Fight the Good Fight Every Moment: Do Recent First Amendment Court Developments Deal a Blow to the Government?

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In the last month, the Food and Drug Administration has suffered setbacks relating to off-label promotion oversight. In both cases, one involving a pharmaceutical company and the other a medical device firm and its Chief Executive Officer, the government's attempt to take enforcement action against dissemination of off-label information was blocked as violating the First Amendment, taking a page from Triumph's 1981 classic rock song, "Fight the Good Fight."

This Bulletin will summarize the Amarin/FDA court settlement and the non-guilty verdict in favor of Vascular Solutions and its CEO. Because we have summarized the previous Amarin court case – see bulletins from August 2015[1] and December 2015[2], we will not repeat the facts or history here. We will conclude with some observations and possible best-guess scenarios of what the FDA-regulated industry might expect and note some unanswered questions that complicate how to determine the type of off-label communication that will be considered permissible going forward

Amarin/FDA Settlement

To briefly recap the litigation history, Amarin Corporation plc successfully defended its ability to disseminate, proactively, information that its FDA-approved Vascepa® (icosapent ethyl) capsules could provide certain potential cardiovascular benefits not in the approved label. The U.S. district court in New York found that Amarin could distribute off-label information, so long as it was "truthful and not misleading," without fear of FDA enforcement. Because Amarin's actions involed accurate and substantiated information about off-label uses, the court said FDA should leave Amarin alone.

Rather than continue the litigation after Amarin won a preliminary injunction in August 2015 against FDA enforcement, the government decided to settle with Amarin. The following are highlights of the settlement:

- FDA and the U.S. government agreed to be bound by the August 2015 court declaration that Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa and, in fact, that certain statements and disclosures that Amarin proposed to make to healthcare professionals were truthful and non-misleading.

- Amarin must assume the responsibility that its communications to doctors regarding off-label use of Vascepa remain truthful and non-misleading.

- The settlement terms are to be interpreted consistent with the August 2015 court opinion and order; the terms should not limit Amarin's constitutional right to free speech concerning Vascepa.

- FDA agreed to provide Amarin with an optional pre-clearance provision through 2020 to review new potential off-label claims, whereby the agency and Amarin will work under specific timeframes, unless they agree to an extension.

1 http://www.agg.com/Another-One-Bites-the-Dust-FDA-Doesnt-Like-the-Fishy-Smell-of-the-Latest-Court-Decision-on-Off-Label-Dissemation-08-19-2015/

2 http://www.agg.com/Off-Label-Promotion-and-Product-Liability-Are-Industrys-Recent-Court-Wins-in-One-Space-a-Win-in-the-Other-12-17-2015/

- The parties agreed to a dispute resolution provision intended to avoid future litigation on matters arising under the proposed settlement order.

- The court will retain jurisdiction over the matter to ensure compliance with, and resolve any future dispute arising from, the settlement order.

Vascular Solutions' Not Guilty Verdict

Separate from the Amarin proposed settlement, the government lost another case in Texas involving its ability to prosecute off-label promotion. The Department of Justice alleged that Vascular Solutions and its CEO promoted its FDA-cleared medical device for unapproved uses. The jury found for the company and the CEO, and the U.S. district court judge entered a final order dismissing the criminal charges. The case is not subject to appeal. It is noteworthy that the judge's jury instructions were that the jury should find the company and CEO not guilty "if you find that VSI's promotional speech to doctors was solely truthful and not misleading." This language is similar to that found in the court's decision in Amarin.

AGG Observations

1. The Amarin settlement is noteworthy, in part, because it marks an FDA acceptance and concession of proactive off-label promotion, albeit with a specific fact pattern. The agency has allowed distribution of scientific and medical publications on unapproved uses, as described in a guidance document, but this is under the guise of scientific exchange of information, not promotion. In the Pacira case, where FDA alleged the drug company promoted off-label claims, which we summarized previously[3], the agency ultimately withdrew the Warning Letter and removed it from its website. The Amarin settlement represents a second FDA retreat in enforcement, but a first in the off-label litigation area (as FDA concluded, ultimately, Pacira's activities were not off-label).

2. The Amarin case is also interesting, because it holds FDA's feet to the fire. It has bound itself to the 2015 court declaration. Now, FDA knows what it is like to have a court looking over its shoulder.

3. The dispute resolution clause in the Amarin agreement helps minimize the risk of new litigation against the company. In addition, the court's oversight should further protect Amarin from FDA trying to reassert itself in this particular case.

4. The pre-clearance option in the settlement would seemingly put Amarin ahead of the line if it wants to seek FDA input on new proposed off-label claims. While any company can ask the agency for guidance or an advisory opinion on proposed claims, the agency is not required to respond at all, much less in a specific timeframe; the response will typically be more formal. With the Amarin settlement, one would expect FDA to be more timely and cooperative, with the court keeping a watchful eye.

5. The settlement, however, does not resolve a number of issues. For example, without clear guidance from FDA, it remains unclear what is meant by the phrase, "truthful and not misleading," and who ultimately makes that decision. A company can contend a particular piece meets this standard, but FDA may disagree with that position, and it is unclear what factors the agency will use to make its determination. The company must then evaluate whether the claim is worth the risk of an FDA enforcement letter or potential litigation (or both). Furthermore, it is not clear what type (and how much) scientific substantiation will be required to support an off-label claim.

6. While the Amarin settlement focused on off-label information to the medical community, it is not clear whether FDA might take a more protective, paternalistic approach towards off-label promotion directed to consumers or allow the settlement principles to apply to information directed to consumers.

3 http://www.agg.com/its-deja-vu-all-over-again--fda-sued-again-in-off-label-promotion-case-09-21-2015/

7. Industry must remember that the Amarin settlement is specific to that company, and the decision only has precedential value in that jurisdiction. FDA has said so directly. Furthermore, Amarin had good facts and extensive evidence that its materials were "truthful and not misleading." While the case is a win for industry and suggests a "truthful and not misleading" standard is evolving, the standard remains somewhat subjective. FDA will not likely abdicate its authority in the off-label space, and one should expect the agency to try to find a better case to flex its enforcement muscles and reassert its role where it finds a case of misleading off-label information or where the statements are unsubstantiated.

8. The Vascular Solutions case is reminiscent of the Caronia decision, which we summarized in a previous bulletin[4]. The court found the Justice Department could not prosecute the company or individual for truthful information dissemination. It is also noteworthy for the medical device industry, as recent cases have affected the pharmaceutical side (e.g., Caronia, Pacira, Amarin), and this is a win for the medical device side.

9. Whether or not FDA stays on the enforcement sidelines in the near term, companies should not forget potential enforcement by the Justice Department or state authorities, or product liability or competitor challenges. We have discussed these issues in previous Bulletins.

10. Companies should continue to utilize internal Promotional Review Committees (where we serve as legal representatives in many cases) to evaluate whether promotional materials comply with FDA requirements, company procedures, and the "truthful, not misleading" standard. Companies must stay current on scientific developments, and train employees accordingly, to ensure that any off-label information disseminated remains truthful and not misleading. In addition, some companies may choose to ask FDA to review potential off-label promotional statements in advance, while others might decide to proceed without FDA permission and ask for forgiveness later, if necessary.

11. False speech is not protected.

12. The Amarin and Vascular Solutions cases are fact-specific and, while the "truthful and not misleading" standard seems to be becoming "the" standard, more guidance from FDA is needed to define this phrase. Yet, any timing of such guidance is unknown, as FDA struggles with what to do next. Otherwise, parties can agree to disagree, but we might see more litigation and others having to fight the good fight.

4 http://www.agg.com/files/uploads/Client-Alerts/Kitchens-Minsk-Second-Circuit-Rules-Off-Label-Promotion-is-Protected-Speech.pdf

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