The Legal Intelligencer
THE OLDEST LAW JOURNAL IN THE UNITED STATES 1843-2013
PHILADELPHIA, WEDNESDAY, JANUARY 15, 2013
An ALM Publication

Caronia: A Serious First Amendment Rebuke to Federal Off-Label Marketing Prosecutions

BY AMARIS ELLIOTT-ENGEL

Of the Legal Staff

John Summers

Dylan Steinberg

An unfortunate aspect of our legal system is that many important legal issues are not resolved by the courts because a controversy is not only too big to try, but also too big to be filed. A good example is federal-government-threatened civil and criminal claims against pharmaceutical manufacturers for "off-label" promotion, i.e., promotion of pharmaceutical products for uses other than those described on their FDA-approved labeling. Pre-litigation settlements in these cases are negotiated in the shadow of the law and, lacking a robust set of court decisions on the scope of liability, potential defendants are bludgeoned into settlements because of substantial uncertainty over the scope of legitimate claims that could result in, effectively, near death sentences. Not surprisingly, in this environment, manufacturers facing threatened off-label marketing prosecution have agreed to enormous settlement payments, recently as large as $3 billion.

The U.S. Court of Appeals for the Second Circuit's recent opinion in *United States v. Caronia*, No. 09-5006-cr (2d Cir. Dec. 3, 2012), is a welcome addition to the body of appellate law in this area. This closely watched and long-awaited appeals court decision calls into question the constitutionality of the FDA's enforcement regime regarding off-label marketing. Applying the Supreme Court's recent decision in *IMS Health v. Sorrel*l, 131 S. Ct. 2653 (2011), the court (2-1) reversed on free speech grounds the criminal conviction of a pharmaceutical sales representative for off-label marketing and cast doubt on the government's authority to regulate or criminalize the dissemination by pharmaceutical manufacturers and their employees of truthful information regarding the use of their products for unlabeled indications. The Caronia decision represents (a) a significant development in the regulation of pharmaceutical sales and marketing practices and, more broadly, (b) another example of the recent judicial expansion of corporate free speech rights.

Federal Regulation of Pharmaceutical Marketing

The Food, Drug and Cosmetic Act (FDCA) makes it a crime to "misbrand" a regulated pharmaceutical product, i.e., to sell it without "adequate directions for use." Historically, convictions for misbranding have required proof that the manufacturer required a specific intent to misbrand the product, namely, that the defendant intended to sell the product for a use other than those for which it is labeled. While a manufacturer's promotional practices could provide evidence of intent, promotion for off-label use was not itself considered misbranding. Since 2009, however, the FDA has taken the position that "an approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include 'adequate directions for use.'" This has fed aggressive off-label marketing prosecutions, producing a recent series of high-profile, substantial pharmaceutical company settlements, two of which exceeded $1 billion.

Remarkably, while the FDCA strictly regulates manufacturers' promotion of pharmaceutical products and prohibits almost all promotion for off-label uses, it does not restrict physicians' ability to prescribe drugs for off-label uses. That's right: While doctors may write prescriptions for off-label uses – uses that the FDA admits are sometimes part of a medically recognized standard of care – manufacturers are prohibited from providing any information to doctors about that permissible off-label use.

The Caronia Decision

Caronia presents a First Amendment challenge in this unusual regulatory approach. Alfred Caronia, a pharmaceutical sales representative who was convicted of misbranding a pharmaceutical product by discussing off-label uses, challenged his conviction on free speech grounds. Caronia argued that the FDCA unconstitutionally restricted speech by criminalizing his truthful, non-misleading promotion of a drug where such use is not itself illegal. The government contended, notwithstanding its 2009 directive, that Caronia's prohibited conduct was not his actual speech – his statements to doctors about the drug – but rather that the government was merely using his speech as evidence of Caronia's intent to sell the products for unlabeled uses. The majority of the court disagreed, finding that the jury instructions

and the government's summation "would have led the jury to believe that Caronia's promotional speech was, by itself, determinative of his guilt" and, therefore, that "the proscribed conduct for which Caronia was prosecuted was precisely his speech in aid of pharmaceutical marketing."

The majority then examined whether the FDCA's prohibition of off-label marketing was constitutionally permissible. Relying heavily on the Supreme Court's recent decision in Sorrell, the majority concluded that it was not.

In *Sorrell*, the Supreme Court struck down a Vermont statute that prohibited the dissemination of certain prescription data to pharmaceutical companies for marketing purposes but allowed other recipients access to those data for any other purpose. The *Caronia* court, analogizing to *Sorrell*, concluded that, because off-label prescribing is both legal and common, "prohibiting the truthful promotion of off-label drug usage by a particular class of speakers [would not] directly further the government's goals of preserving the efficacy and integrity of the FDA's drug approval process and reducing patient exposure to unsafe and ineffective drugs."

The *Caronia* majority dismissed as "paternalistic" the FDCA's attempt to limit the information that physicians and patients could receive from pharmaceutical manufacturers. Quoting *Sorrell,* the majority found that the "'fear that [physicians, sophisticated and experienced customers,] would make bad decisions if given truthful information cannot justify content-based burdens on speech." As a result, the court concluded, "the government's construction of the FDCA essentially legalizes the outcome – off-label use – but prohibits the free flow of information that would inform that outcome.'"

Here are three significant takeaways from Caronia:

Consider Changing the Shadow of the Law by a Direct Challenge to the FDCA

Although Caronia sought to have the FDCA's prohibitions on off-label marketing broadly declared unconstitutional, the court invoked the doctrine of constitutional avoidance and instead construed the FDCA narrowly to avoid the constitutional issues that the court acknowledged would be raised by the near-total ban on off-label marketing the government advocated. The court's reasoning, however, invites a more direct challenge to the constitutionality of the off-label marketing regulatory regime as a whole. Given the amounts in controversy in these types of disputes, manufacturers would do well to consider seriously accepting that invitation and deferring settlement while seeking court ruling on this issue.

The "misbranding" prohibition and its concomitant limitations on the content of pharmaceutical marketing communications are the FDA's primary tool for regulation of drug promotion. Were the prohibition to be struck down or even significantly limited, the FDA's power to oversee drug promotion would be severely curtailed. As the dissent in *Caronia* points out, "if drug manufacturers were allowed to promote FDA-approved drugs for non-approved uses, they would have little incentive to seek FDA approval for those uses." While the long timetables for drug approval and the continuing uncertainty of this area of the law would likely preclude drug manufacturers from opting out the approval process altogether, marketing of products that are commonly prescribed off-label, and, relatedly, their off-label use, could expand tremendously.

How Much Off-Label Marketing Is Protected?

The *Caronia* majority examined constitutional ramifications of prohibiting "truthful" statements about existing products. The *Caronia* dissent, by contrast, raised the specter of a regime in which "any substance that may be legally sold for some purpose may be promoted by its manufacturer for any purpose – so long as the manufacturer's statements are merely unsubstantiated, rather than demonstrably false or misleading." This raises the important question – unexamined in *Caronia* itself – of how broadly the First Amendment protects off-label marketing. Are statements about off-label uses permissible only if they are indisputably true – discussions, for example, of the existence of a particular scientific study – or may manufacturers and their representatives discuss off-label uses with physicians more broadly? While the dissent's concerns about the height of the slippery slope seem likely to be extreme, the striking down of the current prohibition on off-label marketing would require courts to engage in much subtler evaluations of promotional statements in determining whether those statements were entitled to First Amendment protection.

One Way or Another, a Likely Supreme Court Review

The issues in *Caronia* are very significant, making eventual Supreme Court review likely. Not only is any invalidation of a federal prosecution on constitutional grounds significant, but the decision implicates an enormous area of economic activity: Pharmaceutical companies spent more than $30 billion marketing their products in North America in 2011. Layer on that the fact that Caronia's majority and dissent were sharply divided. Whether the Supreme Court waits for more decisions in this area and grants certiorari in the context of a circuit split (more likely) or grants cert in this case (less likely), the issues presented in this case are headed to the Supreme Court. That this controversy concerns the collision between a congressional statute and an expansion of corporate First Amendment speech makes it all the more likely.

Since *Citizens United v. Federal Election Commission*, 130 S.Ct. 876 (2010), corporate speech has been one of the most active – and most controversial – areas of the Supreme Court's docket. Decisions like Sorrell and Caronia demonstrate that promotional activities by pharmaceutical companies are among those at the center of these decisions. Given the Supreme Court's recent broader protections of corporate speech, it may well be receptive to arguments, such as those made in Caronia, that regulation of promotion by corporations is – so long as the promotion is not false or misleading – strictly curtailed by the First Amendment.

John S. Summers *and* ***Dylan J. Steinberg*** *are shareholder and associate, respectively, in the litigation department of Hangley Aronchick Segal Pudlin & Schiller. They focus their practices on complex commercial litigation, including health care and pharmaceutical matters.*