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EXPERT ANALYSIS

A Wolf In Sheep's Clothing: When the Failure To Obtain a 510(K) for a Modification May Be More Than a Regulatory Violation

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The recent issuance of FDA's draft guidance, *Deciding When to Submit a 501(k) for a Change to an Existing Device*, which, when finalized, will replace the guidance of the same name issued in January 1997, was undoubtedly met with both excitement and trepidation for companies with products marketed under a 510(k) clearance.

Trepidation because in 2011, FDA issued a controversial draft guidance on this issue that would have significantly increased the circumstances under which a 510(k) would need to be submitted for a modification. We blogged on that draft guidance at http://bit.ly/2bYuGPS.

And excitement because not only is an update to the 1997 guidance well overdue, but also because in 2012 Congress held FDA accountable for the positions it took in the 2011 draft, required FDA to withdraw that draft and operate under the 1997 guidance, and mandated that FDA provide to Congress a report describing when a new 510(k) is needed for a modification to a cleared device.

FDA is not permitted to finalize the draft guidance for one year after receipt of the report by Congress.

With this background in mind, medical device enthusiasts likely reviewed the draft guidance eager to see how this revised draft modifies the 1997 guidance, looking at it from the regulatory perspective of when a new 510(k) is needed. (Stay tuned for a follow-up post providing an in-depth analysis from this viewpoint.) But while the details will be important, companies should not consider them as solely affecting regulatory decision making.

In fact, the consequences could be far more significant: the failure to obtain a new 510(k) for a modification could expose a company to civil and criminal charges brought by the Department of Justice (DoJ).

FDA has often disagreed with a company's determination that no new 510(k) is needed for a modification to a cleared device, including a labeling change. Such disagreement was usually handled by negotiations between the FDA and the company, and the company's agreement to submit a 510(k) within a specified timeframe.

Often, the FDA did not require the company to take the product off the market during the pendency of the review, so long as there was no known safety issue associated with use of the modified device, and the company kept up its end of the deal to timely submit a 510(k). It was strictly a regulatory issue, and handled appropriately as such.

Now, however, a different approach is afoot, and one that carries with it the potential for far more serious consequences than the need to obtain a new 510(k) clearance. For those of you who are regular readers of this blog, you know that the FDA has suffered several significant losses with respect to its attempts to regulate companies that promote their products for off-label uses. (See our previous posts at http://bit.ly/2c73ajt, http://bit.ly/2bK5wDY and http://bit.ly/2bK4A2w).

The government is taking a new tack: charging medical device companies engaged in off-label promotion with a failure to have a new 510(k), and criminalizing what has traditionally been considered a regulatory violation.

Those cases have demonstrated the power of the First Amendment, and that companies may distribute truthful, non-misleading information about off-label uses of their products without running afoul of the Federal Food, Drug, and Cosmetic Act.

To counter this new defense, the government has adjusted the way it views an off-label promotion violation for medical devices. Typically the government has considered a company engaged in off-label promotion as creating a new intended use for its product, and has alleged that the conduct misbrands the drug or device because the product does not bear adequate directions for its "off-label" intended use. (The government also has alleged that the product's labeling is false or misleading, which of course would not be subject to First Amendment protection.)

Now, to avoid the First Amendment "issue," the government is taking a new tack: charging medical device companies engaged in off-label promotion with a failure to have a new 510(k), and criminalizing what has traditionally been considered a regulatory violation. The difference is subtle but important, by trying to shift the allegation from speech to conduct — the lack of a new 510(k).

This approach has recently been tested in the cases of Vascular Solutions Inc. and Acclarent, Inc., with differing outcomes.

In Vascular Solutions, the government alleged that the company's "Vari-Lase" product line could only be promoted for the treatment of superficial veins, and that the company's promotion for the ablation of "perforator" veins, which connect the superficial vein system to the deep vein system, was outside the scope of the cleared indication.

The government charged the company and its CEO with one count of conspiracy and eight counts of introducing adulterated and misbranded devices into interstate commerce. Before trial, the government dropped the adulteration charges, leaving only the misbranding charges related to the company's failure to have a 510(k) clearance for the perforator use and the typical "adequate directions for use" charge.

The company's defense hinged on whether the specific use for perforator veins was within the general indication cleared by FDA. The jury instructions appear to follow the lines of the 1997 Guidance:

> A device is misbranded if the manufacturer was required to, but failed to provide, a 510(k) notification or information related to that notification as required by law before distributing the device. When a device is already in commercial distribution but is about to be significantly changed in its design or intended use, the manufacturer must submit a new 510(k) notification to the FDA at least 90 days before the manufacturer introduces the modified device into interstate commerce. Significant changes that require a premarket notification include: (1) a change in the device that could significantly affect the safety or effectiveness of the device (e.g., a significant change or modification in design or manufacturing process); or (2) a major change in the intended use of the device. The 510(k) notification must include appropriate supporting evidence to show that the manufacturer has considered what consequences and effects the changes might have on the safety and effectiveness of the device. A 510(k) notification also must contain proposed labeling sufficient to describe the device, its intended use, and the directions for its use. If a 510(k) notification does not contain sufficient information, the FDA may request additional information. If the additional information is not provided within 30 days of the request, the 510(k) notification is considered withdrawn.

After a four-week trial, the jury acquitted the company and the CEO of all counts.

The executives in the Acclarent matter, however, when faced with the same charges for similar conduct, were not as fortunate. In that matter, the government alleged that the Relieva Stratus Microflow Spacer was cleared to be used with saline to maintain sinus openings following surgery, but that the company promoted the device to deliver steroids to the sinus cavity.

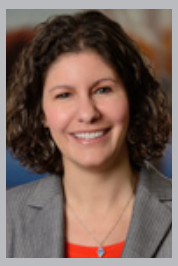
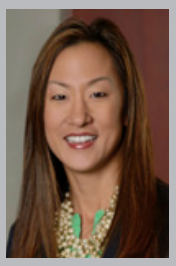
The government charged the company's executives with "Misbranding by Failure to File Premarket Notification," and the court instructed the jury that "a medical device is [] misbranded if the manufacturer introduces the device into interstate commerce for an intended use that is significantly different from the use covered by its 510(k) clearance and without submitting a new premarket notification to FDA regarding the different intended use."

Although the jury acquitted the company's executives of all felony charges based on a lack of evidence of intent to defraud or mislead, the executives were convicted of 10 misdemeanor counts related to the regulatory status of these devices. The company — now owned by J&J — also agreed to pay $18 million to resolve civil allegations related to the same conduct under the False Claims Act.

In light of the above approach to civil and criminal matters, companies now need to consider not only whether the FDA could deem the failure to file a new 510(k) for a labeling change to be a regulatory violation that could be remedied through appropriate regulatory mechanisms, but also whether the failure to file could land the company with civil and/or criminal subpoenas from DoJ.

Perhaps as a result of the loss in Vascular Solutions, the FDA includes in the new draft guidance a specific example of when a more specific use may require a new 510(k), while the 1997 guidance was silent on that issue.

Knowing this, medical device manufacturers should review the draft guidance not only to inform their regulatory activities, but also knowing that DoJ may come knocking. And, as companies prepare their comments on the draft guidance, they should be aware that the stakes could be much higher than receiving a Warning Letter.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