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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

CHERYL HOUGH,

Plaintiff,

v.

XAVIER BECERRA, Secretary of Health and
Human Services,

Defendant.

Civil Action No. _____

COMPLAINT

Plaintiff Cheryl Hough, a natural person residing at [REDACTED] [REDACTED] complains against Xavier Becerra, the Secretary of the United States Department of Health and Human Services, with a principal place of business at 200 Independence Avenue SW, Washington, District of Columbia 20201, as follows:

NATURE OF THE ACTION

1. Plaintiff Cheryl Hough is a Medicare beneficiary who is enrolled in a Medicare prescription drug plan (Part D plan) and who sought coverage from her plan for a medically-

necessary prescribed medication: dronabinol. Ms. Hough seeks judicial review of a final decision of the Secretary, made by the Medicare Appeals Council (the “Council”) on September 27, 2022, denying coverage of the medication. Ms. Hough requires dronabinol for treatment of her debilitating and intractable nausea and vomiting related to gastroparesis, a disease of the digestive system. The Secretary does not question Ms. Hough’s medical need for the drug or its effectiveness, but he has denied coverage based on an overly narrow interpretation of what constitutes a “medically accepted indication” under the statute. Plaintiff seeks reversal of the Secretary’s denial of coverage and declaratory and injunctive relief.

THE PARTIES

2. Plaintiff, Cheryl Hough, is a 68-year-old resident of New Jersey who lives in [REDACTED]. She is and has been a Medicare beneficiary at all times relevant to this action.

3. Defendant, Xavier Becerra, is the Secretary of the United States Department of Health and Human Services (the “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. 42 C.F.R. § 423.2136(d)(1). He is sued in his official capacity.

JURISDICTION AND VENUE

4. 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. Plaintiff has exhausted her administrative remedies. The Administrative Law Judge (“ALJ”) Appeal Number is 3-10828831662. The Council Docket Number is M-22-5134. This Complaint is timely filed, within 60 days of Plaintiff’s receipt of the Council’s September 27, 2022 denial. Jurisdiction is also conferred by 28 U.S.C. § 1331. Plaintiff seeks a declaration of rights pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. Venue is proper in this District by reason of Plaintiff's residence in New Jersey. 42 C.F.R. § 423.2136(b).

LEGAL FRAMEWORK

6. Medicare is the federal health insurance program for people who are at least age 65 or who have certain disabilities. In 2003, Congress added an outpatient prescription drug benefit, known as Medicare Part D, to the program. 42 U.S.C. § 1395w-101 *et seq.* The Secretary contracts with private insurance companies that are approved to sell and administer Part D plans. *Id.* § 1395w-111(b)-(e). Medicare pays for covered Part D drugs, subject to deductible, copayment, and/or coinsurance amounts that are the responsibility of beneficiaries. *See, e.g., id.* § 1395w-102(b).

7. A Medicare Part D plan will only cover the cost of “covered Part D drug[s].” 42 U.S.C. § 1395w-102(e)(1). The statute defines “covered Part D drug[s]” as those that are used “for a medically accepted indication.” *Id.* A “medically accepted indication” is defined in turn as “any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).” *Id.* § 1396r-8(k)(6) (emphasis added); *see also id.* § 1395w-102(e)(4)(A)(ii) (incorporating definition from § 1396r-8(k)(6) into the Medicare statute).

8. In other words, Medicare Part D covers uses approved by the FDA, as well as “off-label” uses—*i.e.*, those *not* approved by the FDA—as long as they are “supported by...[a] citation[]” in one of the approved drug compendia. 42 U.S.C. § 1396r-8(k)(6). The drug compendia are commercial reference sources containing a variety of information about prescription pharmaceuticals.

9. One of the approved drug compendia is Drugdex. 42 U.S.C. § 1396r-8(g)(1)(B)(i). Drugdex cites two FDA-approved uses for dronabinol, the medication in question in this case, neither of which applies to the Plaintiff. It also cites six off-label, non-FDA approved uses. For each use, the Drugdex citation provides an overview of the particular use, its efficacy, grade of recommendation, and strength-of-evidence ratings. It also includes a summary with an explanation of the evidentiary basis for each use. *See Dobson v. Sec’y of Health & Human Servs.*, No. 20-11996, 2022 WL 424813, at *3 (11th Cir. Feb. 11, 2022).

10. One of the off-label uses of dronabinol listed in Drugdex is “Nausea and vomiting, Disease-related, treatment refractory.” The citation states that “[e]vidence favors efficacy,” for this use, and it lists the strength of evidence as Category C, meaning the evidence is “derived from: Expert opinion or consensus, case reports or case series.” *Dobson*, 2022 WL 424813, at *3 (quoting Drugdex, internal quotation marks omitted). The citation also has a “class IIb” recommendation, meaning the medication is “recommended, in some cases” for the use in question. *Id.*

11. For the “Nausea and vomiting, Disease-related, treatment refractory” use, Drugdex summarizes a case study published in the *Journal of Pain and Symptom Management*, a peer-reviewed medical journal covering “the relief of illness burden among patients afflicted with serious or life-threatening illness.” *Tangney v. Burwell*, 186 F. Supp. 3d 45, 49 n.8 (D. Mass. 2016). It discusses a patient diagnosed with metastatic cancer of the gastrointestinal mucosa (lining of the stomach). The authors “characterize the Patient’s ‘main problem’ as ‘intractable nausea and vomiting unresponsive to conventional antiemetics.’” *Id.* at 50.

12. The Drugdex citation explains that the patient’s “severe nausea and vomiting,” which were principally attributed to his gastrointestinal cancer, did not respond to several medications. Eventually, doctors prescribed dronabinol, which succeeded in alleviating the

patient's nausea and vomiting. *Dobson*, 2022 WL 424813, at *3; *see also id.* (“after the study patient was administered dronabinol, his nausea and vomiting completely abated”). The study's authors posited that dronabinol worked by “indirect inhibition of the vomiting center in the medulla as a result of binding to opiate receptors in the forebrain.” *Id.* (quoting study).

FACTUAL BACKGROUND AND ADMINISTRATIVE PROCEEDINGS

13. Cheryl Hough, Plaintiff, is a Medicare beneficiary and is currently enrolled in a Part D drug plan administered by OptumRx. She receives her Medicare benefits through New Jersey's School Employees' Health Benefits Program. After over three decades of teaching, Ms. Hough became disabled and stopped working due to her health problems in or around 2010.

14. Ms. Hough was diagnosed with late-onset Type 1 diabetes in or around 2009 and related gastroparesis in or around 2010. Gastroparesis, or partial paralysis of the stomach, “is a disease in which your stomach can't empty itself of food in a normal fashion.” Cleveland Clinic, *Gastroparesis*, <https://my.clevelandclinic.org/health/diseases/15522-gastroparesis>.

15. As she testified at her ALJ hearing, Plaintiff experiences severe symptoms from her condition, including extreme nausea, vomiting, abdominal pain, and bloating. She stated that she is unable to do anything when she has an attack. Ms. Hough suffered for years, and tried several medications for her nausea and vomiting that were ineffective or contraindicated. It was only when dronabinol was added to her medication regimen that she found effective relief.

16. Ms. Hough received coverage of dronabinol until around 2018 when her Part D plan sponsor changed to OptumRx. She has since been forced to pay for dronabinol out of pocket without any Medicare coverage.

17. The OptumRx formulary requires prior authorization for coverage of dronabinol. Plaintiff's treating physician provided supporting information for his prescription of dronabinol in January 2022, after which the plan denied prior authorization of the claim under review. Plaintiff

then timely appealed to the Independent Review Entity (“IRE”). The IRE denied coverage on February 14, 2022, stating that coverage was not required because the drug was not prescribed for a medically accepted indication.

18. Plaintiff then timely requested a hearing with an ALJ. A telephonic hearing was held on May 25, 2022. Ms. Hough did not have assistance of counsel; her husband acted as her appointed representative at the hearing. OptumRx was represented at the hearing by one of its pharmacists.

19. On June 8, 2022, the ALJ denied Plaintiff’s appeal for Medicare Part D coverage of dronabinol. In her decision, the ALJ “accept[ed] as true that the Enrollee has received significant relief from her symptoms of nausea and vomiting with Dronabinol.” ALJ Decision at 4.

20. The ALJ noted that Drugdex “includes intractable nausea and vomiting as an off-label use,” but stated that “this was limited to intractable nausea and vomiting specifically related to metastatic cancer of the gastrointestinal mucosa, as described in the summary discussing the off-label use for intractable nausea and vomiting.” ALJ Decision at 3-4. The ALJ thus concluded that “...the use of Dronabinol for diabetic gastroparesis is not a medically accepted indication, nor does it fall under the non-FDA approved uses category of ‘Nausea and vomiting, Disease-related, treatment refractory.’” *Id.* at 4.

21. Plaintiff timely requested review by the Medicare Appeals Council, again without assistance of counsel. The Council issued a decision on September 27, 2022. The Council noted that Ms. Hough “has a diagnosis of diabetic gastroparesis and was prescribed dronabinol to treat her associated nausea and vomiting.” It also stated that “we acknowledge the appellant’s assertions regarding the medical necessity of the drug and we do not question the efficacy of the drug in helping to ease the patient’s symptoms.” Council Decision at 2.

22. The Council affirmed the ALJ’s decision and stated that “there are no entries in the approved compendia that support the off-label use of dronabinol ... to treat the appellant’s condition.” It concluded that the Part D plan was not required to cover the medication. Council Decision at 3.

23. Plaintiff timely appeals from the final decision of the Secretary and is properly before this Court. The amount in controversy exceeds \$1,760.00. 42 C.F.R. §§ 423.2136(a)-(d).

24. The Secretary has interpreted the relevant statutory provision – “supported by [a] citation[.]” – incorrectly. *See Dobson*, 2022 WL 424813, at *1, *6-*7 (“Nothing about the common meaning of ‘support’ means that a compendium citation must hyperspecifically identify a prescribed off-label use to tend to show or help prove its efficacy and safety.”); *see also Tangney*, 186 F. Supp. 3d at 55-58.

25. Ms. Hough’s use of dronabinol is for a medically accepted indication within the meaning of § 1972(k)(6) of the Social Security Act, 42 U.S.C. § 1396r-8(k)(6). She is entitled to Medicare coverage of the medication.

26. Ms. Hough’s need for dronabinol is ongoing. She has been and continues to be harmed by the Secretary’s denial of coverage of dronabinol. As an enrollee in New Jersey’s state plan for school employees, she lacks control over which Medicare Part D plan administers her benefits; the plan is likely to change again as it did in or around 2018. She requires declaratory and injunctive relief to fully redress the harms caused by the Secretary’s actions. There is no other adequate remedy available to her.

CAUSE OF ACTION: VIOLATION OF MEDICARE STATUTE

27. Plaintiff realleges and incorporates the foregoing paragraphs as if fully set forth herein.

28. The Secretary's decision denying Plaintiff's claim for Medicare coverage of dronabinol is not supported by substantial evidence and is incorrect as a matter of law, including 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 "medically accepted indication" is unlawfully restrictive.

WHEREFORE, Plaintiff requests that this Honorable Court:

- a. Reverse the decision of the Secretary and award the coverage of dronabinol to which Plaintiff is entitled;
- b. In the alternative, remand the case to the Secretary with instructions to order Medicare to cover Plaintiff's use of dronabinol to treat her nausea and vomiting related to gastroparesis;
- c. Declare that the Secretary's practice of interpreting "medically accepted indication" to require a compendium citation to hyperspecifically identify Plaintiff's off-label use of dronabinol for nausea and vomiting related to gastroparesis, rather than to tend to show or help prove the efficacy and safety of her prescribed off-label use, violates the Medicare statute;
- d. Grant a permanent injunction prohibiting the Secretary from interpreting "medically accepted indication" to require a compendium citation to hyperspecifically identify Plaintiff's off-label use of dronabinol for nausea and vomiting related to gastroparesis to "support" her off-label use, and requiring the Secretary to instead interpret the statute to require a

compendium citation to tend to show or help prove the efficacy and safety of her prescribed off-label use;

e. Award Plaintiff reasonable attorneys' fees and costs; and

f. Grant Plaintiff such additional and alternative relief as may be just and proper under the circumstances of the case.

Certification Pursuant to L. Civ. R. 11.2

The undersigned certifies, in accordance with L. Civ. R. 11.2, that to the best of his knowledge, there are no other proceedings either pending or contemplated with respect to the matter in controversy in this action and that, at this time, there are no other parties known who should be joined in this action.

DATED: November 18 , 2022

Respectfully submitted,

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