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Seeking Counsel: FDA Overreaches in Jurisdictional Power Grab

Letter to Dysport clinical investigator claims promotional violations in magazine interviews. Do clinical investigators really sign away their right to free speech when they conduct a clinical trial for a drug company?

A January 11 Notice of Violation letter from the Food & Drug Administration's Division of Drug Marketing, Advertising, and Communications (DDMAC) to Dr. Leslie Baumann of the Baumann Cosmetic and Research Institute raises serious questions about the jurisdictional reach of FDA's regulatory authority.

Dr. Baumann was a clinical investigator in two trials of *Dysport*, a botulinum toxin product similar to *Botox* that was ultimately approved by FDA for, among other things, treatment of moderate to severe glabellar (smooth area between the eyebrows and just above the nose) lines. An article in *Allure* magazine that appeared before *Dysport* was approved by FDA featured an interview with Dr. Baumann, who was identified as "a syringe superstar, having participated in study after study on injectables. Here, she discusses what she's learned about erasing lines and obliterating wrinkles." The article containing the interview was titled "Needle Work".

In the context of that interview, Dr. Baumann responded to a question about "What's the latest in injectables?" She said that "[*Dysport*], the new *Botox*, will likely come out later this year. Early data shows it may last longer and kick in faster than *Botox*. In will be nice to have competition on the market—the *Botox* people (Allergan) raised their price another 8 percent this year."

Likewise, in an article published before *Dysport* was approved by FDA in the beauty section of *Elle* magazine (titled, "Counter Culture Doctors' Orders: Top Skin MDs Tout the Treatments They Swear By. What Lives Up to the Hype and What's Just High Hopes") Dr. Baumann is one of four "top skin MDs" quoted in a chart responding to inquiries about, among other things, "Coming Attractions".

In that chart, Dr. Baumann is quoted as saying, "I can't wait to use [*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." Dr. Baumann also made similar statements in an appearance on television on the *Today Show*.

Independent of Sponsor

The evidence before FDA, as DDMAC itself conceded, established that the statements in *Allure* and *Elle* attributed to Dr. Baumann were made by her independently—without any involvement, influence, initiation, or direction whatsoever by Medicis, the company responsible for marketing Dysport for glabellar lines. According to the FDA letter, "Medicis indicated, and your signed declaration confirmed, that Medicis had no involvement or influence over your participation in the articles and television segment referred to above, but rather that you were acting independently and not at the initiation or direction of Medicis."

Nevertheless, DDMAC accused Dr. Baumann of violating its regulation on pre-approval promotion, 21 CFR 312.7(a), which provides that: "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).

DDMAC also alleged that the statements by Dr. Baumann claiming that *Dysport* was superior to *Botox* were misleading because they were not supported by substantial evidence consisting of well-controlled head-to-head trials that compare the products to determine which of the two lasts longer or starts working faster.

A Stretch, At Least

There is something profoundly wrong with this picture.

It is self-evidently true that if Dr. Baumann had not been an "investigator" in two clinical studies of *Dysport*, her statements of opinion, based on facts derived from any source or based on no facts at all, would be utterly beyond FDA's jurisdictional reach for any number of reasons, including the First Amendment. Independent physicians, including specialists, are entitled to express their opinions freely on matters of medical practice, subject, of course, to medical ethics and disciplinary rules imposed by state medical licensing boards.

What in the world differentiates Dr. Baumann from every other independent medical speaker? Does a physician surrender to FDA all rights to speak publicly on a subject, at least before a drug's approval, merely by serving as an "investigator" in a clinical study?

What if the statements in question are unrelated to the clinical investigation in which the investigator participated? And on what authority can this be justified, other than on the terms of the FDA regulation itself that broadly prohibits every "investigator" from

engaging in pre-approval *promotion* no matter what the circumstances?

Surely, what the regulation on pre-approval promotion was intended to address was a situation where an investigator, *acting on behalf of a drug sponsor*, was endeavoring to seed the marketplace with favorable information about a drug to develop demand for it, particularly if the statements concern an indication for use that was ultimately not approved by FDA. Here, by contrast, Dr. Baumann was unquestionably acting on her own, independent (as DDMAC itself concedes) of any involvement, initiation, influence or direction from the drug sponsor.

To be sure, Dr. Baumann, in the material quoted in *Allure* and *Elle*, may well have been implicitly touting her broad knowledge and experience in this field and thereby perhaps suggesting that patients might wish to consult her if they were seeking treatment with the drug once it was approved. At the same time, FDA does not regulate the practice of medicine, and should not be entitled to forever preclude a physician from speaking on a topic, even before a drug is approved, on the basis that the individual once served as an "investigator" for the sponsor. There are strong practical and First Amendment reasons for this view.

A Confused Sense of Jurisdiction

Moreover, on what evidentiary basis does DDMAC conclude that Dr. Baumann was engaged in pre-approval "promotion" of *Dysport*? She clearly wasn't trying to sell it because the drug wasn't even available at the time her comments were made. She wasn't acting on behalf of the drug sponsor so on what theory does FDA have jurisdiction over this kind of "promotion"?

FDA only has jurisdiction over promotional activities by drug "sponsors". Dr. Baumann was not acting on behalf of a drug sponsor. Her comments had to do with therapeutic developments in the treatment of glabellar lines that may soon be available and what benefits this treatment might have. Why do these news stories amount to the kind of pre-approval representations in a "promotional context" that DDMAC says its regulation on pre-approval promotion was intended to prohibit?

Ironically, given the specific context of the statements by Dr. Baumann, having to do with *Dysport* and *Botox*, this kind of overreaching by FDA about what does and does not amount to drug "promotion" may well lend credence to the arguments advanced by Allergan in its own First Amendment litigation against FDA challenging the breadth and ambiguity of the agency's undefined "definition" of "promotion" subject to FDA's advertising and labeling jurisdiction. (*See "Allergan's Botox Off-Label Promotion Suit Raises Questions, But Why Would Wall Street Care?" The RPM Report, October 2009.*)

There's more. FDA's accusation that Dr. Baumann's statements were misleading because

they aren't supported by substantial evidence or substantial clinical experience makes a muddle about who it is that FDA in fact has the authority to regulate.

Medical professionals acting independently of drug sponsors are not subject to statutory substantial evidence standards when discussing drug therapy. FDA only has authority over promotional representations by drug sponsors. Indeed, FDA has repeatedly acknowledged that physicians, in the course of the practice of medicine, are free to use approved drugs for any purpose, and that this practice of medicine is beyond FDA's regulatory jurisdiction.

If such off-label use is beyond FDA's authority, on what basis does the agency believe that a physician, acting independently, can somehow be required to base statements to the news media on substantial evidence or substantial clinical experience? Does FDA seriously believe that statutory substantial evidence standards can be imposed on physicians when speaking to the news media independently simply because at one time the physician served as an "investigator" in a study of the drug? Such an approach would muzzle far too much protected speech to be consistent with the First Amendment.

As is evident, there are serious legal and constitutional problems with FDA's jurisdictional power grab in this case. The agency should consider withdrawing this letter as having been improvidently issued in the first place.

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The RPM Report

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