Second Circuit Vacates Conviction Against Sales Representative for Off-Label Promotion

December 5, 2012

The Second Circuit, New York's federal court of appeals, this week issued its long-awaited decision in *United States v. Caronia* and vacated the conviction of a pharmaceutical sales representative for off-label promotion. In a 2-1 decision, the court held that the government cannot prosecute pharmaceutical manufacturers or their sales representatives for promoting the lawful, off-label use of an FDA approved drug.

Important aspects of the court's decision include:

- The truthful off-label promotion of FDA-approved prescription drugs alone is not a crime.
- The ruling applies not only to sales representatives but also to pharmaceutical manufacturers.
- Criminalizing off-label promotion would violate the First Amendment.
- Manufacturers and sales representatives still can be prosecuted for introducing a misbranded drug into interstate commerce or conspiring to do so.
- The jurisdiction of the Second Circuit is New York, Connecticut and Vermont. Therefore, while other courts might look at this decision as persuasive, courts in other states -- such as Massachusetts -- are not bound by this decision.

Misbranding Under the Food Drug & Cosmetic Act (FDCA)

The FDCA makes it a crime to introduce a misbranded drug into interstate commerce or to conspire to do so. A drug is "misbranded" if its labeling does not have adequate directions for use, or, in other words, directions under which a lay person can use a drug safely for the purposes for which it is intended. See 21 C.F.R. § 201.5. The "intended use" is the objective intent of the drug manufacturer. Therefore, a pharmaceutical manufacturer may not intend a use for a product that is different from the on-label use. Historically, the government prosecuted manufacturers for misbranding and relied heavily if not entirely on off-label promotion in which the company was engaged.

Off-Label Promotion After Caronia

So what use can the government make of off-label promotional materials after *Caronia*?

The government still can prosecute a company or an individual for misbranding, and it can use promotional materials as evidence that an off-label use was in fact the company's intended use. In other words, while the government may not prosecute solely for making off-label statements, it can use those statements as evidence that the company intended its product to be used off-label. Although the *Caronia* court in a footnote raised some practical concerns about how this would work, the possibility for now remains open. (While some may believe that the First Amendment will restrict this evidence too, courts have historically allowed statements into evidence to prove intent without running afoul of the First Amendment.) *Caronia* might provide some protection for companies facing either criminal liability or civil liability under the False Claims Act for off-label promotion, but companies that promote a drug off-label still risk liability for misbranding if the government can show that the off-label use was the intended use of the product.

Importantly, too, the Second Circuit's decision is the first in this area, and it is not clear what effect the divided decision will have outside of the court's jurisdiction. Massachusetts, for example, home to many high profile off-label prosecutions, is outside of the Second Circuit and is not bound by its decisions. Whether the Department of Justice will change tactics based on this divided decision, and/or will seek Supreme Court review, remains to be seen.

Background Facts of Caronia

In this case, the government brought criminal charges against a Jazz Pharmaceutical (at the time, Orphan Medical) sales representative for the off-label promotion of Xyrem, a drug which was approved for use with certain narcolepsy patients. Caronia was charged with conspiracy to introduce a misbranded drug into interstate commerce and with introducing a misbranded drug into commerce largely because of statements he had made to physicians about an unapproved indication and an unapproved subpopulation for Xyrem. The company also was charged and, in 2007, pleaded guilty to misbranding and paid $20 million to settle criminal and civil charges.

Caronia proceeded to trial. At trial, the government relied principally on two audio recordings in which Caronia promoted off-label use of Xyrem to a physician. (Companies should bear in mind that the government is relying more and more on recordings such as these in pursuing these cases, and should be aware of the possibility that conversations between sales representatives and physicians may be recorded without the representatives' or companies' knowledge.)

Caronia was convicted of conspiracy by a jury and sentenced to one year of probation and 100 hours of community service. He appealed, arguing that the conviction violated his First Amendment right to free speech.

In yesterday's decision, the Second Circuit agreed. On appeal, the government tried to argue that it was not in fact prosecuting Caronia for his speech, but instead that the speech was only evidence of "intended use." The court, however, found that even if that were permissible, it was not what had happened in this case. Instead, Caronia was prosecuted solely for his speech, and that, the court held, was not allowed.

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