UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

GLAXOSMITHKLINE LLC,

Plaintiff,

v.

THE CHEROKEE NATION and TODD HEMBREE,

Defendants.

Civil Action No.: 13-cv-13010-IT

PLAINTIFF'S REPLY MEMORANDUM OF LAW IN IN SUPPORT OF ITS RENEWED CROSS-MOTION FOR SUMMARY JUDGMENT

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Plaintiff, GlaxoSmithKline LLC ("GSK"), respectfully submits this Reply Memorandum of Law in Support of its renewed cross-motion for summary judgment.

PRELIMINARY STATEMENT

In its opening Memorandum of Law in Support of its Renewed Cross-Motion for Summary Judgment [Dkt. 62] ("GSK Memo."), GSK posed three inter-related questions: (1) does the Release in Paragraph 2 of the Settlement Agreement extend to claims by the Indian Health Service ("IHS") as an "agency" of the United States?; (2) if the Release does extend to claims by the IHS, does it also cover claims by the Cherokee Nation, because the Tribe is deemed by 25 U.S.C. § 450j(k) to be an "executive agency and part of the Indian Health Service" in carrying out its self-governance contract under the ISDEAA?; and (3) do the claims asserted in the Tribal Court lawsuit fall within the scope of "Covered Conduct" as defined in Paragraph E of the Settlement Agreement? The correct answer to each of these questions is "yes," and, accordingly, summary judgment should be entered in GSK's favor.

The Cherokee Nation, in its Memorandum in Support of its Cross-Motion for Summary Judgment [Dkt. 65] ("CN Memo."), and the United States, in its Statement of Interest Regarding the Plaintiff's and Defendants' Cross-Motions for Summary Judgment [Dkt. 63] ("Statement of Interest II"), fail to offer convincing reasons why the Court should not construe the Settlement Agreement to release the Cherokee Nation's claims. GSK responds to their arguments below.

I. THE IHS IS COVERED BY THE RELEASE BECAUSE IT IS AN AGENCY OF THE UNITED STATES.

The Release from the United States was given on behalf of itself and its "officers, agencies and departments."[1] The United States conceded in its initial Statement of Interest that

[1] Hobart Decl. [Dkt. 20-1], Exhibit 5 ("Settlement Agreement") ¶ 2.

the IHS is "an agency within the Department of Health and Human Services ('HHS')," and it repeats that concession here.[2]

Surprisingly, the Cherokee Nation denies that the IHS is an agency of the United States, arguing instead that it is "an Operating Division."[3] It bases this contention on a single page from HHS' website which describes the IHS as one of 11 "Operating Divisions" within HHS.[4] According to the Cherokee Nation, this means the IHS is "not an agency."[5]

The Cherokee Nation is mistaken. The fact that the IHS is considered an "Operating Division" within HHS does not mean that it is not also an "agency." In fact, the referenced HHS web page contains a link to a different HHS web page entitled "HHS Family of Agencies." That page makes clear that the terms "Operating Division" and "agency" are not mutually exclusive, and that the IHS is both an "Operating Division" and an "agency":

> HHS has ***11 operating divisions, including eight agencies*** in the U.S. Public Health Service [including the IHS] and three human services agencies, which administer a wide variety of health and human services and conduct life-saving research for the nation. These ***agencies*** protect and serve all Americans.[6]

The IHS, therefore, is an "agency" of the United States, and its claims for "Covered Conduct" were released.

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[2] Statement of Interest at 3; Statement of Interest II at 4.

[3] CN Memo. at 2.

[4] *See id.* (*citing* http://www.hhs.gov/about/foa/opdivs/index.html).

[5] CN Memo. at 2.

[6] http://www.hhs.gov/about/foa/index.html (emphasis added).

II. THE CHEROKEE NATION IS COVERED BY THE RELEASE BECAUSE THE CHEROKEE NATION WAS DEEMED TO BE AN EXECUTIVE AGENCY AND PART OF THE IHS WHEN IT ACCESSED FEDERAL SOURCES OF SUPPLY.

A. A Tribe Is Deemed to Be an Executive Agency and Part of the IHS When Accessing Federal Sources of Supply.

Section 450j(k) provides that, for purposes of accessing federal sources of supply under section 501 of Title 40, tribal organizations that self-administer their own healthcare programs are deemed to be executive agencies and part of the IHS "when carrying out [a] contract, grant, or cooperative agreement" under the ISDEAA. 25 U.S.C. § 450j(k). The Cherokee Nation and the United States both concede that the Cherokee Nation administers its healthcare programs pursuant to an ISDEAA Compact of Self-Governance with HHS ("Compact"), and that this Compact is the type of cooperative agreement to which § 450j(k) refers.[7] The Compact allows the Tribe to receive from IHS federal money that IHS would otherwise use to provide healthcare services to the Tribe.[8] Because the Cherokee Nation elected to self-administer its healthcare services, § 450j(k) provides that it "shall be eligible to have access to [Federal] sources of supply ***on the same basis*** as employees of an executive agency have such access." (emphasis added).

The Cherokee Nation argues that it is only deemed to be an executive agency and part of the IHS "for the limited 'purpose of Section 105[*sic*]' purchasing goods and services at the federally reduced rate and for none other."[9] Put differently, the Cherokee Nation contends that the ***only*** effect of § 450j(k) is to permit "Indian nations to purchase off the FSS at the discounted rate."[10]

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[7] *See* CN Memo. at 8-10; Statement of Interest II at 5, 7-8.

[8] *See* GSK Memo. at 5-6.

[9] CN Memo. at 11-12.

[10] *Id.* at 10.

This reading of § 450j(k) conflicts with the plain language of the statute and the overall design of the ISDEAA. The ISDEAA permits Indian nations to administer funds that IHS otherwise would spend on Indian healthcare services. In this context, § 450j(k) does not say that tribal organizations are deemed to be executive agencies and part of the IHS solely so that they may purchase pharmaceuticals off the FSS at discounted rates and for no other purpose. Rather, it says that they are deemed to be executive agencies and part of the IHS when they access federal sources of supply in the course of carrying out an ISDEAA compact, and that they do so "***on the same basis***," *i.e.*, on the same terms and conditions, as federal agencies.

Because tribal purchasers are given access to federal sources of supply "on the same basis" as federal purchasers, they have the same rights and remedies as federal purchasers in connection with those purchases. This includes, for example, access to federal investigators and prosecutors to police and prosecute alleged instances of fraud on Indian healthcare programs.[11] In those situations, the United States may invoke a broader range of statutory remedies on behalf of tribal organizations than tribal organizations could invoke on their own, including the civil remedies under the False Claims Act and the Food, Drug, and Cosmetic Act that were the subject of the Release.[12] Because § 450j(k) allows Indian nations to access federal sources of supply "on the same basis" as the IHS, their rights and remedies with respect to those purchases are the same as those of the IHS.

Section 450j(k) is therefore broader and more beneficial to tribal organizations than the Tribe suggests. In addition to allowing tribes to "purchase off the FSS at the discounted rate,"[13]

[11] *See* GSK Memo. at 13 n.34.

[12] *See* Settlement Agreement ¶ E.

[13] CN Memo. at 10.

the statute gives tribal organizations and federal agencies equal benefits across the board. Simply stated, it puts tribal and federal purchasers in the same position under the law. *See* S. Rep. No. 103-374, 12, at 8 (1994) ("[T]he original intent of the Act [was] to place tribes and tribal organizations in the ***same position as those government agencies that would otherwise be carrying out the activities***, so that no benefits or cost savings are lost merely by virtue of the contracting of an activity by a tribal organization." (emphasis added)). Whether IHS directly administers a tribe's healthcare services or the tribe elects to self-administer under the ISDEAA, their purchases of supplies off the FSS should be treated the same, including their rights and remedies for allegedly fraudulent sales.

As a statute in effect at the time of the Settlement Agreement, § 450j(k) is part of the Agreement.[14] Thus, when the United States released Avandia-related claims on behalf of its departments and agencies, including the IHS, it necessarily released the same claims on behalf of tribal organizations that accessed federal sources of supply under the ISDEAA. Because these tribal organizations purchased Avandia "on the same basis" as the IHS, their claims based on those purchases were released to the same extent.

B. The Cherokee Nation's Narrow Interpretation of § 450j(k) Is Not Supported by the Indian Law Canons of Construction or 25 U.S.C. § 458aaa-11(f).

The Cherokee Nation's narrow interpretation of § 450j(k) is also not supported by the Indian law canons of construction.[15] Those canons encourage courts to interpret ambiguous statutes "liberally in favor of the Indians," *Montana v. Blackfeet Tribe of Indians*, 471 U.S. 759,

[14] *See* GSK Memo. at 9-10.

[15] *See* CN Memo. at 12-14.

766 (1985), but the canons do not apply to statutes that are not ambiguous.[16] Because § 450j(k) is not ambiguous, the canons do not apply.

The parties agree that the Settlement Agreement—which incorporates § 450j(k) as a matter of law[17]—is unambiguous, although they disagree about what the Settlement Agreement and statute mean.[18] The Cherokee Nation seizes on this disagreement as a reason to invoke the Indian law canons. It argues that if a statute can be understood in two ways, it must be ambiguous and, therefore, the canons apply.[19] By this logic, the mere existence of a dispute over the proper interpretation of an agreement or statute means the agreement or statute is ambiguous.

Numerous courts have rejected this logic, finding that a mere disagreement over the meaning of the words in an agreement or statute does not mean those words are ambiguous.[20] Indeed, as often as not, the existence of a disagreement among litigants means only that one litigant's interpretation is wrong.[21] Thus, the fact that the parties differ in their interpretation of § 450j(k) does not mean the Settlement Agreement or the statute is ambiguous, and it does not justify resort to the Indian law canons of construction.

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[16] *See* GSK Memo. at 12 n.33.

[17] *See id.* at 9-10.

[18] *See* Statement of Interest II at 9 ("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."); CN Memo. at 6 ("The Settlement Agreement language is clear and unambiguous: the Settlement Agreement does not release claims on behalf of the IHS, the Cherokee Nation, or any Indian Tribe." (quoting Statement of Interest at 9)).

[19] *See* CN Memo. at 12-13.

[20] *See, e.g.*, *Dynamics Corp. of Am. v. United States*, 17 Cl. Ct. 60, 63 (1989) ("The fact that the parties disagree on the meaning of the phrase does not lead to the conclusion that it is ambiguous."); *S. Constr. Co. v. United States*, 364 F.2d 439, 453 (Ct. Cl. 1966) (explaining that "[c]ontracts are not necessarily rendered ambiguous by the mere fact that the parties disagree as to their meaning").

[21] *See Bank of Am. Nat'l Trust & Sav. Ass'n v. 203 N. LaSalle St. P'ship*, 526 U.S. 434, 461 (1999) ("A mere disagreement among litigants over the meaning of a statute does not prove ambiguity; it usually means that one of the litigants is simply wrong.") (Thomas, J., concurring).

But even if the Indian law canons were applicable—which they are not—GSK's arguments concerning the proper application of § 450j(k) are not even remotely adverse to "Indian interests" as embodied in the ISDEAA. As noted, the ISDEAA was intended to put tribal organizations in the same position as government agencies in the delivery of healthcare to their members. GSK's interpretation of § 450j(k) does not diminish any of the rights conferred on Indian nations by the ISDEAA. It does not undermine the right of tribal organizations to design and administer their individual healthcare programs in whatever manner they consider most beneficial to their members. Nor does it reduce the benefits that flow from tribal self-administration or increase the burdens of self-administration. Simply put, GSK's interpretation of § 450j(k) does not diminish any tribal organization's healthcare prerogatives under the ISDEAA or threaten any tribal organization's ability to provide for the health and wellbeing of its members.

Moreover, courts applying the Indian law canons of construction are not required to defer to a tribe's post hoc litigation position, which is what the Cherokee Nation is asking for here. Rather, statutory interpretation under the Indian law canons is governed by a "fair appraisal" of the statutory language and the relevant historical context, without regard to what a tribe's "later claims" might be. *Or. Dep't of Fish & Wildlife v. Klamath Indian Tribe*, 473 U.S. 753, 774 (1985) (citation and internal quotation marks omitted from first quotation). The canons only encourage courts to interpret a statute in a manner that favors Indians with respect to the achievement of the statute's objectives. They do not require courts to construe statutes in a manner that advances a tribe's litigation position in a particular case. *See Gila River Indian Cmty. v. United States*, 776 F. Supp. 2d 977, 990 (D. Ariz. 2011) (citing *EEOC v. Karuk Tribe*

Hous. Auth., 260 F.3d 1071, 1081-82 (9th Cir. 2001)), *rev'd in part on other grounds*, 729 F.3d 1139, 1154 (9th Cir. 2013).

In addition to the Indian law canons of construction, the Cherokee Nation attempts to rely on 25 U.S.C § 458aaa-11(f) of the ISDEAA, which states that "[e]ach ***provision of this part*** and each ***provision of a compact or funding agreement*** shall be liberally construed for the benefit of the Indian tribe participating in self-governance and any ambiguity shall be resolved in favor of the Indian tribe."[22] Section 458aaa-11(f) does not apply in this case because § 450j(k) is neither a "provision of this part" nor a "provision of a compact or a funding agreement."

Section 458aaa-11(f) falls within "Part E" of the ISDEAA. Part E ranges from § 458aaa to § 458aaa-18. Part E does not include § 450j(k), which falls within Part A. Thus, § 458aaa-11(f) has no bearing on how the Court should construe § 450j(k).[23]

C. GSK's Interpretation of the Settlement Agreement and § 450j(k) Does Not Implicate or Undermine the Cherokee Nation's Sovereignty.

At various points in its Memorandum, the Cherokee Nation seeks to portray GSK's legal argument as impugning Indian sovereignty.[24] Nothing could be further from the truth. GSK does not question the Cherokee Nation's sovereignty or its right of self-government. GSK's arguments are entirely compatible with Indian sovereignty.

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[22] CN Memo. at 14 (quoting 25 U.S.C. § 458aaa11(f)) (emphasis added).

[23] The Cherokee Nation also makes a passing reference to 25 U.S.C. § 458aaa-11(a), arguing that it too requires courts to construe ambiguities in the ISDEAA in favor of Indian tribes. *See* CN Memo. at 8-9. The Tribe's reliance on this provision is misplaced. The provision applies only to the Secretary of HHS, not to the courts, and it merely directs the Secretary to interpret federal laws and regulations in a manner that will "facilitate" the inclusion of health programs and services into ISDEAA compacts, "facilitate" the implementation of such compacts, and "facilitate" the achievement of tribal health goals and objectives. Like § 458aaa-11(f), it has no bearing on how this Court should interpret § 450j(k).

[24] *See, e.g.*, CN Memo. at 1, 8-9, 17-18.

Indian sovereign immunity "is not absolute." *Leigh v. Blackfeet Tribe of Blackfeet Indian Reservation*, No. 89-1568-Z, 1990 WL 122398, at *1 (D. Mass. Aug. 17, 1990). Rather, it is subordinate to duly-enacted federal statutes.[25] Section 450j(k) is a federal statute. If GSK's interpretation of the statute is correct, the Cherokee Nation's sovereignty is not an issue.

Moreover, GSK's interpretation of § 450j(k) does not undermine the Cherokee Nation's sovereignty in any way. To the contrary, GSK's reading of § 450j(k) ***affirms*** tribal sovereignty by acknowledging that tribes are free to choose how they purchase medications. The ISDEAA gives tribes the option to purchase medicines through federal channels, rather than through independently-negotiated contracts. Tribes that exercise this option presumably do so based on an individualized assessment of their own sovereign interests and the needs of their members. Tribes make this choice knowing that if they elect to self-administer their own healthcare programs they will be deemed to be executive agencies and part of the IHS. An important part of respecting tribal sovereignty is giving full legal effect to a tribe's freely made decisions, even when, in hindsight, those decisions undermine the tribe's objectives in subsequent litigation. *See Altheimer & Gray v. Sioux Mfg. Corp.*, 983 F.2d 803, 815 (7th Cir. 1993) (asserting jurisdiction over a tribe that "explicitly agreed to submit to the venue and jurisdiction of federal and state courts located in Illinois" despite the tribe's subsequent protests that its sovereignty demanded deference to the tribal court).[26]

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[25] *See* Memorandum of Law in Support of the Cherokee Nation's Motion to Dismiss [Dkt. 12] at 6, 9.

[26] Although this Court has already ruled that it has subject matter jurisdiction [Dkt. 57], the Cherokee Nation presses the argument that "[b]ecause the Cherokee Nation has sovereign immunity, this Court lacks subject matter jurisdiction over the present case." CN Memo. at 18. This attack on the Court's subject matter jurisdiction is misguided because sovereign immunity does not protect tribes from suits for declaratory or injunctive relief. *See TTEA v. Ysleta Del Sur Pueblo*, 181 F.3d 676, 680 (5th Cir. 1999); *Ross v. Flandreau Santee Sioux Tribe*, 809 F. Supp. 738, 744-45 (D.S.D. 1992); *see also Okla. Tax Comm'n v. Citizen Band Potawatomi Indian* (continued…)

D. The United States Could and Did Settle the Cherokee Nation's Avandia-Related Claims.

The Cherokee Nation argues that its claims in Tribal Court were not released because the Settlement Agreement releases only "federal claims," and its claims in Tribal Court are based on alleged violations of "the Cherokee Nation's Constitution, common law, tribal customs and statutory causes of action."[27] It also argues that the "Civil Division of the Department of Justice did not have actual or present authority to assert and compromise the claims of the Cherokee Nation."[28] None of these arguments is correct.

The Release in Paragraph 2 of the Settlement Agreement is not limited to "federal claims." It also releases "common law claims for fraud, payment by mistake, breach of contract, disgorgement and unjust enrichment."[29] These "common law" claims are not restricted to claims arising under "federal" common law, and it would be improper to read such a limitation into the

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Tribe of Okla., 498 U.S. 505, 515-16 (1991) (Stevens, J. concurring); *Moe v. Confederated Salish & Kootenai Tribes of Flathead Reservation*, 425 U.S. 463, 483 (1976) (concluding that a state requirement that Indian retailers collect state taxes imposed on non-Indians does not "frustrate[] tribal self-government"). Moreover, the Court has subject matter jurisdiction over GSK's claims against General Hembree because tribal officials may be sued for declaratory and injunctive relief under the principles set forth in *Ex Parte Young*, 209 U.S. 123 (1908). *See Crowe & Dunlevy, P.C. v. Stidham*, 640 F.3d 1140, 1154-55 (10th Cir. 2011) (holding that a tribal judge may be enjoined from the unlawful exercise of tribal court jurisdiction); *Tenneco Oil Co. v. Sac & Fox Tribe of Indians of Okla.*, 725 F.2d 572, 574-75 (10th Cir. 1984) (per curiam) (holding that members of a tribal business committee lacked sovereign immunity in suit challenging enforcement of tribal ordinances that were allegedly unconstitutional, preempted, and/or an invalid exercise of Indian sovereignty over non-Indians).

[27] CN Memo. at 6-7. The Cherokee Nation's statement is misleading. Its Amended Complaint in the Tribal Court asserts claims for statutory penalties under unspecified state false claims and unfair deceptive trade practice statutes, a claim for redhibition (which is recognized only in Louisiana) and the federal RICO statute. In addition, it filed a putative "Counterclaim Complaint" [Dkt. 49] in this Court, which is the subject of a pending motion to dismiss [Dkt. 60] that seeks to assert federal causes of action, including a claim under RICO. The Cherokee Nation's recent Answer, Affirmative Defenses and Counterclaim Complaint [Dkt. 67] also asserts claims based on federal law.

[28] CN Memo. at 7.

[29] Settlement Agreement ¶ 2.

Release. *See In re New Seabury Co. Ltd. P'ship*, 450 F.3d 24, 35 (1st Cir. 2006) ("Courts will not read language into a contract where it does not appear." (citations omitted)). It is especially improper here, where the Court is being asked to narrow the scope of released claims by reading into the Settlement Agreement an additional term that does not appear in the agreement itself. *See Mathewson Corp. v. Allied Marine Indus., Inc.*, 827 F.2d 850, 856 (1st Cir. 1987) ("the efficient management of litigation, coupled with the policy considerations which counsel in favor of settlement," weigh against "after the fact" efforts to read terms into a settlement agreement).

The Cherokee Nation's petition against GSK in the Tribal Court consists mainly of released "common law" claims. These claims constitute the bulk of the Tribe's claims against GSK, including "fraud," "negligent misrepresentation," "negligence," "unjust enrichment/restitution," and "indemnity."[30] None of these common law causes of action are based on Cherokee Nation's "Constitution," "tribal customs" or "statut[es]."

It is the case that Paragraph 6 of the Settlement Agreement carves out from the release "claims of the United States" based on products liability and breach of "express" and "implied" warranties.[31] But the Cherokee Nation has dropped all such claims from its most recent Amended Complaint in the Tribal Court.[32]

The Cherokee Nation's additional argument that the United States did not have authority to compromise its claims is simply wrong. The Department of Justice's authority to litigate on

[30] Hobart Decl. [Dkt. 20-1], Ex. 6 at 45-57. The Tribe's most recent Amended Complaint continues to assert common law claims for fraud and unjust enrichment. *See* Plaintiff's L.R. 56.1 Response to Defendant's "Statement of Undisputed Facts," Ex. 1 ("CN Am. Compl.").

[31] *See* Settlement Agreement ¶ 6 (emphasis added).

[32] *See* CN Am. Compl. Nor could the Tribe bring a product liability claim, as it is not a user of medications, nor can it be injured by them. *See Rohrbaugh v. Owens-Corning Fiberglas Corp.*, 965 F.2d 844, 846 (10th Cir. 1992) (although "[u]nder Oklahoma law, a manufacturer may have a duty to warn consumers of potential hazards which occur from the use of its product," this duty "only extends to ordinary consumers and users of the products").

behalf of federal agencies, including the IHS, is clear. *See, e.g.*, 28 U.S.C. § 516. The Cherokee Nation is deemed to be an executive agency and part of the IHS. The United States thus has the same authority to settle claims by the Cherokee Nation as it has to settle claims by the IHS.

The Department of Justice also has direct authority to litigate on behalf of tribal organizations: "In all States and Territories where there are reservations or allotted Indians the United States attorney shall represent them in all suits at law and in equity." 25 U.S.C. § 175; *See Heckman v. United States*, 224 U.S. 413, 442 (1912) (noting the federal government's inherent and statutory right to sue on a tribe's behalf as part of its trustee relationship with the tribe).[33] Indeed, the United States can file suit on a tribe's behalf even over the tribe's objection. *See, e.g.*, *United States v. White Mountain Apache Tribe*, 784 F.2d 917 (9th Cir. 1986); *White Mountain Apache Tribe v. Hodel*, 784 F.2d 921 (9th Cir. 1986).

The Tribe's attempt to distinguish *United States v. Minnesota*, 270 U.S. 181 (1926) and *Nevada v. United States*, 463 U.S. 110 (1983), which GSK cited in its opening Memorandum, is unavailing.[34] *Minnesota* recognized that the United States has a right and a duty to represent Indian interests, including by bringing suit, even in instances where the Indians themselves would lack the right to enforce such interests. *Minnesota*, 270 U.S. at 193-95. The case did not establish, as the Tribe asserts, that the United States may ***only*** represent Indian interests in such instances. The Tribe argues that *Nevada* is inapposite because, unlike the present case, it involved "conflicting statutory obligations" on the part of the United States.[35] The *Nevada* opinion in no way disclaims the existence of the Government's "strong fiduciary duty" to Indian

[33] The United States has an express trust relationship with tribes with respect to healthcare. *See e.g.*, 25 U.S.C. §§ 1601(1), 1602.

[34] *See* CN Memo. at 7-8.

[35] *Id.* at 7.

tribes, *Nevada*, 463 U.S. at 142, or its "obligation to represent Indian tribes in litigation," *id.* at 128. Indeed, these obligations would be even stronger in cases (like this one) where the government does not face other conflicting duties. *See id.* at 142.

III. THE CHEROKEE NATION'S CLAIMS FALL WITHIN THE SCOPE OF THE "COVERED CONDUCT" WHICH IS SUBJECT TO THE RELEASE.

A. The Cherokee Nation's Claims Fall Within the Scope of "Covered Conduct" in Paragraph E-(i) Because Its Purchases of Avandia Were Purchases by the "Veterans Affairs Program," Which Is One of the "Government Health Care Programs" Listed in Paragraph D of the Settlement Agreement.

As GSK showed in its opening Memorandum, the Cherokee Nation's claims in Tribal Court involve "Covered Conduct" under Paragraph E-(i) of the Settlement Agreement because its purchases of Avandia were purchases by the "Veterans Affairs Program."[36] The "Veterans Affairs Program" covers numerous purchasers, including the IHS. As previously noted, the IHS actually purchased Avandia as an intermediary for the Cherokee Nation.

Ignoring the broad scope of the Veterans Affairs Program, and its many beneficiaries who are not "veterans," the Cherokee Nation and the United States continue to assert that Paragraph E-(i) is limited to purchases that the Veterans Affairs Program "made on behalf of [veterans]."[37] They base this argument on the fact that Paragraph D of the Settlement Agreement includes a parenthetical citation to 38 U.S.C. §§ 1701-1743, which describe "the hospital, nursing home, domiciliary, and medical care benefits available to eligible veterans."[38] This argument is not persuasive.

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[36] *See* GSK Memo. at 14-18.

[37] *Id.* at 11; CN Memo. at 6.

[38] Statement of Interest II at 11. In its quotations of Paragraph D, the United States repeatedly omits the parentheses that appear in the Settlement Agreement. *See id.* at 3, 11.

The "Veterans Affairs Program" is not limited to purchases by the VA on behalf of "veterans."[39] The VA's procurement program for pharmaceuticals and other medical supplies is comprised of nine schedules on the FSS. The VA administers these schedules for the benefit of government agencies and other specifically authorized buyers, including the IHS, which purchases on behalf of tribes under the ISDEAA. Only about sixty percent of the nearly $11 billion in annual purchases by the Veterans Affairs Program are made by the VA for the benefit of veterans. The remaining forty percent of purchases are made by other eligible purchasers for the benefit of non-veterans, including, among others, federal prisoners, immigration detainees, certain federal agency employees, and Indians. The Veterans Affairs Program includes all drug procurement actions taken by the VA on behalf of all such purchasers.

GSK paid for and received from the United States and its agencies a release for conduct that caused purchases of Avandia by the ***entire*** "Veterans Affairs Program," not just purchases for veterans. The United States concedes that the IHS utilized this program to purchase Avandia for Indian Tribes. The Settlement Agreement did not leave these purchases on the table. It is inconceivable that the Government recovered on only sixty percent of the Program's purchases and that GSK remains vulnerable to claims by the federal agencies that purchased the remaining forty percent. If GSK and the United States had intended to limit the Release to conduct that caused purchases ***by the VA for veterans***, they would have said so. Instead, they agreed that the Release would extend to purchases ***by the Veterans Affairs Program***.

Furthermore, the argument that the parenthetical reference in Paragraph D to "38 U.S.C. §§ 1701-1743" means that the "Veteran's Affairs Program" extends only to the VA's purchases for veterans is undermined by the fact that these sections of Title 38 do not cover all of the VA's

[39] GSK Memo. at 14-16.

purchases for veterans. To the contrary, statutes outside of this range also provide for such purchases. For example, 38 U.S.C. § 1745 states that the VA shall furnish drugs to disabled veterans who do not receive nursing home care, provided the drugs are "ordered on prescription of a duly licensed physician." Under the government's narrow reading of "Veterans Affairs Program," the Release would not cover the VA's purchases for these veterans, because the purchases would not be part of the "Veteran's Affairs Program." This reading of Paragraph D is implausible. Clearly, the "Veteran's Affairs Program" is broader than the government contends.

B. The Cherokee Nation's Claims Also Fall Within the Scope of "Covered Conduct" in Paragraph E-(ii) of the Settlement Agreement.

"Covered Conduct" under Paragraph E-(ii) is not limited to conduct affecting "Government Health Care Programs."[40] Paragraph E-(ii) covers safety-related misrepresentations made to "physicians and other health care providers" generally. In its initial Statement of Interest, the government did not mention, let alone discuss Paragraph E-(ii).[41]

Recognizing that Paragraph E-(ii) cannot be ignored, the government now argues that the release in Paragraph E-(ii) is limited in scope. It contends that Paragraph 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."[42]

The government's new argument is plainly wrong. In fact, Paragraph E-(ii) does not even refer to Avandia's "label." Rather, it refers to alleged "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 healthcare providers in

[40] *See* GSK Memo. at 18-19.

[41] *See* Plaintiff's Memorandum of Law in Response to the Statement of Interest Filed by the United States [Dkt. 30] at 2-3.

[42] Statement of Interest II at 13.

violation of the FDCA . . . ."[43] It is black-letter law that the term "labeling" is much broader than the term "label." Thus, contrary to the government's assertion, Paragraph E-(ii) is not limited to false and misleading representations on Avandia's "label."

A drug's "label" is "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). A label must be approved by the FDA and, in the absence of fraud on the FDA, cannot contain "misleading" representations. *See, e.g.*, *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, No. 09-2067, 2014 WL 866571, at *4 (D. Mass. Mar. 5, 2014) (FDA approval of drug label bars state-law claims that label is "misleading"). "Labeling," on the other hand, is a term of art that encompasses "all labels ***and other written, printed, or graphic matter*** (1) upon any article or any of its containers or wrappers, ***or*** (2) ***accompanying such article***." 21 U.S.C. § 321(m) (emphasis added). The Supreme Court has held that this definition "is not restricted to labels that are on or in the article or package that is transported." *Kordel v. United States*, 335 U.S. 345, 349 (1948). "Labeling," therefore, includes any material "designed for use in the distribution and sale" of a product, even if the material is distributed separately from the product itself. *Id.* at 350.

"Labeling" includes GSK's communications with physicians and other healthcare providers in the course of promoting Avandia. *See id.* (holding that circulars and pamphlets distributed to consumers constituted "labeling" even though they did not physically accompany the product; finding "[o]ne article or thing is accompanied by another when it supplements or explains it"); *see also* 21 C.F.R. § 202.1(*l*)(2) (listing various types of "printed, audio, or visual matter" that constitute "labeling"); *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011) (deferring to FDA interpretation of "labeling" as including "Dear Doctor" letters); *Fulgenzi v.*

[43] Settlement Agreement ¶ E-(ii) (emphasis added).

PLIVA, Inc., 711 F.3d 578, 581 n.1 (6th Cir. 2013) ("The FDA construes 'labeling' broadly, to include not just the written label associated with the drug, but communications with physicians and other healthcare professionals containing additional warnings ('Dear Doctor' letters) and information published in the Physician's Desk Reference."). Indeed, this is precisely what Paragraph E-(ii) is referring to when it states that GSK made "misleading representations about . . . the overall safety of Avandia[] . . . in labeling used during the promotion of Avandia to physicians and other healthcare providers."

The government's attempt to limit the scope of the Release in Paragraph E-(ii) is wrong as a matter of law. That paragraph is not limited to statements on Avandia's "label."[44]

IV. THE SETTLEMENT AGREEMENT IS VALID AND ENFORCEABLE.

Without filing a motion or a proper Statement of Undisputed Facts under Local Rule 56.1, the Cherokee Nation asks this Court to enter summary judgment on its claim that the Settlement Agreement is "void" and "voidable," allegedly because "there was no meeting of the minds" and for other reasons.[45] The Tribe's request for a summary adjudication that the Settlement Agreement is unenforceable is frivolous and should be rejected out of hand.[46]

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[44] As it did previously, the government continues to argue that a contemporaneous Nominal Price Settlement Agreement between GSK and the United States, which released claims on behalf of Medicaid and certain PHS entities, shows that the parties did not "intend" to release claims by "unnamed third parties." *See* Statement of Interest II at 16-17. GSK previously responded to this argument at pages 7-9 of its Memorandum of Law in Response to the Statement of Interest Filed by the United States [Dkt. 30]. GSK incorporates its prior response by reference.

[45] CN Memo. at 18-20.

[46] The Cherokee Nation's failure to file a motion and proper Rule 56.1 Statement is reason enough to deny summary judgment on its contract claim. D. Mass. L.R. 56.1 ("Failure to include such a statement constitutes grounds for denial of the motion."). Indeed, at the time it filed its Memorandum, it had not even filed a valid pleading setting forth its claim that the Settlement Agreement is invalid. *See* Memorandum of Law in Support of Plaintiff's Motion to Dismiss Defendants' Procedurally Improper Counterclaim [Dkt. 60].

First, neither GSK nor the United States contend that their Settlement Agreement is void or voidable. Although GSK and the United States disagree about whether the Settlement Agreement covers the Cherokee Nation's claims, that disagreement does not render the Agreement "void" or "voidable."[47]

Second, the Court may not rescind the Settlement Agreement in this lawsuit because the United States is not a party. If the Cherokee Nation believes it can prove a claim for rescission of the Settlement Agreement based on alleged invalidity, it must sue the parties to the Settlement Agreement, including the United States.[48] (Although the United States would be a necessary party in a suit to rescind the Settlement Agreement, it is not a necessary party in ***this*** case for the reasons set forth in the government's Statement of Interest.)[49]

Third, even if the Court could rescind the Settlement Agreement at this procedural juncture in an action in which the United States is not a party, the Tribe has not come close to showing that the Court should do so. There is obviously no "mutual mistake" as that term is used in contract law, because GSK and the United States both understood that the Settlement Agreement covered claims for "Covered Conduct" by the United States and its "agencies."

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[47] *See Int'l Indus. Park, Inc. v. United States*, 100 Fed. Cl. 638, 651 (Fed. Cl. 2011) (disagreement over contract interpretation did not render contract unenforceable), *on reconsideration in part*, 102 Fed. Cl. 111 (Fed. Cl. 2011), *aff'd*, 496 F. App'x 85 (Fed. Cir. 2013) and *aff'd*, 496 F. App'x 85 (Fed. Cir. 2013).

[48] *See, e.g.*, *Acton Co. of Mass. v. Bachman Foods, Inc.*, 668 F.2d 76, 81–82 (1st Cir. 1982) ("[A]n action seeking rescission of a contract must be dismissed unless all parties to the contract, and others having a substantial interest in it, can be joined."); *Am. Optical Co. v. Curtiss*, 59 F.R.D. 644, 650-51 (S.D.N.Y. 1973) ("It seems self-evident that a decree of cancellation of an agreement will inevitably affect all parties to such an agreement and, therefore, all parties should be present."); 7 Charles Alan Wright, et al., *Federal Practice and Procedure* § 1613 (3d ed.) ("In cases seeking reformation, cancellation, rescission, or otherwise challenging the validity of a contract, all parties to the contract probably will have a substantial interest in the outcome of the litigation and their joinder will be required." (footnotes omitted)).

[49] *See* Statement of Interest II at 18-20.

Although the parties to the Settlement Agreement disagree about how those terms should be interpreted, that disagreement presents a legal question of contract interpretation, rather than a "mutual mistake of fact." *See Morris v. United States*, 33 Fed. Cl. 733, 747 (Fed. Cl. 1995) (citing, *inter alia*, Restatement (Second) of Contracts § 152 (1981)) (identifying the elements needed to prove mutual mistake).

It is equally obvious that the Settlement Agreement may not be rescinded due to "unilateral mistake." The alleged mistake in this case is the United States' mistaken belief that the Cherokee Nation's claims were not released, a mistake that the United States denies making inasmuch as it denies that the Cherokee Nation's claims are released. Again, this is nothing more than a disputed issue of contract interpretation, not a "mistake." *See Morris*, 33 Fed. Cl. at 747 (citing, *inter alia*, Restatement (Second) of Contracts § 153 (1981)) (identifying the elements needed to prove unilateral mistake); *see also Buesing v. United States*, 47 Fed. Cl. 621, 638 (Fed. Cl. 2000).

Finally, the Cherokee Nation complains that the United States failed to consult with it before entering into the Settlement Agreement and did not provide it with any "consideration" after the fact.[50] If true, the Cherokee Nation's recourse, if any, would be to sue the United States for breach of its fiduciary responsibility.[51] The Settlement Agreement itself is valid.

[50] *See* CN Memo. at 19-20.

[51] *See* GSK Memo. at 11 n.30.

CONCLUSION

GSK's renewed cross-motion for summary judgment on its claims for declaratory relief should be granted.

Respectfully submitted,

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Dated: August 7, 2014

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document was served upon the attorney of record for the defendants through the Court's electronic filing system ("ECF") on August 7, 2014.

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