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Promoting Your 510(k)-Pending Device: 5 Questions About FDA's Policy

A 510(K) SUBMISSION RATHER THAN A 510(k) clearance is the threshold that a device firm needs to meet to begin advertising or displaying a product under a long-established, one-sentence agency policy. But important questions remain about proper application of this policy by industry, Hyman, Phelps & McNamara attorney Jeffrey Shapiro writes in this guest column.

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For almost 40 years FDA has allowed firms to advertise and display medical devices after a 510(k) has been submitted, but prior to clearance. This policy was set forth in a short compliance policy guide (CPG 300.600) issued in 1978, which says: "Although a firm may advertise or display a device that is the subject of a pending 510(k) ... a firm may not take orders, or be prepared to take orders, that might result in contracts of sale for the device unless limited to research or investigational use."

It is remarkable how durable the policy has been over the decades. Nonetheless, there are several questions that arise periodically as device companies attempt to comply. It is unfortunate that FDA has not provided any additional guidance. This article is my attempt to clarify some of the most pressing issues.

'Firm May Not ... Be Prepared to Take Orders'

One question that frequently arises is what FDA means by saying a firm may not "be prepared" to take orders. Are there launch-preparation activities that are not permissible while a 510(k) is pending? For example, what about synchronization with the computer systems of potential hospital customers or group purchasing organizations (GPOs)? If a firm must wait until after clearance to engage with customer ordering and billing systems, there could be significant delays because this electronic infrastructure requires time to set up.

> **If a manufacturer communicates to the public that it is not willing to accept orders, and it does not in fact accept orders, that should be sufficient to satisfy CPG 300.600.**

The phrase "be prepared" is best analyzed in context. CPG 300.600 was issued shortly after the Medical Device Amendments of 1976 (MDA) had created a complex new regulatory scheme for medical devices. To ease the transition, the MDA had decreed that devices already in "commercial distribution" as of May 28, 1976, would be allowed to remain on the market for the time being. The purpose of CPG 300.600 was to explain how FDA would determine whether a device would be considered in "commercial distribution" as of May 28 of that year.

Naturally, if a manufacturer had sold at least one unit of a device prior to May 28, it would be obvious that the device was in commercial distribution before the cutoff date. But what if a manufacturer had *offered* the device for sale but no orders had ever been placed? Could the device still be considered to have entered commercial distribution?

FDA answers with a qualified "yes." In CPG 300.600, FDA indicates that it would consider a device as having been in commercial distribution prior to May 28 if: (1) it was "displayed, advertised, or otherwise offered for sale before May 28, 1976, for a specific intended purpose or purposes" (and it was not being offered for research or investigational use) *and* (2) the manufacturer had "accepted, or been prepared to accept, at least one order to purchase the device that resulted, or would have resulted, in a contract of sale."

Almost as an afterthought, FDA applied this reasoning to the situation when a firm has submitted a 510(k) and, while it is pending, proceeds to advertise the device. Would advertising the device constitute unlawful "commercial distribution" prior to 510(k) clearance? The answer in CPG 300.600 is a qualified "no." FDA said it would not consider advertising a device prior to 510(k) clearance to be sufficient by itself to constitute commercial distribution, just as FDA would not consider advertising a device prior to May 28 to be sufficient by itself to constitute commercial distribution. In both cases, the missing ingredient to create commercial distribution was acceptance of orders or at least being "prepared" to do so.

But what does "prepared" mean in this context? FDA has never commented on what it means. In most dictionaries, "prepared" has a dual meaning. It can mean that one is *ready* and *able* from a logistics standpoint. However, it also can mean that one is *willing* from an intent standpoint. The most natural reading of CPG 300.600 is that FDA was using "prepared" in the sense of "willing" rather than "ready" and "able." Realistically, it is easiest for FDA to determine whether a firm is willing to accept orders based on whether the firm has actually accepted orders or has made public statements indicating an intent or "willingness" to do so.

Conversely, it is difficult to see how FDA could draw lines around the degree of readiness that would be permissible in the logistical sense. Drawing these lines would require fact-intensive investigation into a firm's operational activities to determine when it truly became ready and able to accept orders. Furthermore, even if a firm makes itself ready and able to accept orders, there is no danger that it will accept orders unless it has the requisite intent to do so. It would make sense, therefore, to conclude that FDA was focused on preparedness in terms of willingness. In short, if a manufacturer communicates to the public that it is not willing to accept orders, and it does not in fact accept orders, that should be sufficient to satisfy CPG 300.600, regardless of additional logistical steps taken to get ready to sell a device.

New Intended Use?

It is well established under Federal Food, Drug and Cosmetic Act (FDCA) that FDA grants 510(k) clearance or PMA approval to medical devices based upon the concept of "intended use." When a 510(k) clearance or PMA approval is granted, it is based upon a specific intended use. If the manufacturer wishes to offer it for a new intended use, it generally must submit a new 510(k) or PMA.

> **The vagueness of the intended-use regulation tends to empower the agency, because many firms will err on the side of caution rather than risk enforcement action.**

An FDA labeling regulation, 21 C.F.R. § 801.4, defines "intended use" to refer to the "objective intent" of persons labeling the device based upon labeling, advertising, other "expressions" or "the circumstances surrounding the distribution of the article." If a manufacturer promotes a device for a new intended use outside the scope of clearance or approval, FDA may conclude that the manufacturer has altered the intended use. Because the device does not have clearance or approval for the new use, FDA deems it misbranded or adulterated.

What does intended use have to do with CPG 300.600? The issue can be illustrated with a hypothetical. Suppose a device has received 510(k) clearance for "Use A" and is regularly being sold and shipped for Use A. Now suppose the manufacturer files a 510(k) for "Use B," and the 510(k) is pending. May the manufacturer start advertising Use B prior to clearance? We already know from CPG 300.600 that it is lawful to advertise the device for Use B while a 510(k) is pending (so long as the manufacturer does not accept orders and is not prepared to do so). But could FDA still allege that advertisements for Use B effectively alter the intended use of the ongoing sales for Use A, causing the device to be "intended" for Use B as well? If so, then FDA could allege that the devices as shipped while the 510(k) is pending are adulterated and/or misbranded due to the lack of clearance for Use B.

If devices being shipped for Use A cannot be used off-label for the new Use B without physical modification (e.g., a software upgrade is needed), it is difficult to see how FDA could credibly argue that advertising Use B alters the intended use of the devices being shipped for Use A. In the more common case, in which devices shipped for Use A are physically capable of Use B, it is easy to imagine FDA taking the position that the advertisement for Use B alters the intended use of the devices currently being shipped. Because the definition of intended use (21 C.F.R. § 801.4) is broad and subjective, that is certainly a position FDA could take.

On the other hand, if the determination of intended use is based on a manufacturer's labeling and advertising, it ought to be possible to guard against the unintentional creation of a new intended use by using appropriate language in advertising for Use B. For example, a manufacturer might create a separate model for Use B (with different colors and branding) and make clear that it is "not available for sale" and is "under review by FDA, 510(k) pending." The firm might even add language to the labeling and advertising of the device for Use A, making it clear that it is intended only for Use A and not Use B.

If steps like these were taken, FDA would find it much more difficult to argue that the intended use of the devices being shipped had been altered to include Use B. But the vagueness of the intended-use regulation means that a manufacturer adopting this approach risks an enforcement fight with FDA. Most firms understandably do not want to take on this risk, and so they refrain from advertising a device for a new use if it is already on the market for another use. Like so much else in FDA regulation, the vagueness of the intended-use regulation tends to empower the agency, because many firms will err on the side of caution rather than risk enforcement action.

ABOUT THE AUTHOR

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Orders Contingent Upon Clearance

Another question that arises from time to time is whether it is acceptable under CPG 300.600 to take sales orders if they are contingent upon receipt of 510(k) clearance. Although CPG 300.600 does not expressly address this question, FDA officials over the years have consistently indicated that contingent orders are not permissible.

This conclusion makes sense. The purpose of CPG 300.600 is to prevent commercial distribution prior to 510(k) clearance. FDA's position in CPG 300.600 is that accepting orders that might result in contracts of sale is the essence of commercial distribution. That conclusion would hold even if the parties agree to a contingency, *i.e.*, that failure to obtain clearance will excuse delivery. Hence, orders contingent upon 510(k) clearance should be seen as engaging in commercial distribution, which is permissible only after 510(k) clearance is obtained.

What About Advertising Prior to Submitting A 510(k)?

A puzzling aspect of CPG 300.600 is that it permits advertising only for a device with a *510(k) pending*. FDA officials have over the years publicly indicated that the advertising is not permitted until a 510(k) is pending. It is not uncommon for firms to work very hard to get a 510(k) submission filed and pending just before a major trade show so that advertising will be permitted.

But what gives FDA authority to ban advertising before a 510(k) is filed? Certainly, if a firm is taking orders prior

to filing a 510(k), FDA may reasonably take the position that the firm is placing the device into commerce. But what if the firm is not accepting orders and is not prepared to do so? In that case, under the test of CPG 300.600, the device cannot be deemed to have entered commercial distribution under FDA's own test. There is no obvious reason that advertising should not be equally lawful *before* a 510(k) is filed, so long as no orders are taken and the firm is not prepared to accept orders.

What if A 510(k)-Pending Device Has Supporting Clinical Data?

At the time CPG 300.600 was issued, 510(k) submissions were not accompanied by clinical data. In 1990, the Safe Medical Devices Act (SMDA) amended the FDCA, authorizing FDA to require clinical data during a substantial equivalence review. In 1980, FDA had issued regulations prohibiting sponsors from promoting an investigational device or representing it as safe or effective for its investigational use. Today, FDA routinely may request clinical data, albeit in something less than 10% of 510(k) submissions.

Is it permissible to advertise 510(k) submissions with clinical data under CPG 300.600? In the quarter century since the SMDA, FDA has never issued guidance to answer this question. I wrote an article in 1997 taking the view that a regulation trumps a compliance policy guide. I still take that position, but it is disappointing that FDA has never addressed this obvious conflict between the regulations and CPG 300.600.

The short statement in the CPG 300.600 policy has served reasonably well for decades, despite little effort by FDA to elaborate. But the discussion suggests the agency should thoroughly review the policy, along with its other labeling and advertising regulations and policies to ensure that its regulatory objectives are appropriately met in the decades ahead.

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