## **Examining the Youth E-Cigarette Epidemic**

Testimony before the **Subcommittee on Economic and Consumer Policy** 

House Committee on Oversight and Reform United States House of Representatives

July 24, 2019

Testimony of Rae O'Leary, RN, MPH

Public Health Analyst Missouri Breaks Industries Research, Inc. Representing the Cheyenne River Sioux Tribe Health Committee

Chairman Krishnamoorthi, Ranking Member Cloud and members of the Committee:

My name is Rae O'Leary and I am serving as a fact witness for the JUUL investigation representing the Cheyenne River Sioux Tribe (letter in Attachment A). I am a Public Health Analyst and Registered Nurse at Missouri Breaks Industries Research, Inc., located on the Cheyenne River Reservation in South Dakota. I founded the Canli Coalition of the Cheyenne River Sioux Tribe (CRST), a grassroots antitobacco coalition in 2009. Canli is the Lakota word for "commercial tobacco" or "cigarettes." The Canli Coalition opposes use of all commercial tobacco products because of tobacco industry targeting to American Indians and misappropriation of sacred practices involving traditional tobacco. In the past ten years, the Canli Coalition has established itself as one of the most progressive Tribes when it comes to tobacco prevention and control. JUUL has not only been the driver of the youth e-cigarette epidemic, JUUL has also targeted American Indians by exploiting tribal sovereignty, which will eventually negatively impact American Indian youth. The Canli Coalition is emphatically opposed to the offer JUUL made to the CRST, which I will recount below.

## JUUL's Proposal to the Cheyenne River Sioux Tribe

On January 23, 2019, representatives from JUUL Labs, Inc. traveled to Eagle Butte, SD to offer to the CRST Tribal Council, in a specially-called session, a "Switching Program," as well as free starter kits to the CRST Tribe's Chairman, and all Tribal Council members present (a violation of FDA's regulations<sup>1</sup>). Juul was referred to the CRST Health Committee for review, no documents were submitted for the record.

On February 1, 2019, I was notified that three representatives from JUUL had traveled back to Eagle Butte, SD to present a "Switching Program" to the CRST Health Committee (meeting minutes in Attachment B). As a partner of the CRST with a long-standing history of tobacco prevention work, I was requested to attend the presentation. The following is my personal account of what happened.

<sup>&</sup>lt;sup>1</sup> General Rule: Manufacturers, distributors and retailers may not distribute (or cause to be distributed) free samples of any tobacco products, including e-cigarettes. 21 U.S.C. § 387a-1, 21 U.S.C. § 387f(d); 21 C.F.R. § 1140.16(d).

The JUUL representatives introduced themselves as public health professionals and provided a very compelling presentation to the CRST Health Committee members and the public for securing the Committee's approval of the "Switching Program." Robert L. Alexander Jr., PhD, MPH, CHES identified his position with JUUL as Director, Government Services, Health Agency Services. Shawn Johns, an enrolled member of the CRST and son of a former CRST Tribal Health Director, identified his position at JUUL as Sr. Manager, Public Sector-Health Markets. The third JUUL representative, Sean Kilbon did not disclose his position to my knowledge. In this presentation (slides in Attachment C), JUUL made claims that their product is effective for smoking cessation and less harmful than combustible tobacco products (both direct violations of the Food and Drug Administration's regulations<sup>2</sup>). These slides do not match the slides that were presented on the screen, as evidenced by a brief video recording of the presentation (Exhibit 1). Please note the following:

- Slide 2 Legal Disclaimer
  - o Disclaimer was included in printed slides, but the font was very difficult to read and the presenters failed to verbally disclose the information.
  - o Highlights from the disclaimer read "JUUL is not approved by the FDA for the treatment, prevention or cure for any specific disease or condition, including smoking cessation. Nor is the Company, at this time, authorized to market JUUL as a modified risk tobacco product or claim that JUUL is less harmful or presents less of a risk than cigarettes. Any anticipated or potential claim made in this presentation is subject to final regulatory review and approval by the FDA, which cannot be assured. Data provided in this presentation is accurate as of the date it is provided but may change or be modified as new data is generated and information is released. In addition, certain information contained herein has been obtained from published and non-published sources prepared by other parties. While such information is believed to be reliable for the purpose used herein, JUUL does not take any responsibility for the accuracy of such information and encourages individuals to perform their own independent verification."
- Slide 4 JUUL Labs, Inc. Mission
  - o The department mission is reported as "Partnering with Tribes to Improve Lives"
- Slide 5 The Costs of Smoking are Huge
  - o "For every 1% of cigarette smokers who switch to vapor, lifetime costs savings to Medicaid programs would be \$2.9 billion.<sup>4</sup>" Slide references are illegible.
  - o "It's time for an alternative to cigarettes"
  - o It was implied by the presenters that switching to JUUL would result in cost savings to the Tribe.
- Slide 6 Eliminate Combustible Cigarettes
  - o "Elimination of combustible cigarettes is crucial to reduce risk of harm"
- Slide 8

o "JUUL has a clear mission and the Public Sector-Health Markets Team will help Accelerate that Mission"

- o "Improve the lives of the world's one billion adult smokers"
- Slide 12 Regulators & Public Health Officials on E-Cigarettes
  - o "Consistent with FDA regulations, JUUL Labs can not and does not promote its products as less harmful or safer than cigarettes." However, the slide quotes Public Health England

<sup>&</sup>lt;sup>2</sup> General Rule: JUUL is prohibited from making unauthorized drug (cessation) claims and is prohibited from making unauthorized modified risk statements. 21 U.S.C. §§ 387k & 351 *et seq*.

(Feb 2018) that states, "Our new review reinforces the finding that vaping is a fraction of the risk of smoking, **at least 95% less harmful** and of negligible risk to bystanders. Yet over half of smokers either falsely believe that vaping is as harmful as smoking or just don't know." Slide references are illegible.

- The referenced study was conducted in Europe with other electronic cigarette (ecigarette) brands. JUUL is illegal in the European Union because it's nicotine content exceeds the legal limit by almost three times.
- It was stated by one presenter (Exhibit 1) that "We're looking at a lot of different tech solutions to help address health issues, so health issues can be solved and harm can be reduced."
- Slide 14 Here is a JUUL
  - o It was stated by one presenter (Exhibit 1) that JUUL is "...ultimately a tech company, not an e-cigarette company."
- Slide 21
  - o "Have smokers that can't quit? JUUL has created a program where you can help them switch; with minimal cost to you."

The JUUL presenters, who claimed a "public health approach" (Exhibit 1) proposed that healthcare professionals from CRST's Tribal Health Department refer smokers that are 21 years or older to their "Switching Program." Using their referral, patients would enroll in JUUL's online portal, in which the patient would enter personal data about themselves and their tobacco/nicotine behaviors. JUUL would sell starter kits (valued at \$50) to the tribe for \$5. The Tribe would then provide starter kits to patients who enroll in the "Switching Program" for free. The presenters stated in Exhibit 1 that "the value of their initial investment to build the online portal is \$260,000, and per month it's actually a continuation of over \$30,000." Later, after the recording ended, JUUL representatives indicated that their investment was worth over \$600,000.

When asked about youth use of JUUL, one presenter replied, "we have never purposely marketed to children" and then diverted to reduced harm stating, "If you take look at the larger bucket of literature, there are clear studies that document reduced harm by switching from combustible products to ecigarettes" (Exhibit 1).

JUUL representatives did not specify *why* they are interested in offering their "Switching Program" to sovereign Tribal Nations, but it was framed as a public health study. It was made clear that JUUL is "working with other Tribes" (Exhibit 1) including the Confederated Tribes of the Colville Reservation in Washington and the Lumbee Tribe of North Carolina. As a result of my advocacy against Tribes partnering with Tobacco or E-Cigarette Companies, I have learned that JUUL has approached at least two other Tribes, and two national American Indian organizations, the National Congress of American Indians and the National Indian Health Board.

## CRST's Response to JUUL

The CRST Health Committee had several questions and asked that JUUL put its proposal and the "Switching Program" in writing for the Committee's consideration on February 14, 2019 (Attachment B).

As described in the written statement from the CRST Tribal Health Committee, JUUL did not provide written documentation as requested. Instead, they sent a Mutual Non-Disclosure Agreement (NDA) to the Tribe's Attorney General with untrue information that the NDA had been presented to the CRST Tribal Health Committee. The NDA was not signed by CRST (Attachment D).

JUUL did not attend the CRST Health Committee meeting on February 14<sup>th</sup>. Instead, I was invited by the CRST Health Committee Chairwoman to provide a presentation on the Canli Coalition's position on JUUL's "Switching Program" and the research on e-cigarettes.

## The Canli Coalition's Position

The Canli Coalition of CRST opposes promotion of any tobacco product, including e-cigarettes, and specifically, we strongly oppose accepting money or product from JUUL. The Canli Coalition obtained and presented over 20 letters of opposition from local and regional individuals and organization, and 5 letters from national organizations.

The following is a summary of why the Canli Coalition opposes the use and promotion of JUUL and other e-cigarettes.

- JUUL is employing tactics out of Big Tobacco's playbook to target American Indians by lobbying to Tribes and national American Indian organizations, and offering price promotions, coupons, giveaways, and charitable contributions to American Indian Tribes.<sup>3</sup>
- American Indians are an at-risk population for tobacco use because of: psychosocial stresses
  including low socioeconomic status; a young population base; and high rates of tobacco use and
  other addiction, making American Indians prime targets for tobacco and e-cigarette companies.<sup>4</sup>
- Residents of the Cheyenne River Reservation are especially at risk.
  - In recent years, Ziebach County, located on the CRST, was known to be the poorest county in the Nation.<sup>5</sup>
  - The youth population (persons under 18) on CRST counties is much larger than other U.S. counties; the proportion of persons under 18 on CRST is 28.2% in Ziebach county and 37.9% in Dewey county, compared to an average of 22.4% in the U.S.<sup>6</sup>
  - According to the 2012 American Indian Adult Tobacco Survey, 51% of CRST's adult tribal members are current cigarette smokers.<sup>7</sup> This high smoking prevalence was

<sup>&</sup>lt;sup>3</sup> Lempert, L., Glantz, S. Tobacco Industry Promotional Strategies Targeting American Indians/Alaska Natives and Exploiting Tribal Sovereignty. *Nicotine & Tobacco Research*. (0:0); D'Silva, J, O'Gara, E, Villaluz, N. (2018). Tobacco industry misappropriation of American Indian culture and traditional tobacco. *Tob Control*. 27:e57-e64.

<sup>&</sup>lt;sup>4</sup> Tanner, J. et al. Variation in CYP2A6 and nicotine metabolism among two American Indian tribal groups differing in smoking patterns and risk for tobacco-related cancer. *Pharmacogenetic Genomics* (May 2017) (online at <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5382092/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5382092/</a>); American Public Health Association. *Priorities in Tribal Public Health* (2018) (online at <a href="https://www.apha.org/">https://www.apha.org/</a>-

<sup>/</sup>media/files/pdf/topics/environment/partners/tpeh/priorities\_tribal\_health\_2018.ashx?la=en&hash=C06951A62A5 E215BE6C99442A9E1E9DDD060B7C6).

<sup>&</sup>lt;sup>5</sup> U.S. Census Bureau 2010 Data (2012).

<sup>&</sup>lt;sup>6</sup> U.S. Census Bureau 2017 Data (2019) (online at

https://www.census.gov/quickfacts/fact/table/deweycountysouthdakota,ziebachcountysouthdakota,US/NES010217).

<sup>&</sup>lt;sup>7</sup>The Canli Coalition of Cheyenne River (n.d.) (online at <a href="https://www.missouri-breaks.com/canli-coalition-1">https://www.missouri-breaks.com/canli-coalition-1</a>).

- confirmed and published internationally in 2019 by a community-based environmental health study conducted in partnership with the University of New Mexico.<sup>8</sup>
- The CRST is progressive when it comes to research, so much of our health behavior data is published and readily accessible including a study on our differences in our genetics and metabolism of nicotine.<sup>9</sup>
- JUUL users smoke more and quit less. <sup>10</sup> A study by Soneji et al. found that for every 1 cigarette smoker who quits using an e-cigarette, 81 non-smoking adolescents will initiate e-cigarette use. <sup>11</sup>
- The youth e-cigarette epidemic, <sup>12</sup> fueled by JUUL's superior nicotine delivery (nicotine salts), a concealable product and youth savvy design/marketing is evident in South Dakota. <sup>13</sup> In 2017, 17.5% of American Indian middle school students in SD had ever used e-cigarettes, compared to 6.2% of their white counterparts. <sup>14</sup>
- JUUL and other e-cigarettes pose immediate safety threats including nicotine poisoning of small children and battery explosions causing burn injuries and even death. 15
- There are known health risks currently associated with e-cigarette use, such as significantly increased risk of heart attacks and asthma. Long-term disorders, like popcorn lung, cardiovascular disease and cancer will remain unknown until more research is done on these new products.<sup>15</sup>
- JUUL contains toxins, carcinogens, and dangerously high levels of nicotine. 13
  - o JUUL identifies just five ingredients on their package. These include propylene glycol, glycerol, flavor, benzoic acid and nicotine. The package fails to list the potentially toxic

<sup>&</sup>lt;sup>8</sup> O'Donald, E., Miller, C., <u>O'Leary, R.</u>, Ong, J., Pacheco, B., Foos, K., Enright, K., O'Leary, M., Nez Henderson, P., Lewis, J., Erdei, E.,& Henderson, J. Active Smoking, Secondhand Smoke Exposure, and Serum Cotinine Levels among Cheyenne River Sioux Communities in Context of a Tribal Public Health Policy. *Tobacco Control* 2019 (online at <a href="https://doi.org/tobaccocontrol-2019-055056">https://doi.org/tobaccocontrol-2019-055056</a>).

<sup>&</sup>lt;sup>9</sup> Missouri Breaks Industries Research, Inc. (n.d.) (online at <a href="https://www.missouri-breaks.com/projects">https://www.missouri-breaks.com/projects</a>).

<sup>&</sup>lt;sup>10</sup> Rapaport, L. *E-Cigarettes Tied to Less Smoking Cessation*. Medscape (Mar. 26, 2018).

<sup>&</sup>lt;sup>11</sup> Soneji, S. et al. Quantifying population-level health benefits and harms of e-cigarette use in the United States. PLoS ONE 13(3): e0193328 (Mar 14, 2018) (online at https://doi.org/10.1371/journal.pone.0193328).

<sup>&</sup>lt;sup>12</sup> Food and Drug Administration, Statement from FDA Commissioner Scott Gottlieb, M.D., on *New Steps to Address Epidemic of Youth E-cigarette Use* (Sept. 12, 2018) (online at <a href="https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more">https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more</a>); Department of Health and Human Services, *Surgeon General Releases Advisory on E-cigarette Epidemic Among Youth* (Dec. 18, 2018) (online at <a href="https://www.hhs.gov/about/news/2018/12/18/surgeon-general-releases-advisory-e-cigarette-epidemic-among-youth.html">https://www.dec.gov/media/releases/2018/p1002-e-Cigarettes-sales-danger-youth.html</a>).

<sup>&</sup>lt;sup>13</sup> Juul's Nicotine Salts are Dominating the Market – And Other Companies Want In, The Verge (Nov. 21, 2018) (online at <a href="https://www.theverge.com/2018/11/21/18105969/juul-vaping-nicotine-salts-electronic-cigarettes-myblu-vuse-markten">https://www.theverge.com/2018/11/21/18105969/juul-vaping-nicotine-salts-electronic-cigarettes-myblu-vuse-markten</a>); JUULing: What Pediatricians and Families Need to Know, American Academy of Pediatrics (n.d.) (online at <a href="https://www.aap.org/en-us/Documents/AAP-JUUL-factsheet.pdf">https://www.aap.org/en-us/Documents/AAP-JUUL-factsheet.pdf</a>).

<sup>&</sup>lt;sup>14</sup> Da Rosa P., Jodozi-Molengraaf C. *2017 South Dakota Youth Tobacco Survey Report*. South Dakota State University, Office of Nursing Research (2018) (online at <a href="https://doh.sd.gov/prevention/assets/2017YTSReport.pdf">https://doh.sd.gov/prevention/assets/2017YTSReport.pdf</a>).

<sup>&</sup>lt;sup>15</sup> Keller, A. E-cigarette Side Effects. Drug Watch (May 15, 2019) (online at <a href="https://www.drugwatch.com/e-cigarettes/side-effects/">https://www.drugwatch.com/e-cigarettes/side-effects/</a>).

- and carcinogenic "flavor" or aerosol-containing carcinogens (including formaldehyde) that are created as the liquid passes through the heating coil. <sup>16</sup>
- One JUUL pod distributed and sold in the U.S. contains 59 mg/ml of nicotine, which is nearly three times the 20 mg/ml legal limit in the European Union. <sup>17</sup>
- Youth use of JUUL has been associated with severe addictions requiring rehabilitation services, mood disorders, lowering of impulse control, attention deficit/learning challenges, and documented seizures from nicotine poisoning.<sup>18</sup>
- According to my own PubMed.gov literature search, no protective or preventative measures exist for e-cigarettes in American Indian populations.
- It is the belief of the Canli Coalition and Missouri Breaks Industries Research, Inc. that all data collected for or with our tribal members is owned by the Tribe. Releasing demographic and health behavior data to JUUL through the "Switching Programs" online portal poses a great threat to data governance and ownership.

In response to JUUL's youth marketing tactics and the attempt to exploit American Indian tribal sovereignty by using historic tactics of Big Tobacco, the CRST Health Committee passed a resolution on July 1<sup>st</sup>, on behalf of the Canli Coalition (see Attachment E) that declares:

"CRST shall neither solicit nor accept any tobacco, electronic smoking device (ESD) or nicotine-related funding or sponsorship of events or activities, nor will this tribe partner with tobacco, ESD or nicotine-related companies to further their goals or share information on tribal members."

This resolution will be considered by CRST Tribal Council later in July. As a result of advocacy by myself and the Canli Coalition to prevent JUUL from getting American Indian youth and adults addicted to their product, I have provided this mock resolution to more than ten Tribes and the National Indian Health Board interested in preventing exploitation by JUUL.

I join the CRST Health Committee, and other known and unknown Indian Tribes being targeted by JUUL in resisting harmful partnerships with tobacco companies, including JUUL, in order to protect and preserve the health and well-being of American Indian youth and smokers most at risk from JUUL's "Switching Program."

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<sup>&</sup>lt;sup>16</sup> Elena R. O'Donald, Curtis P. Miller, Rae O'Leary, Jennifer Ong, Bernadette Pacheco, Kathryne Foos, Kendra Enright, Marcia O'Leary, Patricia Nez Henderson, Johnnye Lewis, Esther Erdei,\*, Jeffrey A. Henderson. Active Smoking, Secondhand Smoke Exposure, and Serum Cotinine Levels among Cheyenne River Sioux Communities in Context of a Tribal Public Health Policy. Tobacco Control 2019. https://doi.org/tobaccocontrol-2019-055056.
<sup>17</sup> Juul: The Rise of a \$38bn E-cigarette Phenomenon, BBC News (Jan. 6, 2019) (online at <a href="https://www.bbc.com/news/business-46654063">www.bbc.com/news/business-46654063</a>).

<sup>&</sup>lt;sup>18</sup> Know the Risks: E-Cigarettes & Young People, U.S. Department of Health and Human Services. (2019) (online at <a href="https://e-cigarettes.surgeongeneral.gov/knowtherisks.html">https://e-cigarettes.surgeongeneral.gov/knowtherisks.html</a>); Some E-cigarette Users Are Having Seizures, Most Reports Involving Youth and Young Adults, U.S. Food & Drug Administration (April 10, 2019) (online at <a href="https://www.fda.gov/tobacco-products/ctp-newsroom/some-e-cigarette-users-are-having-seizures-most-reports-involving-youth-and-young-adults">https://www.fda.gov/tobacco-products/ctp-newsroom/some-e-cigarette-users-are-having-seizures-most-reports-involving-youth-and-young-adults">https://www.fda.gov/tobacco-products/ctp-newsroom/some-e-cigarette-users-are-having-seizures-most-reports-involving-youth-and-young-adults</a>); Vaping Sent This Teenager Into Rehab, His Parents Blame Juul's Heavy Nicotine Dose. NBC News (Jan 8, 2019). (online at <a href="https://www.nbcnews.com/health/health-news/vaping-sent-teenager-rehab-his-parents-blame-JUUL-s-heavy-n956356">https://www.nbcnews.com/health/health-news/vaping-sent-teenager-rehab-his-parents-blame-JUUL-s-heavy-n956356</a>).

I strongly urge the members of the Oversight and Reform Subcommittee on Economic and Consumer Policy to work with the FDA to create strong regulations to protect all Americans, especially those most at risk from being targeted by JUUL and/or other tobacco companies. The tobacco industry invested billions of dollars to create and market new and enticing products that were not included in FDA's current regulations, and this will continue to happen unless scientific, medical and public health experts and law-makers are jointly advocating for immediate change and control. It is critical that regulations be progressive and comprehensive to avoid loop-holes for tobacco companies and ensure that at-risk Americans, such as youth and minority populations, are not targeted with unacceptable business practices and false information about the safety and efficacy of tobacco and e-cigarette products.

I also urge members of the Subcommittee to enhance federal funding available for e-cigarette research on health effects, and youth and adult e-cigarette prevention/interventions, as well as expand accurate health information concerning e-cigarettes in the media. Financial support should be earmarked to support media efforts and research with at-risk populations, especially youth and minority populations.

Thank you for acknowledging that JUUL's marketing to minority populations is relevant to the youth ecigarette epidemic and thank you for the opportunity to share how the sovereignty of the Cheyenne River Sioux Tribe was unfairly exploited by JUUL.

## Attachment A



CRST Tribal Health Administration PO Box 590 Eagle Butte, SD 57625 Ph. 605-964-0788 Fax 605-964-1062

July 11, 2019

Mr. William Cunningham & Mr. Rich Trumka, Jr.
Congress of the United States House of Representatives
Oversight and Reform Subcommittee on Economic and Consumer Policy
2157 Rayburn House Office Building
Washington, DC 20515-6143

To Whom It May Concern:

On February 1, 2019, three employees of JUUL Labs Inc. (JUUL), Robert L. Alexander, Jr., Sean Kilbon, and Shawn Johns, attended a meeting of the Cheyenne River Sioux Tribe (CRST) Health Committee to present their "switching program." A copy of the minutes from that meeting are attached.

At that meeting the JUUL employees, one of whom, Shawn Johns, was a Tribal member whose mother also attended and spoke for JUUL, presented a power point on their product. The gist of the presentation was that JUUL would sell steeply discounted "starter kits" for their product to the Tribal Health Department, in exchange for the Health Department promoting JUUL as a healthful way for patients to quit smoking by transitioning or "switching" to using JUUL. JUUL wanted the Tribe's Health Department to provide the JUUL starter kits free-of-charge to Tribal members trying to quit smoking as part of our smoking cessation programs. This "switching program" was verbally framed as a public health study, so many Committee members had the impression that JUUL intended to submit a research proposal centered on their switching program.

The Committee had a number of questions and requested that JUUL put its proposal and the "switching program" in writing for the Committee's consideration. Because the JUUL employees did not have with them any written handouts or other papers, other than the powerpoint itself, there was nothing for the Committee to act on. The Health Committee instructed the JUUL representatives to submit a written proposal for review by the Tribe's health attorney prior to the next Health Committee meeting, so that the proposal could be considered and acted on. The JUUL employees wished to present to the full Tribal Council, but the Health Committee

informed them that they would not be given the floor at Council unless and until the Health Committee approved a written proposal. See attached minutes of 2/1/2019.

Instead of sending a written proposal as requested, JUUL employee Sean Johns initiated negotiations of a Mutual Non-Disclosure Agreement (NDA) with the Tribe's Attorney General Tracey Zephier, telling her that the NDA had been presented at Health Committee, which was untrue. See attached NDA. From the conversations the Attorney General had with JUUL, she had the impression that JUUL wished to enter a commercial business relationship with the Tribe, not conduct health research. After correspondence with the Tribe's health attorney, both agreed that an NDA was not necessary at the moment, and that the Tribe should wait to see what JUUL set forth in its proposal to the Tribe. However, JUUL never made any written submission for Committee consideration, and so the project was never considered or acted on by the CRST Health Committee.

Rae O'Leary, an employee of Missouri Breaks Industries Research, Inc. (MBIRI), and leader of the Canli<sup>1</sup> Coalition was present at the February 1, 2019 CRST Health Committee meeting when JUUL presented its "switching program." The Canli Coalition is a community group which partners with MBIRI, the South Dakota Department of Health Tobacco Control Program, and the Great Plains Tribal Chairmen's Health Board to "provide tobacco-free choices for seven generations."

The Cheyenne River Sioux Tribe Health Committee considers Rae O'Leary to be a competent and reliable witness regarding the CRST Health Committee meeting on February 1, 2019, and fully supports her testimony before the Oversight and Reform Subcommittee on Economic and Consumer Policy.

Please let me know if the Cheyenne River Sioux Tribe can provide any further assistance to your investigation.

Pilamaya ye,

Bernita In The Woods

Chairwoman, Health Committee

Cheyenne River Sioux Tribe

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Desnita In The Woods

<sup>&</sup>lt;sup>1</sup> Canli, pronounced "chahn-lee", is the Lakota word for tobacco.

## Attachment B

## Health Committee Meeting February 1, 2019 Indian Health Service Conference Room

P	A	MEMBER	P	Α	MEMBER
X		Bernita In The Woods, Chairman	X		Ryman LeBeau
X		Merri Miller-White Bull, Vice		X	Mark Knight
X		Robert Walters	X		Ted Knife Jr.
	X	Tuffy Thompson	X		John Kessler

The Health Committee meeting was called to order at 9:20 AM by Chairwoman Bernita In The Woods.

**OTHERS PRESENT:** Vicki Ducheneaux/Council Representatives Secretary, Cecil Means/Tribal CEO, Brittany Brewer/I.H.S. CEO, Joe Yracheta, Rae O'Leary and Ali Moran/Missouri Breaks-Canli Coalition, Charlene Red Thunder-Health Consultant, Margaret (Peg) Bad Warrior-Health Legal Counsel, Mary Lee Johns, Shawn Johns, Dr. Robert Alexander, Sean Kilbon/JUUL.

Public Concerns: None.

## **New Business:**

## **Juul E-cigarettes Presentation:**

**Discussion:** Presentation on JUUL e-cigarettes, second hand smoke, asthma, vaping is a fraction of the risk of smoking at least by 95% less harmful. JUUL's goal is to provide transition from cigarettes to a less stimulant product.

Pilot switching program, to target adult smokers, online enrollment process, switch coaches. Harm reduction approach and ability to capture data through use. Peg explained that our ordinance prohibits use of e-cigarettes. JUUL wants to invest \$260K to make product cheaper and targeted traditional smokers, those under 21 years of age prohibited. They want to hire a Behavioral Manager to work with a tribal entity.

Tribe has Smoke-Free Ordinance. Wakinyan Peta, FBHC Licensed Addiction Counselor, discussion on vapes and e-cigarettes also have nicotine and is addictive. He comes from a dual position because technology available now that can provide alternatives.

Rae O'Leary stated that JUUL mentioned preventing the youth from use. Their survey has found kids are using them and get from the adults. Schools have reported use. Flavors are the attraction for the youth and would like to see a restriction of these attracting flavors. Smoke free home study going on now that was approved by council. Research on dual use-someone may switch

with intent but nicotine consumption had increased because they used both. 3 times as much nicotine in JUUL use than regular cigarettes. How is harm measured and length of this data? No long term research done since JUUL is new. Data is inconclusive, but we need to look years from now. Nicotine replacement offered by Indian Health has been successful. Rae O'Leary stated she would work on research with them but not to promote the use of JUUL.

Mary Lee Johns on smoking and how she is against it, watching all her family members die and that she was against her son working for this company but now is 100% for this company.

**Discussion:** Bernita stated that we are not against the product but would like a written proposal submitted for the next Health Committee tentatively scheduled for February 14<sup>th</sup>. They will not attend council but will come back to committee.

Missouri River Breaks: Joe Yracheta

**Discussion:** SPHERE projects and focus group, fairness, data use, date and several other topics. Focus Group – Tribal Community Perspectives on Health Research with funding from Stanford's SPHERE project (Stanford Precision Health for Ethnic and Racial Equity).

**I.H.S. Report:** Brittany Brewer Monthly Report (see attached).

**Discussion:** Rapid City Executive Officer briefing, 3<sup>rd</sup> party dollars, shut down and catch up and anticipation of the next shut down scheduled for February 15th, housing, OEH&E, DME money, nursing SUS session planning,

Mrs. Brewer wanted it to be clear they, IHS, are not building a retaining wall around I.H.S. It is for the safety of the building regarding draining/runoff and is under facility projects.

Tribe requesting PIV cards for tribal health employees. CEO position interviews.

**Tribal Health Report:** Cecil Means Monthly Report (see attached).

**Discussion:** Legal review on Ronald B. Demaray for professional service agreement regarding Direct Contract Support Cost. Funding provided by Tribal Health and sole source provided through review.

**Discussion:** Financial Report.

**Discussion:** 638 Master Health Contract.

**Discussion:** Tribal Council action.

Discussion: SD Medicaid update, Opioid grant, Isabel Manor needs repairs, doors and fire

alarms.

**Discussion:** Field Clinic funding draft letter was sent to Jessica Four Bear for Chairman Frazier's signature when she was acting A.O. and nothing was ever done. This will be taken before Tribal Council in February.

**Discussion:** Drop In Center-638 inclusion. Avera Health proposal for Treatment Center. Clarification on nursing quarters and old I.H.S. houses. Letter received regarding old field clinics, hazardous at this point.

**Discussion:** IRB-Internal Review Board. Sioux San hospital location-letter from RST THPO, Optometry 638 resolution.

**Discussion:** ARC report and Medicine Wheel Village.

**Discussion:** Transfer agreements on old field clinics.

<u>MOTION:</u> by Council Representative Merri Miller-White Bull, 2<sup>nd</sup> by Council Representative Ryman LeBeau, to go into executive session @ 11:20 AM. Yes.4. No 0. Not Voting 0.

Motion Carried.

MOTION: by Council Representative Merri Miller-White Bull, 2<sup>nd</sup> by Council Representative John Kessler, to come out of executive session @ 11:50 AM.

Yes 4. No 0. Not Voting 0. Motion Carried.

MOTION: by Council Representative Merri Miller-White Bull, 2<sup>nd</sup> by Council Representative Ted Knife Jr., to have JUUL submit a written proposal to Margaret Bad Warrior, Health Legal Counsel, to provide legal review and bring back to the Health Committee next month. JUUL associates will be in attendance.

Yes 4. No 0. Not Voting 0. Motion Carried.

<u>MOTION:</u> by Council Representative Ryman LeBeau, 2<sup>nd</sup> by Council Representative John Kessler to recommend to approve by resolution for Advance Appropriations of the Indian Health Service and Margaret Bad Warrior develop for February Council.

Yes 4. No 0. Not Voting 0. Motion Carried.

MOTION: by Council Representative Merri Miller-White Bull, 2<sup>nd</sup> by Council Representative Ryman LeBeau to recommend to approve by resolution \$100,000.00 be transferred from our local Indian Health Service for Durable Medical Equipment (DME) funding to Tribal Health to administer and also to state this is not a proposal. Yes 4. No 0. Not Voting 0. Motion Carried.

<u>MOTION:</u> by Council Representative Merri Miller-White Bull, 2<sup>nd</sup> by Council Representative Ryman LeBeau to recommend to approve by resolution that Cheyenne River Tribal Council be involved in the interview process of the CEO for the local I.H.S. Service.

Yes. 4. No 0. Not Voting 0.

Motion Carried.

<u>MOTION:</u> by Council Representative Merri Miller-White Bull, 2<sup>nd</sup> by Council Representative Ted Knife Jr., to approve by resolution the professional service agreement in the amount of \$65,000.00 with Ronald B. Demaray to renegotiate IDC for CSC, funding provided by Tribal Health.

Yes 4. No 0. Not Voting 0.

Motion Carried.

<u>MOTION:</u> by Council Representative Ryman LeBeau, 2<sup>nd</sup> by Council Representative Ted Knife Jr., to approve the Opioid Grant Consulting Agreement with Missouri Breaks as it was written an approved accordingly.

Yes 4. No 0. Not Voting 0.

Motion Carried.

<u>MOTION:</u> by Council Representative Ryman LeBeau, 2<sup>nd</sup> by Council Representative Ted Knife Jr., to approve Research Review Board (RRB) as no comments were received and to send back Council for final approval.

Yes 4. No 0. Not Voting 0.

Motion Carried.

<u>MOTION:</u> by Council Representative Merri Miller- White Bull, 2<sup>nd</sup> by Council Representative Ted Knife Jr., to adjourn @ 1:30 PM.

Yes 4. No 0. Not Voting 0.

Motion Carried.

Transcribed by Vicki Ducheneaux

Cheyenne River Sioux Tribe

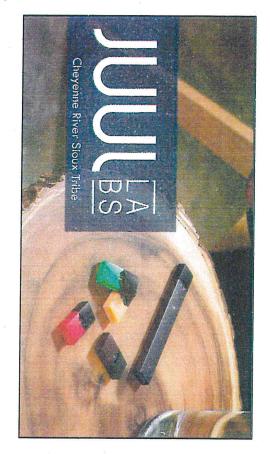
Council Representative Secretary

CC: Health Committee Members (8)

File

## Attachment C





## LEGAL DISCLAIMER

This document and the information contained herein are confidential and solely for the use of the pen or people to whom this document is addressed. After discussion, this document should be returned proto Company. This document is not intended for consumers.

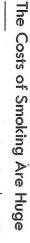
DULL is not approved by the FDA for the reatment, prevention or dure for any specific disease or condition, including smaking cessorian. North the Company, or this tine, authorized to manket JUDL as a modified risk cibacco product or dain that JUDL is sels humand or present ess of a risk time algorettes. Any ambiguated or sometial claim made in this presentation is subject to final regulatory review and approval by the FDA, which counter be assured.

Let a provided in this presentation is accurate as of the date in its provided but may always or be modified as

nation and encourages individuals to partorn their own independent verification.

JUUL Labs, Inc. Mission
Department Mission
Partnering with Tribes to Improve Lives

1/22/2019

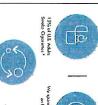


- A 2017 peer-reviewed journal suggest that as many as 6.6 M premature deaths could be averted if all smokers switched to vapor
- Every month without intervention, smoking causes
- 40,000 deaths due to smoking related diseases 2

173,000 life-years lost

\$11 billion in monthly lost productivity costs? \$14 billion in monthly direct health care costs 2

for every 1% of algorate unabers who switch to vapor, lifetime cost savings to Madicaid programs would be \$2.9 billion.<sup>4</sup>











ELIMINATION OF COMBUSTIBLE CIGARETTES IS CRUCIAL TO REDUCE RISK OF HARM

4

We are Driving Innovation to Eliminate

Combustible Cigarettes

The excess cost of healthcare for a smoker vs. a non-smoker over the course of their lifetime is ~527,000 ?

# IT'S TIME FOR AN ALTERNATIVE TO CIGARETTES



#1 cause of preventable death 1 Smoking is the

## Preventable Death Combustible Tobacco, the World's #1 Cause of

- TAKING VALUABLE YEARS OF LIFE
- \*  $2/3^{\rm rd}$  of long-term smokers are expected to die prematurely due to smoking-anniburable diseases  $^{\rm 1}$
- 180K PEOPLE DIE ANNUALLY IN THE US
- Tobacco is accountable for 20% of all preventable deaths.
- TOBACCO IS PREVALENT IN THE MILITARY
- 14% of service members smoke, and 13% use smokeless tobacco<sup>3</sup>
- TOBACCO COSTS THE DoD \$1.6BN ANNUALLY
- Includes sobacco-related medical care, hospitalization, and lost days of work.<sup>4</sup>

## **Gun Related Deaths** 2nd Hand Smoke **Auto Accidents** Cigarettes CAUSES OF PREVENTABLE U.S. DEATHS EACH YEAR <sup>2</sup> Alcohol Obesity



## Defense & Health Markets Mission Enterprise Markets – Public Sector

Mission: Improve the lives of smokers around the world, who are part of the 20(+) million veterans, 2(+) million military service members, 2(+) million government civilians, 5(+) million Native American Indians and Alaskan Natives (NAI/AN), and all those serving our communities, government related industries, and various government regulated entities, including foreign government defense and health entities smokers, while growing JUUL Labs in the government / public sector space.



# Youth Access Prevention and Education































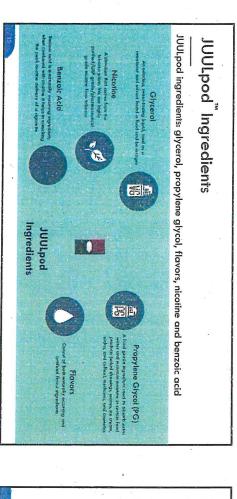
Successfully removed over 1,000 social media posts that violated: community guidelines

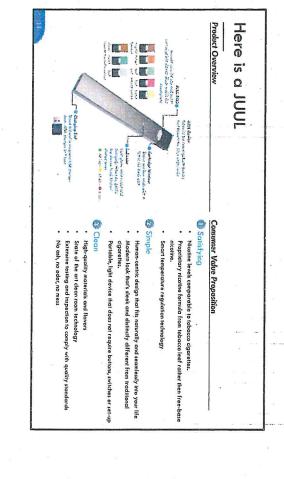
Enforcement actions taken contributed to the removal of JUUL's brand

popular Instagram accounts with over 200,000 combined follower.

Regulators & Public Health Officials on E-Cigarettes Consistent with FDA regulations, JUUL Labs can not and does not promote its products as less harmful or safer "With oppropriate product regulation, new technology, and product moverlian—including new moderation in product moverlian—including new moderation in product on a destinate deliverary systems. (ENDS) = sould paresticute account for page 100 page Public Health England

JUUL Technology & its e-Cigarette





# Systems Benefits of Closed-Pod Electronic Nicotine Delivery

JUUL focuses on quality through closed system approach, patented temperature control and battery control



Closed

Relative to open systems, closed system enables quality control and consistent user experience

Best-in-class temperature control designed to reduce harmful combustion byproducts

Security

Safety

System redundancies and minimized tampering in closed system designed to prevent electrical spikes, overheating, and

## Nicotine, Not Combustion

- Cigarettes deliver nicotine by burning tobacco, at temperatures that can exceed  $\sim 1000^\circ$  C  $^1$
- Combustion yields toxic byproducts linked to cancer, heart disease, COPD and respiratory diseases 2
- Switching completely from cigarettes to non-combustible tobacco products reduces exposure to many of these toxic byproducts, in some cases up to 99% or to levels that are not detectable <sup>3,4</sup>
- Individual and population-level public health benefits and risks of specific products will be characterized over time through additional clinical investigations, epidemiological and other assessments, with rigorous

## CIGARETTE TOXINS 4



Over 7,000 chemicals



carcinogenic compounds



400 other toxins:
tar, carbon monoxids,
formaldshyds, anmonia,
hydrogen cyanids, arsanic, lead
and DDT 3

JUUL in the Market Place

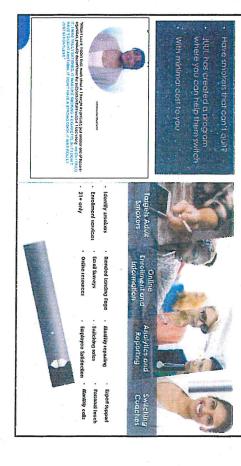
Public Sector:

JUUL Labs today

Available where smokers shop... primarily Tribal and non-Tribal convenience stores, specialty tobacco and vaping shops...

Pilot Switching Program









Counter Party Name (if a company, please put the full company name):	
Counter Party Email (of authorized signer):	
Effective Date:	
Purpose:	

## MUTUAL NONDISCLOSURE AGREEMENT

THIS MUTUAL NONDISCLOSURE AGREEMENT (this "Agreement"), effective as of the effective date as identified above ("Effective Date"), by and between JUUL Labs, Inc., a Delaware corporation, along with its subsidiaries and affiliates ("JUUL"), and the counter party identified in the table above ("Counter Party"). The parties wish to explore a business opportunity of mutual interest (the "Purpose").

- 1. <u>Confidential Information</u>. "Confidential Information" means any and all information furnished to the Receiving Party (defined below) by or on behalf of the Disclosing Party (defined below), whether disclosed orally or disclosed or stored in written, electronic or other form or media, which is either marked as "confidential" or "proprietary" or should reasonably be understood (due to the nature of content of the information, or the circumstances surrounding its disclosure) to be confidential or proprietary, and all analyses, notes and other documents prepared by or for the Receiving Party which contain or otherwise reflect, derive from or are generated from such information. Confidential Information also includes the terms and conditions of this Agreement and the existence of the discussions between the parties.
- 2. <u>Use of Confidential Information</u>. A party which receives Confidential Information under this Agreement ("Receiving Party") may use the Confidential Information only for the purpose of internal evaluation of whether to enter into a business relationship with the party which discloses Confidential Information under this Agreement ("Disclosing Party").
- 3. <u>Disclosure of Confidential Information</u>. The Receiving Party shall: (i) hold Confidential Information in strict confidence and take reasonable precautions to protect such Confidential Information (including, without limitation, all precautions the Receiving Party employs with respect to its own confidential materials); (ii) not divulge any Confidential Information to any third party (other than to employees or contractors as set forth below); and (iii) not copy or reverse engineer any materials disclosed under this Agreement or remove any proprietary markings from any Confidential Information. Any employee or contractor given access to any Confidential Information must have a legitimate "need to know" and shall have signed a non-use and non-disclosure agreement in content similar to the provisions of this Agreement or otherwise shall be legally obligated not to disclose such Confidential Information, and the Receiving Party shall remain responsible for each such person's compliance with the terms of this Agreement. The Receiving Party shall reproduce the Disclosing Party's proprietary rights notices on any such authorized copies of the Disclosing Party's Confidential Information, in the same manner in which such notices were set forth in or on the original. The Receiving Party shall promptly notify the Disclosing

Party of any use or disclosure of the Disclosing Party's Confidential Information in violation of this Agreement of which the Receiving Party becomes aware.

- 4. <u>Exclusions</u>. This Agreement imposes no obligations with respect to information which: (i) was in the Receiving Party's possession before receipt from the Disclosing Party, (ii) is or becomes a matter of public knowledge through no fault of the Receiving Party, (iii) was rightfully disclosed to the Receiving Party by a third party without restriction on disclosure or (iv) is developed by the Receiving Party without use of the Confidential Information and such independent development can be shown by documentary evidence. The Receiving Party may make disclosures to the extent required by law or court order provided the Receiving Party uses diligent efforts to limit disclosure and to obtain confidential treatment or a protective order and has allowed the Disclosing Party to participate in the proceeding.
- 5. Disclaimer. ALL CONFIDENTIAL INFORMATION IS PROVIDED "AS IS AND WITH ALL FAULTS."
- 6. Return of Materials. All Confidential Information, and all copies or extracts thereof, shall be and remain the property of the Disclosing Party and shall be promptly returned to the Disclosing Party or destroyed upon the Disclosing Party's written request (but in any event within fifteen business days of such request) and the Receiving Party shall notify the Disclosing Party in writing upon completion of such return or destruction. Notwithstanding the foregoing, the Receiving Party may retain a single archival copy of Confidential Information provided by the Disclosing Party under this Agreement, which copy shall only be used by the Receiving Party and its legal advisors in connection with the review of its obligations under this Agreement; provided, that such retained Confidential Information shall be retained subject to the confidentiality and use terms contained in this Agreement.
- 7. <u>Non-Solicitation</u>. Counter Party agrees that, for a period of three years from the Effective Date, without the prior written consent of JUUL, Counter Party will not directly or indirectly solicit for employment any employee of JUUL or its affiliates; provided that nothing herein prevents Counter Party from publishing general advertisements for employees (including recruiting efforts through a search firm) that are not targeted at any employees of JUUL.
- 8. <u>Proprietary Rights</u>. Nothing in this Agreement is intended to grant any rights to either party under any patent, mask work right, copyright, trade secret or other intellectual property right of the other party, nor shall this Agreement grant any party any rights in or to the other party's Confidential Information. To the extent that JUUL provides Counter Party with specifications, designs or requirements and Counter Party provides ideas, suggestions or recommendations regarding that information ("Feedback"), such discussions will not constitute joint development. JUUL is free to use and incorporate the Feedback without any obligation to Counter Party, and JUUL will assume all right, title and interest in the Feedback.
- 9. <u>Term.</u> This Agreement shall continue in effect until terminated by either party upon written notice to the other party. The Receiving Party's obligations with respect to Confidential Information under this Agreement expire five (5) years from the date of receipt of the Confidential Information (except that with respect to any trade secrets the obligations shall be perpetual). All provisions of this Agreement shall survive the termination or expiration of this Agreement except for the Receiving Party's right to use the Disclosing Party's Confidential Information.
- 10. <u>Remedies</u>. Each party acknowledges that any breach of this Agreement may cause irreparable harm for which monetary damages are an insufficient remedy and therefore that upon any breach of this Agreement, the Disclosing Party shall be entitled to appropriate equitable relief without the posting of a bond in addition to whatever remedies it might have at law.

11. General. Neither party has an obligation under this Agreement to purchase or offer for sale any item or proceed with any proposed transaction, or to disclose Confidential Information to the Receiving Party. Neither party may assign this Agreement without the prior written consent of the other party and any attempt to do so will be void, except that JUUL without Counter Party's consent may assign this Agreement to an affiliate or any other entity in connection with a reorganization, merger, consolidation, acquisition, or other restructuring involving all or substantially all of the voting securities or assets of JUUL. In the event that any of the provisions of this Agreement shall be held illegal or unenforceable by a court of competent jurisdiction, such provisions shall be limited or eliminated to the minimum extent necessary so that this Agreement shall otherwise remain in full force and effect. This Agreement shall be governed by the laws of the State of California and the United States without regard to conflicts of laws provisions thereof. Unless waived by JUUL in its sole discretion, the jurisdiction and venue for any action arising out of or relating to the subject matter of this Agreement shall be the California state and United States federal courts located in San Francisco, California, and both parties hereby submit to the personal jurisdiction of such courts. This Agreement supersedes all prior discussions and writings and constitutes the entire agreement between the parties with respect to the subject matter hereof. The prevailing party in any action to enforce this Agreement shall be entitled to costs and attorneys' fees. No waiver or modification of this Agreement will be binding upon either party unless made in writing and signed by a duly authorized representative of each party and no failure or delay in enforcing any right will be deemed a waiver. This Agreement may be executed in one or more counterparts, each of, which will be deemed an original, but all of which together will constitute one and the same instrument. Electronic signatures shall be valid and binding.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized representatives, effective as of the Effective Date.

JUUL LABS, INC.	COUNTER PARTY
Signature	Signature
Name (Please Print)	Name (Please Print)
Title	Title
Date:	Date:

## Attachment E

## Resolution on Electronic Smoking Devices and Tobacco Industry Partnerships

## **Resolution #\_\_\_\_\_-2019-CR**

WHEREAS, the Cheyenne River Sioux Tribe of South Dakota is an unincorporated Tribe of Indians having accepted the provisions of the act of June 18, 1934 (48 Stat. 984);

WHEREAS, the Tribe in order to establish its Tribal organization, to conserve its Tribal property, to develop its common resources, and to promote the general welfare of its people has ordained and established a Constitution and By-Laws;

WHEREAS, Article IV, Section 1(m) of the Constitution of the Cheyenne River Sioux Tribe requires the Tribe to protect the public health and morals and to promote the public welfare of the people; and

WHEREAS, the Cheyenne River Sioux Tribe hereby finds the cultural, spiritual, and ceremonial use of traditional tobacco is an integral part of traditional, native life; and

WHEREAS, the Cheyenne River Sioux Tribe fundamental traditional and ceremonial use of traditional tobacco shall not be restricted; and

WHEREAS, American Indian people have the highest rate of commercial tobacco use in the Nation; and

WHEREAS, commercial tobacco use is the leading cause of preventable death and disease and American Indian people suffer serious health consequences including heart disease and cancer; and

WHEREAS, electronic smoking devices (ESD) are not a proven smoking cessation device but are an alternative nicotine delivery device that will maintain or restore the habit, and can addict a new generation to nicotine and nicotine exposure from aerosolized ESD can negatively impact developing fetuses as well as teenage brain development; and

WHEREAS, ESD proponents are deceptively marketing the products to the public—especially to young adults via social media—as a "safe" alternative to smoking and an easy way to quit smoking tobacco cigarettes and entice with flavors attractive to youth; and

WHEREAS, according to the 2016 U.S. Surgeon General's Report on e-cigarette use among youth and young adults, ESDs are now the most commonly used form of tobacco by youth in the United States and 85% of ESD users ages 12-17 use flavored products; and

WHEREAS, direct funding from organizations funded by the tobacco industry will not be accepted; and

WHEREAS, E-cigarette and tobacco industry companies are targeting tribes to engage in a

partnership with them, enticing tribes with incorrect information in exchange for data on tribal members ESD and tobacco use; and,

WHEREAS, the health of our people is of upmost importance and American Indians have taken a lead in addressing health issues throughout the years;

NOW THEREFORE BE IT RESOLVED, the Cheyenne River Sioux Tribe shall neither solicit nor accept any tobacco, ESD or nicotine-related funding or sponsorship of events or activities, nor will this tribe partner with tobacco, ESD or nicotine-related companies to further their goals or share information on tribal members.

BE IT FINALLY RESOLVED, that nothing in this Resolution diminishes, divests, alters, or otherwise affects any inherent treaty, statutory or other rights of the Cheyenne River Sioux Tribe over the property or activities described herein. The Cheyenne River Sioux Tribe expressly retains all rights and authority over the property and activities described herein, including but not limited to legislative, regulatory, adjudicatory and taxing powers.

## **CERTIFICATION**

I, the undersigned, as Secretary of the Cheyenne River Sioux tribe, certify that the Tribal Council
is composed of fifteen () members of whom constituting a quorum, were present at a
meeting duly and regularly called, noticed, convened and held this day of July 2019,
Regular Session; and that the foregoing resolution was duly adopted at such meeting by a roll
call vote of yes, no, abstaining, absent, and not voting.
Ev Ann White Feather, Secretary
Cheyenne River Sioux Tribe