Docket No. FDA-2013-D-0743

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DRAFT GUIDANCE FOR INDUSTRY AND FDA STAFF: "MEDICAL DEVICE REPORTING FOR MANUFACTURERS"

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 78 *FED. REG.* 41069 (JULY 9, 2013)

Richard A. Samp
Cory L. Andrews
Washington Legal Foundation
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302

October 11, 2013

WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, NW
Washington, DC 20036
202-588-0302

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry and FDA Staff:
Medical Device Reporting for Manufacturers
78 Fed. Reg. 41069 (July 9, 2013)
Docket No. FDA-2013-D-0743

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(WLF) appreciates this opportunity to submit comments in response to the Food and Drug Administration's (FDA) Draft Guidance (cited above) regarding Medical Device Reporting for Manufacturers.

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 803 requires the reporting of deaths and serious injuries that a may have caused or contributed to.

However, while we applaud FDA for providing manufacturers with much-needed

guidance, we are concerned that the Proposed Guidance in several instance has imposed new reporting requirements that are neither warranted by safety concerns nor authorized by existing statutes and regulations. A major concern among health care professionals is that so many medical device reports (MDRs) are required to be filed that the significance of the underlying events cannot be properly analyzed. WLF is concerned that the Proposed Guidance does nothing to address that concern and, indeed, exacerbates the problem in several respects. At the very least, before FDA imposes new reporting requirements, it ought to provide a reasoned explanation regarding why it believes those requirements serve the public interest.

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. WLF raised similar concerns with respect to a February 2013 FDA draft guidance. *See* "Distinguishing Medical Device Recalls from Product Enhancements; Reporting Require-ments," 78 Fed. Reg. 12329 (Feb. 22, 2013) (WLF comments filed on May 23, 2013).

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. Congress recognized that even after a manufacturer has received FDA authorization to distribute a medical device, public safety requires that FDA be in a position to monitor the sale and

distribution of the device. Accordingly, the FDCA requires that "[e]very person who is a manufacturer or importer of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary [of HHS] may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness." FDCA Sec. 519(a), 21 U.S.C. § 360i(a). The FDCA further provides that FDA's regulations shall require a device manufacturer to file a report whenever it becomes aware of information suggesting that one of its marketed products "may have contributed to a death or serious injury," or "has malfunctioned and [the] device . . . would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 U.S.C. § 360i(a)(1)(A) & (B).

FDA has issued regulations implementing the FDCA's medical device reporting requirements. *See* 21 C.F.R. § 803.1 *et seq.* FDA has also issued several guidance documents regarding those requirements. The latest Proposed Guidance would replace a guidance document issued in 1997.

III. *Duplicate Report Filing*

All can agree with Congress's assessment that when a medical device has caused or contributed to a death or serious injury, it is important that information regarding the incident be reported to FDA so that it can determine what, if any, corrective measures need to be taken. But in light of significant concerns that the costs and handling of the medical device reporting are becoming unmanageable, it is also important that FDA keep those concerns in mind when adopting new reporting requirements. For example, it makes little sense to impose

administrative burdens on one device company when it is highly likely that the result of those burdens will be the filing of reports that largely duplicate reports filed by others.

The Proposed Guidance creates the danger of costly and wasteful duplicate reporting. That danger is best illustrated by the Proposed Guidance's treatment of companies that manufacture a device under contract with the companies that initiated the specifications and distribute the device. In virtually all such instances, the parties contractually agree that the specification developer will assume all FDA reporting responsibilities, primarily because it is much better positioned to gather the necessary information. The Proposed Guidance states, however, that both companies must maintain the required records and file MDRs when reportable events occur, regardless of any contractual agreement between the companies. Proposed Guidance § 2.17. It states that the two firms may file a formal request with FDA that one of the two firms be exempted from filing, but it sets forth no criteria for determining when an exemption will be granted, and it adds that approval is likely to be conditioned "on agreement by the firm requesting the exemption from reporting to be responsible for ensuring that the required reports are, in fact, submitted to FDA." *Id.*

WLF is concerned that this provision is likely to lead to costly, duplicate effort by the two firms involved. We recommend that detailed criteria for evaluating exemption requests be provided; they should make clear that an exemption will almost always be granted so long as the specification provider makes a reasonable showing that it will carry out its reporting obligations. In the absence of any criteria for obtaining exemptions, there is too great a danger that FDA personnel will arbitrarily deny exemption requests based on a personal preference for duplicate

reporting. Moreover, the requirement that the party seeking the exemption "be responsible for ensuring that the required reports are, in fact, submitted to FDA" should be eliminated. That requirement largely nullifies the cost-saving objectives of an exemption, because firms that have obtained an exemption will nonetheless be required to maintain extensive record-keeping to ensure that the other company is fulfilling its reporting requirements. At the very least, § 2.17 ought to be amended to provide that the exempted firm's obligations should be limited to ensuring reports be filed with FDA for reportable events *of which it is aware*.

Finally, § 2.17 provides, "If Firm A is designated to submit the MDR reports, but failed to do so, we would consider such a failure to report to be sufficient grounds to revoke Firm B's exemption from reporting." That provision has little to recommend itself and almost surely will lead to unnecessary, duplicate reporting. Very often, an FDA determination that a company failed to submit a required MDR involves a good-faith disagreement between the company and FDA staff regarding whether the facts of the case met the FDCA's reporting requirements. Under such circumstances, there is no reason for FDA to conclude that the company cannot be trusted to file future reports when required, and thus that it should turn to Firm B to supply the reports. This provision ought to be amended to include the caveat, "but failed to do so for reasons other than a good-faith disagreement with FDA that a report was required under 21 U.S.C. § 360i(a)(1) . . ."

IV. *Continued Failure to Abide by the FDAAA*

FDA's penchant for the filing of unnecessary and duplicate MDRs is perhaps best illustrated by its continued failure to implement the terms of the Food and Drug Administration

Amendments Act of 2007 (FDAAA), which sought to ease the reporting burden on manufacturers.

The FDAAA amended Sec. 519 of the FDCA to eliminate the regular reporting requirements for most Class I and Class II devices. Instead, Congress provided that reportable events for such devices shall "be in summary form and made on a quarterly basis." 21 U.S.C. § 360i(a)(1)(B)(ii). Congress authorized FDA to create a limited exception to this statutory mandate for any Class I and Class II device which FDA has indicated "by notice published in the Federal Register . . .should be subject to" the full Part 803 reporting requirements "in order to protect the public health." § 360i(a)(1)(B)(i)(III).

In the six years since the adoption of the FDAAA, FDA has done nothing to implement the Act's mandate that the reporting burden for Class I and II device manufacturers be lessened. Rather, in 2011 FDA published a Federal Register notice stating its view that the full reporting requirements continue to apply to *all* Class I and II devices because, until regulations implementing the "summary form" reporting mandate of § 360i(a)(1)(B)(ii) could be adopted, "the interest of public health" dictated that full reporting be continued for *all* devices. *See* "Notice: Medical Device Reporting; Malfunction Reporting Frequency," 76 Fed. Reg. 12743, 12744 (Mar. 8, 2011). Indeed, FDA has provided no public indication that it has developed any timetable for establishing the reporting "criteria" that it is required to establish by § 360i(a)(1)(B)(ii).[1]

[1] In an apparent effort to excuse the agency's tardiness, the 2011 Federal Register notice indicated that FDA intended to adopt the § 360i(a)(1)(B)(ii) criteria by means of formal

Moreover, FDA sought to justify its failure to implement the statutory mandate by mere *ipse dixit*. It failed to provide any rationale for circumventing Congress's intent other than to state, without explanation, that continuing to require full reporting for even the simplest of Class I medical devices was "in the interest of public health." *Id.*

The Proposed Guidance states that FDA will continue indefinitely its policy of failing to implement § 360i(a)(1)(B)(ii). *See* Proposed Guidance § 2.1 ("pending further FDA notice, these [Class I and Class II] devices currently remain subject to 21 CFR Part 803 in order to protect the public health."). That policy is consistent with FDA's apparent desire to expand reporting requirements, yet it cannot be squared with Congress's mandate that FDA adopt streamlined procedures. FDA cannot seriously believe that its six-year delay in implementing the FDAAA complies with the statutory mandate. *See, e.g.*, § 360i(a)(1)(B)(i)(III) (limiting continued application of the Part 803 reporting requirements to "*a type* of device" for which protection of "the public health" requires continued application of the full reporting requirements, thereby indicating that Congress did not authorize FDA to apply this exception across-the-board to all devices) (emphasis added). WLF respectfully suggests that FDA's top priority in updating its guidance on MDRs ought to be to ensure that it comes into compliance with its statutory mandate to reduce overly burdensome reporting obligations rather than to attempt to attain an extra ounce of safety by imposing duplicate filing requirements.

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rulemaking, a more cumbersome and time-consuming process. *See* 76 Fed. Reg. at 12744. FDA cannot justifiably rely on that excuse, because nothing in § 360i(a)(1)(B)(ii) suggests that Congress required that the mandated "criteria" be adopted through formal rulemaking. FDA is entitled to act expeditiously by, for example, issuing a draft guidance.

V. *Requiring Reports Without a "Likelihood" Showing*

The FDCA requires that an MDR be filed when a device has malfunctioned even if the malfunction did not contribute to a death or serious injury, if a repeat of the malfunction "would be likely to cause or contribute to a death or serious injury." 21 U.S.C. § 360i(a)(1)(B). *See also* 21 C.F.R. § 803.3 (defining an "MDR reportable event" as including, *inter alia*, an event that reasonable suggests to a manufacturer that one its devices has "malfunctioned" and that a recurrence "would be likely to cause or contribute to a death or serious injury.") The Draft Guidance is inconsistent with those statutory and regulatory provisions. It states that a malfunction is reportable if "[t]he chance of a death or serious injury occurring as a result of a recurrence of a malfunction is *not remote*." Draft Guidance § 2.14. A chance that is "likely" is a far cry from a chance that is "not remote." FDA should revise § 2.14 of the Draft Guidance to bring it into compliance with its statutory and regulatory mandate.

Under ordinary understandings of the word "likely," stating that the chance of death or serious injury is "likely" means, at the very least, that the chance of death or serious injury resulting from a repeat malfunction is at least 50.1% (*i.e.*, more likely to occur than not to occur). *See, e.g., Webster's New Collegiate Dictionary* (G. & C. Merriam Co. 1981) (defining "likely" as meaning "having a high probability of being true: very probable"). In sharp contrast, the term used by the Draft Guidance, "not remote," suggests a plausible but not necessarily probable outcome, *e.g.*, at least a 5% chance of occurring.

FDA's latest interpretation of the word "likely," as used in § 360i(a)(1)(B), is thus inconsistent with both the statute and FDA's implementing regulations. If FDA now believes

that malfunctions ought to be reported whenever their recurrence could have a "not remote" chance of contributing to death or serious injury, then it ought to go to Congress and seek a change in the statute, not seek to make a unilateral change in Congress's mandate. Moreover, even if (contrary to fact) the word "likely" could plausibly be interpreted to be synonymous with "not remote," FDA is still faced with the inconvenient fact that its own regulation repeats the word "likely" rather than adopting FDA's current preferred interpretation of the statutory language. *See* 21 C.F.R. § 803.3 (defining "MDR reportable event"). If FDA seeks to adopt a new interpretation of a statutory term that is defined in its own regulations, the Administrative Procedure Act requires at the very least that FDA employ notice-and-comment rulemaking before adopting the new definition. *See e.g., Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94-95 (D.C. Cir. 1997).[2]

Finally, FDA has, without explanation, altered its understanding regarding the likelihood that a malfunction will contribute to a death or serious injury if it has done so in the past. Under its 1997 guidance, FDA *presumed* that under those circumstances, recurrence of the malfunction would "likely" lead to death or serious injury, and that presumption continued "until the malfunction has caused or contributed to no further deaths or serious injuries for two years."

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[2] In attempting to justify its "not remote" interpretation of the statutory language, the Proposed Guidance points to language in the preamble to the 1995 proposed version of the Part 803 regulations. Proposed Guidance § 2.14, at 11. But that citation does not explain the failure to provide similar language in the regulation itself, or to repeat that language in the 2005 version of the Part 803 regulations. Indeed, the Supreme Court has expressed extreme skepticism about looking to the preambles of FDA regulations as the basis for an authoritative agency interpretation of the FDCA. *See, Wyeth v. Levine*, 555 U.S. 555, 577 (2009).

The Proposed Guidance does away with the two-year limitation on the presumption but provides no explanation for doing so. The failure to provide an explanation is particularly problematic because FDA cannot seriously contest that the prolonged absence of death or serious injuries resulting from a particular malfunction is a significant indication that future malfunctions are not likely to lead to death or serious injury. It may be that FDA has other criteria in mind that better capture the likelihood of recurrence. But if so, FDA should say so explicitly, so that manufacturers will be able to cite those criteria in seeking an exemption from future reporting of the same malfunction, rather than being left to the unreviewable discretion of FDA reviewers who have no criteria upon which to base the grant or denial of an exemption, other than their own sense of the "precautionary principle." WLF requests that FDA revise § 2.14 in order to adopt a definition of "likely" that is consistent with the discussion above and with the language of 21 U.S.C. § 360i(a)(1)(B).

CONCLUSION

WLF urges FDA to comply with the FDCA and the APA by revising the Proposed Guidance as outlined above.

Sincerely,

/s/ Richard A. Samp
Richard A. Samp
Chief Counsel

/s/ Cory L. Andrews
Cory L. Andrews
Senior Litigation Counsel