UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

ALMA and BENNY VILLARREAL, husband and wife, Plaintiffs, v. INLAND EMPIRE ELECTRICAL WORKERS HEALTH AND WELFARE TRUST ("IEEW"); IEEW BOARD OF TRUSTEES; AETNA INSURANCE COMPANY; REHN AND ASSOCIATES; DAVID KIMMET; KRISTEN KNOX; and JOHN DOES NOS. 1-20, Defendants.	No. 1:16-cv-03114-SAB **ORDER DENYING DEFENDANT'S MOTION FOR JUDGMENT**

INTRODUCTION

Plaintiff Alma Villarreal suffers from a severe case of Stiff Person Syndrome ("SPS"). She sought a proposed treatment, which was denied by Defendant Inland Empire Electrical Workers Health and Welfare Trust ("IEEW"), the administrator of Plaintiffs' health care plan. Plaintiffs filed suit for denial of health care benefits under the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1132(a)(1)(B). Defendant moves for judgment as a matter

of law. On June 13, 2017 the Court held a hearing on the matter. Plaintiffs were represented by J. Jarette Sandlin and Defendant IEEW Trust was represented by Sarah Turner.

The Court heard argument on the pending Motion for Judgment, ECF No. 29, and considered the motion itself; Plaintiffs' responsive memorandum, ECF No. 34; Defendant's reply memorandum, ECF No. 35; and the administrative record.[1] A declaration by Dr. George Georges was filed, but as discussed by previous order, was not considered.

Because the record lacks substantial evidence justifying the administrator's decision, and because the record demonstrates that the administrator applied an arbitrary definition of experimental therapy, the motion is **denied**, the decision of the administrator is **reversed**, and the case is **remanded** for an award of benefits.

Because the First Amended Complaint contains other causes of action, this determination does not end the case. The Court will set a status conference to schedule the process to resolve the other pending causes of action.

FACTS

The IEEW Trust provides Plaintiffs with health insurance. The Trust agreement indicates that trustees hold a fiduciary duty to the Trust. Insurance company Aetna is the claims administrator for the plan, and the plan documents grant the Trust discretionary authority to interpret the plan.

In its discussion of organ and bone marrow transplants, the plan documents state that "[p]roposed transplants will not be covered if considered experimental or investigational for the participant's condition." AR at 43. Elsewhere, the plan states that "[i]n addition to the specific limitations stated elsewhere in this booklet,

[1] Filed as ECF No. 33-1. This order hereinafter refers to this document as AR (Administrative Record). All citations are to ECF page numbers.

the Plan will not provide benefits for the following: . . . Experimental or investigational treatment or services." AR at 44.

Later, the plan defines a medically necessary treatment as one that is, "in the judgment of the Plan, necessary and appropriate for the medical condition, and not experimental, investigational, or in conflict with accepted medical standards." AR at 66. An experimental treatment is defined below:

> Experimental, unproven or investigational services include treatments, procedures, equipment, drugs, drug usage, medical devices or supplies that meet one or more of the following criteria as determined by the Plan:
>
> . . .
>
> There is a lack of reliable evidence demonstrating that the service is effective in clinical diagnosis, evaluation, management or treatment of the condition;
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> . . .
>
> The service is the subject of ongoing clinical trials to determine its maximum tolerated dose, toxicity, safety or efficacy;
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> . . .
>
> Reliable evidence includes but is not limited to reports and articles published in authoritative peer reviewed medical and scientific literature.

AR at 64-65.

Plaintiff suffers from SPS, a painful autoimmune disease where muscles progressively stiffen. Plaintiff began suffering symptoms in 2006, and now experiences spasms in her neck, lower back, head, and throat, causing pain and

difficulty breathing. Plaintiff is bed-ridden. Readily available medical treatments did not stop the progress of Plaintiff's disease.

Plaintiff's doctor requested the treatment under discussion in this motion—hematopoietic stem cell evaluation and transplant. In this procedure, stem cells are harvested from the patient, stored, and later reintroduced, with the aim of reestablishing hematopoietic function.[2] Plaintiff's treatment providers conclude that the proposed treatment is medically necessary. Defendant reviewed the medical files and denied the request after Aetna, the health insurance provider, decided that the treatment was experimental and thus not covered. Aetna decided that clinical studies had not proven the procedure was an effective treatment for SPS.

Aetna provided a letter to Plaintiff's health care provider, Seattle Cancer Care Alliance ("Cancer Care"), notifying them of the denial. The letter informed Cancer Care how to obtain the policy documents it used to determine that the proposed treatment was experimental; that a practitioner could request a peer-to-peer review with Aetna's medical director; and information on appeal rights.

Cancer Care appealed the decision on July 13, 2015. AR at 126. The appeal contained clinical records on Plaintiff's condition and discussion of the appropriateness of the proposed treatment. One attachment described a case report from a medical journal showing two instances where the proposed treatment reversed the symptoms of SPS and allowed for full functioning.

Also attached were various clinical notes from practitioners discussing Plaintiff's case. Dr. John Roberts wrote that he thought the proposed treatment would be reasonable, as current treatments were ineffective and could not be increased without risking respiratory failure. Dr. James Bowen indicated that because Plaintiff was getting worse, she met the criteria for the proposed

[2] Hereinafter "the proposed treatment."

treatment. On March 10, 2015 Dr. George Georges opined that Plaintiff would be a good candidate for the proposed treatment. He noted there was a chance the procedure could be unsuccessful. He stated this is because he was aware of only seven similar successful treatments, and in similar protocols applying the proposed treatment to other autoimmune diseases, Dr. Georges was aware of complications and secondary infections.

The Trust confirmed receipt and sent a denial of the appeal on July 16, 2015. The letter alleges that the administrative review committee considered the correspondence and relevant plan provisions and again decided that the proposed treatment was experimental, and thus uncovered.

On July 30, 2015 the Trust sent a letter to Plaintiff indicating that it would reconsider Plaintiff's appeal and proceeded to examine the submitted materials, findings from a medical review, and the plan provisions. After concluding that more information was needed, the Trustees directed service providers to gather information sufficient to make a determination.

In September 2015 the administrator prepared a memorandum summarizing the administrator's findings. Included was a 2015 medical journal article on SPS which did not mention the proposed treatment in a list of treatment options. One published case study indicated that two individuals who were nonresponsive to traditional therapies underwent successful stem cell treatment.

From this, the administrator concluded the treatment was experimental, and further concluded that the side effects of the treatment could leave Plaintiff worse off. The Trustees sent a final determination to Plaintiff on October 1, 2015 concluding that the proposed treatment was experimental and therefore uncovered by the terms of the plan.

The Trust's stop loss insurer indicated that they would not cover any losses as the proposed treatment was considered experimental, and that an increased deductible would be required due to the risk of complications.

The Court relies on Dr. Georges' March 10, 2015 letter. AR at 145. The letter begins by describing Plaintiff's medical history in detail and the symptomology of her disease. Dr. Georges then describes in detail the process for undergoing the proposed treatment, including preparatory studies and tests, the procedure itself, and post-procedural drug treatment and protective processes to limit infection risks and other side effects.

Dr. Georges then begins discussing the efficacy of the treatment for multiple sclerosis, another immune system disease. He describes this treatment as fairly successful for a large percentage of clinical patients. He also describes how his proposed protocol differs from a non-FDA approved treatment protocol and explains why he would chose to avoid it. He proceeds to describe the risk of secondary infections, cancers, and other potentially deadly side effects.

Dr. Georges also describes the published reports and case studies regarding the proposed treatment for patients suffering from SPS. As described above, two Canadian patients underwent remission after the proposed treatment. A third patient in Canada underwent favorable outcomes after the proposed treatment. He also relates four American patients who presented remarkable recoveries after the proposed treatment was administered. He also concludes that international data shows that the proposed treatment is successful at treating similar diseases.

STANDARD

By default, ERISA cases are reviewed *de novo* by district courts, but if an ERISA plan gives the "administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan," then an abuse of discretion, or arbitrary and capricious,[3] standard applies. *Firestone Tire &*

[3] The "arbitrary and capricious" and "abuse of discretion" standard are largely read together. *Atwood v. Newmont Gold Co., Inc.*, 45 F.3d 1317, 1321 n.1 (9th Cir. 1995) ("The [two] standards differ in name only.").

Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989). Since the plan documents grant the plan administrator discretion in interpreting the plan provisions, the abuse of discretion standard applies, and the administrator's decision on the denial of benefits should be upheld if it is "based upon a reasonable interpretation of the plan's terms and it was made in good faith." *Montour v. Hartford Life & Accident Ins. Co*., 582 F.3d 933, 942 (9th Cir. 2009). "The touchstone of arbitrary and capricious conduct is unreasonableness. [The] inquiry is not into whose interpretation of plan documents is most persuasive, but whether the plan administrator's interpretation is unreasonable." *Barnett v. Kaiser Found. Health Plan, Inc.*, 32 F.3d 413, 416 (9th Cir. 1994).

This means that the Court can reverse an "ERISA plan administrator only if the decision was arbitrary, capricious, made in bad faith, not supported by substantial evidence or erroneous as a matter of law. A decision is not arbitrary or capricious if it is based on a reasonable interpretation of the plan's terms and was made in good faith." *Johnson v. Dist. 2 Marine Engineers Beneficial Ass'n-Associated Mar. Officers, Med. Plan*, 857 F.2d 514, 516 (9th Cir. 1988) (internal citations omitted). A decision is supported by substantial evidence when the administrator's decision is based on "relevant evidence [that] reasonable minds might accept as adequate to support a conclusion even if it is possible to draw two inconsistent conclusions from the evidence." *Snow v. Standard Ins. Co.*, 87 F.3d 327, 332 (9th Cir. 1996) (quoting *Maynard v. City of San Jose*, 37 F.3d 1396, 1404 (9th Cir. 1994)).

The plan documents themselves contemplate this standard, and state that judicial review is limited to determining whether the Trustees "(1) were in error upon an issue of law; (2) acted arbitrarily or capriciously in the exercise of their discretion; or (3) whether their findings of fact were supported by substantial evidence." AR at 76. The Court is to analyze the plan's words' plain meaning. *McDaniel v. Nat'l Shopmen Pension Fund*, 817 F.2d 1370, 1373 (9th Cir. 1987).

ERISA cases are generally limited to a review of the administrative record to provide parties with a speedy determination. *Callow v. Prudential Ins. Co. of Am.*, 2009 WL 1455326, at *1 (W.D. Wash. May 21, 2009). Depending on surrounding facts and on the standard of review governing the case, new evidence, including expert testimony, can sometimes be appropriate. However, as the Court previously concluded, no extrinsic evidence will be heard in this case. *See* ECF No. 40 at 3 (denying a request to consider testimony from Dr. Georges in reliance on *Taft v. Equitable Life Ins. Co.*, 9 F.3d 1469, 1472 (9th Cir. 1993)).

ANALYSIS

Defendant has filed a dispositive motion in this case, seeking judgment on the issue of Plaintiff's claim for ERISA benefits under section 1132(a)(1)(B). This cause of action allows beneficiaries to bring claims for benefits due under the plan, or clarify terms of the plan. Defendant's argument is that the plan precludes coverage of experimental treatments; the plan's administrators and the Trustees concluded that the treatment was an experimental procedure; and thus there was no abuse of discretion in construing the terms of the plan. The question for the Court is this: was the Trust's decision concluding that the proposed treatment is experimental under the terms of the plan arbitrary or unreasonable?

The initial denial for the proposed treatment was sent on April 30, 2015. The letter states that Defendant relied on Clinical Policy Bulletin (G06): Hematopoietic Cell Transplantation for Autoimmune Diseases and Miscellaneous Indications, and denied coverage because "[c]linical studies have not *proven that this procedure is effective for treatment of the member's condition*." AR at 122 (emphasis added). On July 16, 2015 Plaintiff's first appeal was denied[4] while

[4] The plan documents indicate that upon denial, beneficiaries are entitled to an appeal hearing where they may present evidence. AR at 75. However, none of the denial letters sent by Defendant inform Plaintiff of this right.

stating that experimental or investigative treatments aren't covered. AR at 168. The October 1, 2015 final determination letter only informed Plaintiff that the proposed treatment was denied because Aetna determined the treatment to be "experimental and/or investigational." AR at 177.

As far as the Court can tell, this decision was made with a very sparse amount of information in the record. The materials relevant to this decision found in the record are various correspondence; the above-discussed *Journal of the American Medical Association* ("JAMA") article (AR at 128); Dr. Georges' letter (AR at 145); some treatment records and clinical notes; and a memorandum written by Kristen Knox to the Trustees (AR at 170).

These records cite other documents. For example, the initial denial letter states that the Trust examined Clinical Policy Bulletin (G06): Hematopoietic Cell Transplantation for Autoimmune Diseases and Miscellaneous Indications. The Knox memorandum describes a journal article in *Neurology Neurosurgery & Psychiatry* ("NNP") describing treatments for SPS. Since these resources aren't actually in the record, the Court is unable to review them in order to determine whether the decision to deny treatment was reasonable. *See Callow*, 2009 WL 1455326, at *1.

As discussed above, there are two relevant definitions of experimental treatment at issue. The Court examines each of them in turn. First, there is no evidence in the record that would allow a reasonable person to conclude that "[t]here is a lack of reliable evidence demonstrating that the service is effective in clinical diagnosis, evaluation, management or treatment of the condition." AR at 65. Reliable evidence is later defined as evidence which "includes *but is not limited to* reports and articles published in authoritative peer reviewed medical and scientific literature." *Id.* It is apparent the administrator reviewed Dr. Georges' letter, which lays out in detail, as the treating doctor, the evidence he believes supports the conclusion that the proposed treatment will be effective in treating

SPS. Dr. George cites the JAMA article, which is the only published source discussing the application of the proposed treatment to SPS, as well as unpublished case studies which indicate a high level of success for the proposed treatment in regards to SPS.

Against this evidence, the administrator weighed the NNP article, which does not mention the proposed treatment in conjunction with SPS. Thus a large amount of positive evidence that the proposed treatment is "effective in . . . treatment of the condition" was outweighed by the negative inference of the treatment's lack of mention in one article. This weighing was against the substantial evidence in the record and an abuse of discretion insofar as the Trust's decision relied upon it.

There is no argument, analysis, or reasoning in the record why Dr. Georges' opinion, the case study, or the JAMA article weigh less heavily then the absence of discussion of the treatment from another article, nor is there any opinion that these sources are not reliable. Defendant points out that the Knox memo (citing Aetna's medical director) indicates that the medical director is not able to prognosticate whether "Plaintiff would be better or worse off." AR at 171. But such a conclusion appears to ignore the bulk of evidence from the record, which appears to indicate that patients undergoing the proposed treatment have tended to recover. There is no discussion of the actual or potential side effects Dr. Georges describes, the methods Dr. Georges and the JAMA article discuss that minimize side effects, or an attempt to analyze the probabilities and likelihoods that such side effects may impact Plaintiff. Indeed, there is no way to know what likelihood of success Defendants decided existed. There is also no discussion of the appropriate standards to measure successful treatments for such a "rare disease," AR at 128, at when large-scale, clinical studies may be difficult or impossible to construct. Indeed, the authors of the JAMA study indicate that when doctors seek to apply the proposed treatment to "autoimmune neurological diseases other than

multiple sclerosis," evidence is "limited to anecdotes and small case series." AR at 130. Without a discussion of the standard accepted methods for proving efficacy with such small samples, the Court must examine the authors' conclusion that anecdotes and small case series are indeed regular indicators of efficacy for rare autoimmune diseases such as SPS.

Further, there is no indication of the qualifications of Aetna's medical director, or discussion of why his or her opinion or research is more credible or trustworthy than Dr. Georges. Rather, the medical director's opinion that the treatment is experimental is presented in a conclusory manner, without any indication of an effort to construe the term as it is defined in the plan documents or analyze it by the terms of the plan documents. While Defendants have the discretionary authority to construe those plan documents and terms, the failure to do so is an abuse of discretion.

Given the scant materials found in the record, a reasonable person cannot conclude that the weight of the evidence indicates that the proposed treatment is ineffective. When the record does not contain "relevant evidence [that] reasonable minds might accept as adequate to support [the administrator's] conclusion," there is not substantial evidence to support that conclusion. *Snow*, 87 F.3d at 332. And because there is no positive evidence in the record that the treatment is ineffective, denying coverage on the basis of this phrase in the plan is an abuse of discretion as well.

Defendants also argue under the experimental term of the plan that "[the proposed treatment] is the subject of ongoing clinical trials to determine its maximum tolerated dose, toxicity, safety or efficacy." AR at 64. There is no indication that this is the definition of "experimental" that the Trust relied on in any of its determinations. In the first denial letter, the Trust told Plaintiff that "[c]linical studies have not proven that [the proposed treatment] is effective for treatment of the member's condition." AR at 122. The next letter, sent on July 16,

2015, stated that experimental or investigative treatments aren't covered. AR at 168. The October 1, 2015 final determination letter only said that the proposed treatment was denied because Aetna determined the treatment to be "experimental and/or investigational." AR at 177. Only the first letter indicates what *specific* term of the plan Defendant was construing in order to deny benefits, and the letter indicates it was the term that discusses efficacy. As discussed above, any decision to deny benefits under that term was an abuse of discretion.

Thus there is no evidence whatsoever in the record that Defendant used this definition of "experimental" in deciding whether the proposed treatment was covered. However, even if this was the rule the Trust applied during its determination, there is no evidence in the record that Defendant applied a good-faith interpretation, or any interpretation at all, of the definition regarding ongoing clinical trials. The precise phrase set by the plan defines experimental treatment as one where there are "ongoing clinical trials to determine its maximum tolerated dose, toxicity, safety or efficacy." AR at 64. There are some indicia that a study is involved. *See, e.g.*, AR at 128, 157, 160. But there is no "reasonable interpretation of the plan's terms," or even any interpretation at all, of the terms of the definition within the record. *Montour*, 582 F.3d at 942. Without a "reasonable interpretation of the plan's terms," the Court must conclude an abuse of discretion took place. *Johnson*, 857 F.2d at 516.

Further, by Defendant's admission, coverage was denied because "[c]linical studies have not proven that [the proposed treatment] is effective for treatment of the member's condition." AR at 122. But there is no reasonable reading of the plan requirement that treatment not be undergoing "ongoing clinical trials to determine its maximum tolerated dose, toxicity, safety or efficacy" that squares with a conclusion that a treatment hasn't been proven to be effective through clinical trials. The record before the Court indicates that the Trust did not apply the definition of experimental as defined by the plan, thereby abusing its discretion.

The ability of an administrator to construe the terms of a plan does not render it able to change the meaning of words beyond the reasonable understanding of the average person. *Callow*, 2009 WL 1455326, at *1.

CONCLUSION

The record before the Court provides no indication that Defendant applied the plain meaning of the term "experimental" as defined in the plan documents. Defendant's analysis mis-weighed the bulk of evidence in the record, applied a definition not found in the plain text of the plan, and abused its discretion in denying benefits. The Court makes no conclusion on whether the proposed treatment is experimental, or whether it is efficacious. But on the record before the Court, it is clear that the review process was inadequate.

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Accordingly, **IT IS HEREBY ORDERED**:

1. Defendant's Motion for Judgment, ECF No. 29, is **DENIED**.

2. The decision of the Trust is **REVERSED** and remanded for the immediate award of benefits.

3. The Court will shortly reach out to counsel to find a common time to set a status conference regarding other causes of action in this case.

IT IS SO ORDERED. The Clerk of Court is directed to **ENTER** this Order, **ENTER** a judgment in favor of Plaintiff, and **FORWARD** copies to counsel.

DATED this 16th day of June, 2017.

Stanley A. Bastian
United States District Judge