News Release

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WLF CAUTIONS AGAINST MISUSE OF FDA "BLACK BOX" LABELING AUTHORITY

The Washington Legal Foundation (WLF) today cautioned against potential misuse of the Food and Drug Administration's (FDA) authority to require pharmaceutical companies to place "black box" warnings on product labeling. WLF argued that such warning labels should be required only when justified by clinical evidence that use of the product is associated with death or serious injury, and not merely for the purpose of grabbing the attention of patients and health care providers.

WLF pointed to tentative FDA plans to require "black box" warnings for two skin creams used to treat eczema, Elidel and Protopic, as examples of potential misuse of FDA labeling authority. WLF said that there is insufficient evidence to warrant "black box" warnings for those products and that such warnings could unnecessarily scare away patients who could benefit from the drugs. WLF charged that FDA's real motivation appears to be an antipathy to drug promotion activity.

"Black box warnings should be used for the sole purpose of conveying truthful information to consumers about serious dangers associated with the use of a drug. They should not be used to highlight unsubstantiated data for the purpose of scaring consumers away from using a drug. If FDA officials believe that product promotion is encouraging some inappropriate use of a product, they should address those promotional activities directly, not respond by attempting to scare consumers," said WLF Chief Counsel Richard Samp. "The First Amendment protects the right of manufacturers both to speak truthfully about their products and not to be forced to place unsubstantiated warnings on their product labels," Samp said.

In support of its claim that some at FDA may be using "black box" warnings as an effort to counteract drug promotional activity, WLF pointed to a February 15, 2005 meeting of FDA's Pediatrics Advisory Committee. The Committee voted that day to recommend that labeling for Elidel and Protopic be amended to include a "black box" warning regarding cancer risks allegedly associated with use of the products. Several Committee members who supported that recommendation stated that they did so because they believed that advertising for the two drugs had created too much demand among some doctors and patients. They said that the "black box" warnings were one way "to control the marketing" for the drugs, and that the warnings would be unnecessary if the manufacturers had engaged in less promotional activity. WLF charged that such "back-door efforts" to control constitutionally protected marketing activities are a misuse of FDA's labeling authority.

Elidel and Protopic are calcineuron inhibitors that treat eczema and other skin conditions by suppressing the immune system. Recent studies of monkeys who were given very high doses of an oral form of one of the drugs over a long period of time reported an increased cancer risk. But there is no clinical data in humans suggesting an increased cancer risk -- incidence of cancer among Elidel and Protopic users is lower than among the population as a whole, and most of the reported lymphomas are not of the type associated with immunosuppression. Moreover, the level of the drugs in the bloodstreams of human patients to whose skin cream is applied could never approach anywhere near levels achieved in the animal studies; very little Elidel and Protopic is absorbed through the skin, and in most clinical studies, the blood level of the drugs is too low to measure.

FDA nonetheless is contemplating adding a "black box" warning to the product labeling that may include a warning of increased cancer risk. WLF said that such a warning is not justified by the available scientific evidence and might cause some patients and doctors to be scared away from using Elidel and Protopic even though use of those drugs may be medically indicated. WLF noted that a principal FDA concern appears to be that some doctors are prescribing the products for children under two, even though FDA has approved their use only for children two and older. WLF said that such concerns could be addressed by revising the prescribing information without the need to use "black box" warnings.

WLF said that FDA may be resorting more quickly to "black box" warnings in response to recent criticism that it has not been doing enough to ensure the safety of FDA-approved drugs. WLF said that such criticisms have been overblown. WLF said that no drug is 100% safe, and that a principal FDA role should be to ensure that doctors and consumers are being provided with adequate warnings of the risks involved in taking any drug. But WLF warned that public health will suffer if FDA mandates warnings that are not justified by clinical data, with the result that doctors and patients are unnecessarily scared away from using medically indicated products, manufacturers develop misguided liability concerns, and access to medically necessary treatment alternatives is restricted.

WLF is a public interest law and policy center with supporters in all 50 States. WLF for many years has been actively involved in efforts to decrease federal government restrictions on the flow of truthful information about FDA-approved drugs and medical devices, and to limit the circumstances under which the government may compel individuals and companies to speak against their will.

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For further information, call WLF Chief Counsel Richard Samp, (202) 588-0302.