No. 19-17565

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JOHN DOE,
Plaintiff-Appellant,
v.
ALEX AZAR, II, SECRETARY OF U.S. HEALTH AND HUMAN SERVICES, ENVISION INSURANCE COMPANY, BLUE SHIELD OF CALIFORNIA, AND DOES 1-50,
Defendants-Appellees.

APPEAL FROM THE
UNITED STATES DISTRICT COURT
FOR THE
NORTHERN DISTRICT OF CALIFORNIA
Case No. 4:18-cv-05022-HSG

APPELLANT'S OPENING BRIEF

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Restricted Case, Administrative Record Under Seal Pursuant to Procedural Order of the District Court Dated June 18, 2019 Under CAND Local Rule 79-5(d)

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I. JURISDICTION

This Court has jurisdiction pursuant to 42 U.S.C. § 405(g), U.S. Const., Fifth Amend., Due Process Clause, and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794) ("Sec. 504").

II. INTRODUCTION

1. Exhaustion took almost three years. Two Administrative Law Judge (ALJ) Decisions and the Medicare Appeals Council (MAC) Decisions.[1]

2. This is an issue of first impression under Medicare Prescription Drug, Modernization and Improvement Act of 2003 (MMA), 42 U.S.C. § 1395w-101 *et seq*.

3. Appellant, John Doe[2] ("Mr. Doe") was diagnosed with Lipodystrophy, a life-threatening, auto-immune metabolic disease in July 2016 which can result in death. Symptoms include wasting syndrome aka cachexia causing him to undergo a dramatic weight loss to 132 lbs. He is X'XX" tall (AR 82, 54) and organ failure and life spans are estimated to be significantly shorter; the primary organs affected

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[1] HHS's administrative record (AR) of approx. 1500 pages was and is NOT in chronological order. HHS required duplicate exhibits for each of two ALJs. The AR was kept separate because they do 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 ER numbers added since each page filed in the D.C. had two page numbers. The sealed AR is in ER Vol. 3.

[2] John Doe [personal identifying information redacted].

are the liver, kidneys and pancreas (E.R. Vol. 2, Doc. 102-2 (not admitted into the record but two motions with "5 U.S. Department of Health and Human Services ('HHS')/National Institutes of Health ('NIH') documents" were filed in District Court ("D.C.") See Order (E.R. Vol. 1, Doc. 110) on Cross Motions Summary Judgment (MSJs)). At all relevant times Mr. Doe was/is a Medicare, Part D (prescription drug) beneficiary.

4. The only medication that allowed Mr. Doe to gain weight back notwithstanding severe side-effects, is Serostim (Somatropin). (AR 33, 134, 330, 628.) Two Medicare contractors, Blue Shield of California and Envision, denied coverage after his primary care doctor, Luis Cubba, M.D., Diplomate, American Board of Internal Medicine, AAHIVM,[3] prescribed it and Dr. Eveline Stock of the University of California San Francisco Medical Center (UCSF) Lipid Clinic strongly recommended it. (AR 186-88, 297-98, 628, 721.) The reason given by HHS for affirming the insurance carriers was that Mr. Doe had to prove he had another, unrelated auto-immune disease (HIV) based on a false premise: that HIV caused and/or is associated with his Lipodystrophy. (AR 184-85, 297-98, 630-31.)

5. At no time did HHS disclose they knew HIV was unrelated to Lipodystrophy. All they have to do is "push a button" through their components; e.g., NIH, and the Food and Drug Administration ("FDC[4]A") or look at Myalept

[3] American Academy of HIV Medicine
[4] "C" is for cosmetic in "FDCA."

(Metreleptin), a replacement hormone for anyone who has Lipodystrophy; FDA approved in 2014. See Request to take Judicial Notice Request pursuant to Fed. R. Evid. 201 filed concurrently herewith.

III. PROCEDURAL HISTORY

A. The Administrative Proceedings

1. After two ALJs' noticed[5] hearings the Medicare Appeals Council ("MAC") remanded only ALJ Myles to include the "Medicare-approved Compendia," which HHS relies on, and the insurance companies' formularies. (AR 1031-32.) After 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 [Compendia] list that way. The MAC further stated after Mr. Doe complained about not receiving the three Compendia, that he 'should have challenged it harder.' (AR 5, 15.) But the first 2 MAC remands already required the ALJs to include the one Compendia and both formularies. The ALJs and MAC do not recognize statutory "exception" for this prescription as both insurance companies desired the most restrictive definition of an acceptable

[5] 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); Mr. Doe objected to this notice. (AR 66.)

medical indication ("AMI"). 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, 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.

4. After the double remand for the two ALJs (AR 320-24, 1030-32), Mr. Doe first became aware that HHS had known for over 20 years that the population with HIV had their Lipodystrophy caused (and cured) by changing the anti-retroviral medication therapy ("ART") which is the actual cause of Lipodystrophy in HIV patients according to "5 HHS/NIH documents." (AR 54.) At the second ALJ hearing, Mr. Doe argued HHS violated his Due Process and Section 504 of the Rehabilitation Act of 1973. HHS was applying a known false causation theory without ever telling Mr. Doe who had to do considerable independent research into HHS' components. Myalept was approved for Lipodystrophy in February 2014, but not known to Mr. Doe and never mentioned by HHS or the two insurance carrier parties as evidence that HHS does provide research and medication for generalized Lipodystrophy.

B. The District Court ("D.C.")

The D.C. over-controlled[6] the case by erroneously dismissing **with prejudice** Due Process, Sec. 504, denying Mr. Doe's Motion to Supplement the AR which includes access to Compendia evidence, and dismissed Blue Shield and Envision Insurance as parties. (E.R. Vol. 2, Doc. 24, E.R. Vol. 1, Doc. 83.) 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[7] 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 Mr. Doe equal [meaningful] access to its Medicare, Part D program, the D.C. did not consider this gravamen of the case by not mentioning this nonpublic criteria which Plaintiff spent hours talking to patients, doctors and then researching the HHS/NIH online to find the agency's related evidence – HHS' documents relating to non-HIV Lipodystrophy.

Mr. Doe is requesting this Court Order the "5 HHS/NIH documents" (E.R. Vol. 2, Docs. 100 has 1 attachment and 102 has 4 attachments) into evidence. Under Rule 56, summary judgment could not have been granted for HHS if the D.C. had

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[6] A reading of the transcript on the motion to dismiss (Transcript of Proceedings, Doe 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 administrative record (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. (E.R. Vol. 1, Doc. 83.)

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

granted Mr. Doe's motion to allow the "5 HHS/NIH documents" (E.R. Vol. 2, Docs. 100 and 102) into evidence, evidence that HIV is not relevant to covering Serostim for Mr. Doe's life-threatening condition.

IV. ISSUES

A. The HHS Committed Legal Error, in Violation of the Medicare Act, 1. by Requiring HIV, an Irrational Criteria for Coverage of Serostim Because HIV Is Irrelevant and 2. Is There Medical Equivalence in Compendia AMI?

1. This Court Should Order the "5 HHS/NIH Documents" Into Evidence.[8]

2. Denial of Motion to Supplement AR with Access to Compendia Used by HHS, is Legal Error, as this is a Compendia Case.

B. There Are Constitutional (and Statutory) Due Process Violations by Requiring HIV, an Irrational Criteria for Coverage of Serostim, Because HIV Is Irrelevant and by not Informing Appellant about Another Hormone, Myalept, Is Error Because It is for Lipodystrophy not HIV.

C. Whether HHS Violated Section 504 of the Rehabilitation Act of 1973, as Amended.

D. Whether Dismissing Two Insurance Carriers as Parties is Error.

E. Whether Not Granting Statutory Exceptions to a Compendia Listing is Error.

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[8] The Order to Dismiss **with prejudice** (E.R. Vol. 1, Doc. 83) dismisses Due Process (Count B.), Section 504 (Count C.), the two insurance carrier parties, and the motion to supplement the record.

V. STATEMENT OF FACTS

Mr. Doe 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:

1. A Medicare Part D drug is either FDA approved or supported by being listed in or having citation(s) in Compendia or being an EXCEPTION. (AR 52-55.) Plaintiff's primary care physician, Dr. Cubba, and Eveline Stock, M.D., a doctor from the UCSF Medical Center's Lipid Clinic, diagnosed Mr. Doe with a rare metabolic auto-immune disorder, Lipodystrophy, which produces severe weight loss (wasting syndrome). 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[9] 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.)

According to ALJ Gulin, it is FDA approved with a condition that it is for HIV

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[9]*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. (E.R. Vol. 2, Doc. 98.)

patients who need it for wasting syndrome to increase body mass. This is the same use as Appellant's need. (AR 55.)

Plaintiff moved the D.C. to Order the Compendia (E.R. Vol. 2, Doc. 24), 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 AMI or citation is meaningless.

ALJ Gulin goes on to decline coverage because they 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 Mr. Doe's position that the ART, not HIV, causes Lipodystrophy. (AR 704, 707.)

ALJ Myles states:

> "**… Appellant 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.)

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 which 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 to Mr. Doe.

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.*

2. In February 2014, Myalept was FDA approved for people with generalized Lipodystrophy.

3. 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 Mr. Doe's Lipodystrophy's symptomatology - wasting syndrome. (AR 50, 724-26.)

4. ALJ Myles states Mr. Doe was entirely credible and further, that he is sympathetic to his life-threatening predicament. (AR 55, AR 726.)

5. In D.C., Mr. Doe relied on HHS/NIH documents. There is no clear cause and effect and treatment for people with 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 weight loss is treated by Serostim. There are no HIV compounds to change.[10]

6. HHS stated in D.C. that approx. $400.00 outdated 2016 compendium should be purchased by Mr. Doe 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 Mr. Doe 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).

7. The MAC, at AR 7-17, knew Mr. Doe's position was that there was no difference between the wasting symptoms of Lipodystrophy and that changing the ART is a cure for Lipodystrophy. After the ALJ hearings were initiated, Mr. Doe discovered the "5 HHS/NIH documents" which are specific evidence in support of the false premise known and utilized by HHS; i.e., that it is not the Compendia-

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[10] 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.

required HIV that causes life-threatening wasting syndrome. The D.C. denied Mr. Doe's two administrative motions to admit this evidence in its Order granting HHS' MSJ (E.R. Vol. 1, Doc. 110), Docs. 100 with one attachment, 102 with four attachments (E.R. Vol. 2), and ignored this merit argument. I.e., that the Compendia, at least those DrugDex pages Mr. Doe 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 is a fact sheet, which states "…Lipodystrophy will not be a concern for most people who start HIV treatment now." ("HIV and Lipodystrophy,[11]" last reviewed 9/19/2019.) The D.C. said, *inter alia*, that since the Court was going to give HHS a judgment it did not matter that it denied Mr. Doe's motions to admit the 5 HHS/NIH documents. (E.R. Vol. 1, Doc. 110 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 Mr. Doe. 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

[11] AIDS info "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).

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 Mr. Doe checked the costs of DrugDex now owned by IBM and found each year on line subscription was $2,000 to $3,000.[12]

8. HHS in its opposition to Mr. Doe's motion to add one document (E.R. Vol. 2, Docs 101 and 100 to the record), states and generally Mr. Doe 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, notwithstanding this requirement is based on a false premise. According to "HHS' NIH 5 Documents" and another medication, Myalept (generic Metreleptin) is approved since 2014 only for generalized Lipodystrophy.

9. The third MAC Judge omitted the AHFS-DI and USP-DI Compendia for Serostim and stated Mr. Doe 'did not challenge the ALJs hard enough' (AR 5.) To 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. Appellant is only appealing not receiving the three compendia or access thereto in his Motion to Supplement the

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

AR.

VI. STANDARD OF REVIEW

The Court of Appeals reviews the Commissioner's decision in a Social Security case *de novo*. *Burch v. Barnhart*, 400 F.3d 676, 679 (9th Cir. 2005), *Ramirez v. Shalala*, 8 F.3d 1449, 1451 (9th Cir. 1993); "Congress designed [the statute as a whole] to be 'unusually protective' of claimants, *Smith v. Berryhill*, 139 S. Ct. 1765, 1770 (2019). Using criteria unknown to beneficiaries is illegal. *Bowen*, 476 U.S. at 480.

VII. 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. Is There Medical Equivalence in Acceptable Medical 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* 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." *Id*.

> "…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, at 471, 481.*

The underlying truth about the HIV [non causation] was not known to Mr. Doe

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. Also see *Mathews v. Eldridge*, 424 U.S. 319 (1976), 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 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.

1. Mr. Doe Requests This Court Order the "5 HHS/NIH Documents" Into Evidence.[13]

HHS has not followed this Congressional mandate; i.e., 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. There is no good faith reason why HHS should be permitted to willfully disregard life or death of the population with non-HIV Lipodystrophy. In 2014 HHS' FDA component approved Myalept (generic-Metreleptin), a synthetic hormone to replace Leptin produced by lipids, which Lipodystrophy patients do not have. It only requires Lipodystrophy, not HIV.

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 D.C. should have decided on a biochemist expert since this case concerns metabolic and lipid areas of specialization. In accord, the Compendia listing being

[13] The Order to Dismiss **with prejudice** (E.R. Vol. 1, Doc. 83) dismisses Due Process (Count B), Sec. 504 (Count C), the two insurance carrier parties and the motion to supplement the record.

unreasonable has no *Chevron*[14] deference. *Tangney v. Burwell*, 186 F.Supp.3d 45, 51-52 (D. Mass. 2016); *Layzer v. Leavitt*, 770 F.Supp.2d 579 (S.D.N.Y. 2011).

If the D.C. admitted the 5 HHS/NIH documents, there would be a second dispute as to material facts and the Court could not grant HHS' MSJ. The D.C. Order on cross MSJs (E.R. Vol. 1, Doc. 110) relates back to the Order to Dismiss and Motion to Supplement Administrative Record (E.R. Vol. 1, Doc. 83), 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." E.R. Vol. 1, Doc. 110 at 6:n 4.

The rebuttal evidence is clear. The complaint is not a complex facial attack as is *Davis v. Astrue*, 874 F. Supp. 2d 856 (N.D. Cal. 2012); The D.C. cited and relied on *Davis v. Astrue*, 513 F. Supp. 2d 1137, 1145 (N.D. Cal. 2007) in which Mr. Doe was and still is the lead attorney and was the only case cited by this D.C. except for an irrelevant exhaustion case, *Shalala v. Illinois Council*, 529 U.S. 1 (2000). (Order, E.R. Vol. 1, Doc. 83 at 7.) Moreover, it is unlikely that the D.C. considered

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[14] *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984).

any facts from the two ALJ and three MAC decisions in the 1500 page AR filed on 2/5/19 (Doc. 64) since the D.C. did not mention any details or findings from them in this Order issued on 6/18/2019. (E.R. Vol. 1, Doc. 83.)

Not to admit material and relevant evidence (E.R. Vol. 2, Docs. 100, 102) before judgment is an affront to basic conceptions of fundament fairness. *San Luis & Delta Mendota Water Auth. v. Locke*, 776 F.3d 971, 972 (9th Cir. 2014) references *Lands Council v. Forester of Region One of the United States Forest Serv*., 395 F.3d 1019, 1030 (9th Cir. 2004) which states:

> "…Specifically, D.C.s are permitted to admit extra-record evidence: (1) if admission is necessary to determine whether the agency has considered all relevant factors and has explained its decision; (2) if 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 Appellant 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 Doc. 102 (E.R. Vol. 2) causes insulin resistance and organ failure (liver, kidney and pancreas) and; therefore, could result in death. Along with HIV, the 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 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.[15] (ALJ Decision at AR 727.) Historically, the ALJ has a duty to develop the record.

> "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)**Error! Bookmark not defined.**. 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 accord, *Garcia v. Comm'r of Soc. Sec*., 768 F.3d 925, 930 (9th Cir. 2014).

In *Smith* at 1770, 1777 the Supreme 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 D.C. in its judgment for HHS declined to rule on the merits, leaving HHS

[15] ALJ hearings are *de novo.*

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 (Lipodystrophy). The D.C**.** erroneously found "…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…." (E.R. Vol. 1, Doc. 110 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… Mr. Doe 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:

> "…Appellant 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…." (AR 725.)

The D.C. partially misstated the facts after Mr. Doe found the pertinent NIH evidence, going back in time, of the truth about non-HIV Lipodystrophy. The only difference is causation. With non-HIV Lipodystrophy it is either genetic or viral

causation. Mr. Doe also argued "medical equivalence" before ALJ Myles. If the D.C. rationale regarding its lack of competence to rule on the merits were true, the Supreme Court would not have been able to apply the criteria to find individuals could not be subjected to nonpublic policies and practices. *Bowen*, *supra* and this Court of Appeals could not have evaluated the Social Security Administration (SSA) "Listings of Impairments" [20 C.F.R. Pt. 404, Subpt. P, App. 1] as it did in *Lester v. Chater*, 81 F.3d 821 (9th Cir. 1995) when this Court applied medical listings under 20 C.F.R. Pt. 404, Subpt. P, App. 1, § 12.04 ("Listing § 12.04"). Experts were used in *Edmo v. Corizon, Inc*., 935 F.3d 757 (9th Cir. 2019.)

Here Mr. Doe produced specific facts that show the existence of genuine material fact to withstand an MSJ. HHS' reliance on HIV being present is irrational because it is based on a false premise, that ART, not HIV, causes and changing it cures Lipodystrophy. 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 legal error. (E.R. Vol. 1, Doc. 110.) See *T.W. Electrical Service, Inc. v. Pacific Electrical Contractors Ass'n.*, 809 F.2d 626 (9th Cir. 1987). The D.C. should have reversed based on HHS's 5 NIH documents and FDA approval of Myalept or granted a "sentence four" or "sentence six" of a § 405(g) judgment for Mr. Doe remanding the case to HHS to use a biochemist M.D. expert.

2. The Motion to Supplement the AR

All of the exceptions (see *Lands Council, infra*) to supplement an AR apply to the earlier motion filed and rejected in the Order dismissing them. (E.R. Vol. 2, Doc. 24 and E.R. Vol. 1, Doc. 83.) (1) As stated in the Motion to Supplement the AR, the MAC referenced a Compendia of a different year than produced and even in DrugDex, the compendia produced after remand (Myles Dec., AR 787-88) consisted of two pages, not enough to see an introduction on how it is used or citations as the statute provides. (2) Evidence relating to the existence of documents relating to HHS's policy not to update the compendia listings to reveal that HHS knew the HIV population had a cure for Lipodystrophy by changing the ART used to treat HIV. (3) The metabolic effects of Lipodystrophy, including insulin resistance and failure of liver, kidney, and pancreas which apply to Mr. Doe's disorder, is a technical and complex metabolic subject matter. (4) There is a showing of "bad faith" in that the Compendia 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.[16]

Thompson v. United States Dep't of Labor, 885 F.2d 551, 555 (9th Cir. 1989)

[16] 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.

established that the 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. Also see *San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 992 (9th Cir. 2014). Mr. Doe's doctor Eveline Stock, M.D., from UCSF's Lipid clinic is an expert, as is his Primary Care physician, Dr. Luis Cubba, Diplomate, American Board of Internal Med, AAHIVM.

The D.C.'s two orders (E.R. Vol. 1, Docs. 83, 110) on the Motion to Supplement the record (E.R. Vol. 2, Doc. 24) and two MSJs are not in accordance with generally accepted notions of fundamental fairness. There are reasons spelled out in the motions; e.g., the specific Compendia considered by HHS were not produced in the AR and the "5 HHS/NIH documents" are inextricably intertwined with Mr. Doe's argument that there is a showing of bad faith in that the Compendia requirement of HIV is based on a false premise. The D.C. rationale that Mr. Doe's evidence is "…nowhere close to showing 'clear evidence'" (E.R. Vol. 1, Doc. 110 refers to E.R. Vol. 1, Doc.83) 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 three parties' motions to dismiss containing that evidence. (E.R. Vol.

2, Docs. 19, 47, 48 and 49.) Again, had the D.C. read the two ALJ and three MAC decisions it referenced, the "clear evidence" would have been 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. 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 Docs. 98-1 and 98-2. (ER Vol. 2.)

B. Constitutional and Statutory Due Process

The D.C. struck the Due Process Clause of the Fifth Amendment count with prejudice (E.R. Vol. 1, Doc. 83), Mr. Doe filed Objections (E.R. Vol. 2, Doc. 84) which were never ruled upon and then used language in his MSJ similar to "whether through § 405(g) or not." (E.R. Vol. 2, Doc. 90.) There was nothing more Mr. Doe could have done since the Supreme 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* (2019), *Disabled Rights Union v. Shalala*, 40 F.3d 1018 (9th Cir. 1994), *Lopez v. Heckler*, 753 F.2d 1464 (9th Cir. 1985), and *Mathews v. Eldridge*, collaterality required, 424 U.S. 319 (1976). Statutory due process also applies.

Califano v. Yamasaki, 442 U.S. 682, 99 S. Ct. 2545 (1979). 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; 70 S. Ct. 65 (1950). There is no way Mr. Doe could have known using this standard; i.e., AMI, that HIV was really **not** the cause of Lipodystrophy. This is not the first time this Agency has acted surreptitiously and in bad faith.[17] The D.C. erred in relying on *Shalala v. Illinois Council,* 529 U.S. 1 (2000), an exhaustion case. In the related consolidated case to *Davis* cited by this D.C., *Doe v. Astrue,* No. C 09-00980 MHP, 2009 U.S. Dist. LEXIS 72819 (N.D. Cal. 2009), Judge Patel also took jurisdiction of Due Process violations based on a colorable claim and collaterality (in an amended complaint)which has been required for the past 44 years without exhaustion. In accord, *Davis v. Astrue,* 874 F. Supp. 2d 856 (N.D. Cal. 2012.) This is inapposite to this D.C.

The D.C. also erred by dismissing parties, due process and Section 504 of the complaint **with prejudice** contrary to *Morongo Band of Mission Indians v. Rose,* 893 F.2d 1074, 1079 (9th Cir.1990); *DCD Programs, Ltd. v. Leighton*, 833 F.2d

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

183, 186 (9th Cir.1987).[18]

C. Meaningful Program Access Under Sec. 504 Is Cognizable and Should Not Have Been Dismissed by the District Court

It was legal error to dismiss this cause of action with prejudice. It was pled in the first amended Complaint more than legally required and there are plenty of facts alleged in that Mr. Doe stated he did not have equal meaningful program access under 45 C.F.R. § 85.21. Surprisingly, the D.C. found that *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 the judicially created exhaustion in *J.L.* is not under the same statute and requires filing an administrative 504 complaint with the Agency and in 6 months appealing it back to the agency, without ALJs. (E.R. Vol. 1, Doc. 83 at 8.)

As an individual with non-HIV Lipodystrophy, Mr. Doe has no meaningful program access to the medication needed because it is based on a false and misleading premise - that HIV is required to have Serostim for Lipodystrophy. The 5 HHS/NIH documents show knowledge of HHS that people with HIV can be cured of Lipodystrophy. (E.R. Vol. 2, Docs. 100 and 102.) The DrugDex Compendium, a few pages of which were provided for Serostim, reveals that trial groups included HIV patients on their ART without any groups with

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[18] Mr. Doe filed a second amended Complaint (E.R. Vol. 2, Doc. 108, denied E.R. Vol. 2, Doc. 109) alleging HHS' knowledge of 20 plus years that HIV is not the cause of Lipodystrophy based on the "5 HHS/NIH documents."

Lipodystrophy, generalized without HIV or with an ART change to show the Lipodystrophy improved. This information omits all of the 5 NIH non-HIV Lipodystrophy documents without mentioning that they exist and not having any dates of trials. Appellant does NOT have any further burden of proof having found diametrically conflicting evidence from HHS.

D. 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 - Exceptions.** Also see below.

> 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."

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,* an exhaustion case, E.R. Vol. 1, Doc. 83 at 5-7.

2. It is true that under 42 U.S.C. § 405(g) HHS is a proper defendant (see

E.R. Vol. 1, Doc. 83 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 MAC refused to consolidate the two ALJ cases, until after its double remand because there are two insurance contractors, until just before the case went to D.C. (AR 320.) The D.C. cites no binding authority except one D.C. case in its Order dismissing two insurance carriers with prejudice, *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134 (9th Cir. 2010), an exhaustion case. (E.R. Vol. 1, Doc. 83.)

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 over which it has jurisdiction.

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[19] are federal courts which dismissed the two insurance companies lacking the same substantial evidence and including the same legal errors. Both carriers wrongfully refused to consider an exception. A request for exception was made and denied, again under a false premise pursuant to 42 C.F.R. § 423.578 Exceptions process.

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

E. 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

[19] 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. *Id*.

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. (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** appearing in publications which have been identified for purposes of this subclause by the Secretary or 42 U.S.C. § 1396r-8(k)(6)…the DrugDex Information System, and (ii) the peer-reviewed medical literature."

The 5 HHS/NIH documents 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 knew and the carriers knew or should have known that conclusion has a false premise and presumably as such would make large profits.

VIII. CONCLUSION

In that Mr. Doe has a life-threatening auto-immune disease which can result in

death, he requests this Court take the *Garrison v. Colvin*, 759 F.3d 995, 1019-20 (9th Cir. 2014) factors into account when fashioning a remedy to all issues herein.

Factors of (1) mistake… (3) misrepresentation, or misconduct by an opposing party, and/or (6) any other reason that justifies relief, should have led to the admission into evidence the "5 HHS/NIH documents" and the disclosure of Myalept being FDA approved in 2014 for people with generalized Lipodystrophy like Mr. Doe. In the D.C. Order, that Court states, *inter alia,* since there will be a judgment for the government there is no reason to admit the 5 HHS/NIH evidence. E.R. Vol. 1, Doc. 110 at 6:n 4.)

This action is inconsistent with accepted notions of fairness and neutrality. The Supreme Court in *Bowen* held claimants were denied their 'fair and neutral' procedure as required by 42 U.S.C. § 421(a) prior to having their benefits denied. In the D.C. both parties' MSJs discuss a recent case granting a Motion for Interlocutory Appeal, *United States v. Pfizer Inc.*, No. 05-6795, 2017 U.S. Dist. Lexis 96291 (E.D. Pa. June 22, 2017). HHS states in part and Mr. Doe agrees:

> "…that statutory definition allows the coverage of drugs even where they are not listed in any of the compendia if: '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.' 42 U.S.C. § 1395x(t)(2)(B)…." (E.R. Vol. 2, Doc. 99 at 4:4-10.) See 42 U.S.C. § 1396r-8(k)(6) *infra* at 28.

It defeats the purpose of Congressional intent of 42 U.S.C. § 405(g) to not be

heard on the merits (*Smith, supra* at 177) and violates Fed. R. Civ. P. 56 by keeping out material evidence (5 HHS/NIH documents) favorable to Appellant; otherwise, granting the MSJ for Defendant HHS could not have been legally accomplished.

To reverse by remanding only to calculate and pay Medicare benefits and award of attorney fees is warranted as to this issue.

Respectfully, Dated: March 23, 2020

/Steven Bruce/
Steven Bruce, Attorney for Appellant