S. Supreme Court granted certiorari.¹²

III. U.S. SUPREME COURT DECISION IN *SORRELL*

The U.S. Supreme Court quickly determined PCL imposes content- and speaker-based restrictions on the sale, disclosure and use of prescriber-

changes in prescribing patterns. While patients' names are encrypted, the collector is nevertheless able to match individual prescription records to patient surveys taken by another marketing company. This enables the pharmaceutical manufacturer to learn 'what was and was not discussed during the doctor appointment'" Pollack *supra* note 6, at 313.

⁹ Vt. Stat. Ann., tit. 18, § 4631(e) (Supp. 2010); *Sorrell*, 131 S. Ct. at 2660.

¹⁰ *Sorrell*, 131 S. Ct. at 2659-60.

¹¹ *Id.* at 2661-62,

¹² *Id.* at 2662. The decision of the Second Circuit conflicted with decisions of the First Circuit, which reviewed similar legislation enacted by Maine and New Hampshire and determined those prescription confidentiality laws did not violate the First Amendment. *See IMS Health Inc. v. Mills*, 616 F.3d 7 (1st Cir. 2010) (Maine) and *IMS Health Inc. v. Ayotte*, 550 F.3d 42, 91 (1st Cir. 2008) (New Hampshire).

identifying information.¹³ The prohibition against using the prescriber-identifying information for marketing purposes constitutes a content-based restriction, and the prohibition against pharmaceutical manufacturers using the prescriber-identifying information for marketing purposes constitutes a speaker-based restriction. These restrictions terminate detailers' access to the prescriber-identifying information, while providing a wide range of other speakers, with varying purposes and viewpoints, full use of the prescriber-identifying information.¹⁴ Moreover, the legislative findings accompanying the law confirm that PCL was designed specifically to prevent pharmaceutical manufacturers, the only customer who actually pays for the information, from using it to promote the sales of brand name drugs, and to prevent data miners from assembling the information for use by the detailers in their communications with physicians. Indeed, the Court decided, Vermont's determination to cripple drug manufacturers' ability to promote brand name drugs moved beyond content-based discrimination to full-blown viewpoint-based discrimination, justifying the need for heightened judicial review.¹⁵

¹³ Before doing so, the U.S. Supreme Court initially chided Vermont for changing its reading of the prohibition on health insurers, pharmacies, and other similar entities from selling or disseminating prescriber-identified prescription records. During proceedings before the federal district court and the court of appeals, Vermont contended prescriber-identified prescription record information could be sold or given away for purposes other than marketing. At oral argument, however, Vermont changed its position, and insisted pharmacies, health insurers, and similar entities cannot sell prescriber-identified prescription records for any purpose other than the exceptions noted above. Accepting the altered definition offered by Vermont, the U.S. Supreme Court determined PCL could not survive constitutional muster under either definition. For the purposes of its decision, then, the U.S. Supreme Court assumed that the opening clause of § 4631(d) prohibits pharmacies, health insurers, and similar entities from selling prescriber-identifying information, subject to the statutory exceptions set out at § 4631(e)." *Sorrell*, 131 S. Ct. at 2662.

¹⁴ *Id.* at 2663. See *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993) (prohibiting the use of newsracks to disseminate commercial messages requires the application of heightened scrutiny), and *Ward v. Rock Against Racism*, 491 U.S. 781 (1989) (heightened scrutiny is required when the government regulates speech because it disagrees with the message it conveys).

¹⁵ *Sorrell*, 131 S. Ct. at 2661-67. This conclusion enabled the Court to reject Vermont's argument that PCL was merely commercial regulation. While the First Amendment does not prevent commercial regulations from imposing incidental burdens on speech, the Court stated, PCL "is directed at certain content and is aimed at particular speakers," and those detrimental effects are far more than incidental. *Id.* at 2665. See *United States v. United Foods, Inc.* 533 U.S. 405 (2001) (assessments imposed by the Department of Agriculture on members of the mushroom industry for generic advertising programs designed to support the industry violated the First Amendment rights of objecting mushroom growers, when the advertising program was the principal focus of the regulatory scheme and could not be said to be ancillary to more comprehensive regulatory program).

Relying on the U.S. Supreme Court decision in *Los Angeles Police Dept. v. United Reporting Publishing Corp.*,¹⁶ Vermont argued PCL regulated access to government information, not speech.¹⁷ *United Reporting* considered a facial First Amendment challenge to a California statute denying access to state and local government lists of the names and addresses of individuals arrested for crimes unless the recipient declared it would not use the address information directly or indirectly to sell a product or service. Prior to this enactment, the Los Angeles Police Department (LAPD) routinely made this information available to anyone for any purpose. United Reporting Publishing Corporation (URPC) gathered the information from LAPD and sold it to attorneys, insurance companies, drug and alcohol counselors, religious counselors, medical practitioners, and driving schools, which would then offer their respective services to those arrested. Following the enactment of the above-noted statute, LAPD denied URPC access to the information, because it could not attest it would not use the information for commercial purposes. Claiming the statute violated its First Amendment right to commercial speech, URPC obtained declaratory and injunctive relief in the Federal District Court. The U.S. Court of Appeals for the Ninth Circuit affirmed, ruling that the statute violated United Reporting's commercial speech rights under the four-part *Central Hudson* test.¹⁸

The United States Supreme Court reversed the Ninth Circuit. In a relatively short opinion, the Court ruled URPC was not entitled to prevail in its "facial attack" on the statute, because: (1) URPC did not attempt to qualify for the information under the statute and was not threatened with any type of legal punishment; (2) URPC failed to demonstrate the statute suffered from First Amendment overbreadth; (3) the restrictions upon gaining access to the arrest record information did not violate URPC's freedom of speech, because the statute did not prevent URPC from conveying information it already possessed to its clients; and (4) California could deny access to the arrest record information in its possession without violating the First Amendment.¹⁹ In reaching this decision, the Court effectively ruled that the First Amendment protections of commercial speech do not include a right of access to government information, and do not apply to situations in which the speaker is only indirectly impeded (rather than directly prevented) from making commercial solicitations.

Rejecting Vermont's argument, the Court ruled in *Sorrell* that *United Reporting* was distinguishable in two respects. First, the prescriber-

¹⁶ *L.A. Police Dept. v. United Reporting Publ'g Corp.*, 528 U.S. 32 (1999) [hereinafter *United Reporting*].

¹⁷ *Sorrell*, 131 S. Ct. at 2665.

¹⁸ See *supra* note 7.

¹⁹ *United Reporting*, 528 U.S. at 39-40.

identification information resided in private hands and the holders of that information were prohibited from conveying it to others. Restraining the way information might be used or communicated implicates the individual's right to speak.²⁰ Second, unlike URPC which did not attempt to qualify for access to the government list of criminals and hence did not suffer an actual injury, the detailing and drug manufacturing companies sought but were denied access to the prescriber-identification information and suffered a personal First Amendment injury. Hence, PCL imposed a content- and speaker-based burden on the detailing and drug manufacturing companies' own speech, rather than simply denying access to government information.²¹

The U.S. Supreme Court also rebuffed Vermont's argument that heightened judicial scrutiny is not warranted, because the sale, transfer and use of prescriber-identifying information are conduct not speech. On the contrary, the Court insisted, "the creation and dissemination of information are speech within the meaning of the First Amendment,"²² and Vermont's imposition of content- and speaker-based restrictions on the availability and use of prescriber-identifying information is sufficient to trigger heightened judicial scrutiny.²³

²⁰ *Sorrell*, 131 S. Ct. at 2665-66, citing *Seattle Times Co. v. Rhinehart*, 467 U.S. 20 (1984) (protective order maintaining the confidentiality of the names of donors and their contributions to a religious organization obtained through discovery did not violate the First Amendment, because it did not prohibit the dissemination of information and did not bar access to traditionally public information); *Bartnicki v. Vopper*, 532 U.S. 514 (2001) (prohibition against disclosure of content of illegally tapped telephone conversations violated the First Amendment rights of law-abiding possessor of that information); *Florida Star v. B.J.F.*, 491 U.S. 524 (1989) (imposition of fines on *The Florida Star* for publishing the name of a rape victim contrary to a Florida statute prohibiting printing, publishing or broadcasting same violated the First Amendment rights of the newspaper which lawfully obtained that information); and *N.Y.C. Times Co. v. United States*, 403 U.S. 713 (1971) (upholding the right of the press to publish information of great public concern obtained from documents stolen by a third party).

²¹ *Sorrell*, 131 S. Ct. at 2666. In reaching this conclusion, the Court also observed "that restrictions on the dissemination of government-held information can facilitate or burden the expression of potential recipients and so transgress the First Amendment." *Id.*

²² *Id.* at 2667 (citing *Bartnicki*, 532 U.S. at 527 ("[i]f the acts of 'disclosing' and 'publishing' information do not constitute speech, it is hard to imagine what does fall within that category, as distinct from the category of expressive conduct")), *Rubin v. Coors Brewery Co.*, 514 U.S. 476 (1995) (information printed in beer labels is speech); *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749 (1985) (information contained in credit reports is speech). See also *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (restrictions on outdoor and point-of-sale advertisements for cigarettes and tobacco products violated the First Amendment, because they unduly impinged sellers' opportunity to propose legal transactions with adults).

²³ The court noted: "So long as they do not engage in marketing, many speakers can obtain and use the information. But detailers cannot. Vermont's statute could be compared with a law prohibiting trade magazines from purchasing or using ink." *Sorrell*, 131 S. Ct. at 2667).

Significantly, the Court neither defines nor applies heightened scrutiny in *Sorrell*, but resolves the constitutionality of Vermont's ban on prescriber-identified information under classic *Central Hudson* commercial speech principles.²⁴ The court noted: (1) the burden of justifying a content-based law as consistent with the First Amendment rests with the state; (2) the state must demonstrate that the statute directly advances a substantial governmental interest and is crafted to achieve that interest; and (3) there must be a reasonable fit between the legislature's objective and the means chosen to achieve that objective, i.e. the state's interest is proportional to the burdens placed on speech and the law does not suppress a disfavored message.²⁵

Vermont advanced two justifications for PCL: (1) protecting medical privacy (including physician confidentiality), avoiding physician harassment, and maintaining the integrity of the doctor-patient relationship, and (2) achieving improved public health and reducing healthcare costs. Unfortunately for Vermont, the U.S. Supreme Court accepted neither of them.²⁶

With respect to the first justification, the Court had a number of objections: (1) the purported purpose of maintaining physician confidentiality is directly undermined by permitting all parties—for example, insurers, researchers, journalists, law enforcement officers, and Vermont itself—other than detailers and pharmaceutical manufacturers to access prescriber-identifying information; and (2) Vermont chose not to adopt a more tailored approach to maintaining patient privacy by limiting the access to the information to a narrow class of applicants similar to the approach adopted by the Health Insurance Portability and Accountability Act of 1996.²⁷ Further, while doctors have the option of withholding prescription information, that option is designed to favor Vermont's policy position, because it discourages physicians from departing from "the State's goal of burdening disfavored speech by disfavored speakers."²⁸ Likewise, Vermont's contention PCL assists physicians avoid harassment by pharmaceutical marketers is better achieved (and far less intrusive on speech) by the physician's decision not to meet with detailers who use prescriber-identified

²⁴ *Sorrell*, 131 S. Ct. at 2668. *See supra* note 7.

²⁵ *Sorrell*, 131 S. Ct. at 2667-68.

²⁶ There is some support for Vermont's position in *FEC v. International Funding Institution, Inc.*, 969 F.2d 110 (D.C. Cir. 1992) (upholding a provision of the Federal Election Campaign Act, 2 U.S.C. § 438(a)(4), which provides that the list of contributors that a political committee must place on file with the FEC may not be sold or used by anyone else to solicit contributions or for a commercial purpose). The U.S. Supreme Court does not address this decision in *Sorrell*.

²⁷ 42 U.S.C. § 1320d-2.

²⁸ *Sorrell*, 131 S. Ct. at 2669.

information.²⁹ Similarly, Vermont's claim that detailers influence treatment decisions and undermine the doctor-patient relationship fails to address why the myriad other permitted uses of prescriber-identified information do not have the same effect. Indeed, "if pharmaceutical marketing affects treatment decisions, it does so because doctors find it persuasive," and the undocumented concern that pharmaceutical speech might persuade is an insufficient basis for quieting such speech.³⁰

The Court also determined that the second justification—Vermont's desire to lower the cost of medical care and promote public health—was not directly advanced by PCL. Rather, Vermont sought to attain its policy objective "through the indirect means of restraining certain speech by certain speakers," that is, by "diminishing detailers' ability to influence prescription decisions."³¹ Indeed, the Court noted, the basis of Vermont's decision to eliminate pharmaceutical marketing is its insistence that doctors are strongly influenced by pharmaceutical marketing. Such reasoning, the Court insisted, is incompatible with the First Amendment. Just as the First Amendment does not permit the state to ban picketing, slogans, signs and marches in order to drive out disfavored public opinions, the state cannot seek to remove a product it disfavors by prohibiting truthful, non-misleading advertisements that promote the sale of that product.³² Vermont dislikes and mistrusts detailers' use of prescriber-identifying information to promote the sales of brand-name drugs. It should express that view through its own speech, rather than burdening the speech of others to hamstring detailing activity.³³ The Court concluded: "The State has burdened a form of protected expression that it found too persuasive. At the same time, the State has left unburdened those speakers whose messages are in accord with its own views. This the State cannot do."³⁴

²⁹ *Id.* at 2669-70.

³⁰ *Id.* at 2670.

³¹ *Id.*

³² *Id.* at 2671. See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002) (prohibition on pharmacists' advertisements for compounded drugs violated the First Amendment); *Va. State Bd. of Pharm. v. Va. Citizens*, 425 U.S. 748 (1976) (prohibition on licensed pharmacists advertising the prices of prescription drugs violated the First Amendment); *44 Liquormart, Inc. v. R.I.*, 517 U.S. 484 (1996) (Rhode Island statute prohibiting advertising of liquor prices violated the First Amendment); *Linmark Assocs., Inc. v. Willingboro Tp.*, 431 U.S. 85 (1977) (township ordinance prohibiting the posting of real estate "For Sale" and "Sold" signs for the purpose of stemming what the township perceived as the flight of white homeowners from a racially integrated community violated the First Amendment); and *Endenfield v. Fane*, 507 U.S. 761 (1993) (Florida ban on in-person solicitation by CPAs to potential clients violated the First Amendment).

³³ *Sorrell*, 131 S. Ct. at 2671.

³⁴ *Id.* at 2672.

IV. SOWING SOME MISCHIEF INTO COMMERCIAL SPEECH PROTECTION

Having followed the topic of commercial speech since its inception³⁵ and written frequently about its ebbs and flows, the authors of this article were relieved to return to the comfort of a straight-forward First Amendment commercial speech controversy and decision. For the previous fifteen years, the U.S. Supreme Court had found itself entangled in compelled commercial speech issues. In three major decisions, the Court reached three different conclusions. In *Glickman v. Wileman Bros. & Elliott, Inc.*,³⁶ Court ruled that compelling growers and handlers of nectarines, peaches, and plums to contribute money to pay for an advertising campaign for California fruits constitutes a valid economic regulation within the Commerce Clause and does not violate the First Amendment.³⁷ In *United States v. United Foods, Inc.*,³⁸ the Court decided that assessments imposed on the mushroom industry for generic advertising programs designed to promote the industry violated the first amendment, because the assessments were not ancillary to a more comprehensive regulatory program; rather, the advertising in question was the main component of the regulatory scheme. In *Johanns v. Livestock Marketing Ass'n*,³⁹ the Court upheld a mandatory assessment to finance market and food science research into the nutritional value of beef and promotional campaigns to market beef domestically and overseas, because the assessment program constituted government speech which is outside the purview of the First Amendment.⁴⁰

³⁵ The U.S. Supreme Court made its first clear statement that commercial speech was entitled to First Amendment protection in *Va. State Bd. of Pharm. v. Va. Citizens*, 425 U.S. 748 (1976). The Court recognized the importance of price information to consumers in making intelligent decisions, and determined the First Amendment protects the right to advertise any legal product or service, regardless of how tasteless and excessive the advertisement might be. ³⁶ 521 U.S. 457 (1997).

³⁷ The dissenting opinion in *Sorrell* relies on *Glickman* for the proposition that Vermont's PCL is permissible government regulation of a commercial enterprise. *Sorrell*, 131 S. Ct. at 2673.

³⁸ 533 U.S. 405 (2001).

³⁹ 544 U.S. 550 (2005).

⁴⁰ The authors of this article wonder whether a different conclusion might have emerged if the U.S. Supreme Court had taken one more compelled commercial speech decision. Perhaps the court might have addressed the right of the recipient of the compelled advertisements to avoid listening to the advertisement. See *Rowan v. Post Office Dept.*, 397 U.S. 728 (1970) (upholding the constitutionality of a provision in the Postal Revenue and Federal Salary Act of 1967 permitting individuals to require a mailer remove his name from the mailing lists and stop all future mailings to the household). Cf. *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983) (striking down a statutory provision prohibiting the mailing of unsolicited advertisements for contraceptive).

It is comforting to consider restrictions on commercial speech through well worn framework of the *Central Hudson* test⁴¹ and its familiar components: whether the commercial speech is lawful and not misleading, whether the government regulation directly advances a substantial government interest, and whether the government regulation is reasonably tailored to achieve the purported government interest. If nothing else, *Sorrell* is a reassuring sign that commercial speech has returned to its roots after wandering around its antechambers for the past fifteen years.

Sorrell, however, is not without its own brand of mischief. As noted above, the U.S. Supreme Court does not define the heightened judicial scrutiny that may be applied to cases in which there the government imposes a content- and speaker-based burden on commercial speech. *Sorrell* also fiddles with the “reasonable fit” and the “direct support” elements of *Central Hudson*, because it omits the word “reasonable” in its consideration of the “fit between the government’s means and ends” and states at one point that the government’s restriction must “at least” directly support the attainment of a substantial government interest. The Court also substituted the phrase “drawn to achieve” for “no more extensive than necessary” in testing the government restriction.⁴² These mischievous seeds sprouted a bit of confusion in subsequent commercial speech decisions that have carefully examined *Sorrell*.

V. ENSUING CONFUSION IN POST-*SORRELL* COURT DECISIONS

A handful of commercial speech court decisions that have carefully examined *Sorrell* demonstrate how those mischievous seeds have taken on a life of their own. These cases have involved a wide variety of commercial speech issues: banning alcohol advertisements in college newspapers, requiring qualifying language in food label health claims, penalizing in-street employment solicitation, prohibiting inclusion of stale arrest records in background consumer reports, and convicting a sales representative for promoting off-label use of FDA approved medication.

A. Bans on Alcohol Advertisements in College Newspapers

In *Educational Media Company at Virginia Tech, Inc. v. Insley*,⁴³ the Court of Appeals for the Fourth Circuit considered an “as applied” challenge to the alcohol advertisement ban imposed on student newspapers at Virginia

⁴¹ See *supra* note 7.

⁴² *Sorrell*, 131 S. Ct. at 2667-68.

⁴³ *Educ. Media Co. at Virginia Tech, Inc. v. Insley*, 731 F.3d 291 (4th Cir. 2013).

Tech and the University of Virginia (“UVA”) by the Virginia Alcoholic Beverage Control Board (the “ABC”).⁴⁴ Nonprofit corporations, Educational Media and The Cavalier Daily (hereinafter the “College Newspapers”), which own the respective student newspapers, challenged the alcohol advertising ban as violative of the First Amendment. The district court determined that the alcohol advertising ban was an appropriate commercial speech restriction given Virginia’s substantial interest in combating underage and abusive drinking on college campuses, and granted summary judgment in favor of ABC.⁴⁵ The Fourth Circuit disagreed, and, finding that the advertising ban was not appropriately tailored to Virginia’s stated aim, reversed the judgment of the district court.⁴⁶

The Court of Appeals began its analysis by examining the College Newspapers’ argument that the advertising ban had to be reviewed under strict scrutiny, because the advertising restriction involved both content-based (alcohol advertisements) and speaker-based (university newspapers) restrictions. In advancing this argument, the College Newspapers relied on *Sorrell*, which also involved content-based (prescriber-identifying information) and speaker-based (pharmaceutical manufacturers) restrictions and which, the U.S. Supreme Court concluded, warranted heightened scrutiny.⁴⁷ In resolving this argument, the Fourth Circuit emphasized that the U.S. Supreme Court did not apply heightened scrutiny when it struck down Vermont’s ban on revealing prescriber-identification information, because that ban could not survive intermediate scrutiny under *Central Hudson*, and the “outcome [was] the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied.”⁴⁸ The Fourth Circuit, relying

⁴⁴ *Id.* at 293.

⁴⁵ The district court had previously granted the College Newspapers’ motion for summary judgment, determining that ABC’s regulation was unconstitutional on its face. On appeal, a panel of the Fourth Circuit reversed, deciding that ABC’s advertising ban on its face did not violate the first amendment, and remanded the matter to the district court to determine whether the advertising ban was subject strict scrutiny and whether advertising ban as applied to the College Newspapers was unconstitutional. *See Educ. Media Co. v. Swecker*, 602 F.3d 583 (4th Cir. 2010). On cross motions for summary judgment, the district court rejected the College Newspapers argument that the advertising ban was subject to strict scrutiny, and, determining it was constrained by the panel decision, decided the advertising ban as applied to College Newspapers passed muster under *Central Hudson*. *Educational Media*, 731 F.3d at 296.

⁴⁶ *Educational Media*, 731 F.3d at 294.

⁴⁷ *Id.* at 297-98. *See Sorrell*, 131 S. Ct. at 2664.

⁴⁸ *Educational Media*, 731 F.3d at 298. *See also Sorrell*, 131 S. Ct. at 2667. This reflects the lack of clarity in the use of the term heightened scrutiny, which sometimes seems to be used as a synonym for intermediate scrutiny, sometimes is used as a variant of strict scrutiny, and sometimes is used as a level somewhere between intermediate and strict scrutiny. For example, in *Educational Media* heightened scrutiny was deemed the equivalent of strict scrutiny. *Educational Media*, 731 F.3d at 298. In *Clark v. Jeter*, 486 U.S. 456, 461 (1988), heightened scrutiny in resolving an equal protection claim is synonymous with intermediate

on *Sorrell*, applied *Central Hudson* to the alcohol advertising ban and concluded it failed under intermediate scrutiny as set forth in *Central Hudson*.⁴⁹ The Fourth Circuit also noted that *Central Hudson* applies to both facial and as-applied challenges.⁵⁰ In a facial challenge, the burden of proof imposed on the government is to show compliance with *Central Hudson* without regard to the restriction's impact on the plaintiff.⁵¹ In an as-applied challenge, the burden is imposed on the state to "justify the challenged regulation with regard to its impact on the plaintiffs."⁵²

In applying *Central Hudson*, the Fourth Circuit noted that the parties agreed that the speech in question concerns lawful activity and is not misleading, satisfying the first prong, and that the government interest is combating underage and abusive drinking on college campuses is substantial, satisfying the second prong. With respect to the third prong, the Fourth Circuit stated its prior panel decision had determined that the challenged

scrutiny. See Samantha Rauer, *When the First Amendment and Public Health Collide: The Court's Increasingly Strict Constitutional Scrutiny of Health Regulations that Restrict Commercial Speech*, 38 AM. J. L. & MED. 690, 706 (2012) ("If *Sorrell* controls future decisions, the traditional intermediate commercial speech doctrine may disappear entirely. Without further clarification from the Court, it seems possible under *Sorrell* that any other public health regulations, including food labeling requirements and tobacco warnings, could also be categorized as content-based. While previous cases merely implied that the Court was substantively applying a strict scrutiny standard to public health regulations of commercial speech, *Sorrell* suggests that strict scrutiny is actually the proper standard for content-based commercial speech regulations.") See also: Andres J. Wolf, *Detailing Commercial Speech: What Pharmaceutical Marketing Reveals About Bans on Commercial Speech*, 212 W. & MARY BILL RTS. J 1291, 1323 (2013) ("By elevating the scrutiny under *Central Hudson* to strict scrutiny when the law in question enacts a ban, courts can afford commercial speech more protection when the commercial speech appears most in need of judicial intervention. Whether the Court should expand strict scrutiny to commercial speech restrictions that stop short of a ban remains an open question.") Jennifer L. Pomeranz, *No Need to Break New Ground: A Response to the Supreme Court's Threat to Overhaul the Commercial Speech Doctrine*, 45 Loy. L.A. L. Rev. 389, 433-34 (2012) ("Requiring the same protection for commercial and core speech ignores the intricacies within First Amendment jurisprudence and the constitutional values underlying the protection of each. Even worse, subjecting commercial regulations that tangentially implicate speech to First Amendment scrutiny threatens to destroy the regulatory system firmly established in the United States. The Court should maintain the current distinctions between commercial and core speech and reject all future opportunities to overhaul the commercial speech doctrine.")

⁴⁹ *Educational Media*, 731 F.3d at 298.

⁵⁰ *Id.*

⁵¹ *Educ. Media Co. v. Swecker*, 602 F.3d at 588 (4th Cir. 2013). In a facial challenge, the plaintiff claims: (1) there are no circumstances in which the law would be valid or the law is plainly invalid, or (2) the law is overbroad in its application compared to the state's objective. There is no consideration of the impact of the law on the plaintiff. *Educational Media*, 731, F.3d at n.5

⁵² *Educational Media*, 731 F.3d at 298. A court considering an as-applied challenge considers the impact on the plaintiff as established in a developed factual record. *Id.* at n. 5.

regulation directly and materially advances the State's asserted interest. In resolving the fourth prong, the Fourth Circuit decided the application of the advertising ban as applied to the plaintiffs was overbroad, because a clear majority of the readers of the College Newspapers (60% at Virginia Tech and 64% at UVA) are age 21 or older. Hence the College Newspapers had a protected interest in printing the alcohol advertisements and a majority of students at both institutions had a protected interest in receiving information in the ads. For that reason the alcohol advertisement ban was unconstitutionally overbroad.⁵³ Further, the Fourth Circuit noted, the alcohol advertising ban attempts to do what the *Sorrell* court found unacceptable: keeping people in the dark for their own good by removing popular or disfavored products from the marketplace by prohibiting their advertisements.⁵⁴

B. *Qualifying Language in Health Claims on Food Product Labels*

In *Fleminger, Inc. v. U.S. Department of Health & Human Services*,⁵⁵ *Fleminger, Inc.* ("Fleminger"), a manufacturer and retailer of green tea, filed a petition with the Food and Drug Administration ("FDA") on May 21, 2004, seeking authorization to make the following qualified health claims about green tea on the products' labels: "Daily consumption of 40 ounces of typical green tea . . . may reduce the risk of certain forms of cancer. There is scientific evidence supporting this health claim although the evidence is not conclusive."⁵⁶ The FDA reviewed the studies dealing with green tea and the risk of cancer, found they addressed only breast and prostate cancer, determined the scientific evidence in those studies was weak, and concluded that it was "highly unlikely" that drinking green tea reduces the risk of breast

⁵³ *Educational Media*, 731 F.3d at 301. *Accord*, *Pitt News v. Pappert*, 379 F.3d 96, 107-108, 110-113 (3rd Cir. 2004) (The Commonwealth failed to meet its burden on the third Central Hudson prong, because students are otherwise bombarded with alcoholic beverage ads which are not covered by the restriction on college newspapers and hence there is no demonstration the advertising ban will achieve its objective. The alcohol advertisement ban on college newspapers also failed the fourth test, because 67% of University of Pittsburgh students and over 75% of the total University population is over the legal drinking age. Banning alcohol ads in the *Pitt News* prevents the newspaper from gaining access to the those over the legal drinking age and prevents individuals who are over age 21 from receiving the information conveyed in the ads. The Court found additional justification for striking down the ban on alcohol advertising ads, because it imposes a significant financial burden on the newspaper by cutting off advertising revenues from alcohol related ads.)

⁵⁴ *Educational Media*, 731 F.3d at 302.

⁵⁵ *Fleminger, Inc. v. U.S. Dep't of Health & Human Services*, 854 F. Supp.2d 192 (D. Conn. 2012).

⁵⁶ *Id.* at 203.

and prostate cancer.⁵⁷ The FDA informed Fleminger by letter dated June 30, 2005, that it was required to add language to his health claim describing the studies in support of the reduced breast and cancer risk as weak and noting it was unlikely consuming green tea reduced breast and prostate cancer.⁵⁸ On August 5, 2005, Fleminger asked the FDA to consider alternate qualifying language, and the FDA responded on August 19, 2008, denying the request. On September 10, 2008, Fleminger suggested in writing that the FDA permit it to use the following qualifying language: “Green tea may reduce the risk of cancer of the breast and the prostate. There is credible evidence supporting this claim although the evidence is limited.” Because Fleminger’s request was not a formal submission, however, the FDA neither considered nor authorized the new claim.⁵⁹

On February 22, 2010, the FDA issued a warning letter advising Fleminger that the health care claims appearing on its website were unauthorized, false and misleading, and unless corrected would lead to enforcement action. Fleminger responded that those claims were based on its September 10, 2008, letter, to which the FDA did not respond and had not objected.⁶⁰ In light of a more recent district court opinion,⁶¹ and seeking to avoid the impression it endorsed the health claim, the FDA agreed to modify its suggested qualifying language as follows: “Green tea may reduce the risk of breast or prostate cancer. FDA does not agree that green tea may reduce the risk because there is very little scientific evidence for the claim.”⁶² Fleminger then pursued its action in federal district court claiming the FDA’s qualifying language violated its First Amendment rights.⁶³

The Court preliminarily addressed Fleminger’s claim that *Sorrell* modified the traditional *Central Hudson* framework for evaluating commercial speech by omitting the word “reasonable” in its consideration of the “fit between the government’s means and ends” and stating at one point that the government’s restriction must “at least” directly support the attainment of a substantial government interest.⁶⁴ The Court disagreed, noting that *Sorrell* “expressly relied on the Supreme Court’s prior

⁵⁷ *Id.* at 203-04.

⁵⁸ *Id.* at 204.

⁵⁹ *Id.*

⁶⁰ *Id.* at 204-05.

⁶¹ *Alliance for Natural Health U.S. v. Sebelius*, 714 F. Supp. 2d 48, 120 (D. D.C. 2010) (The FDA’s replacement of the plaintiff’s health claim was erroneous because the substituted language contradicted the health claim and defeated the purpose of making the claim, rather than merely qualifying the claim with less restrictive language.)

⁶² *Fleminger*, 854 F. Supp. 2d at 205 (D. Conn. 2012).

⁶³ *Id.* at 206.

⁶⁴ *Id.* at 196.

articulation of the standard for evaluating commercial speech claims in *Central Hudson*” and concluding:

Sorrell did not impact the traditional framework for evaluating commercial speech under the First Amendment and accordingly the government must demonstrate a reasonable fit between its ends and the means chosen to accomplish those ends. The government is therefore not obligated to demonstrate that its restriction is the least restrictive means to achieve its ends.”⁶⁵

The Court then proceeded to apply *Central Hudson* to the qualifying language required by the FDA and decided: (1) the FDA has a substantial interest in determining the validity and truth of health-related claims on food and requiring appropriate disclaimers to reflect the level of scientific evidence supporting those claims and thereby protect public health and prevent consumer confusion;⁶⁶ (2) the FDA has a substantial interest in preventing the consumer from incorrectly thinking the FDA has approved a health claim which is not supported by significant scientific evidence;⁶⁷ (3) Fleminger’s proposed disclaimer language is misleading because it does not accurately reflect the level of scientific support for the claim;⁶⁸ (4) the FDA is not required to provide empirical evidence to support its conclusions Fleminger’s proposed disclaimer language is misleading and will cause the public to assume the FDA approved the health claim;⁶⁹ (5) the FDA’s proposed language that there is little scientific evidence in support of the Fleminger’s health claim was a reasonable fit with its objective of accurately reflecting the level or strength of scientific evidence supporting the claim;⁷⁰ and (6) the FDA’s proposed language that the “FDA does not agree that green tea may reduce that risk” is overbroad, because it completely negates the health claim. Rather, the simple statement that “there is little scientific evidence supporting the claim” achieves the objective of preventing the public from believing the FDA supported the claim in a narrower manner.⁷¹ Hence, having concluded the FDA’s qualifying language on Fleminger’s health claim did not pass muster under *Central Hudson*, the Court remanded the matter to the FDA for further consideration.⁷²

⁶⁵ *Id.* at 196-97.

⁶⁶ *Id.* at 209.

⁶⁷ *Id.* at 211.

⁶⁸ *Id.* at 214.

⁶⁹ *Id.* at 216.

⁷⁰ *Id.* at 217.

⁷¹ *Id.* at 218-19.

⁷² *Id.* at 220.

C. Banning In-Street Employment Solicitation

In *Valle Del Sol Inc. v. Whiting*,⁷³ the Ninth Circuit Court of Appeals affirmed the decision of the federal district court granting an injunction against enforcement of Arizona's Support Our Law Enforcement and Safe Neighborhoods Act ("the Act"), which, among other things, criminalized in-street employment solicitation that impeded or blocked traffic.⁷⁴ Day laborers, who lack a fixed place of employment, perform temporary work such as gardening, moving, construction, house cleaning and elder care. Prior to the passage of the Act, in order to advertise the availability of their services, day laborers gathered in visible locations, such as street corners and sidewalks, and used gestures and signals to communicate their availability to motorists or others congregated at the location. The motorists who wanted to hire workers often stopped in the roadway to negotiate terms and finish the hire. After the passage of the Act, fear of prosecution deterred the day laborers from gathering on public streets and their potential employers from soliciting work from the roadside. Arizona conceded the Act restricted speech, but justified those restrictions by claiming day labor solicitation blocked traffic and presented unique public safety concerns.⁷⁵

The Ninth Circuit agreed with the district court's determination that the day labor provisions were content-based restrictions on commercial speech, not political speech, even though "vital political and economic messages" are conveyed when the day laborers solicited work, because the primary purpose of the day laborers' solicitations was to obtain work and negotiate the terms of employment.⁷⁶ The day labor provisions were content-based, because the day labor provisions targeted one type of speech (day labor solicitation that impedes traffic) without addressing other roadside solicitations and non-solicitation speech. Further, the purported objective of promoting traffic safety was belied by the Act's "purpose clauses," which provided the "provisions of this act are intended to work together to discourage and deter the unlawful entry and presence of aliens and economic activity by persons unlawfully present in the United States."⁷⁷ Likewise, the punishment for violating the day labor provisions were significantly more punitive than

⁷³ *Valle Del Sol Inc. v. Whiting*, 709 F.3d 808 (9th Cir. 2013).

⁷⁴ See *Friendly House v. Whiting*, 846 F. Supp. 2d 1053, 1054 (D. Ariz. 2012) ("A.R.S. § 13-2928(A) makes it unlawful for an occupant of a motor vehicle that is stopped on a street, roadway, or highway and is impeding traffic to attempt to hire a person for work at another location. Similarly, A.R.S. § 13-2928(B) provides that it is unlawful for a person to enter a motor vehicle in order to be hired if the vehicle is stopped on a street, roadway, or highway and is impeding traffic.").

⁷⁵ *Valle Del Sol*, 709 F.3d at 817.

⁷⁶ *Id.* at 818-19.

⁷⁷ *Id.* at 819.

punishments imposed on violations of other similar traffic violations, indicating the restrictions were designed specifically to suppress a particular type of speech.

The Ninth Circuit confirmed the district court's conclusion that the day labor provisions are likely unconstitutional, but differed with the district court's application of a stricter test gleaned from *Sorrell* for gauging the link between the government objectives and the restriction on commercial speech.⁷⁸ Rather, the Ninth Circuit concluded that the day labor provisions were deficient "even under the pre-*Sorrell*, arguably more government-friendly, precedent," and "[deferred] extended discussion of *Sorrell* for a more appropriate case with a more fully developed factual record."⁷⁹ Applying the *Central Hudson* criteria, the Ninth Circuit determined: (1) day laborer solicitation is neither misleading nor related to unlawful activity, because it is legal in Arizona to hire or be hired for day labor and the day labor provisions restrict the rights of the worker and employer from soliciting, negotiating and performing day labor agreements,⁸⁰ (2) the lower court's determination that the day labor provisions directly advanced Arizona's interest in traffic safety, while based on weak evidence, was not an abuse of discretion,⁸¹ and (3) there was a substantial likelihood that the plaintiffs would succeed on their claim, because the government failed to produce any evidence showing existing laws were insufficient to address traffic problems associated with day labor solicitation, and because its restrictions on day labor solicitation do not address other causes of impeded or blocked traffic, and hence will not achieve their purported purpose.⁸² Finding that the district court correctly concluded irreparable harm would occur in the absence of injunctive relief, the Ninth Circuit affirmed the district court's preliminary injunction.⁸³

⁷⁸ *Friendly House*, 846 F. Supp. 2d at 1059-60 ("*Sorrell* modified the commercial speech test originally set forth in *Central Hudson* by holding that a content-based restriction on commercial speech must be drawn to achieve a substantial governmental interest. There must be a fit between the legislature's ends and the means chosen to accomplish those ends. The pre-*Sorrell* version of this element, contained in the *Central Hudson* test, is substantially similar to the time, place, and manner restrictions for content-neutral speech.") (quotation and citation omitted).

⁷⁹ *Valle Del Sol*, 709 F.3d at 821.

⁸⁰ *Id.* at 823.

⁸¹ *Id.* at 825.

⁸² *Id.* at 827-28.

⁸³ *Id.* at 828-29. See *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Worcester*, 851 F. Supp. 2d 311 (D. Mass. 2012), in which the federal district court granted the motion of plaintiffs for summary judgment and a preliminary injunction against enforcement of a City of Worcester ordinance banning outdoor advertising of tobacco products, because the ordinance violated tobacco companies' and tobacco product retailers' First Amendment right of commercial speech. In its opinion, the court relied on *Sorrell* for guidance in applying the third and fourth parts of the *Central Hudson* case, and determined the ordinance was improperly designed to

D. Arrest Record Information in Background Check Consumer Reports

In *King v. General Information Services, Inc.*,⁸⁴ plaintiff, Shamara King applied for a job in early 2010 with the United Postal Service, which ordered a background check consumer report on her from defendant, General Information Services, Inc. (“GIS”). The GIS report stated Ms. King had ten nolle-prossed criminal charges against her related to an arrest for a criminal incident in July 2000.⁸⁵ Under the Fair Credit Reporting Act (“FCRA”),⁸⁶ the consumer report agency is required to omit records of arrest which antedate the report by more than seven years.⁸⁷ Ms. King initiated a class action lawsuit against GIS for its failure to comply with FCRA by willfully including outdated arrest records in its consumer reports. GIS filed a motion for judgment on the pleadings on the grounds the FCRA prohibition on reporting arrest records violated its First Amendment rights.⁸⁸

GIS argued that *Sorrell* made a major shift in the protection given commercial speech by raising the standard of review from intermediate to heightened in the case of content- and speaker-based restrictions on commercial speech, and that the restriction on including stale arrest records in its reports was a prohibition on disseminating truthful information which could not survive heightened scrutiny.⁸⁹

The Court agreed that the GSI consumer reports under review qualified as speech under the First Amendment,⁹⁰ but determined those reports were entitled to reduced constitutional protection, because they conveyed information about purely private matters of sole interest to GIS and its customer and were communicated only to the paying subscriber.⁹¹ The test

remove a popular but disfavored product from the marketplace. The issue of heightened scrutiny was not raised in the opinion. *Id.* at 318-319. *Accord* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001) (striking down Massachusetts’ regulations prohibiting outdoor advertising of tobacco products within 1,000 feet of a school or playground and indoor, point-of-sale advertising of tobacco products lower than 5 feet from the floor of the retail store).

⁸⁴ *King v. Gen. Info. Serv. Inc.*, 903 F. Supp. 2d 303 (E. D. Pa. 2012).

⁸⁵ *Id.* at 305.

⁸⁶ 15 U.S.C. §§ 1681-1681x (2012).

⁸⁷ 15 U.S.C. § 1681c(a)(2) (2012). While exceptions are provided for this exclusion under 15 U.S.C. § 1681(c)(b), they were inapplicable to Ms. King’s employment application. Those exceptions are: (1) credit transactions involving a principal amount of \$150,000 or more; (2) the underwriting of life insurance involving a face amount of \$150,000 or more; and (3) the employment of an individual at an annual salary which equals, or which may be reasonably expected to equal \$75,000 or more. 15 U.S.C. § 1681c(b) (2012).

⁸⁸ *King*, 903 F. Supp.2d at 305.

⁸⁹ *Id.* at 306, 308.

⁹⁰ *Id.* at 307, citing *Dun & Bradstreet, Inc. v. Greenmoss*, *supra* note 22.

⁹¹ *King*, 903 F. Supp. 2d at 307.

for analyzing the reduced First Amendment protection given to consumer reports was intermediate scrutiny as articulated in *Central Hudson*.⁹² Moreover, the Court noted, the core meaning of *Central Hudson* articulation was reaffirmed by *Sorrell*, which “stopped far short of overhauling nearly three decades of precedent.” Rather, the Court emphasized, if the U.S. Supreme Court “wished to disrupt the long-established commercial speech doctrine as applying intermediate scrutiny, it would have expressly done so” and, in the absence of such express affirmation, the Court refrained from “taking such a leap.”⁹³ Finally, the Court emphasized, *Sorrell* was distinguishable. In *Sorrell*, Vermont attempted to squelch speech involving a matter of public concern because it disagreed with it. In contrast, the provision of FCRA under question had nothing to do with favoring one form of speech over another and thereby influencing a public debate.⁹⁴ Accordingly, the Court proceeded to consider GIS’s claim under the commercial speech standard articulated in *Central Hudson*. In doing so, the Court decided: (1) that the FCRA disclosure requirements were designed to achieve a balance between business organizations need for background information and the privacy protection given to consumers; (2) that the limitation on reporting stale arrest records directly advanced the government’s interest in achieving that balance, because it includes exceptions for significant transactions; (3) that the restrictions on stale arrest records are narrowly tailored to achieve the desired balance, and, therefore (4) that GIS’s motion for judgment on the pleadings was denied.⁹⁵

E. *Conviction of Pharmaceutical Sales Representative for Promoting Off-label Use of FDA Approved Medication*

In *United States v. Caronia*,⁹⁶ the Second Circuit Court of Appeals ruled the conviction of Alfred Caronia, a pharmaceutical sales representative of Orphan Medical, Inc. (“Orphan”), for promoting the sale of Xyrem, a powerful central nervous system depressant and an FDA approved medication, for “off-label use” violates the First Amendment.⁹⁷

⁹² *Id.*, citing *Trans Union Corp. v. F.T.C.*, 267 F.3d 1138 (D.C. Cir. 2001) (restrictions on speech of credit reporting agency are subject to intermediate scrutiny, not strict scrutiny).

⁹³ *King*, 903 F. Supp. 2d at 308.

⁹⁴ *Id.* at 309.

⁹⁵ *Id.* at 310-11.

⁹⁶ *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).

⁹⁷ *Id.* at 152, 155. Xyrem is described in the opinion as follows: “Xyrem can cause serious side effects, including difficulty breathing while asleep, confusion, abnormal thinking, depression, nausea, vomiting, dizziness, headache, bedwetting, and sleepwalking. If abused, Xyrem can cause additional medical problems, including seizures, dependence, severe withdrawal, coma,

Under the Federal Food, Drug and Cosmetic Act (the “FDCA”), drugs cannot be distributed in interstate commerce unless the drug manufacturers through clinical trials demonstrate they are safe and effective for specifically identified uses and the FDA approves them for those uses.⁹⁸ The FDA prohibits misbranding of drugs. Misbranding, among other things, includes failure to provide “adequate directions for use,” which is defined as “directions under which the lay [person] can use a drug safely and for the purposes for which it is intended.”⁹⁹ Misbranding is a misdemeanor punishable by imprisonment for not more than three years and fines not to exceed \$10,000.¹⁰⁰ While physicians are permitted to prescribe FDA approved drugs for any use that is appropriate in their medical judgment,¹⁰¹ and while the FDCA does not expressly prohibit marketing of drugs for off-label uses, pharmaceutical manufacturers and their sales representatives can be prosecuted for misbranding if they promote the drug for off label usage, *i.e.*, a use for which the drug was not approved.¹⁰²

Xyrem was approved to treat narcolepsy patients who experience cataplexy and narcolepsy patients who experience excessive daytime sleepiness. Because Xyrem is associated with serious side effects, the FDA required a black-box-warning stating the drug’s safety and efficacy were not established for patients under 16 years of age and elderly patients.¹⁰³ Caronia organized various “speaker programs” for Xyrem, during which physicians for compensation would tout the benefits of the drug for patients with cataplexy and narcolepsy to other physicians in the audience. If attendees asked questions about off-label uses of Xyrem, the physician was permitted to answer but Caronia was not. Instead, he was required to respond that he was not permitted to answer, and Orphan’s sales representatives would forward the physician’s question to Orphan, and Orphan would send information to the inquiring physician.¹⁰⁴

On two occasions, Caronia was audiotaped promoting Xyrem to treat illnesses for which it was not approved and touting use by patients under the age sixteen and elderly patients.¹⁰⁵ The government charged Caronia with introducing a misbranded drug into interstate commerce by marketing the

and death. Xyrem’s active ingredient is gamma-hydroxybutyrate (“GHB”). GHB has been federally classified as the “date rape drug” for its use in the commission of sexual assaults.”

⁹⁸ *Id.* at 153.

⁹⁹ *Id.* at 154.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 153.

¹⁰² *Id.* at 154.

¹⁰³ *Id.* at 155.

¹⁰⁴ *Id.* at 156.

¹⁰⁵ *Id.* at 156-57.

Xyrem for an unapproved use with inadequate directions for such use.¹⁰⁶ Prior to trial, Caronia moved to dismiss the charges, because they violated his First Amendment rights. The trial court denied the motion. A jury trial was conducted, and Caronia was found guilty of two counts of off-label promotion of Xyrem.¹⁰⁷ The court denied Caronia's post trial motion for acquittal, and sentenced Caronia to one year of probation and 100 hours of community service.¹⁰⁸ Caronia's appeal followed.

The core argument raised by Caronia on appeal was that the First Amendment prohibits the government from criminalizing a pharmaceutical firm's truthful and non-misleading promotion for off-label drug use when such use is not illegal and others are permitted to engage in that speech.¹⁰⁹ Notably, the FDCA does not prohibit or criminalize off-label promotion, but makes it a crime to misbrand a drug.¹¹⁰ While the government insisted that it was not prosecuting Caronia for promoting off-label drug use, but merely used evidence of same to demonstrate intention to mislabel the drug,¹¹¹ the Second Circuit rejected that distinction, because the government's conduct and arguments at trial and the court's instructions to the jury clearly showed Caronia was prosecuted for promoting off-label uses for Xyrem. Hence, the government's theory of prosecution was based solely on Caronia's words promoting off-label use of Xyrem rather than on evidence the label accompanying Xyrem was somehow misleading. This permitted the government to prove mislabeling by showing only truthful speech promoting off-label drug uses. In short, the government prosecuted Caronia for speech protected by the First Amendment.¹¹²

In determining whether the prosecution of Caronia for promoting off-label uses of Xyrem passed First Amendment muster, the Court turned to *Sorrell* for guidance. *Sorrell*, the Court observed, decided that pharmaceutical marketing is a form of expression protected by the First Amendment and that the Vermont law prohibiting access to prescriber information constituted both content- and speaker-based restrictions on protected speech, requiring the application of heightened scrutiny.¹¹³ The Court determined that prosecution of Caronia for promoting off-label uses of Xyrem was also a speaker-based (pharmaceutical manufacturers) and content-based (promoting off-label uses of drugs) restriction on speech

¹⁰⁶ *Id.* at 157-58.

¹⁰⁷ *Id.* at 158-59.

¹⁰⁸ *Id.* at 159-60.

¹⁰⁹ *Id.* at 160.

¹¹⁰ *Id.* at 106, 162.

¹¹¹ *Id.* at 160-61.

¹¹² *Id.* at 162.

¹¹³ *Id.* at 163-64.

requiring heightened scrutiny.¹¹⁴ Nonetheless, as the U.S. Supreme Court did in *Sorrell*, the Court turned to *Central Hudson*'s intermediate scrutiny to decide the constitutionality of Caronia's prosecution. The Court found that the first two prongs of *Central Hudson* were easily satisfied: promoting off-label uses of drugs is neither illegal nor misleading, and the government interests in preserving the efficacy and integrity of the FDCA's drug approval process and reducing consumption of unsafe and ineffective drugs are substantial.¹¹⁵

The Court next determined that prohibition of off-label promotion of drugs did not pass the third prong, because the FDCA permitted physicians to prescribe and patients to use drugs for purposes other than those for which the drug was approved and to publicize those off-label uses in scientific journals, but prevented pharmaceutical companies from giving information about those uses to physicians and patients. Regulations that seek to keep people in the dark for what the government determines to be in their best interests demand a high level of skepticism.¹¹⁶ The government's construction of the FDCA as legalizing off-label use but prohibiting the free flow of information about those uses, the Court decided, does not directly advance the government's interest of preserving the efficacy of the FDA drug approval process.¹¹⁷

The Court also determined that the prohibition against off-label promotion of drugs failed the fourth prong, because it was not narrowly drawn to accomplish its purpose. Several alternative, less extensive measures could be employed to do so, such as educational programs, warning systems, safety tiers, clearer identification of intended and possible uses for the drug in the approval process, and prohibiting off-label uses deemed to be dangerous.¹¹⁸ Not having passed *Central Hudson* muster, the criminal prosecution of Caronia for truthful off-label promotion of FDA-approved drugs violated the First Amendment, and Caronia's judgment of conviction was vacated and the matter remanded to the district court.

F. Summary

The five cases analyzed above illustrate the mischief unleashed by *Sorrell* in stating heightened scrutiny applied to content- and speaker-based commercial speech restrictions, but applying the pre-*Sorrell* intermediate scrutiny in striking those restrictions down. In each of those decisions, the court was required to address the application of heightened scrutiny and

¹¹⁴ *Id.* at 165.

¹¹⁵ *Id.* at 165-66.

¹¹⁶ *Id.* at 166-67.

¹¹⁷ *Id.* at 167.

¹¹⁸ *Id.* at 167-68.

ended up applying unadorned intermediate scrutiny. In *Educational Media*, the court of appeals acknowledged heightened scrutiny applied to, but then turned around and used intermediate scrutiny to struck down, Virginia's ban on advertising alcohol beverages in college newspapers. In *Fleminger*, the district court reviewed *Sorrell*, determined it did not alter the *Central Hudson* test, and applied pre-*Sorrell* intermediate scrutiny in striking down the FDA's order to include certain qualifying language in the health claims on the labels of green tea. In *Valle del Sol*, the court of appeals affirmed the granting of a preliminary injunction against the enforcement of Arizona's prohibition of in-street employment solicitation. In doing so, the court of appeals disagreed with the district court's application of heightened scrutiny and instead employed pre-*Sorrell* intermediate scrutiny. In *King*, the district court upheld the FCRA's requirement that stale arrest records be excluded from consumer background reports, determined that *Sorrell* was distinguishable, and applied pre-*Sorrell* intermediate scrutiny. Finally, in *Caronia*, the court of appeals acknowledged that *Sorrell* called for heightened scrutiny in determining the constitutionality of the FDCA's prosecution for misbranding of drugs, but applied pre-*Sorrell* intermediate scrutiny in ruling the conviction of the drug company sales representative for off-label uses of drugs violated the First Amendment.

VI. ADDING SOME STEPS IN REVIEWING CONTENT- AND SPEAKER-BASED RESTRICTIONS ON COMMERCIAL SPEECH

When the authors of this article first reviewed the U.S. Supreme Court decision in *Sorrell*, they were relieved and even happy to see the return to normalcy in First Amendment protection of commercial speech. While the *Sorrell* court for the first time stated content- and speaker-based restrictions on commercial speech warranted heightened scrutiny, it concluded that higher level was not required, because Vermont's law prohibiting dissemination of prescriber identified prescription information could not pass muster under the pre-*Sorrell* intermediate scrutiny test. Lulled by the seemingly straight-forward application of *Central Hudson* intermediate scrutiny test, the authors did not take notice of the subtle changes the majority opinion made to the language of that test: omitting the word reasonable in the fit between government means and ends and requiring at "least direct support" between the two, and substituting "drawn to achieve" for "no more than extensive than necessary" in testing the government restriction. Very clearly, the litigants in the handful of cases summarized above noticed. As those cases indicate, the review of content- and speaker-based commercial speech restrictions in the future will likely require additional steps in the review of those restrictions: (1) confirming whether

the restriction is content- or speaker-based, and, if so, acknowledging heightened scrutiny is the recommended standard; (2) determining whether the restriction can pass First Amendment muster under intermediate scrutiny, and, if not, striking the restriction down; and (3) if the restriction passes muster under intermediate scrutiny, determining whether the restriction can pass muster under heightened scrutiny.

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