

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA**

Case No.

_____)	
DONALD DOBSON,)	
)	
Plaintiff,)	
)	
v.)	COMPLAINT
)	
ALEX M. AZAR II, Secretary of Health)	
Health and Human Services,)	
)	
Defendant.)	
_____)	

I. PRELIMINARY STATEMENT

1. The Plaintiff, Donald Dobson, is a Medicare beneficiary who is enrolled in a Medicare prescription drug plan (Part D plan) and who sought coverage from his plan for a medically necessary prescribed medication, dronabinol. This complaint is for judicial review of a final decision of the Secretary, made by the Medicare Appeals Council (Council) on February 12, 2018, denying coverage of the medication. Mr. Dobson requires dronabinol for treatment of his debilitating nausea and vomiting. The Secretary does not question Mr. Dobson’s medical need for dronabinol, but has denied coverage based on an overly narrow interpretation of what constitutes a “medically accepted indication” under the statute.

II. THE PARTIES

2. The Plaintiff, Donald Dobson, is a 49-year-old resident of Florida who lives in Monroe County. He is, and has been, a Medicare beneficiary at all times relevant to this action.

3. Defendant, Alex M. Azar II, is the Secretary of the United States Department of Health and Human Services ("Secretary") and as such is responsible for the administration of the Social Security Act and the Medicare Program. The Secretary is the proper Defendant in this appeal of a Council decision, and is being sued in his official capacity. *See* 42 C.F.R. § 423.2136.

III. VENUE

4. Venue is proper in this District, by reason of the Plaintiff's residence in Monroe County, Florida. 42 C.F.R. § 423.2136(b).

IV. JURISDICTION

5. The Plaintiff brings this action, pursuant to 42 U.S.C § 1395w-104(h)(1) which incorporates the requirements of 42 U.S.C. § 1395w-22(g)(5) and 42 U.S.C. § 405(g), to appeal a final decision of the Secretary that denied coverage for dronabinol. The Plaintiff has exhausted his administrative remedies. The Administrative Law Judge (ALJ) Appeal Number is 1-6447640885. The Council docket number is M-18-1078. This complaint is timely filed, within sixty days, of the Plaintiff's receipt of the February 12, 2018 Council denial.

V. FACTS AND ADMINISTRATIVE PROCEEDINGS

6. The Plaintiff is a Medicare beneficiary due to disability. His Part D drug plan is administered by UnitedHealthCare. He enrolled in the Part D plan on October 1, 2015. He has severe nausea and vomiting, which did not respond to treatment until he was prescribed dronabinol.

7. In August 2009, the Plaintiff was working as a behavioral therapist at a juvenile treatment facility and was in good health. He was injured while restraining a patient, and suffered hyperflexion of his neck and apparent spinal cord injury. As a result of this injury he had surgery in September 2009. Postoperatively, it was discovered that there was a failure of the

hardware that was implanted, and he needed another surgery, in December 2009, as a “revision” to the previous surgery. Since that time the Plaintiff has had constant severe neck pain and cyclic vomiting. According to a March 2017 letter from his treating physician, Dr. Shaun Corbett, the Plaintiff has debilitating nausea and vomiting on an almost daily basis.

8. The Plaintiff was diagnosed with Eagle Syndrome and central cord syndrome, which have caused him to experience severe nausea and vomiting for many years. The Plaintiff has been prescribed dronabinol by Dr. Corbett since 2015 for palliative treatment of the symptoms of nausea and vomiting related to his conditions. His nausea and vomiting did not respond to treatment until he received dronabinol.

9. The Plaintiff’s treating physician requested coverage of dronabinol from the Plaintiff’s Part D plan. The plan denied coverage on December 8, 2016. The Plaintiff timely appealed the denial to the UnitedHealthCare Part D Appeals and Grievances Department on February 1, 2017. The plan denied his appeal on February 7, 2017.

10. The Plaintiff timely filed a reconsideration request with the Part D Independent Review Entity (IRE), on April 4, 2017. Enclosed with the appeal was a letter from Dr. Corbett, dated March 16, 2017, explaining that dronabinol is necessary for treatment for his symptoms and to prevent serious medical complications, and that other therapies have been tried and failed. On May 8, 2017, the IRE denied coverage.

11. The Plaintiff then timely requested a hearing with an ALJ. A telephonic hearing was held on August 14, 2017, during which Mr. Dobson testified. Included in the record before the ALJ was another letter from Dr. Corbett, dated July 26, 2017, stating that the Plaintiff’s “use of Dronabinol for the nausea and vomiting associated with Central Cord Syndrome and Eagle’s

Syndrome is supported by the DRUGDEX compendium citation for ‘Nausea and vomiting, Disease related, treatment refractory.’”

12. The Plaintiff argued to the ALJ that because his use of dronabinol was supported by one or more citations included in DRUGDEX (one of the Medicare-approved compendia), it met the definition of a “medically accepted indication” and should be covered. *See* 42 U.S.C. §§ 1395w-102(e), 1396r-8(k)(6). The Plaintiff also argued that his case was analogous to *Tangney v. Burwell*, 186 F. Supp. 3d 45 (D. Mass. 2016), which held that a Part D plan must cover dronabinol for a beneficiary who, like Mr. Dobson, also suffered from treatment refractory nausea and vomiting. *Tangney* held that the beneficiary’s use of dronabinol was supported by the DRUGDEX citation for “Nausea and vomiting, Disease-related, treatment refractory,” even though her specific condition was not discussed in that entry, because she was using the medication to treat her symptoms and not her underlying disease. *Id.* at 57.

13. On September 26, 2017 the ALJ issued an unfavorable decision, denying the Plaintiff’s claim for Medicare Part D coverage of dronabinol. The ALJ did not address the Plaintiff’s main legal arguments.

14. The Plaintiff then timely requested review by the Council, which issued a decision on February 12, 2018. The Council decided that the Part D plan was not required to cover the Plaintiff’s use of dronabinol. It declined to adopt the reasoning of the *Tangney* court and held, *inter alia*, that the DRUGDEX citation on which the Plaintiff chiefly relies is solely applicable to nausea and vomiting related to metastatic cancer of the gastrointestinal mucosa that is treatment refractory.

15. The Plaintiff timely appeals from the final, February 12, 2018 decision of the Secretary and is properly before this Court. The amount in controversy exceeds \$1600.00.

16. Donald Dobson's use of dronabinol is for a medically accepted indication within the meaning of §1927(k)(6) of the Social Security Act, 42 U.S.C. §1396r-8(k)(6). He is entitled to Medicare coverage of this drug.

VI. CAUSE OF ACTION

17. The Secretary's decision denying the Plaintiff's claim for Medicare coverage of dronabinol is not supported by substantial evidence and is incorrect as a matter of law, on the following grounds:

- A. Substantial evidence, when the record is reviewed as a whole, supports that dronabinol is a covered Part D drug for the Plaintiff.
- B. The Secretary's decision is based on errors of law in that the Council's decision was made without legal basis and its interpretation of "medical accepted indication" is unlawfully restrictive.

VII. REQUEST FOR RELIEF

WHEREFORE, the Plaintiff requests this Honorable Court to:

- 1. Reverse and set aside the decision of the Secretary and award such benefits as to which Plaintiff is entitled;
- 2. Award Plaintiff reasonable attorney's fees and costs; and
- 3. Grant Plaintiff such additional and alternative relief as equity and justice may require.

DATED: April 6, 2018

Respectfully submitted

/s/Miriam Harmatz
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