

**FOR IMMEDIATE RELEASE****May 15, 2001****FDA URGED TO REJECT OVER-THE-COUNTER STATUS FOR PRESCRIPTION DRUGS**

The Washington Legal Foundation (WLF) this week urged the Food and Drug Administration (FDA) not to force drug manufacturers to accept over-the-counter status for their products if the manufacturers would prefer to have the products continue to be available on a prescription basis only.

WLF's filing came in response to a Citizen Petition filed by a health insurance company regarding three prescription anti-allergy medications. The three drugs -- Allegra, Claritin, and Zyrtec -- are currently available on a prescription basis only. Although the manufacturers would like to maintain the prescription-only status of their medications, an FDA advisory committee determined last week by an 18-5 vote that switching the drugs to over-the-counter (OTC) status would not raise any significant safety concerns. The FDA Commissioner will make the decision whether to accept the advisory committee's recommendations some time in the coming weeks.

The health insurance industry is interested in having the three allergy medications shifted to OTC status because it would save the industry millions of dollars annually -- most health insurance plans do not cover OTC drugs but do cover prescription drugs. The manufacturers of Allegra, Claritin, and Zyrtec oppose the move both because of safety concerns and because a shift to OTC status generally results in greatly reduced drug prices.

In its formal response to the Citizen Petition, WLF noted that FDA has never approved the shift of a drug to OTC status when the drug manufacturer opposes the move. WLF argued that although FDA has legal authority to lift the requirement that a drug may only be sold on the basis of a doctor's prescription, it has no authority to *require* pharmaceutical companies to sell their products without prescriptions.

WLF stated that it is not claiming medical expertise on allergy issues and thus that its opposition to the Citizen Petition is not based on a belief that the safety of consumers might be endangered if they were permitted to purchase the allergy medications without consulting a physician. Rather, WLF's opposition is based on a belief that forcing manufacturers to abandon prescription drug status would significantly reduce incentives for pharmaceutical companies to engage in research and development.

WLF argued that the American pharmaceutical industry has made tremendous

breakthroughs over the past several decades in developing new life-saving therapies for patients. Those breakthroughs have been made possible by the massive spending that manufacturers have devoted to research and development. WLF stated that manufacturers have devoted large sums to R&D because, under existing law, they stand to reap substantial financial rewards in those few instances in which their expenditures bear fruit. WLF argued that if FDA changes existing procedures and begins allowing involuntary switches of drugs from prescription to OTC status, manufacturer confidence that they will be substantially rewarded for developing new products will be substantially undermined. That in turn will lead to reduction in R&D spending and reduction in the development of new, life-saving therapies, WLF argued. WLF stated that such a trend would have significant long-term adverse effects on health care in this country.

WLF also argued that the proposed switch to OTC status would undermine the property rights of pharmaceutical manufacturers. Noting that Allegra, Claritin, and Zyrtec are all protected by existing patents, WLF stated that a switch to OTC status would substantially reduce the value of that property. WLF noted that intellectual property such as patents is fully protected under the Fifth Amendment's Takings Clause, which prohibits the taking of private property by the government without the payment of just compensation. WLF argued that any government action that substantially reduces the value of private property, such as the involuntary switch of a patented drug to OTC status, implicates the Takings Clause and may well require the government to compensate the owner for his loss.

WLF is a public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to promoting the interests of a free-market economy and to defending the property rights of individuals and businesses and their rights to go about their affairs without undue interference from government regulators.

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