Litigation Update

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302

September 26, 2012

COURT OVERTURNS FDA EFFORTS TO MODIFY DRUG/DEVICE CLASSIFICATIONS

(*Prevor v. FDA*)

The U.S. District Court for the District of Columbia yesterday issued a decision that effectively prevents the Food and Administration (FDA) from implementing new product classification rules that could cause numerous medical products previously classified as devices to be reclassified as drugs.

The decision in *Prevor v. FDA* was a victory for the Washington Legal Foundation (WLF), which filed a brief urging the court to block FDA efforts to classify a new product as a "drug," apparently on the basis of FDA's new classification rules. WLF argued that the new rules conflict with the federal statute that defines what constitutes a "device." The court agreed with WLF that the decision to classify the product as a "drug" was "arbitrary and capricious," and it remanded the case back to the agency. In light of its decision, the court did not need to reach an additional argument raised by WLF: that the new rules violate 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 was 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. The court rejected FDA's efforts to distinguish the products cited by Prevor that have been classified as 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 in response to the court's decision. "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. The district court largely agreed; it held that FDA's classification of DSW as a "drug" was arbitrary and capricious in the absence of a reasoned explanation of why it thought that DSW "primary intended purpose" was to be achieved through chemical action, even though the administrative record indicated that DSW's chemical action was relevant to an intended product purpose that was only secondary in nature.

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.

* * *

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.