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Attorneys for Defendant Victor Connelly

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MONTANA  
GREAT FALLS DIVISION**

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|-------------------------------------|---|-------------------------------------|
| <b>TAKEDA PHARMACEUTICALS</b>       | ) |                                     |
| <b>AMERICA, INC.; TAKEDA</b>        | ) |                                     |
| <b>PHARMACEUTICALS U.S.A, INC.,</b> | ) |                                     |
| <b>f/k/a TAKEDA PHARMACEUTICALS</b> | ) |                                     |
| <b>NORTH AMERICA, INC.; and</b>     | ) | <b>Case No. CV-14-50-GF-BMM-RKS</b> |
| <b>TAKEDA PHARACEUTICAL</b>         | ) |                                     |
| <b>COMPANY, LIMITED,</b>            | ) |                                     |
|                                     | ) |                                     |
| <b>Plaintiffs,</b>                  | ) |                                     |
|                                     | ) |                                     |
| <b>v.</b>                           | ) | <b>DEFENDANT’S REPLY BRIEF</b>      |
|                                     | ) | <b>IN SUPPORT OF HIS MOTION</b>     |
| <b>VICTOR CONNELLY,</b>             | ) | <b>TO DISMISS FOR LACK</b>          |
|                                     | ) | <b>OF JURISDICTION</b>              |
| <b>Defendant.</b>                   | ) |                                     |

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COMES NOW the Defendant Victor Connelly, by and through counsel, and hereby respectfully submits his Reply Brief in Support of his Motion to Dismiss the Takeda Plaintiffs' Complaint for lack of jurisdiction on the grounds that they have failed to exhaust their remedies in the Blackfeet Tribal Court as follows:

### **INTRODUCTION**

The Takeda Plaintiffs brought this action seeking a declaratory judgment trying to prevent Victor Connelly from pursuing his action against them in the Blackfeet Tribal Court for various tort claims arising out of his use of the prescription drug ACTOS which Connelly claims caused him to develop bladder cancer.

Falsely asserting that their only conduct with respect to Connelly occurred outside the Blackfeet Indian Reservation, the Takeda Plaintiffs ask this court to declare that the Blackfeet Tribal Court has no jurisdiction over them and to enjoin Connelly from pursuing his Blackfeet Tribal Court action. In their Complaint, the Takeda Plaintiffs wrongly assert that they are not required to exhaust their remedies in the Blackfeet Tribal Court system as required by applicable Federal Indian law principles.

Connelly has responded by filing a Motion to Dismiss for lack of jurisdiction on the grounds that the Takeda Plaintiffs have failed to exhaust their Tribal Court remedies. Connelly has further argued that because tribal court

jurisdiction here is plausible, exhaustion of tribal remedies is mandatory, and that none of the exceptions to the mandatory exhaustion requirement exist in this case.

The Takeda Plaintiffs have now filed their response in which they incorrectly assert that all of their conduct took place outside of the Blackfeet Indian reservation, that they had no consensual commercial relationship with Connelly within the Reservation and that tribal court jurisdiction is therefore plainly lacking. Based on these incorrect assertions, the Takeda Plaintiffs wrongly conclude that they are not required to exhaust their Blackfeet Tribal Court remedies.

As set forth below, the Takeda Plaintiffs attempt to minimize or ignore the fact that they intentionally marketed, sold and distributed their drug (ACTOS) to the Indian Health Service knowing and intending that the drug would be prescribed to and ingested by Indian people, including Defendant Connelly, within Indian Reservations. The Takeda Plaintiffs further attempt to ignore the fact that the drug was prescribed at the Blackfeet Community Hospital (an IHS facility) located on land owned in trust by the Blackfeet Indian Tribe and located within the boundaries of the Blackfeet Indian Reservation. And that Connelly ingested the drug at his home and workplace on Indian trust land also located within the boundaries of the Blackfeet Indian Reservation.

Applying the principles of Federal Indian law, tribal court jurisdiction is clearly plausible, and the Takeda Plaintiffs must therefore be required to exhaust

their remedies in the Blackfeet Tribal Court before asking this court to review the issue of tribal court jurisdiction.

### **JURISDICTIONAL FACTS**

The Defendant hereby incorporates by this reference the Statement of Stipulated Jurisdictional Facts. Doc. 30.

The land on which the IHS clinic/hospital is located on the Blackfeet Reservation is land owned by the Blackfeet Indian Tribe and is held in trust status and leased to the Indian Health Service for a fee of \$1.00 per year. Defendant's Exhibits A1, A2, A3 & A4, Lease Agreements.

The Indian Health Service was created for the purpose of meeting the U.S. Government's trust responsibility to members of Federally recognized Indian tribes pursuant to the U.S. Constitution, treaties, Executive Orders, federal laws and U.S. Supreme Court decisions. "<http://www.ihs.gov/aboutihs/>". The Blackfeet Tribe leases this land for the Blackfeet Community Hospital to the Indian Health Service for the purposes of providing a Hospital to fulfill the federal government's trust responsibility to the Blackfeet tribe and its members. Id., Defendant's Exhibits A1, A2, A3 & A4.

The Actos which Connelly was prescribed and ingested was paid for by the Indian Health Service in fulfillment of its trust responsibility to Connelly as a member of the Blackfeet Indian Tribe.

While no Takeda employees apparently promoted or sold Actos directly on the Blackfeet Indian Reservation, since at least 2005 Takeda engaged in an aggressive marketing plan specifically targeting the Indian Health Service with the intent that the drug be prescribed at all Indian Health Service facilities to Indians including Victor Connelly. Defendant's Exhibit B, Takeda Marketing Strategy/ "Pull Through" Strategy. (filed under seal separately).

Takeda's efforts targeted individual IHS facilities, including IHS's Blackfeet Hospital, through aggressive financial incentives that rewarded higher market share at each facility through its "ACTOS Special Pricing Terms." Defendant's Exhibit B, id. (filed under seal).

Takeda's Managed Markets group was primarily responsible for contacts with the IHS regarding the IHS's inclusion of Actos on the IHS's formulary.

Takeda's Managed Markets employee contacts with the IHS regarding the inclusion of Actos on the IHS prescription drug formulary occurred primarily through the IHS agency offices in Oklahoma City.

Some individual Takeda sales representatives have indicated that they never made direct contact with the Blackfeet Community Hospital. However none of these individuals had responsibility for the area serving the Blackfeet Hospital, and those who were responsible have never been deposed. Defendant's Exhibit C, Depo. of Tadekda Sales Manager Jeffrey McClellan, p. 27, 28, 126. (filed under

seal separately). And at least one Takeda sales representative did visit the Blackfeet Community Hospital, but was told that the hospital was being serviced by the Marketing group. Id.

On these facts, based upon the principles articulated in federal court case law, the Blackfeet Tribal Court has plausible jurisdiction over Connelly's tribal court claims, and the Takeda Plaintiffs must exhaust their remedies in the Blackfeet Tribal Court. No exception to the mandatory exhaustion requirement exists in this case.

### **LAW AND ARUGMENT**

As set forth in Defendant Connelly's opening brief, the jurisdiction of the Blackfeet Tribal Court is plausible under both prongs of the so-called Montana test: "A tribe may regulate, through taxation, licensing, or other means, the activities of nonmembers who enter consensual relationships with the tribe or its members, through commercial dealing, contracts, leases, or other arrangements. A tribe may also retain inherent power to exercise civil authority over the conduct of non-Indians on fee lands within its reservation when that conduct threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the tribe." *Montana v. U.S.*, 450 U.S. 544, 565-66 (*citations omitted*).

The Takeda Plaintiffs' voluntary, intentional commercial dealings which resulted in their drug (ACTOS) being exclusively distributed to Indian Health

Service clinics, including the Blackfeet Community Hospital, within Indian reservations, with the intention that it be prescribed to and ingested by Indian people, constitutes a consensual commercial relationship giving rise to plausible jurisdiction in tribal courts. There is a direct nexus between the Takeda Plaintiffs' marketing, sales and distribution of the subject drug and Defendant Victor Connelly's tort claim based on his ingestion of that drug on Indian land within the Blackfeet Indian Reservation.

Contrary to the Takeda Plaintiffs' claims, their conduct in this regard was conduct which intentionally took place within, not outside, the Blackfeet Indian Reservation. The Takeda Plaintiffs' decision to sell its drug (ACTOS) to the Indian Health Service, with the knowledge and intent that it be prescribed and ingested by Indian people within the Blackfeet Indian Reservation, supplies the requisite voluntary commercial relationship to meet the first exception to the general rule under *Montana v. U.S.*, 450 U.S. 544, 565-566 (1981) (the "consensual commercial relationship" test), with respect to claims arising out of the Blackfeet Indian Reservation. *Phillip Morris U.S.A. Inc. v. King Mountain Tobacco Company*, 569 F.3d 932, 942 nt. 3 (9<sup>th</sup> Cir. 2009).

Diabetes is epidemic among American Indians and Alaskan natives in the United States. *Special Diabetes Program for Indians (SDPI), 2007 Report to Congress: On the Path to A Healthier Future; SDPI 2001 Report to Congress:*

*Making Progress Toward a Healthier Future*, <http://www.ihs.gov/>

MedicalPrograms/Diabetes/ . . .module=programsSDPI. Diabetes occurs in these populations in a rate higher than any other ethnic group in America, causing serious demonstrable economic and health and welfare impacts on American Indian Tribes. *Id.* For these reasons, Congress has enacted special legislation to address this serious health care epidemic among Indian people. See *Indian Health Care Improvement Act*, 25 U.S. C. Sec. 1601 et seq.; *Special Diabetes Program for American Indians*, Pl. 105-33, Section 4922, augmented by Pl. 106-554, Sec. 931. Consequently American Indian Tribes have a direct interest in helping in the regulation of diabetes as a serious and demonstrable threat which imperils the economic security and health and welfare of the Tribes themselves.

Defendant Connelly's claims thus bring the Takeda Plaintiffs under the second prong of the Montana test. (conduct threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the tribe). *Montana v. U.S.*, 450 U.S. 544, 565-566 (1981)

Importantly, it was with this knowledge that the Takeda Plaintiffs targeted the Indian Health Service for distribution of their drug ACTOS, with the intent that it be prescribed to and taken by Indian people within their reservations throughout America. In this regard, Takeda's intentional distribution of its drug (ACTOS) to the Blackfeet Community Hospital brings its actions under the second prong of the



Montana test in that their conduct has a direct, demonstrable impact on the economic security and health and welfare of the Tribe. *Montana v. U.S.*, 450 U.S. 544, 565-566

**1. Takeda's Conduct.**

The Takeda Plaintiffs have argued that because their conduct occurred in Oklahoma, it was not on-reservation conduct for jurisdictional purposes. Takeda then goes on to assert that its marketing activities took place with the Indian Health Service offices in Oklahoma City, Oklahoma and that it had no connection to the Blackfeet Indian Reservation. That approach simply ignores that Takeda was specific purpose was to get the Indian Health Service to list ACTOS on the IHS drug formulary so that it would be distributed to all IHS facilities, including on Indian Reservations. Takeda knew that this was the intended result of its activity and it was foreseeable that any issues arising out of the drug's use would occur within Indian reservations.

In this regard, Takeda's marketing strategy was like that of the cigarette company in *Phillip Morris U.S.A v. King Mountain Tobacco Company*, Id. In the Phillip Morris case, the tobacco/cigarette company admitted that its cigarettes were being sold on the Yakima Indian Reservation by store owners who purchased the cigarettes from Phillip Morris distributors. And Phillip Morris admitted that its

cigarettes were being sold to tribal members within the Yakima Reservation. All of which was intended by Phillip Morris.

On these facts, the Ninth Circuit Court of Appeals opined that if the issue in that case (which was King Mountain's use of cigarette packaging which was similar to Phillip Morris' packaging for sales outside the Reservation) had been King Mountain's sale of its similar packaged cigarettes at stores within the Yakima Reservation, "tribal court exhaustion would be appropriate . . . , as there would be a colorable claim that Phillip Morris's voluntary decision to sell its cigarettes within the Reservation supplies the requisite voluntary commercial relationship to meet Montana's first exception with respect to claims arising in that market." *Phillip Morris U.S.A. Inc. v. King Mountain Tobacco Co.*, 569 F.3d at 942 nt. 3.

The same is true in this case. That is that Takeda was using the Indian Health Service as a governmental distributor of its drug, knowing that the drug would then be distributed to Indian Health Service clinics/pharmacies located on Indian Reservations where it would be prescribed to Indian people for their consumption. First there is a marketing effort to the IHS headquarters for the drug formulary. Then the drug is distributed to local Indian Health Service clinics and pharmacies to be prescribed by local IHS doctors to Indian people within a reservation. Takeda is not engaged in this effort out of altruistic motivation. The motivation is simple: profit. The only difference here is that the Indian Health

Service, out of its trust responsibility to Indians arising from treaties and other agreements, is paying for the drug, rather than the end-user having to pay out of their own pocket.

There is thus a voluntary commercial relationship between Takeda and the Indian Health Service, for which the local Indian person who is prescribed and takes the drug is the end beneficiary. The relationship is without doubt a commercial relationship.

And, just as importantly, the final step in the relationship occurs, not in Oklahoma City, Oklahoma, but in Indian Health Service clinics and pharmacies across Indian country, including and in particular, in this case, on the Blackfeet Indian Reservation. Indeed, Takeda does not dispute that Victor Connelly was prescribed the drug (ACTOS) and ingested that drug on Indian land within the Blackfeet Indian Reservation. Importantly, this is not a case where a manufacturer is distributing a product generally into the stream of commerce, without regard to any specifically targeted area or population. Here, Takeda specifically targeted the Indian Health Service for sole source distribution of its drug to Indian people, knowing of the significant Indian population affected by diabetes and with the purpose of taking economic advantage of the high incidence of diabetes in American Indians. Defendant's Exhibit B.

The cases relied upon by Takeda for its assertion that the Tribal trust land leased by the IHS for the Blackfeet Community Hospital is the equivalent of non-Indian fee land are not applicable here. See Doc.20, pg.11-13. Those cases involved land which had been determined as a matter of law to be non-Indian fee land because the lands were rights-of-way granted pursuant to federal law or where in fact non-Indian fee lands.

**2. Nexus between the voluntary commercial relationship and Connelly's claims.**

The precedent further requires that there be some nexus between the commercial relationship and the underlying claims. See *Phillip Morris U.S.A. v. King Mountain Tobacco Co.*, 569 F.3d 932, \_\_\_ (9<sup>th</sup> Cir. 2009) citing *Atkinson Trading Co. v. Shirley*, 532 U.S. 645, 656 (2001).

In this case, based on the allegations, there is clearly an nexus between the voluntary commercial distribution by Takeda of the drug ACTOS and Victor Connelly's development of bladder cancer. Once again, Takeda intentionally and voluntarily marketed its drug to the Indian Health Service knowing and intending that the drug be prescribed to Indians at IHS facilities, in particular the Blackfeet Community hospital.

Takeda accepted the economic benefit of its commercial relationship with the Indian Health Service. Connelly now seeks to hold Takeda liable for the alleged failure to warn everyone (the IHS, the prescribing physician and Victor

Connelly) about the danger of the drug ACTOS and that the drug could cause bladder cancer. In this case, the Tribe is protecting, through its tribal court, all of its members from the consequences of a bad drug. The fact that the regulation of the Takeda Plaintiffs' conduct takes the form of a tort action in the Blackfeet Tribal Court does not diminish the Tribe's jurisdiction or inherent sovereignty. See. *Dolegencorp, Inc. and Dollar General Corp. v. The Mississippi Band of Choctaw Indians, et al.*, 732 F.3d 409 (5<sup>th</sup> Cir. 2013) , revised opinion 3/14/2014 case no. 12-60668.

Importantly Indian Tribes have a vested interest in protecting the health of their members when it comes to diabetes. Diabetes is epidemic in American Indians and Alaskan Natives who suffer from the disease at rates higher than any other ethnic group in America. SDPI, 2007 and 2011 Reports to Congress, <http://www.ihs.gov/MedicalPrograms/Diabetes/...module=programsSDPI>. For this reason, “[a]ddressing this disease and its consequences for tribal communities is an important health priority for our nation.” *SDPI, 2007 Report to Congress: “On a Path to a Healthier Future”*, pg. 29, <http://www.ihs.gov/MedicalPrograms/Diabetes/...module=programsSDPI..>

**3. Takeda's conduct imperils the health and welfare of the Tribe.**

Considering the epidemic nature of diabetes in Indian County, Takeda callously asserts that its intentional distribution of the diabetes drug ACTOS has no demonstrable impact on the health or welfare of the Blackfeet Tribe.

Contrary to this position is the fact that the United States Congress has recognized that diabetes is epidemic in American Indians who suffer the highest incidence of the disease in America. Moreover, the Special Diabetes Program for Indians expressly recognizes the economic impact of the disease in American Indians not only for Tribes, but for the nation as a whole. SDPI, Id.

“A tribe may also retain inherent power to exercise civil authority over the conduct of non-Indians on fee lands within its reservation when that conduct threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the tribe.” *Montana* 450 U.S. at 565-66 (*citations omitted*). While it is correct that the Supreme Court has further modified this standard to require that the challenged conduct imperil the subsistence of the Tribe be catastrophic to the Tribe, that standard is met here. See *Plains Commerce Bank v. Long Family Land & Cattle Co.*, 554 U.S. 316, 341 (2000); *Evans v. Shoshone Bannock Land Use Policy Comm.*, 736 F.3d 1298, 1305-1306 (9<sup>th</sup> Cir. 2013).

Like the land use in *Brendale v. Confederated Yakima Tribes and Bands of the Yakima Indian Reservation*, 492 U.S. 408 (1989), the activity of Takeda, in the context of the extreme health crises represented by diabetes in Indian Country,

clearly imperils the health and welfare of the Blackfeet Tribe and has the potential to be catastrophic to the Blackfeet Tribe.

**4. No exception to the requirement of exhaustion of tribal remedies exists in this case.**

On the facts of this case, the jurisdiction of the Blackfeet Tribal Court is not plainly lacking, nor would exhaustion of tribal court remedies be futile.

As set forth exhaustively in Defendant Connelly's opening Brief and herein, tribal court jurisdiction is clearly plausible on the facts of this case. Contrary to the arguments of the Takeda Plaintiffs tribal court jurisdiction is not clearly lacking. With respect to the Takeda Plaintiff's assertions regarding the status of the land and the Tribe's lack of authority to control conduct on that land, the cases relied upon by Takeda are all cases where the courts have found the land to be, in essence, non-Indian fee land. That is not the case here. The mere lease of the land to the Indian Health Service does not deprive the Tribe of its ownership or change the character of the land to non-Indian fee land.

Similarly the reliance of the Takeda Plaintiffs on a BIA review as rendering exhaustion of tribal remedies futile, is inapposite. No court has found that a BIA review could be the basis of application of the futility exception. See *Grand Canyon Skywalk Development LLC v. Sa Nyu Wa Incorporated*, 715 F.3d 1196 (9<sup>th</sup> Cir. 2013)(rejecting claims similar to Takeda's claim regarding the Blackfeet Tribal Court as being applicable to the bad faith exception). More importantly,

the BIA continues to fund the Blackfeet Tribal Court pursuant to Pl. 93-638. Additionally, the Tribal Judges have since been legally appointed. See Defendant's Exhibits D1 & D2, Blackfeet Resolutions No. 246-2014 & 248-2014, Appointing Tribal Judges.

### **CONCLUSION**

Because Blackfeet Tribal Court jurisdiction over the underlying claims by Defendant Connelly against the Takeda Plaintiffs is clearly plausible, and no exception to the requirement of exhaustion of tribal court remedies exists, the Takeda Plaintiffs' Complaint must be either dismissed or stayed pending exhaustion of their remedies in the Blackfeet Tribal Court.

DATED this 24<sup>th</sup> day of October, 2014.

\_\_\_\_ss/Joe J. McKay\_\_\_\_\_  
Joe J. McKay, Attorney-at-Law



CERTIFICATION

I hereby certify pursuant to L.R. 7.1(d)(2) that the foregoing Brief in Support of the Defendant's Motion to Dismiss is approximately 3,235 words as determined by Microsoft word, excluding the caption and certificate of compliance.

\_\_\_\_ss/Joe J. McKay\_\_\_\_\_  
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