Docket No. FDA-2013-D-0114

COMMENTS

of

THE WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

DRAFT GUIDANCE FOR INDUSTRY AND FDA STAFF: "DISTINGUISHING MEDICAL DEVICE RECALLS FROM PRODUCT ENHANCEMENTS AND ASSOCIATED REPORTING REQUIREMENTS"

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 78 *FED. REG.* 12329 (FEBRUARY 22, 2013)

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May 23, 2013

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Via Email
Division of Dockets Management (HFA-305)
Food and Drug Administration
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Re: Draft Guidance for Industry and FDA Staff:
Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements
78 Fed. Reg. 12329 (February 22, 2013)
Docket No. FDA-2013-D-0114

Dear Sir/Madam:

The Washington Legal Foundation (WLF) appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) Draft Guidance (cited above) regarding Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements.

The Federal Food, Drug, and Cosmetic Act (FDCA) directs medical device manufacturers, even after receiving marketing approval, to file numerous reports with the Food and Drug Administration (FDA) with respect to a wide variety of events affecting their products. Failure to file required reports can subject manufacturers to severe sanction. Manufacturers often have great difficulty in determining precisely when they are required to file reports. Accordingly, FDA is to be commended for issuing a document (the "Proposed Guidance") that attempts to provide additional guidance to manufacturers in determining when 21 C.F.R. Part 806 requires the reporting of device corrections or removals.

However, Part VI of the Proposed Guidance, entitled "Product Enhancement Reporting Requirements," effects a massive expansion of the Part 806 reporting requirements. FDA states that reporting requirements outlined in Part VI are merely a straightforward interpretation of the Part 806 regulations. That assertion is demonstrably incorrect. Part VI states that a "product enhancement" must be reported if it is "initiated to 'reduce a risk to health posed by the device.'" Proposed Guidance at 12 (quoting 21 C.F.R. § 806.10(a)(1)). It adds, "Some examples of change that FDA would consider reportable under 806 include the addition of a 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." *Id.* Indeed, under FDA's expansive definition of what is reportable under Part 806, virtually any change other than a cosmetic change is reportable – because manufacturers generally make changes for the sole purpose of improving the performance of their devices, and improved performance is closely correlated with reduced risks to health.

Part VI can only be understood as being based on a new, broader FDA definition of the phrase "to reduce a risk to health posed by the device," as used in 21 C.F.R. § 806.10(a)(1). When the Part 806 regulations were adopted in 1997, FDA made clear that reports would never be required unless a "recall" were determined to have occurred. Even then, a report would not necessarily be required. Rather, FDA explained, a report would be required only for Class I and Class II recalls (as defined by 21 C.F.R. Part 7); no report would be required if the "risk to health" posed by the recalled product was relatively slight – a Class III recall.

FDA now proposes to interpret § 806.10(a)(1) as requiring the submission of reports for a

vast number of product changes, even when the change does not constitute a recall. Because that interpretation is contrary to the interpretation espoused by FDA in 1997 and for many years thereafter, the APA prohibits FDA from adopting that interpretation by means of a guidance document. If FDA wishes to change its initial understanding of the meaning of § 806.10(a)(1), it may do so only by initiating formal notice-and-comment rulemaking proceedings designed to amend the regulation. Accordingly, WLF urges FDA to comply with the APA by withdrawing Part VI of the Proposed Guidance.

I. *Interests of WLF*

The Washington Legal Foundation is a public interest law and policy center with members and supporters in all 50 States. WLF regularly appears before federal and state courts and administrative agencies to promote economic liberty, free enterprise, and a limited and accountable government, and the proper use of our state and federal administrative systems. To that end, WLF has frequently appeared in judicial and administrative proceedings to ensure that administrative agencies adhere to the rule of law. *See, e.g., Shinseki v. Sanders*, 556 U.S. 396 (2009).

In particular, WLF focuses much of its work on the activities of the Food and Drug Administration. WLF has repeatedly criticized FDA for failing to comply with the Administrative Procedure Act (APA) when adopting new rules intended to have broad application. For example, litigation filed by WLF on behalf of patients and doctors forced FDA in 1994 to retract rules regarding the regulation of allograft heart valves, after FDA conceded that it had not complied with the APA's notice-and-comment procedures before adopting the

rules. *Washington Legal Found. v. Shalala*, No. 93-5279 (D.C. Cir. 1994). In a recent case in which WLF played an active role, a federal district court overturned an FDA product classification decision, in substantial part because FDA failed to abide by the APA before changing a long-time regulatory interpretation. *Prevor v. FDA*, 895 F. Supp. 2d 90 (D.D.C. 2012). Since 2006, WLF has operated its "OPDP Watch" project, which critiques warning letters and "untitled" letters issued by FDA's Office of Prescription Drug Promotion (formerly known as DDMAC). A recurring theme of WLF's critiques is that OPDP regularly announces new legislative rules by means of its warning letters, yet does so without abiding by the APA's notice-and-comment procedures.

WLF is concerned that the Proposed Guidance, by significantly expanding device manufacturers' reporting obligations, will impose costly burdens on those manufacturers and will ultimately interfere with the ability of patients to obtain access to the latest advances in medical technology.

II. *Historical Background*

Congress adopted the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. §§ 301 *et seq*., to regulate the sale and distribution of drugs and medical devices to the public. Even after a manufacturer has received FDA authorization to distribute a medical device, FDA is authorized to initiate action to remove the product from the market when necessary to protect public health and safety.

FDA has long recognized, however, that the public interest is often better served if an unsafe products can be quickly removed from the market based on a voluntary manufacturer

recall rather than by using FDA's product seizure authority. In 1978, FDA adopted its 21 C.F.R. Part 7 regulations to facilitate such voluntary recalls. As FDA has explained:

> Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibilities to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. This section and §§ 7.41 through 7.59 recognize the voluntary nature of recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. These sections also recognize that recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products.

21 C.F.R. § 7.40.

In the ensuing years, many potentially unsafe medical products were removed from the market by means of voluntary recalls. Congress became concerned, however, that the FDCA did not require manufacturers to let FDA know when they recalled a medical product, and that some manufacturers were not reporting such events to FDA. Accordingly, Congress adopted the Safe Medical Devices Act of 1990 (SMDA), Pub. L. 101-629, to impose a reporting requirement. The SMDA added a new Section 519 to the FDCA, codified at 21 U.S.C. § 360i.[1] Most relevant to this discussion is 21 U.S.C. §360i(g), which provides in pertinent part:

> (1) . . . the Secretary shall by regulation require a manufacturer or importer of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer or importer if the removal or correction was undertaken –

[1] *See* H.R. Rep. 101-808 (1990) (reporting favorably on SMDA) ("Some manufacturers do not report withdrawals and corrections of defective devices to the FDA in a timely fashion. This has seriously interfered with the FDA's ability to take prompt action against potentially dangerous devices. Under this section [later codified at 21 U.S.C. § 360i], all manufacturers importers, and distributors will have to report to the FDA any removal or correction undertaken to reduce risk to health posed by a device or to remedy a violation of the Act.").

> (A) to reduce a risk to health posed by the device, or
>
> (B) to remedy a violation of this chapter caused by the device which may present a risk to health.
>
> A manufacturer or importer of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

III. *FDA's Part 806 Regulations*

The Part 806 Regulations were FDA's response to the SMDA's mandate that the agency adopt reporting regulations. It is important to keep in mind that FDA's pre-existing Part 7 Regulations (governing recalls) served as a backdrop to both the SMDA and the Part 806 Regulations. Both the SMDA and the Part 806 Regulations drew heavily from the Part 7 Regulations, which define the terms "recall" and "correction" and create a three-tiered recall classification scheme – recalls in response to the most serious health concerns are designated as Class I and recalls in those situations least likely to cause adverse health consequences are designated as Class III. *See* 21 C.F.R. § 7.3(g), (h), and (m).

As adopted by FDA in 1997, the Part 806 Regulations provide:

> Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:
>
> (1) To reduce a risk to health posed by the device; or
>
> (2) To remedy a violation of the act caused by the device which may present a risk to health . . .

21 C.F.R. § 806.10(a).[2]

FDA's initial effort to draft the reporting regulations mandated by § 360i(g) was met by stiff industry resistance. Many commenters complained that the proposed regulation went far beyond anything Congress had intended and would require the reporting of many routine product changes that were not designed to address serious safety risks. In response, FDA's final regulations cut back considerably on the reporting requirements; it did so by adopting a more limited definition of what constitutes a "risk to health" for purposes of § 806.10(a)(1) & (2). In its preamble to the final regulation, FDA explained:

> One comment stated that the information manufacturers would be required to report [under the proposed regulations] is far in excess of that which FDA needs for a reporting program, especially in light of the many other controls and reporting programs already in effect that require companies to maintain records and/or make reports about the same type of information. Another comment stated that the criteria for submission of reports of corrections and removals are too subjective and may be difficult to apply in actual practice. *FDA agrees with these comments* and as noted above, has narrowed the definition of "risk to health." The final rule, as revised, applies basically the criteria for class I and class II recalls used successfully by FDA for more than 20 years under part 7.

62 Fed. Reg. 27183, 27188 (May 19, 1997) (emphasis added).

The agency's "narrowed" definition of "risk to health" is found at 21 C.F.R. § 806.2(j):

Risk to health means

(1) A reasonable probability that use of, or exposure to, the product will cause

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[2] For purposes of the Part 806 Regulations, a "removal" is defined as "the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection." 21 C.F.R. § 806.2(i). A "correction" ia defined as "the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." 21 C.F.R. § 806.2(d).

> 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.

As FDA noted in the preamble, this definition of "risk of health" largely parallels the definitions of a Class I recall and a Class II recall set forth in the Part 7 Regulations. *See* 21 C.F.R. § 7.3(m). Accordingly, the preamble to the final regulations clearly articulated FDA's contemporaneous interpretation of the § 806.10(a) reporting requirements: a product change was not reportable unless the change was designed to correct a "risk to health" that was sufficiently severe to warrant a recall. Moreover, not every situation in which a recall was warranted was to be reported; rather, a report to FDA was required if a Class I or Class II recall was warranted but not if only a Class III recall was warranted.[3] In sum, as FDA interpreted its own regulation, the reporting requirement did not kick in simply because a device manufacturer made a change for the purpose of making a safe product even safer; rather, FDA understood that a change was reportable only if the change was designed to alleviate a significant safety concern.

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[3] The preamble includes numerous other statements indicating that FDA narrowly interpreted § 806.10(a)'s "risk to health" language. *See, e.g.,* 62 Fed. Reg. at 27184 ("The definition of 'risk to health' in this rule (§ 806.2(j)) tracks the definitions of class I and class II recalls in § 7.3(m). The effect of using the same language in part 806 is to require reports of corrections and removals for class I and class II recalls. Under part 806, manufacturers, importers, and distributors must keep records of events categorized as class III recalls under part 7."); *id.* ("The definition of 'risk to health' has been narrowed by revising § 806.2(j) to focus explicitly on those corrections and removals undertaken to mitigate the potential for adverse health consequences. The revised definition of 'risk to health' tracks the definitions of class I and class II recall in § 7.3(m)."); *id*. at 27187 ("The practical effect of adopting this revised definition [of "risk to health"] is to require reports of removals and corrections for those corrective actions that would be classified as class I or class II recalls under § 7.3(m).").

IV. *FDA's New Interpretation of the Part 806 Regulations*

In its Proposed Guidance, FDA has adopted an entirely new interpretation of its Part 806 Regulations. The Proposed Guidance discusses "risk of health" without any reference to the "narrowed" regulatory definition of that term (set forth at § 806.2(j)) or to FDA's conscious decision to draw a close parallel between that definition and Part 7's definition of Class I and Class II recalls. Instead, the Proposed Guidance states without relevant qualification, "[A]s long as your change is initiated to reduce a risk to health posed by your device, even if your change is not a recall, you must submit an 806 report . . ." Proposed Guidance at 12. The Proposed Guidance's extremely broad understanding of "risk to health" is evidenced by the examples it provides of reportable changes: "the addition of a 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." *Id.* In none of those examples does FDA indicate that the pre-change device posed a significant safety concern; under each of the three examples listed in the Proposed Guidance, a change motivated by a desire to make a product safer than it was before is deemed sufficient to render the change reportable.

For purposes of these comments only, WLF is willing to concede that the Proposed Guidance's interpretation of the Part 806 Regulations is plausible. FDA is correct, for example, that the regulations never state explicitly that a report is not required if the situation giving rise to the product change does not warrant a recall. But the plausibility of FDA's interpretation is not, in WLF's mind, the key issue. Rather, the key issue is that FDA's current interpretation of the § 806.10(a) reporting requirements (as evidenced by the Proposed Guidance) is in direct

conflict with the interpretation it espoused when it adopted those requirements in 1997. And it is proposing to put that new interpretation into effect without undertaking formal notice-and-comment rulemaking pursuant to the APA.

V. *FDA Must Utilize Formal Rulemaking Proceedings Before It May Adopt a Regulatory Interpretation that Effectively Amends the Regulation*

The Administrative Procedure Act requires that any such new agency position may be adopted only pursuant to the APA's formal notice-and-comment procedures. 5 U.S.C. § 553(b) & (c). A rule is legislative (and thus subject to notice-and-comment procedures) if the rule "effectively amends a prior legislative rule." *Am. Mining Cong. v. Mine Safety & Health Admin*, 995 F.2d 1106, 1112 (D.C. Cir. 1993). As the D.C. Circuit has explained, unless an agency action that modifies its prior interpretation of a formal regulation is subject to notice-and comment rulemaking requirements, "the agency could evade its notice and comment obligation by 'modifying' a substantive rule that was promulgated by notice and comment rulemaking." *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94-95 (D.C. Cir. 1997) (quoting *Paralyzed Veterans of America v. D.C. Arena, L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997)).

The Proposed Guidance effectively amends the Part 806 Regulations. As demonstrated above, FDA's preamble to those regulations makes clear the agency's understanding in 1997 that a device modification that does not qualify as a recall can never be reportable under the regulations because the "risk to health" being reduced thereby is insufficient to meet the narrow regulatory definition set forth in 21 C.F.R. § 806.2(j). The Proposed Guidance makes clear that FDA has adopted a new, more expansive definition of "risk to health": it now contends that a

report is required *any* time a device modification is initiated for the purpose of reducing the device's risk to health – without regard to the amount of that reduction and without regard to whether the pre-modification device posed any significant risk to health. Accordingly, the APA prohibits FDA from adopting the Proposed Guidance without first utilizing formal notice-and-comment procedures.

Indeed, under FDA's expansive definition of what is reportable under Part 806, virtually any change other than a cosmetic change is reportable – because manufacturers generally make changes for the sole purpose of improving the performance of their devices, and improved performance is closely correlated with reduced risks to health. Such mass reporting is likely to provide FDA with far more data than it could possibly analyze, and would run counter to Congress's expressed intent that reporting requirements not be "unduly burdensome to a device manufacturer." 21 U.S.C. § 360(a)(4). In 1997, FDA intentionally narrowed the scope of its reporting regulation because it "recognize[d] that Congress did not want to overburden industry or FDA with excessive reporting requirements and that the reporting requirements apply to the more important postmarket actions." 62 Fed. Reg. at 27183-84. If FDA is now intent on abandoning its prior understanding, at the very least it ought to expose its views to the rigors of formal notice-and-comment rulemaking before doing so.

CONCLUSION

WLF urges FDA to comply with the APA by withdrawing Part VI of the Proposed Guidance.

Sincerely,

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/s/ Cory L. Andrews
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