Press Release

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WLF Faults FDA for Seeking to Expand Onerous Drug Approval Process to Food Studies

(In re: FDA Expansion of IND Requirements)

"Congress has not granted FDA authority to exercise jurisdiction over food research. FDA's expansionist efforts to extend its oversight of human research studies could have a paralyzing effect on clinical research, while stifling innovation and product development."—Richard Samp, WLF Chief Counsel

WASHINGTON, DC—The Washington Legal Foundation (WLF) has called on the Food and Drug Administration to rescind a recently released guidance document that asserts agency approval rights over virtually all human research studies performed in the United States. In formal comments filed this week, WLF told FDA that it lacks statutory authority to require that researchers obtain FDA approval of an IND (investigational new drug) application before undertaking a food study. WLF argued FDA's IND authority extends only to clinical research involving "investigational drugs," not generally to food, dietary supplements, and cosmetics.

FDA issued a final Guidance document last September, asserting for the first time that the Food, Drug, and Cosmetic Act (FDCA) requires researchers to obtain an IND from FDA for many human research studies into the health effects of food, dietary supplements, and cosmetics. The Guidance was issued in final form without first providing interested stakeholders an opportunity to comment on the agency's expanded jurisdictional claim. The Guidance created such consternation within the regulated community that FDA agreed to accept comments for 90 days.

WLF's comments noted that the FDCA explicitly exempts food from its definition of a "drug." WLF argued that unless the clinical study is conducted to support a later FDA application to market the food as a drug, it is not subject to IND authority. WLF stated that preparing an IND can be quite costly. So, subjecting clinical food studies to IND requirements could render them prohibitively expensive. WLF argued that expanding IND could particularly devastate research into "medical foods"—foods formulated to meet the needs of individuals with diseases, such as diabetes, that require them to control their diets. WLF also faulted FDA for adopting the Guidance in violation of the Administrative Procedure Act's notice-and-comment requirements.

After filing its comments, WLF issued the following statement by Chief Counsel Richard Samp: "Congress has not granted FDA authority to exercise jurisdiction over food research. FDA's expansionist efforts to extend its oversight of human research studies could have a paralyzing effect on clinical research, while stifling innovation and product development. It is particularly disturbing that FDA acted here without bothering to comply with the mandatory procedural rules applicable to all federal agencies."

WLF is a public interest law firm and policy center that frequently appears in administrative and judicial proceedings to ensure that administrative agencies adhere to the rule of law.

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