

No.

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**IN THE SUPREME COURT OF THE UNITED STATES**

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THERESE M. WATERS, on behalf of KELLY E. WATERS,  
*Petitioner,*

- v. -

XAVIER BECERRA, Secretary of Health & Human Services  
*Respondent.*

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**APPLICATION TO THE HONORABLE BRETT M. KAVANAUGH  
FOR AN EXTENSION OF TIME WITHIN WHICH TO FILE A  
PETITION FOR A WRIT OF CERTIORARI TO THE UNITED  
STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT**

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To the Honorable Brett M. Kavanaugh, as Circuit Justice for the United States Court of Appeals for the Sixth Circuit:

Pursuant to this Court's Rules 13.5, 22, 30.2, and 30.3, Petitioner Therese M. Waters, on behalf of Kelly E. Waters, respectfully requests that the time to file her Petition for Writ of Certiorari in this matter be extended 45 days, up to and including March 15, 2024. The Sixth Circuit Court of Appeals issued its Opinion on September 11, 2023. That Opinion and the Court's Judgment are attached. The Court of Appeals denied rehearing and rehearing *en banc* on November 1, 2023. That Order is also attached. Absent an extension of time, the Petition for Writ of Certiorari would be due on January 30, 2023. Petitioner is filing this Application more than 10 days before that date. S. Ct. R. 13.5. This Court would have jurisdiction over the judgment under 28 U.S.C. 1254(1). Respondent, through his counsel, does not object to the requested extension.

### **Introduction**

The Secretary provides enteral formula benefit coverage as a prosthetic device under 42 U.S.C. §1395x(s)(8) to Medicare beneficiaries suffering from gastrointestinal tract dysfunctions who cannot ingest regular foods and are treated with enteral formula administered through a feeding tube. The Secretary denied enteral formula benefit coverage as a prosthetic device under 42 U.S.C. §1395x(s)(8) to the Beneficiary who suffers from Homocystinuria, a genetic defect which prevents her liver from metabolizing the proteins in regular foods, because she takes her enteral formula orally, not through a feeding tube. The Secretary thus denied coverage based upon which of the Beneficiary's internal organs is dysfunctional and

the means of delivering her enteral formula. He did so notwithstanding the fact that the Medicare Act covers all internal organ dysfunctions except for dental.

The Secretary argued that “. . . even if this Court concluded that the relevant authorities were ambiguous, it should still affirm because the Secretary’s interpretation is entitled to deference.”<sup>1</sup> Both lower Courts deferred to the Secretary’s interpretation of his Medicare contractor’s Policy Article notwithstanding the fact that the Policy Article did not specifically exclude coverage for persons with permanent impairments and offered no reason whatsoever for doing so.

This case presents questions of significant jurisprudential importance. 50% of homocystinuria patients die before age 25 if not treated.<sup>2</sup> The Circuit Court’s holding that enteral formula is not a covered benefit will affect beneficiaries suffering from at least five rare amino acid metabolism disorders: Homocystinuria, Argininosuccinic Acidemia, Citrullinemia, Maple Syrup Urine Disease (MSUD) and Phenylketonuria (PKU), each of which has been detected in the population at a rate of between 0.36 to 4.64 persons per 100,000 and all of which are treated by “Life-long, orally-administered” amino acid modified enteral formulas.<sup>3</sup> There are also three Organic Acid Metabolism Disorders and one Fatty Acid Disorder that will be affected by the decision in this case.<sup>4</sup> In a country of 335,000,000, the Secretary’s decision to exclude those beneficiaries from enteral formula benefit coverage will affect tens of thousands of persons.

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<sup>1</sup> Brief of Appellee, Document 22, Pages: 30, 34-38.

<sup>2</sup> ECF No. 13, PageID #303.

<sup>3</sup> ECF No. 13, PageID #308.

<sup>4</sup> *Id.*

## Background

The Beneficiary's University of Michigan physician and medical professor prescribed an orally administered amino acid modified enteral formula to treat her homocystinuria. That enteral formula omits the amino acid methionine that the Beneficiary's liver cannot metabolize and contains the amino acid L-cysteine that her liver cannot produce.

The Beneficiary's enteral formula is only available by prescription and is classified by the FDA as "a medical food defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. §360ee(b)(3)) [as] 'a food which is formulated to be *consumed or administered* enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.' FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food. (21 C.F.R. 191.9(j)(8))."<sup>5</sup>

The Secretary's Food and Drug Administration specifically recognizes that "enteral feeding can be achieved by *oral intake or tube*."<sup>6</sup>

The Secretary's National Institutes of Health ("NIH") recognizes that the treatment of homocystinuria includes ". . . a methionine-free amino acid formula

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<sup>5</sup> ECF No. 13, PageID #354; See also, <https://www.fda.gov/media/97726/download>, page 4, updated March 2023. (emphasis added)

<sup>6</sup> ECF No. 13, PageID #353; See also, <https://www.fda.gov/media/97726/download>, pages 4 & 8, updated March 2023. (emphasis added)

supplying the other amino acids (as well as cysteine, which may be an essential amino acid in CBS deficiency) is provided. \* \* \* ”<sup>7</sup>

The relevant statutory provisions include:

- (i) 42 U.S.C. §1395x(s)(8) which provides benefit coverage for “prosthetic devices (other than dental) which replace all or part of an internal body organ,”
- (ii) 42 U.S.C. §1395m(h)(4)(B) which recognizes enteral formula as a covered prosthetic device within 42 U.S.C. §1395x(s)(8),
- (iii) 42 U.S.C. §1395u(s)(2)(D) which identifies “Parenteral and enteral nutrients, equipment and supplies” as items for which the Secretary may implement a ‘statewide or other area wide fee schedule’ under §1395u(s)(1)(A), and
- (iv) National Coverage Determination 180.2 which stated that “Coverage of nutritional therapy [enteral and parenteral nutrition] as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof.”<sup>8</sup>

The Secretary himself confirmed twice that “Enteral nutrition [parenteral and enteral] is covered under the Prosthetic Device benefit (Social Security Act §1861(s)(8)), and coverage is further outlined in the National Coverage Determinations (NCD) Manual (CMS Pub. 100-03), Chapter 1, Section 180.2.”<sup>9</sup> when he retired his contractor’s Policy Article and Local Coverage Determination during the course of these proceedings.

Notwithstanding the foregoing, the Secretary’s position is that enteral formula is not a prosthetic device within 42 U.S.C. §1395x(s)(8), a feeding tube alone is the prosthetic device and “the Beneficiary’s enteral nutrition formula cannot be covered unless it is provided incident to a prosthetic device that replaces all or part of an

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<sup>7</sup> ECF No. 13, PageID #310.

<sup>8</sup> RE 29-6, PageID #544, third full paragraph.

<sup>9</sup> RE 29-13, PageID #562.

internal body organ.”<sup>10</sup> The Secretary has not cited any statute which conditions enteral formula benefit coverage on the use of a feeding tube that is not medically necessary to treat the Beneficiary and is, therefore, excluded from coverage under 42 U.S.C. §1395y(a)(1)(A).

Feeding tubes are inserted through the mouth and into the esophagus, part of the gastrointestinal tract, not into the liver. The Secretary’s argument that enteral formula is not a prosthetic device and is only covered when administered through a feeding tube restricts enteral formula benefit coverage to dysfunctions of the esophagus and gastrointestinal tract only. It excludes all Medicare beneficiaries who suffer from liver dysfunctions from enteral formula benefit coverage notwithstanding the fact that the Act covers all internal organ dysfunctions, except only dental.

The Secretary and lower Courts relied on one sentence in a Medicare contractor’s non-evidence-based Policy Article to deny coverage: “enteral nutrition products that are administered orally and related supplies as noncovered, no benefit” without considering that statement the context of the patients with temporary ingestion impairments it was discussing. If a temporary ingestion impairment partially abates or ceases to exist and that patient can once again consume regular foods, that patient has no need for enteral formula and the Policy Article excluded it from coverage.

The District Court<sup>11</sup> and Circuit Court both concluded that enteral formula is not a prosthetic device within 42 U.S.C. §1395x(s)(8) because it lacks “any degree of

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<sup>10</sup> RE 34, PageID #631; RE 38, PageID #657.

<sup>11</sup> District Court Opinion, RE 42, PageID #680.

lasting permanence outside one’s body.”<sup>12</sup> That inferred permanence requirement conflicts with the Act’s overall purpose which is to provide benefit coverage to disabled persons for items and services which are reasonable and necessary “to improve the functioning of a malformed body member.” 42 U.S.C. §1395y(a)(1)(A).

More importantly, the inferred permanence requirement contradicts 42 U.S.C. §1395m(h)(4)(B) which identifies both short-lived “enteral nutrients” and long-lived “implantable items” as prosthetic devices within 42 U.S.C. §1395x(s)(8). 42 U.S.C. §1395m establishes special payment rules for certain items. While enteral formula is not one of the items subject to those special payment rules, §1395m(h)(4)(B) explicitly recognizes it as a prosthetic device otherwise within 42 U.S.C. §1395x(s)(8) where it states that, for purposes of the special payment rules, “the term ‘prosthetic devices’ has the meaning given such term in section 1861(s)(8) [42 U.S.C. §1395x(s)(8)], **except** such term does not include parenteral and enteral nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1395l(t) of this title.” (emphasis added)

The inferred permanence requirement also contradicts:

- (i) 42 U.S.C. §1395u(s)(2)(D) which identifies “parenteral and enteral nutrients, equipment and supplies” as items for which the Secretary may implement a “statewide or other area wide fee schedule” under §1395u(s)(1)(A),
- (ii) The Secretary’s own statements that “Enteral nutrition is covered under the Prosthetic Device benefit (Social Security Act §1861(s)(8)),”
- (iii) NCD 180.2 which confirmed that the Beneficiary’s enteral formula is a covered benefit as follows: “Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof,”

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<sup>12</sup> Circuit Court Opinion, page 7; See also, pp. 8-9.

- (iv) The NCD's adoption by reference of Chapter 15, §120 of the Medicare Benefits Policy Manual which states "Examples of prosthetic devices include [long-lived] artificial limbs, and [short-lived] parenteral and enteral (PEN) nutrition,"
- (v) 42 C.F.R. §414.104 which states "Payment for PEN [Parenteral and Enteral Nutrients] items and services is made in a lump sum for nutrients and supplies that are purchased..."
- (vi) The NIH's recognition that the standard of care for treating homocystinuria includes ". . . a methionine-free amino acid formula supplying the other amino acids (as well as cysteine, which may be an essential amino acid in CBS deficiency). . .,"
- (vii) The FDA's recognition that "enteral feeding can be achieved by oral intake or tube," and
- (viii) The FDA's recognition that the Beneficiary's enteral formula is "a medical food under 21 U.S.C. §3660ee(b)(3)) which is formulated to be consumed or administered enterally under the supervision of a physician. . ." (emphasis added).

The District and Circuit Court Opinions disregard long established rules of statutory construction. The Circuit Court dismissed 42 U.S.C. §1395m(h)(4)(B) "because those provisions are payment rules." The Circuit Court failed to acknowledge that 42 U.S.C. §1395m(h)(4)(B) and 42 U.S.C. §1395u(s)(1)&(2) are more specific than 42 U.S.C. §1395x(s)(8) and that the canons of statutory construction provide that the more specific statute takes precedence over the more general one. *Edmond v. United States*, 520 U.S. 651, 657 (1997).

The Circuit Court's failure to recognize 42 U.S.C. §1395m(h)(4)(B) and 42 U.S.C. §1395u(s)(2)(D)&(1)(A) also violates the principle of statutory construction that "in interpreting a statute, we do not look at a word or a phrase in isolation. It is fundamental that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Michigan Dept. of Treasury*, 489 U.S. 803, 809 (1989). 42 U.S.C. §1395y(a)(1)(A) identifies the overall statutory scheme here as providing benefit coverage to elderly and disabled persons



for items and services which are reasonable and necessary “to improve the functioning of a malformed body member.”

This Court’s substantial evidence test required the lower courts to determine if the NCD and Policy Article specifically excluded enteral coverage for beneficiaries with permanent impairments who take their enteral formula orally and whether they articulated a “satisfactory explanation” for doing so. *T-Mobile S., LLC v. City of Roswell*, 574 U.S. 293, 301-302 (2015). Neither of the lower Courts’ Opinions do so.

The Circuit Court’s Opinion relied upon limited portions of the NCD and Policy Article to affirm the Secretary’s coverage denial but refused to consider Petitioner’s arguments addressing the remaining text of those same documents because the Petitioner had allegedly failed to exhaust her administrative remedies by challenging the NCD itself. The Court did so notwithstanding the fact that NCD 180.2 confirmed that enteral formula is a covered benefit for the Beneficiary because she has a permanent impairment. The remainder of the text which the Court did not consider merely extended enteral formula benefit coverage to persons who have temporary ingestion impairments.

The Policy Article, Local Coverage Determination and NCD were all retired during the course of this proceeding and cannot now be challenged.

This Court has identified one exception to the requirement in 42 U.S.C. §405(h) that claims “arising under” the Medicare Act be handled through the administrative appeals process and not under section 1331 or 1336 of Title 28. That exception is for instances where “application of § 405(h) would not simply channel review through

the agency, but would mean no review at all.” *Shalala v. Ill. Council on Long Term Care, Inc*, 529 U.S. 1, 19 (2000). That has now occurred.

### **Reasons for Granting an Extension of Time**

This case presents questions of significant jurisprudential importance, including issues of great physical harm and death to Medicare beneficiaries who are denied coverage for orally administered enteral formula.

The undersigned counsel has other obligations including work in Michigan Public Service Commission Case Number U-21049 in which his clients have \$17,018,536 at issue.

Counsel requires the additional requested time to finish researching the issues and prepare an adequate petition for the Court’s consideration.

Counsel for the Secretary has consented to the requested extension and no meaningful prejudice would arise from granting the extension.

### **Conclusion**

For the foregoing reasons, Petitioner hereby requests that an extension of time, to and including March 15, 2024, be granted within which Petitioner may file a petition for a writ of certiorari.

*Respectfully submitted,*  
THE RUNNING WISE LAW FIRM  
ATTORNEYS FOR PETITIONER.

Date: December 27, 2023

By: \_\_\_\_\_

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