News Release

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FOR IMMEDIATE RELEASE **January 20, 2012**

COURT URGED TO OVERTURN FDA EFFORTS TO MODIFY DRUG/DEVICE CLASSIFICATIONS (*Prevor v. FDA*)

The Washington Legal Foundation (WLF) yesterday urged the U.S. District Court for the District of Columbia to prevent the Food and Administration (FDA) from adopting new product classification rules that could cause numerous medical products previously classified as devices to be reclassified as drugs.

In a brief filed in *Prevor v. FDA*, WLF argued that the new classification rules conflict with the federal statute that defines what constitutes a "device." WLF also argued that the new rules violates the Administrative Procedure Act (APA), because all major changes in FDA policy may only be undertaken pursuant to the APA's formal notice-and-comment rulemaking procedures. The case is a challenge to FDA's decision to regulate Diphoterine® Skin Wash ("DSW"), a product manufactured by Prevor, as a drug – even though similar products have previously been regulated as medical devices.

"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 brief. "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.

The dividing line between a "device" and a "drug" can sometimes be difficult to discern. In general, manufacturers would prefer to have their products classified as "devices," a classification that often makes it easier for the manufacturer to obtain marketing clearance from FDA. Under federal law, the principal distinguishing feature between a "device" and a "drug" is set forth in 21 U.S.C. § 321(h)(3); a medical product qualifies as a device only if it "does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and . . . is not dependent on being metabolized for the achievement of its primary intended purposes." 21 U.S.C. § 321(h)(3). If it *does* achieve its "primary intended purposes" through chemical action, then it is classified as a drug.

Classification difficulties arise when a product has multiple intended purposes, some of which involve chemical action and others of which do not. For the past 30 years, FDA's general understanding has been that a product will be classified as a device, even if one of its clinical effects involves a chemical action, if the predominant intended purposes of the product do not involve a

chemical action. For example, if the non-chemical effect provides a clinical benefit for virtually all intended users while the chemical effect provides a clinical benefit for only a small percentage of users, FDA has classified the product as a device.

FDA recently substantially altered the classification rules. It did so in connection with its decision in this case and also through a draft Guidance Document issued in June 2011. The new rule provides that *any* intended clinical benefit of a product should be deemed a "primary intended purpose" within the meaning of 21 U.S.C. § 321(h)(3). Thus, according FDA, a product should be classified as a "drug" if *any* of its clinical effects (no matter how minor) involves a chemical action. As a result, many medical devices may now have to be reclassified as drugs.

In its brief filed with the district court, WLF argued that the new rule conflicts with the clear language of § 321(h)(3). Congress's inclusion of the word "primary" in the phrase "primary intended purposes" indicates that Congress contemplated that some minor "intended purposes" would not be included within the phrase, WLF asserted. But, WLF argued, FDA's new interpretation would – contrary to Congress's intent – eliminate the possibility that an "intended purpose" for a product could ever qualify as a "non-primary" intended purpose.

WLF also argued that, even if the new rule could qualify as a reasonable interpretation of § 321(h)(3), it would still be invalid because FDA issued it without complying with the APA's formal notice-and-comment procedures. WLF argued that compliance with the APA is required whenever, as here, an agency is not merely providing an interpretation of statutes and existing regulations but rather is adopting a brand new policy that conflicts with previous agency policy.

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 reach the market without undue delays. WLF regularly litigates in support of patients who seek expedited access to life-saving medical products.

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