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DC District Court Overturns “Do Over” FDA Ruling, Per WLF’s Request

(Prevor v. Food and Drug Administration)

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WASHINGTON, DC—The U.S. District Court for the District of Columbia issued a ruling this week that prevents the Food and Drug Administration (FDA) from adopting new product classification rules that could reclassify as drugs numerous medical products previously classified as medical devices. FDA has been attempting to expand the definition of “drug” in order to subject more products to the more rigorous pre-market product testing requirements applicable to drugs.

The decision was a victory for Washington Legal Foundation (WLF), which filed a brief urging the court to overturn FDA’s decision to regulate Diphoterine® Skin Wash (“DSW”) as a drug—even though similar products have previously been regulated as medical devices. The court agreed with WLF that FDA “acted arbitrarily and capriciously” and misinterpreted statutes defining “drugs” and “devices.” It remanded the case to FDA for a classification decision under the proper standard.

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 it *does* achieve its “primary intended purposes” through chemical action, then it is classified as a drug. DSW, a product applied to the skin, achieves most of its “primary intended purpose”—prevention of chemical burns—by means of physical action, not chemical action. Rejecting FDA’s argument that a product is a “drug” if chemical action plays *any* “meaningful” role in preventing burns, the court held that use of the word “achieve” indicates that a product is not a drug unless the product’s “chemical action” is significant.

We have been down this road before. Applying a different expanded definition, FDA ruled in 2009 that DSW was a drug. The district court held in 2012 that FDA’s classification then was arbitrary and capricious, and it ordered FDA to reconsider and explain its decision fully. This week’s decision struck down FDA’s second attempt at a standard; the court held that FDA’s interpretation was not entitled to deference because it conflicted with earlier agency interpretations.

In response to the decision, WLF issued the following statement by Chief Counsel Richard Samp: “FDA has once again been called to account for making up the law as it goes along. When the agency decides to reverse previous policy, it is required to provide a reasoned explanation. And if it is unhappy with the law as written, it needs to ask Congress to amend the law, not simply ignore it to reach a predetermined result. The law gives FDA 60 days to classify a product; it has now delayed nearly 1800 days—almost five full years—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 expedited access to life-saving medical products denied them by regulatory red tape.