



## Feds, Pharma, and Free Speech

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**R**ecent cases involving promotion to doctors have challenged off-label promotion enforcement actions based on due process and First Amendment grounds, as well as physicians' need for scientific information.



# Off-Label Drug and Device Promotion in the Wake of *Amarin*

From 2010 to 2012, the federal government collected billions of dollars in settlement money from medical drug and device manufacturers from claims of misbranding under the Food, Drug, and Cosmetic Act (FDCA) and the



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False Claims Act (FCA). See Monica Marrero, *Off Label Promotion of Pharmaceutical Drugs Under the Caronia and Amarin Cases*, 43 J. of Health Care Fin. 1, 5–7 (2016). It is important to note that up to now, the U.S. Food and Drug Administration’s focus has been on alleged oversteps in promotion involving drugs and devices potentially implicating federally funded insurers, not purely aesthetic drugs and devices. Additionally, the off-label promotion cases have focused on speech to physicians, not direct-to-consumer advertising. The recent string of cases and settlements have challenged such off-label promotion enforcement actions based on due process and First Amendment principles as well as the physician’s need for such scientific information to facilitate innovation and patient care.

In the wake of *Amarin* and its progeny, industry and other stakeholders have asked the U.S. Food and Drug Administration (FDA) to promulgate uniform guidance relating to (1) the determination of truthful, non-misleading off-label communications; (2) the exchange of medical and scientific information between man-

ufacturers and physicians; and (3) good reprint practices. And, though the FDA has repeatedly promised action, including an official statement regarding reexamination in 2014, it has yet to issue formal guidance. In December 2015, Janet Woodcock, Director of the FDA Center for Drug Evaluation and Research (CDER), announced that one of the CDER’s “front burner priorities” for 2016 was to “[r]e-evaluate [the] regulation of drug advertising and promotion in light of current jurisprudence around the 1st Amendment.” See David L. Rosen *et al.*, *How Will FDA Regulate Off-Label Communications in the Post-Facteau World?*, Food and Drug Policy Forum (Sept. 26, 2016), available at <http://www.fdpi.org>. Representative Fred Upton (R-MI), Chairman of the House Committee on Energy and Commerce, wrote to the U.S. Department of Health & Human Services Secretary Sylvia Burwell on May 26, 2016, to express his dissatisfaction with the lack of progress, stating that he was “perplexed by the agency’s unwillingness or inability to publicly clarify its current thinking on these issues in a coherent manner.” See *id.*

## Misbranding or Legitimate Off-Label Promotion?

The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits the misbranding of drugs or medical devices or introduction of a misbranded drug or medical device into interstate commerce. 21 U.S.C. §331(a). A drug or device is misbranded if its labeling does not contain adequate directions for use or if it contains false or misleading information. 21 U.S.C. §§352(a)–(n). Use instructions that are not approved by the FDA, as reflected in the drug or device’s labeling, are considered “off-label.” Because promotional statements can serve as proof of a drug’s intended use, 21 C.F.R. §201.5, off-label promotional statements made by a manufacturer or its representatives may constitute evidence of an intended use that is not FDA approved, resulting in misbranding. See Marrero, *supra*, at 1, 5–7. Hence, off-label *promotion* is prohibited by law, but off-label *use* is not. In one case, *United States v. Vascular Solutions, Inc.*, the court explained the distinction when it instructed the jury as follows:

Doctors may use medical devices that have been approved or cleared for one use for a different use that has not been cleared or approved by the FDA. This is often referred to as unapproved use or off-label use. This is not illegal. It is also not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device. If you find that VSI’s promotional speech to doctors was solely truthful and not misleading, then you must find the Defendants not guilty of the misbranding offense.

Final Jury Instructions at 12, *United States v. Vascular Solutions, Inc.*, No. 14-cr-00926-RCL, 2016 WL 1743175 (W.D. Tex. Jan. 27, 2016), ECF No. 282.

The FDA has frequently prosecuted drug and device companies for misbranding based on off-label promotions even though using drugs for off-label purposes is generally common and widely approved of in the medical community. In the most comprehensive study of off-label prescription use in the United States, conducted in 2001, it was found that 21 percent of prescriptions were given for off-label uses. Christopher M. Wittich *et al.*, *Ten Common Questions (and Their Answers) About Off-label Drug Use*, Mayo Clinic Proceedings, Oct. 2012. For

example, a drug only approved for adults may still be extremely beneficial to children in smaller doses. Healthcare professionals may also prescribe the same drug for two conditions that are pathologically or physiologically similar, even though the drug has only been approved for one.

The consequences of misbranding are criminal, and misbranding can be asserted

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against the company itself or its representatives. 21 U.S.C. §333(a)(2). *See also United States v. Facticeau, et al.*, No. 15-10076-ADB, (D. Mass. 2016) (U.S. Department of Justice charged two former executive officers of Accelerant, Inc., a medical device manufacturer, with wire fraud, conspiracy, and FDCA violations based on off-label marketing of Accelerant's Relieva Stratus Microflow Spacer). While showing that a defendant had intent to deceive or defraud makes the offense a felony with a significantly larger penalty, a misdemeanor charge may be brought successfully with little to no evidence of intent. 21 U.S.C. §333. Nevertheless, despite the widely accepted nature of off-label drug uses, it was not until recently that manufacturers had gained any traction in their defense against misbranding claims.

### **Caronia: A Shift for Off-Label Promotion and the Commercial "Free Speech" Defense (December 3, 2012)**

In 2012, *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), the district court convicted a pharmaceutical sales representa-

tive of conspiracy to misbrand after he was caught on tape marketing to doctors an FDA-approved drug for unapproved uses. The drug involved was Xyrem, a powerful central nervous system depressant with potentially hazardous side effects, also known as the "date rape drug." The Second Circuit vacated the conviction, finding that the representative's marketing tactics were constitutionally protected commercial speech as truthful promotion of an FDA-approved drug for un-approved uses.

While on appeal, the government tried to rebut the freedom of speech defense by stating that the charges were based on conduct, and Caronia's speech was only used as "evidence of intent." The court disagreed, stating that the government's case made clear that Caronia's prosecution was for his *verbal* promotion and marketing efforts. This failed distinction between conduct and speech is one that Caronia's progeny continued to tout unsuccessfully in defense of off-label promotion claims.

In response to *Caronia*, the FDA issued updated draft guidance on the dissemination of scientific or medical journal articles, authorizing the distribution of articles pertaining to unapproved uses of approved drugs as long as the articles were accompanied by certain disclosures. Additionally, the FDA specifically denounced the distribution of such articles as promotional materials or along with other promotional materials. Throughout the draft guidance, the FDA consistently maintained that if sales representatives characterized such articles as definitively making the drug safe or effective for unapproved uses, that the agency could use such speech as evidence of intent to promote misbranding.

The FDA justified this seemingly direct contradiction to *Caronia* by narrowly construing *Caronia's* ruling as particularly fact based and turning on the existence of specific circumstances.

### **Amarin Pharma, Inc. v. USFDA (May 7, 2015)**

While the ruling in *Caronia* paved the way for multiple rulings in favor of the drug and device manufacturing community, the most widely cited and recognized is *Amarin Pharma, Inc. v. U.S. Food and Drug Administration*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

On May 7, 2015, Amarin filed a complaint in the United States District Court for the Southern District of New York. Amarin was actively seeking a preliminary injunction to prohibit the FDA from bringing against it a misbranding action for what it claimed were truthful, accurate, and non-misleading statements made to doctors regarding the off-label use of its drug, Vascepa.

Vascepa is a drug comprised of solely omega-3 fatty acids, developed by Amarin to improve cardiovascular health. In 2012 Amarin had received FDA-approval for use of Vascepa by adult patients with "very high triglycerides," but Amarin still sought approval for use by adult patients with "persistently high triglycerides." It is undisputed that Vascepa is safe and effective in reducing triglyceride levels, as reflected by an FDA-approved study (the ANCHOR study), but the FDA contended that other recent scientific studies left it unclear whether reducing triglyceride levels in persons with persistently high triglycerides actually reduced the likelihood of cardiovascular-related incidents. For these reasons, the FDA denied approval of Amarin's "special protocol assessment" (SPA) agreement, something that the FDA has done only 10 times out of approximately 1,000 such agreements. David C. Gibbons, *A Victory for Amarin Further Erodes FDA Regulation of Off-label Promotion*, FDA Law Blog: Hyman, Phelps & McNamara, P.C. (Aug. 10, 2015).

Amarin appealed the decision through three successive levels of FDA review with no success, and on April 27, 2015, the FDA issued a "complete response letter" (CRL) finalizing its decision. In the CRL, the FDA acknowledged that Amarin had fulfilled all the negotiated requirements under the SPA agreement and that the ANCHOR study had successfully proved that Vascepa reduces triglyceride levels in patients with persistently high triglycerides, but Amarin had failed to show any correlation between the reduction of triglycerides and a reduction of risk for major adverse cardiovascular events. Although the FDA then continued, stating that the final results from another on-going trial may very well satisfy this deficiency, the FDA explained that if Vascepa in the meantime were to be marketed alongside the ANCHOR results, the FDA would pursue prosecution for misbranding.

The FDA's threat gave Amarin the ammunition necessary to proceed in court. In its complaint for preliminary injunction, Amarin sought approval to release 13 peer-reviewed scientific publications, a statement and summary of the FDA-approved ANCHOR study, three textual statements, and five textual disclosures supporting Vascepa's ability to reduce triglyceride levels in its promotion of Vascepa. This was exactly what the FDA had warned against. Most likely in an attempt to avoid imminent litigation, the FDA proposed a resolution to the dispute, by providing altered versions of the requested submissions. In good faith, Amarin replied with further revisions; however, the parties could not reach an agreement.

After briefly addressing whether Amarin had standing to bring the case in light of the responsive negotiations, Judge Engelmayer dove into the substance of the argument: the likelihood of success for Amarin's case in light of the decision in *Caronia*. Specifically, Judge Engelmayer analyzed the merits of the FDA's argument that *Caronia* was particularly fact based, conducting a close inspection of *Caronia's* language and reasoning to reach its ultimate conclusion:

By its explicit terms and its clearly-articulated reasoning, *Caronia* simply cannot be read as the proverbial 'ticket good for one day only.' On the contrary, the Second Circuit, at the close of its *Caronia* analysis presented its holding as a definitive one of statutory construction[,] [...] 'we construe the misbranding provisions of the FDCA as not prohibiting and criminalizing the truthful off-label promotion of FDA-approved prescription drugs [...] we conclude simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speed promoting the lawful, off-label use of an FDA-approved drug.'

*Id.* at 226 (quoting *United States v. Caronia*, 703 F.3d 149 (2nd Cir. 2012)) (other internal citations omitted) (emphasis added).

Additionally, the court emphasized that *Caronia's* holding did not leave the FDA with a loophole to prosecute manufacturers for misbranding conduct with speech evidence. Conduct that is alleged to be illegal only because of the speech associated with it still has some constitution protections. As explained by Judge Engelmayer, "*Caronia's*

holding was that the FDCA's misbranding provisions cannot constitutionally criminalize, and therefore do not reach, the act of truthful and non-misleading speed promoting off-label use." *Id.*

The court stated definitively that truthful, accurate, and non-misleading speech regarding the off-label promotion of a drug cannot be used to support a misbranding prosecution. For purposes of the preliminary injunction, not only did Amarin have a *likelihood* of succeeding on a subsequent claim, but it was almost definitive. The court ultimately analyzed each and every suggested piece of promotional language that Amarin wished to use, agreeing with no changes to the uncontested pieces, and altering and piecing back together the truthful and non-misleading language in the remaining contested pieces. On the condition that Amarin use this revised language, the court granted the injunction.

Not long after the ruling, on March 8, 2016, the judge entered a Stipulation and Order of Settlement. Through the settlement, Amarin could use the court's finalized language, as well as any other language that was truthful, accurate, and non-misleading. Under the terms of the settlement, the parties agreed to establish a special procedure by which Amarin would obtain FDA clearance for off-label promotion of its drug Vascepa, before releasing such communications to the public. Moreover, the settlement agreement permits Amarin to submit promotional materials for feedback twice every calendar year through 2020, in addition to the FDA proving continued access to optional procedures for feedback made available to *all* drug applicants. The FDA agreed not to appeal the district court decision, binding both parties to the district court's holding from August 2015, which stated that the FDA could not prosecute Amarin for any truthful and non-misleading statements made regarding the off-label use of Vascepa. The FDA has provided, and will continue to provide as part of the settlement, guidance to Amarin regarding the future promotion of Vascepa and Amarin's other products. In return, the injunction against the FDA is lifted.

#### ***Pacira Pharmaceuticals, Inc. v. USFDA (December 15, 2015)***

Even before the holding in *Amarin*, manufacturers were starting to push back against

the FDA. EXPAREL is a non-opioid pain drug used to produce postsurgical analgesia, created by the company Pacira Pharmaceuticals. Following two pivotal Phase 3 studies, the FDA approved EXPAREL on October 28, 2011, for "administration into the surgical site to produce postsurgical analgesia." While the "Clinical Studies" section of the approved prescribing infor-

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mation described the two studies (one following hemorrhoidectomy surgeries and one following bunionectomy surgeries) and stated that "EXPAREL has not been demonstrated to be safe and effective in other procedures," the "Indications and Usage" section authorized general use without any limitations to bunionectomies and hemorrhoidectomies. Pacira marketed its product consistent with the broad indications.

Three years after approval, on September 22, 2014, Pacira received a warning letter from the FDA, which alleged that Pacira's marketing of EXPAREL for use other than for bunionectomies and hemorrhoidectomies constituted unlawful off-label promotion. The letter also stated that Pacira's advertising claims regarding pain control that lasts up to 72 hours were misleading and an overstatement. While Pacira disagreed with the FDA's allegations, it agreed to cease distribution of any relevant promotional materials, in addition to issuing a corrective message to customer's regarding its approved use in two specific types of studies.

After briefly consulting with legal counsel, Pacira received a subpoena from the U.S. Attorney's Office for the District of New Jersey that requested a broad range of documents pertaining to the marketing and promotional practices related to EXPAREL. *Client Alert Commentary: Lessons from Latham & Watkins' Representation of Pacira Pharmaceuticals In*

*Ground-Breaking Settlement with FDA*, No. 1912, Latham & Watkins, Jan. 5, 2016. Pacira threatened suit under the Administrative Procedure Act (APA) and the First and Fifth Amendments to the Constitution, stating that the FDA was trying to revise the broad scope of EXPAREL's original approval, ignoring the normal administrative procedures and exceeding the author-

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ity granted to the agency under the FDCA. When Pacira's request to find an amicable solution failed to receive a response, on September 8, 2015, it filed a Complaint and Motion for Preliminary Injunction in the United States District Court for the Southern District of New York. *Pacira Pharmaceuticals, Inc. v. U.S.F.D.A.*, 2015 WL 5256628, No. 1:15-cv-07055 (S.D.N.Y.). The same court had just a month earlier granted Amarin's preliminary injunction.

Shortly after the lawsuit was filed, settlement discussions began, and in a decision announced on December 15, 2015, the FDA publicly renounced its warning letter along with conceding to Pacira's APA claim. In a resounding victory for Pacira, the FDA approved a labeling supplement stating that EXPAREL was never limited to bunionectomies and hemorrhoidectomies and providing clarity on the drug's durational effect.

### ***United States v. Vascular Solutions, Inc. (February 26, 2016)***

In an even more recent case, medical device manufacturing company Vascular Solutions, and its CEO, Howard Root, were acquitted by a jury in the United States District Court for the Western District of Texas. *U.S.A. v. Vascular Solutions, et al.*,

Criminal No. 5:14-CR-00962 (W.D.TX. Feb. 26, 2016). Vascular Solutions launched its Vari-Lase device in June 2007, for the treatment of varicose veins. This "Vari-Lase" laser device was cleared by the FDA for "the treatment of varicose veins and varicosities associated with the Great Saphenous Vein, and for the treatment of incompetence and reflux of superficial veins in the lower extremity." *Unbroken: The Howard Root/Vascular Solutions Acquittal—An Off-label Case About an On-label Use*, Duval Client Alert: Passing on Tribal Knowledge of FDA Law, available at <http://www.duvalfdalaw.com>.

Soon after, Vascular Solutions designed a "short kit," a shorter version of the Vari-Lase procedure kit to be used specifically in treating "short vein segments." In an attempt to cover all its bases, Vascular Solutions sought clearance through a 510(k) to add the "perforator vein" (a type of short vein segment) to its labeling. The FDA reviewer demanded clinical work, which was not required of its competitor, so the 510(k) was withdrawn. Vascular Solutions continued to market the product, specifically for the use on perforator veins, because its original clearance covered treatment of all varicose veins.

The U.S. Department of Justice charged Vascular Solutions and Root personally with conspiracy to distribute misbranded and adulterated medical devices and with distributing misbranded and adulterated medical devices. While the government had plenty of evidence that the company engaged in various sales schemes for the treatment of perforator veins, the case turned less on whether the speech and promotions existed, and more on whether that speech was unlawful.

Though Vascular Solutions spent twenty-five million dollars defending its case, it never called one witness, resting its case after the government rested. Through cross-examination, many of the witnesses had all but conceded that promotions of the short kit were not only truthful, but they may have been covered by the original clearance language. Moreover, the defense successfully moved for a jury instruction stating, "[i]t is [...] not a crime for a device company or its representatives to give doctors wholly truthful and non-misleading information about the unapproved use of a device." While the jury's exact line of

thought is unknown, the resulting acquittal showed that the manufacturing industry may finally hold the upper hand, at least regarding truthful promotions.

### **Reactions to Amarin and Its Progeny**

*Amarin* and its progeny surely clarify that truthful, accurate, non-misleading speech, even when it is commercial in nature, is protected by the First Amendment. While the industry was eagerly awaiting updated draft guidance from the FDA, an article written for the Mayo Clinic Proceedings' June 2016 issue suggested that *Amarin's* holding "effectively shift[ed] the decision-making process of what is considered truthful off-label promotion to industry rather than the FDA by giving deference to manufacturers in making the initial decision." Tim K. Mackley & Bryan A. Liang, *After Amarin v. FDA: What Will the Future Hold for Off-label Promotion Regulation*, 91 Mayo Clinic Proc. 701, June 2016.

On July 27, 2016, the Pharmaceutical Research & Manufacturers of America (PhRMA) and the Biotechnology Innovation Organization (BIO) endorsed the "Principles on Responsible Sharing of Truthful and Non-Misleading Information about Medicines with Health Care Professionals and Payers." Jeffrey Francer & Deborah Shelton, PhRMA, PhRMA & BIO Release Joint Principles on Communications with Health Care Professionals and Payers (July 22, 2016), available at <http://catalyst.phrma.org>. By issuing these nine principles, the two groups intended to "guide the establishment of responsible, science-based parameters for accurate and trusted information-sharing under a modernized regulatory framework." *Id.* The principles call for many things, including, but not limited to, accurate and both scientifically and statistically sound information sharing, clear labeling of what is an off-label use, more disclosure of sophisticated scientific knowledge for prescribers including the use of disclaimers, and the public sharing of new drugs and devices in the regulatory pipeline to the medical community. Bexis, *Off-Label Marketing—Industry Groups Step into the Breach*, Drug & Device Law Blog (Aug. 8, 2016), available at <https://www.druganddevicelawblog.com>. Most poignantly, the sixth principle articulates that manufacturers should be able

to communicate truthfully, publicly, and appropriately within the medical community about uses for their products that are outside the FDA-approved labeling.

While these principles are notably unprecedented in their distinguishable disregard for the FDA's outdated regulatory scheme, they provided much-needed guidance for an industry that the FDA had left in the dark. With this action, the manufacturing industry reclaimed control over the dissemination of medical research, effectively asking the FDA to stay out of professional scientific dialogues, and instead, stick to consumer protection. The FDA will always play an integral role in safeguarding public health by ensuring post-market communications do not misrepresent the benefits or risks of a particular treatment. But manufacturers are encouraging full, truthful disclosure regardless of the source, and they also seek authorization for responsible distribution of scientific knowledge, which ultimately may help accelerate medical innovation.

On August 31, 2016, the FDA issued a notification of a public hearing, asking for comment on communication of unapproved uses of approved or cleared medical products. *Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products*, 81 Fed. Reg. 60,299, (Sep. 1, 2016) (public hearing and request for comments regarding 21 C.F.R. §15). The hearing took place on November 9 and 10, 2016, and the FDA accepted public comment, though electronic or written comments, until January 9, 2017.

Within the FDA's announcement, it conceded that "relevant, truthful, and non-misleading scientific or medical information about an unapproved use may help health care professionals make better individual patient decisions." *Id.* at 60301. Still, the FDA requested comment on how such truthful information should or should not be communicated by medical firms, considering that it is already available to medical professionals through scientific journals and clinical practice guidelines. It seems as if the FDA has recognized that there are First Amendment protections for truthful speech, though it is still concerned with promoting public safety. Joanne Hawana & Joseph Lipchitz, *FDA Announces Dates for Long-Awaited Public Hearing on Its Regu-*

*lation of Off-Label Communications*, Mintz Levin: Health Law & Policy Matters (Sept. 1, 2016), available at <https://www.healthlawpolicymatters.com>. Striking a balance between protecting consumers and encouraging scientific and medical innovation will be key for the FDA during the hearing and comment review.

Many critics are suggesting that due to the nature of the FDA's request, it may be long into 2017 (or later) before manufacturers receive updated guidance. Jeff Overley, *3 Takeaways From FDA's Off-Label Forum Plan*, Law360 (Aug. 31, 2016, 9:23 P.M.), available at <http://www.Law360.com> (requiring subscription registration). Others, including PhRMA, have stated that they are pleased and hopeful, given the FDA's open-mindedness to truthful, non-misleading speech and the weight of the recent litigation, which reasonably has left the FDA much to consider.

In the meantime, the fight for many companies is not yet over. For example, prior executives of the company Acclarent are currently appealing a jury's decision to convict on multiple misdemeanors. Brian Amaral, *Ex-Acclarent Execs Want Misdemeanor Convictions Tossed*, Law360 (Aug. 2, 2016, 1:49 P.M.), available at <http://www.law360.com> (requiring subscription registration). Former CEO William Facteau and former Vice President of Sales Patrick Fabian were brought to court under multiple charges involving the misbranding of a medical instrument, called the Stratus, which was used for clearing patients' sinuses. While the device had been cleared for public use, prosecutors contended that the FDA had approved the device only for use with a saline solution or salt water and that instead, sales representatives were encouraged to promote use of the Stratus with a liquid steroid.

While both Facteau and Fabian were acquitted of all felony charges, showing that the jury found no intent by either party to defraud medical professionals or mislead consumer usage, the strict-liability misdemeanor misbranding charges stuck. On appeal, in light of *Amarin's* wide publicity, Facteau and Fabian are likely to reargue their First Amendment claims. Yet, they may also push the legality of misbranding misdemeanors under 21 U.S.C. §333, which would officially ask the court

to take a stance on the role intent in off-label promotion.

## Conclusion

While the discussion seems far from settled, it appears that the industry and regulatory agencies are moving toward accepting recent court pronouncements that truthful, accurate, non-misleading speech regard-

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ing the off-label use of medical drugs and devices is protected by the First Amendment. Some industry members are lobbying the FDA to promulgate a regulatory scheme that promotes a free flow of medical and scientific information that is consistent with "the nine industry principles" proposed by PhRMA and BIO. The court pronouncements and lobbying efforts have driven the FDA to schedule a forum for the medical drug and device community to articulate its proposed changes to off-label standards and regulations. Changes to the guidance will likely carry over to drug and medical device litigation, during which the learned intermediary defense is commonly asserted.

