UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

GLAXOSMITHKLINE LLC,	*	
	*	
Plaintiff,	*	
	*	
v.	*	Civil Action No. 13-cv-13010-IT
	*	
THE CHEROKEE NATION and TODD HEMBREE,	*	
	*	
	*	
Defendants.	*	

MEMORANDUM & ORDER

October 15, 2014

TALWANI, D.J.

I. Introduction

The dispute in this case centers on a 2012 settlement agreement entered into by Plaintiff GlaxoSmithKline LLC ("GlaxoSmithKline" or "GSK") in connection with its plea in a criminal proceeding, United States of America v. GlaxoSmithKline, LLC, Criminal Action No. 12-10206-RWZ (D. Mass). GlaxoSmithKline now seeks a declaratory judgment that claims brought by the Cherokee Nation in the District Court of the Cherokee Nation were released by the settlement agreement. Presently at issue are GlaxoSmithKline's Renewed Cross-Motion for Summary Judgment [#61] and the Cherokee Nation's Cross-Motion for Summary Judgment [#64]. For the following reasons, GlaxoSmithKline's motion is DENIED and the Cherokee Nation's motion is ALLOWED.

II. Background

In 2012, GlaxoSmithKline and the United States entered into a settlement agreement (the "Settlement Agreement") relating to Avandia, a drug used to treat Type 2 diabetes. Pl.'s

Statement Undisputed Material Facts Supp. Its Cross-Mot. Summ. J. ¶ 1 [#16] [hereinafter GlaxoSmithKline Facts]. The Settlement Agreement provides, in relevant part:

> This Settlement Agreement ("Agreement") is entered into by and among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS"), the TRICARE Management Activity ("TMA"), the United States Department of Veteran [sic] Affairs ("VA"), and the United States Office of Personnel Management ("OPM") (collectively the "United States"), and GlaxoSmithKline LLC ("GSK"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."
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> . . . .
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> D. The United States alleges that GSK caused claims for payment for the Covered Drugs to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk . . . ; the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C.§§ 1396-1396w-5 . . . ; the TRICARE program, 10 U.S.C. §§ 1071-1110b; the Federal Employees Health Benefits Program . . . , 5 U.S.C.§§ 8901-8914; the Federal Employees Compensation Act Program, 5 U.S.C. § 8101, et. seq.; and caused purchases of the Covered Drugs by the Veterans Affairs Program, 38 U.S.C. § 1701-1743 (collectively, the "Government Health Care Programs").
>
> E. The United States contends that it and the Medicaid Participating States have certain civil claims, as specified in Paragraph 2, below, against GSK for engaging in the following conduct at certain times between January 2000 and December 2010 (hereinafter referred to as the "Covered Conduct"):
>
> (i) GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's lipid profile, effect on cardiovascular biomarkers, and the overall safety of Avandia and as a result, GSK knowingly caused false or fraudulent claims for Avandia to be submitted to, or caused purchases by, one or more of the Government Health Care Programs. . . .
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> . . . .
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> (ii) GSK made false and misleading representations about Avandia's lipid profile, effect on cardiovascular biomarkers, and the overall safety of Avandia in labeling used during the promotion of Avandia to physicians and other health care providers in violation of the [Food, Drug and Cosmetic Act], 21 U.S.C. §§ 331(a) and 352(a), and through the sale and distribution of a misbranded product, GSK obtained proceeds and profits to which it was not entitled . . . .
>
> . . . .
>
> 2. Subject to the exceptions in Paragraph 6 below (concerning excluded claims), in consideration of the obligations of GSK set forth in this Agreement, conditioned upon GSK's payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agencies, and departments) agrees to release GSK, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, and assigns and their current and former directors, officers, and employees, individually and collectively, from any civil or administrative monetary claim that the United States has or may have for the Covered Conduct under

> the False Claims Act . . . ; the Program Fraud Civil Remedies Act . . . ; the Food, Drug and Cosmetic Act . . . ; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise . . . , and common law claims for fraud, payment by mistake, breach of contract, disgorgement and unjust enrichment.
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> . . . .
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> 6. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person are the following claims of the United States:
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> . . . .
>
> (d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct . . . .
>
> . . . .
>
> 16. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the District of Massachusetts . . . .

Settlement Agreement, 1, 2–3, 5, 8, 10, 15 [#63-1].

On June 27, 2012, GlaxoSmithKline entered into a written plea agreement (the "Plea Agreement") that incorporated the Settlement Agreement into its terms. See GlaxoSmithKline Facts ¶ 2. At a plea and sentencing hearing, Judge Zobel adopted the terms of the Plea Agreement, and those terms were embodied in the court's Judgment. Id.

On August 9, 2013, the Cherokee Nation filed a Third Amended Petition, regarding Avandia, against GlaxoSmithKline in the District Court of the Cherokee Nation. See id. ¶¶ 3–4.

GlaxoSmithKline subsequently filed suit here seeking a declaratory judgment that the causes of action asserted against GlaxoSmithKline in the District Court of the Cherokee Nation are released claims, in whole or in part, under the Settlement Agreement, and that the Cherokee Nation courts do not have jurisdiction over the claims in the Third Amended Petition.[1] Although

[1] GlaxoSmithKline further seeks a declaratory judgment that GlaxoSmithKline "is not a citizen of the Cherokee Nation, nor did it engage in conduct that vests the Cherokee Nation's courts with jurisdiction over the claims asserted in the [Cherokee Nation's] Petition." Compl. ¶ 36 [#1]. Although the motions currently before this court are styled as cross-motions for summary judgment, this element of GlaxoSmithKline's second cause of action is not addressed here.

GlaxoSmithKline has not named the United States in its Complaint, the United States has submitted a Statement of Interest in which it sets forth its position that the Settlement Agreement between the United States and GlaxoSmithKline did not release claims on behalf of the Indian Health Service of the Cherokee Nation. See United States' Statement Interest Regarding Defs.' Mot. Dismiss & Pl.'s Cross-Mot. Summ. J. [#26].

III. Discussion

A. Jurisdiction and Venue for Resolving Disputes Concerning the Settlement Agreement

The Settlement Agreement provides that "[t]he Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement shall be the United States District Court for the District of Massachusetts." Settlement Agreement ¶ 16 [#63-1]. The Settlement Agreement was incorporated into GlaxoSmithKline's plea agreement, which was accepted and approved by this court and formed the basis for the judgment. As such, this provision gives this court jurisdiction over the dispute between the parties to the agreement. See Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 379–81 (1994) (holding that a court has jurisdiction to "vindicate its authority" and "effectuate its decrees"); Baella-Silva v. Hulsey, 454 F.3d 5, 10 (1st Cir. 2006) ("Ancillary jurisdiction exists where the district court has ensured its continuing jurisdiction to enforce a settlement agreement . . . by incorporating the terms of the settlement agreement in the court's order." (quotation marks and citation omitted)); Lipman v. Dye, 294 F.3d 17, 20 (1st Cir. 2002) (explaining that a district court can "ensure[] its continuing ancillary jurisdiction by making 'the parties' obligation to comply with the settlement agreement . . . part of the order of dismissal' . . . . by incorporating the terms of the settlement agreement in the court's order" (quoting Kokkonen, 511 U.S. at 380)).

B. The Parties to the Agreement

Because the court has jurisdiction over disputes between the parties regarding the Settlement Agreement, the threshold question is whether the Cherokee Nation is a party to the Settlement Agreement.

The Settlement Agreement does not explicitly identify the Cherokee Nation as a party. Instead it provides that the Settlement Agreement

> is entered into by and among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS"), the TRICARE Management Activity ("TMA"), the United States Department of Veteran[s] Affairs ("VA"), and the United States Office of Personnel Management ("OPM") (collectively the "United States"), and GlaxoSmithKline LLC ("GSK"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

Settlement Agreement, 1 [#63-1]. GlaxoSmithKline ignores this paragraph, arguing that the Cherokee Nation accessed price schedules for Avandia under 25 U.S.C. § 450j, and that in doing so, the Cherokee Nation "shall be deemed an executive agency and part of the Indian Health Service" under 25 U.S.C. § 450j(k). GlaxoSmithKline contends that the Cherokee Nation is therefore a party to the release given by the United States on behalf of itself, its officers, agencies, and departments, see Settlement Agreement ¶ 2, and in any event, that the Department of Justice has the authority to enter into settlements on behalf of Indian tribes. But this secondary issue—whether the Cherokee Nation's claims were released by the United States when it released claims on behalf of its agencies—does not help with the threshold question of whether the Cherokee Nation is a party to the Settlement Agreement and therefore a party over which this court has jurisdiction.

The first paragraph of the Agreement (as well as the signature lines to the agreement) make clear that the parties who agreed to the Settlement Agreement and to this court's

jurisdiction are: (1) the United States (on behalf of the Office of Inspector General of the United States Department of Health and Human Services), (2) the TRICARE Management Activity of the United States Department of Defense, (3) the United States Department of Veterans Affairs, (4) the United States Office of Personnel Management, and (5) GlaxoSmithKline. The Cherokee Nation is not one of these entities and therefore is not a party that has agreed to this court's jurisdiction.

This conclusion is bolstered by the longstanding understanding that Indian tribes "remain 'separate sovereigns'" from the United States, Michigan v. Bay Mills Indian Cmty., 134 S. Ct. 2024, 2030 (2014) (quoting Santa Clara Pueblo v. Martinez, 436 U.S. 49, 56 (1978)), an understanding that is incorporated into the Indian Self-Determination and Education Assistance Act itself, see 25 U.S.C. § 450n ("Nothing in this subchapter shall be construed as . . . affecting, modifying, diminishing, or otherwise impairing the sovereign immunity from suit enjoyed by an Indian tribe").

Because there is no explicit waiver of sovereign immunity in the Settlement Agreement, see Santa Clara Pueblo, 436 U.S. at 58 ("[A] waiver of sovereign immunity cannot be implied but must be unequivocally expressed." (citations and quotation marks omitted)), and because there is no indication that Congress statutorily waived the Cherokee Nation's sovereign immunity, see id. (explaining that Congress may in some circumstances waive tribal sovereignty), the Settlement Agreement's reference to the Department of Health and Human Services as a party to the agreement did not waive the Cherokee Nation's sovereign immunity or make the Cherokee Nation a party to the Settlement Agreement.

C. The Release of Claims

Even if the Cherokee Nation had waived its sovereign immunity or if GlaxoSmithKline

had sued the United States for a declaratory judgment that the United States had released the Cherokee Nation's claims, GlaxoSmithKline's request would fail because the United States released only its own claims and not claims held by the Cherokee Nation.

GlaxoSmithKline argues that the Indian Health Service is an agency of the Department of Health and Human Services under 42 U.S.C. § 2001 and that the Cherokee Nation may be deemed "an executive agency and part of the Indian Health Service" under 25 U.S.C. § 450j(k). Therefore, GlaxoSmithKline argues, when the United States released claims on behalf of its agencies, it also released claims on behalf of the Cherokee Nation. This argument fails at the outset because under the Settlement Agreement, the claims that are released are *those held by the United States*.

The Preamble makes clear that the Settlement Agreement was not concerned with all claims relating to Avandia but instead claims held by the United States and certain States. The Agreement states that "[t]he United States contends that *it* and the Medicaid Participating States have certain civil claims . . . against GSK for engaging in [specified] conduct at certain times between January 2000 and December 2010 (hereinafter referred to as the 'Covered Conduct')." Settlement Agreement ¶ E [#63-1] (emphasis added). The release provides that subject to certain exceptions,

> the United States (on behalf of itself, its officers, agencies, and departments) agrees to release GSK, together with its predecessors, current and former parents, direct and indirect affiliates, divisions, subsidiaries, successors, transferees, and assigns and their current and former directors, officers, and employees, individually and collectively, *from any civil or administrative monetary claim that the United States has or may have* for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq.; any statutory provision creating a cause of action for civil damages or civil penalties for which the Civil Division of the Department of Justice has actual and present authority to assert and compromise pursuant to 28 C.F.R. Part 0, Subpart I, 0.45(d), and common law claims for fraud, payment by mistake, breach of contract, disgorgement and unjust

enrichment.

Id. ¶ 2 (emphasis added). The release, although made on behalf of officers of the United States, does not release claims those officers may hold individually. Similarly, the release made on behalf of agencies and departments—even if the Cherokee Nation were deemed an agency of the United States when it purchased Avandia—releases only claims held by the United States, not claims held by the Cherokee Nation.

D. "Covered Conduct" Under the Settlement Agreement

Even if the Settlement Agreement could be construed to release claims held by the Cherokee Nation and not just those held by the United States, any such release is limited to "Covered Conduct." That limitation is found both in the release in paragraph 2 which releases "any civil or administrative claim that the United States has or may have *for the Covered Conduct*," id. (emphasis added), and also in paragraph 6, which reserves claims of "[a]ny liability to the United States (or its agencies) for any conduct other than Covered Conduct," id. ¶ 6(d). The Cherokee Nation's claims do not concern Covered Conduct.

The Preamble explains that the Covered Conduct in which the United States contends GlaxoSmithKline engaged includes:

> GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's lipid profile, effect on cardiovascular biomarkers, and the overall safety of Avandia and as a result, GSK knowingly caused false or fraudulent claims for Avandia to be submitted to, or caused purchases by, one or more of the Government Health Care Programs.

Id. ¶ E(i). The Settlement Agreement defines the Government Health Care Programs as:

> the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk ("Medicare"); the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C.§§ 1396-1396w-5 ("Medicaid"); the TRICARE program, 10 U.S.C. §§ 1071-1110b; the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C.§§ 8901-8914; the Federal Employees Compensation Act Program, 5 U.S.C. § 8101, et. seq.; and . . . the Veterans Affairs Program, 38 U.S.C. § 1701-1743 (collectively, the "Government

Health Care Programs").

Id. ¶ D.

GlaxoSmithKline argues that because the Cherokee Nation, through the Indian Health Service, purchased Avandia through the Department of Veterans Affairs' contract with the pharmaceutical prime vendor, the Cherokee Nation's purchases of Avandia were purchases of Covered Drugs by "the Veterans Affairs Program, 38 U.S.C. § 1701-1743."

Again, this argument rests on the faulty assumption that the Indian Health Service is one of the Government Health Care Programs covered by the Settlement Agreement. In defining the Government Health Care Programs, the Settlement Agreement specifically limited the Veterans Affairs Program with a reference to "38 U.S.C. § 1701-1743." Id. Title 38 is entitled "Veterans' Benefits." Chapter 17 is entitled "Hospital, Nursing Home, Domiciliary, and Medical Care" and describes such benefits for veterans only. Because the Settlement Agreement limits its reference to purchases by the Veterans Affairs Program under the statutory provision for benefits for veterans, only those purchases fall within the scope of the Settlement Agreement.

GlaxoSmithKline argues that the term Veterans Affairs Program is used in the trade to refer to the program establishing federal ceiling prices for pharmaceuticals procured by four designated agencies: the Department of Veterans Affairs, the Department of Defense, the Coast Guard, and the Public Health Service (including the Indian Health Service). This argument cannot be squared with the language of the Settlement Agreement for three reasons. First, the term "Veterans Affairs Program" in the Agreement is followed by the statutory reference of "38 U.S.C. §§ 1701-1743." The statutory provision setting price ceilings for purchases by the Department of Veterans Affairs, the Department of Defense, the Coast Guard, and the Health Service (including the Indian Health Service) is found in an entirely different provision, 38

U.S.C. § 8126. Second, the Settlement Agreement does not apply to purchases "through" or "under" or "pursuant" to the Veterans Affairs Program but purchases "*by*" the Veterans Affairs Program." Settlement Agreement ¶ D [#63-1] (emphasis added). Finally, if purchases by the Veterans Affairs Program implicitly included purchases by the agencies listed in 38 U.S.C. § 8126, the separate reference to the Department of Defense's TRICARE program, 10 U.S.C. §§ 1071-1110b8, would not have been necessary. The TRICARE program, however, like the Veterans Affairs Program, is separately listed in the Settlement Agreement. The Indian Health Service is not. Accordingly, the Settlement Agreement's reference to purchases "by the Veterans Affairs Program, 38 U.S.C. § 1701-1743" does not include purchases by the Indian Health Service.

GlaxoSmithKline argues further that even if the Cherokee Nation does not fall within the Government Health Care Programs as defined by the Settlement Agreement, the Cherokee Nation's claims still fall within a second paragraph concerning Covered Conduct. The Settlement Agreement provides, in relevant part, that the United States contends that

> [GlaxoSmithKline] made false and misleading representations about Avandia[] . . . in violation of the [Food, Drug and Cosmetic Act], 21 U.S.C. §§ 331(a) and 352(a), and through the sale and distribution of a misbranded product, [GlaxoSmithKline] obtained proceeds and profits to which it was not entitled.

Settlement Agreement ¶ E(ii) [#63-1].

GlaxoSmithKline argues that Covered Conduct "includes making misrepresentations about the safety of Avandia that enabled GSK to obtain proceeds and profits to which it was not entitled." The Covered Conduct, however, is more specific, namely, making "false and misleading representations about Avandia[] . . . in violation of the [Food, Drug and Cosmetic Act]." Id. Although GlaxoSmithKline argues that the Cherokee Nation's suit alleges exactly this conduct, the Cherokee Nation cannot (and does not) bring a claim under the provisions of

the Food, Drug and Cosmetic Act cited in Paragraph E(ii). See 21 U.S.C. § 337(a) ("Except as provided in subsection (b) of this section [which permits states to bring certain actions], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.").

IV. Conclusion

For the foregoing reasons, GlaxoSmithKline's Renewed Cross-Motion for Summary Judgment [#61] is DENIED and the Cherokee Nation's Cross-Motion for Summary Judgment [#64] is ALLOWED.

IT IS SO ORDERED.

Date: October 15, 2014

/s/ Indira Talwani
United States District Judge