

# What's Left for Plaintiffs in Off-Label Pharmaceutical

In the December 2012 *United States v. Caronia* decision, the Second Circuit held that the prohibition and criminalization of certain types of off-label promotional speech by pharmaceutical companies and their representatives violates the First Amendment. In light of the significant settlements achieved by the federal government, third-party payors and consumer plaintiffs based on off-label promotional speech claims, many have wondered whether such claims have a viable future.

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# Promotion Cases After *United States v. Caronia*?

In the past decade, in addition to numerous criminal convictions, the federal government (as well as a number of third-party payor and consumer plaintiffs) have achieved significant settlements from pharmaceutical companies based on claims that the companies improperly promoted pharmaceuticals for off-label, unapproved uses in violation of the U.S. Food and Drug Administration (FDA) regulations. A recent decision by the U.S. Court of Appeals for the Second Circuit has left many wondering about how viable such claims will be in the future.

In the December 2012 *United States v. Caronia*<sup>1</sup> decision, the Second Circuit held that the prohibition and criminalization of certain types of off-label promotional speech by pharmaceutical companies and their representatives violates the First Amendment. As a result, the court overturned the conviction of a pharmaceutical representative for his *truthful* promotion of a drug for uses for which the drug had not been approved. This article will analyze that decision as well as Judge Debra Ann Livingston's strong dissenting opinion and then consider what is next for off-label marketing claims brought by the government or third-party plaintiffs both in the Second Circuit and elsewhere in a post-*Caronia* world.

## The Legal Framework

Underlying the Second Circuit's opinion in *Caronia* is the dichotomy between the way the law treats physicians and pharmaceutical manufacturers when it comes to the "off-label" use

of pharmaceutical drugs. The Federal Food, Drug and Cosmetic Act (FDCA) states that "[n]o person shall introduce or deliver into interstate commerce any new drug" without approval by the FDA.<sup>2</sup> Upon FDA approval, "prescription drugs can be prescribed by doctors for both FDA-approved and unapproved uses."<sup>3</sup> While doctors can prescribe drugs for unapproved uses, however, pharmaceutical manufacturers and their representatives cannot market an FDA-approved drug for the same unapproved uses. Specifically, an FDA guidance document states that "[a]n approved drug that is marketed for unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include adequate directions for use."<sup>4</sup> This dichotomy exists because the FDA, as a general matter, does not regulate doctors or how doctors use FDA-approved drugs.

The FDCA regulatory framework on misbranding prohibits certain acts including "[t]he introduction or delivery for introduction into interstate commerce of" drugs that are "misbranded."<sup>5</sup> A drug is "deemed to be misbranded" if "its labeling is false or misleading in any particular."<sup>6</sup> It is also misbranded, however, if its labeling fails to bear "adequate directions for use."<sup>7</sup> "Adequate directions for use" are defined under the FDA regulations to "[mean] directions under which the layman can use a drug safely and for the purposes for which it is intended." Intended use is further defined as "the objective intent of the persons legally responsible for the labeling of drugs," which includes "oral or written statements by such persons or their representatives."<sup>8</sup> Intended use also includes "the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." Pharmaceutical companies or their representatives who misbrand drugs run afoul of the FDCA and FDA regulatory framework and subject themselves to criminal sanctions.<sup>9</sup>

Interestingly, the FDCA and FDA do not expressly prohibit the promotion or marketing of drugs for off-label uses. The "regulations do," however, "recognize that promotional statements

by a pharmaceutical company or their representatives can serve as proof of a drug's intended use."<sup>10</sup> The key statutory silence on the promotion or marketing of drugs for off-label uses was important to the Second Circuit in its analysis of the government's arguments in *Caronia*. Specifically, the court noted that it was the government, and not the FDCA or the FDA that "treated promotional speech as more than merely evidence of a drug's intended use" and therefore "construed the FDCA to prohibit promotional speech as misbranding itself."<sup>11</sup> The Second Circuit ultimately rejected this broad construction because, as the analysis below demonstrates, the court concluded that such a construction ran afoul of the First Amendment.

## The Factual Background

On Dec. 3, 2012, the Second Circuit, in a 2-1 opinion, concluded that "the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug."<sup>12</sup> *Caronia* centered on Alfred Caronia, a pharmaceutical sales representative, who was found guilty in a jury trial of conspiracy to introduce a misbranded drug into interstate commerce, a misdemeanor violation of 21 U.S.C. §§ 331(a) and 333(a)(1). Caronia, a representative for Orphan Medical, had promoted the prescription narcolepsy drug Xyrem for the use in patients as young as 14 as well as in patients over the age of 65, despite the fact that the FDA required an explicit "black box" warning for Xyrem, finding, "among other things, that the drug's safety and efficacy were not established in patients under 16 years of age, and the drug had very limited experience among elderly patients."<sup>13</sup> On appeal of his conviction, Caronia primarily argued that the government's construction of the FDCA misbranding provisions and accompanying regulations prohibiting off-label promotion unconstitutionally violated his First Amendment rights. Specifically, Caronia argued that the First Amendment did "not permit the government to prohibit and criminalize a pharmaceutical manufacturer's truthful and non-misleading promotion of an FDA-approved drug to physicians for off-label use where such use is not itself illegal and others are permitted to engage in speech."<sup>14</sup>

The Second Circuit agreed with Caronia, vacating Caronia's conviction because it found that the government had prosecuted Caronia for truthful, off-label promotion. The court reviewed and dismissed the government's first argument, that Caronia's speech was used as evidence of intent.<sup>15</sup> The court's opinion detailed government statements as well as jury instructions in which the government focused on Caronia's speech in promoting Xyrem rather than focusing on Caronia's speech as evidence of intended use of Xyrem.

Instead, the Second Circuit focused on the key question of "whether the government's prosecution of Caronia ... only for promoting an FDA-approved drug for off-label use was constitutionally permissible" under the First Amendment.<sup>16</sup> In assessing Caronia's First Amendment challenge, the Second Circuit emphasized the statutory silence in the FDCA and its accompanying regulations regarding the prohibition or criminalization of off-label promotional speech. The court observed that the "FDCA" statute "and ... accompanying regulations" under which Caronia was convicted did not "expressly prohibit or criminalize off-label promotion." Rather, the statute and accompanying regulations "define[d] misbranding in terms of whether a drug's label [was] adequate for its intended use." Intended use was further explained "by reference to promotional

statements made by drug manufacturers or their representatives." Thus, the FDCA statute and accompanying regulations were silent with respect to off-label promotion.<sup>17</sup>

Further, the Second Circuit relied on the Supreme Court's decision in *Sorrell v. IMS Health*,<sup>18</sup> when deciding that heightened scrutiny applied to Caronia's First Amendment claim that the government's construction represented an impermissible restriction on speech. In *Sorrell*, the Supreme Court considered a Vermont statute's speech restrictions on pharmaceutical marketing in deciding that "speech in aid of pharmaceutical marketing ... is a form of expression protected by the ... First Amendment." Because the Vermont statute "disfavored speech with a particular content (marketing) when expressed by certain disfavored speakers (pharmaceutical manufacturers), the Court held that it unconstitutionally restricted speech."<sup>19</sup>

Similarly, the Second Circuit determined that the government's construction of the misbranding provisions should be subject to heightened scrutiny because the government's construction of these provisions as prohibiting and criminalizing the promotion of off-label drug use by pharmaceutical manufacturers was both content and speaker-based. The Second Circuit offered two arguments in support of this conclusion. First, the government's construction of the misbranding provisions was content-based because "it distinguish[ed] between favored speech and disfavored speech on the basis of ideas or views expressed." Specifically, "speech about government-approved use of drugs" was favored and permitted while "certain speech about the off-label use of drugs" was disfavored and prohibited.<sup>20</sup>

Second, the government's construction was speaker-based because "it targets one kind of speaker—pharmaceutical manufacturers—while allowing others to speak without restriction." The Second Circuit noted that the Court in *Sorrell* reviewed a statute under which "pharmaceutical companies were barred from obtaining and using prescriber-identifying information for marketing purposes" while "a wide range of others speakers ... could acquire and use the information." Similarly, Caronia's appeal involved a distinction between pharmaceutical companies and other speakers, including doctors. Moreover, the Second Circuit found that Caronia's First Amendment claim was more compelling than the claim at issue in *Sorrell* because Caronia was subject to a criminal regulation.<sup>21</sup>

The court, however, did not stop there. It held that even if the restrictions on Caronia's speech were not subject to heightened scrutiny, the government could not justify a criminal prohibition even under the intermediate scrutiny analysis outlined in the Supreme Court's four-step test set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.<sup>22</sup>

The court found that *Central Hudson's* first step—that the speech in question not be misleading or that it concern lawful activity—was easily satisfied because "promoting off-label drug use concern[ed] lawful activity (off-label drug use)" which was "not in and of itself false or misleading." Likewise, the second step requiring that the government's asserted interest be substantial was also clearly met.<sup>23</sup>

Thus, most of the Second Circuit's analysis focused on the third and fourth prongs of the *Central Hudson* test. The court found that the third step—that the regulation directly advance the government's interest—was *not* met for two reasons. First, "off-label drug usage [was] not unlawful, and the FDA's approval process

generally contemplate[d] that approved drugs w[ould] be used in off-label ways.” Because off-label uses were not prohibited, the Second Circuit said, “it did not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers” directly advanced the government’s interest. Second, the Second Circuit found that the regulation did not directly advance the government’s interest because “prohibiting off-label promotion by a pharmaceutical manufacturer while simultaneously allowing off-label use paternalistically interfere[d] with the ability of physicians and patients to receive potentially relevant treatment information.” Indeed, the FDA “itself recogniz[ed] that public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved drugs” because the FDA permitted “the dissemination of off-label information through scientific journals.”<sup>24</sup>

Although the Second Circuit did acknowledge that “some off-label information could certainly be misleading or unhelpful,” it found that Caronia’s case did not involve either misleading or unhelpful information. Rather, it found that “in the field of medicine and public health ... it only furthers the public interest to ensure that decisions about the use of prescription drugs, including off-label usage, are intelligent and well-informed” because such information can “save lives.” In effect, the “government’s construction” of the misbranding provisions “legaliz[ed] the outcome—off-label use—but prohibit[ed] the free flow of information that would inform the outcome.” Thus, the Second Circuit found that the “government’s prohibition of off-label promotion by pharmaceutical manufacturers provides only ineffective or remote support for the government’s purpose.”<sup>25</sup>

Finally, the Second Circuit also determined that the fourth *Central Hudson* step—requiring that the government’s regulation be narrowly drawn to further the interests served—was not met. The court held that the government, by construing the misbranding provisions to impose a complete and criminal ban on off-label promotion by pharmaceutical manufacturers, was imposing a more extensive regulation than necessary to achieve its substantial interests.

The court noted that “several alternatives without excessive First Amendment restrictions” were available, including “non-criminal penalties,” “guiding physicians and patients in differentiating between misleading and false promotion, exaggerations and embellishments, and truth or non-misleading information,” or “develop[ing] warning or disclaimer systems, or develop[ing] safety tiers within the off-label market, to distinguish between drugs.”<sup>26</sup> In light of these numerous possibilities, the Second Circuit found that the government had not “established a reasonable fit among its interests in drug safety and public health, the lawfulness of off-label use, and its construction of the FDCA to prohibit off-label promotion.”<sup>27</sup>

As a result of the government’s failure to meet the third and fourth steps of the *Central Hudson* test, the Second Circuit “declin[ed] to adopt the government’s construction” of the misbranding provisions “to prohibit manufacturer promotion alone as it would unconstitutionally restrict free speech.” Thus, it construed “the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of the FDA-approved drugs.” The Second Circuit made clear, however that its conclusion was “limited to FDA-approved drugs for which off-label use is not prohibited.”<sup>28</sup> In her dissent, Judge Livingston focused on her agreement with the government that Caronia was not prosecuted for his

speech. Rather, Judge Livingston contended that Caronia’s speech was used as evidence of objective intent, to show “that promotion of a use may demonstrate an objective intent that the drug be used for that purpose.” This was because “[s]peech alone [was] not ... sufficient to sustain a conviction” under the misbranding provisions.<sup>29</sup>

Judge Livingston, however, went further and assessed the strength of the majority’s First Amendment argument. She opined that, even if “Caronia’s speech as evidence of intent was not *necessarily* constitutionally permissible,” she believed that “the correct application of commercial speech principles required” the Second Circuit “to uphold Caronia’s conviction.” This was because, in Judge Livingston’s view, the misbranding provisions “directly advanc[ed] a substantial government interest and [were] narrowly drawn to further that interest.” Specifically, the “prohibition on off-label marketing directly advanc[ed] the interest of” the FDCA “in ensur[ing] that any product regulated by the FDA [was] safe and effective for its intended use.”<sup>30</sup>

**On appeal of his conviction, Caronia primarily argued that the First Amendment did “not permit the government to prohibit and criminalize a pharmaceutical manufacturer’s truthful and non-misleading promotion of an FDA-approved drug to physicians for off-label use where such a use is not itself illegal and others are permitted to engage in speech.**

Moreover, Judge Livingston thought that the majority’s emphasis on the misbranding provisions targeting “a particular class of speakers—namely, drug manufacturers” was misplaced. In her view, “drug manufacturers [were] the precise group that the government must encourage to participate in the new drug approval process.” A prohibition that “applied to any broader class of speakers ... would likely fail *Central Hudson*’s fourth requirement that a regulation be narrowly drawn.”<sup>31</sup>

Additionally, Judge Livingston noted that the government in *Sorrell* did not argue the statute at issue “prevent[ed] false or misleading speech.” “In contrast, Congress intended the FDA approval process to prevent dangerous products with false or misleading labels from entering the market, and also to provide a base of reliable, objective information about prescription drugs that could help physicians and patients identify potentially misleading claims.” As a result, Judge Livingston believed that, even if the government’s criminalization and prohibition was considered a direct regulation of speech, it, nevertheless, was “a regulation that directly advanc[ed] a substantial government interest in a manner not more extensive than necessary to serve that interest.” Thus, in her view, the regulation was constitutional under both *Central Hudson*’s intermediate scrutiny analysis as well as *Sorrell*’s heightened scrutiny analysis.<sup>32</sup>

## What Next for Off-Label Marketing Claims Against Pharmaceutical Companies Post-*Caronia*?

Several commentators have reported that the government has decided not to appeal *Caronia*.<sup>33</sup> These observers have found the FDA's decision to be a wise one insofar as higher review could "[expand] the ruling's reach" and also create a tough precedent by giving "drugmakers more room for off-label marketing."<sup>34</sup> For its part, the FDA has been quoted as stating that it "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."<sup>35</sup> Specifically, Thomas W. Abrams, the director of the FDA's Office of Prescription Drug Promotion, stated that, "[t]he court of appeals did not address the constitutionality of the theory of the liability of which the government has defended the conviction" but rather focused on erroneous jury instructions, and, thus, did not "preclude enforcement based on false or misleading statements."<sup>36</sup>

Even in the Second Circuit, where presumably the *Caronia* decision will remain the law for at least the near future, it is important to note that the decision itself was limited in several important ways. Most significantly, *Caronia* was convicted for *truthful* speech. The Second Circuit's holding was that the FDA's regulation prohibiting and criminalizing *truthful*, off-label promotion of FDA-approved drugs *for which off-label use is not prohibited* could not withstand constitutional muster. Most of the successful government and third-party payor settlements in the past decade or so have not alleged truthful misbranding, but rather have alleged that the defendant drug company fraudulently made misleading statements in connection with its off-label marketing. For example, the government reached a \$3 billion settlement with GlaxoSmithKline (GSK) in 2012 for, among other things, GSK's allegedly false and misleading off-label marketing statements with respect to the drugs Paxil, Advair and Avandia.<sup>37</sup>

Similarly, in 2009, third-party payors reached a \$89 million settlement for allegations that "Pfizer falsely marketed Bextra and Celebrex as having benefits greater than non-selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) like ibuprofen or naproxen," "[t]hat the marketing of Bextra and Celebrex was inconsistent with their FDA-approved labels," and that "this allegedly false marketing cause plaintiffs to pay a greater price for Bextra and/or Celebrex instead of less expensive alternative NSAIDs or no medication at all."<sup>38</sup> Likewise, in 2008 third-party payors reached a \$40 million settlement with GSK involving "alleg[ations] that GSK promoted Paxil ... for prescription to persons under 18 years of age while allegedly withholding and concealing negative information concerning its safety and effectiveness."<sup>39</sup> And in 2007, drug maker Serono reached a \$24 million settlement with a class of consumers and third-party payors that followed on the heels of a 2005 settlement with the DOJ in which the drug manufacturer agreed to pay \$704 million in fines and pled guilty to criminal charges.<sup>40</sup> The Serono complaints involved allegations that the drug manufacturer had engaged in a fraudulent scheme to promote its drug Serostim for off-label uses targeted at a vulnerable population of AIDS patients.<sup>41</sup> All the above cases presumably would still survive the Second Circuit's analysis in *Caronia*, assuming, of course, that the government or plaintiffs in those cases were ultimately able to prove their allegations of fraud.

Additionally, under the Second Circuit's analysis, as noted above, the First Amendment defense is only available in an off-label market-

ing case in which it is actually legal to prescribe the drug in question off-label. There may be some cases where the facts alleged are that the drug company actually promoted a drug for a use that was contraindicated. Under the Second Circuit's reasoning in *Caronia*, it appears that no such First Amendment defense would be available.

Indeed, five years ago, the U.S. Court of Appeals for the Seventh Circuit was able to duck the First Amendment question in a medical device case using this reasoning. In *United States v. Caputo*,<sup>42</sup> the defendant raised a First Amendment challenge to a criminal conviction involving fraud when promoting medical devices for off-label uses that were not FDA-approved. The court declined to rule on the challenge, however. The Seventh Circuit noted that the Supreme Court's First Amendment decision in *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council*,<sup>43</sup> and its progeny rested on the assumption that the law allowed the activity that the speaker sought to promote. In *Caputo*, the jury had determined that the device in question could not lawfully be sold: "Unless the machine itself could be sold lawfully, there were no lawful off-label uses to promote."<sup>44</sup> Thus, the court concluded, "we need not decide today whether a seller of drugs or medical devices has a constitutional right to promote off-label uses."<sup>45</sup> The Seventh Circuit has not yet revisited a First Amendment challenge to an off-label marketing charge.

In fact, except for the Second Circuit's recent decision in *Caronia*, the only other circuit to even discuss a First Amendment challenge in the context of a charge of off-label marketing has been the U.S. Court of Appeals for the District of Columbia (D.C.) Circuit in its 2000 opinion in *Washington Legal Foundation v. Henney*.<sup>46</sup> The challenge by the Washington Legal Foundation focused on the rights of physicians to receive information, with the foundation challenging the "FDA's and Congress' attempts to regulate ... promotional strategies," including "manufacturer dissemination to physicians of independent medical and scientific publications" and "manufacturer support for Continuing Medical Education (CME) programs for doctors that focus[ed] on off-label uses."<sup>47</sup> Specifically, the foundation challenged certain guidance documents which it claimed "violated the First Amendment right of its physician members to receive information about off-label uses from manufacturers."<sup>48</sup> The district court had agreed with the foundation's First Amendment challenge. In a lengthy opinion, the lower court determined first that the guidance documents at issue should be classified as commercial speech. It then applied *Central Hudson's* four-prong test, held that the guidance documents violated the First Amendment and issued an injunction.

Although the matter was appealed to the D.C. Circuit, at oral argument, the government stated that nothing in either of the challenged provisions provided the FDA with independent authority to regulate manufacturer speech. "[I]n light of the government's position as refined and explained at oral argument," the foundation said, "it no longer ha[d] a constitutional objection to the Act or the CME Guidance."<sup>49</sup> As a result of both parties' agreement, the court did not "think it at all appropriate to rule on the constitutionality of a hypothetical interpretation of a statute."<sup>50</sup>

The U.S. Court of Appeals for the Ninth Circuit will likely be the next court of appeals to review a First Amendment challenge to an off-label marketing criminal conviction. In *United States v. Harkonen*, the government charged Harkonen, the chief executive officer of a California-based pharmaceutical company, with felony misbranding of a drug, as well as with wire fraud.<sup>51</sup> The wire fraud

count alleged that Harkonen approved a press release that contained materially false information regarding the drug Actimmune and falsely portrayed the drug as reducing mortality in patients with idiopathic pulmonary fibrosis, a rare and fatal disease.<sup>52</sup>

In defense of the wire fraud claim, Harkonen argued that his speech was protected by the First Amendment. Both before and after his trial, the district court rejected this argument, finding instead that “it is well settled that the First Amendment does not protect fraud.”<sup>53</sup> In its 2009 pretrial decision, the district court cited the Seventh Circuit’s 2008 opinion in *Caputo*, as well as the lower court’s opinion in *Caronia*, noting that the case law was in an “unsettled” state and that this would present a thorny issue for the court, but for the fact that the allegations of the indictment did not trench anywhere near the bounds of speech that could be deemed controversial (i.e., bona fide scientific and education speech that appeared in independent and peer-reviewed sources).<sup>54</sup> “While questions remain about when such ‘pure’ speech gets converted to a ‘less pure’ form of commercial speech when a drug company is involved (e.g., by funding the studies or by disseminating the speech through various promotional activities),” the court observed, “they are of no moment here because nowhere does the indictment invoke any ‘pure’ scientific speech.” The *Harkonen* case is now pending before the Ninth Circuit.

As noted above, even within the Second Circuit, for plaintiffs and the government alleging claims against pharmaceutical manufacturers based upon off-label promotion of FDA-approved drugs, *Caronia* is by no means the death knell for future claims—so long as those claims sound in fraud and/or are based upon the defendant’s promotion of a drug for an *illegal* use. Outside the Second Circuit, it is not at all certain that other courts will rush to adopt the *Caronia*’s reasoning. Most fact scenarios—at least those that wind up reported as significant settlements or in reported decisions—are more akin to the *Harkonen* decision (where the defendant is accused of fraudulent or misleading statements) rather than that in *Caronia* (where the defendant allegedly made truthful off-label marketing statements). In light of the axiom that the First Amendment does not protect fraud, it remains unclear what creative arguments might be attempted to extend *Caronia*’s reach beyond the realm of truthful statements and how successful such arguments could be. Moreover, even if a fact scenario similar to that in the *Caronia* case were to present itself in a different circuit, it is not altogether clear—especially in light of Judge Livingston’s strongly worded dissent—that another circuit would follow the Second Circuit’s majority reasoning. Of course, should future courts adopt analyses that differ from the majority opinion in *Caronia*, we could see interesting fodder for a Supreme Court certiorari petition in the coming decade. ☉

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## Endnotes

<sup>1</sup>703 F.3d 149, 169 (2d Cir. 2012).

<sup>2</sup>21 U.S.C. § 355(a).

<sup>3</sup>*Caronia*, 703 F.3d at 153.

<sup>4</sup>21 U.S.C. § 331(a).

<sup>5</sup>U.S. Dept’ of Health and Human Services, Food and Drug Administration, Office of the Commissioner, Office of Policy, *Guidance for Industry, 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 1, 2–3* (2009), [www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D0053-gdl.pdf](http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D0053-gdl.pdf).

<sup>6</sup>21 U.S.C. § 352(a).

<sup>7</sup>21 U.S.C. § 352(f)(1).

<sup>8</sup>21 C.F.R. § 201.128.

<sup>9</sup>21 U.S.C. § 333(a)(2).

<sup>10</sup>*Caronia*, 703 F.3d at 154.

<sup>11</sup>*Id.* (citations omitted).

<sup>12</sup>*Id.* at 169.

<sup>13</sup>*Id.* at 155.

<sup>14</sup>*Id.* at 160.

<sup>15</sup>In its analysis of the government’s contention that speech was used as evidence of intent, the Second Circuit noted, among other things, that the government “repeatedly argued that *Caronia* engaged in criminal conduct by promoting and marketing the off-label use of Xyrem, an FDA-approved drug.” *Id.* at 161 (citations omitted). Further, the jury’s instructions and the government’s “summation ... left the jury to understand that *Caronia*’s speech was itself the proscribed conduct.” *Id.* (citations omitted). Based on the government’s arguments including the foregoing, the Second Circuit concluded that “the government did prosecute *Caronia* for his speech.” *Id.* (citations omitted).

<sup>16</sup>*Id.* at 160.

<sup>17</sup>*Id.* at 154.

<sup>18</sup>*Id.* at 160, 162 (citations omitted).

<sup>19</sup>131 S. Ct. 2653 (2011)

<sup>20</sup>*Caronia*, 703 F.3d at 165.

<sup>21</sup>*Id.*

<sup>22</sup>*Id.* (citations omitted).

<sup>23</sup>*Id.* at 166-67.

<sup>24</sup>*Id.*

<sup>25</sup>*Id.* at 167.

<sup>26</sup>*Id.*

<sup>27</sup>*Id.* at 168.

<sup>28</sup>*Id.*

<sup>29</sup>*Id.* at 168-69, 173, 175 (citations omitted).

<sup>30</sup>*Id.* at 177 (citations omitted).

<sup>31</sup>*Id.* at 178-79 (citations omitted).

<sup>32</sup>*Id.* at 180.

<sup>33</sup>*See, e.g.*, Thomas M. Burton, *FDA Won't Appeal Free-Speech Marketing Decision*, WALL ST. J. L. BLOG (Jan. 23, 2013, 8:20 PM), [online.wsj.com/article/SB10001424127887324539304578260323575925896.html](http://online.wsj.com/article/SB10001424127887324539304578260323575925896.html); Greg Ryan, *FDA Wise to Duck High Court Off-Label Ruling, Atty Says*, LAW360 BLOG (Jan. 24, 2013, 9:51 PM), [www.law360.com/newyork/articles/408974/fda-wise-to-duck-high-court-off-label-ruling-attys-say](http://www.law360.com/newyork/articles/408974/fda-wise-to-duck-high-court-off-label-ruling-attys-say).

<sup>34</sup>Ryan, *supra* note 32.

<sup>35</sup>*Id.* (citations omitted).

<sup>36</sup>Erica Teichert, *FDA Official Says Off-Label Ruling Won't Limit Enforcement*, LAW 360 BLOG (Jan. 30, 2013, 2:58 PM), [www.law360.com/lifesciences/articles/411478?utm\\_source=shared\\_articles&utm\\_medium=email&utm\\_campaign=shared\\_articles](http://www.law360.com/lifesciences/articles/411478?utm_source=shared_articles&utm_medium=email&utm_campaign=shared_articles).

<sup>37</sup>*See, e.g.*, *GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data*, U.S. DOJ (July 2, 2012), [www.justice.gov/opa/pr/2012/July/12-civ-842.html](http://www.justice.gov/opa/pr/2012/July/12-civ-842.html) (last visited Jan. 30, 2013) (documenting settlement with GlaxoSmithKline for false and misleading claims with respect to the drug Paxil and its marketing to patients under 18); *id.* (documenting settlement with GlaxoSmithKline for false and misleading statements with respect to the safety of Avandia).

<sup>38</sup>*Bextra and Celebrex Settlement Information Website*, THIRD-PARTY PAYOR HOME PAGE, [www.bextracelebrexsettlement.com/TPPHomepage.htm](http://www.bextracelebrexsettlement.com/TPPHomepage.htm) (last visited Jan. 30, 2013).

<sup>39</sup>*Pediatric Paxil Third-Party Payor Settlement*, PEDIATRIC PAXIL THIRD-PARTY PAYOR SETTLEMENT INFORMATION, [www.pediatricpaxiltp settlement.com/docs.htm](http://www.pediatricpaxiltp settlement.com/docs.htm) (last visited Feb. 1, 2013).

<sup>40</sup>*Deadline for Serostim Settlement Extended to Sept. 27!*, PRESCRIPTION ACCESS LITIG. BLOG, [blog.prescriptionaccess.org/?cat=142](http://blog.prescriptionaccess.org/?cat=142) (last visited Feb. 1, 2013).

<sup>41</sup>*Id.*; *Civil Settlement Agreement between the United States and Serono, Inc.*, [www.corporatecrimereporter.com/documents/Serono-CivilSettlementAgreement.pdf](http://www.corporatecrimereporter.com/documents/Serono-CivilSettlementAgreement.pdf); *Serono to Pay \$704 Million for the Illegal Marketing of AIDS Drug*, U.S. DOJ, [www.justice.gov/opa/pr/2005/October/05\\_civ\\_545.html](http://www.justice.gov/opa/pr/2005/October/05_civ_545.html) (last visited Feb. 1, 2013).

<sup>42</sup>517 F.3d 935 (7th Cir. 2008).

<sup>43</sup>425 U.S. 748 (1976).

<sup>44</sup>517 F.3d at 940.

<sup>45</sup>*Id.*

<sup>46</sup>202 F.3d 331 (D.C. Cir. 2000).

<sup>47</sup>*Id.* at 333.

<sup>48</sup>*Id.*

<sup>49</sup>*Id.* at 336.

<sup>50</sup>*Id.*

<sup>51</sup>Memorandum and Order Re: Defendant's Post-Trial Motion to Dismiss the Indictment, for Acquittal or for a New Trial, No. C 08-00164 MHP, 2010 U.S. Dist. LEXIS 75528, at \*1 (N.D. Cal. July 27, 2010).

<sup>52</sup>*Id.* at \*\*2-3.

<sup>53</sup>*Id.* at \*47 (citations omitted).

<sup>54</sup>Memorandum and Order Re: Defendant's Motions in Limine re: "Labeling" and to Exclude Protected First Amendment Speech or, in the Alternative, to Dismiss the Indictment, No. C 08-00164 MHP, 2009 U.S. Dist. LEXIS 47255, at \*17 (N.D. Cal. June 3, 2009) (citations omitted).

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will arise between the physician and the hospital. A hospital might be paying a doctor fair market value according to some national standard, but a lack of commercial reasonableness could still be alleged because the collections from the doctor's direct services do not cover the doctor's compensation and his or her fair share of overhead. Moreover, a hospital-employed physician's compensation may not be "determined" in a manner that takes referrals of designated health services including ancillary services and other hospital services, into account.<sup>25</sup>

Defendant Sulzbach's Motion for Summary Judgment was granted on the grounds that this case was barred by the statute of limitations. Although no final decision was entered, the government does not tread lightly and the penalties are severe.

### Case in Point—Covenant Medical Center in Waterloo, Iowa

Covenant Medical Center in Waterloo, Iowa, agreed to pay the United States \$4.5 million to resolve allegations that it violated the False Claims Act. The United States accused Covenant of violating the Stark Law by paying commercially unreasonable compensation, far above fair market value, to five employed physicians who referred their patients to Covenant for treatment. These physicians were among the highest paid hospital-employed physicians not just in Iowa, but in the entire United States. Two of the physicians were reportedly each paid more than \$2 million per year.<sup>26</sup>

Underscoring the government's intent to ardently pursue cases of

fraud, U.S. Attorney Matt M. Dummermuth of the Northern District of Iowa stated: "This payment is the largest ever related to claims of healthcare fraud in the Northern District of Iowa ... we are actively working with our investigative partners to ensure Medicare funds are properly spent, and we will continue to aggressively pursue all types of fraud in order to protect federal healthcare dollars."<sup>27</sup>

Hospitals may be willing to pay what it takes to hold on to their most profitable physicians. Yet, both physicians and hospitals need to recognize the significant risks in establishing such relationships, and find a balance. This may necessitate engaging an independent valuation agent for objective appraisal of the agreed-upon compensation.

### Accountable Care Organizations as an Alternative

Accountable Care Organizations (ACOs) are a creation of the Medicare statute and were created by Congress in the Accountable Care Act (ACA) as part of the Medicare shared savings program. They are a type of clinical integration in which groups of hospitals, physicians, and other providers come together in one integrated model to coordinate services to a designated group of patients, providing quality care, and sharing in costs savings realized as a result of their joint efforts.<sup>28</sup>

The ACO program is designed to improve beneficiary outcomes and increase the value of care by promoting accountability and requiring coordinated care, as well as encouraging investment in infrastructure and redesigned care processes.<sup>29</sup> Hospitals employing