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What Does the Second Circuit's Recent Decision in *United States v. Caronia* Not Say?

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TABLE OF CONTENTS

I. Introduction & Background 1

II. Major Issues in Dispute 2

A. The Court Did Not Rule That Drug Companies May Engage in Promotional Activities That Render a Drug's Labeling Misleading or Inadequate for Use 2

B. The Court Did Not Rule Against the *Park* Doctrine and Misdemeanor Misbranding Prosecutions 3

C. The Greatest Impact of *Caronia* May Be Felt in How the Ruling Influences the Exercise of Prosecutorial Discretion Going Forward, Both in the Manner of Proving Misbranding Cases, and the Decision to Initiate Misbranding Prosecutions 4

III. Policy Recommendations and Conclusion 5

Endnotes 7

About the Author 9

About the Food and Drug Policy Forum 10

About FDLI 10

What Does the Second Circuit's Recent Decision in *United States v. Caronia* Not Say?

I. INTRODUCTION & BACKGROUND

On December 3, 2012, a three-judge panel of the United States Court of Appeals for the Second Circuit decided *United States v. Caronia*, a case that has been closely followed by the pharmaceutical industry and free speech advocates for its potential impact on the promotional activities of drug manufacturers. Alfred Caronia was a sales representative for a pharmaceutical company selling a specialty drug called Xyrem that was approved by the U.S. Food and Drug Administration ("FDA") for narcolepsy patients suffering from excessive daytime sleepiness and a muscular condition known as cataplexy.[1] In September 2008, Caronia was tried and convicted of misdemeanor conspiracy to introduce a misbranded drug into interstate commerce based on his activities in promoting Xyrem for unapproved indications. A two-judge majority[2] then vacated Caronia's conviction under the First Amendment, holding that Caronia had been wrongfully prosecuted for protected truthful "speech in aid of pharmaceutical marketing." *United States v. Caronia,* ___ F.3d ___, 2012 WL 5992141 at *9 (Dec. 3, 2012) (2d Cir.).

Much has been made of the Second Circuit's majority ruling, with commentators on all sides speculating about what the decision may portend about the future of misbranding prosecutions under the Federal Food Drug & Cosmetic Act ("FDCA") and the continued viability of the FDA's regulatory scheme prohibiting off-label promotion by pharmaceutical companies. But perhaps it would make sense to pause for just a bit, and take a closer look at what the majority did *not* say in its written opinion.

As discussed below, when one looks more closely at the majority opinion, it becomes apparent that the ruling in *Caronia* did not really change much, if anything, in the current FDA regulatory landscape, at least in terms of the government's ability to prosecute misbranding offenses arising from "off-label" marketing activities.[3] *Caronia*, however, may well impact how the government chooses to prosecute such cases in the future and could, in certain instances, influence the exercise of prosecutorial discretion in ways that cause the government not to seek criminal charges.

POLICY RECOMMENDATIONS

1. Prosecuting drug or device misbranding arising from "off-label" promotional activities is different from prosecuting truthful "off-label" promotional speech, and the two should be accurately distinguished to ensure a clear understanding of the kind of conduct that is criminalized under the Federal Food Drug & Cosmetic Act (FDCA).

2. Courts should not, in the name of protecting truthful speech in aid of pharmaceutical marketing, prohibit or discourage the use of such speech as evidence that a drug or device has been marketed for an intended use inconsistent with its approved labeling.

3. The Government should frame misbranding prosecutions in ways that closely tie "off-label" promotional evidence to a product's intended use and approved labeling, as this will more clearly reference the conduct that is actually criminalized under the FDCA and also make it less likely that courts will scrutinize the motives of prosecutors from a First Amendment standpoint.

4. Before initiating a misbranding prosecution, the Government would be best served by fully assessing the degree to which its case depends on the truthful "off-label" statements of marketing personnel, and whether or not such proof is part of a larger body of evidence demonstrating that the manufacturer has marketed a drug or device for an intended use not included in the product's approved labeling.

II. MAJOR ISSUES IN DISPUTE

A. The Court Did Not Rule That Drug Companies May Engage in Promotional Activities That Render a Drug's Labeling Misleading or Inadequate for Use

Although the majority held that the misbranding provisions of the FDCA do not prohibit or criminalize "the truthful off-label promotion of FDA-approved prescription drugs," and 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," the majority acknowledged that the FDA retains the authority to regulate the *marketing* of prescription drugs.[4] Moreover, the majority sought to distinguish truthful "off-label" promotional speech from the type of behavior prohibited under the misbranding statute, which it described as relating to "whether a drug's labeling is adequate for its intended use."[5] The majority readily conceded that misleading promotional speech is not protected under the First Amendment and, further, that the government is, indeed, entitled to prove the "intended use" of a drug by reference to promotional statements made by drug manufacturers and their representatives.[6] The majority rested its ruling, however, on

its insistence that "Caronia was not prosecuted on this basis" and that "the government's theory of prosecution identified Caronia's speech alone as the proscribed conduct."[7]

The distinction sought to be drawn by the majority in overturning Caronia's conviction—*i.e.*, the distinction between the impermissible prosecution of truthful promotional speech and the permissible use of promotional speech as evidence of a drug's intended use—ultimately limits the sweep of the *Caronia* decision to the peculiar facts of that case, as interpreted by the two-judge majority. This is because the majority explicitly accepted the concept that the government may demonstrate, by reference to promotional speech, as well as other evidence, that a pharmaceutical manufacturer is marketing a drug for an intended use other than one approved by the FDA, which could, in turn, render the drug mislabeled.[8] Indeed, the majority could hardly have done otherwise without essentially granting pharmaceutical manufacturers permission to circumvent the FDA's new drug approval process altogether.[9] Such conduct is, by definition, "off-label" marketing, and would presumably lead to prosecution under the FDCA's misbranding provisions on the ground that the marketed drug has not been properly labeled for its intended use. Instead, the majority only took issue with what it perceived to be the government's theory of prosecution against the defendant in *Caronia*, which the majority argued focused exclusively on the defendant's "off-label" promotional speech, without connecting that evidence to Xyrem's intended use and the adequacy of its labeling.[10]

Boiled down to its essentials, therefore, the *Caronia* decision arguably has more to do with the majority's case-specific reaction to the manner in which the defendant was prosecuted—as reflected in the words chosen by prosecutors in arguing the case to the jury and the jury instructions provided by the trial court[11]—than it does with the continued viability of the FDA's regulatory scheme prohibiting off-label promotional activities by the pharmaceutical industry. Accordingly, nothing in the majority's opinion should fairly be interpreted as green-lighting "off-label" marketing by drug companies.

B. The Court Did Not Rule Against the *Park* Doctrine and Misdemeanor Misbranding Prosecutions

The majority's ruling also should not be seen as a declaration that misdemeanor misbranding prosecutions under the *Park* doctrine are somehow inherently suspect.

Under the *Park* doctrine, violating the FDCA's misdemeanor misbranding provision (21 U.S.C. §§ 331(a), 333(a)(1))—*i.e.*, introducing a misbranded or adulterated drug into interstate commerce *without* harboring any intent to defraud or mislead—is a "strict liability" offense, which means that one can violate the statute without intending to do so, or even knowing that a violation has occurred. In *United States v. Park*,[12] the Supreme Court addressed a situation in which the president of a large national food chain was criminally charged under the FDCA because food held for sale in one of the company's warehouses had been exposed to rodent contamination, rendering the product adulterated under the statute. The High Court upheld the president's misdemeanor conviction under the FDCA, even in the absence of evidence that he had personally participated in the events underlying the charges or had been consciously aware of any wrongdoing, writing:

> [T]he [FDCA] imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them ….
>
> The [FDCA] does not…make criminal liability turn on 'awareness of some wrongdoing' or 'conscious fraud.'…[T]he Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of the facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so. The failure thus to fulfill the duty imposed by the interaction of the corporate agent's authority and the statute furnishes a sufficient causal link. The considerations which prompted the imposition of this duty, and the scope of the duty, provide the measure of culpability.[13]

The *Park* doctrine continues in force today, and there is really nothing in the majority's opinion that suggests otherwise. To the contrary, the majority's ruling was not predicated on any stated discomfort with the "strict liability" nature of the offense conduct, but rather with the fact that, in the majority's view, the government had targeted the defendant's speech for prosecution rather than his conduct in marketing a misbranded drug—*i.e.*, marketing a drug the labeling of which was not adequate for its intended use. Based on the majority's stated rationale, it must be assumed that if the government had focused its arguments on the evidentiary connection between Caronia's promotional activities and the intended used of the drug, and had argued that the drug's labeling was inadequate for its intended use, that the majority would have ruled differently. It must be remembered, moreover, that the misdemeanor misbranding provision encompasses a far broader range of conduct than "off-label" marketing activities, and includes any marketing of a drug or device that may be misbranded or adulterated for any of a plethora of reasons defined in the FDCA. In any event, *Caronia* should not be seen as evidence that misdemeanor misbranding is dead or on life support.

C. The Greatest Impact of *Caronia* May Be Felt in How the Ruling Influences the Exercise of Prosecutorial Discretion Going Forward, Both in the Manner of Proving Misbranding Cases, and the Decision to Initiate Misbranding Prosecutions

As noted, the *Caronia* majority did not rule that truthful "off-label" promotional speech could not be used as some evidence of a drug's intended use for the purpose of demonstrating that the drug is mislabeled and thus misbranded, but only that such speech could not be the sole focus of the government's criminal prosecution under the FDCA's misdemeanor misbranding provision. In

Caronia, the majority's conclusion that the government had prosecuted Caronia for his speech was based in large part on statements by the government to the jury that the majority decided betrayed an intention to prosecute Caronia for his words in promoting Xyrem for unapproved indications.[14]

Given how the majority in *Caronia* arrived at its ruling, it can be expected that, going forward, prosecutors will be more careful in how they marshal the evidence and structure their closing arguments in misdemeanor misbranding cases. To avoid a similar result, the government will likely make special efforts to connect the evidentiary dots demonstrating the relationship between "off-label" promotional speech and a manufacturer's intended use for a drug or device, and to explain how that intended use is not encompassed by the product's FDA approved labeling which, in turn, renders the product misbranded under the FDCA. On the other hand, after *Caronia*, there also could be instances in which prosecutors decide, based on the misbranding evidence presented to them, that a case might be too heavily dependent on a sales representative's truthful "off-label" promotional speech as evidence of intended use (*i.e.*, without other corroborating evidence in the form of company emails, advertising materials, and/or other documents), and hence too risky to prosecute.

III. POLICY RECOMMENDATIONS AND CONCLUSION

In summary, while the decision in *Caronia* is certainly thought-provoking for its stated rationale in overturning Caronia's conviction and its holding that truthful "off-label" promotional speech cannot be prosecuted by the government consistent with the First Amendment, it is far less clear that the ruling will have significant lasting legal impact or influence. As noted, the majority did not dispute the government's right to rely on promotional speech as evidence of a drug's intended use in order to prove misbranding under the FDCA, but rather concluded that, in *Caronia*, the government had engaged in an altogether different, and unconstitutional, exercise by prosecuting the speech itself. Certain key observations, however, do emerge from the foregoing discussion.

Initially, it is essential when discussing the subject of misdemeanor misbranding prosecutions to distinguish between the criminal prosecution of truthful "off-label" promotional speech, on the one hand, and the evidentiary use of such speech *in furtherance of* misbranding prosecutions, on the other hand. The *Caronia* majority ruled that the former is constitutionally infirm, even while acknowledging that the latter is constitutionally permissible under Supreme Court precedent. Thus, it will be incumbent upon the courts hearing these cases to carefully differentiate government efforts to criminalize truthful "off-label" promotional speech as misbranding from other, legitimate efforts to prove, including by reference to "off-label" promotional speech, that a manufacturer's intended use for a drug or device is not contemplated by that product's FDA approved labeling.

In addition, following *Caronia*, the government likely will be more careful, both, when initiating misdemeanor misbranding prosecutions in the area of "off-label" marketing, and when framing those prosecutions in court. The safer cases for prosecution will be those in which a manufacturer's intended use for a drug or device is evidenced not only by a sales representative's "off-label" promotional statements, but also by other proof evincing a corporate mindset to market the product for uses not included in its approved labeling. In the future, prosecutors probably will be

more hesitant in initiating misdemeanor misbranding prosecutions which are based entirely on "off-label" promotional statements that are not part of a larger collection of evidence demonstrating the manufacturer's intention to market the drug or device for indications which are not approved by FDA and included in the product's approved labeling. Moreover, in prosecuting "off-label" cases after *Caronia,* the government probably will want to ensure that its presentation of the evidence and its arguments to the jury are closely tied to the underlying behavior actually criminalized by the FDCA misdemeanor misbranding statute—*i.e.*, the introduction into interstate commerce of drugs or devices which are in a misbranded condition because their intended uses are inconsistent with their approved labeling.

ENDNOTES

1. Xyrem carried a "black box" warning required by the FDA, the most serious warning placed on prescription pharmaceuticals. Xyrem's active ingredient is gamma-hydroxybutyrate ("GHB"), which is often referred to as the "date rape drug" because of its past use in sexual assaults. As noted by the Second Circuit in *Caronia*, "Xyrem can cause serious side effects, including difficulty breathing while asleep, confusion, abnormal thinking, depression, nausea, vomiting, dizziness, headache, bedwetting, and sleepwalking. If abused Xyrem can cause additional medical problems, including seizures, dependence, severe withdrawal, coma and death." United States v. Caronia, 2012 WL 5992141 at *3 (Dec. 3, 2012) (2nd Cir.).

2. Judges Denny Chin and Reena Raggi ruled for the majority. In dissent, Judge Debra Ann Livingston wrote: "Alfred Caronia was convicted of conspiring to introduce a prescription drug into interstate commerce with the intent that it be used in ways its labeling neither disclosed nor described. This intent was revealed, *inter alia*, through his speech. Because the First Amendment has never prohibited the government from using speech as evidence of motive or intent…I would affirm Caronia's conviction." United States v. Caronia, 2012 WL 5992141 at *15 (Dec. 3, 2012) (2nd Cir.).

3. The FDA apparently reached the same conclusion, as the Agency has decided not to seek appellate review of the Second Circuit's decision. As reported by the Wall Street Journal on January 23, 2013, the FDA declined to appeal the decision because 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." Wall Street Journal, January 23, 2013, "FDA Won't Appeal Free-Speech Marketing Decision" (emphasis added).

4. *See supra,* note 2.

5. *Id*. at *10.

6. The majority was forced to accept this proposition in light of prior Supreme Court precedent holding that speech may be used as evidence of criminal conduct. *See* Wisconsin v. Mitchell, 508 U.S. 476, 489, 113 S.Ct. 2194, 124 L.Ed.2d 436 (1993) (stating that "[t]he First Amendment…does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent."). Further, as noted by the dissent, "[d]etermining a product's 'intended uses' has long been a central concern of food and drug law." Id. at *16. Judge Livingston further commented:

> The concept originated in the Pure Food and Drugs Act of 1906…which prohibited introducing adulterated or misbranded drug into interstate commerce, and which defined 'drug' to include 'any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease…Courts found violations of that statute where, as in this case, a manufacturer's speech demonstrated an intended use that brought it within the scope of the statute such that its label was required affirmatively to disclose certain information….
>
> …
>
> The modern FDCA continued to define 'drugs' (and 'devices') on the basis of an article's intended uses…The concept of 'intended uses' therefore largely defines the scope of the FDA's regulatory authority.
>
> Id. at *16-17 (citations omitted).

7. *United States v. Caronia*, 2012 WL 5992141 at *10 (Dec. 3, 2012) (2nd Cir.). Having concluded that the government had prosecuted Caronia under the FDCA for his speech, based on a construction of the FDCA's misbranding provision that prohibits and criminalizes truthful "off-label" promotional speech by pharmaceutical manufacturers, the majority reviewed the constitutionality of the government's approach under the tests articulated by the Supreme Court in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011) and *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980). The majority declined "to adopt the government's construction of the FDCA's misbranding provisions to prohibit manufacturer promotion alone as it would unconstitutionally restrict free speech." *Caronia*, 2012 WL 5992141 at *15.

8. *Id*. at *8.

9. On this subject, the dissent in *Caronia* commented: "[A]llowing drug manufacturers to promote off-label uses would undermine the FDA's approval process for not only new uses of pre-approved drugs, but also for entirely new drugs…when determining whether a drug should be approved, the FDCA requires consideration not only of the drug's safety, but also its effectiveness…If a drug manufacturer must be allowed to distribute a drug for any use so long as it is approved for one use, the government's balancing of a drug's benefits against its risks becomes very difficult or even impossible. Drugs viewed as safe for certain uses might be considered unsafe overall if the benefits and risks being weighed are not for a specific intended use but rather for any use at all, whether supported by evidence or not." *Id*. at *24.

10. The majority commented: "Thus, the government has treated promotional speech as more than merely evidence of a drug's intended use—it has construed the FDCA to prohibit promotional speech as misbranding itself." *Id.* at *3.

11. *Id*. at *7-8.

12. 421 U.S. 658, 673 (1975).

13. 421 U.S. 672-674 (citations omitted).

14. The majority noted: "The record makes clear that the government prosecuted Caronia for his off-label promotion, in violation of the FDCA. The government, in its summation and rebuttal, repeatedly asserted that Caronia was guilty because he, with others, conspired to promote and market Xyrem for off-label use." *Id.* at *7.

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Geoffrey R. Kaiser is the founder of Kaiser Law Firm, PLLC, and the former Chief of Health Care Fraud Prosecutions in the United States Attorney's Office for the Eastern District of New York ("USAO"). Mr. Kaiser's practice concentrates in healthcare fraud, white-collar crime, internal investigations, business frauds and the False Claims Act, and anti-counterfeiting/brand protection. As further background, Mr. Kaiser, while at the USAO, had initiated the prosecution of Alfred Caronia on felony misbranding charges. After Mr. Kaiser departed the USAO for private practice, but before the Caronia case proceeded to trial, the USAO elected to reduce the felony charges to misdemeanors pursuant to 21 U.S.C. § 333(a)(1). The defendant appealed his subsequent conviction for misdemeanor misbranding conspiracy to the Second Circuit Court of Appeals.

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