

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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JUDITH M. LAYZER, :
 :
 Plaintiff, :
 v. :
 MICHAEL O. LEAVITT, in his official : Docket No. _____
 capacity as SECRETARY OF THE :
 UNITED STATES DEPARTMENT OF :
 HEALTH AND HUMAN SERVICES, :
 :
 Defendant. :
 :
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COMPLAINT

Plaintiff Judith M. Layzer, by her undersigned attorneys, for her
Complaint in this action alleges as follows:

INTRODUCTION

The Medicare prescription-drug benefit established in January 2006 was intended to bring improved health care and increased financial security for older adults and people with disabilities. For years, many people with Medicare—increasingly reliant on prescription drugs—had tried to cobble together coverage for their medications through an unwieldy and often inadequate combination of programs. Often people with Medicare had been left with the choice of paying for their prescription medicines at the expense of other basic needs.

Yet the new Medicare prescription-drug benefit (Part D) has still left many people who enrolled in it without coverage for the prescriptions they need. Indeed, many people with Medicare were actually better off before the drug benefit was introduced.

Among those in this situation are the many people, such as Plaintiff Judith M. Layzer, whose doctors have prescribed medically necessary medications for “off-label” uses. Drugmakers seek Food and Drug Administration (“FDA”) approval for specific uses of their products, and they conduct trials to test their drugs’ safety and effectiveness in patients with specific conditions. If the FDA approves a drug, the drug manufacturer must sell the drug with a label that lists only its FDA-approved uses. Any other use is referred to as “off-label.” Over 20 percent of prescriptions written for the 500 most commonly used drugs are for off-label uses.

Regulations issued last year by the Defendant, Health and Human Services Secretary Michael O. Leavitt, prohibit Part D coverage of off-label prescriptions, unless the prescribed use is supported in one of three specific medical compendia, which print overviews of uses of medications that are supported by surveys of clinical studies and peer-reviewed medical literature. If a drug’s prescribed use is not listed in the compendia, however, then a Part D plan cannot cover the drug—even if research published in peer-reviewed medical journals shows that the drug is effective for the prescribed use, and even if the drug is medically necessary for the patient.

People who take off-label prescriptions often have tried treatment after treatment to no avail—sometimes experiencing debilitating side effects over a period of years. They, along with their doctors, are thrilled to finally find medications that ease

their discomfort or, in some cases, preserve their lives. Yet they then discover that even though the drugs are on their Medicare Part D plans' formularies, the drugs cannot be covered for them. Without coverage of off-label prescriptions, people face increased suffering. And Medicare often bears increased costs, because of the need for more drastic care, such as emergency hospitalizations, that results when people do not receive the medicines that they need.

The exclusion from Medicare Part D coverage of off-label prescriptions that lack support in the compendia hurts the most vulnerable people with Medicare. The exclusion of these off-label prescriptions also conflicts with standard medical practice.

This action is brought on behalf of Mrs. Layzer to enjoin the Secretary of Health and Human Services from denying coverage of a prescription that is indisputably medically necessary to her fight against ovarian cancer. This action also seeks a declaration that the Secretary's interpretation of the Medicare statute, to bar coverage of certain medically necessary off-label medications that are not otherwise excluded from Part D coverage, is unlawful.

NATURE OF THE ACTION

1. Plaintiff Judith M. Layzer, a 66-year-old widow, is a survivor of ovarian cancer. Since 1999, Mrs. Layzer has taken a medication called Cetrotide, which her doctors have prescribed to treat and limit her cancer. Until January 2006, Mrs. Layzer's out-of-pocket monthly co-payment for her Cetrotide never exceeded \$40.

2. On January 1, 2006, the federal government launched its Medicare prescription-drug program, known as Medicare Part D. Once enrolled in Part D,

Mrs. Layzer was denied coverage of her Cetrotide prescription. As a result of this denial, Mrs. Layzer has paid co-payments of *over \$7,000 per month* for her prescription.

3. Cetrotide is essential to maintaining Mrs. Layzer's health and preserving her life. Mrs. Layzer's doctors have repeatedly stated that Cetrotide is medically necessary to treat her ovarian cancer. Her doctors' conclusion has strong support in peer-reviewed medical literature.

4. Because Cetrotide is medically necessary to Mrs. Layzer's health, the denial of Medicare Part D coverage of her prescription is dangerous and unlawful.

5. In the initial stages of coverage determination, the denial was based on the misconception that Mrs. Layzer used Cetrotide as a fertility drug. Mrs. Layzer has had both ovaries removed. She does not use Cetrotide as a fertility drug.

6. Later, Mrs. Layzer was denied coverage on the ground that Cetrotide can never be a "covered Part D drug" when used to treat ovarian cancer, even though—according to Defendant and his agents—Cetrotide is a "covered Part D drug" for other purposes, including treating prostate cancer. This distinction is arbitrary and capricious.

7. Defendant's claim that Cetrotide is not a "covered Part D drug" when used to treat ovarian cancer stems from a misreading of the Part D statute.

8. Mrs. Layzer brings this action to compel the Secretary of the United States Department of Health and Human Services ("HHS") to fulfill his statutory duty to ensure that Plaintiff receives Part D coverage of a life-saving prescription drug.

Mrs. Layzer also seeks a declaration that Defendant’s interpretation of the statute at issue, 42 U.S.C. § 1395w–102(e), is unlawful.

JURISDICTION AND VENUE

9. This Court has jurisdiction of this action pursuant to 5 U.S.C. § 702 and 28 U.S.C. § 1331. This action arises under the Medicare Prescription Drug Improvement and Modernization Act of 2003 (“MMA”), as codified in the Social Security Act. This action also arises under the Administrative Procedure Act (“APA”).

10. This Court has jurisdiction of this action also because the amount in controversy—over \$100,000—far exceeds the 2007 threshold of \$1,130.

11. Venue in this district is proper pursuant to 28 U.S.C. § 1391(e), as a substantial part of the events or omissions giving rise to the claim occurred within the Southern District of New York, and Mrs. Layzer resides within this District.

THE PARTIES

12. Plaintiff Judith M. Layzer is a 66-year-old widow who resides in the County of New York.

13. Defendant Michael O. Leavitt (the “Secretary”) is sued in his official capacity as the Secretary of the United States Department of Health and Human Services (“HHS”). The Secretary has responsibility for the conduct and policies of HHS. HHS includes the Centers for Medicare and Medicaid Services (“CMS”), which administers the Medicare program.

THE FACTS

Judith Layzer, Her Cancer, and Her Cetrotide Prescription

14. Judith M. Layzer is a 66-year-old Medicare beneficiary. She has Granulosa Cell Tumor (“GCT”), a rare form of ovarian cancer. She was first diagnosed with GCT in 1971. In 1987, Mrs. Layzer had a serious recurrence of GCT, and during the ensuing decades, she has been treated with surgery, radiation, and medication.

15. In 1999, after one of Mrs. Layzer’s tumors ruptured, several gynecological oncologists advised that she take Cetrotide to control her cancer. Mrs. Layzer has been prescribed Cetrotide since 1999.

16. The Food and Drug Administration (“FDA”) has approved Cetrotide as a safe and effective medication.

17. Cetrotide has reduced the hemorrhaging that had plagued Mrs. Layzer, and it has stabilized her tumor growth. That is why Robert Bast, M.D., Mrs. Layzer’s oncologist at the University of Texas M.D. Anderson Cancer Center, has prescribed Cetrotide for Mrs. Layzer for the past several years.

18. Dr. Bast’s determination that Cetrotide is medically necessary to Mrs. Layzer has been confirmed by many other doctors, including Dr. Rogerio A. Lobo, former Chairman of the Obstetrics and Gynecology Department at the Columbia University Medical Center; Dr. J. Gregory Mears, a senior medical oncologist at the Columbia University Medical Center; Dr. Andrzej Kudelka, a senior medical oncologist at the Stony Brook Medical Center; Dr. Jimmie Holland, a psychiatric oncologist at the

Memorial Sloan-Kettering Cancer Center; and Dr. Peter E. Schwartz, Assistant Chief of the Obstetrics and Gynecology Department at the Yale–New Haven Hospital.

The Denial of Part D Coverage of Mrs. Layzer’s Prescription

19. Prior to the implementation of Medicare Part D, Mrs. Layzer’s prescription for Cetrotide was covered by her New York City retiree insurance, administered by Group Health Incorporated (“GHI”). With this coverage, Mrs. Layzer’s out-of-pocket co-payment for Cetrotide never exceeded \$40 per month.

20. On July 1, 2005, Mrs. Layzer became eligible for Medicare, the federal program that provides comprehensive health-insurance coverage at affordable cost to persons who are elderly or who have disabilities. Medicare was established by Congress in 1965 to ensure continuity of care, allowing full choice of doctors and hospitals, for groups of people whom private insurers had considered to be “bad risks.”

21. With the Medicare drug benefit, however, the only way that people with Medicare, including Mrs. Layzer, can receive the drug benefit is by buying coverage from a private insurance plan.

22. In January 2006, after the implementation of the MMA, Mrs. Layzer’s prescription-drug coverage was modified. Mrs. Layzer’s former employer, the City of New York, moved its retiree members to the City of New York Enhanced Medicare Part D Program, a plan also administered by GHI. Almost immediately, in Mrs. Layzer’s first six weeks of being on this plan, GHI denied Part D coverage of Mrs. Layzer’s Cetrotide prescription.

23. Mrs. Layzer requested a Redetermination of this decision, in accordance with statutory Part D administrative-appeal procedures. On February 10, 2006, GHI issued a Redetermination Notice affirming its denial of Medicare Part D coverage, stating the drug was “not covered under Medicare Part D.” Mrs. Layzer appealed once more. On February 24, 2006, GHI denied coverage again, and again stated that Cetrotide is not covered under the Medicare Part D benefit.

24. In February 2006, GHI announced that it would cover Mrs. Layzer’s Cetrotide for one year (which was later extended another year) under the “enhanced” portion of her plan, but GHI imposed a massive co-payment. From April 2006 to June 2007, Mrs. Layzer paid a co-payment of at least \$7,208 each month.

25. On April 5, 2006, Mrs. Layzer appealed GHI’s denial of coverage to the Independent Review Entity (“IRE”), Maximus Federal Services (“Maximus”).

26. On April 17, 2006, Maximus issued an unfavorable decision, claiming that GHI “is not required to provide coverage for Cetrotide because it is not being used for a medically accepted indication.” The Maximus decision stated that “a medically accepted indication means a use that is approved by the FDA or a use that is supported by one or more citations in [one or more of three enumerated] drug compendia.” The Maximus physician reviewer stated that “while a literature search verified that Cetrotide has anticancer activity in *in vitro* and *in vivo* ovarian cancer models, I can find no evidenced [sic] based medical literature supporting the use of this drug for her clinical condition.”

27. In fact, there has been at least one study of Cetrotide in humans as a treatment for ovarian cancer, and it has been hailed as producing “results [that] are quite remarkable.” Other medical research has shown that Cetrotide is effective against ovarian-cancer cell lines.

ALJ Smith’s Decision Denying Coverage: The Denial Is “Frustrating,” Is “Contrary,” and “Makes No Sense”

28. Mrs. Layzer then appealed the denial of coverage to The Honorable Gary D. Smith, a United States Administrative Law Judge (“ALJ”) with the Office of Medicare Hearings and Appeals (“OMHA”), Midwestern Region.

29. Judge Smith determined, as a factual finding, that “the medical necessity of Cetrotide to treat the Appellant’s ovarian cancer . . . has been firmly established by three prominent and highly qualified physicians who are familiar with the Appellant and with her uniquely serious medical condition.” Judge Smith found that “[t]he evidence clearly establishes that the use of Cetrotide to treat [Mrs. Layzer’s] ovarian cancer is reasonable and necessary.”

30. Judge Smith also found that peer-reviewed medical literature recognizes and supports the use of Cetrotide to treat ovarian cancer.

31. Judge Smith also determined that no other drug on the GHI formulary is as effective as Cetrotide in treating Mrs. Layzer’s cancer.

32. Nonetheless, Judge Smith ruled that Cetrotide was not covered under Medicare Part D. Judge Smith wrote that his own ruling was “frustrating” and that it “makes no sense.”

33. In particular, Judge Smith noted that his ruling created a discrepancy in Medicare’s coverage of Mrs. Layzer’s Cetrotide prescription: Part D would not cover it, but Part B—the part of Medicare that covers outpatient care and certain medications administered by doctors—would. As Judge Smith noted, “It seems contrary to allow Medicare Part B coverage of an ‘off-label’ use that is supported by peer reviewed literature, yet not allow Medicare Part D coverage” of the very same use.

**The MAC’s Failure To Render a
Decision Within the 90-Day Time Limit**

34. Mrs. Layzer appealed Judge Smith’s decision to the Medicare Appeals Council (“MAC”) on April 23, 2007.

35. As of September 25, 2007, the MAC had taken no action on Mrs. Layzer’s appeal. On that day, through counsel, Mrs. Layzer wrote to the MAC, stating that the 90-day time limit for MAC review, as established by the regulations governing Medicare Parts A and B—and arguably incorporated into Parts C and D—had expired. She therefore requested that her appeal be escalated to federal district court, as the Parts A and B regulations permit.

36. On the same day, the MAC wrote back to Mrs. Layzer, through its counsel. The MAC took the position that the 90-day time limit that applies to Medicare Parts A and B does not apply to Medicare Part D. The MAC therefore denied Mrs. Layzer’s request that her appeal be escalated to federal district court. The MAC failed to acknowledge any limit on the time that it could take to review Mrs. Layzer’s case, and effectively took the position that unlike an appeal under Part A or Part B, a

Part D appeal can never be escalated to federal district court. No reason was given for this determination.

37. Mrs. Layzer replied on the following day, September 26, 2007. In this letter, Mrs. Layzer asserted that the 90-day time limit that applies to the rest of Medicare should apply to Medicare Part D as well. Mrs. Layzer also told the MAC that she “reserve[d] her rights to construe the [MAC’s denial] Letter as a notice under 42 C.F.R. § 405.1132(a)(2) and to act accordingly.”

38. The MAC then remanded Mrs. Layzer’s case to Judge Smith, ostensibly because the MAC had not been able to locate two exhibits in the record. The MAC’s remand letter, issued on October 23, 2007, was the first indication that Mrs. Layzer ever received that any exhibit was missing from the record.

39. On November 12, 2007, Mrs. Layzer sent Judge Smith copies of the two exhibits that the MAC had stated were missing from its record. (Judge Smith had previously had at least one of these exhibits in his possession, because Mrs. Layzer first received it from Judge Smith’s office.)

40. As of this date, Mrs. Layzer’s case remains with Judge Smith. Judge Smith’s decision of February 22, 2007, is therefore the last HHS decision on whether Mrs. Layzer is entitled to Part D coverage of her Cetrotide prescription.

41. Mrs. Layzer has appealed to her Part D plan, to the Part D IRE, to Judge Smith, and to the MAC. These four appeals have taken 22 months, and there is no end in sight. Mrs. Layzer has exhausted her administrative remedies.

42. In addition, to wait still further for the MAC to decide Mrs. Layzer's appeal would, on information and belief, be futile. In another appeal raising exactly the same legal issue, the MAC reversed an ALJ's decision that was favorable to the Part D beneficiary. The MAC's decision in that appeal was dated October 31, 2007. That decision emphasized that the MAC lacks the authority to consider the argument that Mrs. Layzer raises here—that the HHS regulations that limit the definition of "covered Part D drug" are inconsistent with the plain meaning of the governing statute.

COUNT ONE
(Medicare Prescription Drug Improvement and Modernization Act,
42 U.S.C. § 1395w-101 *et seq.*)
The Secretary Has Failed To Ensure Prescription-Drug
Coverage for a Beneficiary Statutorily Entitled to Such Coverage

43. Mrs. Layzer incorporates by reference the allegations of paragraphs 1 through 42 of this Complaint as if fully set forth herein.

44. Under the MMA, as of January 1, 2006, every eligible person is entitled to prescription-drug coverage under a Part D plan. The Secretary has the statutory duty to ensure that each eligible participant in Part D receives access to "covered Part D drugs."

45. The Secretary has failed to ensure that Mrs. Layzer, an eligible and enrolled Part D participant, receives coverage for a "covered Part D drug."

46. As a result, Mrs. Layzer has been denied her statutory right to prescription-drug coverage under Part D.

47. Mrs. Layzer has also sustained money damages for which she is entitled to reimbursement.

COUNT TWO
(Administrative Procedure Act, 5 U.S.C. § 706(1))
The Secretary Has Unlawfully Failed To Prevent the
Denial of Coverage of a Medically Required Covered Part D Drug

48. Mrs. Layzer incorporates by reference the allegations of paragraphs 1 through 47 of this Complaint as if fully set forth herein.

49. Under the MMA, the Secretary has a statutory duty to provide access to all “covered Part D drugs.”

50. In Mrs. Layzer’s case, the Secretary has unreasonably withheld a statutorily required determination and has unlawfully failed to take a required action.

51. The Secretary’s failure to make a legally required determination, and to take a required action, has damaged Mrs. Layzer.

52. As a result of the Secretary’s failures, Mrs. Layzer has been denied her statutory right to Medicare Part D coverage of her Cetrotide prescription.

COUNT THREE
(Administrative Procedure Act, 5 U.S.C. § 706(2))
The Secretary’s Actions Are Arbitrary and
Capricious in Violation of the APA and the MMA

53. Mrs. Layzer incorporates by reference the allegations of paragraphs 1 through 52 of this Complaint as if fully set forth herein.

54. The action of the Secretary in denying Part D coverage of Mrs. Layzer’s Cetrotide prescription is unlawful and should be set aside for depriving a Medicare beneficiary of statutory right as provided by the MMA.

55. The finding of the Secretary that Cetrotide as used by Mrs. Layzer is not a covered Part D drug should be set aside as unlawful, short of statutory right, unwarranted by the facts, and arbitrary and capricious.

PRAYER FOR RELIEF

WHEREFORE, Mrs. Layzer respectfully requests that this Court enter judgment:

- a. Declaring that a prescription drug need not be prescribed for a “medically accepted indication,” as defined by 42 U.S.C. § 1396r-8(k)(6), to be a “covered Part D drug,” as defined by 42 U.S.C. § 1395w-102(e);
- b. Declaring that Cetrotide, as used by Mrs. Layzer to treat her ovarian cancer, is a “covered Part D drug”;
- c. Enjoining the Secretary from denying Part D coverage of Mrs. Layzer’s Cetrotide prescription;
- d. Directing the Secretary immediately to ensure that the Medicare Part D program covers Mrs. Layzer’s Cetrotide prescription;
- e. Awarding to Mrs. Layzer such money damages as she has sustained, together with interest thereon;
- f. Awarding Mrs. Layzer her costs and expenses incurred or advanced in this action, as well as reasonable attorneys’ fees; and

g. Granting Mrs. Layzer such other and further relief as this Court
may deem just and proper.

Dated: New York, New York
November 26, 2007

Robert M. Hayes (RH6136)
Medicare Rights Center
520 Eighth Ave.
North Wing, 3rd Floor
New York, New York 10018
phone 212-869-3850
fax 212-869-3532

Jeremy C. Bates (JB2112)
125 Broad Street, 32d Floor
New York, New York 10004-2498
phone 212-558-4000
fax 212-558-3588

*Attorneys for Plaintiff
Judith M. Layzer*