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ANTI-CORRUPTION COMMITTEE

United States v. Caronia: Effects and Implications

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Government regulation of pharmaceutical companies' marketing strategies has become an increasingly important issue, both from a First Amendment and public health perspective. Large pharmaceutical companies, collectively known as "Big Pharma," routinely spend billions of dollars per year marketing and advertising blockbuster drugs to the public. In fact, according to Neilsen, "Pharma marketers laid out more than $2.7 billion on consumer marketing in the U.S." in 2012, with that number only rising in subsequent years.[1] With increasingly advanced marketing strategies, thanks in large part to the advent of the internet, Big Pharma's ability to reach a large swath, if not virtually every part, of the American public is beyond dispute.[2] At the same time, hand-in-hand with the pharmaceutical companies' obvious financial incentives is the associated public health risk of companies marketing "bad" drugs to the public. Indeed, it is that fear – the unauthorized marketing of drugs which could lead to public health implications– that compels the government's regulation, usually through the Food and Drug Administration (FDA), of pharmaceutical companies and their marketing strategies.

The government's ability to regulate branding and labeling, however, is not without constitutional limit. Such issues rose to the forefront of the legal world in *United States v. Caronia*.[3] In that case, the Second Circuit, in what was widely seen as a "sea change" for drug regulation, held that the government's practice of prohibiting truthful off-label promotional speech[4] by either pharmaceutical companies or their representatives was a violation of the First

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[1] Joan Voight, *Welcome to the New Face of Big Pharma: On the eve of Obamacare, brands shift marketing from pill pusher to best friend*, Adweek (Sept. 29, 2013), *available at* http://www.adweek.com/news/advertising-branding/welcome-new-face-big-pharma-marketing-152767.
[2] Steve Brozak, *Big Pharma Learned the Wrong Marketing Lesson*, Forbes (May 5, 2013), *available at* http://www.forbes.com/sites/stephenbrozak/2013/05/25/big-pharma-learned-the-wrong-marketing-lesson/.
[3] 703 F.3d 149 (2nd Cir. 2012).
[4] Off-label promotion is discussed at length in Section I.

Amendment right to the freedom of speech.[5] The practical implication of the case was that the FDA could no longer construe the Food, Drug, and Cosmetic Act (FDCA) to prohibit off-label promotion, provided that the promotion was truthful.[6]

At first glance, *Caronia* seems to be a notable break from the past, especially given the number of commentators who were surprised, if not outright shocked by the case's outcome. As one writer noted, "[i]n the immediate aftermath of the [Second Circuit's] *U.S. v. Caronia* decision, the reactions of some federal officials and public health activists bordered on apocalyptic."[7] Despite such initial reaction to the Second Circuit's holding, this article argues that, while not inconsistent with the commercial speech doctrine, *Caronia*'s holding was not as significant as it seems. In fact, the government's decision not to seek a petition for *certiorari*, along with its continued (and successful) prosecutions of pharmaceutical companies, illustrates the limited reach of the decision. Nevertheless, and despite the government's decision not to appeal from the case, this article contends that the government's position regarding off-label promotion is too restrictive, and perhaps short-sited, in the wake of *Caronia* and the rise of technological and pharmaceutical advancement. It concludes by providing two recommendations on how the government can update its enforcement regime to maximize public health outcomes while also keeping up with pharmaceutical companies' increasingly technical marketing strategies.

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[5] *Caronia*, *supra* note 3, at 168-69.
[6] Kellie Combs and Albert Cacozza, *Drug Promotion in the Post-Caronia World*, Ropes & Gray Updates (March/April 2013), *available at* http://www.ropesgray.com/~/media/Files/articles/2013/03/Drug-propotion-in-the-post-caronia-world.pdf.
[7] Mit Spears, *Greater Clarity Needed Regarding what Scientific Information Biopharmaceutical Companies can Communicate to Healthcare Providers*, PhRMA (Jan. 31, 2014), *available at* http://www.phrma.org/catalyst/Briefing-Assesses-Impact-of-US-v-Carolina-Ruling-on-Regulation-of-Off-Label-Speech.

I. What is Off-Label Promotion?

Pharmaceutical companies must seek the FDA's approval for new drugs before they may promote the drug to the public.[8] In order to receive FDA approval, "drug manufacturers are required to demonstrate, through clinical trials, the safety and efficacy of a new drug for each intended use or indication."[9] Off-label promotion, more specifically, refers to any marketing or promotion of the product for any use that has not been approved by the FDA.[10] As such, any promotion of a non-FDA approved use is considered to be illegal off-label promotion. At the same time, an important distinction, as is apparent through the statutory scheme discussed below, is that while off-label *promotion* is illegal, off-label *use* is not.[11]

From a statutory perspective, the FDCA does not directly forbid off-label promotion. Rather, the FDA has relied principally on two statutes, 21 U.S.C. §355(a) and 21 U.S.C. §331(a), to regulate off-label promotion. Under §355(a), pharmaceutical companies are required to seek FDA approval prior to introducing new drugs and drug labels into interstate commerce.[12] Under §331(a), pharmaceutical companies are prohibited from marketing and introducing misbranded drugs into interstate commerce.[13] The DOJ, through a combination of the two statutes, has brought successful, front-page prosecutions against some of the biggest names in the industry for

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[8] Harvard Law Review, *First Amendment – Commercial Speech – Second Circuit Holds that Prohibiting Truthful Off-Label Promotion of FDA-Approved Drugs by Pharmaceutical Representatives Violates First Amendment – United States v. Caronia*, 127 Harv. L. Rev. 795 (2013).

[9] *Caronia, supra* note 3, at 153.

[10] *Caronia, supra* note 3, at 152 (stating that off-label promotion occurs when it the drug is "promoted…for a purpose not approved by the [FDA].").

[11] Ara B. Gershengorn, *United States v. Caronia – "A Tale Full of Sound and Fury"*, Boston Bar Association (June 2013), *available at* http://healthlawreporter.bbablogs.org/2013/06/28/united-states-v-caronia-a-tale-full-of-sound-and-fury/.

[12] Section 355(a) provides "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug." *Id*. A "new drug" is further defined as "any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof…" 21 U.S.C. §321(p).

[13] Section 331(a) provides that "[t]he following acts and causing thereof are prohibited: [t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded." *Id*.

misbranding and off-label promotion violations. Some of the most notable examples include: Johnson & Johnson ($2.2 billion settlement, November 2013)[14]; Pfizer ($490.9 million, July 2013; $55 million, December 2012)[15]; GlaxoSmithKline ($3 billion, July 2012)[16]; Abbott Labs ($1.5 billion, May 2012)[17]; and Warner-Lambert ($430 million, May 2004)[18]; among a host of other notable prosecutions.

Despite the fact that pharmaceutical companies can be forced to pay out huge settlements, there exists an important distinction regarding *who* can be prosecuted for off-label promotion. As noted by Thomas Sullivan, founder of Rockpointe Corporation, a bio-medical education company, "[r]ight now there exists a paradox where anyone can talk about the efficacy of a drug's off-label use, except for the manufacturer – the actor with the most information about that drug."[19] Government prosecutions are only aimed at pharmaceutical companies, while individuals, principally doctors and other marketers unrelated to the company, are not prohibited from prescribing drugs for reasons not on the label.[20] Health care practitioners are shielded from

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[14] *Johnson & Johnson to Pay more than $2.2. Billion to Resolve Criminal and Civil Investigations,* Department of Justice: Office of Public Affairs (Nov. 4, 2013), *available at* http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html.

[15] *Wyeth Pharmaceuticals Agrees to Pay $490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses,* Department of Justice: Office of Public Affairs (July 30, 2013), *available at* http://www.justice.gov/opa/pr/2013/July/13-civ-860.html.

[16] *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data,* Department of Justice: Office of Public Affairs (July 2, 2012), *available at* http://www.justice.gov/opa/pr/2012/July/12-civ-842.html.

[17] *Abbott Labs to Pay $1.5 Billion to Resolve Criminal & Civil Investigations of Off-Label Promotion of Depakote,* Department of Justice: Office of Public Affairs (May 7, 2012), *available at* http://www.justice.gov/opa/pr/2012/May/12-civ-585.html.

[18] *Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability relating to Off-Label Promotion,* Department of Justice (May 13, 2004), *available at* http://www.justice.gov/opa/pr/2004/May/04_civ_322.htm..

[19] Thomas Sullivan, *U.S. v. Caronia, One Year Later: FDA's Position on Off-Label Promotion Remains the Same, But Changes are Looming,* Policy and Medicine (Feb. 20, 2014), *available at* http://www.policymed.com/2014/02/us-v-caronia-one-year-later-fdas-position-on-off-label-promotion-remains-the-same-but-changes-are-looming.html.

[20] *See* Michele L. Adelman & Catherine N. Karuga, *A Low Dose Prescription: Criminal Prosecution of Off-Label Drug Promotion*, Boston B.J. (Nov. 2007), at 17 (stating "[w]hile doctors are allowed to prescribe for off-label uses, drug companies are prohibited from promoting drugs [for off-label] uses in most circumstances.").

prosecution, and even interference, under Title 21.[21] The Supreme Court has reaffirmed practitioners' ability to prescribe drugs for off-label uses, regardless of the effect on the government's ability to regulate the pharmaceutical market.[22] Even more, pharmaceutical companies are often charged with paying illegal kickbacks to physicians who prescribe, often for off-label uses, to patients.[23]

II. *United States v. Caronia*

A. Factual Background

The Second Circuit grappled with many of these same issues in *Caronia*. The case dealt with Orphan Medical, Inc. ("Orphan") and its drug Xyrem.[24] Xyrem, principally meant to treat narcolepsy, had serious side effects, "including difficulty breathing while asleep, confusion, abnormal thinking," among others, and if abused, could lead to coma or death.[25] Given its severe side effects, although the FDA approved Xyrem for two conditions in 2002 and 2005[26], the FDA required that the drug have a "black box" warning. A black box warning is considered to be the "most serious warning placed on prescription," and in this case, stated "that the drug's safety and efficacy were not established for patients under 16 years of age, and [that] the drug had 'very limited' experience with elderly patients."[27] In March 2005, Orphan hired Alfred Caronia as a

[21] Title 21 provides that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. §396.
[22] *See Buckman Co. v. Plaintiffs' Legal Comm*, 531 U.S. 341 (2001) ("Thus, the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals."). *See also In re Neurontin Marketing and Sales Practices and Products Liability Litigation*, 2010 WL 3169485 (D. Mass. 2010).
[23] *See e.g., Johnson & Johnson, supra* note 14.
[24] At the time of the case, Orphan had been acquired by Jazz Pharmaceutical. Orphan specialized in developing "drugs to treat pain, sleep disorders, and central nervous system disorders." *Caronia*, *supra note* 3, at 155.
[25] *Id*.
[26] First, to treat narcolepsy patients who experienced cataplexy. Second, to treat narcolepsy patients who suffered from excessive daytime sleepiness. *Id*.
[27] *Id*. In addition, the FDA only allowed one centralized pharmacy to distribute Xyrem nationally.

Specialty Sales Consultant "to promote Xyrem."[28] In July of the same year, Caronia started "speaker programs" to market the drug, and later hired Dr. Peter Gleason to promote the drug through the programs. Later that year, the federal government launched an investigation into Orphan and Gleason focused on off-label promotion of Xyrem.[29] The basis of the investigation, and subsequent prosecution, were two audio-records which captured Caronia and Gleason discussing and promoting Xyrem for unapproved uses, "including for unapproved indications and unapproved subpopulations."[30]

On August 19, 2008, the government charged Caronia with two criminal offences[31] under the FDCA. In turn, Caronia filed a motion to dismiss, *inter alia*, arguing that the government's interpretation of the FDCA violated his right to free speech under the First Amendment.[32] The District Court denied Caronia's motion, using a two-part analysis.[33] First, citing to *Bolger v. Youngs Drug Products*,[34] the court held that the speech was commercial speech, and therefore privy to First Amendment protection.[35] Second, the court, relying on *Central Hudson Gas & Electric Corp. v. Public Service Commission*,[36] found that the relevant provisions of the FDCA were consistent with the First Amendment.[37] The jury ultimately convicted Caronia on the first felony count.

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[28] *Id*. at 155-156.
[29] *Id*. at 156.
[30] *Id*.
[31] He was charged with conspiracy to introduce misbranded drug into interstate commerce (§§331(a) and 333(a)(2)), and introducing a misbranded drug, Xyrem, into interstate commerce (§§331(a) and 333(a)(2)).
[32] *Caronia*, *supra* note 3, at 158.
[33] *United States v. Caronia*, 576 F. Supp. 2d 385, 403 (E.D.N.Y. 2008).
[34] 463 U.S. 60, 66-68 (1983).
[35] *Caronia (Dst)*, *supra* note 33, at 396. Under *Bolger*, in order for promotional activity to be protectable as commercial speech, "a court must look to (1) whether the expression is an advertisement; (2) whether it refers to a specific product; and (3) whether the speaker has an economic motivation for speaking." *Bolger*, *supra* note 34, at 66-68.
[36] 447 U.S. 557 (1980) ["*Central Hudson*"].
[37] *Central Hudson* provides a four part test to determine if the speech is protected by the First Amendment. First, the speech must "concern lawful activity and not be misleading." *Id*. at 566. Second, the governmental interest must be

B. Second Circuit's Opinion

The Second Circuit, by a 2-1 vote, vacated the conviction and remanded the case for further proceedings. The majority, authored by Judge Chin, partook in a two-part analysis.

First, the court rejected the government's argument that the First Amendment was not implicated because Caronia's statements were merely evidence of intent and not speech.[38] Specifically, the government argued that Caronia's promotion of Xyrem "for off-label use served merely as 'evidence of intent' or evidence that the 'off-label uses were intended ones for Xyrem.'"[39] The court rejected this argument on two bases: first, that the government had relied on Caronia's specific speech in a way that belied their argument in front of the court, and second, that "the government clearly prosecuted Caronia for his words – for his speech."[40] Having determined that the Caronia was prosecuted for his speech, the court relying on *Sorrell v. IMS Health, Inc.*,[41] held that the FDA's construction of the FDCA was both an impermissible content- and speaker-based restriction,[42] and therefore warranted heightened scrutiny.[43]

Second, despite finding that heightened scrutiny could be used, the court, applying the less burdensome *Central Hudson* analysis, held that the FDCA regulation was an unconstitutional violation of the First Amendment. The court found that the regulation met the

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substantial. Third, the regulation must "directly" advance the governmental interest. Fourth, the regulation must be narrowly tailored, *i.e.* the regulation must not be "more extensive than is necessary to serve that interest." *Id*.

[38] *Caronia*, *supra* note 3, at 160. The dissent agreed with this contention.

[39] *Id*.

[40] *Id*. at 160-162.

[41] 131 S.Ct. 2653 (2011). The *Sorrell* court held that "[s]peech in aid of pharmaceutical marketing ... is a form of expression protected by the ... First Amendment….[The] creation and dissemination of information are speech within the meaning of the [Constitution]." *Id*.

[42] The court found that the government's interpretation of the misbranding provisions was content-based because it distinguished between favored speech and disfavored speech on the basis of ideas or views expressed. The court then found that the government's construction was speaker-based because it targeted one kind of speaker – pharmaceutical manufacturers – while allowing others to speak without restriction. *Caronia*, *supra* note 3, at 165.

[43] The court did not clarify which kind of heightened scrutiny, *i.e.* intermediate, strict, or some other kind of strict scrutiny, could have been applied.

first two prongs of the *Central Hudson test*.[44] But as to the third prong, namely the requirement that the regulation "directly advance the government's interests,"[45] the court found that because off-label use itself was not prohibited, "it does not follow that prohibiting the *truthful* promotion of off-label drug usage by a particular class of speakers would directly further the government's goals of preserving the efficacy and integrity of the FDA's drug approval process…."[46] The court also noted that the government's interference with off-label *promotion*, while allowing off-label *use*, was unduly paternalistic.[47] Finally, the court held that the regulation failed the final prong of *Central Hudson*, as it was not narrowly tailored to the interest it sought to regulate. The court reasoned that the government could take a number of different approaches to limiting the speech in a more narrow fashion.[48]

III. The Government's Reaction to *Caronia*

In the aftermath of the decision, reaction across both the media[49] and legal writers[50] was swift, with many waiting "anxiously to find if the FDA would seek further review of the ruling, either by an *en banc* court of the Second Circuit or by the Supreme Court."[51] However, in

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[44] *See Central Hudson*, *supra* note 36, at 165-166. ("First, promoting off-label drug use concerns lawful activity (off-label drug use), and the promotion of off-label drug use is not in and of itself false or misleading…Second, the government's asserted interests in drug safety and public health are substantial.").
[45] *Id*.
[46] *Id*. (emphasis added).
[47] *Id*. citing to *Va. Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).
[48] For example, the court stated: "If the government is concerned that off-label promotion may mislead physicians, it could guide physicians and patients in differentiating between misleading and false promotion, exaggerations and embellishments, and truthful or non-misleading information." *Caronia*, *supra* note 3, at 168.
[49] *See, e.g.*, Katie Thomas, *Ruling Is Victory for Drug Companies Promoting Medicine for Other Uses*, The New York Times (Dec. 3, 2012), *available at* http://www.nytimes.com/2012/12/04/business/ruling-backs-drug-industry-on-off-label-marketing.html?_r=0.
[50] *See, e.g.*, Michael Loucks, *Caronia and Harkonen – Lessons for the Gov't*, Law 360 (Apr. 23, 2013), *available at* http://www.law360.com/articles/434448/caronia-and-harkonen-lessons-for-the-gov-t (stating "Some writers urged that the government needed to rethink the entire campaign; others predicted that the decision would eviscerate federal law enforcement in this arena, and still others predicted that the government would not easily abandon an arena in which it has been quite successful in reaping huge monetary settlement."); Brian J. Malkin, *Free Speech and Off-Label Drug Promotion: Should Recent Cases Change Your Business Practices*?, 2013 Aspatore Special Rep. 5, at *4 (2013) (stating "*Caronia* cast doubt on the FDA's ability to prohibit truthful off-label promotion in the Second Circuit, with the reverberations felt throughout the country.").
[51] Gershengorn, *supra* note 11.

January 2013, Tom Abrams, Director of the Office of Prescription Drug Promotion at the Center for Drug Evaluation and Research, announced that the government would not be seeking further review. According to Director Abrams: "The government has determined not to seek further review of the Second Circuit's decision in *United States v. Caronia*, No. 09-5006-cr (2d Cir.). The FDA does not believe that the Caronia decision will significantly affect the agency's enforcement of the drug misbranding provisions of the Food, Drug, and Cosmetic Act."[52]

Although the government's decision not to appeal may seem surprising at first blush, there are a number of rationales that support its choice. This section discusses a few of those reasons, while also illustrating why the *Caronia* decision, from both a legal and practical standpoint, has not been as significant as first thought.

A. *Caronia* only applies in cases where the off-label promotion was truthful

Perhaps the largest limitation of the *Caronia* court's holding is that it only applies to situations in which the off-label promotion is actually truthful. As many off-label promotion cases involve false and/or misleading information being disseminated to the public, the effect of the Second Circuit's decision is limited to a minority of cases. Director Abrams noted this limitation in his statement in response to *Caronia*: "Because the court…acknowledged that the First Amendment does not preclude an enforcement action based on speech regarding unapproved uses that is false or misleading, the Second Circuit's decision does not bar the government from continuing to enforce the misbranding provisions of the FD&C Act, including…in cases involving off-label promotion."[53]

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[52] Jill Wechsler, *Tom Abrams: Caronia Won't Stop Off-Label Enforcement*, PharmExec.com (Jan. 30, 2013), *available at* http://blog.pharmexec.com/2013/01/30/tom-abrams-caronia-won%E2%80%99t-stop-off-label-enforcement/.
[53] *Id*.

Caronia's limited reach was further highlighted by the Ninth Circuit's decision in *United States v. Harkonen*.[54] In that case, the Ninth Circuit affirmed a defendant's criminal conviction[55] for issuing a fraudulent press release that endorsed positive results for an off-label use of Actimmune.[56] The press release allegedly led doctors to "prescribe, or patients to seek prescriptions of Actimmune."[57] Although Harkonen presented a similar free speech defense to those made in *Caronia*, the Ninth Circuit mooted the constitutional issue by noting, at the outset of the opinion, that because the speech was fraudulent,[58] the First Amendment did not provide any protection for the speech.[59] Notably, the court did not cite to *Caronia* throughout the decision. That omission illustrates two things: first, that *Caronia* is not an oft-cited precedent[60], a far cry from its original reception and second, that the oversight highlights the limits of the Second Circuit's holding to *truthful* off-label promotion cases alone.

B. Caronia only applies to the Second Circuit, and the government did not want to risk the Supreme Court affirming the decision

The government's decision not to appeal *Caronia* is also logical from a legal perspective for two reasons. First, *Caronia* is binding only in the Second Circuit.[61] That inherent limitation, along with the fact that *Caronia* has not been used consistently as persuasive authority by other

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[54] 510 Fed. Appx. 633 (9th Cir. 2013). For a good summary of the case, *see* Han Helen Yan, *Off-Label Promotion is Protected Speech: Second Circuit Sweeps Away Pharmaceutical Representatives Misbranding Conviction under the First Amendment – United States v. Caronia*, 39 Am. J.L. & Med. 189, 191 (2013).
[55] W. Scott Harkonen was the CEO of the pharmaceutical company in that case.
[56] *Harkonen*, *supra* note 54, at 636.
[57] *Id*.
[58] If the speech had been part of some "genuine scientific debate," then it would have fallen outside of the "the scope of the mail and wire fraud statutes." *Id*. at 637. However, the Ninth Circuit, relying on the jury's finding, found that the alleged speech was not part of any such debate, and therefore was fraudulent.
[59] *Id*. at 636 (stating "Constitutional facts determine 'the core issue of whether the challenged speech is protected by the First Amendment.' The First Amendment does not protect fraudulent speech…so the core constitutional issue in Harkonen's case is whether the facts the jury found establish that the Press Release was fraudulent.").
[60] The case has only been cited by some thirty decisions since being handed down. In addition, other courts have found the case to be unpersuasive. *See, e.g.*, *Hawkins v. Medtronic, Inc.*, No. 1:13-CV-00499 AWI, 2014 WL 6611876, at *4 (E.D. Cal. Nov. 20, 2014) (finding that the *Caronia* decision has "gained little traction" in the 9th Circuit).
[61] *See, e.g.*, *The First Amendment and Off-Label Promotion: United States v. Caronia*, Quinn Emanuel Urquhart & Sullivan, LLP (Apr. 11, 2013), *available at* http://www.jdsupra.com/legalnews/the-first-amendment-and-off-label-promot-77738/. The Second Circuit covers only Vermont, New York, and Connecticut.

Circuits, provides substantial support for the government's decision not to file an appeal to the Supreme Court. Further, given that most U.S. Attorney's Offices, including the "very active" Massachusetts and Pennsylvania components, are not bound by the decision, and also have the ability to prosecute companies located within the Second Circuit, the practical implications of the decision are relatively minor.[62]

Second, and perhaps more importantly, the government likely did not want to risk the Supreme Court affirming *Caronia*. The government's concern was likely well-founded, as *Caronia* appears to be consistent with the commercial speech doctrine. The doctrine provides that speech that "does no more than propose a commercial transaction," warrants first amendment protection.[63] The *Virginia Pharmacy* court further reasoned that "advertising, however, tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to who is producing and selling the product….To this end, the free flow of commercial information is indispensable."[64] Applying the doctrine to facts of *Caronia*, off-label promotion would seem to fall within the ambit of the free flow of commercial information.[65] Under the doctrine, promotion, especially if truthful as in *Caronia*, is exactly the kind of information that the Supreme Court, through the doctrine, looks to protect. As such, given the inherent geographical and jurisdictional limitations of the Second Circuit along with the strong legal basis of the decision, the government's decision not to appeal the *Caronia* judgment is quite understandable.

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[62] Gershengorn, *supra* note 11.
[63] *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 761-762 (1976); *see generally* Samuel A. Dilullo, *The Present Status of Commercial Speech: Looking for a Clear Definition*, 90 Dick. L. Rev. 705 (1986) (analyzes the historical and current status of the commercial speech doctrine).
[64] *Virginia*, *supra* note 63, at 765.
[65] *See* Harvard Law Review, *supra* note 8, at 798 (analyzing the application of the commercial speech doctrine).

C. The government has continued prosecutions on other grounds

The limited scope of the *Caronia* holding also means that it cannot limit government prosecutions relying on other statutes, specifically the False Claims Act.[66] The FCA, which generally imposes liability on any individual, group of individuals, or corporations that defraud the government[67], is considered to be "the Government's 'primary litigation tool' for recovering losses resulting from fraud."[68] The FCA also allows for *qui tam* actions, *i.e.* private right of actions, thus increasing the number of cases that can be brought under it.[69]

The *Caronia* holding, which rejected of the government's construction of the FDCA, does not limit the government's use of the FCA against pharmaceutical companies. This is because the "basis of these false claims cases rests not on the marketing but on the plaintiff's ability to establish that prescribing physicians would not have written prescriptions for the drugs at issue paid for by Medicaid or Medicare, but for the off-label marketing."[70] To state the distinction in a different way, the FCA does not actually prohibit off-label promotion, and thus does not implicate any First Amendment rights; rather, the FCA aims to prohibit *conduct* that may cause the submission of false claims that ultimately leads to fraud against the government.

The government made this very distinction in its "Statement of Interest" in *United States ex rel. Matthew Cestra, et al. v. Cephalon, Inc, et al.*[71] Although the government was not a party to the case, the government submitted its Statement of Interest "to advise the Court of its position

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[66] 31 U.S.C. §§ 3729-3733 [hereinafter "FCA"].
[67] The FCA imposes civil penalties and often treble damages on any individual or corporation that "knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim" in an attempt to defraud the government. 31 U.S.C. § 3729(a)(1)(B).
[68] *U S ex rel Stuery v. Cardinal Health*, 625 F. 3d 262, 267 (5th Cir. 2010).
[69] *Id*.
[70] Ellyn L. Sternfield, *FDA will not Appeal Second Circuit Decision in U.S. v. Caronia*, Mintz, Levin, Cohn, Glovsky and Pepeo, P.C. (Feb. 1, 2013), *available at* http://www.martindale.com/government/article_Mintz-Levin-Cohn-Ferris-Glovsky-Popeo-PC_1671718.htm.
[71] 10 Civ. 6457 (SHS) (S.D.N.Y) (Nov 7, 2013). The basic facts of the case were that Cestra, the Relator, who was previously a senior manager at Cephalon, filed the action alleging that the company promoted two of its drugs for off-label uses, and that the off-label promotion led to false claims being submitted to federal health care programs, specifically Medicare and Medicaid.

that the Second Circuit's recent decision in *Caronia* does not preclude a cause of action under the False Claims Act based on a manufacturer's off-label marketing of a prescription drug *causing the submission of false claims to federal health care programs*."[72] In its Statement, the government distinguished actions under the FCA and FDCA by arguing that "the FCA does not prohibit off-label promotion of prescription drugs; rather the FCA prohibits conduct that causes the submission of false claims to the Government for payment. The First Amendment is, thus, not implicated…."[73] The Statement also distinguished *Caronia* from FCA cases that are based on false or misleading off-label marketing, noting that "[t]o the extent…that Cephalon engaged in false and misleading promotion of the drugs, the Court should reject Cephalon's assertion that its alleged conduct is somehow protected by the First Amendment."[74]

The distinction seems to be an effective one. Within two weeks of the *Caronia* decision, the DOJ announced one its largest ever settlements with Amgen Inc.[75] Amgen agreed to pay $762 million for illegally marketing its drug, Aranesp. Notably, the vast majority of that fine, some $612 million, was administered to "resolve False Claims Acts suits."[76] That settlement gives credence to the argument that the government has continued to meaningfully prosecute pharmaceutical companies. It also illustrates the rather limited, or at least non-sweeping, holding of *Caronia*.

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[72] Heidi A. Wendel and Toni-Ann Citera, *United States: Government Files Statement of Interest Distinguishing "Caronia" in Off-Label Promotion False Claims Act (FCA) Case*, Jones Day (Dec. 3, 2013), *available at* http://www.mondaq.com/unitedstates/x/278644/Government+Contracts+Procurement+PPP/Government+Files+Statement+Of+Interest+Distinguishing+Caronia+In+OffLabel+Promotion+False+Claims+Act+FCA+Case. (emphasis added).

[73] *Id*. The government continued its analysis, arguing that "the False Claims Act does not on its face create liability for off-label promotion of a drug. Instead, the FCA prohibits conduct that knowingly causes the submission of false claims, such as claims for treatments that are not 'reasonable and necessary.'"

[74] *Id.*

[75] *Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, NY.; Pays $762 Million to Resolve Criminal Liability and False Claims Act Allegations*, Department of Justice: Office of Public Affairs (Dec. 19, 2012), *available at* http://www.justice.gov/opa/pr/2012/December/12-civ-1523.html.

[76] *Id*.

IV. What Should the Government Take from *Caronia*?

Despite its billing at the time it was handed down, *Caronia* has not had the effect that many thought it would have. Nevertheless, the decision presents a number of important questions about the government's current regulations and whether they should be revisited. This section argues that the current FDA regulation scheme, related to off-label promotion and otherwise, is too restrictive and fails to provide the public with the maximum amount of health and safety information relating to FDA-regulated products.

A. Pharmaceutical companies have the most information regarding the potential uses for a drug

The government's rationale for regulating off-label promotion is a relatively straight-forward one: it wants to protect the public from misinformation that could have deleterious public health implications. Through its construction of the FDCA, the government is able to ensure that pharmaceutical companies are only able to promote drugs for uses that have been specifically authorized by the FDA. However, this construction, through handcuffing the pharmaceutical companies, has two negative outcomes.

First, given the prohibitive costs of FDA approval, pharmaceutical companies often will not apply for authorization for additional pharmacological uses, meaning that it will not be able to educate the public on all of the possible benefits of a certain drug. Before the FDA will approve a specific use for a drug, at which time the promotion for that use would no longer be considered off-label, the FDCA requires "drug manufacturers to show not only that the drug is safe but also to show by 'substantial evidence' that the submitted drug 'will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or

suggested.'"[77] From a practical standpoint, drugs, in the course of meeting the substantial evidence standard, must pass through basic research, animal testing, and then a three-phase system of clinical trials (known as Phase I trials, Phase II trials, and Phase III trials).[78] The FDA, given its considerable discretion to interpret the FDCA, further requires that two such studies – meaning two iterations of the trials – be performed before the drug can be approved for its tested use.[79]

In order to meet the FDA's requirements, pharmaceutical companies often have to go through a multi-year process while footing massive bills[80] before they can begin to market the drug. Given those high demands, many pharmaceutical companies, rather than reapplying for FDA approval for additional uses, may choose to forego the reapplication process and simply rely on others promote the new use. The effect of this approach is that the entity with the most information about a drug's potential uses, *i.e.* the pharmaceutical company, is prohibited from speaking about those uses. This presents two distinct issues: first, that a drug's true effectiveness is stymied by the lack of information reaching the public, which in turn affects public health. Second, because a single drug cannot be promoted for all of its possible uses, a company cannot recoup its massive investment as effectively, all of which leads to higher health care costs[81] and

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[77] *Warner-Lambert Co. v. Heckler*, 787 F.2d 147, 151 (3d Cir. 1986) (citing 21 U.S.C. §355(d)(5)). The substantial evidence standard is defined as: "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed." *Id*.

[78] *See generally* Avik Roy, *How the FDA Stifles New Cures, Part I: The Rising Cost of Clinical Trials*, Forbes (Apr. 24, 2012), *available at* http://www.forbes.com/sites/aroy/2012/04/24/how-the-fda-stifles-new-cures-part-i-the-rising-cost-of-clinical-trials/. Phase III trials, which are often multiyear studies with thousands of human subjects, are the most economically demanding and time consuming.

[79] *Id*.

[80] *Id*. (stating that the 12 leading pharmaceutical companies spent $802 billion to gain FDA approval for 139 drugs from 1997 to 2011, averaging out to $5.8 billion per drug).

[81] *See generally* Michael R. Ward, *Drug Approval Overregulation*, Regulation: The Cato Institute, *available at* http://www.cato.org/sites/cato.org/files/serials/files/regulation/1992/10/reg15n4e.html.

also creates perverse incentives for researchers.[82] The *Caronia* court recognized this very issue noting that "prohibiting off-label promotion by pharmaceutical manufacturer while simultaneously allowing off-label use 'paternalistically' interferes with the ability of patients to receive potentially relevant treatment information; such barriers to *information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions*."[83]

A closely related, yet distinct, third issue is that pharmaceutical companies may well be willing to rely on physicians to promote on their behalf rather than seeking approval for every potential use.[84] This presents similar public health issues, in that it shifts the burden to physicians, who are not limited by off-label promotion statutes,[85] to be well-versed in all of the possible applications of a certain drug. However, naturally, from an information standpoint, doctors may not be an appropriate – much less sufficient – replacement for pharmaceutical companies that developed the drug. Indeed, "when it comes to…important health-affecting products, [the public] depends on doctors, and *they, in turn, depend on medical researchers*."[86]

This is not to say that the FDA's approach is void of value as protecting the public from financially incentivized companies may well serve the public welfare. However, it does seem

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[82] *See* Roy, *supra* note 78 (stating: "This cost burden creates a system of perverse incentives for researchers and industry, which discourages the rational allocation of resources for drug development. After all, only one in 12 drugs that enter human clinical trials end up gaining approval from the FDA. This risk profile has led smaller companies to go bankrupt when they have faced setbacks in clinical studies. Many private investors are withdrawing venture capital support for start-up drug companies, fearing that their investments will vanish if there is the slightest hiccup in the development process."); *see also* Yan, *supra* note 54, at 192 ("Several scientific leaders agree with the *Caronia* dissent and caution that loosening the FDA's authority to regulate off-label marketing will provide drug companies with fewer incentives to sponsor clinical trials showing that off-label therapies work, which would 'harm patients and discourage good science.'").
[83] *Caronia*, *supra* note 3, at 166 (emphasis added).
[84] The company is prohibited from paying doctors kickbacks for any prescriptions of their drugs.
[85] *See e.g. Caronia*, *supra* note 3, at 165 (noting that the government's construction of the FDCA "has the effect of preventing [pharmaceutical manufacturers]—and only [pharmaceutical manufacturers]—from communicating with physicians in an effective and informative manner.") (citing *Sorrell*).
[86] David Frum, *Drug industry's free speech helps doctors*, CNN Opinion (Dec. 10, 2012), *available at* http://www.cnn.com/2012/12/10/opinion/frum-off-label-use-of-drugs/ (emphasis added).

likely that the FDA, through its current scheme, "risks depriving doctors of early notice of information that could treat and cure their patients."[87]

B. The government's current scheme does not adequately protect the public

Caronia, although limited, highlighted a key fault within the government's construction of the FDCA. The government's interest in regulating pharmaceutical companies, ultimately, is one of protecting the public from the use of detrimental drugs.[88] However, the government's current construction does more to stop a drug's promotion and, in doing so, limiting possibly important information to the public, than to actually limiting the drug's use. The *Caronia* majority found this distinction significant, noting that "[t]he government's construction of the FDCA essentially legalizes the outcome—off-label use—but prohibits the free flow of information that would inform that outcome." [89] The court continued that "[i]f the government's objective is to shepherd physicians to prescribe drugs only on-label, criminalizing manufacturer promotion of off-label use while permitting others to promote such use to physicians is an indirect and questionably effective means to achieve that goal."[90]

The government's current off-label construction is further problematic as physicians are not only burdened with having to communicate off-label uses without any assistance from pharmaceutical companies, but also because physicians, under the FDCA, are unregulated. In this regard, the scheme pushes the entire burden of information dissemination onto physicians but does not apply FDA oversight to those same individuals. This discrepancy, while illustrating

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[87] *Id*.
[88] The poster child for this concern can be linked to the tragic fall-out of Thalidomide. The drug was used widely in Europe during the late 1950s and early 1960s as a treatment for nausea in pregnant women. However, the drug led to severe birth defects in thousands of children. The drug was not approved in the United States thanks in large part to FDA officer Frances Kelsey. *See* Margaret Hamburg, *50 Years after Thalidomide: Why Regulation Matters*, FDA Voice (Feb.7, 2012), *available at* http://blogs.fda.gov/fdavoice/index.php/2012/02/50-years-after-thalidomide-why-regulation-matters/.
[89] *Caronia*, *supra* note 3, at 167.
[90] *Id*.

that the government's construction may not be narrowly tailored as a legal framework, seems to, at an even more basic level, miss the overall goal of protecting the public from unregulated use rather than mere promotion.

One counterargument to this position is that, over the years, the FDA has recognized that public health might be served by manufacturers distributing information to physicians, and as such, has created rules and policies that allow, or in some cases require, disclosure of new uses.[91] In addition, the FDA has created four "safe harbors," through which a company is legally allowed to disclose off-label uses to physicians in certain circumstances.[92] These examples illustrate that the FDA is not insensitive to the complete lack of coherence in its policies. At the same time, though the FDA provides guidance and safe harbors to companies, such provisions do not do enough to combat the issues created by the policies for at least three reasons.

First, given the huge litigation and liability costs of stepping over the line from providing legal information to illegal promotion, many companies will choose the more conservative approach of not releasing information about new uses that may be to the public's benefit. Second, the rules and safe harbors are extremely vague, leaving companies unclear about what they are obliged to do, what they should do, and what they cannot do. This is largely because the rules either are not written down at all, or when they are, they are vague and difficult to maneuver.[93] Third, the safe harbors and exceptions to general regulation of pharmaceutical

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[91] For example, mandatory disclosure requirements "can arise out of federal securities law or from legislation requiring manufacturers to disclose information about their clinical trials on www.clinicaltrials.gov." *See* Coleen Klasmeier, *FDA Regulation of Off-Label Promotion: An Answer*, (Feb 5, 2012), *available at* http://www.masonlec.org/site/files/2012/04/FDA-Regulation-of-Off-Label-Promotion_An-Answer.pdf (this is a draft article, and has not been published. However, this author received permission from Ms. Klasmeier to cite her article).

[92] For example, the FDA allows manufacturers to disclose new uses for already approved products "in response to unsolicited" requests. *Id*. at 7.

[93] *Id*. ("The 'rules' the manufacturers are expected to follow often are not written down anywhere (or at least, nowhere that anyone can find easily, or are impossible to apply in any specific situation. The 'safe harbors' use

companies do little to abate the pressure on physicians. Under the current scheme, physicians still have to seek information that would, in an ideal world, be provided to them. Using the example from above, even though the results of various clinical trials are online, the only way that those results become relevant to the general public welfare is if physicians and other interested parties were to monitor the relevant website on a regular basis. Such a regime is not only inefficient, in that it forces the party with less incentive to also be the party to take the most action[94], but it also assumes that physicians have the time, ability, or simply desire to follow up on every possible new use for every drug that they might prescribe.

C. The FDA's construction is unclear in the face of technology[95]

The rise of technology, specifically the internet, presents interesting and potentially game-changing implications for the FDA's regulation scheme. Given that often the first stop for a typical person, or even a physician, with a health-related question is the internet[96], "[h]uge incentives exist [for pharmaceutical companies] to expand on-line information links."[97] Although the FDA recognized this issue as early as 1996[98], the FDA's current regime is difficult to apply to the internet. For instance, the FDA's scheme is unclear on what constitutes illegal off-label

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terms that are vague or are interpreted differently by FDA over time, and in any case are recognized by prosecutors only in the breach.").

[94] Pharmaceutical companies have an obvious financial incentive to tell physicians directly about as many uses of their drug as possible. Physicians, given that kickbacks are largely illegal, have no such incentive.

[95] Unlike the previous two subsections, this issue was not addressed in *Caronia*. Nevertheless, it is worthy of discussion as it illustrates the problems inherent in the FDA's current position.

[96] *America's House Call Network to Go On-Line By Year* End, F-D-C Rep. ("The Tan Sheet"), July 3, 1995, at 11 (providing that about twenty-five percent of internet traffic is related to health).

[97] Marc J. Scheineson, *Legal Overview of Likely Fda Regulation of Internet Promotion*, 51 Food & Drug L.J. 697 (1996).

[98] In 1997, Byron Tart, the director of promotion of Center for Devices and Radiological Health (CDRH) at the time, announced that the FDA was close to completing a draft guide to extol the FDA's position on promotion over the internet. However, that effort failed, as the FDA later confirmed that the FDA was suspending the effort indefinitely. *See* Jeffrey K. Shapiro, *BOTTOM Line: A Practical Guide to FDA's Regulation of Promotion and Advertising on the Internet*, MD+DI (June 1, 2000), *available at* http://www.mddionline.com/article/bottom-line-practical-guide-fdas-regulation-promotion-and-advertising-internet.

promotion on the internet.[99] A related question is whether web links on a company's webpage are "direct-to-consumer" advertisements[100] or not. If a company's website is construed to be direct advertising, the company must meet a number of requirements to ensure that it does not mislead the public, including, for example, that "the information distributed must include a bibliography of other articles that discuss the off-label use of the drug or device in question."[101] Such a requirement is unworkable in an online format, further emphasizing the disconnect between the current rules and their application to the internet.

For its part, the FDA has been trying to provide guidance to the pharmaceutical industry on how to handle off-label promotion over the internet. In December 2011, the FDA released "Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices"[102] in an effort to address the issue. The Draft Guidance focused on the difference between responses to unsolicited inquiries regarding off-label promotion, which are legal, and responses to solicited inquiries, which are considered off-label promotion (and hence not legal). Although the Draft Guidance shed light on that particular distinction, a number of commentators have noted that there are still significant issues that were left unresolved under the FDA's new approach.[103] Furthermore, given the many other distinctions and issues that may arise in applying the FDCA to the internet, such guidance,

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[99] Scheineson, *supra note* 97, at n. 21 ("For example, when a drug manufacturer includes information and links on its home page, at what point does the information contained or cross-linked qualify as marketing of products and particular uses of products? Are the drug companies reaching out to the public in a form of advertisement, or are they simply providing them with a resource they can examine at their own initiation?").

[100] An even more basic question, and one that further illustrates the difficulty of applying the FDCA to internet use, is the difference between "labeling" and "advertising." *See generally* David E. Dukes, James F. Rogers, *What You Should Know About Direct-to-Consumer Advertising of Prescription Drugs*, 68 Def. Couns. J. 36, 38 (2001) (stating "In the Internet age, it is not clear whether Internet promotion is 'advertising' or more akin to 'labeling.'").

[101] *Id*. at 40-41.

[102] *Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices*, Food and Drug Administration (Dec. 2001), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM285145.pdf [hereinafter "Draft Guidance"].

[103] *See e.g. FDA's New Off-Label Guidance: What I Says and What it Leaves Unanswered*, Fox Rothschild LLP (May 2012), *available at* http://www.foxrothschild.com/newspubs/newspubsArticle.aspx?id=15032386001.

absent the government revisiting its position on off-label promotion, is likely insufficient or simply too slow.

V. Recommendations on How to Amend the Current Regulation Scheme

Although the previous section paints an unattractive picture of the FDA's current enforcement scheme, the regulation system is unlikely for see serious change in the near future. Indeed, for both practical and lack of necessity reasons, such drastic change is gratuitous. Rather, this section argues that two key changes, specifically a relaxation in the requirements to have new uses approved for already-approved drugs and the introduction of an analogy test to be applied to actions on the internet, may solve the shortfalls of the current regime.

A. Lowering the Requirements of Approval for New Uses

As discussed at length above, the prohibitive costs of seeking approval for new uses for a previously approved drug leads to two unfortunate outcomes: first, that many companies do not seek approval, and thus are unable to promote and educate the public on all of the possible beneficial health effects of the new use. Second, that it shifts the burden to physicians to become informed on a drug's various uses and communicate those benefits to patients. At the same time, in weighing these externalities against the government's mission to protect the public from another Thalidomide-like disaster[104], it is equally clear that the standard for approval of new uses must be more demanding.

However, the government's current construction of FDCA Section 505(d), which has been construed to require at least two studies – which include the massive and expensive Phase III trials – is cost-prohibitively high, particularly with regards to drugs that have already received FDA approval for other uses. Rather than continue to construe the "substantial evidence" requirement under section 505(d) to include two clinical investigations, the government should

[104] *See* Hamburg, *supra* note 88.

opt for a less demanding testing regime for drugs that have already been approved for a different use. This position is supported by the fact that at least one study has found that the two clinical trial requirement is excessive to determine whether a proposed secondary use for a previously authorized drug is safe.[105] A lower, but not substantively vacated, standard ensures that the government can still continue to protect the public, while at the same time not limiting the pharmaceutical company, the entity with the most knowledge of the specific drug, to the side lines.

In terms of what the lower standard might be, it is unclear what the perfect level of requirement would entail. One proposal might be that that a single clinical investigation should suffice. A second, particularly interesting proposal is the one put forth by Coleen Klasmeier[106], who argues that Section 505 should include a special rule for uses that involve drugs that have already received FDA approval: "[t]he special rule would state that, if the preponderance of the evidence related to a drug use shows that the drug is effective, or shows that the therapeutic benefits of the use generally outweigh its risk, then the labeling must state that there is evidence that the drug is effective for that use."[107] A third proposal would be to grant "conditional approval" for new uses that successfully complete the second of the three-level approval process. This approach, championed by Avik Roy, has at least two distinct benefits.[108] First, by allowing the pharmaceutical company to gain revocable approval prior to the expensive Phase III trials, the FDA would allow companies to begin to make a profit sooner in the process. In turn, this would incentivize companies to actually complete the FDA's complete approval process rather

[105] Coleen Klasmeier & Torrey Cope, NDA Approval Under FDCA Section 505(b)(1) Based on Effectiveness Data from One Clinical Trial (Soc. Sci. Res. Net., Working Article, January 10, 2012), available at http://ssrn.com/abstract=1991427.
[106] Ms. Klasmeier is the head of Sidley Austin, LLP's Food Drug and Medical Regulatory practice.
[107] *See* Klasmeier, *supra* note 91, at 13.
[108] Avik Roy, *How the FDA Stifles New Cures, Part III: A Proposal for Reform,* Forbes (Apr. 26, 2012), *available at* http://www.forbes.com/sites/aroy/2012/04/26/how-the-fda-stifles-new-cures-part-iii-a-proposal-for-reform/.

than choosing not to pursue it at all. Second, given that the first two phases of the approval scheme are significant hurdles, allowing drugs that have passed those two phases to reach patients sooner rather than later would likely have substantial public health benefits.

Although there is no error proof way of telling which of these three proposals, among a number of other possibilities, is the correct standard, it is clear that the current regime's requirement should be altered to better balance the government's interest in protecting the public against the pharmaceutical company's interests.

B. Create a reason-by-analogy test to apply to companies' promotions on the internet

The application of the government's regulations, specifically of the FDCA, to the internet is a particularly difficult issue. Based on the fact that the government is currently taking a piece-meal approach towards updating procedures for the internet, as evidenced by Draft Guidelines on discreet parts of government regulation, implementation of the internet into the FDCA promises to be disjointed and likely unclear.

Rather than embark on this current slow march, the government would do well to create a reason-by-analogy test, in which it would use examples of what is considered to be off-label promotion in the pre-internet world and compare those to actions that are similar in the current day. In creating such a test, the government could look for inspiration from the family resemblance test found in *Reves v. Ernst & Young*.[109] In that case, the Supreme Court adopted the family resemblance test to determine whether certain demand notes issued by a private cooperative were securities within the meaning of the Securities Exchange Act of 1934. Under the family resemblance test, the court, *inter alia*, first created a list of notes that were securities under the 1934 Act, and second, compared the demand notes in question to that list of securities.

[109] 494 U.S. 56 (1990).

In finding that the demand notes were similar to the notes typically thought of as securities, the court held that the demand notes were securities.[110] The government could create a similar test for this circumstance, *i.e.* one that compares a company's actions on the internet to what would be considered illegal off-label promotion in a pre-internet context.[111]

Such a test would be effective for two reasons. First, the FDA, in its guidance memorandums, already includes a multitude of examples that are meant to illustrate what actions are legal and illegal. By creating list of actions that are presumptively illegal as off-label promotion, the government would be simplifying those examples into a list, and then using that list to compare company actions that occur over the internet. Second, adopting such a test would amount to a single, uniform step in the regulation of off-label promotion on the internet, rather than the government's current approach. Admittedly, there are problems with this novel approach. First, and perhaps most obviously, the government and courts may be unwilling to fashion a test based on securities law for off-label promotion purposes, as the two underlying issues are not similar. Second, distilling a list of actions that look like off-label promotion is likely much more difficult than creating a list of items that are securities.

To be sure, there would be issues in applying a family resemblance-like test, but the benefits would outweigh the cost. The government's current position and its existing haphazard plan for off-label promotion regulation on the internet going forward are unclear, inconsistent, and likely far too slow to truly amount to anything approaching an effective parameter. Although such a test might be difficult to implement, it would be an innovative leap forward, and a much needed update to an otherwise largely outdated scheme.

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[110] *Id*. at 76.

[111] This is not to say that the family resemblance test can be applied directly to off-label promotion cases. However, a similar test could be devised.

VI. Conclusion

United States v. Caronia, at the time it was handed down, was considered to be a signature victory for pharmaceutical companies and a crushing blow to the government's ability to regulate and criminalize off-label promotion. Since the decision, however, that resonance does not seem to ring true. Despite its billing, the decision has not limited the government's ability to criminalize off-label promotion, in large part because of the holding's limited reach both as a matter of law and as a matter of jurisdiction, and the fact that the government has other avenues, namely, the False Claims Act, to bring multi-million to billion dollar suits against Big Pharma.

At the same time, however, this article offers at least three lessons that the government can take from the *Caronia* decision, each of which illustrate that the government's position regarding off-label promotion not only fails to achieve its overall goal of protecting the public, but also that it is stagnant in the face of a changing industry. This is not to say that current scheme is without merit – this article does not call for a whole-sale change to the current FDA scheme. Rather, it suggests two changes to the current scheme not only to enhance the public health, but also to bring the government's regulation of off-label promotion to the modern day.