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FDA Will Not Appeal Second Circuit Decision in U.S. v. Caronia

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After the Second Circuit's split decision in **U.S. v. Caronia**, holding that truthful off-label marketing is protected under the First Amendment and thus cannot be prosecuted under the misbranding provisions of the **Food Drug and Cosmetic Act (FDCA)**, I predicted in a previous post that the government would file a motion for rehearing and would eventually take the case to the U.S. Supreme Court. But the government has apparently has decided to take no action.

The FDA recently let a January 16th deadline for filing a Motion for Rehearing pass, and then, on January 23rd, the Wall Street Journal and many other media outlets reported that the FDA has decided not to seek Supreme Court review. Although the federal government technically has until March 2013 to make a decision, the FDA has stated that it "does not believe that the Caronia decision will significantly affect the agency's enforcement" of the FDCA's misbranding provisions.

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As noted in my prior post, the government has historically relied upon the FDCA's misbranding provisions in the prosecution of off-label marketing cases. According to the government, misbranding occurs when a drug is marketed for unapproved uses because its existing label does not adequately address the off-label uses. In recent years, the government has pursued a number of off-label cases using parallel proceedings under federal and state civil false claims acts. In those cases, the government has claimed that the off-label marketing caused Medicaid and Medicare to pay for prescriptions that would not have been written but for the off-label marketing. Off-label marketing allegations have also been part of State Attorneys General consumer protection cases alleging that consumers were misled into requesting prescriptions for the products at issue by inaccurate or incomplete information.

If the FDA ultimately declines to seek Supreme Court review, it likely will be doing so to cut its losses. The Second Circuit did not strike down any portion of the FDCA in Caronia, nor did it limit the government's authority to prosecute individuals or entities under the FDCA for off-label marketing that is allegedly false or misleading. But the Second Circuit ruling relied heavily on the 2011 U.S. Supreme Court decision in Sorrell v. IMS Health, which held that speech in aid of pharmaceutical marketing is a form of expression protected by the First Amendment. The FDA may have concerns that the Supreme Court could use Caronia to potentially expand the holding in Sorrell. By not appealing Caronia, the FDA preserves the enforcement authority left intact by Caronia and its First Amendment arguments for a FDCA case in which it has a stronger position, such as when the marketing at issue is alleged to be false or misleading.

So what does the FDA's decision not to appeal Caronia mean for the future of government enforcement of off-label marketing allegations in the short term, under both the FDCA and federal and state civil statutes? A few key points to consider:

Caronia is valid precedent only in the Second Circuit. While any government attempt to pursue truthful off-label

marketing under the FDCA in other jurisdictions will certainly be met with a First Amendment challenge, another circuit may be persuaded by the government's argument that off-label marketing is merely evidence of misbranding and not the offense itself.

Caronia does not prohibit prosecution of false or misleading off-label marketing as misbranding under the FDCA, such as allegations of suppression of clinical studies, use of ghost-written publications, misrepresentation of FDA approval status, or even inaccurate labels or inserts.

Caronia may help weed out or deter some parallel federal or state civil false claims actions for off-label marketing, but will not stop them all together. 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. To prove those allegations, government or whistleblower attorneys generally must drill down to develop evidence and testimony that the prescribing physicians were actually misled into prescribing the drugs at issue through inaccurate or incomplete information provided during marketing, and that claims for these prescriptions were actually presented to Medicaid or Medicare.

Caronia likely will not impact the pursuit of off-label marketing cases under state consumer protection statutes. Under many state consumer protection laws, causes of action are developed based upon alleged misstatements of material fact or omissions of material fact, not upon truthful statements. The only open question is whether truthful off-label marketing that fails to include an affirmative statement regarding the lack of FDA approval for that purpose, may be actionable under some states' state consumer protection statutes as an omission of a material fact.

In short, despite Caronia, federal and state attorneys are expected to continue to pursue off-label marketing cases, both under the FDCA and under applicable civil statutes, but they likely will be more selective about the cases they choose to pursue.