

Presentation to Northwest Portland Area Indian Health Board

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Agenda

- Affordable Care Act Litigation
- Juul MDL
- Opioids MDL
- Section 105(/) Litigation
- Contract Support Costs Litigation
- 340B Program Update

Affordable Care Act Litigation

Texas v. United States

Legal Challenges to the Affordable Care Act: *Texas v. United States*

- Case brought by Texas and other “Red States” arguing that the individual mandate to the Affordable Care Act (ACA) is unconstitutional.
- Plaintiff States also argued that the individual mandate is so central to the statutory scheme that the entire ACA must be struck down.
- In December 2018, a federal District Court in Texas held that, following passage of the Tax Cuts and Jobs Act of 2017, the “individual mandate” provision of the ACA can no longer be considered a valid exercise of Congress’s power to tax and is therefore unconstitutional.
- The District Court also held that the individual mandate is not severable from the remainder of the Act and that the ACA is constitutionally invalid in its entirety.

District Court Decision Impact on Tribal Health

- The District Court's ruling extends to Section 10221 of the ACA, which amended and permanently authorized provisions of the Indian Health Care Improvement Act (IHCIA), and to other Indian-specific health care provisions incorporated into the Act, even though they are not dependent on the ACA's individual mandate.
- If the District Court's decision is upheld in full, the IHCIA amendments and other Indian-specific provisions in the ACA would be struck down.

Fifth Circuit Court of Appeals

- The District Court's decision was appealed to the Fifth Circuit Court of Appeals.
- The U.S. House of Representatives intervened in the case, siding with California and other "Blue States" in support of upholding the ACA.
- United States change of litigation position:
 - In the District Court, the United States agreed that the individual mandate is now unconstitutional, but argued that most of the rest of the ACA should be preserved.
 - In the Court of Appeals, the United States changed its position, supporting the District Court's decision holding that the entire law must be struck down.

Tribal Amicus

- An amicus brief was submitted on behalf of a national coalition of Tribes and Tribal Organizations, arguing:
 - That the District Court did not correctly apply long-established severability rules requiring that a court should preserve as much of a statute as possible when one provision is found unconstitutional.
 - The IHClA and certain other Indian-specific provisions in particular should be preserved, because:
 - (1) they can operate as intended by Congress without the individual mandate in place;
 - (2) the IHClA's legislative history shows that it originated as a freestanding bill in 1976, separate from the rest of the ACA, underscoring that it operates independently of the remainder of the ACA; and
 - (3) there is no evidence whatsoever that Congress would have wanted the IHClA and other Indian provisions to fail if the individual mandate were deemed unconstitutional.

Fifth Circuit Court of Appeals Decision

- The 5th Circuit panel upheld the District Court's decision that the individual mandate is unconstitutional.
- The panel criticized the District Court's analysis on the question of severability and remanded the case back to District Court to re-consider whether the individual mandate provisions are severable from the remainder of the ACA.
- In January 2020, parties filed petitions for review in the Supreme Court.

US Supreme Court

- Briefing began in March and is now completed.
- Coalition of Tribes and Tribal Organizations submitted an *amicus* brief defending the validity of the IHCA and other Indian provisions in the ACA.
- As in the Court of Appeals, the United States declined to defend the ACA.
- The Court has scheduled oral argument for November 10, 2020.
- Key issues to be decided by Court include:
 - standing;
 - constitutionality of ACA provisions in light of removal of the individual mandate; and
 - application of severability doctrine.
- If the Court gets past threshold procedural questions regarding standing, a decision from the Court could:
 - disagree that any provision of the ACA is unconstitutional;
 - uphold the District Court's decision;
 - agree with the 5th Circuit and remand back to the District Court; or
 - agree with 5th Circuit and make its own decision on what provisions are severable.

Impact of Make Up of the US Supreme Court

- How will the make up of the Court impact the case?
- Make up of the Court is different from 2012 ACA SCOTUS decision decided by a 5-4 vote:
 - Justice Scalia and Kennedy no longer on Court;
 - Justice Gorsuch and Kavanaugh are new on Court; and
 - Justice Ginsberg's death and a potential new Justice Barrett.
- Less ideological differences on the Court on severability doctrine than on other issues.

Juul Multidistrict Litigation (MDL)

Juul Litigation

- Several tribes represented by our firm have sued e-cigarette maker Juul, Philips Morris USA, and Altria Group, Inc., alleging that the companies have engaged in a deceptive marketing scheme targeting Native youth that has resulted in significant damages.
- The tribes seek injunctive relief, abatement to combat the e-cigarette epidemic, and compensatory damages.
- The lawsuits will be processed as part of the Multidistrict Litigation in the U.S. District Court for the Northern District of California brought by many non-tribal plaintiffs in the same federal court.
- We expect more tribes and tribal schools will file suit in the MDL in the near future.

Allegations Against Juul

- The complaints allege that Juul has aggressively and deceptively marketed its products as a safe alternative to cigarettes, without disclosing the known dangers of addiction and vaping-related illnesses that the products can create or aggravate.
- The complaints assert that Juul's design, marketing, and distribution of products to minors—specifically targeting tribal youth, despite knowing that they are more susceptible to addiction than non-Native Americans.
- As a result of Juul's misconduct, tribes have been forced to expend scarce resources on public health, law enforcement, and education programs. The tribes seek to recoup these expenses and stop the deceptive marketing practices moving forward.

Tribal Leadership Sub-Committee and PSC Tribal Representative Appointment

- On August 21, 2020, Judge William Orrick granted a motion filed by our firm recommending four members to serve on a Tribal Leadership Sub-Committee and appointing me to serve as the Tribal Representative on the Plaintiffs' Steering Committee (PSC), which consists of lawyers who coordinate litigation on behalf of all plaintiffs.
- The members of the Tribal Leadership Sub-Committee participate in tribal specific issues, discovery, and case management matters in the litigation.
- On the PSC, I serve as a liaison between the Tribal Leadership Sub-Committee, draw attention to tribal specific issues, and actively participate in litigation strategy and case management matters.

Upcoming Hearing on Motions to Dismiss

- On September 21, 2020, Judge Orrick heard argument on the defendants' pending motions to dismiss cases filed by individual plaintiffs and government entities, which include a group of seven school districts from around the country.
- Many of the arguments in the motions, including those involving the Racketeer Influenced and Corrupt Organizations Act (RICO), will have an impact on the tribal complaints.
- The issues involved are complex and the court's decisions on the motions to dismiss could be issued any day.

Opioid MDL

Opioid Crisis

- Disproportionately impacting Indian Country.
 - Health services have been overwhelmed.
 - Education and addiction therapy costs have substantially increased.
 - Evictions from housing for drug-related criminal activity.
 - Almost every tribal member has been affected.

Opioid Litigation

- Over 2,000 cases filed by Tribes, States, cities, counties, and other categories of plaintiffs. Most cases, other than States, consolidated in multidistrict litigation (MDL) in federal court.
- Defendants are Manufacturers and Distributors of prescription opioids, and Retail Pharmacies.
- Plaintiffs are seeking payment from those who created and benefited from the crisis to cover the damages incurred, abatement costs, and some injunctive relief.
- MDL Judge has stated goal of “global settlement.”

Opioid Litigation

- MDL Judge initially created several litigation “tracks” with different “bellwether” plaintiffs, including two tribal cases (Muscogee Creek & Blackfeet).
- Bulk of claims in those bellwether cases survived initial motions to dismiss. Early cases settled before trial.
- To move MDL along, Judge later remanded several additional cases to other courts, including Cherokee.
- Several cases across the country now headed toward trial; only one so far has gone to judgment (Oklahoma against J&J, judgment now pending appeal).

Opioid Settlement

- Purdue Pharma (manufacturer of OxyContin) and Mallinckrodt plc filed for bankruptcy and are negotiating bankruptcy plans with plaintiffs/creditors that would include a tribal allocation.
- Three major Distributors (Cardinal, McKesson, and AmerisourceBergen), as well as J&J, are also in active settlement discussions with government plaintiffs including Tribes.
- Other defendants expected to follow.
- Tribes fought for seat at the negotiating table, and will need to agree on distribution of tribal abatement funds.

105(I) Leasing Issues

Section 105(I) Leasing; *Jamestown* case

- Facility is eligible if T/TO (1) owns, or holds a leasehold or trust interest in, facility; and (2) uses it to carry out an ISDEAA agreement.
- *Jamestown S'Klallam Tribe v. Azar* (D.D.C.): Can IHS deny lease compensation for space allocable to services to non-beneficiaries?
- Section 813 of the IHClA deems such services to be provided under the T/TO's ISDEAA agreement.

Section 105(l) Leasing; *Jamestown* case

- Court ruled for IHS on September 11, 2020, holding that the Tribe's proposal that IHS fund the entire facility, including space for services to non-beneficiaries, was not *reasonable*, as required by 105(l) and the regulations.
- Under Section 813, the full costs of serving non-beneficiaries must be recouped from those patients, not from IHS, said the court.

Section 105(l) Appropriations

- FY 2021 House draft appropriations bill would establish a new mechanism to fully fund 105(l) leases: a separate, indefinite appropriation.
- Bill also contains several restrictions on 105(l) lease compensation; e.g., funds may only be used for space needed to carry out the “Federal program”—apparently endorsing IHS’s position in the *Jamestown* case.

Contract Support Cost Issues

Contract Support Cost Issues

- Both IHS and BIA are committed to fully funding CSC from indefinite appropriations provided by Congress, yet conflicts remain.
- Recent and current litigation:
 - *Navajo Health Foundation – Sage Memorial Hospital v. Burwell.*
 - *Swinomish Indian Tribal Community v. Azar.*
 - *San Carlos Apache Tribe v. Azar.*

Contract Support Cost Issues (Con't)

- *Sage Memorial* (D.N.M.): IHS must pay CSC in support of services funded by third-party revenues.
- *Swinomish* (D.D.C.): IHS need NOT pay CSC in support of services funded by third-party revenues. Currently on appeal in D.C. Circuit. Oral argument October 1, 2020.
- *San Carlos Apache* (D. Ariz.): Follows *Swinomish* in denying CSC on expenditures of third-party revenues; court finds *Sage Memorial* unpersuasive.

340B Program Update

340B Program Overview

- 340B Program assists covered entities, including tribal outpatient health programs, by requiring drug companies provide certain covered drugs at discounted prices
- The Public Health Service Act, 42 USC 256b requires drug manufacturers to participate in the program as a condition of receiving payment from Medicaid or Medicare Part B for their outpatient drugs
- Covered entities, like tribal health programs, generally have drugs shipped to contract pharmacies that then fill the prescriptions for patients

Illegal Restriction of 340B Access

- Drug companies have taken two steps to restrict access to 340B pricing:
 - Refusing to ship to contract pharmacies, so patients now cannot get discounted drugs at those pharmacies
 - Refusing to provide discount pricing if health programs do not agree to participate in burdensome reporting requirements
- Neither of these efforts to restrict 340B access is authorized by statute or regulation
 - HRSA specifically authorizes shipping to contract pharmacies, including to multiple contract pharmacies
 - There is an audit process established in statute that is the mechanism for ensuring compliance

Efforts to Address 340B Restriction

- Tribes have requested HRSA and the HHS Office of Inspector General to take action
- HRSA is looking into whether it has authority to act, and has sent a harsh letter to Eli Lilly warning that covered entities could bring a False Claim Act suit
- Ryan White Clinics for 340B Access filed suit against HHS on October 9
 - Seeks to compel action against the drug companies
 - Seeks to compel promulgation of an administrative dispute resolution HHS was required to create by statute but has not
- House Energy & Commerce and Senate HELP Committee are examining statutory fixes and have requested comments by October 30

Questions?

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