



REED V. TOWN OF GILBERT PORTENDS A POSITIVE SIGN FOR FIRST AMENDMENT ARGUMENTS REGARDING OFF-LABEL SPEECH

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At first blush, a case involving a pastor’s challenge to a local ordinance regulating the posting of directional signs might not appear to have much to do with the Food & Drug Administration’s regulation of off-label promotion of pharmaceutical products. But because this case involves the First Amendment, it does. The U.S. Supreme Court’s decision in *Reed v. Town of Gilbert, Arizona*, 135 S. Ct. 2218 (2015), significantly affects the regulation of truthful and non-misleading speech generally, in both commercial and non-commercial contexts.

Content-based restrictions on speech must normally satisfy the daunting strict-scrutiny standard to pass constitutional muster—government regulations that turn on the substance of speech must be “narrowly tailored to serve a compelling state interest.”¹ Strict scrutiny has not historically applied to all restrictions on speech, however; the most notable exception is commercial speech, which courts define as speech that proposes no more than a commercial transaction,² or “expression related solely to the economic interests of the speaker and its audience.”³ Content-based restrictions on commercial speech traditionally undergo an intermediate level of scrutiny per the four-prong test of *Central Hudson*.

Under *Central Hudson*, an enactment regulating commercial speech is constitutional if: (1) the speech at issue concerns lawful activity and is not misleading; (2) the asserted government interest is substantial; (3) the regulation directly advances the government interest asserted; and (4) the statute is no more extensive than is necessary to serve that interest. Thus, while political speech must satisfy strict scrutiny, commercial speech has been easier to regulate because restrictions need only satisfy the intermediate scrutiny test under *Central Hudson*.

Courts, however, are beginning to apply heightened scrutiny to some commercial-speech restrictions. Heightened scrutiny “is something short of a least-restrictive-means standard that the government must meet under strict judicial scrutiny” and requires “a fit that is not necessarily perfect, but reasonable;

¹ See, e.g., *Citizens United v. Fed. Election Comm’n*, 558 U.S. 310, 340 (2010) (“laws that burden political speech are ‘subject to strict scrutiny,’ which requires the Government to prove that the restriction ‘furthers a compelling interest and is narrowly tailored to achieve that interest’”).

² *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 66 (1983) (quoting *Virginia State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976)).

³ *Central Hudson Gas. & Elec. Corp. v. Pub Serv. Comm’n of New York*, 447 U.S. 557, 561 (1980) (quoting *Virginia State Bd. of Pharmacy*, 425 U.S. at 762).

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that represents not necessarily the single best disposition but one whose scope is in proportion to the interest served; that employs not necessarily the least restrictive means but ... a means narrowly tailored to achieve the desired objective.” *Retail Digital Network, LLC v. Appelsmith*, ___ F.3d ___, 2016 U.S. App. Lexis 140, at *19-20 (9th Cir. Jan. 7, 2016) (quoting *Bd. of Trs. of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 477, 480 (1989)).

Reed Expands the Application of Strict Scrutiny

Reed concerned a township sign code that prohibited display of certain outdoor signs without a permit. *Reed*, 135 S. Ct. at 2224. Exempted categories included “Ideological Signs,” “Political Signs,” and “Temporary Directional Signs,” but these categories were each subject to greater restrictions with respect to the number, size, and duration of display.

Prior to *Reed*, such an ordinance would have been subject to strict scrutiny only if designed to suppress speech with which the government did not agree. Therefore, the Ninth Circuit applied a lower level of scrutiny, concluding that the sign code did not violate the First Amendment, because it was “content-neutral.” *Id.* at 2226 (quoting *Reed v. Town of Gilbert, Ariz.*, 707 F.3d 1057, 1071-72 (9th Cir. 2013)).

The Supreme Court, in a 6-3 decision, overturned that ruling and concluded that strict scrutiny should apply more broadly. The majority held that any law that discriminates based on a *topic* must overcome strict scrutiny, irrespective of the legislative motive behind the law. *Reed* thus requires courts to determine initially “whether the law is content neutral on its face.” *Id.* at 2228. The Court explained that “[a] law that is content based on its face is subject to strict scrutiny regardless of the government’s benign motive, content-neutral justification, or lack of ‘animus toward the ideas contained in the regulated speech.’” *Ibid* (quoting *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 429 (1993)).

The *Reed* majority also relied on *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011), for the proposition that “[g]overnment regulation of speech is content based if a law applies to particular speech because of the topic discussed or message expressed.” *Reed*, 135 S. Ct. at 2227, quoting *Sorrell*, 131 S. Ct. at 2663-2664. In *Sorrell*, the same six justices had struck down a commercial-speech restriction, stating that “the statute disfavors specific speakers, namely pharmaceutical manufacturers.” *See Sorrell*, 131 S. Ct. at 2663. *Sorrell* applied heightened (but not “strict”) scrutiny to what the lower courts had treated as traditional commercial speech.

Reed was not a commercial-speech case—demonstrating that the U.S. Supreme Court is eroding the distinction between the levels of scrutiny that previously applied to commercial and non-commercial speech. As a result, going forward more regulations must overcome strict scrutiny to be valid: a government regulation no longer avoids strict scrutiny by being well-intentioned, regardless of whether commercial or non-commercial speech is at issue.

Reed also applied strict scrutiny in prohibiting discrimination based on the identity of the speaker: “Speech restrictions based on the identity of the speaker are all too often simply a means to control content” and thus “laws favoring some speakers over others demand strict scrutiny when the legislature’s speaker preference reflects a content preference.”⁴ Once again the result was consistent with *Sorrell*, holding that content-and-speaker-based restrictions are unconstitutional. Six justices have now employed the same

⁴ *Reed*, 135 S. Ct. at 2230 (citing *Citizens United v. FEC*, 558 U.S. 310, 340 (2010) and *Turner Broadcasting System, Inc. v. FCC*, 512 U.S. 622, 658 (1994)).

First Amendment analysis twice—first in *Sorrell* to impose “heightened” scrutiny on some commercial speech, and now in *Reed* to raise scrutiny to strict levels where the government would discriminate among “topics” or “speakers.”

If Off-Label Promotion is Topic-Based Speech, Does FDA Regulation Pass First Amendment Muster after *Reed*?

The term “off-label use” refers to the use of a pharmaceutical or a medical device “for some other purpose than that for which it has been approved by the FDA.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 350 (2001). Off-label use is both legal and common. *Ibid.* Further, the off-label use of prescription drugs and medical devices is “an accepted and necessary corollary of the FDA’s mission to regulate in this area without directly interfering with the practice of medicine.” *Id.* at 350. Indeed, off-label use is frequently considered the medical standard of care. *See, e.g., Memorandum of the AMA House of Delegates, Resolution 820, Off-Label Use of Pharmaceuticals* (Sept. 21, 2005) (“[u]p to date, clinically appropriate medical practice at times requires the use of pharmaceuticals for ‘off-label’ indications”).

Despite off-label use being common and legal, the FDA claims to prohibit off-label “promotion,” which is roughly defined as marketing a drug or device for a use that the agency has not approved to appear as an “indicated use” on product labeling. Although the controlling statute does not “expressly prohibit the promotion or marketing of drugs for off-label use,” *United States v. Caronia*, 703 F.3d 149, 154 (2d Cir. 2012), FDA regulations require any manufacturer seeking to promote an off-label use to submit a new application and undergo new clinical trials in order to demonstrate the safety and effectiveness of that use. 21 C.F.R. § 314.70. A violation of the Food, Drug and Cosmetic Act can result in criminal misbranding charges.

FDA’s regulation of speech regarding off-label use is topic based—meaning speech is prohibited if on one topic (off-label uses) but permitted if on another (on-label uses). It is also speaker based, in that anyone other than a regulated manufacturer is free to make the same statements about a product’s off-label uses that would subject the manufacturer to an FDA enforcement action. As a result, *Reed*’s holding has the potential to impact FDA regulation of off-label promotion. Consistent with *Reed*, FDA’s regulation of truthful, non-misleading speech about the off-label use of pharmaceutical products or medical devices would not be subject to the usual intermediate scrutiny via the commercial-speech doctrine of *Central Hudson*, but rather at least to the “heightened” scrutiny of *Sorrell*.

Courts have previously struck down topic-based regulations, and thus it is not a stretch to apply *Reed*’s rationale to off-label promotion. *See Cahaly v. Larosa*, 796 F.3d 399 (4th Cir. 2015) (statute prohibiting only robocalls “for the purpose of making an unsolicited consumer telephone call” but not those “of a political nature including, but not limited to, calls relating to political campaigns” was an unconstitutional content-based restriction on speech); *Norton v. City of Springfield, Ill.*, 612 Fed. Appx. 386 (7th Cir. 2015) (statute banning oral panhandling, but not other forms of requests for money, was a content-based restriction on speech that could not satisfy strict scrutiny).

The Effect of *Reed* on Off-Label Promotion

Reed suggests that FDA’s current off-label promotion regime cannot satisfy strict scrutiny. *Reed*’s holding is consistent with the recent ruling in *Amarin Pharma, Inc. v. FDA*, ___ F. Supp. 3d ___, 2015 WL 4720039 (S.D.N.Y. Aug. 7, 2015), granting a preliminary injunction preventing FDA from taking enforcement action against a manufacturer’s truthful, non-misleading speech about an off-label use of its product.

In addition, in a post-*Reed* decision applying *Sorrell*, the Ninth Circuit reversed itself on the constitutionality of a California statute restricting advertising by alcoholic-beverage manufacturers. In overturning its prior decision—which was grounded in the pre-*Sorrell*, *Central Hudson* approach to commercial speech—the Ninth Circuit held:

Consistent with *Sorrell*'s plain language, we rule that *Sorrell* modified the *Central Hudson* test for laws burdening commercial speech. Under *Sorrell*, courts must first determine whether a challenged law burdening non-misleading commercial speech about legal goods or services is content- or speaker-based. If so, heightened judicial scrutiny is required.

Retail Digital Network, LLC, 2016 U.S. App. Lexis 140, at *17-18. The description “non-misleading commercial speech about legal goods or services” is equally applicable to the off-label promotion at issue in *Amarin*.

FDA's approach to off-label promotion has long been criticized as violative of the First Amendment. WLF brought the first such action two decades ago. See *Washington Legal Foundation v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *vacated in part as moot*, 202 F.3d 331 (D.C. Cir. 2000). *Reed* may fully and finally vindicate WLF's position. Even with regard to the sign ordinance, the Court rejected a paternalistic approach and cautioned that “[i]nnocent motives do not eliminate the danger of censorship presented by a facially content-based statute.” *Reed*, 135 S. Ct. at 2229.

The direct impact of *Reed*, however, is not entirely clear. Lower courts are only beginning to consider its holding in commercial-speech cases. However, by citing to *Sorrell* (commercial speech) to support its position that a church sign ordinance (non-commercial speech) is unconstitutional, the majority opinion suggests that the Court is no longer concerned with maintaining a strict division between commercial and non-commercial speech, at least in the context of content- or speaker-based discrimination.

Should *Reed* ultimately be applied to off-label promotion, one potential positive result in the pharmaceutical context will likely be *more* truthful, non-misleading information flowing from manufacturers to physicians, who can then make informed decisions about proper treatment for patients, using their training and expertise.