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Free Speech and the Future of Off-Label Pharmaceutical Marketing Regulation After *United States v. Caronia*



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The U.S. Court of Appeals for the Second Circuit has thrown a large wrench in the United States' regulation of the so-called "off-label" promotion of pharmaceuticals with its recent and path-breaking free speech ruling in *United States v. Caronia*, No. 09-5006-CR, 2012 BL 316528 (2d Cir. Dec. 3, 2012). The Food and Drug Administration, pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA), requires that every new drug have all of its approved uses listed on an FDA-approved label. Nothing in the act purports to criminalize the promotion of pharmaceuticals for uses besides those approved uses set forth on the label. But the FDA, through its regulations and enforcement strategy, has

targeted such "off-label" promotion as violating the act's prohibition on "misbranded" drugs, defined as those drugs whose labels do not include adequate directions for use.

Alfred Caronia, a pharmaceutical sales representative for Orphan Pharmaceuticals, was prosecuted and convicted in 2009 of conspiracy to introduce a misbranded drug into commerce based on his off-label promotion of the drug Xyrem. But the Second Circuit vacated Caronia's conviction on First Amendment grounds, holding that the government cannot prosecute pharmaceutical manufacturers and their representatives for speech promoting the lawful, off-label use of an FDA-approved drug. That decision represents the first time a court has recognized the First Amendment as a successful defense to a criminal misbranding conviction. Although *Caronia* has some important limitations on its holding, it may well represent the crucial first crack in the FDA's off-label regulatory and enforcement edifice.

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FDA Regulation of Off-Label Marketing

By way of background, the FDA is tasked by Congress with ensuring that only safe and effective drugs are sold. 21 U.S.C. §§ 355(a), (b)(1), (d). The FDA does so by requiring that pharmaceutical companies go through a rigorous and expensive new drug approval process to ensure that drugs are safe and effective for specifically designated uses, which must be set forth clearly on an FDA-approved label. But the FDA generally does not regulate how such drugs are prescribed. Instead, doctors, who are regulated primarily by the states, may prescribe drugs for the use specified on the label ("on-label"), or for other uses not so specified

(“off-label”). Accordingly, “[o]nce a drug product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens of patient populations that are not included in approved labeling.” 59 Fed. Reg. 59,820, 59,821-22 (Nov. 18, 1994) (internal formatting modified).

This leads to the somewhat contradictory scenario in which off-label uses of a company’s drugs are legitimate and permissible, but the company talking about—promoting—those uses is not. The reason that the FDA provides for treating “off-label” promotion as illegal and constraining such promotion by pharmaceutical companies (but not medical professionals) is its view that the federal law’s safety and effectiveness goals could come into tension with or be undermined by both the economic incentives of pharmaceutical companies and the therapeutic goals of doctors. For instance, the FDA may wish to encourage rigorous FDA testing and approval of each specific use before drugs are prescribed to the public, while also preventing pharmaceutical companies from exerting undue “influence” over doctors’ medical decisionmaking in prescribing drugs to individual patients. *See, e.g.*, 65 Fed. Reg. 14,286, 14,287 (March 16, 2000). At the same time, a pharmaceutical company, in seeking increased sales, may want doctors to prescribe its drug for as many safe and effective uses as possible, even though it may not have the means or ability to obtain FDA approval for every such use. And a doctor may want to have the most up-to-date information on effective treatment options and the standard of medical care, whether those uses are indicated on the label or are experimental.

The FDA’s resolution of this tension between the competing goals of those who regulate, sell, and prescribe drugs has not, except in rare circumstances, been to restrict the ability of doctors to prescribe approved drugs off-label. Nor has it been to cut off the flow of off-label information entirely, which the FDA acknowledges is a beneficial practice in limited circumstances. *See Dep’t of Health and Human Servs., Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices*, available at <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm> (last updated Aug. 6, 2009) (“*Good Reprint Practices*”) (outlining guidelines for sharing medical publications by pharmaceutical companies because the “FDA recognizes that the public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved or cleared medical products”).

Instead, the FDA’s solution has been to prohibit, through fines and criminal sanctions, virtually all forms of off-label marketing of the otherwise approved drugs by the pharmaceutical companies’ spokespersons and salespeople. Thus, under the existing regime, doctors may freely recommend off-label uses to their colleagues and patients. Researchers may publish their off-label use findings in medical publications. Journalists may describe off-label uses in news articles and magazines. But if a pharmaceutical salesperson says the same thing and promotes an off-label use, he or she faces a year in jail and a \$250,000 fine.

That is exactly what happened to Alfred Caronia, a New York City-based sales consultant with Orphan

(now Jazz) Pharmaceuticals, who was convicted in 2009 for conspiracy to promote the off-label use of Xyrem, a drug approved for narcolepsy and cataplexy in populations 16 and older.¹ FDA regulations make it a strict liability misdemeanor to introduce a drug into interstate commerce that is “misbranded” or that has not been approved by the FDA. *See* 21 U.S.C. §§ 331(a), (d); 333(a). If the off-label promotion involves “intent to defraud or mislead,” the crime becomes a felony punishable by three years in jail, along with a \$250,000 fine for individuals and \$500,000 for corporations, *see id.* at § 333(a)(2)—or even higher if the government can show that it suffered a loss or that the company enjoyed a gain as a result of the conduct, *see* 18 U.S.C. § 3571.

Congress deems a drug “misbranded” if, among other things, it does not contain “adequate directions for use.” 21 U.S.C. § 352(f). The FDA has interpreted this to mean “directions under which the layman can use a drug safely and for the purposes for which it is intended.” 21 C.F.R. § 201.5. “Intended use,” in turn, “refer[s] to the objective intent of the persons legally responsible for the labeling of drugs,” which can be shown by the “label,” as broadly defined to include advertising and promotional materials, or even, as relevant here, “oral or written statements by such persons or their representatives.” *Id.* at § 201.208.²

In other words, the FDA’s “misbranding” theory is that, even though the drug’s *container* might never change—its label, after all, must conform to what the FDA already has approved—a salesperson’s statement can reveal the company’s intent to market a drug for a use not indicated on the label, thereby immediately rendering the drug “misbranded.” *See Good Reprint Practices, supra* (“An approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include ‘adequate directions for use.’”). As the *Caronia* decision points out, this legal theory to date has been uniformly successful, resulting in many misbranding convictions based on off-label promotion by pharmaceutical companies and their representatives. *See Caronia*, 2012 BL 316528, at *2 (citing multiple examples of judgments, agreed forfeiture orders, and press releases).

Importantly, the federal government often pairs such criminal charges with civil allegations under the False Claims Act for promoting off-label uses that ultimately are reimbursed by government health programs like Medicare or Medicaid. *See* 31 U.S.C. § 3729(a)(1) (False Claims Act imposes liability if someone “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” or conspires to do the same). Such prosecutions can net the government

¹ Because it is considered unethical to test pharmaceuticals on minors, doctors’ off-label prescriptions are often the only way to learn about effective treatment options for minors.

² FDA regulations define “labeling” to include “[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published . . . for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor[.]” 21 C.F.R. § 202.1(l)(2).

hundreds of millions or sometimes even *billions* of dollars in civil and criminal fines, penalties, and forfeitures—such as GlaxoSmithKline’s \$3 billion off-label settlement with the Justice Department this past summer. See U.S. Dep’t of Justice, *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012), available at <http://www.justice.gov/opa/pr/2012/July/12-civ-842.html> (disclosing plea agreement involving \$1 billion in criminal penalties and \$2 billion in False Claims Act settlements).

The First Amendment and Off-Label Marketing

The Supreme Court set the stage for Caronia’s First Amendment challenge to the FDA’s off-label regime in *Sorrell v. IMS Health Inc.*, which broadly declared that “[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment,” 131 S. Ct. 2653, 2659 (2011). That case involved a pharmaceutical marketing practice called “detailing,” by which pharmaceutical manufacturers promote their drugs through doctor-identifying information purchased from pharmacies, which is then used to refine marketing practice and increase drug sales. A Vermont statute proscribed, among other things, the use of such information for marketing or promoting a prescription drug without the doctor’s consent, but freely allowed other uses of the information in research, journalism, or for the state’s own purposes. *Id.* at 2660, 2668.

The Supreme Court struck down the Vermont statute for violating the First Amendment. Writing for the majority, Justice Anthony M. Kennedy noted that the statute imposed content- and speaker-based restrictions on the sale, disclosure, and use of prescriber-identifying information and, as a result, the “First Amendment requires heightened scrutiny” of the law. *Sorrell*, 131 S. Ct. at 2664. The court did not determine the precise level of scrutiny it needed to apply, however, because “the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied.” *Id.* at 2667. Even “[u]nder a commercial speech inquiry,” the court held, “it is the State’s burden to justify its content-based law as consistent with the First Amendment,” which required it to show “at least that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest.” *Id.* at 2667-68. Despite Vermont’s “significant” (*id.* at 2659) asserted interests in protecting (i) medical privacy and physician confidentiality, as well as (ii) improved public health and reduced health care costs, the Supreme Court determined that “[n]either justification withstands [First Amendment] scrutiny.” *Id.* at 2668.

With regard to privacy and confidentiality considerations, the Supreme Court noted that the law was not narrowly drawn to serve those interests because “[t]he explicit structure of the statute allows the information to be studied and used by all but a narrow class of disfavored speakers.” *Id.* at 2668. Thus, because the law “permits extensive use of prescriber-identifying information” by non-detailers, it “does not advance the State’s asserted interest in physician confidentiality.” *Id.* at 2669.

With regard to the state’s public health and reduced cost justification, the court emphasized that “[t]he State nowhere contends that detailing is false or misleading within the meaning of this Court’s First Amendment precedents,” *id.* at 2672, and thus the state’s simple “fear that people would make bad decisions if given truthful information” cannot justify content-based burdens on speech, *id.* at 2670-71 (internal quotations omitted). While “content-based restrictions on protected expression are sometimes permissible,” including for commercial speech, *id.* at 2672, the court forcefully declared that “[t]he State’s interest in burdening the speech of detailers . . . turns on nothing more than a difference of opinion.” *Id.*; see *id.* at 2672 (state cannot “burden[] a form of protected expression that it found too persuasive” while leaving “unburdened those speakers whose messages are in accord with its own views”).

Doctrinally, *Sorrell* builds upon the jurisprudence of a Supreme Court that recently has been very hospitable to free speech claims, even in pursuit of commercial goals. In fact, one of the cases the court relied on most heavily was another free speech case holding that an amendment to the FDCA that restricted the ability of pharmacies to advertise or promote certain “compounded” drugs infringed the First Amendment. See *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 368 (2002). In *Thompson*, the parties agreed that the advertising and soliciting prohibited by the act constituted commercial speech, but disagreed about its constitutionality under the four-part “intermediate” test for commercial speech outlined in *Central Hudson Gas & Electric Corp. v. Public Serv. Comm’n of N.Y.*, 447 U.S. 557 (1980), which provides that government may restrict commercial speech that is (i) lawful and not misleading if, and only if, (ii) the asserted government interest is substantial, (iii) the regulation directly and materially advances governmental interests, and (iv) the regulation is narrowly drawn and not more intrusive on speech than necessary.

It is worth noting that before the *Thompson* court held the speech-related provisions at issue unconstitutional under *Central Hudson*, it first remarked that the foundational premise of *Central Hudson*—that commercial speech occupies a lower rung of First Amendment protection deserving of a distinct test—has been questioned repeatedly over the years. See *Thompson*, 535 U.S. at 367-68 (citing cases). While *Sorrell* ultimately found no need to discard that principle either, the court hemmed in the doctrine substantially by giving *Central Hudson* short shrift and holding that, as long as speech is truthful and not misleading, “[i]n the ordinary case it [will be] all but dispositive to conclude that a law is content-based” to have it invalidated, whether the speech is “commercial” or not. *Sorrell*, 131 S. Ct. at 2667.

Beyond those doctrinal considerations, *Sorrell* is most notable for its muscular defense of “[s]peech in aid of pharmaceutical marketing” *Sorrell*, 131 S. Ct. at 2659, as fully protected expression, liberated from the traditional limitations of commercial speech protection. Among other things, the court championed consumers’ need “for the free flow of commercial speech . . . in the fields of medicine and public health, where information can save lives,” *id.* at 2664; suggested that “[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for

what the government perceives to be their own good,” *id.* at 2671; and held that “the State cannot engage in content-based discrimination to advance its own side of a debate” on medicine safety and effectiveness. *Id.* at 2672.

In short, *Sorrell* enunciated a new-found and extraordinarily strong defense of the free speech rights of those who market drugs, particularly because “the audience, in this case prescribing physicians, consists of ‘sophisticated and experienced’ consumers.” *Sorrell*, 131 S. Ct. at 2671 (internal citation omitted). And that holding set the stage for application of those same free speech principles in *Caronia* to restrictions on off-label speech. Indeed, many commentators on the implications of the majority decision in *Sorrell*—not the least of which was Justice Stephen G. Breyer (joined by Justices Elena Kagan and Ruth Bader Ginsburg) in dissent, *see id.* at 2678—saw the writing on the wall and predicted that the decision necessarily would lead to “significant judicial interference with widely accepted regulatory activity” related to pharmaceutical labeling and promotion, *id.* *Caronia* bore that prediction out.

The Second Circuit’s Decision

In the spring of 2005, Orphan Pharmaceuticals’ employee, Alfred Caronia, was caught on tape conspiring with the late Dr. Peter Gleason, a Maryland psychiatrist and a company-paid promoter of Xyrem, to market the off-label use of the drug to a second physician, who actually was a government cooperator posing as a prospective Xyrem customer. The government brought charges against Orphan, Caronia, and Dr. Gleason, charging the latter two with conspiring to violate the misbranding provisions of the Federal Food, Drug, and Cosmetic Act. After trial, Caronia was convicted of a single count of conspiracy to introduce a misbranded drug into commerce and sentenced to a year’s probation, 100 hours of community service, and a \$25 special assessment.³

The Second Circuit reversed. Relying on the principle of constitutional avoidance, by which courts construe statutes to avoid the creation of serious constitutional problems in their operation, the court of appeals “construe[d] the FDCA as not criminalizing the simple promotion of a drug’s off-label use because such a construction would raise First Amendment concerns.” *Caronia*, 2012 BL 316528, at *8. Because the court further determined that Caronia was prosecuted solely because of such off-label promotion, it vacated Caronia’s criminal conviction. *See id.*

The court of appeals began by rejecting the government’s main argument, which was that Caronia’s conviction was based only on the fact that the drug actually was misbranded for its “intended use” by Orphan Phar-

maceuticals, and that the First Amendment therefore was not implicated. More specifically, the government had argued that off-label promotion is not by itself illegal, but instead contended that such off-label promotion plays only an evidentiary role in determining whether the uses Caronia promoted were the ones actually intended by the company and for which Xyrem’s labeling failed to provide direction. The court assumed for the sake of decision that the government is permitted to offer such promotional evidence in proving a drug’s “intended use,” but found “that is not what happened in this case.” *Caronia*, 2012 BL 316528, at *8.

In particular, the court emphasized the government’s repeated argument at trial that “Caronia engaged in criminal conduct” purely “by promoting and marketing the off-label use of Xyrem,” with such promotion highlighted over 40 times in the government’s summation and rebuttal. *Caronia*, 2012 BL 316528, at *8; *see, e.g., id.* at *6 (“He knew the rules: you can’t promote and market Xyrem for uses that have not been approved by the FDA. He admits it[.]”) (citation omitted). The Second Circuit pointed out that the government never argued in summation that the promotion was mere evidence of intent or that Caronia had engaged in any form of misbranding other than simply promoting the off-label use, and further noted that the district court had “flatly stated to the jury that pharmaceutical representatives are prohibited from engaging in off-label promotion.” *Id.* at *9. Citing *Sorrell*’s holding that “[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment,” 131 S. Ct. at 2659, the court concluded that “the government clearly prosecuted Caronia for his words—for his speech.” *Id.*

The Second Circuit next recognized that, like the Vermont law at issue in *Sorrell*, the government’s construction of the FDCA’s misbranding provisions to prohibit and criminalize the promotion of off-label drug use imposes restrictions on speech based on both the content of the speech (promotional marketing of a truthful use) and the speaker’s identity (pharmaceutical manufacturers are forbidden to say what doctors are permitted to say), and accordingly was subject to heightened scrutiny. Rather than determine the precise level of heightened scrutiny, however, the court of appeals mirrored the *Sorrell* court’s approach and held that the criminal prohibition would fail even under a less-rigorous commercial speech test.

Applying the “intermediate” test for commercial speech outlined in *Central Hudson*, the court of appeals first “easily” found that the speech at issue was lawful and not misleading. *Caronia*, 2012 BL 316528, at *13. The court also found that the government’s interests in drug safety and public health—specifically, “in preserving the effectiveness and integrity of the FDCA’s drug approval process” and “in reducing patient exposure to unsafe and ineffective drugs”—are substantial. *Id.*

The court then addressed whether the speech restriction directly advanced the government’s interest, and found that it did not. Because the behavior of off-label prescription and use was itself legal, the court reasoned that “it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers” would further the government’s goals. *Caronia*, 2012 BL 316528, at *13. The main problem with the government’s construction of the FDCA, the court explained, was that it “essentially legalizes the outcome—

³ Dr. Gleason and Orphan each pleaded guilty to a single misdemeanor count of introducing a misbranded drug into interstate commerce with intent to defraud and mislead, 21 U.S.C. §§ 331(a), 333(a)(2). In November 2007, the court entered a criminal judgment against Orphan requiring it to pay \$12,262,078 in restitution, \$5 million in a criminal fine, and an assessment of \$400. *See United States v. Caronia*, 576 F. Supp. 2d 385, 389 (E.D.N.Y. 2008), *vacated and remanded*, 09-5006-CR, 2012 BL 316528 (2d Cir. Dec. 3, 2012). In January 2010, Dr. Gleason was sentenced to one year of probation and a special assessment of \$25. *See id.*

off-label use—but prohibits the free flow of information that would inform that outcome.” *Id.* at *14. The court concluded: “[T]he government’s construction of the FDCA’s misbranding provisions does not directly advance its interest in reducing patient exposure to off-label drugs or in preserving the efficacy of the FDA drug approval process because the off-label use of such drugs continues to be generally lawful.” *Id.* at *15.

Finally, the court also rejected the argument that the FDA’s construction of the act was narrowly drawn, noting several possible alternative regulatory approaches, such as developing off-label warning or disclaimer systems, or even prohibiting off-label uses altogether. *See id.* at *14-15. But what the FDA could not do, the court concluded, was “prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug.” *See id.* at *16.⁴

What’s Next?

It is easy to view *Caronia* as a shot across the bow of the entire off-label promotional regulatory regime—not just the criminal and civil penalty structure in place, but also the highly lucrative off-label False Claims Act prosecutions that often go hand in hand with such enforcement actions. And it may well be that *Caronia* is the beginning of the end of the FDA’s regime of prosecuting off-label speech. But the full impact of the decision remains to be seen for a number of reasons.

First, although the government opted not to challenge the *Caronia* decision further in the Second Circuit or before the Supreme Court, at some point the high court likely will have to weigh in on the relationship between free speech and off-label marketing. This issue and related ones already are pending elsewhere, in cases like *Par Pharm. Inc. v. United States*, No. 11-cv-1820 (D.D.C.) (more on that below), and *United States v. Harkonen*, Nos. 11-10209, 11-10242 (9th Cir.), which was argued just a few days after *Caronia* came down and involves whether a scientific statement made in support of pharmaceutical marketing is protected by the First Amendment. The true impact of *Sorrell* on off-label marketing thus will not be known until the Supreme Court steps in.

Second, until the Supreme Court decides to address the question or Congress amends the FDCA, the government has some options at hand to avoid similar setbacks and thus to preserve the key components of its regulatory regime. For example, the government’s strategy in *Caronia*’s prosecution—which focused on oral statements alone rather than any other evidence of misbranding, and relied on tape-recorded promotion as the primary illegal behavior in the conspiracy, *see Caronia*, 2012 BL 316528, at *4-7—turned out to be an error that is not likely to be repeated by future prosecutors, who presumably will be more circumspect about proving intent solely through representative-to-doctor

oral communications. In addition, the *Caronia* court made clear that the First Amendment does not protect false or misleading speech, and that “some off-label information could certainly be misleading or unhelpful,” but noted that “this case does not involve false or misleading promotion.” *Id.* at *14. Pharmaceutical manufacturers therefore can expect the government to bring and prosecute cases on a false-or-misleading promotion theory the next time around.

Third, beyond the facts of this case, there is an even more fundamental reason why the FDA’s off-label regulatory regime, at least as it applies to *companies* rather than their representatives, is not likely to change significantly in the short term. That is because of the enormous leverage the government can bring to bear in prosecuting off-label suits against those companies. In particular, if the government successfully prosecutes a company under either the FDCA or the False Claims Act, it can result in automatic or discretionary exclusion from participation in Medicare and other government health programs for years—and not just exclusion for the drug in question, but the company as a whole. *See* 42 U.S.C. §§ 1320a-7(a), (b); 42 C.F.R. §§ 1001.101, 1001.201. Such a consequence is serious enough to put many companies out of business, and that fact, along with the crippling financial liability False Claims Act defendants can face, puts enormous pressure on companies to settle with the government rather than to gamble on pressing First Amendment (and other) defenses in court. *See Ohio Hosp. Ass’n v. Shalala*, 978 F. Supp. 735, 740 (N.D. Ohio, 1997), *aff’d in part, rev’d in part*, 201 F.3d 418 (6th Cir. 1999) (“Because the risk of loss in a False Claims Act case carries potentially devastating penalties,” defending themselves in court is a risk that defendants often “feel they cannot take—even if they believe their chances of prevailing would be great.”).

One apparent case in point involves Allergan, a pharmaceutical company that was faced with criminal charges and civil liability for its off-label promotion of its successful product Botox. In October 2009, Allergan brought a high-profile First Amendment challenge seeking to have the FDA’s off-label regulatory regime declared unconstitutional on First Amendment grounds as applied to its Botox marketing. *See Allergan Inc. v. United States*, No. 09-cv-1879 (D.D.C.). But the company ultimately settled the pending criminal charge against it, pleading guilty to one misdemeanor count of misbranding in connection with its off-label marketing, and paying a \$375 million fine plus \$225 million to settle the civil False Claims Act claims. *See Dep’t of Justice, Allergan Agrees to Plead Guilty and Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox®*, available at <http://www.justice.gov/opa/pr/2010/September/10-civ-988.html>. Importantly, as part of the settlement, Allergan was required to dismiss its First Amendment lawsuit, which it did in October 2010.

More recently, Par Pharmaceutical, the subject of a multiyear parallel criminal and civil investigation relating to its marketing of the drug Megace ES, brought a similar First Amendment challenge in October 2011, seeking a preliminary injunction against the FDA along with a declaration that FDA regulations are unconstitutional as applied to criminalize Par’s truthful off-label promotional speech. This suit (along with *Caronia*) was viewed by many as a test case for pressing the free speech limits on the FDA’s regulatory regime. But the

⁴ Judge Debra Ann Livingston, in dissent, attacked the majority’s position as inconsistent with *Caronia*’s conviction, which in her view was not for his speech itself, but rather merely revealed his intent to commit the misbranding crime with which he was charged and tried. *Caronia*, 2012 BL 316528, at *16. She also warned that “the majority calls into question the very foundations of our century-old system of drug regulation.” *Id.*

matter has been stayed since May 2012 while “[t]he parties continue to engage in global discussions to resolve all pending litigation and investigations, including the present suit,” which “will eliminate any need for this court to reach the merits of the instant suit or resolve pending motions.” Joint Motion to Stay, *Par Pharm. Inc. v. United States et al.*, No. 11-cv-1820 (D.D.C. May 5, 2012). Just as with Allergan’s lawsuit, the FDA appears likely to avoid a constitutional ruling on Par’s First Amendment challenge.

The point is thus that, outside of the (less-common) *Caronia*-like prosecution of individual pharmaceutical representatives, it is not clear that companies will have the stomach to spend the money or accept the risk of bringing these First Amendment challenges or defenses to resolution, rather than simply accepting a favorable negotiated settlement. And until more such cases go to judgment (or the Supreme Court intervenes), it largely may be business as usual for the FDA and federal prosecutors.

For instance, just 10 days after the *Caronia* decision, the government filed an intervening \$20 million complaint in a False Claims Act qui tam suit involving off-label allegations. See *United States v. Vascular Solutions Inc.*, No. A-10-CA-883-SS (W.D. Tex.). And less than a week after that, prosecutors in the Eastern District of New York—that is, the same U.S. Attorney’s Office that prosecuted *Caronia* and *Orphan*—announced a massive three-quarters-of-a-billion-dollar settlement with Amgen, including approximately \$150 million in criminal fines and forfeitures to go along with a \$612 million False Claims Act settlement. The company’s crime was to promote the use of *Aranesp*, a drug to treat anemia in cancer patients, for those who *were not* undergoing chemotherapy when the drug’s approval

was only for patients who *were* receiving such treatment. In so doing, prosecutors said, the company “illegally pursued corporate profits while jeopardizing the safety of vulnerable consumers suffering from disease.” Dep’t of Justice, *Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, N.Y.; Pays \$762 Million to Resolve Criminal Liability and False Claims Act Allegations* (Dec. 19, 2012), available at <http://www.justice.gov/opa/pr/2012/December/12-civ-1523.html>. Those prosecutors, at least, have not received the message that *Caronia* changed the landscape. Quite the opposite, they announced: “To all who might consider introducing misbranded drugs into the marketplace, you are on notice: we remain steadfastly committed to prosecuting such violations of law.” *Id.*

Conclusion

Despite its limited short-term impact, *Caronia* is nevertheless an important free speech decision that, by taking the Supreme Court at its word in *Sorrell*, presages a more narrowly tailored off-label regulatory and enforcement regime. If nothing else, the Second Circuit’s decision is a wake-up call to the FDA and prosecutors that courts in the post-*Sorrell* world cannot rely on lax judicial oversight of First Amendment boundaries just because this speech occurs in a quasi-commercial context. From now on, the government may see new First Amendment defenses and independent lawsuits wend their way through the courts, promising potentially dramatic changes in the way the FDA regulates off-label promotion and use in the years to come as other courts of appeals—and eventually the U.S. Supreme Court—weigh in.