

**FOR IMMEDIATE RELEASE****April 20, 2005**

WLF AND PATIENT GROUPS OPPOSE PUBLIC CITIZEN ON CANCER DRUG

The Washington Legal Foundation (WLF) filed comments today with the Food and Drug Administration opposing a petition from the Nader group Public Citizen, Inc. in which Public Citizen seeks the immediate withdrawal of the cancer drug Iressa (gefitinib). WLF's comments in response to the petition were joined by two patient groups, the Abigail Alliance for Better Access to Developmental Drugs and the Lorenzen Cancer Foundation.

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

In its petition, Public Citizen argued that Iressa should be withdrawn from the market because a recent clinical trial did not find a statistically significant effect on patients' survival and because a small number of patients taking Iressa have died from interstitial lung disease (ILD). In its response, WLF noted that despite the results of the trial, there is no serious dispute that Iressa does, in fact, dramatically benefit some patients with lung cancer. The lack of statistical significance simply reflects the averaging of the subgroups of patients who respond very positively to Iressa with the patients who do not. WLF noted that the drug's sponsor, AstraZeneca, is conducting additional testing to identify which patients will tend to benefit from it, building on work already done by others. (Initial evidence indicates that Iressa has a statistically significant effect on the survival of Asian patients and non-smokers for whom other therapies have failed.)

WLF argued that Public Citizen's reliance on the occurrence of ILD is unpersuasive because ILD is a known complication in lung cancer patients, with or without Iressa, and because it is reasonable to allow terminally ill patients the choice of accepting a risk of side effects, particularly when they have already tried other therapies unsuccessfully.

Finally, WLF argued that leaving Iressa on the market preserves its availability to lung cancer patients for whom it represents the best available care – for example, those already on the drug and experiencing clinical benefit, or future patients who run out of other options.

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

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.