
COMMENTS

of the

**WASHINGTON LEGAL FOUNDATION,
ABIGAIL ALLIANCE FOR BETTER ACCESS
TO DEVELOPMENTAL DRUGS,
LORENZEN CANCER FOUNDATION,
AND LUNG CANCER ALLIANCE**

to the

**CENTERS FOR MEDICARE & MEDICAID SERVICES,
U.S. DEPT. OF HEALTH AND HUMAN SERVICES**

Concerning

**NON-COVERAGE OF CANCER DRUG
IRESSA (GEFITINIB) UNDER PART D**

Daniel J. Popeo
David Price
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., N.W.
Washington, D.C. 20036
(202) 588-0302

August 19, 2005

WASHINGTON LEGAL FOUNDATION
2009 MASSACHUSETTS AVE., N.W.
WASHINGTON, D.C. 20036
(202) 588-0302

August 19, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Bldg.
200 Independence Ave., S.W.
Washington, D.C. 20201

Re: Non-Coverage of Cancer Drug Iressa (Gefitinib) Under Part D

Dear Dr. McClellan:

The Washington Legal Foundation (WLF), the Abigail Alliance for Better Access to Developmental Drugs, the Lorenzen Cancer Foundation, and the Lung Cancer Alliance are submitting these comments to express our concerns regarding a recent statement by CMS that it will not require Iressa (gefitinib) to be included on formularies in the Part D program. *See Why is CMS requiring “all or substantially all” of the drugs in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories?* (undated) (hereinafter cited as “Guidance Document”).¹ As detailed below, we believe this exclusion is contrary to the sound purposes of CMS’s overall policy requiring coverage of “all or substantially all” cancer drugs under Part D and will harm Medicare patients who are fighting cancer.

¹ Available for download at <http://www.cms.hhs.gov/pdps/formularyqafinalmm1.pdf>.

I. Interests of Commenters

Commenter 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. *See Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D. D.C. 1998), *appeal dismissed*, 202 F.3d 331 (D.C. Cir. 2000).

Commenter 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 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.

Commenter 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.

Commenter 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.

II. Background

In implementing the Part D benefit program, CMS has appropriately determined that carrier formularies must include “all or substantially all” prescription drugs “in the antidepressant, antipsychotic, anticonvulsant, anticancer, immunosuppressant and HIV/AIDS categories” that are available on January 1, 2006. Guidance Document at 1, 2. CMS noted that “[d]iseases associated with these six categories of drugs . . . have among the highest predicted drug costs” and thus pose the highest risk of “selection and/or discrimination” issues. CMS also 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.

An attachment to the guidance, however, provides for certain “exceptions” to the “all or substantially all” requirement. Guidance Document at 3. The attachment states, *inter alia*, that

“Iressa is not required on formularies, as is reflected in current formulary practices related to the pending clinical data currently under review by the Food and Drug Administration.” Part D and Medicare Advantage Plans are thus apparently free in CMS’s eyes to exercise discretion to deny reimbursement for this medicine.

Iressa, a cancer drug approved by regulatory authorities in 36 countries, is a targeted therapy that inhibits the epidermal growth factor receptor tyrosine kinase (EGFR-TK) that is expressed on the cell surface of many cancer cells. Iressa was approved in the United States 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 after failure of platinum-based and docetaxel chemotherapies. Approximately 4,000 patients are currently being treated with Iressa in this country.

The FDA directed on June 17, 2005, that the label information for Iressa be revised to state that Iressa is to be used only for the “continued treatment” of patients “who are benefiting or have benefited from Iressa.” This action effectively limits the use of Iressa in the United States to the patients currently being treated with it. Commenters have urged FDA to discontinue this limitation in view of the likelihood that it will cause harm in the future to lung cancer patients who have no other approved treatment options and who may benefit from this medicine. It is important to note, however, that CMS’s exclusion would appear to reach even those patients who have already experienced benefit from treatment with Iressa. With regard to these patients, Iressa remains “approved for safety and effectiveness as a prescription drug” under the terms of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 42 U.S.C.

§ 1395w-102e(1)(A)(i). Moreover, as to these patients, the exclusion flies in the face of CMS's own well-founded recognition that "beneficiaries should be permitted to continue utilizing a drug in these categories [including anticancer drugs] that is providing clinically beneficial outcomes." Guidance Document at 1.

III. The Exception for Iressa Represents Unsound Policy

CMS's overall policy of protecting access to oncologic drugs is a proper exercise of its supervisory authority under the Part D program. The statement that CMS will not require access to Iressa on any formulary contravenes the logic of this policy. Indeed, to Commenters' knowledge, it represents the first occasion ever on which CMS has acted to block patients' access to an FDA-approved oncologic drug for *on-label* use.

The "pending clinical data" referenced by the Guidance Document is presumably the Iressa Survival Evaluation in Lung Cancer Study (ISEL), also known as Trial 709, which did not find a statistically significant improvement overall under its primary analysis in survival of patients with non-small cell lung cancer treated with Iressa who had undergone one or two prior chemotherapy regimens and were refractory or intolerant to their most recent regimen. These findings (as well as those of the SWOG 0023 study, to similar effect) do not warrant the exclusion of Iressa from Part D formularies. There is no serious dispute that Iressa does, in fact, dramatically benefit some patients with non-small cell lung cancer; indeed, the revised FDA-approved label expressly references patients receiving benefit. The lack of statistical significance in the primary analysis simply reflects the averaging of the subgroups of patients who respond

very positively to Iressa (roughly 10%, as indicated by multiple studies) with the patients who do not.

The statistical results at issue were based on a total number of deaths in the trial of 632 of 1,129 patients getting Iressa (56%) and 337 of 563 getting a placebo. If the number of deaths in the placebo arm had been 340 – three more – the survival rate in the Iressa arm would have been statistically significant. It defies belief that terminally ill patients who have already demonstrated a benefit from a drug, one that may be their last hope, would be frustrated in obtaining it under Medicare Part D on this hyper-technical basis.

A key reason this drug received approval in the first place was the testimony of patients who had clearly received very substantial clinical benefit. Oncologists who use the drug report that it works well, and sometimes dramatically, for a small percentage of patients, in rare cases extending their lives by years. The statistics do not reflect that direct observational data. Iressa should remain fully accessible under Part D to non-small cell lung cancer Medicare patients for whom it may represent the best available care, particularly patients who have already benefited from treatment with it.

CONCLUSION

For the foregoing reasons, the Washington Legal Foundation, the Abigail Alliance, the Lorenzen Cancer Foundation, and the Lung Cancer Alliance respectfully request that CMS adhere to its overall policy requiring inclusion of anticancer drugs on Part D formularies, reverse its policy allowing the exclusion of Iressa from those formularies, and thereby ensure that

Comments on Non-Coverage of Iressa
August 19, 2005
Page 7

patients who have benefited from Iressa maintain access to it under Medicare after January 1, 2006.

Respectfully submitted,

Daniel J. Popeo

David Price

WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., N.W.
Washington, D.C. 20036
(202) 588-0302

Counsel for Commenters