

# The Aftermath of *Caronia* in Pursuing Off-Label Cases

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*A version of this article originally appeared in [InsideCounsel](#) on March 10, 2014.*

In December 2012, the 2nd Circuit issued a groundbreaking 2-1 decision, holding that the First Amendment protects the truthful, non-misleading off label promotion of pharmaceutical products. In *U.S. v. Caronia*, the court vacated the conviction of Alfred Caronia, a pharmaceutical sales representative found guilty of conspiring to introduce a misbranded drug into commerce in violation of the Food, Drug and Cosmetic Act (FDCA), finding that his conviction, premised solely on his promotion of the drug for off label use, violated his free speech rights under the First Amendment. The court held that the FDCA does not prohibit “the truthful off-label promotion of FDA-approved prescription drugs.”

Although the decision was significant because of the First Amendment protection it extended to defendants facing allegations of off label marketing in certain instances, it was not clear whether it would actually affect the government’s future prosecution of these cases.

The government did not seek a rehearing of the case *en banc* and did not appeal the decision to the Supreme Court. As reported by *The Wall Street Journal*, the FDA said that it did “not believe that the Caronia decision will significantly affect the agency’s enforcement of the drug misbranding provisions” of the FDCA.

Because *Caronia* protected only *truthful, non-misleading* off label promotion, one would expect that in future off label cases the government would allege that the promotion included false or misleading messages (*e.g.*, overstating the drug’s efficacy or minimizing safety issues). In fact, since the decision, the government has alleged false or misleading off label promotion in each of the high-profile cases it has settled:

- Just over two weeks after the *Caronia* decision was announced, the Department of Justice (DOJ) and U.S. Attorney’s Office for the Eastern District of New York (the same U.S. Attorney’s Office that had prosecuted Caronia) announced a \$762 million settlement with Amgen relating to the off label promotion of several drugs, in which

Amgen pled guilty to one misdemeanor count under the FDCA. The government alleged that off label studies given to doctors were the same studies that the FDA had rejected as insufficient when Amgen applied to expand the indication for one of the drugs at issue.

- In March 2013, Par Pharmaceutical entered into a \$45 million settlement regarding its off label promotion of Megace ES and pled guilty to one misdemeanor count under the FDCA. The DOJ contended that Par promoted the drug off label and made claims that were unsubstantiated, false and misleading. As part of its plea agreement, Par was required to dismiss, with prejudice, a lawsuit it had filed against the government, challenging on First Amendment grounds the government's application of the FDCA to "criminalize Par's truthful and non-misleading speech" about on label uses of Megace ES.
- In July 2013, Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc., entered into a \$490.9 million settlement regarding its off label marketing of Rapamune and pled guilty to a misbranding violation under the FDCA. Among other allegations, the government claimed that Wyeth downplayed serious safety issues associated with the off label use at issue.
- In November 2013, Johnson & Johnson entered into a \$2.2 billion settlement and pled guilty to a violation of the FDCA to resolve allegations that it promoted several drugs off label and made false and misleading statements about the safety and efficacy of Risperdal.

In addition, *Caronia* does not yet appear to have gained traction in any context other than the criminal prosecution of an individual. For example, in *McDonald-Lerner v. Neurocare Assocs., P.A.*, a products liability suit, two individuals sued medical device company Medtronic, a doctor and the doctor's practice, alleging that the doctor operated on one of the plaintiffs using Medtronic's device off label — which Medtronic allegedly had promoted off label — injuring the plaintiff. Defendants, citing *Caronia*, argued that "there is nothing illegal or improper about off-label uses, or the promotion of off-label uses, of FDA approved medical devices." The district court rejected the argument, calling the *Caronia* majority opinion "ill-considered" and inapplicable to civil cases.

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Not surprisingly, the government has also recently taken the position that *Caronia* is inapplicable to cases litigated under the civil False Claims Act (FCA). In a Statement of Interest it filed in *U.S. ex rel. Cestra v. Cephalon, Inc.*, a case in which it had declined to intervene, the

United States asserted that *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.” The United States distinguished the FDCA from the FCA, arguing that the latter prohibits any conduct that causes the submission of false claims to the government, which include any claim for a use not approved by the FDA or supported by a compendium listing. According to the government, even if that conduct is carried out through truthful speech — the same speech that *Caronia* holds may be constitutionally protected under the FDCA — FCA liability could still attach.

If truthful and non-misleading off-label statements are protected by the First Amendment, then it is difficult to understand how the government could argue that the claims resulting from such statements are false and thus not reimbursable — or, at the very least, how the government could seek treble damages and penalties under the FCA from companies for claims that result from such truthful off-label statements.

In sum, since *Caronia* was decided, the government has not been dissuaded from pursuing off-label cases in either the civil or criminal contexts and views its holding as limited. Because the government will continue pursuing off label cases, it will be interesting to continue monitoring how, if at all, the implications of *Caronia* play out in various contexts involving promotion of pharmaceuticals and medical devices.

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