UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

HILL DERMACEUTICALS, INC.,

Plaintiff,

v. Case No: 6:16-cv-833-Orl-40TBS

ANTHEM, INC.,

Defendant.

ORDER

This case comes before the Court on Plaintiff, Hill Dermaceuticals, Inc.'s Motion to Compel Documents Responsive to Plaintiff's September 7, 2016 Requests for Production, Request for Sanctions/Attorneys' Fees (Doc. 93). Defendant Anthem, Inc., has filed a response in opposition to the motion (Doc. 110).

Actinic keratosis ("AK") is a precancerous skin condition that affects an estimated fifty-eight million people in the United States (Doc. 25, ¶ 14). Plaintiff developed, manufactures and distributes Tolak® (fluoracil) 4% Cream ("Tolak") to treat AK (Id., ¶¶ 1, 14). It contends that Tolak is safer, as effective, and has a lower wholesale acquisition cost than the other existing brand name and generic AK drugs (Id., ¶¶ 16-19).

Defendant provides coverage to Medicare Part D participants (Id., ¶ 8). Plaintiff asked Defendant to add Tolak to Defendant's Medicare Part D formularies (Id., ¶ 22). Defendant denied the request, citing "insufficient evidence" to show the advantages of Tolak over the other AK drugs already included in its formularies (Id., ¶ 23). Plaintiff alleges that it gave Defendant "overwhelming scientific evidence," and that Defendant improperly rejected Tolak because it receives significant rebates from other drug

manufacturers (Id., ¶ 45). Plaintiff, which does not provide rebates on Tolak, contends that Defendant's decision not to include Tolak in its Medicare Part D formularies subjects "Medicare patients to drugs that cause more severe adverse effects, and are unnecessarily expensive to Medicare Part D participants and the federal government." (Id., ¶ 27).

Defendant counters that the Medicare Prescription Drug Improvement and Modernization Act, which established the Part D benefit, contemplates the negotiation of prices between plan sponsors and pharmaceutical companies on behalf of Medicare beneficiaries (Doc. 110 at 5). Defendant also contends that "[r]ebates and discounts which are 'properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity' are protected under the discount exception and safe harbor provisions of the federal anti-kickback statute." (Id.) (quoting 42 U.S.C. § 1320a-7b(b)(3)(A)).

Plaintiff's amended complaint seeks a preliminary and permanent injunction compelling Defendant to withdraw or suspend its refusal to include Tolak in its Medicare Part D formularies (Doc. 25 at 15). Plaintiff also prays for a declaratory judgment that Defendant's decision not to list Tolak in its Medicare Part D formularies violates Federal regulations and Section 1860D-4(b) of the Social Security Act (Id., ¶ 36). Plaintiff alleges that Defendant has tortuously interfered with its customers (Id., ¶ 39), and that Defendant's actions violate the Florida Deceptive and Unfair Trade Practices Act (Id., ¶ 42). Lastly, Plaintiff alleges that Defendant's actions constitute an unlawful restraint on trade in violation of 15 U.S.C. § 1 and FLA. STAT. § 542.18 (Id., ¶¶ 47-61).

According to Defendant, before a drug can be included in its formularies, it must first be reviewed by the Clinical Review Committee ("CRC") (Doc. 110 at 22). Defendant

says the CRC is an independent committee charged with reviewing "drugs for efficacy, safety, effectiveness, and clinical aspects in comparison to similar drugs within a therapeutic class or used to treat a particular condition." (Id.). Defendant asserts that the CRC "may NOT include or consider the following: Rebates or potential rebates; Costs to the health plan, member or risk bearing entity; Economic outcomes; and/or Benefit types." (Id. at 22-23). Defendant maintains that the Medicare Part D regulations require that clinical decisions be based "'on the strength of scientific evidence and standards of practice, including assessing peer-reviewed outcomes research data, and other such information as it determines appropriate.'" (Id. at 23) (quoting 42 C.F.R. § 423.120(b)(1)(v)).

Defendant explains that the insufficient evidence designation given to Tolak is used "when based upon the data available at the time of the review, the drug has an unclear treatment profile for the majority of individuals taking the product as compared to other available products within the therapeutic class of drugs or other available treatment options." (Doc. 110 at 23, ¶ 9). Defendant maintains that when the CRC reviewed Tolak "there were no published scientific literature studies available relating to the risks/benefits of Tolak." (Id. at 23). Defendant says its decision was "[b]ased upon the lack of published scientific literature available on Tolak." (Id. at 24). Plaintiff counters that Tolak has been placed on at least half of all Medicare Part D formularies based on the same clinical data that was submitted to Defendant (Doc. 49-1, ¶ 20).

Before this lawsuit was filed, Tolak was on Defendant's commercial health insurance formulary with no preconditions, precautions or restrictions (Doc. 55, ¶ 3). After the lawsuit was filed, Defendant issued a new formulary policy on the commercial health insurance side which provides, *inter alia*:

> APPROVAL CRITERIA
>
> Requests for a non-preferred topical agent may be approved when the following criterion is met:
>
> I. Individual has had a trial and inadequate response or intolerance to one preferred topical agent.
>
> Preferred agents: Carac, fluorouracil topical solution/cream, imiquimod
>
> Non-preferred agents: Efudex (brand), Fluoroplex, Tolak
>
> II. Requests for topical fluorouracil agents (Carac, Efudex, Fluoroplex, fluorouracil, Tolak) for individuals less than 18 years of age will be reviewed on a case-by-case basis.

(Doc. 110 at 18).

After Defendant made this policy change, Plaintiff filed a motion for sanctions alleging that Defendant was engaged in retaliatory conduct and bad faith (Doc. 55). Plaintiff maintains that the policy change to Defendant's commercial formulary "is clearly retaliatory as a result of the instant litigation intentionally designed to hurt and harm [Plaintiff] economically." (Doc. 55 at 2). Defendant has filed a response in which it argues that Plaintiff failed to satisfy the requirements of FED. R. CIV. P. 11 before filing the motion (Doc. 74 at 1-2). Defendant also argues that Plaintiff's motion does not allege litigation misconduct relevant to this action, Plaintiff has not shown that Defendant's conduct rises to the level of bad faith or the violation of a Court order, there is no plead or actual violation of law on the part of Defendant, and sanctions are not appropriate to remedy conduct in the commercial market which is unrelated to Medicare Part D (Id., at 3-6). The Court has the motion under advisement.

After filing its motion for sanctions, Plaintiff asked Defendant to produce:

> REQUEST NO. 1: All Documents relating to or referring to the July 18, 2016 commercial formulary changes to fluorouracil

> medications as evidenced by Anthem memorandum attached hereto as Exhibit A.

(Doc. 93 at 5).

Defendant's response includes two pages of preliminary statements and general objections followed by the following specific response:

> RESPONSE: Anthem objects to Request No. 1 to the extent it seeks documents that are privileged. Anthem also objects to Request No. 1 on the grounds that it seeks production of documents that are not relevant to the issues in dispute or calculated to lead to the discovery of admissible evidence. First, other, non-Tolak, fluorouracil medications are not relevant to this case. Second, none of the claims asserted by Hill in its Amended Complaint (Dkt. 25) deal with Anthem's approach to Tolak, or any other drug, in the commercial market (which is separate and distinct from the government's Medicare Part D program). Moreover, Hill acknowledges that its lawsuit only addresses Tolak with respect to Medicare Part D (Dkt. 55, pg. 11), and Hill has made no attempt to further amend its complaint to add additional claims/allegations related to Anthem's commercial (non-Medicare Part D) approach or practices. Thus, there is no rationale for requesting documents relating to other, non-Tolak, fluorouracil medications, much less commercial formularies. Anthem also objects to Request No. 1 to the extent the Request seeks protected, confidential, proprietary or trade secret subject matter without an appropriate Non-Sharing of Disclosures Protective Order Stipulation being agreed to or entered in the case.

(Doc. 93-1 at 1-5).

Plaintiff argues that Defendant's objections are insufficient, it has not produced a privilege log, and the request is relevant to its claims that formulary decisions are solely motivated by financial reasons, as well as its assertion that Defendant has engaged in retaliatory conduct (Doc. 93 at 6-7). Defendant argues that its commercial pre-authorization practices are irrelevant to its decision to not include Tolak on its Medicare Part D formularies (Doc. 110 at 4). Defendant also argues that proprietary and

confidential information regarding Plaintiff's competitors is not relevant to Plaintiff's claims made in this case (Id., at 2).

Federal Rule of Civil Procedure 26 guides the Court's determination of whether the information Plaintiff seeks is discoverable. The rule provides that:

> Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense4 of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

FED. R. CIV. P. 26(b)(1).

The term "relevant," as used in Rule 26 encompasses "any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case." Oppenheimer Fund, Inc. v. Sanders, 437 U.S. 340, 351-52, 98 S.Ct. 2380, 57 L.Ed.2d 253 (1978). "[T]he onus is on the party resisting discovery to demonstrate specifically how the objected-to request is unreasonable or otherwise unduly burdensome." Donahay v. Palm Beach Tours & Transp, Inc., No. 06 61279 CIV, 242 F.R.D. 685, 687 S.D. Fla. May 30, 2007).

While the scope of discovery is broad, there are limits. "Claims and defenses determine discovery's scope." Brannies v. Internet ROI, Inc., No. CV414-155, 67 F.Supp.3d 1360, 1362 (S.D. Ga. Dec. 4, 2014) (citing Chudasama v. Mazda Motor Corp., 123 F.3d 1353, 1368 (11th Cir. 1997)). "[R]equiring relevance to a claim or defense 'signals to the court that it has the authority to confine discovery to the claims and defenses asserted in the pleadings, and signals to the parties that they have no

entitlement to discovery to develop new claims or defenses that are not already identified in the pleadings.'" Builders Flooring Connection, LLC v. Brown Chambless Architects, No. 2:11CV373-MHT, 2014 WL 1765102, at *1 (M.D. Ala. May 1, 2014) (quoting GAP Report of Advisory Committee to 2000 amendments to Rule 26). "As the Advisory Committee Notes say, '[t]he Committee intends that the parties and the court focus on the actual claims and defenses involved in the action.'" Liese v. Indian River Cty. Hosp. Dist., 701 F.3d 334, 355 (11th Cir. 2012) (quoting the GAP Report).

Setting aside the matters raised in the motion for sanctions, Plaintiff has alleged that Anthem's formulary decisions are improperly based solely on financial motives and not on clinical evidence. The information sought here (Defendant's evaluation and classification of the drug at issue) falls within the broad scope of discovery with respect to that issue. Accordingly, Plaintiff's motion to compel its first request is **GRANTED**. Defendant shall produce its documents relating to or referring to the July 18, 2016 commercial formulary changes referenced in pages 18-19 of docket entry 110 within 14 days from the rendition of this Order.

Plaintiff has also asked Defendant to produce:

> **DOCUMENT REQUEST NO. 2**: All Documents, studies, and literature produced by drug manufacturers and evaluated or considered by Anthem's P&T Committee for all other drugs on Anthem's Medicare Part D formularies for the treatment of actinic keratosis including but not limited to: Carac (fluorouracil) Cream, 0.5%; Picato (ingenol mebutate) Topical Gel, 0.015%, 0.05%; Efudex® (fluorouracil) Topical Cream 5%, and Fluorouracil 5% Topical Cream.

(Doc. 93 at 8).

Defendant's response includes the same preliminary statements and general objections it made to Plaintiff's first request for production (Doc. 93-1 at 5). Then,

Defendant specifically responded to this request as follows:

> **RESPONSE:** Anthem objects to Request No. 2 to the extent it seeks documents that are privileged or otherwise accessible to Plaintiff or attempts to draw or present legal conclusions. Anthem also objects to Request No. 2 on the grounds that, as framed regarding "All Documents," the lack of limited or defined scope for "Anthem's Medicare Part D formularies," and the lack of a time limitation makes the Request overly broad and unduly burdensome. Anthem also objects to Request No. 2 on the grounds that it seeks production of documents that are not relevant to the issues in dispute or calculated to lead to the discovery of admissible evidence; other, non-Tolak, fluorouracil medications are irrelevant to Tolak's individual Insufficient Evidence designation. Anthem also objects to Request No. 2 to the extent the Request seeks protected, confidential, proprietary or trade secret subject matter without an appropriate Non-Sharing of Disclosures Protective Order Stipulation being agreed to or entered in the case.

(Id.).

Plaintiff argues that this is a narrow request for the clinical evidence the CRC[1] evaluated when it considered the drugs on Defendant's formulary that are used to treat AK (Doc. 93 at 8). Defendant argues that the information is not relevant because it made its decision on Tolak "based on the dearth of any published scientific literature, because no substantive comparison could be conducted due to the lack of published scientific literature." (Doc. 110 at 6-7).

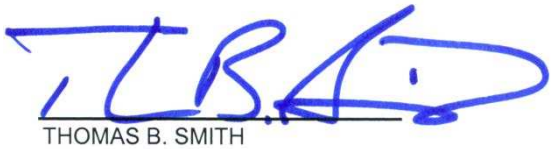
When the CRC reviewed Tolak, it gave the drug an insufficient evidence designation. This makes the type, quality and quantity of information the CRC had when it approved other AK drugs for inclusion on Defendant's Medicare Part D formulary relevant to the legitimacy and sincerity of Defendant's decision on Tolak. Accordingly, the motion

[1] The request refers to Defendant's "P&T Committee," but the Court understands that the pharmacy and therapeutic review process involves the CRC and the Value Assessment Committee ("VAC") (Doc. 110 at 22). The Court is under the impression that Tolak was rejected by the CRC before it reached the VAC.

to compel request number 2 is **GRANTED**. Within 14 days from the rendition of this Order, Defendant shall produce for inspection and copying, the studies and literature produced by drug manufacturers that were evaluated or considered by the CRC when it approved the drugs on Defendant's Medicare Part D formularies for the treatment of AK.

Any additional relief sought in Plaintiff's motion to compel is **DENIED**.

DONE and **ORDERED** in Orlando, Florida on November 23, 2016.



THOMAS B. SMITH
United States Magistrate Judge

Copies furnished to Counsel of Record