No.

IN THE
Supreme Court of the United States

Ninth Circuit. Case No. 19-17565

[redacted],

Petitioner,

v.

ALEX AZAR II,
Secretary of the U.S. Dept. of Health and
Human Services, BLUE SHIELD INSURANCE CO., and ENVISION
INSURANCE Co.,

Respondents.

On Petition for a Writ of Certiorari to
the United States Court of Appeals
for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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Certiorari Questions

This is Compendia case, a case of first impression under *Shalala v. Illinois Council*, 529 U.S. 1 (2000).

1. Can the U.S. Court of Appeals for the Ninth Circuit ("9th Circuit") sidestep all issues under Medicare, Part D by not looking behind a compendium's Medically Acceptable Indications ("MAI") also known as 'on or off label' when the evidence leads to an underlying false and misleading premise for a prescription, i.e., no rational basis also under Fifth Amendment, Due Process and Section 504 of the Rehabilitation Act of 1973 ("Sec. 504")? The medication, Serostim, as listed in a compendium requires that the patient also have HIV an unrelated condition that does not treat HIV, only lipodystrophy, a life-threatening condition which prevents Petitioner from retaining lipids.

2.a Does *Shalala v. Illinois Council*, 529 U.S. 1 (2000), an exhaustion case, preclude Due Process and/or Sec. 504? Was it an abuse of discretion not to allow Petitioner to amend the Complaint as to a Sec. 504 claim or constitutional due process?

b. Does 42 U.S.C. § 405(h) - if it arises under the Social Security Act, mean that a beneficiary cannot pursue his Due Process and Sec. 504 rights when there is a false and fraudulent premise in HHS policy? Or does § 405(h) only bar actions under 28 U.S.C. §§ 1331 and 1346?

3. Can insurance carriers which are Medicare contractors, be sued for not making statutory exceptions under Medicare, Part D? Can HHS not permit statutory peer reviewed articles from the National Institutes of Health (NIH) into account and can the 9th Circuit prevent this evidence favorable to Petitioner to be considered in cross motions for summary judgment?

LIST OF ALL PROCEEDINGS[1]

1. In re [redacted], Enrollee/Beneficiary. Office of Medicare Hearings and Appeals, ALJ Appeal Number 1-5125326621 (Myles, ALJ), issued March 30, 2018 (AR 720-727), after remand.

2. In re [redacted], Enrollee/Beneficiary. Departmental Appeals Board Docket ("Doc.") No. M-17-7463. Remand order issued December 20, 2017 (AR 320-24).

3. In re [redacted], Enrollee/Beneficiary. Office of Medicare Hearings and Appeals, ALJ Appeal Number 1-6176167691R1 (Gulin, ALJ), issued March 15, 2018 (AR 49-566), after remand.

4. Objections to Agency for not making findings on Sec. 504 of the Rehabilitation Act of 1973 (Sec. 504), due process and regarding non-development of record (AR 0007-0009); In re [redacted] Enrollee/Beneficiary. Departmental Appeals Board Doc. No. M-18-4059. Order issued December July 12, 2018 (AR 12-17).

5. In re [redacted], Enrollee/Beneficiary. Departmental Appeals Board Doc. No. M-18-5595; Order issued September 7, 2018 (AR 2-6).

6. [redacted] *v. Alex M. Azar II, et al.* U.S. District Court ("D.C.") for the Northern District of California, Matter No. 18-cv-05022-HSG. Order Granting Motions to Dismiss and Administrative Motion to File Under Seal, and Denying Motions to Supplement the Record, filed June 18, 2019.

7. Order on Cross Motions for Summary Judgment by U.S. D.C., Northern District of California, filed December 16, 2019. (D.C. Doc. No. 110)

8. [redacted] *v. Alex M. Azar II, et al.* 9th Circuit Court of Appeals No. 19-17565. Memorandum Disposition. 9th Circuit Court of Appeals, filed October 20, 2020.

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[1] The two administrative law judge decisions after remand and the three appeals council decisions are in a sealed Excerpts of Record, Vol. 3, ordered sealed by the agency, the D.C. and by the 9th Circuit Court of Appeals.

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3. Plaintiff's Notice of Motion, Motion and Memorandum of Points and Authorities in Support of Motion to Supplement the Administrative Record, filed October 25, 2018. (D.C. Doc. 24)

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IN THE

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Petitioner,

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ALEX AZAR II,
As Secretary of the U.S. Dept. of Health and
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_____

**On Petition for a Writ of Certiorari to the
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PETITION FOR WRIT OF CERTIORARI

I. JURISDICTION

The unpublished opinion of the court of appeals was entered on October 20, 2020. This Court has jurisdiction pursuant to 28 U.S.C. § 1254, 42 U.S.C. § 405(g) of the Social Security Act; 21 U.S.C. §§ 360aa-360dd, as amended and the Modernization and Improvement Act of 2003 (MMA), 42 U.S.C.S. § 1395w-101 et seq. U.S. Const., Fifth Amend., Due Process Clause; Sec. 504; Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.,* the Orphan Drug Act of 1983 (ODA), 21 U.S.C. §§ 360aa-360dd as amended.

II. STATEMENT OF THE CASE

A. Introduction

Exhaustion took over two years with three Administrative Law Judges (ALJ) Decisions and three Medicare Appeals Council (MAC) Decisions.[2] This is an issue of first impression under Medicare, Prescription Drug Modernization and Improvement Act of 2003 (MMA), 42 U.S.C.S. § 1395w-101 *et seq.* That is, should Medically Acceptable Indications (MAIs) be broadly interpreted with medical equivalence and should federal courts take into account underlying false and/or fraudulent underlying rational for Compendia MAIs by U.S. Department of Health and Human Services ("HHS") and insurance companies. Petitioner has argued this basis for false HHS premises based on 5 HHS/NIH peer review documents because of a false premise given by HHS in not permitting coverage. Regrettably, both lower courts have denied admitting these material and relevant documents into evidence. Had they been admitted, the D.C. could not have granted HHS' Motion for Summary Judgment (MSJ).App. No. 2

Petitioner, [redacted] was diagnosed with lipodystrophy, a life-threatening, auto-immune metabolic disease which can result in death in July 2016. Symptoms include wasting syndrome aka cachexia causing him to undergo a dramatic weight loss to 132 lbs. He is 5'11" tall (AR 82, 54), organ failure and life spans are estimated to be significantly shorter. The primary organs affected are the liver, kidneys and pancreas (App. ("App.") Nos. 9 and 10, not admitted into the record but two motions with "5 HHS NIH documents" were filed

[2] HHS's administrative record ("AR") of approximately 1,500 pages was and is not in chronological order. HHS required duplicate exhibits for each of two ALJs. The AR was kept separate because HHS does not consolidate ALJ cases even for the same issues. Two duplicate post remand ALJ decisions were removed leaving two ALJ decisions, Myles and Gulin. The AR is sealed and there would be too many numbers with E.R. numbers added since each page filed in the D.C. had two page numbers. The sealed AR is in E.R. Vol. 3.

in D.C. See App. No. 5, Order on Cross Motions for Summary Judgment (MSJs)). At all relevant times [redacted] was/is a Medicare, Part D (prescription drug) beneficiary.

The only medication which allowed [redacted] to gain weight back, notwithstanding severe side-effects, is Serostim (Somatropin). (AR 33, 134, 330, 628.) Its retail price is $18,000 per month in 2020. Two Medicare contractors, Blue Shield of California and Envision, denied coverage. The reason given by HHS for affirming the insurance carriers was that [redacted] had to prove he had another, unrelated auto-immune disease (HIV) based on a false premise - that HIV caused his lipodystrophy. (AR 184-85, 297-98, 630-31.) He has non-HIV lipodystrophy.

At no time did HHS disclose they knew HIV was unrelated to lipodystrophy. All they had to do is look at their own components; NIH, and the Food and Drug Administration ("FDA") or look at Myalept (Metreleptin), a replacement hormone for anyone who has lipodystrophy, which the FDA approved in 2014. See Request to take Judicial Notice Request pursuant to Fed. R. Evid. 201 filed in D.C., the 9th Circuit. (App. Nos. 3, 4.) HHS states its position is not law but its own policy; that this lipodystrophy medication, Serostim, will only be available to people who also have HIV knowing it does not treat HIV.

B. Procedural History

1. The Administrative Proceedings

1. After two ALJs' noticed[3] hearings the Medicare Appeals Council ("MAC") remanded both ALJ decisions to so the administrative record (AR) includes the

[3] All Notices of Hearing stated overly vague generic issues; e.g., "The issues before the ALJ include all of the issues brought out initially; by redetermination; that were not decided in a party's favor, specified in the request for hearing." (AR 73, 756, 1059, 1203-04); [redacted] objected to this notice. (AR 66.)

"Medicare-approved Compendia," which HHS relies on, and the insurance companies' formularies. (AR 1031-32.) ALJ Gulin did not conduct a hearing until the MAC ordered him to do so. After the next appeal to the MAC, it affirmed the ALJ decisions on 7/12/18 (AR 10-17.)

2. Both of the ALJ decisions (Myles, AR 720-27 and Gulin- AR 49-56) were appealed a third time (AR 8-9) to the MAC, which stated this result is required because it is on the compendium list that way. The MAC further stated after [redacted] complained about not receiving the three Compendia, that he 'should have challenged it harder.' (AR 5, 15.) But the first two MAC remands already required the ALJs to include the compendia and formularies. The ALJs and MAC do not recognize the statutory "exception" for this prescription as both insurance companies desired the most restrictive definition of a MAI. See all MAC decisions, generally. (AR 2-6, AR 12-17 AR 320-24 and AR 1030-1032.)

3. In response to an objection letter to the MAC (AR 8-9) based on absence of Due Process and Sec. 504 findings after having raised it, the MAC stated HHS had no jurisdiction over Due Process or Sec. 504. (AR 4.) HHS is correct regarding Due Process and incorrect about Sec. 504. See 45 C.F.R. Pt. 85 for federal agencies and Part 84 for federal contractors (the insurance companies.)

4. After the double remand for the two ALJs (AR 320-24, 1030-32), [redacted] first became aware that HHS had known for over 20 years that the population with HIV had their lipodystrophy cured by changing the HIV anti-retroviral therapy ("ART") which apparently is the actual cause of lipodystrophy in HIV patients according to 5 HHS/NIH documents submitted to the D.C. as evidence. (App. Nos. 9, 10. At the second ALJ hearing, [redacted] argued HHS violated his Due Process and Sec. 504 rights. HHS was applying a known false causation theory without ever telling [redacted], who had to do considerable independent research into HHS' NIH peer review articles. Myalept was approved for lipodystrophy treatment in February 2014, but not known to [redacted] and never mentioned by HHS or the

two insurance carriers as evidence that HHS does provide research and medication for generalized lipodystrophy.

2. The D.C.

The D.C. over-controlled[4] the case by erroneously dismissing **with prejudice** Due Process, Sec. 504, denying [redacted] Motion to Supplement the AR which includes access to Compendia evidence other than the two pages put in the AR, and dismissed Blue Shield and Envision Insurance as parties. (App. Nos. 3, 5.) Plaintiff filed objections to this Order (E.R. Vol. 2, Doc. 84.) Although the D.C. stated, at oral argument on the MSJs (TR DC MSJ[5] at 7:8), that the D.C. understood Plaintiff's allegations of bad faith, intrinsic fraud, and misrepresentations under the Due Process Clause and Sec. 504 precluding [redacted] equal [meaningful] access to its Medicare, Part D program, the D.C. did not consider this gravamen of the case by not mentioning this substantially nonpublic criteria which Plaintiff spent hours talking to patients, doctors and then researching the HHS/NIH online to find the agency's relevant evidence, HHS' documents relating to non-HIV lipodystrophy.

3. The Court of Appeals

The 9th Circuit affirmed the D.C. with little or no analysis, did not apply its own *de novo* legal review standard and did not look at any of the underlying issues regarding HHS's lack of rational basis in the compendium for Serostim which to be a MAI required that one have another unrelated auto-immune condition, HIV in addition to lipodystrophy. Accordingly, that court glossed over constitutional due

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[4] A reading of the transcript on the motion to dismiss (Transcript of Proceedings, [redacted] v. Alex M. Azar, II, et al., 4:18-cv-05022-HSG (Feb. 28, 2019), (E.R. Vol. 1)) reveals a D.C. anxious to dismiss most of the complaint without taking into account any facts from the approx. 1500 pages of the (AR), which was not filed until 2/5/19, because the D.C. did not mention any detail or findings of the two ALJ and three MAC decisions in this Order. (App. No. 5.)

[5] Reporter's Transcript of Proceedings, [redacted] *v. Alex M. Azar, II, et a*l., 4:18-cv-05022-HSG (Dec. 5, 2019) (E.R. Vol. 1).

process, Sec. 504 and the Medicare, Part D statute as it speaks to peer review bases for statutory exceptions, statutory consumer protections or any other primary disputed issue in this case. It issued a short 4-page, unpublished decision.

[redacted] is requesting this Court take into account the "5 HHS/NIH documents," App. Nos. 9 and 10 (App. No. 9 has one attachment and App. No. 10 has four attachments) into evidence. Under Fed. R. Civ. P. 56, summary judgment could not have been granted for HHS if the D.C. had granted [redacted] motion to allow the 5 HHS/NIH documents into evidence, evidence that HIV is not relevant for covering Serostim for his life-threatening condition. Nor did it grant [redacted] motion to take Judicial Notice of Myalept the only other medication for generalized lipodystrophy approved by the FDA. It made no mention of the FDCA, 21 U.S.C. 301 *et seq.* or the Orphan Drug Act of 1983 (ODA), 21 U.S.C. §§ 360aa-360dd, as amended.

C. Statement of Facts

The 9th Circuit stated that the parties agree with the facts and; therefore, omitted any recitation of facts. [redacted] generally agrees with the facts in the two ALJ decisions (Gulin and Myles) after MAC remand (AR 49-56 and 720-27), summarized as follows (and disagrees with some facts including that HHS has no Sec. 504 jurisdiction and the facts in the 5 NIH articles):

1. A Medicare Part D drug is either FDA approved or supported by being listed in or having citation(s) in Compendia or being a statutory **exception**, or based on peer review (AR 52-55.) Plaintiff's primary care physician, Dr. Cubba, and Eveline Stock, M.D., a doctor from the University of California at San Francisco Medical Center's Lipid Clinic, diagnosed [redacted] with a rare metabolic autoimmune disorder, lipodystrophy, which produces severe weight loss (wasting syndrome).

2. The only treatment is human growth hormone, Somatropin (brand name, Serostim). lipodystrophy can result in death. (AR 22, 36, 82 *et. seq.*) An NIH web

source is cited[6] in ALJ's Myles decision containing a link to the Compendia (AR 726) and in ALJ Gulin's decision. (AR 55.)

> "A 'medically accepted indication' is any use for a covered outpatient drug which is approved under the Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] 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) of this section. (Title XVIII, § 1927(k)(6) of the Act)." (AR 54.)

3. According to ALJ Gulin, Serostim is FDA approved with a condition that it is for HIV patients who need it for wasting syndrome to increase body mass. This is the same use as Petitioner's need. (AR 55.)

4. Petitioner moved the D.C. to Order the Compendia (App. No. 3), relied on by the MAC by decision dated 7/12/18 (AR 14-15), produced including the introduction relating to how it is used. Without the three Compendia, which are not provided to Medicare [or apparently to Medicaid] beneficiaries, the statutory requirement of an MAI or citation is unclear as to, e.g., benefits of "off label" prescriptions or similar drugs.

ALJ Gulin declined coverage because ALJs are bound by the implementing regulations (AR 54-55) and twice states at the hearing he cannot/will not follow case law but will research [redacted] position that the ART, not HIV, causes lipodystrophy. (AR 704, 707.)

ALJ Myles stated:

> "**… Petitioner argued that HIV drug treatment, rather than the HIV, causes weight loss or cachexia. Therefore, Serostim should be considered a treatment for weight loss and wasting rather than one for HIV. This view is supported by medical literature from the NIH.…**" (AR 725.)

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[6] www.nihlibrarycampusguides.com.ezproxyhhsnihlibbrary.nih.gov/c.php?g=38325&p=245138 It is not available to public; apparently this is an agency intranet. See Declarations of the AUSA and Ann Marie Chandler, attachments to Plaintiff's MSJ Reply brief, which both state this Compendia evidence is not publicly available. (App. No. 8.)

ALJ Myles stated he is not permitted to follow law but can only apply HHS policies and regulations. (AR 726-27.) ALJ Myles found that if that NIH literature supports the conclusion argued by Plaintiff; i.e., that **it is the ART that causes lipodystrophy, not HIV,** there is nothing he can do - he is bound by what is exactly printed in the Compendia…. he has no authority but to affirm the insurance carrier. (AR 727.) Also "see" which is not a Compendium but an FDA list cited by the ALJs: http://www.accessdata.fda.gov/scripts/cder/daf. Per HHS, there are no additional off-label uses for Serostim included in the American Hospital Formulary Service (AHFS-DI) database. (AR 726.) Access to AHFS-DI was requested, but not provided.

HHS stated "…a court cannot waive the Part D requirements simply because an enrollee's condition is rare…." (E.R. Vol. 2, Doc. 94 at 13:11, citing a 2015 D.C. in Ohio.) HHS, in the same listing in the two pages of the DrugDex compendia (in ALJ Myles decision), lists *short bowel syndrome.*

5. In February 2014, Myalept was FDA approved for people with generalized lipodystrophy.

6. The ALJs and D.C. declined to discuss any law relating to the false requirement (causal condition), agency misrepresentation and/or intrinsic fraud on the public. Both ALJs concur that Serostim has been the only prescription drug that works with [redacted] lipodystrophy symptomatology - wasting syndrome. (AR 50, 724-26.)

7. ALJ Myles states [redacted] was entirely credible and further, that he is sympathetic to his life-threatening predicament. (AR 55, AR 726.)

8. In D.C., [redacted] relied on HHS/NIH documents. There is no clear cause and effect and treatment for people with non-HIV lipodystrophy and severe weight loss and those with HIV and "wasting" syndrome. In fact, if one has both HIV and lipodystrophy caused lipid loss it is treated [cured] by changing the anti-viral HIV compounds, historically. Treatment for lipodystrophy cachexia is treated by

Serostim. There are no HIV compounds to change.[7]

9. HHS stated in D.C. that an approximately $400.00 outdated 2016 compendium should be purchased by [redacted] on Amazon.com rather than provide access to the current electronic Compendia. (E.R. Vol. 2, Doc. 77 at 4:n 3.) Recently, HHS represented to another D.C. that the same (or 2015) compendium HHS told [redacted] to buy through Amazon.com was too outdated to be relied upon. *Aloi v. Azar*, 337 F. Supp. 3d 105 (D.C. RI, Oct. 2018).

10. The MAC, at AR 7-17, knew [redacted] position was that there was no difference between the wasting symptoms of lipodystrophy and that changing the HIV ART is a cure for lipodystrophy. The 5 HHS/NIH documents, are specific evidence in support of the false premise known and utilized by HHS; i.e., that it is not the Compendia-required HIV that causes life-threatening wasting syndrome. (See App. Nos. 9 and 10.) The D.C. denied [redacted] two administrative motions to admit this evidence in its Order granting HHS' MSJ (App. No. 2), App. No. 9 with one attachment, App. No. 10 with four attachments, and ignored this merit argument. I.e., that the Compendia, at least those DrugDex pages [redacted] was permitted to see, did not reference the true underlying facts, that HHS has known for over 20 years that HIV was not the cause or related to the cause, ART, of lipodystrophy. The "5 HHS/NIH documents" are dated September and November 2019, September 2015, March 2010, and October 2008 and are examples of NIH evidence relating to non-HIV lipodystrophy. The first NIH document (App. No. 9, article 1) is a fact sheet, which states "…Lipodystrophy will not be a concern for

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[7] The primary therapy for severe lipodystrophy, particularly lipoatrophy, is a change in Anti-Retroviral Therapy (ART). Finkelstein, Julia L *et al.* "HIV/AIDS and lipodystrophy: implications for clinical management in resource-limited settings." *Journal of the International AIDS Society* vol. 18, 1 19033. 15 Jan. 2015, doi:10.7448/IAS.18.1.19033, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4297925/ (last visited Mar. 4, 2020) from the U.S. National Library of Medicine National Institutes of Health website.

most people who start HIV treatment now." ("HIV and Lipodystrophy.")[8] The D.C. said, *inter alia*, that since the Court was going to give HHS a judgment it did not matter that it denied [redacted] motions to admit the 5 HHS/NIH documents. (App. No. 2 at 6:n 4.) If HIV was a cause of lipodystrophy HHS' position would not be irrational. The MAC, like the two ALJs, does not dispute the facts presented by [redacted]. The MAC states that off-label uses are from Medicare Compendia known as AHFS-DI, or DrugDex, or USP-DI or its successor. No Compendia has been produced except for a partial Micro-DrugDex entry for Serostim and a formulary which is used by Envision (AR 738-49; AR 787-88.) In December 2019 [redacted] checked the costs of DrugDex now owned by IBM and found each year online subscription was $2,000 to $3,000.[9]

11. HHS, in its opposition to [redacted] motion to add one document (E.R. Vol. 2, Doc. 101 and App. No. 9) to the record, states and generally [redacted] agrees, that there is no causation requirement for prescription medications; however, that is not what HHS is doing. The Agency requires a patient to have HIV in order to receive Serostim, notwithstanding this requirement is based on a false premise. According to the 5 HHS/NIH documents, another medication, Myalept (generic Metreleptin), has been approved since 2014 only for generalized lipodystrophy.

12. The third MAC Judge omitted the AHFS-DI and USP-DI Compendia for Serostim and stated [redacted] 'did not challenge the ALJs hard enough' (AR 5.) To

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[8] HIVinfo.NIH.gov, "Side Effects of HIV Medicines, HIV and Lipodystrophy Last Reviewed: September 19, 2019" *available at* https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/22/61/hiv-and-lipodystrophy (last visited Mar. 12, 2020).

[9] Multiple year subscriptions are requested (per the IBM business development person on the phone Dec. 2019.)

the contrary, the MAC in its first Remand Order required ALJ Myles to obtain the Compendia and Formularies as exhibits; but only a few pages of one Compendium, DrugDex, were produced by ALJ Myles. (AR 320-24, AR 1030-32.)
On 2/5/2019 HHS filed the AR with the D.C. Petitioner is only appealing not receiving the three compendia or access thereto in his Motion to Supplement the AR.

13. Request to Take Judicial Notice and Relevant and Material Evidence in Favor of Petitioner: The 9th Circuit affirmed the DC's 1. denial of Petitioner's request to take judicial notice of Myalept, a synthetic hormone produced by lipids and the only other lipodystrophy treatment in addition to Serostim (see App. No. 4) and 2. The 5 HHS/NIH documents in support of petitioner. (App. Nos. 9 and 10.)

D. Bases for Federal Jurisdiction

The bases for federal jurisdiction in the D.C. are pursuant to 42 U.S.C. § 405(g) of the Social Security Act; U.S. Const., Fifth Amend., Due Process Clause; Sec. 504; FDCA, 21 U.S.C. § 301, *et seq.,* and the (ODA), as amended and MMA, 42 U.S.C.S. § 1395w-101 *et seq.*

III. ARGUMENT

A. Nonpublic Criteria (Procedures, Practices and/or Policies) Are Illegal when Used Under the Social Security Act, 42 U.S.C. § 400 et seq. The HIV Requirement "Rationale" Is Contradicted by HHS/NIH Documents Erroneously Not Admitted into Evidence. There is Medical Equivalence in Medically Acceptable Indications.

Nonpublic criteria (procedures, practices and/or policies) are illegal when used under the Social Security Act. Fundamental rights such as Due Process are cognizable under *Smith v. Berryhill*, 139 S. Ct. 1765 (2019) at 1717, which states "…Congress wanted more oversight by the courts rather than less under § 405(g) and that "Congress designed [the statute as a whole] to be 'unusually protective' of claimants."

> "…Where the Government's secretive conduct prevents plaintiffs from knowing of a violation of rights, statutes of limitations have been tolled until such time as plaintiffs had a reasonable opportunity to learn the facts concerning the cause of action…." *Bowen v. City of New York*, 476 U.S. 467 (1986) at 481.

The underlying truth about the HIV [non causation] was not known to [redacted] until after the administrative exhaustion process started. "…it has not suggested that it intended for the SSA (previously Appellee, HHS) to be the unreviewable arbiter of whether claimants have complied with those procedures…." *Smith* at 1770.

The underlying purpose of 42 U.S.C. §§ 405(g) and 405(h) is to develop a factual record. See *Weinberger v. Salfi,* 422 U.S. 749 (1975), not to keep out material facts. Also see *Mathews v. Eldridge*, 424 U.S. 319 (1976) for applicable due process, affirmed in *Smith*.

42 U.S.C. § 1396r-8(k)(6), states: The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act ("FDCA") 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).

The MMA, Part D, 42 U.S.C. § 1395 *et seq.* has consumer protections built in:

Sec. 1860D-2. [42 U.S.C. 1395w-102] (a) Requirements. —

> "…(C) Update.—For purposes of applying subparagraph (A)(ii), the **Secretary shall revise the list of compendia** (emphasis added) described in section 1927(g)(1)(B)(i) **as is appropriate for identifying medically accepted indications for drugs**. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1861(t)(2)(B) Sec. 1860D-2. [42 U.S.C. 1395w-102] (a) Requirements. — "… (II) the carrier involved determines, **based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs**, **that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications** which have been identified for purposes of

> this subclause by the Secretary. (emphasis added) …The Secretary may revise the list of compendia in clause (ii)(I) as is appropriate for identifying medically accepted indications for drugs. On and after January 1, 2010, **no compendia may be included on the list of compendia under this subparagraph unless the compendia have a publicly transparent process for evaluating therapies** and for identifying potential conflicts of interests (emphasis added.)

HHS has not followed this Congressional mandate, but continues to utilize a false premise with regard to HHS' known findings that HIV is unrelated to lipodystrophy which can be treated and cured by those afflicted with HIV by changing the ART used to treat HIV. Serostim does not treat HIV. In 2014 HHS' FDA component approved Myalept (generic-Metreleptin), a synthetic hormone to replace Leptin produced by lipids, which lipodystrophy patients do not have.

B. On Remand Expert Opinion Should Have Been Required Given the Lower Courts Refused to Consider Material and Relevant Evidence in NIH Peer Review Articles

In *United States v. King-Vassel*, 728 F.3d 707, 716 (7th Cir. 2013) the Court stated about compendia that an expert may be required: "They seem to be intended primarily for an audience of health care professionals, but again, were specifically incorporated by Congress into the statutory standard for a 'medically accepted indication.' 42 U.S.C. § 1396r-8(k)(6)…."

Here applying the same rationale, the ALJs (stated they had no authority) and the 9th Circuit should have decided on a biochemist expert since this case concerns metabolic areas of specialization.

If the 9th Circuit and the D.C. admitted the 5 HHS/NIH document evidence, there would be a dispute as to material facts and the D.C. could not have granted HHS' MSJ. The D.C. Order on cross MSJs (App. No. 2) relates back to the Order to Dismiss and Motion to Supplement Administrative Record (App. No. 5), and states in part:

> "…Plaintiff failed to rebut with clear evidence the presumption that the record is complete, or present any evidence that an exception applies to allow the Court to consider extra-record evidence. *See* Dkt. No. 83 at 10–11. Accordingly, the Court **DENIES** Plaintiff's administrative motions to file additional documents. *See* Dkt. Nos. 100, 102. And even were the Court to consider the additional materials Plaintiff seeks to introduce, the Court finds that these materials would not change its analysis." (App. No. 2 at 6:n 4.)

This is plain legal error in that this material and relevant evidence should not have been omitted under Fed. R. Civ. P. 56. Had it been discovered later, Fed. R. Civ. P. 60 would have required the judgment be set aside.

The D.C and 9th Circuit relied on a misinterpreted exhaustion case, *Shalala v. Illinois Council*, 529 U.S. 1 (2000). (App. Nos. 1, 5 at 7.) Moreover, it is unlikely that the D.C. considered any facts from the two ALJ and three MAC decisions in the 1500-page AR filed on 2/5/19, E.R. Vol. 3, sealed since the D.C. did not mention any details or findings from them in its Order issued on 6/18/2019. (App. No. 5.)

Not to admit material and relevant evidence (App. Nos. 9 and 10) before judgment is an affront to basic conceptions of fundamental fairness. *Lands Council v. Forester of Region One of the United States Forest Serv.*, 395 F.3d 1019, 1030 (9th Cir. 2004) which states:

> "…a reviewing court may consider extra-record evidence where admission of that evidence (1) is necessary to determine 'whether the agency has considered all relevant factors and has explained its decision,' (2) is necessary to determine whether 'the agency has relied on documents not in the record,' (3) 'when supplementing the record is necessary to explain technical terms or complex subject matter,' or (4) 'when plaintiffs make a showing of agency bad faith.'…"

In the HHS' MSJ (E.R. Vol. 2, Doc. 94 7:8-10), HHS argued the FDA does not have to approve treatment for rare disorders like lipodystrophy, but in truth it does. (In 2014 the FDA approved Myalept.) Lipids, which people like Petitioner cannot retain, produce a hormone called Leptin which helps people with generalized lipodystrophy. It helps against the metabolic consequences of

lipodystrophy which according to NIH second abstract attached to App. 10 causes insulin resistance and organ failure (liver, kidney and pancreas) and; therefore, can result in death. Along with HIV, the approx. two pages of the DrugDex compendium in the AR state Serostim is also for short bowel syndrome, another rare disorder. The HIV limitation has no rational basis. The HIV causation requirement was before both ALJs and HHS had a duty to develop this record and inform any Medicare (or Medicaid) beneficiary that Myalept was approved for lipodystrophy without HIV. ALJ Gulin stated at the hearing his staff would research this; there is no evidence that it happened. (Tr., AR 704.) ALJ Myles said because of the insurance carrier determination, the reconsideration, and the MAC remand, he has to affirm.[10] (ALJ Decision at AR 727.) Historically, the ALJ has a duty to develop the factual record. *Weinberger,* 422 U.S. at 758-60.

> "Social Security proceedings are inquisitorial rather than adversarial… It is the ALJ's duty to investigate the facts and develop the arguments both for and against granting benefits, see *Richardson* v. *Perales,* 402 U. S. 389, 400-401 (1971), and the Council's review is similarly broad. *Sims v. Apfel*, 530 U.S. 103, 111–12 (2000). An ALJ has a duty to develop the record further "when there is ambiguous evidence or when the record is inadequate to allow for proper evaluation of the evidence."

In *Smith* at 1770*,* 1777 this Court held that:

> "…Congress wanted more oversight by the courts rather than less under §405(g)… "Congress designed [the statute as a whole] to be 'unusually protective' of claimants….Congress has not suggested that it intended for the SSA to be the unreviewable arbiter…" (Internal citations omitted).

The 9th Circuit affirmed the D.C. in its judgment for HHS, declining to rule on the merits by not applying its legal review standard (*de novo)*, and leaving HHS as the final arbiter. The D.C.'s rationale in its Order on the MSJs is legal error, factually wrong and inherently discriminatory based on disability (non-HIV

[10] ALJ hearings are *de novo*.

lipodystrophy). The D.C. erroneously found and the 9th Circuit affirmed "…Whether Part D *should* cover Plaintiff's use of Serostim to treat his condition because it has similar symptoms to those of patients with covered conditions is a policy matter not within the Court's competence to decide…." (App. No. 2 at 7:14-16.) ALJ Gulin stated:

> "… NIH studies lead to the conclusion that it is not the HIV that leads to lipodystrophy, but the anti-viral agents used to treat HIV… [redacted] cited to the National Institutes of Health ("NIH") study included in the record in response to Ms. Lester [Blue Shield]. Current research leads to the conclusion it is not really the HIV, but the agents used for HIV, that cause lipodystrophy. There is federal case law describing how the statute, rather than the compendia is read more inclusively for the beneficiary. Simply citing the compendia is not always enough to deny coverage. (Hearing CD) …." (AR 54-55.)

ALJ Myles states he cannot use statutory interpretation but cites a contradictory regulation, 42 C.F.R. § 423.2063(a) *Applicability of laws, regulations, CMS Rulings, and precedential decisions*. (AR 726-27.)

This ALJ also stated:

> "…Petitioner argued that HIV drug treatment, rather than the HIV, causes weight loss or Cachexia. Therefore, Serostim should be considered a treatment for Cachexia or wasting rather than one for HIV…." (AR 725.)

The D.C.'s rationale that resolution of the underlying issue is "**beyond the competence of the D.C**." is not based on substantial evidence and is clear legal error. (App. No. 2.) The D.C. should have reversed based on the 5 HHS/NIH documents evidence and FDA approval of Myalept or granted a "sentence four" or "sentence six" remand of a § 405(g) judgment for [redacted] remanding the case to HHS to use a biochemist M.D. expert or just reversed for payment of benefits.

C. HHS Suppressed Evidence (App. Nos. 9 and 10)

All of the exceptions; e.g., see *Lands Council, infra* to supplement an AR apply to the earlier motion to supplement the record filed and rejected in the Order

dismissing them. See App. Nos. 3 and 5. HHS knew the HIV population had a cure for lipodystrophy by changing the ART used to treat HIV; The metabolic effects of lipodystrophy, including insulin resistance and failure of liver, kidney, and pancreas which apply to [redacted] condition, is a technical and complex metabolic subject matter; (4) There is a showing of "bad faith" in that the Compendium requirement of HIV is based on a false premise that may have been believed in the 1980s, but since then the HHS/NIH documents make clear that requiring a patient with a lipid auto-immune disorder to have another irrelevant auto-immune disorder (HIV) is in reckless disregard of the truth.[11]

This court made it clear that building a factual record is the underlying purpose of administrative exhaustion. 42 U.S.C. §§ 405(g) and 405(h) are to develop a factual record, see *Weinberger,* 422 U.S. 749; not to keep out material facts. Other appellate courts; e.g., *Thompson v. United States Dep't of Labor,* 885 F.2d 551, 555 (9th Cir. 1989) established that a court may look beyond the administrative record to determine whether the agency considered all relevant factors, to determine whether the agency's "course of inquiry" was sufficient or inadequate. Courts often require medical experts in the correct area of specialization. See *Biestek v. Berryhill,* 139 S. Ct. 1148 (2019), *Bragdon v. Abbott,* 524 U.S. 624 (1998). [redacted] lipid doctors from UCSF's Lipid Clinic are experts who recommended Serostim be used in this non HIV lipodystrophy case.

The Court of Appeals' affirmation of the D.C.'s two orders (App. Nos. 1, 5, 2), including the Motion to Supplement the record with the Compendia, is legal error. (App. No. 3). The "5 HHS/NIH document evidence" are inextricably intertwined with [redacted] position that there is a showing of bad faith in that the Compendium requirement of HIV is based on a false premise. The D.C. rationale

[11] The Order to Dismiss (Doc. 83) covers Due Process (Count B), Sec. 504 (Count C), the two insurance carriers and the motion to supplement the record with compendia access.

that [redacted] evidence is "…nowhere close to showing 'clear evidence" (App. No. 2 refers to App. No. 5) at that point in the litigation is highly regrettable because HHS claims three Compendia, citations, references and peer reviewed literature can be the basis for coverage. See First Amended Complaint and Opposition to HHS, motion to dismiss containing that evidence. (App. Nos. 6, 7, Again, had the D.C. taken into account the two ALJ and three MAC decisions it referenced; the "clear evidence" would have been even more apparent.

HHS falsely represented the Compendia is publicly available. See HHS Opposition to Motion to Supplement. (E.R. Vol. 2, Doc. 77 at 5.) The Agency states it is public through a link; however, the link referred to is not a Compendium link. The NIH library used by HHS's lawyer is not open to the public. See the Declaration of Kimberly Robertson, AUSA, who only mentioned one compendium on March 6, 2019, and Anne Marie Chandler, Legal Assistant, both filed concurrently herewith as App. No. 8. The HHS tried to conceal the information from a Medicare beneficiary.

D. Constitutional Due Process

The 9th Circuit affirmed the D.C. striking the Due Process Clause count with prejudice (App. Nos. 1, 5.) [redacted] filed Objections (E.R. Vol. 2, Doc. 84) which were never ruled upon and then stated in his MSJ that due process is applicable whether through § 405(g) or not. (E.R. Vol. 2, Doc. 90.) This Court has consistently ruled for the past 44 years that Due Process applies without exhaustion under the Social Security Act so long as there is a colorable claim which is collateral. *Smith v. Berryhill, supra*, *Lopez v. Heckler*, 753 F.2d 1464 (9th Cir. 1985), revered on other grounds 469 U.S. 1082), and *Mathews v. Eldridge,* collaterality required, 424 U.S. 319 (1976). Moreover, notice is constitutionally defective where it was not reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present meaningful objections thereto. *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306,

314, 319 (1950). [redacted] did not know using this standard; i.e., MAI, that HIV was really **not** the cause of lipodystrophy. This is not the first time this Agency has acted surreptitiously and in bad faith.[12] The 9th Circuit erred in relying on *Shalala* v. *Illinois Council*, 529 U.S. 1 (2000), an exhaustion case.

The 9th Circuit also erred by dismissing the insurance carriers as parties, and Sec. 504 of the complaint **with prejudice** contrary to its own case law requiring leave to amend a complaint: *Morongo Band of Mission Indians v. Rose*, 893 F.2d 1074, 1079 (9th Cir. 1990); *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 186 (9th Cir. 1987).

E. Meaningful Program Access Under Sec. 504 Is Cognizable and Should Not Have Been Dismissed by the D.C. and Affirmed by the 9th Circuit.

Cases that arise under the Social Security Act do not override a Congressional mandate applying Sec. 504 to federal agencies especially when an agency has no rational basis for disparate treatment of individuals with a disability, non-HIV lipodystrophy. It is also legal error to dismiss this cause of action with prejudice. It was pled in the first amended Complaint alleging that [redacted] stated he did not have equal meaningful program access under 45 C.F.R. § 85.21. Surprisingly, the 9th Circuit affirmed the D.C., finding that *Shalala v. Illinois Council,* a Social Security Act Title XVIII exhaustion case overruled a Rehabilitation Act of 1973 exhaustion case, *J.L. v. Soc. Sec. Admin.*, 91 F.2d 260 (9th Cir. 1992) even though this judicially created exhaustion in *J.L.* is not under the same statute (Social Security Act) and required filing an administrative Sec. 504 complaint with the Agency and in 6 months appealing it back to the agency, without ALJs. (App. No. 5 at 8).

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[12] Samuel Estreicher & Richard L. Revesz, Professor of Law, New York University, *Nonacquiescence by Federal Administrative Agencies*, 98 Yale L.J. 679 (1989).

Moreover, the 9th Circuit stated the parties are familiar with the facts, so there is no need to recite them. A regrettable statement as to Sec. 504. Petitioner did allege sufficient facts and Respondents alleged the opposite. The complaint, first amended, states "… By providing coverage for Serostim only to individuals who have HIV, Envision and Blue Shield denied Plaintiff, as an individual with a disability ([l]ipodystrophy), the opportunity to participate in, or benefit from, Envision's and Blue Shield's aids, benefits, or services afforded to those with HIV. There is no rational basis for providing Serostim to treat cachexia, wasting syndrome or lipodystrophy only to individuals who have been also diagnosed with HIV…. Defendants provided no evidence to the contrary." ¶¶ 49, 50. Opposition to HHS' Motion to Dismiss Sec. 504 states in pertinent part "… – there is no rational basis to deny coverage for Plaintiff's wasting syndrome/cachexia because it is not also accompanied by HIV… Plaintiff challenges the arbitrary classification requiring HIV as it does not provide meaningful access to individuals with disabilities such as Plaintiff, who has the underlying condition that Serostim was envisioned to treat…."

The Court of Appeals should have applied its *de novo* review standard and found either there were sufficient facts based on the opposition to HHS' Motion to Dismiss and found the Complaint could be amended or there was sufficient evidence as quoted herein under 9th Circuit law. The Court of Appeals' lack of analysis on disputed issues is regrettable. Again, the underlying purpose of 42 U.S.C. §§ 405(g) and 405(h) is to develop a factual record, see *Weinberger,* 422 U.S. 749, not to keep out material facts.

As an individual with non-HIV lipodystrophy, [redacted] has no meaningful program access to the medication needed because it is based on a false and misleading premise - that HIV is required in order to receive Serostim for lipodystrophy. The 5 HHS/NIH evidence show knowledge of HHS that people with HIV can be cured of lipodystrophy. (App. Nos. 9 and 10.) Petitioner does

not have any further burden of proof having found this conflicting evidence from HHS.

F. The Two Insurance Carriers, Blue Shield and Envision, Are Proper Defendants and Should Not Have Been Dismissed with Prejudice

1. The insurance companies are proper defendants and Congress has mandated that they perform a pivotal role in initiating exceptions when listings are not in the Compendia. See Section E – An Exception Should Have Been Granted.

> Sec. 1860D-2. [42 U.S.C. 1395w-102] (a) Requirements. — "…(C) Update.—… the Secretary shall revise the list of compendia described in section 1927(g)(1)(B)(i) as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1861(t)(2)(B) Sec. 1860D-2. [42 U.S.C. § 1395w-102] (a) Requirements. — "… (II) **the carrier involved determines**, **based upon guidance provided by the Secretary to carriers** for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence **in peer reviewed medical literature** (emphasis added) appearing in publications which have been identified for purposes of this subclause by the Secretary." Emphasis added

The claim is not a derivative claim, which the D.C. states is the primary reason for there being no jurisdiction under *Shalala v. Illinois Council, supra* at 14 (App. No. 5 at 5-7.)

It is true that under 42 U.S.C. § 405(g) HHS is a proper defendant (see App. No. 5 at 5-7) under 42 C.F.R. § 423.2136(d)(1). Because HHS is a proper defendant does not lead to the conclusion that the two federal contractors are not. The Sec. 504 regulations that cover federal contractors are found at 45 C.F.R. Pt. 84. It cannot be presumed that the insurance contractors have no knowledge that lipodystrophy is not caused by HIV or that not covering this population on the basis of this disability violates the requirement of equal meaningful program participation in the

Medicare prescription drug program. Blue Shield and Envision Insurance employ doctors and had one testify, Dr. Watson, an internist (the wrong area of specialization). Blue Shield lists Serostim in its formulary and should also be presumed to have and seek medical opinions. The lower courts cite no binding authority except purportedly, *Shalala v. Illinois Council, supra* at 14 (App. No. 5 at 5-7) and *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134 (9th Cir. 2010), an exhaustion case in its Order dismissing two insurance carriers with prejudice. (App. No. 5)

45 C.F.R. § 85.61(l) provides that the agency may delegate its authority for conducting complaint investigations to a component agency or other federal agencies, except that the authority for making the final determination may not be delegated. Here HHS has an incurable conflict of interests to enforce compliance with Blue Shield and Envision since HHS' own policy, being based on a false premise, cannot enforce compliance under 45 C.F.R. Pt. 84.

If it is true that the lower Courts believed there was insufficient evidence pled under Sec. 504, it was an abuse of discretion to dismiss with prejudice without leave to amend.

HHS did not refer the administrative cases to the DOJ or elsewhere for Sec. 504 compliance and enforcement. The only realistic process for remedies under both Sec. 504 and Due Process violations[13] are federal courts which dismissed the two insurance companies lacking the same substantial evidence and including the same legal errors.

Finally, by dismissing Sec. 504, Due Process and the two HHS insurance contractors, there is no process to adjudicate the violations of Blue Shield and

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[13] As with HHS, *Mathews* requires a colorable claim and collaterality which exists by legal definition since, as HHS states, it has no jurisdiction under Fifth Amendment's Due Process and benefits under the Social Security Act are "property" under the Due Process Clause. -(*Mathews v. Eldridge*, 424 U.S. 319.)

Envision under Sec. 504 and it is unlikely that Due Process violations would ever be rectified.

G. An Exception Should Have Been Granted

An exception to obtain coverage was "denied" by the MAC under 42 C.F.R. § 423.578 *Exceptions process* which requires the prescribing physician to state why it is necessary, which he did; but both carriers denied they had to cover the medication. 42 C.F.R. § 423.578(e) "formulary process cannot be used to cover a drug that does not meet the definition of a Part D drug."

The MAC uses circular reasoning; i.e., using the most restrictive definition instead of a broader definition which is indicated under rules of construction. (AR 5, 17.) The Blue Shield carrier references it at AR 399, 400, and 402, *et seq.*, but to no avail. "…You and your provider can ask the plan to make an exception…" which was done and it should not have been rejected by HHS. 42 U.S.C. § 1395x(t)(2)(B) applies even if not on a compendia list: "…that such use is medically accepted based on supportive clinical evidence **in peer reviewed medical literature** (emphasis added) appearing in publications which have been identified for purposes of this subclause by the Secretary"

Indeed, the 5 HHS/NIH evidence kept out of the record are peer reviewed literature. See 42 U.S.C. § 289a - Peer review requirements. It does meet the statutory exception requirements. The insurance companies argued before the ALJs that it is not coverable except if HIV is present (presumably as a cost-saving mechanism). HHS, like Blue Shield and Envision, wanted to restrict the definition only as to the written version in DrugDex even though HHS and the carriers knew or should have known that conclusion has a false premise and presumably as such would make large profits.

H. The FDCA and Therefore a MAI Requires Safety and Effectiveness as a Matter of Law

The FDCA, 21 U.S.C. § 301 *et seq.* is the applicable statute being violated here and this Court states that "…FDCA requires premarket approval of any new drug, and further that the Food and Drug Administration (FDA) shall issue an order refusing to approve an application of a new drug if it is not **safe and effective** for intended purpose. 21 U.S.C. §§ 355(a)(b). If the FDA discovers after approval that a drug is unsafe or ineffective (emphasis added), …." 21 U.S.C.S. §§ 355(d)(1)-(2), (4)-(5), 21 U.S.C.S. §§ 355(e)(1)-(3). See *FDA v. Brown Williamson Tobacco Corp.,* 529 U.S. 120 (2000).[14]

This case concerns a false theory sometimes referred to as "implied or false certification." HHS, Blue Shield and Envision, in circular reasoning, ask Medicare beneficiaries and the federal judiciary to believe that the HIV requirement is based on FDA's current scientific reasoning based on trials. This is more accurately described as based on a false premise. In *Sekhar v. United States*, 570 U.S. 729 (2013) this Court holds that claims or, by logical extension, misrepresentation which omit critical information; i.e., that having HIV is required to qualify for Serostim for non-HIV lipodystrophy is actionable misrepresentation. This is analogous to the present case wherein the 5 NIH documents are evidence that HHS is intentionally misrepresenting to the public. This could not be for "safety and effectiveness" under the FDCA because Serostim is not a HIV treatment according to NIH research documents filed with the D.C.

I. HHS' POSITION

HHS' position is an irrational agency policy: specifically, that it wants to keep the lipodystrophy medication, Serostim only within the HIV-lipodystrophy population and not in the non-HIV lipodystrophy population. The agency further states that since Congress allows broader MAI for cancer patients, it should not allow the Medicare statutory language to apply peer review literature to this

[14] Superseded by statute in 2005, Tobacco Control Act, 21 U.S.C.S. § 387 et seq.

orphan drug. In 2013, 42 U.S.C. § 1395w-102(e)(4) allowed prescriptions to be used to treat epilepsy, cancer, or a chronic mental health disorder and Benzodiazepines. Peer review, the mission statement of NIH is a basis for broadening MAIs. Also see the (ODA) as amended, provides incentives to drug manufacturers to research treatment for diseases which affect a small portion of the population and, as such, is a Congressional mandate to provide prescription drugs for disorders affecting usually under 200,000 people such as non-HIV lipodystrophy, Huntington's disease, ALS (Lou Gehrig's disease), Tourette syndrome, and muscular dystrophy and/or other conditions as set forth in the ODA. Myalept which Petitioner requests this court take judicial notice (See App. No. 7) and Serostim, both FDA approved, fall under these categories.

IV. CONCLUSION

Based on the foregoing, Petitioner requests that his Petition be granted.

Dated: November 23, 2020

Respectfully submitted,
/s/ Steven Bruce

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V. APPENDIX

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NOT FOR PUBLICATION

FILED

OCT 20 2020

MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

[redacted]

Plaintiff-Appellant,

v.

ALEX M. AZAR II, Secretary of the U.S. Department of Health and Human Services; et al.,

Defendants-Appellees.

No. 19-17565

D.C. No. 4:18-cv-05022-HSG

MEMORANDUM*

Appeal from the United States District Court
for the Northern District of California
Haywood S. Gilliam, Jr., District Judge, Presiding

Submitted October 15, 2020**
San Francisco, California

Before: McKEOWN and NGUYEN, Circuit Judges, and VITALIANO,*** District Judge.

[redacted] appeals from the district court's orders granting motions to

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

** The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

*** The Honorable Eric N. Vitaliano, United States District Judge for the Eastern District of New York, sitting by designation.

dismiss filed by Blue Shield, Envision, and the Department of Health and Human Services ("DHHS") and granting DHHS's summary judgment motion on the remaining claim against it. [redacted] claims that DHHS's denial of coverage under Medicare Part D for Serostim—a drug he was prescribed to treat his lipodystrophy and wasting syndrome—was not supported by substantial evidence and violated the Fifth Amendment Due Process Clause and Section 504 of the Rehabilitation Act. The parties are familiar with the facts, so we do not repeat them here. We affirm.

The Medicare Appeals Council's decision that Serostim was not a covered Part D drug is supported by substantial evidence and not based on legal error. *See Magallanes v. Bowen*, 881 F.2d 747, 750 (9th Cir. 1989). For purposes of the Medicare Act, a "covered part D drug" includes "any use of a covered part D drug for a medically accepted indication." *See* 42 U.S.C. § 1395w-102(e)(1)(B). A "medically accepted indication" is, in turn, defined as "any use for a covered outpatient drug" which is approved by the FDA or supported by citations in one of three pharmaceutical compendia. *See id.* §§ 1396r-8(k)(6), 1396r-8(g)(1)(B)(i). Serostim is FDA-approved for wasting syndrome in individuals with HIV and short bowel syndrome. There is no evidence that any of the compendia list non-HIV-related wasting syndrome—the condition [redacted] suffers from—as an approved use of Serostim. Because [redacted] was not prescribed Serostim for a

"medically accepted indication," the prescribed Serostim does not satisfy the Medicare Act's definition of a "covered part D drug."

[redacted] argues that a "medically accepted indication" may also be supported by peer reviewed medical literature. *See* 42 U.S.C. § 1395x(t)(2)(B). However, the broader definition of "medically accepted indication" contained in § 1395x(t)(2)(B) applies only to drugs used in anticancer chemotherapeutic regimens and thus is not applicable here. *See id.* § 1395x(t)(2)(A). [redacted] argument that he is entitled to a medical necessity exception pursuant to 42 C.F.R. § 423.578 also fails because this section does not "allow an enrollee to . . . request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug." 42 C.F.R. § 423.578(e).

The district court lacked jurisdiction over [redacted] due process and Rehabilitation Act claims against DHHS under 42 U.S.C. § 405(h). That section, which "purports to make exclusive the judicial review method set forth in [42 U.S.C.] § 405(g)," *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 10 (2000), provides that "[n]o action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of title 28 to recover on any claim *arising under* [the Medicare Act]," 42 U.S.C. § 405(h) (emphasis added). "[O]ur case law establishes that where, at bottom, a plaintiff is complaining about the denial of Medicare benefits—[such as]

drug benefits under Part D—the claim 'arises under' the Medicare Act." *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1142–43 (9th Cir. 2010). Because [redacted] due process and Rehabilitation Act claims are, at bottom, about the denial of Medicare benefits, these claims "arise under" the Medicare Act and § 405(h) bars judicial review of them.

[redacted] claims against Envision and Blue Shield, the insurers that administered [redacted] Medicare Part D prescription drug plan, are also about the denial of Medicare benefits and arise under the Medicare Act. As such, those claims, too, are subject to 42 U.S.C. §§ 405(h) and (g) and related Medicare regulations. Pursuant to these statutes and regulations, Envision and Blue Shield were not properly named as defendants in this action. *See* 42 C.F.R. § 423.2136(d)(1) (providing that in a civil action seeking court review of a Medicare Appeals Council decision, the Secretary of DHHS is "*the* proper defendant" (emphasis added)); *Do Sung Uhm*, 620 F.3d at 1145 ("[Appellants] cannot circumvent § 405(h)'s requirements by suing [the Part D prescription drug provider].").

Finally, the district court did not abuse its discretion in denying [redacted] motion to supplement the administrative record. The administrative record is presumed to be complete, and [redacted] did not present "clear evidence to the contrary" rebutting this presumption. *See In re United States*, 875 F.3d 1200, 1206

(9th Cir. 2017), *cert. granted, judgment vacated on other grounds*, 138 S. Ct. 443 (2017). Nor did [redacted] demonstrate that any of the narrow exceptions allowing the reviewing court to consider extra-record evidence applied. *See San Luis & Delta–Mendota Water Auth. v. Locke*, 776 F.3d 971, 992–93 (9th Cir. 2014).

AFFIRMED.[1]

[1] [redacted] motions to take judicial notice (Dkt. 7) and supplement the record on appeal (Dkt. 29) are denied.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

[redacted]

Plaintiff,

v.

ALEX M. AZAR,

Defendant.

Case No. 18-cv-05022-HSG

ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 90, 94

United States District Court
Northern District of California

Pending before the Court are the parties' cross motions for summary judgment. Dkt. Nos. 90 ("Pl. Mot"), 94 ("Def. Mot"). The Court held a hearing on the motions on December 5, 2019. After carefully considering the papers and the parties' arguments, the Court **DENIES** Plaintiff's motion for summary judgment and **GRANTS** Defendant's motion for summary judgment.

I. BACKGROUND

Plaintiff [redacted] filed this action on August 16, 2018, seeking judicial review of the final decision by the Medicare Appeals Council ("MAC") denying Plaintiff coverage for the drug Serostim. Dkt. No. 1. The Court provides the relevant statutory framework and facts below.

A. Part D of the Medicare Act

The Medicare Act, established under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, provides coverage for certain medical services to eligible aged and disabled individuals. *Maximum Comfort Inc. v. Sec'y of Health & Human Servs.*, 512 F.3d 1081, 1083 (9th Cir. 2007). At issue here is Part D of the program, which is a voluntary prescription drug benefit program established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act"). Pub. L. No. 108–173, 117 Stat. 2066 (2012). Part D provides coverage for certain types of drugs: (1) prescription drugs; (2) biological products;

(3) insulin and insulin supplies used to inject insulin; and (4) vaccines. *See* 42 U.S.C. § 1395w-102(e).

Under the statute, the term "covered part D drug" includes "any use of a covered part D drug for a medically accepted indication." *Id.* § 1395w-102(e)(1). The definition of "medically accepted indication" depends on whether the medication is used in an "anticancer chemotherapeutic regimen." *Id.* § 1395w-102(e)(4). If not, as is the case here, "medically accepted indication" is defined by cross-reference to 42 U.S.C. § 1396r-8(k)(6), which states:

> The term "medically accepted indication" means 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). The "compendia described in subsection (g)(1)(B)(i)" consist of: (1) the American Hospital Formulary Service Drug Information ("AHFS-DI"); (2) United States Pharmacopeia-Drug Information ("USPDI") (or its successor publication); and (3) the DRUGDEX Information System. *Id.* § 1396r-8(g)(1)(B)(i).

B. Plaintiff's Requests for Coverage of Serostim

Plaintiff is a Medicare beneficiary enrolled in Part D, administered by Envision in 2016 and Blue Shield in 2017. AR 49, 720.[1] In July 2016, he was diagnosed with lipodystrophy or wasting syndrome (used interchangeably in Plaintiff's case), a rare disorder which causes Plaintiff to suffer from severe and progressive weight loss. AR 82. To halt this weight loss, his primary physician, Dr. Louis J. Cubba, M.D., prescribed Serostim, which Dr. Cubba said was the only medication "that was able to successfully halt his progressive, life threatening, weight loss." *Id.*

Plaintiff submitted a request for coverage of Serostim to his insurers, Envision in 2016 and Blue Shield in 2017. *See* AR 184–85, 192–94, 630–31. Both insurers denied coverage because Plaintiff's use of Serostim for lipodystrophy was not prescribed for a "medically accepted indication." *See id.*

[1] References to AR refer to the certified administrative record filed and attached as exhibits to the Declaration of Kimberly A. Robinson. Dkt. Nos. 64-7, 64-8, 64-9, 64-10.

i. Plaintiff's Appeal in 2016

In September 2016, Plaintiff filed a reconsideration request with the independent review entity ("IRE"). AR 1217–18. The physician reviewer found that the "Part D Plan was correct in denying the request for Serostim," because it was prescribed for "off-label (non-FDA) approved uses," and the Medicare-approved compendia "do not contain any citations to support the use of this drug for these conditions." AR 1217.

Plaintiff requested a hearing before an administrative law judge ("ALJ"). AR 997. ALJ James Myles held a telephone hearing with Plaintiff on October 21, 2016, and on November 15, 2016, ALJ Myles issued a decision against Plaintiff. AR 997–1003. ALJ Myles stated that while he was "sympathetic to [redacted] situation," he was bound by Medicare Part D coverage requirements, which state that the "proposed used of Medication must be supported by approved on label use by the FDA or Medicare-recognized compendia." AR 1002. Based on the record and evidence presented, ALJ Myles found that Plaintiff was requesting coverage of Serostim for "off-label, non-FDA approved uses which are not 'medically accepted indications' as defined by Medicare law." AR 1002–03. Therefore, he concluded that Plaintiff's Plan was not required to provide coverage for Serostim. AR 1003.

Plaintiff appealed ALJ Myles's decision to the MAC. AR 1031–32. The MAC remanded the case back to ALJ Myles, because the claim file did not include a copy of "either the FDA label or the Medicare-approved compendia." AR 1032. The MAC instructed the ALJ to obtain a copy of the Plan's "Evidence of Coverage and formulary for 2016, the FDA label, and the Medicare-approved compendia." *Id.*

On remand, ALJ Myles issued another unfavorable decision on March 30, 2018. AR 720–27. He did not dispute Plaintiff's credibility, or that Serostim is helpful for Plaintiff to maintain his weight. AR 726–27. However, he concluded that "[g]iven the information found on the FDA's label and the Medicare approved compendia, Serostim is not prescribed for a medically accepted indication." AR 727. Plaintiff again appealed the decision. *See* AR 12.

ii. Plaintiff's Appeal in 2017

After Blue Shield denied coverage in 2017, Plaintiff filed a reconsideration request with

the IRE. *See* AR 619. The IRE, after conducting a "new and independent review of the appeal," concluded that Plaintiff's Part D Plan was not required to cover Serostim. *Id.* The physician reviewer determined that there "are no citations in the Medicare approved compendia that support the use of Serostim for the diagnosed condition," and as a result, "the drug is not being prescribed for a medically accepted indication as defined by Medicare law." AR 620.

Plaintiff then requested an ALJ hearing on May 1, 2017. AR 660. ALJ Jeffrey Gulin dismissed the request because he found that ALJ Myles's decision was based "on the same facts and on the same issues" as the appeal before him and thus binding. *Id.* The MAC remanded the case back to ALJ Gulin, because it found that the facts in the decision by ALJ Myles were "not the same as the facts at issue here," given Plaintiff was seeking coverage under two different Medicare Part D prescription drug plans (in other words, under Envision in 2016 and Blue Shield in 2017). AR 323. After a telephone hearing, ALJ Gulin issued an unfavorable decision on March 15, 2018. AR 49–56. Based on the evidence and record presented, he found that Serostim was not being used for a medically accepted indication. AR 56. Plaintiff appealed the decision. *See* AR 12–17.

iii. MAC Decision

The MAC reviewed and adopted both ALJs' decisions. *Id.* In its July 12, 2018 order, the MAC acknowledged Plaintiff's argument "that there is no realistic difference between the Human Immunodeficiency Virus and the virus which the appellant asserts has caused the autoimmune disease that is the basis for his condition." AR 16. However, the MAC found that "the similarity of a diagnosis to a covered diagnosis is simply not a basis on which we direct Part D coverage." *Id.* Because the FDA label and Medicare compendia did not list Plaintiff's prescribed use, the MAC concluded that Part D did not cover Serostim in Plaintiff's case.[2] *Id.*

C. This Action

Following the MAC's decision, Plaintiff filed this civil action challenging the July 2018

[2] Plaintiff also sent a letter to the Administrative Appeals Judge, requesting that the MAC "make findings on the Section 504 of the Rehabilitation Act of 1973, the due process clause of the Fifth Amendment, and offer a reason for why [the MAC] remanded these cases without including the above copy of the 'FDA label or the AHFS-DI' for Serostim." AR 8–9. The MAC construed the letter as a request to reopen its July 2018 decision and held that Plaintiff did not show good cause for reopening. AR 2.

MAC decision. Dkt. No. 1. He named Blue Shield, Envision, and Alex M. Azar II, Secretary of the United States Department of Health and Human Services ("DHHS"), as Defendants. *Id.* Defendants filed motions to dismiss, which the Court granted on June 18, 2019. Dkt. No. 83. Currently, the only remaining Defendant is DHHS, and the only remaining cause of action is Plaintiff's first cause of action, which seeks review of the final decision by the MAC.[3] *See id.*

II. STANDARD OF REVIEW

A Medicare beneficiary may obtain judicial review of the MAC's final decision denying Part D coverage under 42 U.S.C. § 405(g). *See* 42 U.S.C. § 1395w-104(h) (incorporating Part C's judicial review provision, § 1395w–22(g), which provides for judicial review under § 405(g)). The governing regulations specify that a Part D beneficiary may obtain court review if the amount in controversy meets the threshold requirement estimated annually by the Secretary of DHHS. 42 C.F.R. § 423.2136(a).

Under the Administrative Procedure Act, the district court may set aside an agency decision that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Palomar Med. Ctr. v. Sebelius*, 693 F.3d 1151, 1159 (9th Cir. 2012) (citation and quotations omitted). A district court may disturb the decision to deny benefits only if the decision is either not supported by substantial evidence, or is based on legal error. *Burch v. Barnhart*, 400 F.3d 676, 679 (9th Cir. 2005). "Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. The evidence must be more than a mere scintilla, but may be less than a preponderance." *Molina v. Astrue*, 674 F.3d 1104, 1110–11 (9th Cir. 2012) (quotations and citations omitted). The court must consider the administrative record as a whole, weighing both the evidence that supports the decision and the evidence that detracts from it. *McAllister v. Sullivan*, 888 F.2d 599, 602 (9th Cir. 1989). If the evidence can rationally

[3] The Court dismissed Plaintiff's second and third causes of action, which alleged that Defendants violated Plaintiff's due process rights and Section 504 of the Rehabilitation Act of 1973, because the Court determined that it did not have subject matter jurisdiction over those two claims under *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1 (2000). Dkt. No. 83 at 5–8. Plaintiff attempts to relitigate those issues in his motion for summary judgment. Pl. Mot. at 13–15. But the Court declines to do so, and will not consider Plaintiff's arguments as to those two causes of action.

be interpreted in more than one way, the court must uphold the agency's decision. *Mayes v. Massanari*, 276 F.3d 453, 459 (9th Cir. 2001).

III. DISCUSSION

A. Plaintiff's Prescription for Serostim Is Not For a "Medically Accepted Indication"

As already discussed, Plaintiff's use of Serostim is covered by Part D only if it is used for a "medically accepted indication," meaning it is prescribed for an FDA-approved use or listed in one of the approved compendia. *See* 42 U.S.C. § 1396r-8(k)(6). Upon review of the record presented, the Court finds that Serostim was not used for a medically accepted indication.

The FDA label included in the record states that Serostim is "indicated for the treatment of HIV patients with wasting or cachexia to increase lean body weight, and improve physical endurance." AR 317; *see also* AR 16 (MAC decision citing to the FDA website and finding the same). Plaintiff does not dispute this, nor does he dispute that he does not have HIV-related wasting syndrome. As to the compendia requirement, the DRUGDEX compendium included in the administrative record lists the following uses for Serostim: cachexia associated with AIDs, growth hormone deficiency, and short bowel syndrome. AR 787–88. It also lists fat maldistribution for HIV infection as a non-FDA (or off-label) use. AR 788. ALJ Gulin noted that the AHFS-DI compendium did not identify any uses for Serostim outside the FDA approved indications.[4] AR 25. Based on the administrative record, there is no suggestion that any of the relevant compendia list non-HIV-related lipodystrophy as a use for Serostim.

Plaintiff argues that the phrase "medically accepted indication" is merely "illustrative, not definitional." Dkt. No. 98 at 5. But as DHHS notes, district courts in this circuit have rejected

[4] Plaintiff, in his reply brief, again seeks to supplement or complete the administrative record, a request the Court previously denied. Dkt. No. 98 at 6. He also filed two administrative motions requesting to file extra-record evidence. Dkt. Nos. 100, 102. The Court incorporates its prior analysis finding that Plaintiff failed to rebut with clear evidence the presumption that the record is complete, or present any evidence that an exception applies to allow the Court to consider extra-record evidence. *See* Dkt. No. 83 at 10–11. Accordingly, the Court **DENIES** Plaintiff's administrative motions to file additional documents. *See* Dkt. Nos. 100, 102. And even were the Court to consider the additional materials Plaintiff seeks to introduce, the Court finds that these materials would not change its analysis.

that very same argument. *See, e.g.*, *Nievod v. Sebellius*, No. C 11-4134 SBA, 2013 WL 503089, at *10 (N.D. Cal. Feb. 8, 2013); *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1047 (C.D. Cal. 2016) ("We note, however, that CMS and a clear majority of district courts have read this clause to incorporate the medical acceptance limitation, while only one district court has read it differently." (collecting cases)); *Broome v. Burwell*, No. 6:14-CV-01248-MC, 2015 WL 1526532, at *4 (D. Or. Apr. 1, 2015); *Rickhoff v. U.S. Sec'y ex rel. Dep't of Health & Human Servs.*, No. CV-11-2189-PHX-DGC, 2012 WL 6177411, at *4 (D. Ariz. Dec. 11, 2012). The Court agrees with the reasoning of these decisions, and finds it clear under the plain terms of the statute that a covered Part D drug must satisfy the medically accepted indication requirement.[5]

According to Plaintiff, providing coverage only to those who have HIV-related lipodystrophy, and not to those who have non-HIV-related lipodystrophy, is "unreasonable based on the lack of [a] relevant connection." Pl. Mot. at 12; *see also* Dkt. No. 98 at 8 (arguing it is "irrational and violative of substantive due process" to require Plaintiff to have HIV with lipodystrophy to qualify for coverage). Whether Part D *should* cover Plaintiff's use of Serostim to treat his condition because it has similar symptoms to those of patients with covered conditions is a policy matter not within the Court's competence to decide. The Court echoes the sentiments expressed by the MAC and ALJs, and is sympathetic to Plaintiff's situation. But the only issue before the Court is whether the MAC's decision to deny coverage either was not supported by substantial evidence or constituted legal error. Based on the record and for the reasons already discussed, the Court finds the MAC's decision to be supported by substantial evidence and not based on legal error.

B. 42 C.F.R. § 423.578 Exception

Plaintiff also argues that the MAC failed to apply an exception under 42 C.F.R. § 423.578.[6] Pl. Mot. at 14. Contrary to Plaintiff's argument, the MAC did consider this exception and held that Plaintiff did not qualify. AR 6. To qualify for a formulary exception under 42

[5] The Court finds Plaintiff's out-of-circuit cases inapposite or not persuasive. *See* Dkt. No. 98 at 5, 9 (citing cases).

[6] Plaintiff appears to invoke 42 C.F.R. § 421.2112(a) as another exception, Pl. Mot. at 14, but this regulation outlines the requirements for requesting review of an ALJ action.

C.F.R. § 423.578(b), the drug must be "medically necessary, consistent with the physician's or other prescriber's statement under paragraph (b)(5) of this section, and that the drug would be covered but for the fact that it is an off-formulary drug." 42 C.F.R. § 423.578(b). However, "[n]othing in this section may be construed to allow an enrollee to use the exceptions process set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug." *Id.* § 423.578(e).

The MAC found that the "formulary process cannot be used to cover a drug that does not meet the definition of a Part D drug." AR 6. Because Serostim in Plaintiff's case "does not meet the definition of a Part D drug," the MAC concluded that "there is no basis on which a formulary exception for Serostim can be granted." *Id.* As already discussed, Plaintiff has not shown that his prescribed use of Serostim meets the definition of a Part D drug. Thus, the Court does not find the MAC's determination to be arbitrary, capricious, or not in accordance with the law.

IV. DISCUSSION

The Court **DENIES** Plaintiff's motion for summary judgment, **GRANTS** Defendant's motion for summary judgment, and **DENIES** Plaintiff's administrative motions to file additional documents. Dkt. Nos. 90, 94, 100, 102. The MAC's decision is affirmed. The Court directs the Clerk to enter judgment in Defendant's favor and close the case. No further filings will be accepted in this closed case.

IT IS SO ORDERED.

Dated: 12/16/2019

Haywood S. Gilliam, Jr.

HAYWOOD S. GILLIAM, JR.
United States District Judge

United States District Court
Northern District of California