Press Release

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WLF Asks FDA to Revise Draft Regulations on Classifying Products as Drugs or Devices

(In re FDA Product Jurisdiction Rule)

"Medical-product manufacturers face far greater regulatory burdens if their products are classified as 'drugs' instead of 'devices.' Consumers pay for those burdens through higher prices and availability delays. But FDA's proposed regulations improperly skew classification decisions toward a 'drug' classification."
—Richard A. Samp, WLF Chief Counsel

WASHINGTON, DC—On July 16, 2018, urged the Food and Drug Administration (FDA) to revise its proposed regulations governing how it classifies a medical product (*e.g.,* a drug, a medical device, or a biological product) when a manufacturer seeks FDA marketing approval. In formal **comments** filed with FDA, WLF argues that the proposed regulations are inconsistent with FDA's statutory mandate (under the Food, Drug, and Cosmetic Act (FDCA)) and improperly skew decision-making in favor of a drug classification.

It can often be difficult to differentiate a "drug" from a "medical device"; federal law defines those two categories of medical products quite similarly. The principal distinction focuses on whether the product "achieve[s] its primary intended purposes through chemical action." If so, the product is a drug; if not, the product usually is classified as a device. Disputes frequently arise between FDA and manufacturers regarding the meaning of the terms "achieve" and "primary intended purposes." FDA, which generally prefers that products be classified as drugs (thereby subjecting them to more onerous product-approval requirements), has repeatedly sought to expand the definition of "primary intended purposes" and contract the definition of "achieve." Several recent federal court decisions have rejected FDA's proposed definitions of those terms.

In May, FDA issued proposed revisions to its product-classification regulations. WLF's comments criticize the proposed regulations for failing to address the meaning of key statutory terms in the FDCA. Indeed, WLF comments argue, the proposed regulations suggest that FDA does not intend to abide by the recent federal-court decisions interpreting those statutory terms. WLF urges FDA to amend its proposed regulations to provide manufacturers with badly needed guidance regarding the product-classification process and to bring its regulations into compliance with the FDCA. WLF also faults FDA for failing to heed several recent FDCA amendments, in which Congress directed FDA not to skew the classification process too heavily towards "drug" classifications.

Celebrating its 41st year, WLF is America's premier public-interest law firm and policy center advocating for free-market principles, limited government, individual liberty, and the rule of law.

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