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Contact: Nathan Heggem  
Policy and Communications Associate  
212-204-6286

## **Judge Rules in Favor of Plaintiffs Seeking Medicare Coverage of Off-Label, Medically Necessary Drugs**

*-- Restrictive Coverage Requirement for Off-Label Drugs Ruled Invalid --*

New York, NY – In a decision published yesterday, a federal judge held that regulations that bar Medicare drug plans from covering medically necessary, “off-label” prescription drugs are unreasonable and do not reflect Congress’s intent to cover such drugs. The judge ruled that the plaintiffs’ off-label drug costs should be covered because the denial of coverage was based upon an “unsound interpretation” of the federal law providing drug coverage to people with Medicare.

“This is a victory for our plaintiffs and sets an important precedent for all people with Medicare,” said Joe Baker, president of the Medicare Rights Center. “Since the start of the Medicare drug benefit, the Medicare Rights Center has received calls from consumers who have struggled to obtain coverage of off-label, medically necessary drugs. This ruling brings us closer to removing a sizeable obstacle to coverage of these drugs.”

The Medicare Rights Center filed suit more than three years ago on behalf of two plaintiffs, Judith M. Layzer, diagnosed with ovarian cancer, and Ray J. Fischer, diagnosed with muscular dystrophy, whose doctors prescribed medically necessary prescription drugs for off-label treatments—treatments for which the drugs are not approved by the Food and Drug Administration. The suit contested regulations that restricted Medicare Part D coverage of these drugs by requiring that consumers seeking coverage find support in one of three drug guides known as compendia. Because of this requirement, consumers like Mrs. Layzer and Mr. Fischer—whose treatments are not cited in compendia but are supported by other medical evidence—are left without coverage. The suit noted that in the United States over 20 percent of prescriptions written for the 500 most commonly used drugs are for off-label uses.

In his decision, Judge Harold Baer, Jr., of the U.S. District Court in the Southern District of New York, held that the statutory language in the federal law that created the Medicare drug benefit made clear that “Congress did not intend to impose the Compendia Requirement.” The government had argued that federal law limits Medicare coverage to drugs prescribed for an on-label use, or for an off-label use found in the compendia. Judge Baer ruled that Medicare law was not meant to be restrictive in this instance, but rather that Congress included compendia as an illustrative example of the materials that may be used to determine coverage.

“This decision is a crucial victory for our clients, and potentially for 35 million people with Medicare around the country,” said Jeremy Bates, who, along with Nuri Frame and Aryeh Zuber, served as pro bono counsel for the plaintiffs. “A federal court has now held that in the Medicare Part D program, doctors should be free to prescribe the drugs that are medically necessary for their patients. This decision will help our nation’s doctors prescribe the drugs that their patients need.” Bates is a lawyer at Matalon Shweky Elman in New York.

The ruling comes nearly two years after the Medicare Rights Center secured coverage for Mrs. Layzer of a drug she needed to treat a rare form of ovarian cancer through a change in law effected by the Medicare Improvements for Patients and Providers Act (MIPPA). MIPPA, which took effect in January 2009, clarified that peer-reviewed medical literature may be used to determine coverage of off-label drugs prescribed to treat cancer. Although Mrs. Layzer, now deceased, gained coverage in 2009, this week’s decision will provide reimbursement to her estate for thousands of dollars of medication she used before 2009.

The Medicare Rights Center continues to advocate for passage of legislation by Congress that would clarify coverage guidelines for off-label uses of non-cancer drugs. Currently, the organization is working closely with Representative Mac Thornberry of Texas and Representative Russ Carnahan of Missouri to reintroduce legislation that was offered in the U.S. House last year under the title “Part D Off-Label Prescription Parity Act.” The Act would increase access to off-label drugs that are recommended by doctors and shown to be effective by research published in peer-reviewed journals, such as the *New England Journal of Medicine*. This change in law would not only create coverage parity across the entire Medicare program, but would also ensure that people with Medicare have access to safe, effective and medically necessary off-label drugs.

[Read Judge Baer’s decision.](http://www.medicarerights.org/pdf/Layzer-v-Leavitt-Decision-030711.pdf) (<http://www.medicarerights.org/pdf/Layzer-v-Leavitt-Decision-030711.pdf>)

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**Medicare Rights Center** is a national, nonprofit consumer service organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives.

520 Eighth Avenue, North Wing, 3<sup>rd</sup> Floor · New York, New York 10018  
1224 M Street, NW, Suite 100 · Washington, D. C. 20005 · [www.medicarerights.org](http://www.medicarerights.org)