

Press Release

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Ave., NW
Washington, D.C. 20036
202.588.0302

FOR IMMEDIATE RELEASE

February 10, 2004

MEDICARE AGENCY URGED TO CONTINUE COVERING CANCER DRUGS *(In re CMS Cancer Drug Reimbursement Policy)*

The Washington Legal Foundation (WLF) today filed a petition 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 not to terminate coverage of “off-label” uses of certain cancer drugs. The petition is in response to national coverage reviews in which CMS is considering whether to end those reimbursements.

One of CMS’s national coverage reviews is focused on reimbursement for the non-Hodgkin's lymphoma drugs ibritumomab tiuxetan (Zevalin) and tositumomab (Bexxar). The other review at issue is focused on the drugs oxaliplatin (Eloxatin) and irinotecan (Camptosar), which have been in use in treatment regimens for colorectal cancer and pancreatic cancer.

In the petition, WLF noted that off-label prescribing – that is, a physician’s use of a drug for conditions other than the specific ones for which the FDA has given marketing approval – is common and important to medical practice in obstetrics, pediatrics, and AIDS treatment, as well as cancer treatment. WLF is concerned that a denial of reimbursement for cancer drugs will not only deny the treatments of choice to thousands of dying cancer patients, but will set a precedent for denying proper treatment to other patients.

The petition argues that CMS has no authority from Congress to deny reimbursement on the basis of the factors that it has cited – namely, that a drug “represents a novel, complex or controversial treatment, may be costly to the Medicare program, may be subject to overutilization or misuse, or received marketing approval based on the use of surrogate outcomes.” Congress directed in 1993 that CMS is to reimburse for off-label uses of FDA-approved cancer drugs if the off-label use is listed in any of a number of medical reference books or if the off-label use is approved by the pharmacy committee of the hospital’s medical staff.

WLF filed its comments on behalf of itself and two patient advocacy and support organizations, the Abigail Alliance for Better Access to Developmental Drugs and the Lorenzen Cancer Foundation. The Abigail Alliance is a nonprofit organization based in Arlington, Virginia, dedicated to helping terminally ill patients obtain access to the medicines they need. The Abigail Alliance was founded in 2001 by Frank Burroughs, who is now its president. The group is named for Burroughs's daughter, Abigail, who died of cancer on June 9, 2001, after she was stymied in her efforts to obtain new cancer drugs that her physician believed could save her life, but which were still in clinical trials. The Abigail Alliance has numerous members and supporters who are suffering from terminal illness or who have lost family members to terminal illness. WLF is also representing the Abigail Alliance in a lawsuit against the Food and Drug Administration, *Abigail Alliance v. McClellan*, seeking earlier access to investigational drugs for terminally ill patients with no approved treatment options.

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.

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. 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.

* * *

For further information, contact WLF Senior Vice President for Legal Affairs David Price, (202) 588-0302.