Press Release

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WLF Seeks to Overturn "Do Over" FDA Ruling

(Prevor v. Food and Drug Administration)

"FDA needs to stop making up the law as it goes. When it decides to reverse a previous policy, it is required to provide a reasoned explanation. If it dislikes a law as written, it must ask Congress to amend the law, not just ignore it."
—Richard Samp, WLF Chief Counsel

WASHINGTON, DC—The Washington Legal Foundation (WLF) this week urged the U.S. District Court for the District of Columbia to prevent the Food and Drug Administration (FDA) from adopting new product classification rules that would reclassify numerous medical products as drugs that were previously treated as devices. FDA wants to expand the definition of "drug" in order to increase the number of products subject to the more rigorous pre-market product testing requirements applicable to drugs.

In a brief filed in *Prevor v. FDA*, WLF argues that the new classification rules conflict with the federal statute that defines what constitutes a "device" and that FDA again has acted arbitrarily and capriciously. The case challenges FDA's decision to regulate Diphoterine® Skin Wash ("DSW") as a drug—even though similar products were previously regulated as medical devices.

We have been down this road before. Applying an expanded definition, FDA ruled in 2009 that DSW was a drug. The district court held in 2012 that FDA's new classification was arbitrary and capricious, and it ordered FDA to reconsider and to explain its decision fully. FDA then adopted a different new standard for differentiating drugs and devices that once again classified DSW as a drug. WLF's brief argues that FDA continues to ignore its statutory mandate.

Federal law provides that 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." If a product *does* achieve its "primary intended purposes" that way, then it is a drug. DSW, which is applied to the skin to prevent chemical burns, accomplishes one intended purpose through a chemical action; at issue is whether that intended purpose constitutes a "primary" one.

After filing its brief, WLF issued the following statement by Chief Counsel Richard Samp: "FDA needs to stop making up the law as it goes. When it decides to reverse a previous policy, it is required to provide a reasoned explanation. If it dislikes a law as written, it must ask Congress to amend the law, not simply ignore it. Under federal law, FDA only has 60 days to classify a medical product; it has now delayed this case nearly five years, for a valuable product that is already widely available in other countries, yet it still has not issued a valid decision."

WLF is a public interest law firm and policy center that regularly litigates in support of patients who seek access to life-saving medical products denied them by regulatory red tape.

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