News Release

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COURT URGED TO REBUFF FDA EFFORTS TO CRIMINALIZE DRUG COMPOUNDING

(***United States v. Franck's Lab, Inc.***)

The Washington Legal Foundation (WLF) this week urged the U.S. Court of Appeals for the Eleventh Circuit in Atlanta to prevent the Food and Administration (FDA) from adopting new rules that would, in effect, criminalize the activities of a significant percentage of pharmacies in this country.

In a brief filed in *United States v. Franck's Lab, Inc.*, WLF argued that the "compounding" of drugs by pharmacists has long been regulated by the States, not the federal government, and that Congress never intended to authorize FDA to prohibit compounding. WLF further argued that even if FDA were so authorized, it may not implement its new anti-compounding rules without first complying with notice-and-comment rulemaking requirements.

"We recognize that there is a danger that some pharmacists may attempt to engage in the large-scale manufacture of new drugs, under the guise of compounding. FDA clearly has authority to prevent such activity," WLF Chief Counsel Richard Samp said after filing WLF's brief. "But FDA is now taking the extreme position that *all* compounding of animal drugs violates federal laws that bar distribution of a 'new drug' until after FDA has certified the drug as safe and effective. Because it is not feasible to obtain FDA approval for every drug compounded by a pharmacist for an individual patient, FDA's position in effect outlaws all compounding. Congress could not have intended that result," Samp said.

"Compounding" entails mixing together pharmaceutical ingredients to create a medication tailored to the needs of an individual human or animal patient. As the Supreme Court recently recognized, it is a traditional component of the practice of pharmacy and is taught as part of the standard curriculum at most pharmacy schools. When there are no FDA-approved drugs to treat a specified condition, or where they are available only in dosages inappropriate for a patient, compounding fills an important health care need. Indeed, FDA itself recognized that compounding serves important health purposes. Moreover, from the time that the Federal Food, Drug, and Cosmetic Act (FDCA) was adopted in 1938 until sometime in the 1990s, FDA's position was that pharmacy compounding was subject only to regulation by the States (which generally impose strict licensing requirements on pharmacists).

Starting in the 1990s, however, FDA began to conclude that compounding by some large-scale pharmacies was more akin to drug manufacturing than to traditional compounding, and it began to assert regulatory authority over some compounding pursuant to the FDCA. In the ensuing years, FDA's assertion of regulatory authority has become increasingly aggressive, so that it now takes the position that *all* compounding of animal drugs – regardless whether undertaken on a small scale or in response to prescriptions written by a veterinarian – is a federal crime. Because compounding of animal drugs is widespread and is recognized as essential to

administering health care to animals, FDA says it will overlook most of the "criminal" activity and instead will only bring enforcement actions against those pharmacies that are straying the farthest from traditional compounding.

Franck's Lab, Inc. is a Florida pharmacy devoted exclusively to compounding drugs for non-food-producing animals (*e.g.*, horses but not cows). Franck's contends that its compounding is of a "traditional" variety – it only compounds in response to prescriptions written by individual veterinarians for specific animals. FDA filed suit against Franck's in 2010, seeking an injunction to prevent Franck's from undertaking any more animal compounding. Although FDA asserts that Franck's is not a "traditional" compounder and that Franck's was targeted because its activities are more akin to those of a drug manufacturer, FDA has not based its case on that theory. Instead, it asserts that the FDCA prohibits *all* animal drug compounding, and that it need do nothing more than prove that Franck's is engaged in compounding. The district court dismissed the complaint, ruling that the FDCA does not prohibit traditional, small-scale compounding. FDA appealed to the Eleventh Circuit.

In its brief urging the appeals court to affirm, WLF argued that although the FDCA is broadly worded, there is no evidence that Congress, when it adopted the FDCA is 1938, intended to outlaw compounding. WLF asserted that if Congress really had intended to shift pharmacy regulation from the States to the federal government, one would expect Congress to have said so explicitly. The fact that Congress did not assert jurisdiction for more than 50 years after adoption of the FDCA is another indication that the statute was not intended to expand FDA's jurisdiction in such a dramatic fashion, WLF stated. WLF also argued that the Administrative Procedure Act requires a federal agency, *before* it seeks to adopt a policy that reverses its prior position, to provide notice of its policy change and an opportunity for comment on the change. FDA did not take those steps in this case.

WLF is a public interest law and policy center with supporters in all 50 states. WLF regular participates in litigation in support of its view that FDA must engage in formal rulemaking before adopting new policies.

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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.