Legal Backgrounder

WLF Washington Legal Foundation

Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

Vol. 28 No. 9 August 2, 2013

FDA's DEVICE RECALL GUIDANCE: SIGNIFICANT ENHANCEMENT REQUIRED

by
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*'When **I** use a word,' Humpty Dumpty said . . . 'it means just what I choose it to mean — neither more nor less.'*

*'The question is,' said Alice, 'whether you **can** make words mean so many different things.'*

Lewis Carroll, *Through the Looking Glass* (1872)

There is a bit of a *Through the Looking Glass* quality to the Food and Drug Administration's (FDA) recent draft guidance on distinguishing recalls from product enhancements.[1] The guidance interprets familiar terms in new ways, and introduces entirely novel terms as if they have a well-established regulatory meaning. Although purportedly intended to allay the anxiety of manufacturers seeking to make improvements to their medical devices, the regulatory interpretation offered by the draft guidance appears to have already exacerbated it, if the roughly two-dozen, overwhelmingly critical comments submitted to FDA's docket are any indication.

The draft guidance purports to create a completely new category of potentially reportable activity, the "product enhancement," which it defines as "a change or improvement to a non-violative device as part of continuous device improvement activities." Product enhancement activities "include, but are not limited to, changes designed to better meet the needs of the user, changes to make the product easier to manufacture, and changes to the appearance of the device that do not affect its use." According to the draft guidance, a product enhancement is "(1) a change to improve performance or quality of a device, and (2) *not* a change to remedy a violation [of the Federal Food, Drug, and Cosmetic Act (FDCA)] caused by the device."

The draft guidance states that a "product enhancement is not a recall." At the same time, it asserts that a product enhancement may constitute a "correction" or "removal" if it involves a change to a product that was initiated to "reduce a risk to health" posed by the device. According to the draft guidance, enhancements that would be considered reportable under Part 806 include "the addition of a

[1] Draft Guidance for Industry and Food and Drug Administration Staff: Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements (Feb. 22, 2013).

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new warning to a device's label in order to reduce a health risk, a manufacturing change to a sterile device to reduce the likelihood of contamination, or a design change to improve a product's safety profile."

The draft guidance creates a new category of reportable activities that were previously considered and rejected by FDA after careful consideration, through the rulemaking process, of the scope of its statutory authority and of the proper balance between public health protection and administrative burden. In its current form, the draft guidance would present a true dilemma for device manufacturers: (1) avoid making product enhancements, even when they would improve patient safety and potentially avert adverse events; or (2) treat all product enhancements as reportable corrections, which could in turn trigger a recall, with its attendant regulatory burdens, negative publicity, and tort liability risks, if FDA determines in retrospect that the enhancement was undertaken to remedy a violation.

To appreciate the interpretive errors manifest in the draft guidance, a brief review of the statutory and regulatory history underlying device removal and correction is necessary. Congress enacted the Safe Medical Devices Act (SMDA) of 1990, in part, to enhance FDA's postmarket surveillance capabilities for medical devices so that FDA could timely receive and evaluate information about already-marketed devices that were potentially dangerous and, informed by such information, initiate further regulatory or enforcement action if necessary.

To that end, the SMDA directed FDA to require reporting of deaths and injuries associated with a medical device, which FDA implemented through 21 C.F.R. Part 803 (Medical Device Reporting). Further, Section 519(f) of the SMDA (which is now 519(g)) directed FDA to require reporting of "corrections and removal" actions taken by device manufacturers, distributors, and importers that were undertaken to (1) reduce risk to health posed by a device, or (2) remedy a violation of the act caused by a device which may present a risk to health.

FDA implemented the correction and removal provision of the statute in 21 C.F.R. Part 806. In doing so, FDA recognized that Congress "did not want to overburden industry or FDA with excessive reporting requirements." [FR at 27184]. In keeping with this burden-minimization goal, FDA modified its initially-proposed definition of "risk to health" so as to focus specifically on those corrections and removals that addressed "more serious risks to health." The final rule defined "risk to health" as (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote."

Part 806 does not include a definition of product "enhancement." Although the draft guidance acknowledges this, it ironically does not appear to recognize that this omission from the regulations was intentional. In issuing the final Part 806 regulations in 1997, FDA explicitly rejected comments suggesting that a definition of "device enhancement" be included, on the basis that if "a correction or removal is initiated in order to enhance a device in the absence of a risk to health, no report is required" and that the "central question" in assessing reportability is "whether there is a risk to health and not whether the device is enhanced." [FR at 27186]. The draft guidance therefore sharply departs from FDA's longstanding position that product enhancements are beyond the scope of Part 806.

Under the draft guidance's reasoning, any time a manufacturer introduces a new version of an existing device that has been modified to improve its safety, the manufacturer must report the change to the modified device under Part 806, since if the device could be made safer, then the motivation to introduce the new version was necessarily to reduce an existing risk to health.

It is clear from the legislative history of the SMDA that Congress wanted FDA to have real-time information about corrections or removals of devices already in the field, but not to probe manufacturer motivations for making changes to devices that had not yet been distributed. It is equally clear from the rulemaking history of Part 806 that FDA understood the limitations of Congress' mandate.

An even more central departure from Part 806—and, more fundamentally, from the mandate of Section 519(f) of the FDCA—is the draft guidance's conflation of retrospective and prospective product changes. Section 519(f) authorized FDA only to require notification when a manufacturer removed a product or made a change to an *existing* one that has already been distributed; it did not authorize FDA to require notification of *prospective* design changes to not-yet-distributed devices, even if the motivation for such changes was to reduce a risk to health. To the extent the draft guidance requires reporting of prospective changes to not-yet-distributed devices, it is quite simply *ultra vires* of the statute.

A rule that requires device makers to report prospective design changes could also result in duplicative reporting. Such duplication would be contrary to the FDA's earlier stated intent—in the context of Part 806 rulemaking—of minimizing manufacturers' reporting burden. In many, if not most, instances, a prospective design change will be undertaken in response to an identified risk connected to a device already in the field. In such cases, the manufacturer will already have been required to make a report to FDA, either under Part 803—if the risk has resulted in an adverse event or a malfunction—or under Part 806, if the manufacturer has implemented correction or removal procedures for the devices in the field. Moreover, these prospective device changes, depending on their significance, may trigger a new 510(k) submission under 21 CFR Part 807 or a Pre-Market Approval supplement under Part 814. Thus, the existing regulatory scheme already includes mechanisms for FDA to learn about prospective design changes that are undertaken in response to identified risks, and requiring reporting under Part 806 adds manufacturer burden with no apparent FDA benefit.

In some cases, a manufacturer may undertake a prospective design change to improve safety even when the manufacturer has not received reports of adverse events associated with its device. The draft guidance would appear to require the manufacturer to submit a notice of correction under such circumstances. For example, Manufacturer A learns through review of a competitor's Medical Device Reporting that user error resulted in a serious adverse event. Although Manufacturer A has received no similar adverse event reports, the manufacturer recognizes that its device could, if similarly misused, also result in injury. Manufacturer A therefore adds a new warning to its own products to *prevent* such injuries, and alerts its customers to the new warning. Did the manufacturer undertake these efforts to "reduce a risk to health"? Undoubtedly yes, as the impetus for the new warning was the manufacturer's desire to avert an adverse event similar to the one reported by its competitor. Was the risk to health "posed by the device"? From an 806 perspective, the answer should be no, since Manufacturer A's device had not been associated with an adverse event. Yet the draft guidance would require the manufacturer to report its change in labeling as a correction. Similarly, the draft guidance would require the reporting of similar injury-preventive changes such as "a manufacturing change to a sterile device to reduce the likelihood of contamination, or a design change to improve a product's safety profile." [Draft Guidance at 12].

The draft guidance therefore foreseeably could discourage manufacturers from making prospective changes to their devices in order to prevent injury, since they would need to report such

changes and thereby call into question the safety of the already-marketed versions of their devices. In addition to being legally unsupportable, such a result would be fundamentally at odds with the health care sector's current emphasis on continuous quality improvement as a means to constantly improve patient safety. Rather than creating a disincentive to proactive device manufacturer efforts to improve safety, FDA should embrace such efforts as fully consistent with the agency's own initiatives—such as the Medical Device Home Use Initiative—to prevent device-related adverse events.

Finally, there is reason to be skeptical of the draft guidance's assertion that a "product enhancement is not a recall." In fact, a subset of corrections and removals are, under current regulations, considered recalls. This overlap was specifically addressed in the Part 806 rulemaking. In that context, FDA was asked to "clarify the relationship between the reports of corrections and removal regulations and FDA's voluntary recall policy under Part 807." [FR at 27184]. In response, FDA noted that the definition of "risk to health" in Part 806 tracked the definition of class I and class II recalls under Part 7, and that "the effect of using the same language in part 806 is to require reports of corrections and removals for class I and II recalls." The preamble further stated that it is "appropriate and necessary, and in the interest of the public health, for FDA to review reports of corrections and removal to determine if any further remedial action such as a recall or safety alert is required. . .." It is therefore quite foreseeable that, in practice, a manufacturer's report of a "product enhancement" to FDA could, in the eyes of a district-level recall coordinator, be classified as a voluntary recall. In addition to the reputational and liability risks that result from the publicity surrounding product recalls, the recall process is simply ill-suited to device changes undertaken to improve product safety prospectively. Given the historical associations in the public mind between the term "recall" and dangerous products, treating product enhancements as recalls can be expected to cause significant public confusion and anxiety.

Finally, as a procedural matter, the draft guidance purports to significantly reinterpret and expand the scope of Part 806. Even if the new, expanded interpretation could be supported by the underlying statute—which it cannot, for the reasons discussed above—such a change may be accomplished only through notice and comment rulemaking. Indeed, according to FDA's own administrative regulations [21 CFR § 10.85(d)(1)], FDA's prior statement in the Federal Register that the term "enhancement" should not be defined in Part 806 has the status of an advisory opinion and, as such, may be amended or revoked only through additional notification in the Federal Register.

Certainly there is room for clarification of the existing correction, removal, and recall regulations, as the example above involving Manufacturer A's labeling changes illustrates. But the issuance of ill-conceived and legally insupportable guidance will not provide such clarity. Nor can it be expected to improve the safety of the medical devices that are critical to sustaining and supporting life and health.

Available online at
http://www.wlf.org/upload/legalstudies/legalbackgrounder/08-02-13Javitt_LB.pdf

  ISBN 1056 3059