News Release

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FOR IMMEDIATE RELEASE May 24, 2013

FDA Urged To Withdraw Draft Guidance Regarding Product Change Reporting

The Washington Legal Foundation (WLF) yesterday urged the Food and Drug Administration (FDA) to withdraw a Draft Guidance it issued in February regarding medical device manufacturers' responsibilities to file reports with FDA when they make safety-related changes to their products.

In formal comments filed with FDA, WLF argued that the Draft Guidance conflicts with formal regulations issued by FDA in 1997, which made clear that the FDA reporting requirements kick in if and only if the prior version of the medical device raised serious safety issues and was thereby subject to recall. The Draft Guidance would dramatically expand the reporting requirements, by requiring a manufacturer to report *all* product enhancements that are initiated to reduce a risk to health posed by the device – even if the prior version of the device was perfectly safe. WLF charged that the Administrative Procedure Act (APA) bars federal agencies from (as here) attempting to amend an existing formal regulation without going through the APA's formal notice-and-comment procedures.

"As the size of the administrative state grows, it is important that citizens continue to have a meaningful opportunity to participate in the operation of their government," said WLF Chief Counsel Richard Samp after filing WLF's comments. "The APA is an important part of that effort. It ensures that agencies will be bound not only by congressional laws but also by their own internal rules. FDA needs to cease its practice of ignoring APA requirements," Samp said.

If a medical device is approved for marketing by FDA and is later found to raise serious safety concerns, the manufacturer will often "recall" the device and replace it with an updated version that addresses the safety concerns. In 1990, Congress concluded that some manufacturers were not informing FDA of their product recalls, thereby depriving FDA of the opportunity to investigate health and safety issues related to the recall. Accordingly, Congress amended the Federal Food, Drug, and Cosmetic Act (FDCA) in 1990 to require that recalls be reported to FDA. The FDA regulations issued in 1997 to implement the new law – the "Part 806 Regulations" – made clear that the reporting requirement applied only to recalls, and even exempted some recalls that did not raise serious safety concerns.

The Draft Guidance proposes to reinterpret the Part 806 Regulations such that manufacturers would be required to report many more device modifications to FDA. Under the reinterpretation, a report would be required whenever a device modification was initiated to reduce a risk to health, without regard to whether the previous version of the device posed a significant safety concern.

WLF's comments noted that under FDA's expansive definition of what is reportable under the Part 806 Regulations, 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," WLF charged.

WLF also argued that FDA is seeking to adopt the Draft Guidance in violation of the APA. It is uncontested that FDA has not complied with the APA's formal notice-and-comment procedures. FDA apparently takes the view that those procedures are inapplicable. WLF argued that those procedures are applicable when, as here, an agency seeks to modify its previous interpretation of existing formal regulations. Courts have subjected an agency's changed interpretation of an existing regulation to the APA's requirements, reasoning that otherwise an agency could avoid the need ever to write new regulations by simply announcing the reinterpretation of existing regulations.

WLF is a public interest law and policy center with supporters in all 50 states. Among WLF's members are doctors and patients who desire to advance health care by ensuring that innovative and safe medical products – as well as routine enhancement of those products – reach the market without undue delays. WLF regularly litigates in support of patients who seek expedited access to life-saving medical products.

For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.