



February 25, 2006

COURT DECLINES TO REIN IN FDA'S ENFORCEMENT POWERS

(United States v. Rx Depot, Inc.)

The U.S. Court of Appeals for the Tenth Circuit in Denver this week declined an opportunity to prevent the Food and Drug Administration (FDA) from exercising enforcement powers that the evidence suggests were never delegated to it by Congress. The court's decision in *U.S. v. Rx Depot, Inc.*, affirming FDA's authority to seek a massive damage award against an Internet pharmaceutical distributor, was a setback for the Washington Legal Foundation (WLF), which had filed a brief urging the court to deny FDA that authority.

In its brief, WLF argued that FDA has no power to seek disgorgement or restitution from companies alleged to have violated the Federal Food, Drug, and Cosmetic Act (FDCA). WLF also filed a brief in a Third Circuit case, *United States v. Lane Labs-USA, Inc.*, which raised nearly identical issues regarding FDA's enforcement powers. The *Lane Labs* case was decided adversely to WLF last October.

WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that disgorgement and restitution are not among them. WLF further argued that FDA, throughout most of its history, never asserted a right to seek disgorgement; 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. The Tenth Circuit did not dispute those contentions; it nonetheless upheld FDA's authority to seek disgorgement on the grounds that the FDCA's grant of authority to "restrain" violations of the Act should be read broadly to include all forms of equitable relief.

"FDA cannot be allowed to get away with this power grab," said WLF Chief Counsel Richard Samp after reviewing the Tenth Circuit's decision. "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. WLF has pledged to continue to litigate the issue should it arise in other courts of appeals.

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. The Tenth Circuit's decision sends the case back to the district court, which will now decide whether (and if so, how large) a disgorgement award is appropriate.

In its brief in opposition to FDA's appeal, 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, including the power to seek disgorgement of allegedly ill-gotten gains. WLF charged that FDA now asserts power to seek restitution and disgorgement solely as a means of coercing large settlements from drug companies. WLF also argued that FDA realizes that no company can risk contesting FDA's claims in court when it potentially faces a multi-billion dollar disgorgement or restitution award.

In reaching a contrary result, the Tenth Circuit relied primarily on the Supreme Court's 1960 *Mitchell* decision, a decision it felt bound to follow. The appeals court said that *Mitchell* mandates a finding that a regulatory statute grants the courts broad remedial powers to enter all forms of equitable relief, in the absence of clear evidence that Congress intended to preclude such relief.

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

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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.