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Expert Analysis

Revisiting 'Off-Label' Drug Promotion Resolutions in Light of 'Caronia'

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Over the last decade, the government has extracted billions of dollars from pharmaceutical manufacturers to resolve "off-label" drug promotion investigations. Pharmaceutical manufacturers have strong incentives to resolve such investigations, given the substantial penalties and disabilities that result from being indicted, let alone convicted, including the threat of exclusion from federal health care programs such as Medicare and Medicaid. The government's central theory in many of these cases is that it is unlawful for companies to promote FDA-approved drugs for unapproved, or "off-label," uses, even though doctors may lawfully prescribe these drugs for the same unapproved uses.[1]

But no federal statute expressly criminalizes the promotion of prescription drugs for "off-label" uses. Rather, the Food, Drug, and Cosmetic Act (FDCA) makes criminal "[t]he introduction or delivery for introduction into interstate commerce of any…drug…that is misbranded."[2] A drug is misbranded if, inter alia, its labeling fails to bear "adequate directions for use,"[3] which the FDA defines by regulation as "directions under which the lay[person] can use a drug safely and for the purposes for which it is intended."[4] The regulations recognize that promotional statements by the sales force of a pharmaceutical company can evidence a drug's intended use. Therefore, the government reasons, "[a]n approved drug that is marketed for an unapproved use…is misbranded because the labeling of such drug does not include 'adequate directions for use.'"[5]

The recent much-anticipated decision by the U.S. Court of Appeals for the Second Circuit in *United States v. Caronia*[6] has cast serious doubt on the government's theory criminalizing off-label promotion. The court vacated and remanded the misdemeanor conviction of a pharmaceutical sales representative for conspiracy to introduce a misbranded drug into interstate commerce in violation of the FDCA on the ground that his conviction rested solely on truthful speech promoting off-label uses for a drug that the FDA approved for other uses. *Caronia* holds that truthful, non-misleading speech by sales representatives is not enough, standing alone, to support a misdemeanor misbranding prosecution.[7]

'Caronia's' restrictive interpretation of the FDCA calls into question the government's theory underlying many prior off-label promotion cases.

The *Caronia* majority reasoned that a contrary reading of the FDCA would raise serious First Amendment questions. Invoking the Supreme Court's recent decision in *Sorrell v. IMS Health*,[8] the majority applied heightened scrutiny to the government's reading of the FDCA because it imposed speech restrictions that were both content-based, allowing speech about FDA-approved uses and not speech about off-label uses, and speaker-based, targeting one category of speakers, namely, pharmaceutical manufacturers, while allowing others to speak without restriction.

The majority noted that the FDCA permits doctors to prescribe, and patients to use, drugs for off-label purposes, and that the promotion of off-label uses is not in and of itself false or misleading. The majority concluded that the government's construction of the FDCA does not directly advance the government's substantial interests in preserving the effectiveness and integrity of the FDCA's drug approval process because off-label drug use itself is not prohibited. Prohibiting pharmaceutical manufacturers from sharing truthful, non-misleading information about lawful off-label uses "paternalistically" interferes with the ability of doctors and patients to receive potentially relevant treatment information, thereby potentially undermining public health.

While *Caronia* addressed a prosecution based only on truthful speech by a sales representative, the logic of the decision would seem to reach more broadly. If 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," as the *Caronia* majority found, then it is hard to see what remains of the government's off-label marketing theory, save for cases involving false or misleading statements or where a manufacturer promoted a drug for which there were no approved uses at the time of promotion.

Caronia's restrictive interpretation of the FDCA thus calls into question the government's theory underlying many prior off-label promotion cases. Pharmaceutical manufacturers should consider whether *Caronia* allows them to seek redress to recover the large criminal fines, forfeitures, and related civil settlements paid to settle off-label prosecutions. Their options are discussed below.

Guilty Pleas

A guilty plea to conduct that is not criminal is invalid.[9] Corporate defendants who have already pleaded guilty to introducing, or conspiring to introduce, a misbranded drug into interstate commerce, in violation of the FDCA, based only on truthful, non-misleading speech, may seek to withdraw their pleas, or, if the time to do so has run, may petition for a writ of error coram nobis pursuant to the All Writs Act.[10] Although coram nobis relief is an "extraordinary remedy" that is used only when necessary "to achieve justice," this relief may be obtained to correct "a legal or factual error, so long as that error is fundamental.[11]

To establish a right to coram nobis relief, a corporate defendant must satisfy four requirements.[12] First, a petitioner must show that it continues to suffer from continuing consequences of the allegedly invalid conviction. For many corporate defendants, this element is likely easily established, as the government has required most corporations that have pleaded guilty to execute corporate integrity agreements and install federal monitors.

Second, a petitioner must show that "sound reasons" exist for failing to seek relief earlier. Sound reasons

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can include the futility of seeking such relief prior to *Caronia*, because truthful, non-misleading speech by sales representatives had been recognized by courts as a valid basis for a misbranding conviction.[13] Third, the petition must show that no alternative remedies are available. Again, this requirement would seem to be easily met for a company whose time to move to vacate its plea has expired.

Fourth, the petitioner must establish that the writ is needed to correct error that is so fundamental as to "render the proceeding itself irregular and invalid."[14] Where a defendant is convicted and punished "for an act that the law does not make criminal[,] there can be no room for doubt that such a circumstance 'inherently results in a complete miscarriage of justice' and 'present[s] exceptional circumstances' that justify collateral relief."[15] For example, in the wake of the Supreme Court's decision in *Skilling v. United States*, which determined that, without more, an undisclosed conflict of interest does not give rise to honest services fraud in violation of the mail fraud statute, several defendants who previously pleaded guilty to honest services fraud based entirely on an undisclosed conflict of interest were allowed by the district courts to vacate their pleas.[16]

Agreements

Various pharmaceutical manufacturers have resolved off-label promotion cases prior to indictment through the use of deferred prosecution agreements (DPAs) or non-prosecution agreements (NPAs), by which the government agreed to delay or forgo prosecution in exchange for a corporation agreeing to refrain from further violations of the law and to undertake specific cooperation and compliance obligations. DPAs and NPAs, like plea agreements, are contractual in nature and are therefore interpreted in accordance both with principles of contract law and in light of special due process considerations.[17]

Pharmaceutical manufacturers may cogently argue that their DPAs or NPAs are vitiated under the contract doctrine of mutual mistake. The Restatement of Contracts defines three requirements to establish a mutual mistake: first, the mistake must go to a basic assumption on which the contract was made; second, it must have a material effect on the agreed exchange of performances; and third, it must not be one of which the party bears the risk.[18]

Although few DPAs or NPAs have benefited from judicial review, plea agreements are often scrutinized by courts. Several courts have concluded that a plea agreement that rests on a mutual mistake of fact—particularly a mistake that renders meaningless a key promise by the government—may be avoided, particularly where the mistake goes to an essential element of the charge.[19]

The government might argue the company assumed the risk of a beneficial change in the law. But arid application of principles of contract law, such as the assumption of risk doctrine, may provide an inadequate framework for interpretation of DPAs and NPAs. Faced with the ruinous consequences of potential indictment, corporations—and pharmaceutical companies and medical device manufacturers in particular—lack any practical choice as to whether to agree to a DPA or NPA. The Second Circuit has already recognized, in another context, that the traditional commercial model of two rational economic actors allocating the risk of loss may not neatly apply in criminal investigations, given the coercive power of the government to indict.

In *United States v. Stein*,[20] the Second Circuit noted that, because an indictment would have been "fatal" to KPMG, "it could be expected to do all it could, assisted by sophisticated counsel, to placate and appease the government," given that "its survival depended on its role in a joint project with the government to advance government prosecutions." The court found that "it was unrealistic to expect KPMG to exercise uncoerced judgment" after government lawyers expressed disappointment with KPMG's initial decision to cover reasonable attorney fees for employees not identified by the government as subjects, "[h]aving assumed a supine position in the DPA—under which KPMG must continue to cooperate with the government fully."

Pharmaceutical manufacturers may cogently argue that their deferred prosecution agreements or non-prosecution agreements are vitiated under the contract doctrine of mutual mistake.

Government Discretion

Caronia should also cause the government to question whether it should oppose efforts to unwind prior resolutions based upon truthful off-label promotion. In the past, the government has consented to vacating guilty pleas when it became evident that the theories on which it would have proceeded were not criminal. For example, in *United States v. Finnerty*,[21] (one of several so-called "Specialists Cases"), after a defendant was acquitted of securities fraud after the district court set aside the jury's verdict after trial, and when the Second Circuit affirmed the judgment of acquittal, the government consented to the motions to vacate convictions filed by several alleged coconspirators who had pleaded guilty to substantially the same conduct.

Likewise, the government did not object to motions to withdraw guilty pleas filed by cooperating witnesses after the government determined that it could not sustain a criminal conviction for accounting fraud based on the conduct alleged in *United States v. Stockman*.[22] When the government became convinced that no crime had been committed, it did not stand in the way of defendants who had pleaded guilty to have their pleas vacated.

Caronia provides another opportunity for the government to exercise its prosecutorial discretion and step back from resolutions that extracted billions of dollars in settlements for conduct that, in light of *Caronia*, may not have been criminal.

1. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); John E. Osborn, "Can I Tell You the Truth? A Comparative Perspective on Regulating Off-Label Scientific and Medical Information," 10 Yale J. Health Pol'y L. & Ethics 299, 303 (2010) ("Physicians may prescribe FDA-approved drugs…for any therapeutic use that is appropriate in their medical judgment").
2. 21 U.S.C. §331(a).
3. 21 U.S.C. §352(f).
4. 21 C.F.R. §201.5.
5. Food and Drug Administration, Draft Guidance, 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 2-3 (2009).
6. 703 F.3d 149 (2d Cir. 2012).
7. The government declined to seek certiorari in *Caronia*. In comments made after its decision not to seek certiorari, the government pledged to continue to prosecute cases involving false or misleading speech. Erica Teichert, "Drug Misbranding Investigations Remain Top Priority: DOJ," Law 360 (Jan. 29, 2013), available at http://www.law360.com/whitecollar/articles/411149?.
8. 131 S. Ct. 2653 (2011).
9. *Bousley v. United States*, 523 U.S. 614 (1998).
10. See 28 U.S.C. §1651(a). There is some possibility that corporations still on probation could proceed by way of a petition pursuant to 28 U.S.C. §2255, rather than coram nobis.
11. *Denudo v. United States*, 129 S. Ct. 2213, 2220-21 (2009).
12. *United States v. Stoneman*, 870 F.2d 102, 106 (3d Cir. 1989). The government has sometimes argued that coram nobis petitioners must also show either cause and prejudice for the failure to appeal or actual innocence of the crime of conviction, but at least two courts have rejected this argument when, in light of a supervening decision, the information to which the defendants pled guilty did not allege any criminal conduct. See *Lynch*, 807 F.Supp.2d at 233 (citing *Bousley*, 523 U.S. at 624); *Panarella*, 2011 WL 3273599, at *8.
13. See *United States v. Caputo*, 288 F.Supp.2d. 912, 919-20 (N.D. Ill. 2003) (holding that FDA regulations restricting commercial speech did not violate the First Amendment); *Sorrell v. IMS Health*, 131 S. Ct. 2653, 2678 (Breyer, J., dissenting) (Noting that a pharmaceutical company "could not suggest to a potential purchaser (say, a doctor) that he or she might put a pharmaceutical drug to an 'off label' use."); *Lynch*, 807 F.Supp.2d at 234 ("Prior to the Supreme Court ruling in *Skilling*, this Circuit recognized undisclosed conflict of interest as a valid basis for an honest services fraud conviction. The Court thus concludes that Lynch could not have sought relief earlier.") (internal citations omitted); *Panarella*, 2011 WL 3273599, at *10.
14. *United States v. Stoneman*, 870 F.2d 102, 106 (3d Cir. 1989).
15. Id. at 105 (quoting *Davis v. United States*, 417 U.S. 333 (1974)).
16. See, e.g., *United States v. Woodward*, No. 12-11431-DPW, 2012 WL 4856055 (D. Mass. Oct. 10, 2012); *United States v. Tehin*, No. CR 03-00236, 2012 WL 3638543 (N.D. Cal. Aug. 22, 2012); *United States v. Lynch*, 807 F.Supp.2d 224 (E.D. Pa. 2011); *United States v. Panarella*, No. CR 00-655, 2011 WL 3273599 (E.D. Pa. Aug. 1, 2011).
17. *United States v. Hyles*, 521 F.3d 946, 952 (8th Cir. 2008); *United States v. Brunetti*, 376 F.3d 93, 95-96 (2d Cir. 2004) (per curiam); *United States. v. Baird*, 218 F.3d 211, 229 (3d Cir. 2000); *United States v. Castaneda*, 162 F.3d 832, 835 (5th Cir. 1998);
18. Restatement (Second) of Contracts §152; see *McKeever v. Warden SCI-Graterford*, 486 F.3d 81, 88 (3d Cir. 2007).
19. See, e.g., *United States v. Bradley*, 381 F.3d 641 (7th Cir. 2004) (invalidating a plea agreement as the result of both parties' mutual mistake as to an essential element of the charge).
20. 541 F.3d 130, 142, 147 (2d Cir. 2008).
21. 533 F.3d 143 (2d Cir. 2008).
22. Press Release, U.S. Department of Justice, Statement on *United States v. David Stockman, et al.* (Jan. 9, 2009) , available at http://www.justice.gov/usao/nys/pressreleases/January09/stockmanetalstatement.pdf ; Order, *United States v. Galante*, No. 07-CR-224 (S.D.N.Y. May 14, 2009), ECF No. 15; Order, *United States v. Goughery*, No. 07-CR-223 (S.D.N.Y. May 14, 2009), ECF No. 11; Order, *United States v. Jones,* No. 07-CR-227 (S.D.N.Y. May 14, 2009), ECF No. 14; Order, *United States v. Williams*, No. 07-CR-229 S.D.N.Y. May 14, 2009), ECF No. 14.