

Recent Off-Label Device Cases Are A Road Map For The Future

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On July 20 a jury in Massachusetts convicted former Acclarent Inc. executives William Facteau and Patrick Fabian of 10 misdemeanor counts of misbranding and adulteration based on alleged off-label promotion of the Stratus sinus spacing device. They were acquitted of 14 related felony charges, but they have vowed to fight the misdemeanor convictions in future motions and appeals. The Facteau verdict contrasts with the clean sweep obtained by Vascular Solutions and its CEO, Howard Root, last February, when a Texas jury acquitted them of all counts of misbranding and conspiracy for allegedly promoting the Vari-Lase varicose vein device off-label. The two cases are different in significant respects, which may account for the disparate results. But they also bear many similarities, which provide a road map for medical device and pharma manufacturers to future off-label prosecutions in the wake of recent First Amendment precedents.



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Facteau and Root both invoked the defense made viable in *United States v. Caronia*[1]: that the government cannot prosecute truthful, nonmisleading off-label promotion without violating the First Amendment. In each case, the U.S. Department of Justice responded by asserting it didn't seek to prosecute the alleged off-label promotion per se, but merely sought to use off-label speech as evidence of the defendants' intent to distribute for an unapproved use without providing the FDA with required premarket notification. The courts' instructions on this critical issue in each case differed markedly. D.C. District Court Senior Judge Royce Lamberth, sitting by designation in San Antonio, instructed the Root jury that:

It is not a crime for a device company or its representatives to give doctors wholly truthful and nonmisleading 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.

In contrast, Massachusetts District Court Judge Allison Burroughs instructed the Facteau jury as follows:

The indictment in this case does not charge any defendant with the crime of promoting a device off-label, because that is not itself a crime. Rather, the FDCA crimes charged are conspiring to introduce, and causing the introduction of, devices into interstate commerce that were adulterated or misbranded. Although you may not convict a defendant of a crime based solely on truthful, nonmisleading statements regarding off-label use, even truthful statements about an off-label use can be considered as evidence. To put it another way, to convict, there must be a

criminal act. Truthful, nonmisleading speech cannot be a criminal act in and of itself, but it can be evidence and therefore used by you to determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent.

So while the Root court was silent on the government's "evidence of intent" theory — and even appeared to foreclose a verdict based on it — the Facteau court clearly embraced it.

One may question whether the jury instruction on this point made a significant difference in Root, since the defense was based largely on an entirely different question: whether the general, cleared indications for Vari-Lase actually included the specific use in question. But whether the instruction had an impact on the verdict in Facteau cannot seriously be disputed. The jury specifically found in that case that the product's labeling was not false or misleading, and that the product did not lack adequate instructions for use. Had the jury been instructed as it had in Root, these findings would have made the misdemeanor convictions unlikely, if not impossible.

Whether the Root instruction, or the Facteau instruction, is correct remains to be seen. Facteau's attorneys have stated that in future challenges to the verdict they will argue the jury instructions impermissibly allowed convictions based on truthful, nonmisleading statements, in violation of the First Amendment: so the government's "evidence of intent" theory will be directly in the defendants' cross-hairs on appeal. Until a decision is reached on this issue, and adopted by a majority of circuit courts, manufacturers should continue to be wary of the risk that truthful off-label promotion will simply be recast as "evidence of intent" in a future misbranding prosecution.

Although this question — whether the government may properly use off-label speech as evidence of intent to misbrand — is likely to remain unsettled for years to come, both Root and Facteau offer clues to the government's future off-label prosecution strategies, notwithstanding how that question is resolved. For example, both indictments included felony conspiracy counts for allegedly defrauding the FDA. "The defendants knew they intended to sell the device for a use not covered by their 510(k) notification and defrauded the FDA by failing to disclose that at the time," or so the argument goes. The difficulty with this argument is that it's hard to make fraud charges stick: Root and Facteau were both acquitted of fraud. If a company clears a device for one use with knowledge that doctors are likely to use it for another, has the company defrauded the FDA? In September 2015, the FDA formally proposed dropping the "knowledge" prong from its intended use rules, and has actively disavowed any interpretation of its regulations as allowing prosecution based on mere knowledge that a drug or device will be put to an off-label use.[2] But what if the company actually developed the device for the uncleared purpose and then marketed it that way in Europe when its application to clear that use in the U.S. was rejected? Is that enough to show fraud? While the line between "fraud" and future or past intention is murky at best, the government seems poised to use this strategy whenever possible.

Prosecutors will also stretch the definition of "misleading" promotion in an effort to occupy the space left open by First Amendment case law. The maxim that the First Amendment does not protect lies has never been questioned, but what makes something "misleading?" Prosecutors are likely to argue that promotion is "misleading," based not only on affirmative misrepresentations, but also on what was omitted from sales presentations. Is it misleading to market a device for an uncleared use without affirmatively stating at the time that the use isn't cleared? This claim appeared in both Facteau and Root. Is it misleading to withhold information about unfavorable (and unpublished) clinical study results regarding an off-label use — even if the FDA's own guidelines discourage distributing such results? The government in Root made similar assertions. Manufacturers should be mindful that sales representatives can be called into question not just for what they say, but also for what they *don't* say to

prospective customers.

The government will similarly sift through the facts in an effort to find evidence of other crimes associated with the promotion in question. If a sales representative has entertained customers too extravagantly, or given Medicare coding advice that is anything but unassailable, a kickback or Medicare fraud claim could be proffered to undermine the First Amendment defense. Root and Vascular Solutions were never charged with Medicare fraud, but the government alleged that misrepresentations about Medicare coverage rendered the purported off-label promotion of Vari-Lase “misleading.”

Finally, as direct off-label promotion claims become more difficult to prosecute, the government will rely more heavily on the argument that devices lack adequate instructions for the off-label use allegedly promoted. A device is deemed misbranded if its labeling does not bear “adequate directions” for the uses for which it is intended — including off-label uses.[3] This requirement creates a Catch-22 under which manufacturers must label their devices with instructions for known off-label uses, while knowing they could be prosecuted as result of such labeling. Prosecutors deployed this strategy in both Facticeau and Root and are certain to use it again.

Manufacturers cheered as Caronia and its sister cases have chipped away at the government’s once unquestioned authority to prosecute off-label promotion, but revising corporate policy to allow this practice now would be foolish. As these cases illustrate, the FDA will not give up easily, and the government has other paths on the road ahead to continue targeting promotional speech.

—By Dulce J. Foster, Fredrikson & Byron PA

DISCLAIMER: Dulce Foster was a member of the Howard Root trial defense team.

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[1] 703 F.3d 149 (2d Cir. 2012).

[2] Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding “Intended Uses”, 80 Fed. Reg. 57756, 57757 (Sept. 25, 2015); (“As FDA has previously stated, however, the Agency would not regard a firm as intending an unapproved new use for an approved or cleared medical product based solely on the firm's knowledge that such product was being prescribed or used by doctors for such use.”).

[3] 21 U.S.C. § 352; 21 C.F.R. §§ 801.5, 801.4.

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