UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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Judith M. Layzer and Ray J. Fischer,

Plaintiffs,

- against -

The Hon. Michael O. Leavitt,
Secretary of the United States Department
of Health & Human Services,

Defendant.

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07 Civ. 11339 (HB)

OPINION & ORDER

Hon. Harold Baer, Jr., District Judge:

Judith M. Layzer[1] and Ray J. Fischer ("Plaintiffs") bring this action pursuant to § 205(g) of the Social Security Act (the "Act"), 42 U.S.C. § 405(g), for review of a final decision of the Secretary of Health and Human Services ("Secretary" or "Defendant") that denied them reimbursement for certain prescription drugs. The dispute centers on the question of whether the prescription drugs at issue are covered by Medicare Part D, a voluntary prescription drug benefits program. The Defendant moves for judgment on the pleadings affirming the denial of coverage and dismissing the complaint. Plaintiffs bring a cross-motion for judgment on the pleadings. For the reasons that follow, Secretary's motion is denied and the Plaintiffs' motion is granted.

BACKGROUND

1. The statutory framework

Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. § 1395 *et seq.*, establishes the Medicare program, which provides health insurance to Americans aged 65 and over, as well as Americans with certain qualifying disabilities. The Secretary administers the Medicare program, one component of which is Part D. *See* 42 U.S.C. § 1395w-101 *et seq.* In 2003 Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act ("MMA"), under which a plan sponsor is required to provide coverage of qualified prescription

[1] Mrs. Layzer passed away during this lawsuit and her estate's executor has been substituted in her place.

drugs. 42 U.S.C. §§ 1395w-102-§ 1395w-104. Section 1395w-102(e) of the MMA defines what may be considered a "covered Part D drug" (the "Definition).

The Definition refers to the term "medically accepted indication" as defined at 42 U.S.C. § 1396r-8(k)(6): "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A § 301 *et seq.* (the "FDCA")] or the use of which is supported by one or more citations included or approved for inclusion in any of [three compendia]."[2] The Secretary promulgated a regulation implementing the Definition, and it requires that to be a "covered Part D drug", a drug must be prescribed for a "medically accepted indication." *See* 42 C.F.R. § 423.100.[3] In this case, coverage of the Plaintiffs' drugs was denied because the uses for which the drugs were prescribed were not approved or listed in any of these compendia. Because FDCA approval is not an issue in this case, the "medically accepted indication" requirement set forth in 42 C.F.R § 423.100 will simply be referred to as the "Compendia Requirement."

2. Factual and procedural history

Mrs. Layzer is a Medicare beneficiary with granulose cell tumor, a rare form of ovarian cancer. AR 244. Several oncologists urged her to take the drug Cetrotide to control her cancer, including Robert Bast, M.D., her oncologist at the University of Texas M.D. Anderson Cancer Center, who prescribed the drug for Mrs. Layzer for several years. *See* Compl. ¶ 21, 23; AR 313. According to Dr. Bast, Cetrotide retards the growth of Mrs. Layzer's cancer and prevents her tumors from hemorrhaging. AR 309, 313. He has warned that the medicine "is essential for my patient. There is no substitute at this time. Furthermore, if the medicine is stopped, even tempor[ari]ly, it is likely that the remaining tumors will grow quickly and she will suffer grave

[2] The compendia are (1) the American Hospital Formulary Service Drug Information; (2) the United States Pharmacopeia-Drug Information; and (3) the DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(1)(B)(i).

[3] The regulation reads:

> Part D drug means-
>
> (1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1860D-2(e)(4) of the Act)-
>
> (i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act.
>
> (ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act.

consequences." AR 309. Other physicians have echoed the conclusion that Cetrotide is critical to Mrs. Layzer's treatment. *See* AR 159, 264, 270-71. Peer-reviewed medical literature has also recognized the unique and effective capacity of Cetrotide to treat ovarian cancer. *See* AR 317, 325, 340, 363. Mrs. Layzer's plan sponsor denied full coverage, stating that Cetrotide "is a fertility agent," AR 491, and "not covered under Medicare Part D." AR 304; Compl. ¶ 30.

Mr. Fisher is a Medicare beneficiary diagnosed with myotonic muscular dystrophy type 2 ("DM2"), a rare and degenerative form of muscular dystrophy that results in muscle weakness and cardiac abnormalities, among other things. AR 700. The drug Increlex proved significantly helpful in slowing or stopping the deterioration of Mr. Fisher's muscle; it also helped him regain strength and range of motion, and allowed him to function without a hand-arm tremor. AR 693, 756. Mr. Fisher's physician, Richard Moxley, M.D., Director of Research at the Rochester Medical Center's Neuromuscular Disease Center, noted that Increlex has "helped to optimize [Mr. Fisher's] quality of life and maintain his present level of independence." AR 650. Mr. Fisher's plan sponsor denied coverage, explaining that Increlex "is not FDA approved for the diagnosis provided." AR 622.

On appeal, the respective denials of coverage were affirmed by a Medicare Part D Independent Review Entity, which concluded that the plan sponsors were not required to provide coverage because the drugs were not being used for a medically accepted indication. AR 308, 666. It explained that "a medically accepted indication means a use that is approved by the FDA [sic] or a use that is supported by one or more citations in . . . drug compendia." AR 308.

The Plaintiffs' respective denials were again affirmed by Administrate Law Judges. Judge Smith found that "the medical necessity of Cetrotide to treat [Mrs. Layzer's] ovarian cancer . . . has been firmly established . . . No other drug on the Plan's formulary is as effective as Cetrotide for treating [her]." AR 244. He also noted that "[u]nfortunately, the lack of the 'required' compendium listing is likely due to the rarity of [Mrs. Layzer's] cancer." AR 249. Judge Sterner denied Mr. Fisher's appeal, noting that while Mr. Fisher's situation "is a compelling one," Administrative Law Judges do not possess the power to promulgate the law, and he was bound by 42 C.F.R. § 423.100. AR 786.

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42 C.F.R. § 423.100.

Plaintiffs appealed to the Medicare Appeals Council, which affirmed the denials of coverage, noting that it too was bound to follow 42 C.F.R. § 423.100 and lacked authority to consider whether that regulation was inconsistent with the statute. AR 8, 625. Plaintiffs seek review in this Court and argue that the Compendia Requirement should be set aside as inconsistent with the Act.

DISCUSSION

1. Standard of Review

Plaintiffs do not argue that the decisions below were in error; rather, the crux of their argument is that the regulation imposing the Compendia Requirement, 42 C.F.R. § 423.100, is inconsistent with the language of the Definition. The parties agree that the *Chevron* test governs whether or not this Court should defer to the Secretary's interpretation of that language.

Under *Chevron* Step One, courts must first consider whether Congress has "clearly spoken" on the issue at hand. If Congress has clearly spoken, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Cohen v. JP Morgan Chase*, 498 F.3d 111, 116 (2d Cir. 2007). To ascertain congressional intent, courts start with the statutory text. *Id.* If the language is ambiguous, courts may look to canons of statutory construction and legislative history, in that order, to see whether such "interpretive clues" indicate congressional intent. *Id.*

If the court is still unable to conclude that Congress has addressed the question at issue, courts will move to *Chevron* Step Two. *Cohen*, 498 F.3d at 116 (quoting *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843–44 (1984)). Here, courts will generally defer to the agency's interpretation of ambiguous statutory language so long as it is reasonable. *See id.* at 124 (citing *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001)).

2. Analysis

Because this appeal turns on whether the Act's definition of a Part D drug supports the Secretary's imposition of the Compendia Requirement, I start with the definitional language:

> (1) Except as provided in this subsection . . . , the term "covered part D drug" means-
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> -
>
> **(A)** a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r-8(k)(2) of this title; or

> **(B)** a biological product described in clauses (i) through (iii) of subparagraph (B) of such section . . . ,
>
> *and such term includes* a vaccine licensed under section 262 of this title . . . and any use of a covered part D drug for a medically accepted indication [as defined in § 1396r-8(k)(6)].
>
> (2) Exclusions
> . . .
> (3) Application of general exclusion provisions
> . . .

42 U.S.C.A. § 1395w-102(e) (emphasis added). Looking only at § 102(e)(1)(A)–(B), Plaintiffs' drug use would be covered because (A) and (B) are written in the disjunctive, and (A) merely requires FDA approval for reimbursement.[4] However, the dispute centers on the final paragraph before subparagraph (2). Specifically, the parties disagree on whether to construe the phrase "and such term includes" as illustrative (introducing several examples) or as definitional (introducing additional factors required to meet the Definition).

The issue at *Chevron* Step One then is whether Congress defined "covered part D drug" in a way that unambiguously precludes the Compendia Requirement. The statutory language and several canons of statutory construction make clear that Congress did not intend to impose the Compendia Requirement. Even if the Definition does not provide a model of statutory clarity, the Secretary's regulation is not a reasonable interpretation.

a. Statutory language

One district court has concluded that the plain language of the statutory scheme indicates that "the medically accepted indication clause must be read as a limitation." *Kilmer v. Leavitt*, 609 F. Supp. 2d 750, 754 (S.D.Ohio 2009). That court reasoned that

> Congress specifically and expressly included "such term," which means that this Court must credit that usage as having some point-i.e., to make clear that the definition was continuing and that "includes" means in context essentially "also means" or "as well as" so that the "such term includes ..." clause means "a drug that is used for a medically accepted indication."

[4] Subparagraph (A)(i) of § 1396r–8(k)(2) requires FDA approval, and there is no dispute that both Cetrotide and Increlex have both been approved by the FDA.

Kilmer v. Leavitt, 609 F. Supp. 2d 750, 754 (S.D.Ohio 2009). For the following reasons, I respectfully disagree.

The Act provides that the word "'includes' . . . when used in a definition contained in this chapter shall not be deemed to exclude other things otherwise within the meaning of the term defined." 42 U.S.C. § 1301(b). In other words, the term "includes" as used in the Definition does not introduce an exhaustive category of covered Part D drugs because it does not exclude "other things" that would fall within the preceding Definition. This makes it difficult to accept the position that the word "includes" introduces a set of limiting criteria that exclude drugs that would otherwise fall within the Definition.

If Congress' intent had been to impose the Compendia Requirement as the Secretary urges, the paragraph in issue would be better expressed in the following way:

> and such term includes *and is limited to* a vaccine licensed under section 262 of this title . . . and any use of a covered part D drug for a medically accepted indication [as defined in § 1396r-8(k)(6)].

Had Congress intended this meaning, it would have said so. Moreover, if "includes" introduces further limiting terms, both limitations cited in the paragraph must be addressed. As drafted, they are connected by the word "and" which requires the conclusion that they are conjunctive requirements, i.e. a covered Part D drug would have to be (1) a vaccine licensed under § 262 *and* (2) used for a medically accepted indication. The Secretary does not argue for such an interpretation, but only that a drug which meets the requirements of subsection (A) or (B) must also be used for a medically accepted indication. In that formulation, the two requirements should be joined by the word "or." The fact that they are not indicates further discord between the Secretary's interpretation and the statutory language.

The Secretary argues that the word "includes" must be read as definitional because the clause that follows "is highly specific, undermining any suggestion that the clause was intended as merely one example of what might be considered a covered drug." Def. Mem. at 19. The Secretary fails to explain why a specific clause must be definitional rather than illustrative.

b. Canons of statutory construction

The Secretary argues its interpretation is required to avoid surplusage. *See Bennett v.* Spear, 520 U.S. 154, 173 (1997) (a court must "give effect, if possible, to every clause and word of a statute rather than to emasculate an entire section."). He contends that Plaintiffs' interpretation would cover *all* FDA-approved drugs, and "drugs used for a medically accepted indication" would be a superfluous category because such drugs fall wholly under the larger category of "all FDA-approved drugs." Defendant further argues that Congress would not have taken such care to define "medically accepted indication" if it had meant it to be "mere surplusage." Def. Mem. at 16–17.

The force of this argument is eroded by the fact that the term "medically accepted indication" is found in a different subchapter of Title 42, 42 U.S.C. § 1396r-8(k)(6). It is merely cross-referenced in the subchapter at issue here. Plaintiffs' interpretation does not render the term superfluous because the term exists elsewhere.

The Secretary's next argument is based on statutory context. *See Cohen*, 498 F.3d at 117 ("statutory language must be read in context,"). He argues that there were two definitions of "medically accepted indication" in the Act, and the fact that the Definition cited to the narrower rather than the broader is further proof that Congress intended for there to be a Compendia Requirement. Def. Mem. at 17. Had Congress intended to allow off-label uses, the Secretary opines, it could have done so by citing the broader definition of "medically accepted indication."

In fact, Congress subsequently expanded the definition of "medically accepted indication" at issue here to allow for certain off-label uses. *See* 42 U.S.C. § 1395w-102(e)(4)(A)(i).[5] However, the Secretary's argument fails for the independent reason that it essentially rehashes the argument directed to the specificity of the language following "includes", addressed above. In short, the fact that Congress made a choice as to which

[5] On July 15, 2008, Congress passed the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), P.L. 110-275. Under MIPPA, effective January 1, 2009, the relevant definition of "medically accepted indication" was expanded to include drugs utilized in an anticancer chemotherapeutic regimen even if supported solely by peer-reviewed medical literature, i.e. the Compendia Requirement no longer applies to this category of drug use. *See* 42 U.S.C. § 1395w-102(e)(4)(A)(i). Mrs. Layzer brought a separate administrate action pursuant to MIPPA, and was awarded Part D coverage of her Cetrotide prescription, effective January 1, 2009. She continues to seek coverage for Part D benefits that were denied prior to 2009.

definition to reference sheds no light on whether it meant that reference to be illustrative or definitional. I have considered the Secretary's remaining arguments and find them unavailing.

More compelling statutory construction arguments confirm that Congress did not intend to impose a compendium requirement. In general, remedial legislation should be broadly construed. *See Henrietta D. v. Bloomberg*, 331 F.3d 261, 279 (2d Cir. 2003). In particular, the Second Circuit has said that the Social Security Act should be "liberally construed in favor of beneficiaries." *Hurley v. Bowen*, 857 F.2d 907, 912 (2d Cir. 1988). The "intent" of the Act "is inclusion rather than exclusion," *Vargas v. Sullivan*, 898 F.2d 193, 196 (2d Cir. 1990), and a more inclusive definition is consistent with these exhortations.

Additionally, the Definition "should be interpreted to avoid untenable distinctions and unreasonable results whenever possible." *Amer. Tobacco Co. v. Patterson*, 45 U.S. 63, 71 (1982); *United States v. Dauray*, 215 F.3d 257, 264 (2d Cir. 2000). The Secretary's interpretation would create arbitrarily fine and unreasonable distinctions between uses that are covered in the compendia and those that are not. Significantly, as Judge Smith suggested, the Compendia Requirement precludes coverage of effective yet newly discovered prescription drug treatments— particularly for rare diseases—because FDA-approved uses often lag behind knowledge about actual effective treatment. As Judge Smith explained, the "lack of the 'required' compendium listing is likely due to the rarity of [Mrs. Layzer's] cancer." AR 149.[6] The more rare the disease, the more difficult it is for researchers to (1) determine which drugs provide effective treatment and (2) secure FDA approval to use the drugs for that particular treatment.

Finally, the Compendia Requirement is defeated by the principle of *expressio unius est exclusio alterius*, "the mention of one thing implies the exclusion of the other." *Cordiano v. Metacon Gun Club, Inc.*, 575 F.3d 199, 221 (2d Cir. 2009). Because subparagraph (2), which is titled titled "Exclusions", contains a number of express exclusions, it is implied that the language in subparagraph (1) should not be construed to express additional exclusions. It does not make

[6] *See also* Abbey S. Meyers, President, National Organization for Rare Disorders (NORD), Workshop on Ultra-orphan genetic Disease Therapeutics for Clinical Development and Regulatory Approval: Surrogate Markers & Related Issues (Washington, D.C. May 8-9, 2003) ("FDA requires a sufficient number of patients to participate in each clinical trial in order to prove 'statistical significance," and "for rare diseases, it is sometimes impossible to find enough patients.") (available at http://rarediseases.org/news/speeches/workshop_ultraorph_gen_disease (last visited

sense that Congress would create both (1) a general definition with exceptions imbedded; and (2) a list of explicit exceptions immediately following. *See Cordiano v. Metacon Gun Club, Inc.*, 575 F.3d 199, 221 (2d Cir. 2009) (relying on *expressio unius* to interpret a regulatory definition). This is confirmed by the fact that the Definition begins with the proviso "Except as provided in this subsection . . ." 42 U.S.C. § 1395w-102(e)(1). This indicates that Congress did not intend to import the definition of "medically accepted indication" in § 1396r-8(k)(6) as a limiting element of the Definition.

c. Legislative history

Because I conclude on the basis of the statutory text and canons of construction that Congress did not intend to impose the Compendia Requirement, I need not turn to the legislative history. *Cohen*, 498 F.3d at 116. The parties' various arguments relating to the legislative history of the MMA and MIPPA provide little or no help in resolving the question at bar. Moreover, the Second Circuit "has been reluctant to employ legislative history at step one of [the] *Chevron* analysis." *Mizrahi v. Gonzales*, 492 F.3d 156, 166 (2d Cir. 2007).

Nonetheless, the Secretary's argument that Congress has acquiesced in his interpretation merits some discussion. He points out that the regulation at issue, 42 C.F.R. § 423.100, was brought to the attention of Congress, yet Congress failed to controvert that regulation when it revised the statute by passing MIPPA on July 15, 2008. The Secretary argues that this amounts to Congressional acquiescence in its interpretation, citing *Bellevue Hosp. Center v. Leavitt*, 443 F.3d 163, 176 (2d Cir. 2006) ("[O]nce an agency's statutory construction has been fully brought to the attention of the public and the Congress, and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned.") (internal citation omitted).

The Congressional acquiescence theory is unpersuasive for two reasons. First, the parties agree that 42 C.F.R. § 423.100 was a major rule for purposes of the Congressional Review Act; that statute prohibits courts from inferring any Congressional intent "from any action or inaction of the Congress with regard to such rule." 5 U.S.C. § 801(g). *See also Becker v. FEC*, 230 F.3d 381, 393, n.15 (1st Cir. 2000). Second, *Bellevue* relied on Congressional acquiescence to

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February 3, 2011)).

determine that a regulation was reasonable. *See Bellevue Hosp. Center v. Leavitt*, 443 F.3d 163, 176 (2d Cir. 2006). In other words, it was a *Chevron* step two case, and did not rely on the acquiescence theory to determine whether the statute was ambiguous, but rather whether the regulation filling in the ambiguous statute was reasonable. *Id.*

d. The reasonableness of the Secretary's interpretation.

Even if the language in § 1395w-102(e)(1) is not crystal clear as a whole, it does not support a Compendia Requirement. To construe the category of drugs described following the term "includes" as a conjunctive requirement rather than an example contravenes the plain meaning of the language as well as Congress's explicit mandate that the word "includes . . . *shall not*" have exclusive effect. 42 U.S.C. § 1301(b) (emphasis added). Given this clear directive, not to mention the import of the interpretive canons discussed above, I cannot conclude that the Secretary's interpretation is a reasonable one. *See Cohen*, 498 F.3d at 116. Because this is in large measure a statutory interpretation case, I have consciously dispensed with any policy considerations. This is not to say, however, that the policy behind the statute under consideration here, to say nothing of the Social Security scheme itself, do not urge this result.

CONCLUSION

The statutory language that Congress used to define what is meant by "covered part D drug," along with the canons of statutory interpretation described above, make clear that the Act does not impose a Compendia Requirement. The Secretary's motion is accordingly DENIED, and the Plaintiffs' motion is GRANTED. Because the reasons stated for denying coverage of Plaintiffs' medications rested on an unsound interpretation of the law, the denial is reversed and the Secretary is directed to provide the appropriate coverage, consistent with this Opinion.

The Clerk of the Court is directed to close the matter and remove it from my docket.

SO ORDERED
March 4, 2011
New York, New York

Hon. Harold Baer, Jr.
U.S.D.J.