

**FOR IMMEDIATE RELEASE****August 19, 2005**

## **WLF URGES COVERAGE OF ALL CANCER DRUGS IN MEDICARE DRUG PLANS**

*(In re CMS Guidance on “Part D” Drug Formularies)*

The Washington Legal Foundation (WLF) filed comments today with the Centers for Medicare & Medicaid Services (CMS), the agency of the U.S. Department of Health and Human Services that operates the Medicare program, asking the agency to withdraw its plan to allow the exclusion of the lung cancer drug Iressa (gefitinib) from drug plans under the new “Part D” prescription drug benefit. WLF filed the comments on behalf of itself, the Abigail Alliance for Better Access to Developmental Drugs, the Lorenzen Cancer Foundation, and the Lung Cancer Alliance.

WLF’s comments are in response to a guidance document from CMS in which the agency stated that carriers offering coverage under the new benefit program must include in their formularies “all or substantially all” drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories. The guidance excluded a number of drugs, including Iressa, from this requirement.

WLF stated in its comments that CMS’s general requirement of coverage for cancer drugs was sound in light of its determination that “[d]iseases associated with these six categories of drugs [including cancer drugs] . . . have among the highest predicted drug costs” and thus pose the highest risk of “selection and/or discrimination” issues. CMS noted that this requirement is consistent with the structure of widely-used formularies such as those of the Blue Cross-Blue Shield Federal Employees Program and many state Medicaid programs. WLF argued that the exception with respect to Iressa is inconsistent with that rationale, and appears to represent the first occasion ever on which CMS has acted to block patients’ access to an FDA-approved oncologic drug for on-label use. WLF noted that Iressa is believed to represent the best available care for many lung cancer patients for whom other therapies have failed.

The Abigail Alliance 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 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.

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 nonprofit public interest law and policy center based in Washington, D.C., with supporters nationwide. Since its founding in 1977, WLF has engaged in litigation and advocacy to defend and promote individual rights and a limited and accountable government, including in the area of patients' rights. For example, WLF successfully challenged the constitutionality of Food and Drug Administration restrictions on the ability of doctors and patients to receive truthful information about off-label uses of FDA-approved medicines. *Washington Legal Found. v. Friedman*, 13 F. Supp.2d 51 (D.D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000). WLF has previously submitted comments to CMS concerning Medicare coverage of off-label uses of FDA-approved cancer drugs under Part B, Part D, and the Section 641 demonstration program, and concerning the agency's draft guidance on coverage tied to participation in clinical trials or other evidence development programs.

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