



October 24, 2005

COURT DECLINES TO REIN IN FDA'S ENFORCEMENT POWERS

(United States v. Lane Labs-USA, Inc.)

The U.S. Court of Appeals for the Third Circuit in Philadelphia 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. Lane Labs-USA, Inc.*, upholding a massive restitution award against a dietary supplement manufacturer, was a setback for the Washington Legal Foundation (WLF), which had filed a brief urging the court to overturn the award.

In its brief, WLF argued that FDA has no power to seek restitution from manufacturers alleged to have violated the Federal Food, Drug, and Cosmetic Act (FDCA). WLF filed its brief with the pro bono assistance of Jeffrey A. Lamken and Aaron M. Streett of the law firm of Baker Botts L.L.P. WLF also filed a brief in a pending Tenth Circuit case, *United States v. Rx Depot, Inc.*, which raises nearly identical issues regarding FDA's enforcement powers. The *Rx Depot* case is scheduled for oral arguments in November.

WLF argued that Congress has spelled out precisely what enforcement powers it has given to FDA, and that restitution is not among them. WLF argued that FDA, throughout most of its history, never asserted a right to seek 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. The Third Circuit did not dispute those contentions; it nonetheless upheld FDA's authority to seek restitution 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 Third 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 and to support Appellants in any further appeals they may file.

The case involves Lane Labs-USA, Inc., a dietary supplement manufacturer. Such manufacturers are permitted to market their products as promoting good health; but unless a product has gone through FDA's lengthy drug approval process, they may not make claims that the product is effective in curing or treating a disease. Any such claim transforms the dietary supplement into an "unapproved new drug," the marketing of which violates the FDCA.

FDA charged that Lane Labs was promoting its three largest-selling products (which accounted for the bulk of its \$30 million in annual sales) as effective in curing or treating disease, and brought an enforcement action against Lane Labs in federal court in New Jersey. The court granted summary judgment to FDA in July 2004 and issued a permanent injunction against further marketing. The court also granted FDA the draconian penalty it sought: it ordered Lane Labs to refund the full product cost to every consumer who purchased any of the three largest-selling Lane Labs products in the prior five years. That restitution order exceeds \$109 million and, if enforced, will drive both Lane Labs and its president into bankruptcy. Lane Labs appealed the restitution order.

In its brief in support of Lane Labs's challenge to the restitution order, 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 restitution for consumers. WLF charged that FDA now asserts power to seek restitution 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 award.

In reaching a contrary result, the Third 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.