



FLORIDA HEALTH JUSTICE PROJECT

FOR IMMEDIATE RELEASE

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Federal appeals court rules Medicare must cover patient's "off-label" prescription

ATLANTA — The U.S. Court of Appeals for the 11th Circuit **found Feb. 11** that Medicare must provide coverage for a beneficiary's off-label use of a medication in a case brought on behalf of Florida resident Donald Dobson, who had been denied coverage for a critically needed medication.

Dobson, who was represented by lead counsel Center for Medicare Advocacy and co-counsel Florida Health Justice Project and Akin Gump Strauss Hauer & Feld, had been denied coverage for dronabinol (brand name Marinol), under his Medicare Part D plan. He could not afford the drug without coverage, and it was the only medication that had proven effective for the constant and severe suffering cause by his intractable nausea and vomiting. His doctors had tried numerous other medications in vain; nothing worked except dronabinol.

Miriam Harmatz, advocacy director and founder of the Florida Health Justice Project, said the ruling, which overturned the lower court's decision, is consistent with other federal court Medicare and Medicaid cases concerning coverage of drugs used to treat "off-label" conditions, meaning it was for a non-FDA approved use. Off-label prescribing is a routine and necessary medical practice, and both the Medicare and Medicaid statutes require coverage if the drug is prescribed for a "medically accepted indication," which the statutes define as a use which is either approved by the FDA (an "on-label" use) or a use which is supported by citation(s) in one of the Congressionally specified compendia. These cases include *Tangney v. Burwell*, a nearly identical case in Massachusetts, and *Edmonds v. Levine*, a Florida Medicaid case.

“This ruling not only ensures that Mr. Dobson will get the medication he desperately needs, but it will also help ensure appropriate application of both Medicare and Medicaid law governing off-label uses in other cases,” Harmatz said.

Alice Bers, litigation director for the Center for Medicare Advocacy said the decision is both logical and humane. “We are grateful for the court’s thorough analysis,” Bers said.

The legal advocates argued that the Medicare agency was using an overly narrow interpretation of the law to deny coverage of a drug that it did not dispute was medically necessary for Dobson.

The 11th Circuit agreed, finding that for an off-label use to be “supported by” a compendium citation, the citation need only “tend to show or help prove the efficacy and safety of the prescribed off-label use,” not “that the citation must match the prescribed off-label use precisely.”

Using this commonsense meaning of the word “support,” the court concluded in [Dobson v. Secretary of Health & Human Services](#), No. 20-11996, 2022 WL 424813 (11th Cir. Feb. 11, 2022) that Medicare must cover Dobson’s off-label use of dronabinol.

The Center for Medicare Advocacy plans to issue additional material with further details and practice tips for advocates in light of the decision, assuming it stands.

About the Florida Health Justice Project

The [Florida Health Justice Project](#) seeks to improve access to affordable health care for Floridians, with a focus on vulnerable low-income populations. FHJP expands the advocacy community’s capacity to resolve individual access issues and educate consumers; identify and address systemic barriers to healthcare; and protect Medicaid and other safety-net programs.

About the Center for Medicare Advocacy

The [Center for Medicare Advocacy](#) is a national, non-profit law organization that works to advance access to comprehensive Medicare coverage, health equity, and quality health care for older people and people with disabilities by providing exceptional legal analysis, education, and advocacy.

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