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Off-Label Enforcement Developments (*Vascular Solutions, Inc.* Acquittal and *Amarin* Settlement)

Two important cases involving the permissible scope of speech regarding off-label marketing recently resolved in ways that should bolster efforts by drug and device manufacturers to secure their First Amendment rights to make truthful, non-misleading statements about potential off-label uses of their products. First, in a closely watched case in federal court in Texas, a jury acquitted a medical device manufacturer and its CEO of all charges, which included numerous off-label-related allegations. Second, the Food and Drug Administration ("FDA") settled a First Amendment lawsuit filed against it by a drug manufacturer, preserving a significant win that the manufacturer achieved earlier in the case.

Vascular Solutions, Inc. Acquittal

On February 26, 2016, a jury in the United States District Court for the Western District of Texas returned acquittals across the board in a case involving allegations that a medical device manufacturer engaged in off-label promotion. In *United States v. Vascular Solutions, Inc.*, Cr. No. 14-926 (W.D. Tex.), a jury found Vascular Solutions, Inc. ("VSI"), and its chief executive officer, Howard Root, not guilty of all charges.

VSI manufactures the Vari-Lase device, a laser console that is used to treat varicose veins by ablation, meaning to dissipate them with intense heat. The FDA cleared the Vari-Lase device for treatment of superficial veins, but doctors sometimes used the device off-label to treat perforator veins, the short veins that connect the superficial and deep vein systems. VSI unsuccessfully sought FDA clearance for use of the Vari-Lase device to treat perforator veins and developed a special Vari-Lase "Short Kit" that, according to the government, was designed to make it easier to treat perforator veins.

The Department of Justice ("DOJ") charged VSI and Root in federal court in San Antonio with conspiracy to distribute misbranded and adulterated medical devices, and with distributing misbranded and adulterated medical devices, in violation of the Food, Drug, and Cosmetic Act ("FDCA"). DOJ alleged that VSI unlawfully distributed and promoted the Vari-Lase device, including the Short Kit, for a new intended (*i.e.*, off-label) use to treat perforator veins; additionally, DOJ alleged that VSI misrepresented clinical data about the safety and effectiveness of the product for perforator vein ablation and misinformed doctors that Medicare and private payers would cover perforator vein procedures.

A significant portion of the pretrial briefing focused on how the First Amendment and its protection of truthful, non-misleading speech about off-label uses applied to DOJ's allegations against VSI and Root. At issue were the Second Circuit's landmark decision in *United States v. Caronia*, 703 F.3d 149 (2012), and a recent decision from the Southern District of New York, *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (2015). In *Caronia*, the Second Circuit reversed a pharmaceutical sales representative's conviction for conspiracy to introduce a misbranded drug into interstate commerce 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." 703 F.3d at 169. *Amarin* extended *Caronia*, granting a drug manufacturer preliminary injunctive relief against the FDA and holding that all truthful and non-misleading speech about off-label uses is protected, including proactive, promotional statements made by a pharmaceutical manufacturer. 119 F. Supp. 3d at 226-28.

DOJ and the defendants sparred repeatedly about the impact of *Caronia* and *Amarin* on *VSI*. The district court ultimately charged the jury that if it found that "VSI's promotional speech to doctors was solely truthful and not misleading" it could not be the basis for a misbranding conviction.

On the second day of deliberations, the jury returned verdicts of not guilty on every count. VSI immediately issued a press release criticizing DOJ in harsh terms, calling for a review of "every current investigation of a medical device company concerning 'off-label' promotion." While the acquittals themselves have no precedential value, DOJ's loss, despite pursuing the prosecution in a supposedly favorable venue, raises serious questions about the continued viability of the government's off-label enforcement theories.

Amarin Settlement

Twelve days after the jury's verdict in *VSI*, on March 8, 2016, Amarin Pharmaceuticals, Inc. ("Amarin")—the plaintiff in the *Amarin* case on which the *VSI* defendants had based many of their First Amendment arguments—settled its lawsuit against FDA. The *Amarin* case had remained stayed since the district court issued its preliminary injunction opinion, which extended *Caronia* and endorsed many of Amarin's positions regarding the importance of protecting truthful, non-misleading speech about off-label use. A previous Ropes & Gray Alert, discussing the *Amarin* court's preliminary injunction ruling, is available here.

In the settlement, which the district court has already approved, FDA agreed to be bound by the district judge's rulings regarding the scope of permissible speech about Amarin's drug. *See* Stip. & Order of Settlement, *Amarin Pharma, Inc. v. FDA*, No.15 Civ 3588, ECF no. 84 (Mar. 8, 2016). Importantly, FDA recognizes "that Amarin may engage in truthful and non-misleading speech promoting [ ] off-label use" of its product and that "such speech may not form the basis of a prosecution for misbranding." *Id.* ¶ 1. The settlement also sets up a safe harbor process for the next four years by which Amarin and FDA may enter into a dialogue about "up to two proposed communications per calendar year" regarding off-label use and, should they disagree, seek the Court's intervention. *Id.* ¶ 5.

The biggest value in the Amarin settlement, however, is that it preserves the judge's preliminary injunction opinion. Until the parties settled, FDA had the option to attempt to limit or overturn the decision either in permanent injunction proceedings or on appeal. While the decision is not technically binding on any other courts, its persuasive value is likely to be significant, given the paucity of decisions in this area and the thorough, careful analysis in the opinion.

Conclusion

The jury's verdict in *VSI* and the *Amarin* settlement are the latest setbacks to the government's off-label enforcement efforts, which have suffered high-profile blows from courts' increasing willingness to protect the First Amendment right of drug and device manufacturers to make truthful, non-misleading statements about potential off-label uses of their products. The next major bellwether in off-label prosecutions is likely to be *United States v. Facteau*, No. 1:15-cr-10076-ADB (D. Mass. filed Apr. 8, 2015), a case in federal court in Boston in which two former executives of a device company are charged with various offenses related to alleged off-label promotion. A number of pretrial motions are pending in *Facteau*, including motions that raise First Amendment defenses.

If you have questions about these recent developments regarding off-label enforcement, please consult your usual Ropes & Gray advisor.