News Release

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

FOR IMMEDIATE RELEASE **May 12, 2005**

COURT URGED TO REIN IN FDA'S ENFORCEMENT POWERS

(United States v. Rx Depot, Inc.)

The Washington Legal Foundation (WLF) yesterday urged the U.S. Court of Appeals for the Tenth Circuit in Denver to prevent the Food and Drug Administration (FDA) from attempting to exercise enforcement powers that Congress has never delegated to it. In a brief filed in *United States v. Rx Depot, Inc.*, WLF argued that FDA has no power to order a company to disgorge profits earned as a result of alleged violations of the Federal Food, Drug, and Cosmetics Act (FDCA).

WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that restitution and disgorgement are not among them. WLF argued that FDA, throughout most of its history, never asserted a right to seek disgorgement or restitution; WLF charged that FDA only recently began asserting that power, in order to have a big club with which to intimidate manufacturers who might otherwise seek to challenge FDA directives. This marks the second time this year that WLF has challenged FDA's authority to seek restitution/disgorgement as a remedy for a violation of the FDCA. In February 2005, WLF filed a brief in the Third Circuit in *United States v. Lane Labs-USA, Inc.*, seeking to overturn a $120 million restitution order issued against a dietary supplement manufacturer found to have violated the FDCA.

"FDA cannot be allowed to get away with this power grab," said WLF Chief Counsel Richard Samp after filing WLF's brief. "The American economy suffers, and public safety and health are jeopardized, when FDA seeks to exert power beyond its authority, upsetting the delicate balance struck by Congress in its attempt to both preserve the public welfare and encourage valuable pharmaceutical innovations," Samp said.

The case involves Rx Depot, Inc., a company accused by FDA of brokering illegal purchases by American consumers of prescription drugs from Canadian pharmacies. Rx Depot allegedly solicited valid drug prescriptions given to American patients by their doctors, and then (for a fee) would arrange for a low-cost Canadian pharmacy to fill the prescription. FDA charged that Rx Depot's conduct violated FDCA provisions that prohibit the reimportation of drugs originally manufactured in the United States, and also prohibit the distribution of drugs that pose a risk to public health. As part of a consent decree entered into between the parties, Rx Depot admitted that its conduct violated the FDCA and agreed to cease its illegal activities.

The district court subsequently denied FDA's request for restitution and disgorgement. The court held that restitution to injured consumers was unwarranted because consumers did not perceive themselves as having been injured by Rx Depot. The court further held that disgorgement of ill-gotten gains was not among the remedies contemplated by Congress when it adopted the FDCA. FDA appealed to the Tenth Circuit, raising only the disgorgement issue.

In its brief urging affirmance of the district court decision, WLF argued that the FDCA grants FDA authority "to restrain violations" of the FDCA; to seize the offending food, drug, or cosmetic; and to impose criminal penalties including fines. WLF argued that because the FDCA spells out in such detail the remedial powers granted to FDA, one can only conclude that Congress did not intend to grant FDA other equitable powers *not* enumerated in the FDCA, including the power to seek restitution or disgorgement. WLF also argued that denying FDA the power to seek disgorgement is consistent with FDA's mission to protect public health and safety. WLF noted that disgorgement is generally associated with punishing wrongdoers, not health and safety issues.

WLF also argued that even though the relevant statute was adopted in 1938, FDA did not begin seeking restitution/disgorgement as a remedy until 1951. A federal appeals court ruled in 1955 that FDA lacked power to seek restitution/disgorgement, and FDA did not again assert otherwise until 1995. WLF argued that that long history of FDA and congressional acquiescence to the 1955 decision suggests that both bodies agreed with the decision. WLF charged that FDA now asserts power to seek restitution/disgorgement solely as a means of coercing large settlements from drug companies. WLF argued that FDA realizes that no company can risk contesting FDA's claims in court when it potentially faces a multi-billion dollar restitution/disgorgement award.

WLF is a public interest law and policy center with supporters in all 50 states. WLF devotes a significant portion of its resources to efforts to promote the rule of law by seeking to confine federal administrative agencies to their statutorily authorized powers.

* * *

For further information, contact WLF Chief Counsel Richard Samp, 202-588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.