UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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

THE UNITED STATES' STATEMENT OF INTEREST REGARDING THE PLAINTIFF'S AND DEFENDANTS' CROSS-MOTIONS FOR SUMMARY JUDGMENT

The United States submits this Statement of Interest pursuant to 28 U.S.C. § 517 to respond to certain arguments raised by plaintiff GlaxoSmithKline, LLC ("GSK"), and defendants the Cherokee Nation and Todd Hembree (collectively, "the Cherokee Nation"). The parties' dispute centers on a civil settlement agreement ("the Settlement Agreement") that the United States and GSK entered into on July 2, 2012. The United States has a keen interest in ensuring that the Settlement Agreement is interpreted in accordance with its terms and the intent of the parties. In addition, because the Settlement Agreement included provisions that are commonly found in the United States' health care fraud settlements, the declaratory judgment sought by GSK could have significant ramifications for similar agreements reached between the United States and other parties.

This brief is organized into two parts. In the first part, the United States sets forth its position that the Settlement Agreement between the United States and GSK did not release claims on behalf of the Indian Health Service or the Cherokee Nation. In the second section, in response to the Court's invitation at the status conference on July 2, 2014, the United States explains why it does not intend to intervene in this action at this time.

THE SETTLEMENT AGREEMENT DID NOT RELEASE THE CHEROKEE NATION'S CLAIMS

I. BACKGROUND

A. The Settlement Agreement

The primary facts related to the Settlement Agreement are undisputed. In July 2012, the United States entered into the Settlement Agreement with GSK to resolve civil allegations related to GSK's unlawful conduct arising from its marketing, sale, and promotion of the drugs Avandia, Avandamet, and Avandaryl (collectively, "Avandia"). The Settlement Agreement was one piece of a multi-part settlement between the United States and GSK that resolved GSK's criminal and civil liability for allegations related to two drug marketing investigations, including the Avandia investigation, and civil liability for allegations that GSK falsely reported drug prices to the Department of Health and Human Services ("HHS"). In total, GSK entered into three civil settlement agreements with the United States, including the Settlement Agreement at issue here.[1]

[1] At the status conference on July 2, 2014, counsel for the Cherokee Nation indicated his belief that the Court approved the Settlement Agreement based on a determination that it was fair to the parties involved. The United States wishes to clarify the record. While the Plea Agreement, which included as an attachment the executed civil Settlement Agreement, was approved by the Court, there was no pending civil case related to Avandia that was resolved by or terminated as a result of the civil settlement, and the

In the Settlement Agreement, the United States alleged that GSK caused claims for payment for Avandia "to be submitted to 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"); . . . and caused purchases of [Avandia] by the Veterans Affairs Program, 38 U.S.C. § 1701-1743." Ex. 1 ¶ D. The Settlement Agreement defined these programs as the "Government Health Care Programs." *Id*. As GSK tacitly acknowledges (GSK Mem. 5, Dkt. No. 17), neither the Indian Health Service nor the Cherokee Nation are named as one of the "Government Health Care Programs."

Paragraph E of the Settlement Agreement defined the scope of the "Covered Conduct,"[2] and alleged that "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*." Ex. 1 ¶ E(i) (emphasis added).

Paragraph E further alleged that "GSK made false misrepresentations 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 FDCA [Food, Drug and Cosmetic Act], 21 U.S.C. §§

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parties did not seek independent approval of the fairness of the civil Settlement Agreement itself.

[2] The parties agree that Subparagraph E(iii), which relates to state Medicaid agencies, is inapplicable to this dispute. *See* GSK Reply 3, fn. 1, Dkt. No. 30.

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." Ex. 1 ¶ E(ii).

Pursuant to Paragraph 2, the United States released GSK from "any civil or administrative monetary clams that the United States has or may have for the Covered Conduct" under specific, enumerated statutes, including the False Claims Act and the Food, Drug and Cosmetic Act, and the common law claims for fraud, payment by mistake, breach of contract, disgorgement, and unjust enrichment. Ex. 1 ¶ 2. The Settlement Agreement specifically reserved and excluded all claims not released, including claims for express or implied warranty and personal injury claims. Ex. 1 ¶ 6.

B. The Indian Health Service

In 1954, Congress transferred responsibility for the health care of eligible American Indians and Alaska Natives from the Department of the Interior to what is now the Indian Health Service ("IHS"), an agency within HHS. 42 U.S.C. § 2001. IHS provides health care to American Indians and Alaska Natives through three separate mechanisms: (1) by administering health care services directly through IHS facilities; (2) by contracting with tribes and tribal organizations to allow tribes to independently operate health care delivery programs previously operated by IHS; and (3) by funding contracts and grants to organizations operating health programs for urban Indians. S. Rep. No. 102-392, at 4 (1992), *reprinted in* 1992 U.S.C.C.A.N. 3943, 3946.

C. The Indian Self-Determination and Education Assistance Act

In 1975, Congress enacted the Indian Self-Determination and Education Assistance Act ("ISDEAA"), codified at 25 U.S.C. § 450 *et seq.*, which was designed to foster Indian self-governance by permitting the transfer of certain Federal programs to

tribal governments and other tribal organizations. 25 U.S.C. § 450. Tribes and tribal organizations enter into "self-determination contracts" with IHS under Title I of the ISDEAA, 25 U.S.C. §§ 450f-450n, and also enter into "self-governance compacts" under Title V of the ISDEAA, *id.* §§ 458aaa-458aaa-18.

The ISDEAA directs the Secretary of HHS to "negotiate and enter into a written compact with each Indian tribe participating in self-governance in a manner consistent with the Federal Government's trust responsibility, treaty obligations, and the government-to-government relationship between Indian tribes and the United States." 25 U.S.C. § 458aaa-3, 25 U.S.C. § 458aaa(6) (defining Secretary). The self-governance compact process begins when a tribe or tribal organization submits a compact proposal, approved by tribal resolution, to IHS. A tribe can choose to contract for any portion of a program, function, service, or activity, including pharmacy services, administered at any level by IHS.

In keeping with the spirit of the ISDEAA, which was enacted to expand opportunities for Indian self-governance, the ISDEAA specifically provides that "[n]othing in this subchapter shall be construed as affecting, modifying, diminishing, or otherwise impairing the sovereign immunity from suit enjoyed by an Indian tribe . . . ." 25 U.S.C. § 450n(1); 25 U.S.C. § 458aaa-15(a) (applying § 450n "to compacts and funding agreements authorized by this part").

D. The IHS Pharmaceutical Purchasing Framework

IHS has the legal authority to purchase drugs, such as Avandia, at the federal ceiling price through Federal Supply Schedule ("FSS") contracts awarded and administered by the Department of Veterans Affairs ("VA"). The drugs may be

purchased directly from the manufacturer or through a pharmaceutical prime vendor. IHS and other federal agencies are eligible to use FSS under the Federal Property and Administrative Services Act of 1949, 40 U.S.C. § 501, *et seq*.

In addition to negotiated FSS pricing, section 603 of the Veterans Health Care Act of 1992, Pub. L. No. 102-585, *codified at* 38 U.S.C. § 8126, established federal ceiling prices for pharmaceuticals procured by the four designated agencies covered in the Act: VA, Department of Defense, Coast Guard, and the Public Health Service (including IHS). All drug manufacturers participating in Medicaid must agree to provide federal ceiling prices and to offer those drugs on FSS. If the manufacturer of the drug elects dual pricing, the federal ceiling price is usually lower than the FSS price negotiated by VA for the same drug, allowing the four specified agencies to realize greater savings. Section 602 of the Veterans Health Care Act made similar discounts available to certain other entities such as AIDS drug purchasing assistance programs, community health centers, and disproportionate share hospitals, through the Drug Pricing Program, 42 U.S.C. § 256b, which is codified as part of the Public Health Service Act, 42 U.S.C. § 201 *et seq*. Under the Drug Pricing Program, pharmaceutical manufacturers participating in the Medicaid program must enter into a second agreement, called a pharmaceutical pricing agreement, with the Secretary of HHS, under which the manufacturer agrees to provide the statutorily specified discount to these other entities.

Finally, VA has entered into a contract with a pharmaceutical prime vendor that acts as a distributor between the pharmaceutical companies and the entities identified in the contract as eligible to purchase through the pharmaceutical prime vendor. IHS is one of the non-VA customers included as an eligible purchaser in the prime vendor contract.

Department of Veterans Affairs Office of Acquisition and Logistics, Pharmaceutical Prime Vendor (PPV), *available at* http://www.va.gov/oal/business/nc/ppv.asp (last accessed July 23, 2014). Pricing for drugs distributed through the pharmaceutical prime vendor reflects FSS or federal ceiling prices.

E. Tribal Access to Federal Sources of Supply under the ISDEAA

In 1994, Congress added subsection 105(k) to the ISDEAA, permitting tribes and tribal organizations contracted with IHS under the Act to access FSS, including pharmaceutical schedules managed by VA. Subsection 105(k) provides in pertinent part:

> For purposes of section 501 of title 40 (relating to Federal sources of supply, including lodging providers, airlines and other transportation providers), a tribal organization carrying out a contract, grant, or cooperative agreement under this subchapter shall be deemed an executive agency and part of the Indian Health Service when carrying out such contract, grant, or agreement and the employees of the tribal organization shall be eligible to have access to such sources of supply on the same basis as employees of an executive agency have such access. For purposes of carrying out such contract, grant, or agreement, the Secretary shall, at the request of an Indian tribe, enter into an agreement for the acquisition, on behalf of the Indian tribe, of any goods, services, or supplies available to the Secretary from the General Services Administration or other Federal agencies that are not directly available to the Indian tribe under this section or under any other Federal law, including acquisitions from prime vendors. All such acquisitions shall be undertaken through the most efficient and speedy means practicable, including electronic ordering arrangements.

25 U.S.C. § 450j(k); *see also* 25 U.S.C. § 458aaa-15(a) (applying § 450j(k) to Section V compacts). This authority allows tribes to place orders directly with FSS vendors for supplies and services available under the schedules. In short, tribes may access such sources of supply under the same terms and conditions as an executive agency.

In addition, IHS is authorized to enter into agreements with other agencies to permit tribal access to prime vendor contracts that tribes may not access directly. For example, tribal access to the VA prime vendor contract has been memorialized in the interagency agreement between VA and IHS and negotiated with VA's prime vendor, currently McKesson Corporation. Tribes do not currently order directly from the prime vendor. Instead, IHS acts as an intermediary for tribal facilities, providing contract management functions for which IHS charges a full cost recovery fee to tribes. *See* 25 U.S.C. § 458aaa-7(e) ("In the event an Indian tribe elects to carry out a compact or funding agreement with the use of . . . other Federal resources (including supplies, services, and resources available to the Secretary under any procurement contracts in which the Department is eligible to participate), the Secretary shall acquire and transfer such personnel, supplies, or resources to the Indian tribe.").

II. DISCUSSION

It is well-established that "[a] valid settlement agreement is an enforceable contract . . . ." *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 17 (1st Cir. 1996). "Courts look to the apparent intentions of the contracting parties when interpreting contracts." *Id.* Under federal common law, "an unambiguous contract must be enforced according to its tenor. . . . Plain meaning prevails." *Cent. Pension Fund of Int'l Union of Operating Eng'rs & Participating Emps. v. Ray Haluch Gravel Co.*, 695 F.3d 1, 8-9 (1st Cir. 2012) (internal citation omitted), *rev'd on other grounds*, 134 S. Ct. 773 (2014); *see also Blocher v. Blocher*, No. 12-10174-GAO, 2013 WL 5329029, at *4 (D. Mass. Sept. 19, 2013) ("When a contract is unambiguous, a court will enforce the plain meaning of its terms.").

GSK's contention that the Settlement Agreement released the claims now being asserted by the Cherokee Nation cannot be reconciled with the plain language of the Settlement Agreement for a variety of fundamental reasons, including: (1) the Settlement Agreement did not release claims on behalf of IHS or the Cherokee Nation, (2) the Settlement Agreement did not release all safety related claims, (3) the Settlement Agreement did not release any claims arising under Cherokee Nation law, and (4) extrinsic evidence confirms that the parties did not intend to compromise claims relating to the marketing and promotion of Avandia on behalf of IHS and the Cherokee Nation.

A. The Settlement Agreement did not release any claims on behalf of the Indian Health Service, the Cherokee Nation, or any other tribe.

The United States does not dispute that: (1) the Cherokee Nation has a compact with HHS to provide health care services to the Cherokee Nation's members, (2) the Cherokee Nation was permitted to and did purchase Avandia through the pharmaceutical prime vendor arrangement administered by the VA, and (3) the Cherokee Nation purchased Avandia at discounted rates that Congress has extended to a number of federal agencies and non-federal entities.[3] Those agreed-upon facts have no bearing, however, on whether the Cherokee Nation's claims were released in the Settlement Agreement. The Settlement Agreement language is clear and unambiguous and does not release any claims on behalf of IHS, the Cherokee Nation, or any other Indian tribe.

[3] *See* 38 U.S.C. § 8126 (extending the federal ceiling prices to specified agencies, including the Indian Health Services) *and* 42 U.S.C. § 256b (extending discounts to other entities such as AIDS drug purchasing assistance programs, community health centers, and disproportionate share hospitals).

GSK's argument that the Cherokee Nation is covered by the Settlement Agreement rests on two equally unsound assertions, both of which are contradicted by the plain language of the Settlement Agreement.

First, GSK asserts that the release in the Settlement Agreement "is binding on the Cherokee Nation because the United States – which is defined in the Settlement Agreement to include HHS – released *claims* 'on behalf of itself, its officers, agencies and departments.'" GSK Mem. 14, Dkt. No. 17 (emphasis added). GSK then goes on to argue that IHS is an agency of HHS, and therefore falls within the scope of the Settlement Agreement.

GSK's argument is misleading. The Settlement Agreement did not generally release "claims" on behalf of HHS and its various named and unnamed agencies; the Settlement Agreement only released "any civil or administrative claim that the United States has or may have *for the Covered Conduct* . . . ." Ex. 1 ¶ 2 (emphasis added).[4] Thus, the scope of the release is explicitly limited to the Covered Conduct, defined in Paragraph E, which alleges that "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*." Ex. 1 ¶ E(i) (emphasis added). Neither IHS nor the Cherokee Nation is named as one of the Government Health Care Programs. *See* Ex. 1 ¶ D. The fact that HHS was a party to the Settlement Agreement, which is unsurprising given that HHS administers two programs – Medicare and Medicaid – for which the United States

[4] To eliminate any doubt, the Settlement Agreement further provides: "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: . . . (d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct." Ex. 1 ¶ 6.

did release claims, does not ipso facto make the release applicable to IHS given the other limiting language in the agreement.

Next, GSK attempts to shoehorn the Cherokee Nation into the Veterans Affairs Program, and argues that the release of purchases by that program includes purchases through the FSS on behalf of the Cherokee Nation (and other tribes). *See* GSK Mem. 14-16, Dkt. 17; *see also* GSK Reply 4, Dkt. No. 25. This proposed interpretation is flatly contradicted by the Settlement Agreement. Paragraph D, which defines the Government Health Care Programs, states that GSK "caused purchases of [Avandia] by the Veterans Affairs Program, 38 U.S.C. § 1701-1743." Ex. 1 ¶ D. Title 38 is entitled "Veterans' Benefits," and Chapter 17 of that title describes the hospital, nursing home, domiciliary, and medical care benefits available to eligible veterans. By its very terms, the Settlement Agreement limits the reference to the "Veterans Affairs Program" only to benefits provided to veterans, and thus only releases those purchases that the Veterans Affairs Program made on behalf of these beneficiaries. Accordingly, there is no basis for GSK's contention that the Settlement Agreement's use of the term "Veterans Affairs Program" incorporates all purchases through the FSS on behalf of the Cherokee Nation.

This conclusion is further bolstered by the fact that the operative portion of the "Government Health Care Program" definition provides that GSK "caused purchases of [Avandia] ***by*** the Veterans Affairs Program, 38 U.S.C. § 1701-1743." Ex. 1 ¶ D (emphasis added). The use of the word "by," rather than "through" or "under," is significant: the Settlement Agreement only includes purchases made by the Veterans Affairs Program, as defined in 38 U.S.C. §§ 1701-1743, and does not include entities that

purchase pharmaceuticals "through" the FSS or the pharmaceutical prime vendors, as GSK's argument requires this court to conclude.[5]

The Settlement Agreement defined the term "Government Health Care Programs" to include only the enumerated federal health care programs for which the United States provided a release. Having carefully negotiated such a precise definition, GSK now asks the Court to declare that "Government Health Care Programs" actually includes other, unnamed entities.[6] Such an interpretation runs counter to the "apparent intentions" of the parties, which is clear from the unambiguous language of the Settlement Agreement. *Ross-Simons of Warwick, Inc.*, 102 F.3d at 17. The Court should reject GSK's belated attempt to expand the scope of the Settlement Agreement's release to include claims as to which the parties did not bargain and for which GSK provided no consideration.

B. The Settlement Agreement does not release all safety related claims.

GSK further argues that, even if its attempt to expand the definition of Government Health Care Programs to include the Cherokee Nation fails, all of the

[5] In support of its attempt to read the Cherokee Nation into the Settlement Agreement's reference to the Veterans Affairs Program, GSK cites to the Department of Veterans Affairs website. GSK Reply 5, Dkt. No. 30. The website, however, does not even use the term "Veterans Affairs Program." Dep't of Veterans Affairs, VA Federal Supply Schedule Service, http://www.fss.va.gov (last accessed July 23, 2014) (emphasis added). In any event, it is the language of the Settlement Agreement which governs here.

[6] The problem with GSK's position is further illustrated by the fact that, under its own interpretation, even GSK cannot identify which federal programs may have been included in the Settlement Agreement release. *See* GSK Reply 5, Dkt. No. 25. While GSK suggests that it is unnecessary to reach such a "hypothetical question," *id.*, the government submits that it was absolutely necessary for the parties to define the universe of claims *prior to* reaching a settlement so that the relevant agencies could be appropriately engaged in the settlement process, the government would be able to evaluate whether it was receiving appropriate consideration, GSK would understand the limits of the release it received, and the government would be able to allocate the settlement proceeds accurately. It is for these reasons that the release carefully delimited what programs were covered by the Settlement Agreement.

Cherokee Nation's claims are released under Paragraph E(ii) of the Covered Conduct. GSK Resp. 3-5, Dkt. No. 30. GSK claims that this subparagraph "covers safety-related misrepresentations made to 'physicians and other health care providers' generally." *Id*. at 4. But the actual language of the Settlement Agreement says nothing about "safety-related misrepresentations." Subparagraph E(ii) is narrowly tailored to allege that GSK violated the Food, Drug and Cosmetic Act by making false and misleading representations on Avandia's label. And, not surprisingly, the Food, Drug and Cosmetic Act is one of the limited statutory causes of action released in the Settlement Agreement. Ex. 1 ¶ 2. GSK's attempt to convert the paragraph into a broad release of any safety-related misrepresentations to any health care provider misreads the Settlement Agreement.

In any event, even if the Court agreed with GSK's proposed interpretation, it does not help them here, as the Cherokee Nation cannot bring a claim under the cited provisions of the FDCA. *See* 21 U.S.C. § 337(a) ("Except as provided in subsection (b) of this section [permitting 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."); *see also Phillips v Medtronic, Inc.*, 754 F. Supp. 2d 211, 218 (D. Mass. 2010) (noting that there is no private right of action under the FDCA).

C. The Settlement Agreement did not release the claims being pursued by the Cherokee Nation.

The Settlement Agreement release is limited to "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." Ex. 1 ¶ 2.

GSK argues that the Settlement Agreement's release of common law claims includes claims arising under "tribal" common law. GSK Resp. 10, Dkt. No. 30. The release, however, is limited to claims that the *United States* may bring, and GSK cites to no authority that would permit the United States to sue GSK under the Cherokee Nation's common law.

GSK, undoubtedly, will assert that this limitation on the release is no bar to its declaratory judgment action because "United States" actually includes any tribe that purchased pharmaceuticals through the VA FSS. To reach this tortured meaning of the term "United States," one would have to conclude that the parties adopted a definition of "United States" that encompasses tribes that have long been recognized as separate sovereigns. *See, e.g., Michigan v. Bay Mills Indian Cmty.*, 134 S. Ct. 2024, 2030 (2014) (noting that Indian tribes "remain separate sovereigns pre-existing the Constitution") (internal citations and quotations omitted). GSK's position runs counter to the purpose, structure, and language of the ISDEAA. In enacting the ISDEAA, Congress proposed to foster Indian self-government by permitting the transfer of certain Federal programs to tribal governments and other tribal organizations. Congress explicitly stated its commitment to this goal:

> The Congress declares its commitment to the maintenance of the Federal Government's unique and continuing relationship with, and responsibility to,

> individual Indian tribes and to the Indian people as a whole through the establishment of a meaningful Indian self-determination policy which will permit an orderly transition from the Federal domination of programs for, and services to, Indians to effective and meaningful participation by the Indian people in the planning, conduct, and administration of these programs and services.

25 U.S.C. § 450a(b). The ISDEAA further provides that "The Secretary shall negotiate and enter into a written compact . . . in a manner consistent with . . . the *government-to-government* relationship between Indian tribes and the United States." 25 U.S.C. § 458aaa-3(a) (emphasis added); *see also* 25 U.S.C. § 450n(1) (reaffirming that the ISDEAA does not abrogate tribes' sovereign immunity); 42 C.F.R. § 137.3(a) (same).

Once the proposition is rejected that the reference to the "United States" encompasses the Cherokee Nation, it is clear that the Settlement Agreement does not release the claims asserted by the Cherokee Nation against GSK. The complaint filed by the Cherokee Nation alleges violations of "the Cherokee Nation's Constitution, common law, tribal customs and statutory causes of action." Cherokee Nation Compl. ¶ 2, Dkt. No. 1-1, Ex. 2. The complaint expressly disavows any cause of action arising under or founded on federal law. *Id.* ¶ 11.

Furthermore, even if the Settlement Agreement could be deemed to include tribal claims, it does not release the specific claims asserted by the Cherokee Nation. The Cherokee Nation complaint seeks recovery for common law causes of action such as products liability and breach of express and implied warranty that are expressly excluded from the Settlement Agreement's release. *Id.* ¶¶ 164-76, 196-206. And it is beyond dispute that the Settlement Agreement does not release any claims arising under the Cherokee Nation's Constitution and statutes.

As a result, even if this Court were to accept GSK's argument that the Covered Conduct in the Settlement Agreement implicitly subsumes the Cherokee Nation – a proposition that the United States vigorously disputes – it is clear that the Settlement Agreement does not absolve GSK of the particular claims asserted by the Cherokee Nation in its complaint. For this reason alone GSK's request for a declaratory judgment should be denied.

D. GSK fully understood that a release for an additional program or party must be explicitly stated.

As discussed above, the Settlement Agreement is clear and unambiguous. *See Farmers Ins. Exch. v. RNK, Inc.*, 632 F.3d 777, 783 (1st Cir. 2011) (to determine whether a contract is ambiguous, the court must first examine the contract's language). Should the Court nonetheless find ambiguity in the language of the Settlement Agreement, the factfinder may consider extrinsic evidence to ascertain the parties' intent. *Den Norske Bank AS v. First Nat. Bank of Boston*, 75 F.3d 49, 52 (1st Cir. 1996); *see also Blocher*, 2013 WL 5329029, at *3-4 ("Extrinsic evidence may be considered only in the construction of ambiguous contract language."). The United States submits that another contemporaneous settlement agreement between the United States and GSK further reinforces the only reasonable and logical reading of the Settlement Agreement, specifically, that the parties intended only to provide a release for those programs that are specifically named in Paragraph D of the Settlement Agreement.

As previously noted, the United States and GSK executed three settlement agreements in July 2012, and, as GSK states, these settlement agreements were attached to the Plea Agreement. GSK Mem. 4-5; Dkt. No. 17. One of these agreements resolved civil liability for alleged false price reporting practices ("the Nominal Price Settlement").

Ex. 2. As with the Settlement Agreement, HHS was a party and a signatory to the Nominal Price Settlement, which released specified claims on behalf of Medicaid. The Nominal Price Settlement, however, also explicitly released certain claims on behalf of Public Health Service entities ("PHS entities"), such as AIDS drug purchasing assistance programs, community health centers, and disproportionate share hospitals. The PHS entities – much like Indian tribes that have signed compacts with HHS pursuant to the ISDEAA – are entitled to drug discounts under the Drug Pricing Program. *See infra* at 6. In the Nominal Price Settlement Agreement, the covered conduct language set forth the allegations pertaining to the PHS entities and established a separate mechanism by which GSK would pay a specified portion of the settlement amount to them, leaving no question that the release included claims related to the PHS entities. Ex. 2 ¶¶ I, J(iv)-(v), 1(c). The Nominal Price Settlement Agreement shows that, had the parties intended to include tribes such as the Cherokee Nation in the Settlement Agreement, the parties knew how to do so expressly. The absence of such a mechanism in the Avandia Settlement Agreement, which was executed contemporaneously with the Nominal Price Settlement, further evidences GSK's understanding that the Avandia Settlement Agreement did not release the claims of unnamed third parties, such as the PHS entities or tribes with a self-governance compact, that received statutorily-required price discounts.

THE UNITED STATES' STATEMENT ON INTERVENTION

At the status conference on July 2, 2014, the Court invited the United States to consider intervention. The United States agrees with GSK that the United States is not a necessary and indispensable party because the United States is not a "required party" pursuant to Rule 19(a). A party is considered a "required party" under Rule 19(a)(1)(A) if, "in that person's absence, the court cannot accord complete relief among existing parties" or, under Rule 19(a)(1)(B), "that person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may: (i) as a practical matter impede the person's ability to protect the interest; or (ii) leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest." Fed. R. Civ. P. 19(a)(1).

Under Rule 19(a)(1)(A) the Court may accord complete relief among existing parties because GSK's complaint for declaratory judgment relates solely to whether the Cherokee Nation's claims in the District Court of the Cherokee Nation were already extinguished by GSK's settlement with the United States. Although the Cherokee Nation has filed a counterclaim complaint against GSK seeking rescission or cancellation of three settlement agreements executed in July 2012 to which the United States is a party (Dkt. No. 49), the counterclaim complaint is framed in the alternative: the Cherokee Nation will attempt to invoke the Court's jurisdiction only if the Court determines that the Avandia settlement agreement released claims on behalf of the Cherokee Nation. Counterclaim Compl. ¶ 6, Dkt. No. 49. Because that claim remains merely conditional, there is no basis for concluding that the United States is a required party to the action at this time. Should the Cherokee Nation seek to invoke the Court's jurisdiction under the

counterclaim complaint, the Cherokee Nation and GSK will have an opportunity to brief whether the United States is required and can be joined.

The United States is also not required under Rule 19(a)(1)(B) because disposing of the action in the absence of the United States would not "as a practical matter impede the person's ability to protect the interest." If the United States is not a party, it is not bound by any judgment the Court may issue, a point that both parties concede. *See United States v. Candelaria*, 271 U.S. 432, 443-44 (1926); *Narragansett Tribe of Indians v. S. R. I. Land Dev. Corp.*, 418 F. Supp. 798, 810 (D.R.I. 1976); *see also* GSK Mem. 28, Dkt. No. 17 ("A ruling in GSK's favor – or in favor of the Tribe – would not implicate the interests of the United States."); CN Mem. 14, Dkt. No. 12 ("[I]n the United States' absence, it would not be bound by the disposition of this action."). Furthermore, because the United States has been given an opportunity to provide its views through filing a Statement of Interest, full party status is not required to advise the Court of the views of the United States or to protect the United States' interests.

Nor has the Cherokee Nation pointed to "double, multiple, or otherwise inconsistent obligations" which it would incur if the United States is not made a party. The Cherokee Nation implies that there may be "inconsistent obligations" because the United States will not be bound by the Court's judgment, and separate litigation may result. CN Mem. 14, Dkt. No. 12. The First Circuit has distinguished between inconsistent obligations and inconsistent results: "[i]nconsistent obligations occur when a party is unable to comply with one court's order without breaching another court's order considering the same incident. . . . In contrast, inconsistent adjudications or results occur when a party wins on a claim in one forum and loses on another claim from the same

incident in another forum." *Bacardi Int'l Ltd. v. Suarez & Co., Inc.*, 719 F.3d 1, 12 (1st Cir. 2013). If GSK obtains the declaratory judgment it seeks here, the Cherokee Nation may seek to proceed with a counterclaim complaint against GSK in this court and opt to sue the United States in another forum[7], but it is unclear how such suits would impose any obligations on the Cherokee Nation. At most, the Cherokee Nation may be subject to inconsistent results, but, under First Circuit law, that is insufficient to establish that a party is required and thus compelled to participate in and subject itself to jurisdiction under Rule 19(a)(1)(B)(ii).

CONCLUSION

For the foregoing reasons, GSK's cross-motion for declaratory judgment should be denied. Additionally, the United States respectfully submits that this action may proceed in the absence of the United States as a party.

[7] "[T]he United States cannot be sued absent an express waiver of its immunity as a sovereign." *Coggeshall Dev. Corp. v. Diamond*, 884 F.2d 1, 3 (1st Cir. 1989) (citing *Block v. North Dakota ex rel. Bd. of Univ. & Sch. Lands*, 461 U.S. 273, 287 (1983)). With respect to certain contract actions, the Tucker Act, 28 U.S.C. § 1491(a)(1), provides a waiver of sovereign immunity for claims brought against the United States in the Court of Federal Claims. The Tucker Act's counterpart, known as the Indian Tucker Act, 28 U.S.C. § 1505, similarly waives sovereign immunity for specified actions brought by Indian tribes. However, because the Cherokee Nation has not filed suit against the United States, it is premature to assess whether the Cherokee Nation could assert a claim under 28 U.S.C. § 1505 and invoke the jurisdiction of the Court of Federal Claims.

Respectfully submitted,

THE UNITED STATES OF AMERICA

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