IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

No. 5:09-CV-00152-BO

LYLE D. GARDNER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	ORDER
	)	
GROUP HEALTH PLAN d/b/a WELLPATH SELECT, INC.	)	
	)	
	)	
Defendant.	)	
	)	

This matter is before the Court on Defendant's Motion to Strike Plaintiff's Affidavit (DE # 21), Defendant's Motion to Strike Dr. Sameer Keole's Affidavit (DE # 36), and Defendant's Motion for Summary Judgment (DE # 23).

The Court GRANTS Defendant's Motion to Strike Plaintiff's Affidavit in part (DE # 21). The Court DENIES Defendant's Motion to Strike Dr. Keole's affidavit. (D.E. # 36). Finally, the Court GRANTS Defendant summary judgment. (DE # 23).

FACTS

Plaintiff claims that Defendant wrongly denied him benefits under his health insurance plan ("the Plan"). Plaintiff enrolled in Defendant's Plan in 2002 and was diagnosed with prostate cancer in February 2008. Plaintiff's treating physician was Dr. Sameer Keole of the University of Florida Proton Therapy Institute. Dr. Keole recommended proton beam therapy ("PBT") for treatment instead of standard radiation therapy because he said that PBT had a higher cure rate,

lower complication rate, and a lower risk of radiation-caused malignancy. Dr. Keole's Aff., ¶2, Am. Complaint ¶ 9.

On April 18, 2008, the Defendant denied Plaintiff coverage for PBT. In its initial denial letter to Plaintiff, Defendant stated "[t]his request is not approved for reimbursement because PBT to treat prostate cancer is considered to be experimental and investigational by the Coventry Health Care Technology Assessment and as such is not eligible for coverage...This decision is based on the specific limitations and exclusions for coverage outlined in your Certificate of Coverage on page 42, item # 15."

The Coventry Health Care Technology Assessment referred to in the denial letter is a three page document on "Proton Beam Therapy in Treatment of Prostate Cancer" that purports to summarize several medical studies regarding PBT. S.R. 57-60. This document was created by medical professionals in a company called Coventry Health Care, a national insurer, and is updated annually. Defendant is a Coventry Health Care plan. Dr. Cokingtin's Aff., §2.

The denial letter also references the Plan's "specific limitations and exclusions." The Plan excludes "Procedures or treatments that We [the Defendant] conclude to be Experimental or Investigational." S.R. 20. The term "Experimental or Investigational" is defined elsewhere in the Plan:

> A health product or service is deemed Experimental or Investigational if one or more of the following conditions are met:
>
> - Any drug not approved for use by the FDA; any drug that is classified as IND (investigational new drug) by the FDA; any drug requiring pre-Authorization that is proposed for off-label prescribing;
> - Any health product or service that is subject to Investigational Review Board (IRB) review or approval;
> - Any health product or service that is subject to a clinical trial that meets criteria for Phase I, II, or III as set forth by FDA regulations, except for limited services required by law. Please refer to —Covered Clinical Trials|| in Section 6.5.D for a description of these limited services;

- Any health product or service that is not considered to have demonstrated value based on clinical evidence reported by Peer-Review Medical Literature and by generally recognized academic experts.

(S.R. 19; 21-22).

After its initial denial of benefits, Defendant granted Plaintiff a first level appeal. The Administrator of Billing Services at the University of Florida Proton Therapy Institute submitted a letter for this appeal, which discusses PBT and states that PBT treatment is "medically necessary and essential" in treating Plaintiff's prostate cancer. S.R. 96-96, Amend. Compl. ¶14. Among other supporting material, Plaintiff also submitted the results of a clinical investigation conducted by physicians at the Loma Linda University reporting favorable results from PBT treatment. Amend. Compl. ¶14, S.R. 98-102. Defendant's committee met on June 3, 2008 and affirmed the denial the next day. Amend. Compl. §15, S.R. 159. Plaintiff pursued a second-level appeal, and the denial was again affirmed on June 11, 2008.

Plaintiff then sought an independent external review coordinated by the North Carolina Department of Insurance pursuant to North Carolina law; the independent review organization affirmed the denial.

Despite his denial of coverage, Plaintiff decided to undergo PBT treatments. Plaintiff has spent approximately $145,000 to undergo these treatments. Amend. Compl. ¶ 10.

Plaintiff sued Defendant on April 7, 2009. He initially had two claims: a claim under 29 U.S.C. § 1132(a)(1)(B) for recovery of benefits improperly denied under the Employee Retirement Income Security Act (ERISA) and an ERISA claim for breach of fiduciary duty. It is undisputed that the Plan qualifies as an employee welfare benefit plan under ERISA. The Court dismissed the second claim on December 14, 2009. (D.E. #11.) Only the §1132 claim remains.

It is undisputed that the Plan excludes "experimental and investigational" treatment. Plaintiff argues, however, that Defendant improperly interpreted the Plan's definition of experimental and investigational in denying his benefits for PBT. Specifically, Plaintiff argues that Defendant wrongfully relied on the Coventry Health Care Technology Assessment to reject his benefits. Plaintiff claims that the Assessment does not comport with the Plan's definition of experimental or investigational procedures, and that PBT would not be experimental and investigational under the Plan's definition. Plaintiff further argues that the Assessment is a nonclinical, non-peer reviewed survey of medical literature, and it is not an accurate summary of the state of PBT. Finally, Plaintiff argues that Defendant should have individually assessed his particular circumstances to determine whether PBT treatment would be appropriate.

Plaintiff seeks reimbursement for his out-of-pocket costs for the PBT treatment, or in the alternative, reimbursement for the cost of standard radiation therapy that is normally covered by Defendant for treatment of prostate cancer. Plaintiff also seeks costs and attorneys' fees.

In addition to the stipulated record (DE # 16), Plantiff has submitted his own affidavit and that of his treating physician, Dr. Sameer Keole of the University of Florida Proton Therapy Institute. Defendant has submitted two affidavits from Dr. Diane L. Cokingtin, Corporate Medical Director of New Technology for Coventry Health Care.

DISCUSSION

The Court grants Defendant's Motion to Strike Plaintiff's Affidavit in part. The Court denies Defendant's Motion to Strike Dr. Keole's affidavit. The Court also grants Defendant's Motion for Summary Judgment.

Defendant's Motion to Strike Plaintiff's Affidavit (DE # 21)

The Court grants Defendant's Motion to Strike Plaintiff's affidavit in part as the affidavit contains impermissible argument.

Under Federal Rule of Civil Procedure 56(e), affidavits must be made on "personal knowledge, set[ting] out facts that would be admissible in evidence, and show[ing] that the affiant is competent to testify on the matter stated." Affidavits should not contain legal or factual argument. In resolving a motion to strike, the Court should use "a scalpel, not a butcher knife" to strike portions of an affidavit that do not satisfy the requirements of Rule 56(e). Upshaw v. Ford Motor Co., 576 F.3d 576, 593 (6th Cir. 2009) (internal citations omitted).

Here, the joint discovery plan states that "each party may introduce up to two affidavits that explain or illuminate how Defendant interpreted or should have interpreted portions of the administrative record." In response, Plaintiff submitted an 18-page affidavit consisting almost entirely of factual and legal arguments concerning the Plan, stipulated record and Dr. Cokingtin's affidavit, at some points even discussing case law.[1] Plaintiff justifies these arguments by pointing to the discovery plan's "explain or illuminate" language. Pl.'s Memo in Opposition. However, Plaintiff's affidavit should only have used facts based on his personal knowledge to "explain or illuminate" his position; argument is only appropriate in a memorandum of law. Fed. R. Civ. P. 56(e).

The Court thus strikes all aspect of the Plaintiff's affidavit containing argument and statements not based on facts within his personal knowledge. Therefore, the only allowable portions of Plaintiff's affidavit are paragraph 8 and portions of paragraph 10, which describe Plaintiff's understanding of the term "Investigational Review Board."

Thus, Defendant's Motion to Strike is granted in part and denied in part.

[1] It is undisputed that Plaintiff has no legal training.

Defendant's Motion to Strike Dr. Sameer Keole's Affidavit (DE # 36)

The Court denies Defendant's Motion to Strike Dr. Keole's affidavit. (DE # 35). Defendant argues that Plaintiff's submission of the affidavit on November 1, 2010 was untimely. The Court assumes, without finding that Plaintiff's affidavit was untimely filed.[2] However, its submission is justified and would cause no prejudice to the Defendant.

In Southern States Rack and Fixture, Inc. v. Sherman-Williams Co., the Fourth Circuit adopted a five-factor test to determine whether to exclude evidence when a party has failed to timely disclose. The factors are (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the non-disclosing party's explanation for its failure to disclose 318 F.3d 592, 597 (4th Cir. 2003).

These factors support admission of the affidavit. First, Defendant suffers no surprise; the affidavit is consistent with Dr. Keole's letter mailed to Defendant in 2008 recommending PBT as medically necessary for Plaintiff. S.R. 207. Indeed, Defendant concedes that "the information contained in the affidavit is largely contained in the Stipulated Record as a whole" and "contains almost nothing new." Def.'s Reply at 1. As there was no surprise, it is unnecessary for the Defendant to cure. Accordingly, there is no indication that this affidavit would disrupt trial.

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[2] The parties dispute the interpretation of the discovery order. It states, "Any such affidavits shall be served within sixty (60) days before the date for dispositive motions, and any such depositions of affiants shall occur within thirty (30) days before the date for dispositive motions." Dispositive Motions were due September 30, 2010.

Defendant argues that affidavits are due 60 days before dispositive motions (July 30th) while Plaintiff argues that affidavits are due anytime between July 30th and September 30th. The parties' briefing contains extensive debate on this issue.

Thus Defendant also argues that Plaintiff's affidavit, filed on September 24, 2010, was untimely, but it decided not to object. In turn, Plaintiff argues that Defendant's submission of Dr. Cokingtin's affidavit filed on September 30, 2010 was untimely, and thus Defendant has unclean hands in this matter.

The Court finds it unnecessary to resolve these issues.

Finally, the affidavit addresses a key issue in this case: whether PBT is an experimental procedure.

Thus, Defendant's Motion to strike is denied.

Summary Judgment

The Court grants Defendant summary judgment as the Plan clearly excludes PBT as experimental and there is no issue of material fact regarding whether Defendant abused its discretion in denying benefits.

Standard of review

A court should grant summary judgment if there are no genuine issue of material fact so that judgment is appropriate as a matter of law. Fed. R. Civ. P 56. On a motion for summary Judgment, a Court must view facts in a light most favorable to the non-moving party.

ERISA claims under § 1132(a)(1)(B) carry special review guidelines. When a plan provides a plan administrator discretionary authority to determine eligibility, courts must exercise "a deferential standard of review," determining only whether there has been an abuse of discretion. Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 109, 115 (1989). Under this "abuse of discretion" standard, a plan administrator's decision is reasonable "if it is the result of a deliberate, principled reasoning process and if it is supported by substantial evidence." Bernstein v. Capitalcare, Inc., 70 F.3d 783, 788 (4th Cir. 1995). "Substantial evidence" is evidence which a reasoning mind would accept as sufficient to support a particular conclusion. It consists of more than a mere scintilla of evidence but may be somewhat less than a preponderance." LeFebre v. Westinghouse Elec. Corp., 747 F.2d 197, 208 (4th Cir. 1984). A court may only consider evidence that was before the plan administrator at the time it made its decision. See, e.g., Stup v. Unum Life Ins. Co. of Am., 390 F.3d 301, 307 (4th Cir. 2004).

If the administrator "is operating under a conflict of interest, that conflict must be weighed as a 'facto[r] in determining whether there is an abuse of discretion.'" Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 109 (1989). A conflict of interest exists when the plan administrator is also the plan insurer, meaning the same entity decides whether an employee is eligible for benefits, as well as pays benefits out of its own pocket. Metropolitan Life Ins. Co. v. Glenn, 554 U.S. 105, 108 (2008.) "The significance of this factor will depend upon the circumstances of the particular case." Id.

In this case, the parties stipulate that the Plan grants Defendant discretionary authority to determine benefits. It is additionally stipulated that the Defendant is both the plan administrator and insurer. The Court thus reviews Defendant's decision to deny Plaintiff benefits under the abuse of discretion standard, considering Defendant's conflict of interest.

The Court notes that the Fourth Circuit has crafted seven factors,[3] in addition to the conflict of interest factor, to guide courts in determining whether an administrator has abused its discretion in denying benefits. Carden v. Aetna Life Ins. Co., 559 F.3d 256, 261 (4th Cir 2009) citing Booth v. Wal-Mart Stores, Inc. Associates Health & Welfare Plan, 201 F.3d 335 (4th Cir.2000). The consideration of these factors is not mandatory; instead a court "may" consider them. Booth, 201 f. 3d at 342. Indeed, these factors are usually only helpful when a plan administrator exercises its discretion to interpret broad or ambiguous plan language, as is often the case with ERISA claims. See, e.g., Id. (analyzing administrator's interpretation of a "quite broad" preexisting-condition provision); Carden, 559 F.3d at 263 (interpreting plan's ambiguous

[3] The eight factors are: (1) The language of the plan; (2) the purposes and goals of the plan; (3) the adequacy of the materials considered to make the decision and the degree to which they support it; (4) whether the fiduciary's interpretation was consistent with other provisions in the plan and with earlier interpretations of the plan; (5) whether the decision making process was reasoned and principled; (6) whether the decision was consistent with the procedural and substantive requirements of ERISA; (7) any external standard relevant to the exercise of discretion; (8) any conflict of interest.

Courts utilizing these factors often only consider some of these factors. See, e.g., Carden, 559 f. 3d 256 (only analyzing factors 1, 2, 4 and 8).

use of the word "disability"). As explained below, the Plan's relevant language here is unambiguous. The Court thus finds consideration of these factors unhelpful and irrelevant in determining whether Defendant abused its discretion.

Defendant did not abuse its discretion

The Court grants Defendant summary judgment. Defendant has shown that PBT is excluded from coverage under the Plan's clear definition of "experimental and investigational" procedures. Accordingly, no reasonable jury could find that Defendant abused its discretion in denying coverage for PBT as experimental.

The Plan states that it excludes coverage for, "[p]rocedures or treatments that We [the Defendant] conclude to be Experimental or Investigational." (S.R. 20). The Plan provides four conditions that constitute experimental or investigational product and services. One condition is "[a]ny health product or service that is subject to Investigational Review Board (IRB) review or approval."

Defendant has shown that PBT was in fact "subject to Investigational Review Board (IRB) review or approval."[4] As explained in Dr. Cokingtin's First Affidavit,

> An IRB is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans, with the aim to protect the rights and welfare of the research subjects. Federal law and regulations define IRBs and require them for all research that receives funding, directly or indirectly, from the Department of Health and Human Services ("DHHS"). An IRB does not have jurisdiction over treatment that is considered by the institution to be the current standard of care.

(DE # 17, Cokingtin's First Aff. ¶5). Dr. Cokingtin states that PBT is "subject to review and approval by many Institutional Review Boards ("IRB"). Id. Dr. Cokingtin supports this

[4] The Defendant also claims that PBT falls under the "subject to a clinical trial that meets criteria for Phase I, II, or III as set forth by FDA regulations" and the "not considered to have demonstrated value" definitions of experimental coverage. The Court finds it unnecessary to address these arguments.

statement with a list of clinical trials studying PBT's treatment of prostate cancer supervised by IRBs. Id. at ¶4-5.

Plaintiff does not contest that PBT is the subject of IRB review or approval. Nor does the Plaintiff dispute Dr. Cokingtin's description of an "IRB." Instead, Plaintiff argues the Plan incorrectly defines the IRB acronym as "*Investigational* Review Board" instead of using what he claims is the correct term, "*Institutional* Review Board." (emphasis added).

Plaintiff's affidavit states that his "research" of the term "Investigational Review Board," revealed the existence of a private company called "The Independent Investigational Review Board, Inc." which refers to itself as "Independent IRB, Inc." (DE # 18, Lyle Gardiner Aff. ¶ 8). This company is evidently one of the many IRBs operating under federal law. The Plaintiff argues that because PBT is not subject to "review or approval" by this particular private company, then this condition under the Plan is not satisfied. Alternatively, Plaintiff argues that the Plan's erroneous definition of the IRB acronym creates ambiguity in the Plan's language.

Plaintiff's arguments are unpersuasive. First, the Plan clearly referenced all IRBs, and not any one particular IRB. More importantly, Dr. Cokingtin's second affidavit explains that "Investigational Review Board" is just another term for an "Institutional Review Board:"

> IRBs are committees that have been formally designated to approve, monitor, and review medical research involving humans. In the medical profession, Institutional Review Boards are usually referred to as —IRBs. While the actual full name is —Institutional Review Boards, IRBs are sometimes referred to in full in the medical profession as Investigational Review Boards, as well as independent ethics committees and ethics review boards. Anyone in the medical profession would understand an Investigational Review Board to be such a committee. Furthermore, an internet search of the term Investigational Review Board directs users to websites relating to IRBs.

(Cokingtin's Second Aff. ¶ 3.) The Plaintiff does not submit any evidence refuting the testimony that "Investigational Review Board" is interchangeable with the term "Institutional Review

Board."[5] The Court thus finds the Plan's use of the term "Investigational Review Board" is unambiguous. Indeed, even assuming this term was ambiguous, the Plan's use of the formal and commonly used acronym "IRB" would resolve any confusion.

As the IRB provision is clear, Defendant's conflict of interest played no significant role in the denial of benefits. Even assuming the IRB provision was ambiguous, Defendant's interpretation of the provision is undoubtedly the "best interpretation." Carden, 559 F.3d at 263 (finding Aetna's conflict irrelevant when their interpretation of the word "disability," "was a reasonable one, if not the best one").

Plaintiff's briefing tries to bury the IRB issue. Instead, it primarily argues that Defendant wrongly relied on the Assessment in denying his claims. Plaintiff states the Assessment "is problematic because it strays from the plain language of the Plan." This argument only holds weight, however, if one accepts Plaintiff's premise that the Plan's language is more favorable than the Assessment, and that Plaintiff would be able to recover under the Plan's language. As already shown, however, Plaintiff cannot recover under the Plan's clear language. Thus, Plaintiff's arguments regarding the assessment are in vain.

Plaintiff's situation is undoubtedly sympathetic. However, Defendant's decision to deny coverage was reasonable, supported by substantial evidence, and in no way an abuse of

[5] Plaintiff argues, without citing any legal support, that Dr. Cokingtin's statement about what "anyone in the medical profession knows," is "inadmissible hearsay and not on personal knowledge." This argument is baseless. Dr. Cokingtin is a medical doctor, and is free to comment on her experience in the medical community and the common understanding of a term used in the medical community. Her statement is not hearsay.

Plaintiff also argues that Dr. Cokingtin's testimony is unhelpful because it discusses how medical professionals understand "Investigational Review Board," as opposed to what a "reasonable insured" person would understand it to mean. This argument is also unconvincing. Dr. Cokingtin testified that an internet search of the term "Investigational Review Board" directs users to websites relating to IRBs; this evidences how a reasonable insured would understand the term. Additionally, Dr. Cokingtin's reference to medical professionals was appropriate as "Investigational Review Board" is a term undoubtedly used most often in the medical community. Importantly, Plaintiff has not provided any evidence disputing that the term "Investigational Review Board" is interchangeable with "Institutional Review Board."

discretion. Indeed, it is the only conclusion Defendant could have made under the clear language of the plan.

Denying Plaintiff's Request for Costs of Traditional Treatment

Plaintiff is entitled to no damages.

Plaintiff asks that if the Court determines that Defendant reasonably interpreted the Plan, that he nonetheless be awarded an amount equal to what traditional, covered radiation treatment would have cost him. Amend. Compl. ¶ 33. The Plaintiff can cite no legal support for this claim and abandons this argument in its Memorandum in Opposition to Summary Judgment. DE # 28.

The Supreme Court has held that remedies for a violation of § 1132(a)(1)(B) are exclusive: a plaintiff can only file an action pursuant to § 1132(a)(1)(B) to recover accrued benefits, to obtain a declaratory judgment that he is entitled to benefits under the provisions of the plan contract, and to enjoin the plan administrator from improperly refusing to pay benefits in the future. Mass. Mut. Life Ins. Co. v. Russell, 473 U.S. 134, 147 (1985) (stating "[w]e are reluctant to tamper with an enforcement scheme crafted with such evident care as the one in ERISA.").

Plaintiff's demand is denied.

Denying Defendant Attorney Fees and Costs

Defendant's request for attorney fees and costs are denied. Under ERISA, "reasonable attorney's fee and costs" are available to either party at the court's "discretion." 29 U.S.C. §1132(g)(1). See Hardt v. Reliance Std. Life Ins. Co., 130 S. Ct. 2149 (2010). The Court sees no reason to award the Defendant attorney fees in this case.

CONCLUSION

The Court GRANTS Defendant's Motion to Strike Plaintiff's Affidavit in part (DE # 21). The Court DENIES Defendant's Motion to Strike Dr. Keole's affidavit. (D.E. # 36). Finally, the Court GRANTS Defendant's Motion for Summary Judgment. (DE # 23).

SO ORDERED, this 2 day of April, 2011.

TERRENCE W. BOYLE
UNITED STATES DISTRICT JUDGE