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FDA Law Update

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Clinical Investigators Beware: FDA is Reviewing What You Say

While it is common knowledge that the Food and Drug Administration ("FDA") is being more active in its review of prescription drug advertising by drug product manufacturers, it may not be widely known that FDA is reviewing what clinical investigators are stating about drugs for which they served as an investigator and which are not yet FDA approved. Recently, FDA posted on its website a Notice of Violation Letter sent January 11, 2010, to Dr. Leslie Baumann of the Baumann Cosmetic and Research Institute. The letter – coded MACMIS #18181 – can be found here.

Dr. Baumann was a clinical investigator involved in trials of the product abobotulinumtoxinA for Injection, also known as Reloxin and Dysport. FDA alleged that Dr. Baumann made statements in violation of FDA requirements in certain magazines (allure, ELLE) as well as on a TODAY show segment entitled "Today's Health: Better Than Botox?" FDA acknowledged that the drug product sponsor and Dr. Baumann had provided statements that the drug product sponsor "had no involvement or influence over" what Dr. Baumann said in the article or on TV, that she acted independently and was not paid for the allegedly violative activities in which the statements were made.

The statements she made that FDA objected to were, among others, as follows:

- "Reloxin, the new Botox, will likely come out later this year. Early data shows it may last longer and kick in faster than Botox. It will be nice to have competition on the market—the Botox people (Allergan) raised their price another 8 percent this year!" (allure article)
- "I can't wait to use Reloxin, known in Europe as Dysport. This Botox alternative will be available in the U.S. next year. Effects last a month longer than Botox and, hopefully, it will cost less." (ELLE article)
- "It's time that we have something that lasts a little bit longer, and I'm hoping that the minute the FDA approves this, I'll be able to use it in my practice." (Today Show)

FDA alleged that the statements

> "…clearly suggested that Dysport was safe and effective before it was approved, and that it was in fact superior to the approved product Botox because it lasts longer and starts working faster than Botox. These statements thus violate 21 CFR 312.7(a)[i] because they represented that Dysport was safe and effective before the product was approved, and otherwise promoted the drug before it was approved (i.e., as superior to the approved product Botox). We note that this suggestion of superiority, in addition to promoting the product before approval, is also misleading in that it is not supported by substantial evidence or substantial clinical experience. In fact, we are not aware of **any** adequate and well-controlled head-to-head trials that compare Dysport to Botox to determine whether Dysport lasts longer or starts working faster than Botox."

FDA concluded by stating that representations by a clinical investigator that an investigational new drug is safe or effective, or representations that otherwise promote use of an investigational drug, violate the Federal Food, Drug and Cosmetic Act and FDA regulations – when made "in a promotional context".

What does this mean for drug product sponsors and clinical investigators?

First of all, it does not mean clinical investigators cannot comment upon an investigational drug for which they have served as a clinical investigator. FDA conceded that "[t]here are mechanisms by which investigators and sponsors may engage in the full exchange of scientific information concerning drugs that are under investigation…" As long as an investigator limits his/her comments about a drug to venues involving a peer review setting allowing for a balanced presentation of scientific information[ii], and the investigator is not paid by the drug product sponsor to make statement, he or she should not be concerned about potential FDA action.

Second of all, it does mean that clinical investigators – at least in FDA's review – do not have an unlimited right to discuss – in a promotional context – drugs that are under investigation, if they have served as a clinical investigator on studies of that product. Of course, what constitutes "a promotional context" is always potentially an issue; there is no FDA guidance for what type of activities – beyond magazine articles and TV appearances – FDA may consider to fall within their definition of "a promotional context". Clinical investigators, if they wish to avoid the bad publicity that could arise from such a letter,[iii]will need to think twice before making any public statements about an investigational product outside of the peer review context.

Third, it does mean both drug product sponsors and their clinical investigators need to be aware that FDA is reviewing what investigators say and the context in which they are making statements. While there may have been an impression that clinical investigators as doctors have an unlimited right to express their scientific and medical judgment, FDA is taking action that reflects a view that those rights are not unlimited. This puts doctors in a position where they may be wondering what they can and cannot say.[iv]

Whether actions such as this will have a chilling effect on independent statements of doctors remains to be seen, but there may be more reason for concern than the medical profession and the drug industry have been led to believe.

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i. That regulation provides: A sponsor or **investigator**, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug" (emphasis added).

ii. See, eg, Guidance for Industry: Industry Supported Scientific and Educational Activities, 62 Fed. Reg. 64093 (December 3, 1997).

iii. The FDA letter to Dr. Baumann was the subject of an article in the Business Day section of **The New York Times** on February 1, 2010, entitled *F.D.A. Aims At Doctors' Drug Pitches*, at page B1. According to the article, Dr. Baumann said she had discussed the matter with FDA and the matter is considered closed.

iv. Id., at B6.