

**FOR IMMEDIATE RELEASE****July 25, 2005**

## **WLF AND PATIENT GROUPS ASK FDA FOR WIDER AVAILABILITY OF CANCER DRUG**

The Washington Legal Foundation (WLF) filed comments today with the Food and Drug Administration asking the agency to withdraw or modify its order for the restrictive labeling of the lung cancer drug Iressa (gefitinib). WLF's comments were joined by three patient groups, the Abigail Alliance for Better Access to Developmental Drugs, the Lorenzen Cancer Foundation, and the Lung Cancer Alliance.

Iressa was approved in May 2003 under the FDA's accelerated approval program. It was approved for the treatment of patients with locally advanced or metastatic non-small cell lung carcinoma who have tried chemotherapy unsuccessfully. Oncologists who prescribe the drug report that it works well, and sometimes dramatically, for a minority of these patients, in some cases extending their lives by years.

WLF's comments are in opposition to the FDA-mandated relabeling of Iressa announced on June 17, 2005. FDA's action effectively limits the use of Iressa in the United States to the approximately 4,000 patients already being treated with it. WLF's comments argued that this limitation on the availability of Iressa will harm lung cancer patients in the future who have no other approved treatment options and who may benefit from this medicine. WLF's comments noted that FDA's reliance on clinical trial results in which Iressa did not prolong survival among patients *on average* failed to take into account that some patients unquestionably benefit from the drug. WLF further noted FDA's action has the effect of denying the drug to patients in two groups – Asian patients and non-smokers – that did show a statistically significant increase in survival.

Finally, WLF argued that the broad dissemination of information to doctors about the drug's limitations ("I have got more notice about this drug than I have credit card applications," one cancer doctor told the FDA) justifies treating the decision to prescribe Iressa as a matter within a physician's discretion, like the many issues presented in the practice of medicine that require consideration of risks and potential benefits in light of the individual patient's circumstances.

The Abigail Alliance for Better Access to Developmental Drugs is a nonprofit organization based in Arlington, Virginia, dedicated to helping terminally ill patients obtain access to the medicines they need. Abigail Alliance was founded in 2001 by Frank Burroughs, who is now its president. The group is named for Burroughs's daughter, Abigail, an honors

student at the University of Virginia. Abigail died of cancer on June 9, 2001, after she was stymied in her efforts to obtain new cancer drugs that her oncologist believed could save her life, but which were still in clinical trials. Abigail Alliance has numerous members and supporters who are suffering from terminal illness or who have lost family members to terminal illness.

The Lorenzen Cancer Foundation is a nonprofit organization based in Monterey, California, providing assistance to patients fighting pancreatic cancer. The Foundation maintains a large database of clinical trials of pancreatic cancer therapies, as well as current medical news, to aid these patients and their physicians in keeping up to date on the range of available treatment options for pancreatic cancer. The chairman of the Foundation is Lee Lorenzen, who founded it in response to the diagnosis and subsequent passing of his brother Gary Lorenzen due to metastatic adenocarcinoma of the pancreas. Iressa is undergoing multiple clinical trials specifically for pancreatic cancer.

The Lung Cancer Alliance is a national non-profit organization dedicated solely to advocating for people living with lung cancer or those at risk for the disease. Its initiatives aim to educate public policy leaders of the need for greater resources for lung cancer research while changing the face of lung cancer and reducing the stigma associated with the disease.

WLF is a public interest law and policy center with supporters in all 50 states. It devotes a substantial portion of its resources to defending free enterprise, individual rights, and a limited and accountable government. WLF has frequently advocated before the FDA and litigated against it in support of the needs of sick Americans, including in the landmark case of *Washington Legal Foundation v. Friedman*, 56 F. Supp. 2d 81 (D.D.C. 1999), *appeal dis'm*, 202 F.3d 331 (D.C. Cir. 2000), in which the U.S. District Court for the District of Columbia agreed with WLF that the FDA's restrictions preventing drug manufacturers from disseminating accurate information about off-label uses were in violation of the First Amendment. WLF, representing itself, the Abigail Alliance, and the Lorenzen Cancer Foundation, has also filed comments with the Centers for Medicare and Medicaid Services urging the agency to continue coverage for the full range of off-label uses of modern cancer drugs.

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For further information, contact WLF Senior Vice President for Legal Affairs David Price, (202) 588-0302. A copy of the comments is posted on WLF's web site, [www.wlf.org](http://www.wlf.org).