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Update

Second Circuit Ruling Presents a Win and a Loss for Drug Manufacturers

In a split decision, the U.S. Court of Appeals for the Second Circuit ruled that drug manufacturers that promote their products for off-label uses are protected by the First Amendment and, as such, are guarded against suits by the government. Under previous standards, a drug manufacturer who "misbranded" their drug by promoting its off-label uses faced federal misdemeanor or felony charges.

Under the Federal Food, Drug and Cosmetic Act (the "FDCA"), once a drug has received FDA approval, it can be prescribed by doctors for both FDA-approved and unapproved uses. The FDCA, however, prohibits the "misbranding" or "the introduction or delivery for introduction" of any drug that is mislabeled. 21 U.S.C. 331(a). A drug is mislabeled if its labeling fails to provide directions under which a layperson can use the drug safely and for the purposes for which it is intended. Although the FDCA and its accompanying regulations do not expressly prohibit the off-label promotion or marketing of drugs, the regulations do recognize that promotional statements by a drug manufacturer or its representatives are indicative of a drug's intended use. As such, the government has been able to treat off-label promotion as "misbranding" since an FDA-approved label will not contain directions regarding non-FDA-approved uses. This approach has allowed the government to repeatedly prosecute -- and convict -- pharmaceutical companies and their representatives for misbranding based on their off-label promotions.

The Second Circuit's ruling in *U.S. v. Caronia* overturned the U.S. District Court for the Eastern District of New York's conviction of a pharmaceutical sales representative under the FDCA. Defendant-Appellant Alfred Caronia appealed his criminal conviction for conspiracy to introduce a misbranded drug into interstate commerce, a misdemeanor violation of U.S.C. §§ 331(a) and 333(a)(1). Caronia's conviction stemmed from his off-label promotion of the drug Xyrem -- a powerful nervous system depressant containing the ingredient GHB -- for muscle-relaxing and chronic pain management purposes. Caronia argued that his actions were protected by the First Amendment's Right to Free

Speech. The Second Circuit, using a heightened scrutiny standard, agreed with Caronia and held 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."

Although the Court's ruling focused mainly on First Amendment issues, its decision may have dramatic effects on the pharmaceutical industry and on the defenses available to drug manufacturers involved in litigation. Relying on the Second Circuit's decision, a drug manufacturer may now tout their products' off-label uses without fear of federal prosecution for "misbranding." Any benefit to the drug-maker's bottom line, however, may be outweighed by the decision's potential effects limiting a drug-maker's defenses against personal injury lawsuits. In the past, a drug manufacturer facing certain lawsuits based on a drug's use would be able to rely on the preemption defense –that its product had met all FDA labeling requirements and, as such, the manufacturer was not liable for failure-to-warn claims. After this ruling, a drug company that promotes a drug's uses that are not FDA approved will likely not be able to then avail itself of the protections that come along with FDA approval.

In a lengthy dissent, Judge Livingston vigorously questioned the effects that this ruling would have on "our century-old system of drug regulation." Notably, she is concerned the ruling would provide little incentive for drug companies to seek FDA approval for non-approved uses. Indeed, this ruling will likely force the FDA to alter the manner in which it regulates the off-label promotion and use of FDA-approved drugs. The far-reaching effects of this decision will likely cause it to be reviewed by the entire Second Circuit sitting en banc and/or by the Supreme Court of the United States. While the preemption defense as it applies to FDA labeling continues to evolve, it would be prudent for drug manufacturers to wait before availing themselves of any protection this Court's decision may seemingly provide.

Further information

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Further advice should be taken before relying on the contents of this summary.