Litigation Update

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MEDICARE AGENCY PLEDGES TO CONTINUE COVERING OFF-LABEL USES

(*In re Section 641 Demonstration Project*)

The Centers for Medicare & Medicaid Services (CMS), the agency of the U.S. Department of Health and Human Services that operates the Medicare program, has advised the Washington Legal Foundation (WLF) that the agency's limitations on coverage of off-label drug prescriptions in a forthcoming demonstration project will not set a precedent for the forthcoming prescription drug benefit program.

WLF filed comments with the agency on June 25, 2004, asking the agency to reconsider its decision to exclude "off-label" uses of cancer drugs from its demonstration project for self-administered cancer drugs. In that demonstration project, mandated by Congress in Section 641 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS is to cover certain self-administered drugs on an interim basis prior to implementation of the full drug benefit (known as "Part D") in 2006. Under current law, Medicare reimburses for drugs only if administered in a doctor's office, hospital, or clinic.

In its comments, WLF expressed concern that a denial of reimbursement for off-label prescriptions would not only deny the treatments of choice to thousands of dying cancer patients, but could set a precedent for denying proper treatment to patients under the Part D program. CMS subsequently announced publicly that it was reversing its decision to exclude all off-label prescriptions from the demonstration project, and that it would cover a narrow class of off-label uses – those for which "such indication is being reviewed by the FDA" and for which the FDA has stated that "no filing issues remain."

In a separate e-mail communication to WLF, the agency has stated, "We appreciate the special nature of oncology treatment and role that off-label uses of certain medications plays. . . . As the Part D drug benefit that will be implemented in 2006 is not limited to replacement drugs, we do not believe that our decision in this matter is relevant to what will occur in 2006." The agency indicated that it believed its authority to exclude some off-label uses from the demonstration was grounded in the language of the statute authorizing the demonstration, and that this language does not appear in the statutory language creating the "Part D" prescription drug benefit program.

WLF filed its comments on the Section 641 demonstration 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. 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 medicine, and has opposed efforts by CMS to curtail reimbursement for off-label prescriptions of cancer drugs.

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