

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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September 5, 2019

Dr. Ned Sharpless
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Sharpless:

On July 24 and July 25, the Subcommittee on Economic and Consumer Policy held a two-part hearing examining JUUL's role in the youth e-cigarette vaping epidemic. Your predecessor, Scott Gottlieb, when he was Food and Drug Administration (FDA) Commissioner, pointed to JUUL as a primary cause of the epidemic.¹

Testimony from our hearing supports that conclusion. It demonstrates that JUUL appears to be violating FDA regulations against making unapproved express and implied claims that its product helps users stop smoking cigarettes and is safer than cigarettes.

Claims that a product helps users quit smoking are "therapeutic claims," subject to FDA jurisdiction under the drug/device provisions of the Food, Drug, and Cosmetic Act (FD&C Act). Such drugs or devices must be approved by FDA, and if they are not, they are unapproved drugs or devices being marketed illegally under the FD&C Act.²

FDA must consider the full picture in order to determine if therapeutic claims are being made. Therapeutic claims need not be express for a product to be subject to FDA's drug/device jurisdiction. Rather, FDA must look past the overt claims and determine the product's intended use, which it may do by considering "labeling claims, advertising matter, or oral or written statements" by the company and its representatives. It also may be shown how the company

¹ *Scott Gottlieb's Last Word as FDA Chief: Juul Drove a Youth Addiction Crisis*, Vox (Apr. 5, 2019) (online at www.vox.com/science-and-health/2019/4/5/18287073/vaping-juul-fda-scott-gottlieb).

² 21 U.S.C. § 321(g); *Sottera Inc. v. Food and Drug Administration*, 627 F. 3d 891 (U.S. App. DC 2010); Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices or Combination Products; Amendments to Regulations Regarding "Intended Uses," 82 Fed. Reg. 2193 (Jan. 9, 2017) ("A product will be regulated as a drug, device or combination product if: (a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, **including use in the cure or treatment of nicotine addiction (e.g. smoking cessation)**, relapse prevention, or relief of nicotine withdrawal symptoms.") (emphasis added) and ("statements related to quitting smoking generally create a strong suggestion that a product is intended for a therapeutic purpose.").

knows that product is actually being “offered and used for a purpose for which it is neither labeled nor advertised.”³

Manufacturers of tobacco products may not claim that their products are healthier or safer than cigarettes (“modified risk claims”) unless they have a marketing order from the FDA. JUUL does not have a marketing order from FDA that would allow it to make these “modified risk claims.” Making modified risk claims without a marketing order violates Section 911 of the FD&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act.⁴

The following evidence from testimony received by the Subcommittee bears directly on matters within FDA’s jurisdiction and ability to act.

JUUL’s Marketing of its Product as a Smoking Cessation Device

Over two days of hearings, the Subcommittee uncovered significant evidence of JUUL marketing its product as a smoking cessation device. JUUL did so plainly and directly to the Cheyenne River Sioux Tribe, to children in their high school, by marketing directly to community-based smoking cessation groups, and with its “switching” advertising.

JUUL’s Testimony Made Clear that its Product is a Smoking Cessation Device

During the hearing on July 25, JUUL Co-Founder James Monsees made various admissions that JUUL presents its product as a smoking cessation device that should be subject to FDA regulation as a drug, device, or combination drug/device. For example, he stated:

- Adam and I smoked. We tried to quit and we failed. We were on our way to becoming one of the nearly 500,000 Americans who die each year from smoking-related disease. For us, giving up smoking required an alternative which did not exist at the time. We founded JUUL Labs to invent one.
- The product we developed holds the promise to do what no previous technology has done—help adult smokers stop smoking combustible cigarettes on a widespread and consistent basis.
- Seventy percent of the world’s 1 billion smokers want to stop smoking immediately. Now the first and most important thing that they can do to improve

³ 82 Fed. Reg. at 2201.

⁴ Food and Drug Administration, *Section 911 of the Federal Food, Drug, and Cosmetic Act-Modified Risk Tobacco Products* (Jan. 7, 2018) (online at www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-911-federal-food-drug-and-cosmetic-act-modified-risk-tobacco-products) (“No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product”) and (defining “modified risk tobacco product” as “any tobacco product that is sold or distributed for use to reduce harm of the risk of tobacco-related disease associated with commercially marketed tobacco products.”).

their life expectancy is move away from cigarettes. Now that is the stage that we are at right now. JUUL does a great job of that.

- The history of cessations products have extremely low efficacy. That is the problem we are trying to solve here. So, if we can give consumers an alternative and market it right next to other cigarettes, then we can actually make something work.
- [T]raditional nicotine replacement therapies, which are generally regarded as the gold standard for tools, right, for quitting, those are nicotine in a patch or a gum form, typically, and the efficacy rates on those hover just below about a 10 percent or so. JUUL—we ran a very large study of JUUL consumers, ex-smokers who had picked up JUUL, and looked at them, looked at their usage on a longitudinal basis, which is usually the way that we want to look at this, in a sophisticated fashion ... what we found was that after 90 days, 54 percent of those smokers had stopped smoking completely, for a minimum of 30 days already. And the most interesting part of this study is that if you follow it out further, to 180 days, that number continues to go up dramatically, and that is quite the opposite of what happens with traditional nicotine replacement therapies.
- Yes. I would say nearly everyone uses our product as an alternative to traditional tobacco products (In response to Congressman Grothman's question of whether people buy JUUL to stop smoking).⁵

During the hearing, JUUL's Chief Administrative Officer, Ashley Gould, also made various admissions that JUUL presents its product as a smoking cessation device that should be subject to FDA regulation as a drug, device, or combination drug/device:

- [S]moking is by far the leading cause of preventable death in the United States and worldwide. More than 34 million Americans still smoke, and if they persist in doing so, it will kill about half of them. JUUL products have the potential to help millions of them switch and stop smoking entirely.
- JUUL says that our product is intended to help smokers stop smoking combustible cigarettes.⁶

⁵ Testimony of James Monsees, Co-founder and Chief Product Officer, JUUL Labs, Inc., Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL's Role in the Youth Nicotine Epidemic: Part 2* (July 25, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-ii>).

⁶ Testimony of Ashley Gould, Chief Executive Officer, JUUL Labs, Inc., Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL's Role in the Youth Nicotine Epidemic: Part 2* (July 25, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-ii>).

JUUL Pitched Its Product as a Smoking Cessation Device to a Native American Health Committee

Rae O’Leary, a health clinician that works closely with the Cheyenne River Sioux Tribe in South Dakota (CRST), testified that JUUL marketed its product to the Tribe as a smoking cessation device. She described JUUL’s proposal to the Tribe as follows:

In January and February of 2019, three representatives from JUUL ... proposed that healthcare professionals from the CRST Health Department refer smokers that are 21 years or older to their switching program. Using their referral, American Indian patients would enroll in JUUL’s online portal by entering personal data and health behaviors.

JUUL proposed to sell starter kits valued at \$50 to the tribe for \$5 apiece. The tribe would then turn around and provide free JUUL starter kits to patients who enroll in the switching program. **Throughout JUUL’s presentation, they made multiple claims that their product is effective for smoking cessation** and less harmful than tobacco products. These claims as well as JUUL’s actions to hand out free product are all clear violations of the Family Smoking Prevention and Tobacco Control Act.

JUUL indicated that their investment in the tribe switching program was worth over \$600,000 to the tribe. Initially, some tribal council members were convinced that JUUL’s switching program could help members of the Cheyenne River Sioux Tribe quit smoking, improving their quality of life for smokers, and eventually resulting in fewer healthcare costs to the tribe.⁷

Ms. O’Leary’s written testimony (Attachment A) states that “JUUL made claims that their product is effective for smoking cessation and less harmful than combustible tobacco products.” Included in Ms. O’Leary’s written testimony is a statement of the CRST Tribal Health Committee, in which it describes that JUUL wanted it to:

promote JUUL **as a healthful way for patients to quit smoking**. 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 program**.⁸

Ms. O’Leary explained that “the impression of the tribal council members who were on the other end of this presentation” was that JUUL was a smoking cessation product.⁹

⁷ Testimony of Rae O’Leary, Public Health Analyst, Missouri Breaks Industries Research, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL’s Role in the Youth Nicotine Epidemic: Part 1* (July 24, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-i>) (emphasis added).

⁸ Attachment A (emphasis added).

⁹ *Id.*

JUUL Told Children in High School to Use JUUL as a Smoking Cessation Device

Representatives of Parents Against Vaping e-cigarettes (PAVe) testified that JUUL entered their high school and marketed itself to the children as a smoking cessation device in a closed-door session not attended by any adults. High school student Philip Fuhrman testified that JUUL entered the school under the guise of an anti-addiction presentation, but instead marketed JUUL as a cessation device to the children.¹⁰ The following is Philip's description of his exchange with the JUUL presenter:

Rep. Krishnamoorthi: Phillip, let me ask you a couple of questions. What was your experience speaking to the presenter?

Mr. Fuhrman: So, we went up and talked to him, and Caleb asked a question about what can you do if your friend is addicted to nicotine.

Rep. Krishnamoorthi: Phillip, were you addicted to JUUL at the time of this presentation?

Mr. Fuhrman: I was.

Rep. Krishnamoorthi: And when Caleb asked the presenter what he should do if he had a friend that was addicted to nicotine, was Caleb referring to you?

Mr. Fuhrman: He was.

Rep. Krishnamoorthi: How did the presenter answer Caleb's question of how he could help his nicotine-addicted friend, namely you?

Mr. Fuhrman: Since Caleb was not specific on what kind of nicotine he was addicted to, whether it was an e-cigarette or cigarettes, the speaker thought that he was talking about cigarettes. And he said that he should mention JUUL to his friend because that is a safer alternative than smoking cigarettes, and it would be better for the kid to use.

Rep. Krishnamoorthi: So, let me get this straight. He wanted you to switch from a combustible cigarette to JUUL?

Mr. Fuhrman: Yeah.

Rep. Krishnamoorthi: Did the presenter demonstrate the product to you?

Mr. Fuhrman: He didn't use it, but he did take it out and show it to us.

¹⁰ Testimony of Philip Fuhrman, High School Student Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL's Role in the Youth Nicotine Epidemic: Part 1* (July 24, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-i>).

Rep. Krishnamoorthi: Okay. This is very disturbing behavior to say the least. A person connected to JUUL pulled out a JUUL device to demonstrate its safety to teenagers, and then lied about the product being “totally safe.” Did he say anything else about whether the government had approved JUUL?

Mr. Fuhrman: He mentioned that the FDA was about to come out and say that JUUL was 99 percent safer than cigarettes, and he said that that would happen very soon, and that it was in FDA approval while the talk was going on.¹¹

JUUL Marketed its Product to Community-Based Smoking Cessation Groups

During the hearing, we introduced a contract (Attachment B) through which JUUL hired the Trevino Consulting Group to market JUUL to smoking cessation programs run by community-based groups, including veterans organizations. The contract states: “In order to market its technology, JUUL must form strategic partnerships and develop programs that resonate with adults for prevention and cessation.” It also states:

Objective 1: Smoking cessation for adults

Strategy: Position JUUL as a proponent of smoking cessation among adults. Engage in outreach to specific community-based organizations (faith-based groups, community service organizations, minority groups, advocacy groups, professional associations and other business-related organizations) who provide smoking cessation education and assistance to current smokers.

...

Tactic: Identify strategic sponsorship opportunities for JUUL to support and expand existing cessation education programs in partnership with selected community-based organizations.¹²

Attempts to market its product as a smoking cessation device are of concern to the Subcommittee since FDA has not approved JUUL as a smoking cessation device.

JUUL Presented its Product as a Smoking Cessation Device in “Switching” Ads

JUUL “switching” ads also present its product as a smoking cessation device. During the hearing, Rep. Rashida Tlaib displayed the following advertisement:

¹¹ *Id.*

¹² Attachment B.

hope that there might be a way to quit cigarettes for good?

Mr. Monsees. I think the intention of this ad is to make it very clear to consumers that there is an alternative, finally, to combustible cigarettes. I am one of those people.¹³

JUUL Told the U.S. Trade Representative that Its Product is a Smoking Cessation Device

On June 14, 2019, JUUL sent a letter to the U.S. Trade Representative about the Administration's tariffs on lithium batteries, which are used in JUUL products. The letter stated:

Imposing a 25% duty on JUUL's portable charging case will indirectly increase the costs of health care. Levying an additional duty ... would cause undue harm to ... American consumers who are hoping to improve their lives by reducing or eliminating their use of combustible tobacco products... . Making JUUL's product cost-prohibitive for ... consumers may, in turn, lead them to revert to the use of combustible tobacco products, which may increase the costs of health care to those consumers as well as US health insurers.¹⁴

These appear to be very direct smoking cessation claims, as well as modified risk claims.

JUUL's Unapproved Modified Risk Claims

JUUL has made numerous unfounded and unapproved claims that its product is safer and healthier than cigarettes. For example, JUUL's Chief Administrative Officer, Ashley Gould explained that JUUL is "dedicated to helping the world's smokers switch to an alternative that will improve their lives."¹⁵

JUUL Markets its Product to Kids in Schools as "Totally Safe"

PAVe representatives testified that at the school presentation described above, JUUL marketed its product to children as healthier than cigarettes. PAVe Co-Founder Meredith Berkman testified that the JUUL presenter claimed that JUUL "was much safer than cigarettes [and] the FDA would approve it any day."¹⁶ Her son, Caleb Mintz described the presentation in the following exchange:

¹³ Testimony of James Monsees, Co-founder and Chief Product Officer, JUUL Labs, Inc., Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL's Role in the Youth Nicotine Epidemic: Part 2* (July 25, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-ii>).

¹⁴ Attachment C.

¹⁵ Testimony of Ashley Gould, Chief Executive Officer, JUUL Labs, Inc., Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL's Role in the Youth Nicotine Epidemic: Part 2* (July 25, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-ii>).

¹⁶ Testimony of Meredith Berkman, Co-founder, Parents Against Vaping, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL's Role in the Youth Nicotine*

Rep. Krishnamoorthi: Caleb, what grades were you and Phillip in the year of the JUUL presentation?

Mr. Mintz: Ninth grade.

Rep. Krishnamoorthi: What were students told about the presentation before it began?

Mr. Mintz: We were told that we were having a mental health/addiction seminar that we have 3 times a year, and the teachers are told to leave the room so it is a safe space for kids to talk.

Rep. Krishnamoorthi: Did most of your classmates believe JUUL was safe prior to the presentation?

Mr. Mintz: I think many kids were already JUULing and had their doubts to if it was safe, but I think a lot of kids still thought it was possibly dangerous.

Rep. Krishnamoorthi: Did the presenter ever mention his connection to JUUL, and were your teachers in the room when he spoke?

Mr. Mintz: He did mention his connection to JUUL, and my teachers were not in the room when he spoke.

Rep. Krishnamoorthi: **Did the presenter ever say that JUUL was safe?**

Mr. Mintz: **Yes.**

Rep. Krishnamoorthi: **Did the presenter call JUUL “totally safe” more than once?**

Mr. Mintz: **Yes.**

Rep. Krishnamoorthi: **What impact did those “totally safe” comments have on your classmates, some of whom may have already started vaping?**

Mr. Mintz: **For my classmates who were already vaping, it was a sigh of relief because now they were able to vape without any concern.**

Rep. Krishnamoorthi: Were there kids who had never been JUULing that were more likely to try after hearing it was “totally safe?”

Mr. Mintz: I can't say for sure, but **I believe that after this meeting, kids were more inclined to vape because now they thought it was just a flavor device that didn't have any harmful substances in it.**

Rep. Krishnamoorthi: You and Phillip approached the presenter when the assembly concluded. What motivated you to even approach him in the first place?

Mr. Mintz: I believed the presenter was sending mixed messages by saying JUUL is totally safe and following up every “totally safe” statement with “but we don’t want you as customers.” And I saw a mixed message being sent, and I believed that the presenter was playing on the rebellious side of teens where when teens are told not to do something, they are more likely to do it.¹⁷

Caleb’s classmate, Phillip Fuhrman, also testified about the JUUL representative’s presentation:

He mentioned that the FDA was about to come out and say that JUUL was 99 percent safer than cigarettes, and he said that that would happen very soon, and that it was in FDA approval while the talk was going on.¹⁸

JUUL Markets its Product to Native American Tribes as “Healthful”

Ms. Rae O’Leary testified that JUUL made multiple “harm reduction claims” in its pitch to CRST’s Tribal Health Committee. She testified:

So they went to the health committee, and at that meeting, that is when they made those claims of less harm and smoking cessation. And I will reiterate that that is not allowed. They cannot claim smoking cessation or at less harm at this point.¹⁹

Ms. O’Leary pointed to the JUUL presentation materials, stating: “In slide 6 of their presentation, they state ‘Elimination of combustible cigarettes is crucial to reduce the risk of harm,’ and on slide 12, ‘Vaping is a fraction of the risk of smoking, at least 95 percent less harmful.’”²⁰ These claims came within a sales pitch to the Tribe.²¹

¹⁷ Testimony of Caleb Mintz, High School Student, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL’s Role in the Youth Nicotine Epidemic: Part 1* (July 24, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-i>) (emphasis added).

¹⁸ Testimony of Philip Fuhrman, High School Student Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL’s Role in the Youth Nicotine Epidemic: Part 1* (July 24, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-i>).

¹⁹ Testimony of Rae O’Leary, Public Health Analyst, Missouri Breaks Industries Research, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL’s Role in the Youth Nicotine Epidemic: Part 1* (July 24, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-i>).

²⁰ *Id.*

²¹ *Id.*

Ms. O’Leary’s written testimony (Attachment A) also states that “JUUL made claims that their product is ... less harmful than combustible tobacco products.” Included in Ms. O’Leary’s written testimony is a statement of the CRST Tribal Health Committee, in which it describes that JUUL presented itself as a “healthful way for patients to quit smoking.”²²

JUUL Markets its Products to Employers and Insurers as a Way to “Save People’s Lives”

JUUL has created an Enterprise Markets Team to pitch JUUL to companies and insurers to help their employees stop smoking and lower health care costs. The underlying premise of the team’s sales pitch is that JUUL is safer than cigarettes. JUUL Co-Founder, James Monsees, admitted that in the following exchange:

Rep. Tlaib: You created an enterprise markets team of at least 20 people to pitch JUUL to companies and insurers to help their employees stop smoking and supposedly lower their health care costs. You hired Douglas Roberts, a former health care executive, to run that team. Why would employers or insurers partner with JUUL unless you were conveying that JUUL was effective for smoking cessation or safer than cigarettes?

Mr. Monsees: I think the real opportunity here is to improve lives of a billion people worldwide, and work together—

Rep. Tlaib: But why would JUUL tell employers and insurers about supposed health benefits of JUUL?

Mr. Monsees: Look, I just explained that. There is an opportunity here for public health. Why would insurance companies not want to explore all options—

Rep. Tlaib: But you are saying it is a healthier option?

Mr. Monsees: —to save people’s lives.²³

JUUL Asked the U.S. Trade Representative Not to Tariff JUUL Consumer Products Because They Are Healthier Than Cigarettes

JUUL’s June 14, 2019, letter to the U.S. Trade Representative claimed that its product lowers the cost of health care. It also claimed that if people lost access to JUUL, they would “revert to the use of combustible tobacco products, which may increase the costs of health care to those consumers as well as US health insurers.”²⁴ These appear to be very direct modified risk claims.

²² Attachment A.

²³ Testimony of James Monsees, Co-founder and Chief Product Officer, JUUL Labs, Inc., Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Examining JUUL’s Role in the Youth Nicotine Epidemic: Part 2* (July 25, 2019) (online at <https://oversight.house.gov/legislation/hearings/examining-juul-s-role-in-the-youth-nicotine-epidemic-part-ii>).

²⁴ Attachment C.

Conclusion

The testimony from the Subcommittee's two-part of hearing are extremely concerning. The Subcommittee urges FDA to evaluate the admissions and statements set forth above, as well as the entire transcript and documents submitted for the record, and expeditiously take all appropriate enforcement action to protect the American public from the fraudulent and unapproved medical claims made by JUUL.

Sincerely,



Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Mike Cloud, Ranking Member

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 anti-tobacco 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 regulations¹). 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.

¹ 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 regulations²). 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
 - Disclaimer was included in printed slides, but the font was very difficult to read and the presenters failed to verbally disclose the information.
 - 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
 - The department mission is reported as "Partnering with Tribes to Improve Lives"
- Slide 5 – The Costs of Smoking are Huge
 - "For every 1% of cigarette smokers who switch to vapor, lifetime costs savings to Medicaid programs would be \$2.9 billion.⁴" Slide references are illegible.
 - "It's time for an alternative to cigarettes"
 - It was implied by the presenters that switching to JUUL would result in cost savings to the Tribe.
- Slide 6 – Eliminate Combustible Cigarettes
 - "Elimination of combustible cigarettes is crucial to reduce risk of harm"
- Slide 8
 - "JUUL has a clear mission and the Public Sector-Health Markets Team will help Accelerate that Mission"
 - "Improve the lives of the world's one billion adult smokers"
- Slide 12 – 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 than cigarettes." However, the slide quotes Public Health England

² 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 (e-cigarette) 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
 - It was stated by one presenter (Exhibit 1) that JUUL is “...ultimately a tech company, not an e-cigarette company.”
- Slide 21
 - “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 e-cigarettes” (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 14th. 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.³
- 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.⁴
- 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.⁵
 - 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.⁶
 - According to the 2012 American Indian Adult Tobacco Survey, 51% of CRST's adult tribal members are current cigarette smokers.⁷ This high smoking prevalence was

³ 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.

⁴ 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 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5382092/>); American Public Health Association. *Priorities in Tribal Public Health* (2018) (online at https://www.apha.org/-/media/files/pdf/topics/environment/partners/tpeh/priorities_tribal_health_2018.ashx?la=en&hash=C06951A62A5E215BE6C99442A9E1E9DDD060B7C6).

⁵ U.S. Census Bureau 2010 Data (2012).

⁶ U.S. Census Bureau 2017 Data (2019) (online at <https://www.census.gov/quickfacts/fact/table/deweycountysouthdakota,ziebachcountysouthdakota,US/NES010217>).

⁷ The Canli Coalition of Cheyenne River (n.d.) (online at <https://www.missouri-breaks.com/canli-coalition-1>).

confirmed and published internationally in 2019 by a community-based environmental health study conducted in partnership with the University of New Mexico.⁸

- 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.⁹
- JUUL users smoke more and quit less.¹⁰ 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.¹¹
- The youth e-cigarette epidemic,¹² fueled by JUUL's superior nicotine delivery (nicotine salts), a concealable product and youth savvy design/marketing is evident in South Dakota.¹³ 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.¹⁴
- 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.¹⁵
- JUUL contains toxins, carcinogens, and dangerously high levels of nicotine.¹³
 - 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

⁸ O'Donald, E., Miller, C., O'Leary, R., 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 <https://doi.org/tobaccocontrol-2019-055056>).

⁹ Missouri Breaks Industries Research, Inc. (n.d.) (online at <https://www.missouri-breaks.com/projects>).

¹⁰ Rapaport, L. *E-Cigarettes Tied to Less Smoking Cessation*. Medscape (Mar. 26, 2018).

¹¹ 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>).

¹² 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 <https://www.fda.gov/news-events/press-announcements/fda-takes-new-steps-address-epidemic-youth-e-cigarette-use-including-historic-action-against-more>); Department of Health and Human Services, *Surgeon General Releases Advisory on E-cigarette Epidemic Among Youth* (Dec. 18, 2018) (online at <https://www.hhs.gov/about/news/2018/12/18/surgeon-general-releases-advisory-e-cigarette-epidemic-among-youth.html>); Centers for Disease Control and Prevention, *Sales of JUUL E-cigarettes Skyrocket, Posing Danger to Youth* (Oct. 2, 2018) (online at <https://www.cdc.gov/media/releases/2018/p1002-e-Cigarettes-sales-danger-youth.html>).

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

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

¹⁵ Keller, A. E-cigarette Side Effects. *Drug Watch* (May 15, 2019) (online at <https://www.drugwatch.com/e-cigarettes/side-effects/>).

- and carcinogenic “flavor” or aerosol-containing carcinogens (including formaldehyde) that are created as the liquid passes through the heating coil.¹⁶
- 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.¹⁷
 - 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.¹⁸
 - 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 1st, 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.”

¹⁶ 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>.

¹⁷ *Juul: The Rise of a \$38bn E-cigarette Phenomenon*, BBC News (Jan. 6, 2019) (online at www.bbc.com/news/business-46654063).

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

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 e-cigarette 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 Canli¹ 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
P.O. Box 590
Eagle Butte, SD 57625-0590
(605) 848-1164
bernita.inthewoods@crst-nsn.gov

¹ 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	A	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 14th. 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, 3rd 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.

MOTION: by Council Representative Merri Miller-White Bull, 2nd 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, 2nd 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, 2nd 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.

MOTION: by Council Representative Ryman LeBeau, 2nd 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, 2nd 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.

MOTION: by Council Representative Merri Miller-White Bull, 2nd 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.

MOTION: by Council Representative Merri Miller-White Bull, 2nd 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.

MOTION: by Council Representative Ryman LeBeau, 2nd 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.

MOTION: by Council Representative Ryman LeBeau, 2nd 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.

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

Yes 4. No 0. Not Voting 0.

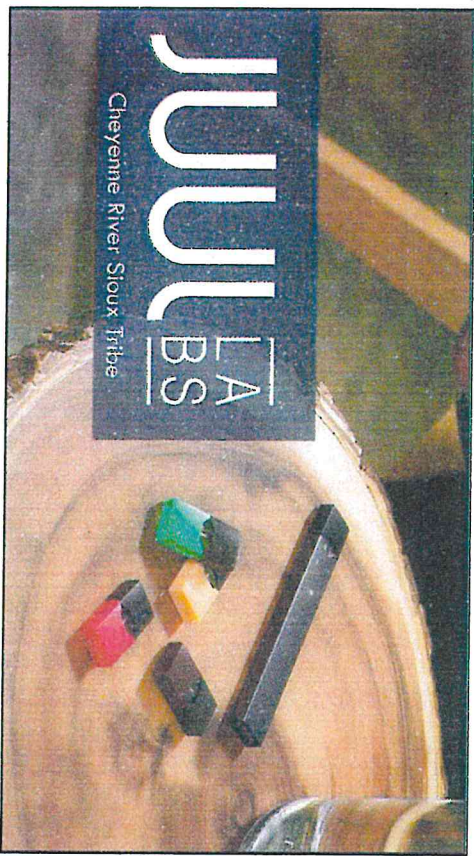
Motion Carried.

Transcribed by Vicki Ducheneaux



Cheyenne River Sioux Tribe
Council Representative Secretary

CC: Health Committee Members (8)
File



LEGAL DISCLAIMER

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

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.

Attachment C

Overview/Agenda

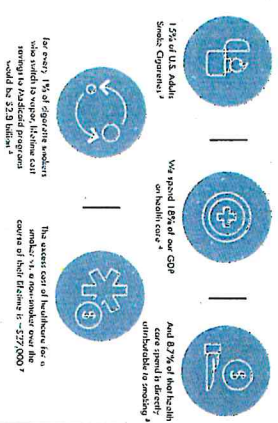
- ✓ JUUL Mission, Partnering with Tribes to Improve Lives
- ✓ JUUL Prevention Education
- ✓ JUUL Technology & its e-Cigarette
- ✓ JUUL in the Market Place
- ✓ JUUL Switching Program
- ✓ Conclusion, Questions & Next Steps



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

The Costs of Smoking Are Huge

- A 2017 peer-reviewed journal suggest that as many as **6.6 M** premature deaths could be averted if all smokers switched to vapor technology.¹
- Every month without intervention, smoking causes **40,000** deaths due to smoking related diseases?²
- 173,000** life-years lost!¹
- \$14 billion** in monthly direct health care costs?²
- \$11 billion** in monthly lost productivity costs?²

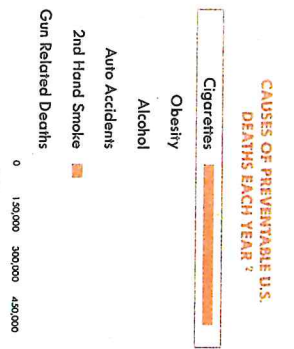


IT'S TIME FOR AN ALTERNATIVE TO CIGARETTES

Source: 1. Journal of the American Medical Association, 2017. 2. Journal of the American Medical Association, 2017. 3. Centers for Disease Control and Prevention, 2014. 4. Journal of the American Medical Association, 2017. 5. U.S. Department of Commerce, Bureau of Economic Analysis, 2017. 6. Journal of the American Medical Association, 2017. 7. Journal of the American Medical Association, 2017.

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

- TAKING VALUABLE YEARS OF LIFE**
 - 2/3rd of long-term smokers are expected to die prematurely due to smoking-related disease!
- 480K PEOPLE DIE ANNUALLY IN THE US**
 - Tobacco is accountable for 20% of all preventable deaths!¹
- TOBACCO IS PREVALENT IN THE MILITARY**
 - 14% of service members smoke, and 13% use smokeless tobacco!²
- TOBACCO COSTS THE DoD \$1.6BN ANNUALLY**
 - Includes tobacco-related medical care, hospitalization, and lost days of work!³



We are Driving Innovation to Eliminate Combustible Cigarettes

ELIMINATION OF COMBUSTIBLE CIGARETTES IS CRUCIAL TO REDUCE RISK OF HARM



Smoking is the #1 cause of preventable death!¹

1. Journal of the American Medical Association, 2017.

Improve the lives of the world's one billion adult smokers

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



Enterprise Markets – Public Sector Defense & Health Markets Mission

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.

JUUL Youth Prevention & Education

Youth Access Prevention and Education

And we are actively exploring and investing in new solutions

21+

We Support 21+ Nationwide

- We support raising the legal minimum age of purchasing vapor & tobacco products to 21+ nationwide

Community Outreach

- In ongoing dialogue with parents, educators, law enforcement and government officials on youth prevention, education and enforcement

Investing \$30 million over the next three years into:

- Youth education
- Parent education
- Community engagement
- Independent research

Social media monitoring + underage content removal

- Successfully removed over 1,000 social media posts that violated:
- community guidelines
- JUUL's brand
- Trademarks

Enforcement action taken contributed to the removal of popular Instagram accounts with over 200,000 combined followers

Shifting age + ID verification online

- At point of purchase and proactive 21+ online age-gate nationwide (despite majority of states on 18+)

Investigating and pushing retailer compliance

- ID checks via Social Shopper program
- Over 6 months ago we began secret-shopping retail locations to ensure proper age verification

Youth Prevention Helpline

- The company receives inquiries sent out to 1-800-438-3838 and 1-800-438-3838
- Product to be provided every email received

Regulators & Public Health Officials on E-Cigarettes

Consistent with FDA regulation, JUUL Labs can not and does not promise in products or in advertising or other non-discrete.

For those who cannot or will not quit tobacco use, completely switching to the alternative level of risk and addiction, non-combustible products, including liquid harmful, non-combustible products with ultrahigh nicotine, ultrahigh tar, eliminate the health benefit from tobacco.

With appropriate product regulation, new technology, and product innovation – including new medicinal nicotine products and e-cigarettes – can reduce the health burden of tobacco and stay quit.

Our new review indicates the finding that vaping is a less harmful function of the risk of smoking at least 95%.

and of respiratory and cardiovascular. Yet over half of smokers either fully believe that vaping is as harmful as smoking or just don't know.

The public health impact of e-cigarettes... the introduction of a new, reduced-risk nicotine delivery system that may prevent 10 percent from dying in a year, or even more than that, is a public health breakthrough.

11. **Public Health**

12. **Public Health**

JUUL Technology & its e-Cigarette

JUULpod™ Ingredients

JUULpod ingredients: glycerol, propylene glycol, flavors, nicotine and benzoic acid

Glycerol
An odorless, sweetening liquid, used as a vegetable and animal based alcohol and beverage.

Nicotine
A natural plant derived from the tobacco plant, JUUL uses high-purity, grade nicotine from tobacco.

Benzoic Acid
Benzoic acid is a naturally occurring ingredient, which is used in JUUL pods to stabilize the nicotine and extend its shelf life.

Propylene Glycol (PG)
A food grade ingredient used in tobacco-free moist and aromatic e-cigarettes. PG is a common product, found in many foods, including bread, butter, and coffee, and is used in JUUL pods to carry the nicotine and flavors.

Flavors
Choice of both naturally occurring and artificial flavor ingredients.

JUULpod Ingredients

Here is a JUUL

Product Overview

Consumer Value Proposition

- Satisfying**
 - Nicotine levels comparable to tobacco cigarettes.
 - Proprietary nicotine formula from tobacco leaf rather than free-base nicotine.
 - Smart temperature regulation technology.
- Simple**
 - Human-centric design that fits naturally and seamlessly into your life.
 - Modern look that's sleek and distinctly different from traditional cigarettes.
 - Portable, light device that does not require buttons, switches or set-up.
- Clean**
 - High-quality materials and flavors.
 - State of the art clean room technology.
 - Extensive testing and inspection to comply with quality standards.
 - No ash, no odor, no mess.

Benefits of Closed-Pod Electronic Nicotine Delivery Systems

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

Closed System

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

Security

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

Safety

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

Nicotine, Not Combustion

- Cigarettes deliver nicotine by burning tobacco, at temperatures that can exceed ~1000° 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 ^{3,4}
- 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 FDA review

CIGARETTE TOXINS ⁴



Over 7,000 chemicals



69 known carcinogenic compounds



400 other toxins: tar, carbon monoxide, formaldehyde, ammonia, hydrogen cyanide, arsenic, lead and DDT ⁵

1. Health Effects Institute. *Health Effects of Passive Smoking: Tobacco Without a Filter*. New York: Health Effects Institute; 1987. 2. Health Effects Institute. *Health Effects of Smoking: A Review of the Literature*. New York: Health Effects Institute; 1987. 3. Health Effects Institute. *Health Effects of Smoking: A Review of the Literature*. New York: Health Effects Institute; 1987. 4. Health Effects Institute. *Health Effects of Smoking: A Review of the Literature*. New York: Health Effects Institute; 1987. 5. Health Effects Institute. *Health Effects of Smoking: A Review of the Literature*. New York: Health Effects Institute; 1987.

JUUL in the Market Place

JUUL Labs today



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

Public Sector:
Pilot Switching Program



Have smokers that can't quit?
JUUL has created a program
where you can help them switch
with minimal cost to you



When Lisa A. Leon first made JUUL a target in 2014, she didn't know she'd be helping people quit smoking. She was just trying to help people quit smoking. She was just trying to help people quit smoking. She was just trying to help people quit smoking.

Targets Adult Smokers

- Identify smokers
- Enrollment coaches
- 21+ only

Online Enrollment and Information

- Banned landing page
- Local surveys
- Online resources

Analytics and Reporting

- Identify repeating
- Scheduling rules
- Employee Satisfaction

Switching Coaches

- Expert Support
- Personal Touch
- Weekly edis

Conclusion & Questions

JUUL has enabled millions of adult smokers to replace cigarettes.

OUR WAY TO HELPING 20 MILLION MAKE THE SWITCH BY 2020

Contact: Shawn Johns, Sr. Manager,
Public Sector - Health Markets
Phone: 703-869-3762
email: PublicHealth@juul.com
email: shawn.johns@juul.com



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. Confidential Information. “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. Use of Confidential Information. 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. Disclosure of Confidential Information. 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. Exclusions. 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. Non-Solicitation. 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. Proprietary Rights. 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. Term. 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. Remedies. 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 utmost 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



Counter Party Name:	<u>Trevino Consulting Group</u>
Counter Party Email:	
Effective Date:	
End Date:	
Requesting Department:	
Contract Total Value:	
Approved By:	
Budgeted?: Y/N	

JUUL LABS, INC.
CONSULTING AGREEMENT

This Consulting Agreement (this “**Agreement**”) is made by and between JUUL Labs, Inc., a Delaware corporation, (the “**Company**” or “**JUUL**”), and ~~[Name of Co. or Individual]~~ Trevino Consulting Group, an [choose one: Entity Type or Individual] (“**Consultant**”), effective as of 15 JUNE 2018 (the “**Effective Date**”).

Recitals

The Company desires to the engage Consultant, and Consultant desires to render services to the Company as a consultant, under the terms and conditions of this Agreement.

Agreement

Based upon the premises in the recital above and the mutual promises below, the parties hereby agree as follows:

1. The Services. The Company hereby engages Consultant to perform the services as specified in “Scope of Services” in Schedule A hereto (the “**Services**”), as such Schedule may be amended from time to time in writing by the Company and Consultant. As the only consideration due Consultant regarding the subject matter of this Agreement, the Company will pay Consultant in accordance with Schedule A. The Company and Consultant agree that Schedule A sets forth the entire compensation the Company will be obligated to pay Consultant for the Services, and will otherwise be governed by this Agreement.

2. Term: Termination.

a. Term. This Agreement commences on the Effective Date and will terminate automatically on the earlier of prior written notice by either party to the other of

termination (“**Termination Notice**”) of the consulting services (subject to Section 2(b) below), any unforeseen event or circumstance hindering Consultant’s ability to perform under this Agreement, or two (2) years from the Effective Date.

b. Termination Notice. If either party gives a Termination Notice, then this Agreement will terminate one (1) week after the Termination Notice, provided that in lieu of one week’s notice, the Company may in its discretion pay Consultant one week’s compensation.

c. Effect of Termination. Termination of this Agreement will constitute termination of the consultancy services and any compensation set forth in Schedule A. Notwithstanding the foregoing, Sections 4 through 10 of this Agreement will survive termination of this Agreement and Consultant shall remain bound thereby.

3. Location of Services; Employees. Unless otherwise specified in the applicable Scope of Services, Consultant will perform the services at Consultant’s place of business and use Consultant’s tools and equipment. Consultant shall not subcontract or assign Services, without the Company’s prior written consent. If Consultant is a corporation or other entity, (a) Consultant hereby represents and warrants that the undersigned has authority to bind Consultant to this Agreement and that all of Consultant’s employees and contractors who will provide Services hereunder have executed written agreements with Consultant containing confidentiality and assignment of invention provisions consistent with those in Section 8 hereof, (b) Consultant shall be solely responsible for all acts and omissions of its employees and contractors and for all payments to its employees and contractors, including, without limitation, tax withholding.

4. Expenses & Billing. The Company will reimburse Consultant for all reasonable and necessary expenses incurred in rendering the Services provided the Company approves such expenses in writing before Consultant incurs the expense. Consultant will invoice the Company at least on a monthly unless a different timing for invoices is agreed to in Schedule A. Invoices will include a detailed accounting of Services performed, including without limitation, where Services are performed on a time and materials basis, the number of hours of Services provided by each such person by date and the hourly rates therefor and other information as reasonably necessary for the Company to verify the accuracy of the invoice amounts. The Company shall pay each undisputed invoice for accepted Services within 30 days after receipt of invoice (unless a different timeframe for payment is agreed to in Schedule A).

5. Taxes. Consultant hereby directs the Company not to withhold any income, social security, state disability, or other taxes that may be applicable to Consultant. Consultant hereby represents that Consultant is an independent contractor and will pay such taxes on Consultant’s own behalf. Consultant hereby agrees to indemnify the Company for any taxes, interest, and penalties incurred by the Company as a result in whole or in part from the Consultant not paying and/or withholding such taxes on Consultant’s own behalf.

6. Compliance with Laws and No Infringement. Consultant represents and warrants that Consultant’s performance of all the terms of this Agreement will not breach any applicable law or regulation that is relevant to the Services, any invention assignment, proprietary information, confidentiality or similar agreement with any third party. Additionally, Consultant further represents and warrants that the provision of the Services do not infringe, misappropriate

or violate in any way any rights of third parties including any copyrights, patents, trademark, trade secrets, or other proprietary rights.

7. Conflict of Interest.

a. Conflict of Interest. During the term of this Agreement, Consultant will not without the prior written approval of the CEO of the Company directly or indirectly participate in or assist any business which is a current or potential supplier, customer, or competitor of the Company. However, Consultant may invest to an extent not exceeding one percent (1%) of the total outstanding shares in each of one or more companies whose shares are listed on a national securities exchange or quoted daily by NASDAQ.

b. No Conflicts Representation. Consultant covenants, warrants and represents that:

- (i) Consultant's performance of all the terms of this Agreement and Consultant's work for the Company does not and will not breach any invention, assignment or proprietary information agreement with any former employer or other party, or create any conflict of interest with anyone.
- (ii) Consultant will not disclose to the Company or use for the benefit of the Company any confidential information of a third party or derived from sources other than engagement with the Company or association with the Company during any period of consultancy.
- (iii) If there is any uncertainty regarding the confidential status or proprietary nature of any information, Consultant will refer to the management of the Company the question of whether such information is available for disclosure and use for the benefit of the Company.
- (iv) Consultant will not enter into any other agreement with any other person or entity, either written or oral, in conflict with the terms of this Agreement.

8. Non-Disclosure and Retention of Certain Company Information.

a. Non-Disclosure of Company Confidential Information.

(1) Consultant will regard and preserve as confidential, and will not divulge to unauthorized persons or use, or authorize or encourage persons who are under Consultant's direction or supervision to use, for any unauthorized purposes, whether during or after the term of this Agreement, any information, matter, material or thing of a secret, confidential, or private nature connected with the business of the Company or any of its suppliers, customers or their affiliates ("**Confidential Information**") without the prior written consent of the Chief Executive Officer of the Company. Confidential Information shall include, without limitation: (i) all matters of a technical nature, such as trade secrets, intellectual property, know-

how, formulae, computer programs, source code, object code, machine code, routines, algorithms, software and documentation, secret processes or machines, inventions and research projects; (ii) all matters of a business nature, such as information about costs, profits, markets, sales, customers, business contacts, suppliers, and employees (including salary, evaluation, and other personnel data); (iii) all plans for further development; and (iv) any other information that is confidential or proprietary to the Company.

(2) In this regard, although certain information or technology may be generally known in the relevant industry, the fact that the Company uses it, and how the Company uses it, may not be so known, and therefore is subject to non-disclosure and non-use. Furthermore, the fact that various fragments of information or data may be generally known in the relevant industry does not mean that the manner in which the Company combines them and the results obtained thereby are so known; and in such instance that fact also is subject to non-disclosure and non-use.

(3) Excluded from the restrictions of Subsections 8(a)(1) and (2) is information Consultant knew before the Company disclosed the information to Consultant, information which is public knowledge (other than as a result of disclosure by Consultant), and information which has been disclosed to Consultant by a third party without restriction as a matter of right. Consultant may, without violating Sections 8(a)(1) and (2), disclose Confidential Information that is required to be disclosed by court order or similar governmental authority provided that Consultant promptly informs the Company of the requirement, cooperates in seeking a protective order or confidential treatment prior to disclosure, and discloses only the Confidential Information that is required to be disclosed.

(4) Consultant agrees that, before making any disclosure or use of Confidential Information not previously approved in writing by the Chief Executive Officer of the Company in reliance upon any of the exclusions set forth in Subsection 8(a)(3), Consultant will give the Company at least ten (10) business days prior written notice, specifying the applicable exclusion and the circumstances giving rise to it. Consultant will have the burden of proving by clear and convincing evidence that the given exclusion applies to the information under the circumstances.

b. Assignment of Inventions.

(1) Consultant will promptly disclose in writing to the Chief Executive Officer of the Company all inventions, improvements, designs, formulas, works of authorship, trade secrets, technologies, mask works, circuits, layouts, algorithms, computer programs, ideas, processes, techniques, marks, know-how and data, whether or not patentable or registrable (collectively "**Inventions**") made or conceived or reduced to practice or developed by Consultant, either alone or jointly with others, during the term of this Agreement in connection with the Services or which relate to the Company or its current or proposed business, products or research and development.

(2) All Confidential Information and all title, patents, patent rights, copyrights, mask work rights, trade secret rights, and other intellectual property and rights anywhere in the world (collectively "**Rights**") in connection therewith shall be the sole property of the Company. Consultant hereby assigns to the Company any Rights Consultant may have or

acquire in such Confidential Information.

(3) Consultant agrees that all Inventions which Consultant makes, conceives, reduces to practice or develops (in whole or in part, either alone or jointly with others) during or prior to the term of this Agreement in connection with the Services or which relate to the Company or its current or proposed business, products or research and development, and all Rights therein, shall be the sole property of the Company and works for hire in favor of the Company. Consultant agrees to assign and hereby assigns to the Company all Inventions and all Rights to any such Inventions.

(4) Consultant agrees to perform all acts deemed necessary or desirable by the Company to permit and assist it, at Consultant's reasonable rate, in evidencing, perfecting, obtaining, maintaining, defending and enforcing Rights and/or Consultant's assignment with respect to such Inventions in any and all countries. Such acts may include, but are not limited to, execution of documents and assistance or cooperation in legal proceedings. Consultant hereby irrevocably designates and appoints the Company and its duly authorized officers and agents, as Consultant's agents and attorneys-in-fact to act for and on behalf and instead of Consultant, to execute and file any documents and to do all other lawfully permitted acts to further the above purposes with the same legal force and effect as if executed by Consultant.

(5) If any Rights or Inventions assigned hereunder are based on, or incorporate, or are improvements or derivatives of, or cannot be reasonably made, used, reproduced and distributed without using or violating technology, intellectual property or Rights owned or licensed by Consultant and not assigned hereunder, Consultant hereby grants the Company a perpetual, worldwide royalty-free, non-exclusive sublicensable right and license to exploit and exercise all such technology, intellectual property and Rights in support of the Company's exercise or exploitation of any assigned Rights or Inventions (including any modifications, improvements and derivatives thereof).

c. Retention of Company Data and Records. All data and records coming into Consultant's possession or kept by Consultant in connection with Consultant's engagement and any period of consultancy, including, without limitation, notebooks, drawings, and blueprints; computer programs, software, and documentation; bulletins, parts lists, reports, and customer lists; production, cost, purchasing, and marketing information; and employment data, including policies and salary information, are and shall remain the exclusive property of the Company. Consultant will return to the Company all originals and copies of such data and records promptly upon termination of Consultant's engagement, unless Consultant obtains specific written consent from the CEO of the Company to retain any such data or records.

9. Non-Solicitation. During Consultant's engagement with the Company and for one year after the termination of the engagement with the Company for any reason, in order to enable the Company to maintain a stable work force and to operate its business, Consultant shall not either directly or indirectly solicit, induce, recruit or encourage any of the Company's employees or contractors to leave their employment or engagement with the Company, either for Consultant or for any other person or entity.

10. General.

a. Independent Contractor. The Company and Consultant are and will remain independent contractors as to each other, and no joint venture, partnership, agency or other relationship which would impose liability upon one party for the act or failure to act of the other will be created or implied hereby or herefrom. Consultant will not be covered under the Company employee benefit plans. Except as expressly set forth herein, each party will bear full and sole responsibility for its own expenses, liabilities, costs of operation and the like. Neither party will have any power to bind the other party or to assume or to create any obligation or responsibility, express or implied, on behalf or in the name of the other party.

b. Severability; Waiver. If the application of any provision or provisions of this Agreement to any particular facts or circumstances is held to be invalid or unenforceable by any court of competent jurisdiction, then the validity and enforceability of such provision or provisions as applied to any other particular facts or circumstances and the validity of other provisions of this Agreement will not in any way be affected or impaired thereby. The waiver of any one default will not waive any other default.

c. Arbitration. Any controversy or claim arising out of or related to this Agreement or the breach thereof, except when injunctive relief or specific performance is sought, will be settled by arbitration at the office of the American Arbitration Association (“AAA”) in the County of San Francisco, California in accordance with the rules of the AAA. In the event a dispute is submitted to arbitration, the arbitrator may award costs and reasonable attorneys’ fees to the prevailing party. The award of the arbitrator will be of the same force and effect as a final enforceable judgment of a court of competent jurisdiction.

d. Notices. Any notice to be given pursuant to this Agreement will be in writing and will be deemed to have been given at the time of delivery in person to a party, if an individual, or to an officer of a party otherwise or upon the earlier of (i) actual receipt by the addressee and (ii) three (3) days after deposit in the U.S. mail when sent postage prepaid and addressed to the address of the intended recipient thereof set forth below or such other address as any party hereto will have designated in writing and given notice thereof to the other party pursuant to this subsection. The current addresses for the parties for purposes of notice are:

Company: JUUL Labs, Inc., at the address set forth on the signature page hereto.

Consultant, at the address set forth on the signature page hereto.

e. Miscellaneous.

(1) California law governs this Agreement without reference to choice of laws provisions as applied to instruments, persons and transactions which have legal contacts and relationships solely within the State of California. This Agreement constitutes the full and complete understanding of the parties, superseding all previous agreements on the subject matter hereof, including, without limitation, any previous consulting engagement agreements or purchase orders of Consultant. The language of this Agreement will be construed as a whole according to its fair meaning, and not strictly for or against any of the parties.

(2) This Agreement may be amended only by a written amendment executed by Consultant and an authorized officer of the Company.

(3) Consultant shall not assign this Agreement without the prior written consent of the Company (which may be withheld in its discretion). This Agreement will inure to the benefit of and will be binding upon the successors and permitted assigns of the parties, including any entity acquiring all or substantially all of the assets or stock of the Company and any wholly-owned U.S. subsidiary of the Company.

(4) The section headings in this Agreement are solely for convenience and will not be considered in its interpretation.

(5) Any lawsuit or proceeding which arises out of or relates to this Agreement that is not arbitrated pursuant to Section 9(c) above will be brought in the State of California in San Francisco County (and for the purpose of any such suit irrevocably submit and consent to the personal and subject matter jurisdiction and venue of any court located there, and waive all defenses of inconvenient forum). Service of process may be effected in the same manner notice is given pursuant to Section 9(d) above. The prevailing party will be entitled to recover reasonable attorneys' fees and costs.

(6) This Agreement may be executed in any number of counterparts, each of which will be an original, but all of which together will constitute one instrument. The exhibits referred to herein and annexed hereto are hereby incorporated into and made a part of this Agreement.

f. Publicity and Disclosure of Agreement. Neither Party may use the logo or name of the other party without written consent, however, Consultant hereby authorizes the Company to disclose this Agreement and Consultant's responsibilities hereunder to any person or entity, including, without limitation, Consultant's future clients.

Authorized Signatures

For the purpose of binding the parties to this Agreement, the parties or their duly authorized representatives have signed their names below. Consultant understands that notwithstanding the date of execution or acceptance by the Company, this Agreement is effective as of the Effective Date set forth above.

COMPANY:

CONSULTANT:

| JUUL LABS, INC.

Trevino Consulting GroupNAME

By: _____

By: _____

Name: _____

Name: _____

Title: _____

Title:

Address: 560 20th Street

Address: BUSINESS ADDRESS

San Francisco CA 94107

SCHEDULE A-1

SCOPE OF SERVICES AND COMPENSATION

Consultant Contact:

Company Contact: ~~Insert INTERNAL BUSINESS SPONSOR~~ Nat Sillin

~~Scope of Services:~~

OVERVIEW:

JUUL was created to serve as an alternative to cigarettes, and to give those who do smoke the resources they need to reduce or eliminate their consumption of cigarettes. JUUL is the first product of its kind that has shown what smoking technology can do for current smokers. Although the brand is well-recognized, the benefits of this technology are not widely known. In order to market this innovative technology, JUUL must form strategic partnerships, analyze their current presence in the community through focus groups and develop programs that resonate with adults for prevention and cessation.

OBJECTIVES, STRATEGIES AND TACTICS:

Objective #1: Smoking cessation for adults

Strategy: Position JUUL as a proponent of smoking cessation among adults. Engage in outreach to specific community-based organizations (faith-based groups, community service organizations, minority groups, advocacy group, professional associations and other business-related organizations) who provide smoking cessation education and assistance to current smokers.

Targets for Partnership: Statewide networks of established advocacy and service organizations such as the LULAC, UnidosUSA, NAACP, National Urban League, American GI Forum (Latino veterans organization), other veterans organizations, churches and community-based groups

Tactic: Identify strategic sponsorship opportunities with US Hispanic Chamber of Commerce, US Black Chamber of Commerce, their state and local affiliates, among others

Tactic: Identify strategic sponsorship opportunities for JUUL to support and expand existing cessation education programs in partnership with selected community-based organizations

Tactic: Deepen and expand targets for partnership through outreach and research in each market

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Objective #2: Gauge the opinion of smokers through focus groups

Strategy: Oversee and manage focus groups (ten in Houston and five in San Antonio) to gauge the perception, attitude, beliefs and values around smoking prevention and cessation and JUUL as a whole.

Population Targets: Houston is the fourth largest metropolitan area in the US with 6.2 million residents of which 41 percent are Latinos. San Antonio, with five major military bases, is home to the largest concentration of military personnel and retirees. Many military personnel started smoking while in the military, which makes this population a good target for focus groups targeting veterans that are former or current smokers.

Focus Groups: In Houston, recruit a diverse group of 15 participants per session; over the age of 21; all socio-economic backgrounds; current smokers and former smokers; in San Antonio, specifically target the veteran community*

*Focus group proposal may be amended in consultation with JUUL’s CESR department.

Objective #3: Smoking prevention for youth

Tactic: Engage in outreach and education through partnerships with selected specific community-based organizations whose programs are focused on youth

Targets for Partnership: Youth education groups (such as the Boys & Girls Clubs of America), school districts, church groups and smoking cessation organizations working with minority groups

Tactic: Introduction and promotion of JUUL’s smoking prevention information and education materials (English and Spanish language); extend support to existing minority youth focused with the intent of expanding smoking prevention programs

Tactic: Develop funding model to attract and incentivize community engagement and education partners for JUUL thus enhancing JUUL’s corporate social responsibility image

TIMELINE AND CONSULTING FEE:

Comment [A1]: How long is this engagement expected to last?

Treviño Consulting Group (TCG) respectfully requests a monthly retainer of \$20,000.00 (plus reimbursements) commencing on June 15, 2018. The retainer covers both development and implementation of a community engagement and outreach program and oversight and management of the focus group project.

JUUL will be invoiced on the first of each month.

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Invoicing and Payment:

Consultant shall submit written invoices to apaccounting@juul.com with time broken out in 30 minute increments on the 1st of each month and include specific and detailed time entries for Services performed.

Payment for Services is subject to the Company’s acceptance of the Services to its satisfaction.



June 14, 2019

Ambassador Robert E. Lighthizer
US Trade Representative
600 17th St. NW
Washington, DC 20508

RE: Docket No. USTR-2019-0004: Comments of JUUL Labs, Inc., Concerning Proposed Modified Action Pursuant to Section 301(b) of the Trade Act of 1974

Dear Ambassador Lighthizer,

JUUL Labs, Inc. ("JUUL") submits the following comments in response to the US Trade Representative's ("USTR") proposed modification of action taken under Section 301 of the US Trade Act of 1974, issued on May 17, 2019, and associated with the USTR's investigation of China's technology transfer, intellectual property, and innovation acts, policies, and practices ("May 17th Proposed Modification of Action").¹

JUUL produces and imports into the US vaping devices, components, and accessories, including a portable charging case for use with JUUL-produced vaping devices. This portable charging

¹ Request for Comments Concerning Proposed Modification of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation, <https://www.federalregister.gov/documents/2019/05/17/2019-10191/request-for-comments-concerning-proposed-modification-of-action-pursuant-to-section-301-chinas-acts>.

case is classified under HTSUS 8507.60.0020. HTS subheading 8507.60, which provides for, “Electric storage batteries, including separators therefor, whether or not rectangular (including square); parts thereof: Lithium-ion batteries” is among the HTSUS subheadings targeted by the USTR for a proposed fourth tranche of 25% additional tariffs on China-origin goods under the May 17th Proposed Modification of Action (“Tranche Four List”).

For the reasons set forth further below, JUUL respectfully requests that the USTR exempt HTSUS 8507.60.0020 from its final Tranche Four List of proposed Section 301 tariffs.

Background on JUUL and JUUL’s products

JUUL is an American company based in San Francisco, California, that produces and sells a vapor alternative to combustible tobacco products, and related accessories. JUUL was founded with the goal of improving the lives of the world’s one billion adult smokers. As a company, JUUL envisions a world where fewer people smoke cigarettes, and where people who smoke cigarettes have the tools to reduce or eliminate their consumption altogether.

Since JUUL was founded in 2017, more than one million smokers have switched to JUUL products, and JUUL has become the fastest-growing vaping product producer in the US. Based on a recent Nielsen report, cigarette volumes have faced a decline of 11.2% in monthly sales year-over-year, while sales of JUUL’s products continue to increase.² This indicates that JUUL’s

² Cigarette Sales in the U.S. Reach Largest Ever Year-Over-Year Decline in May 2019, <https://newsroom.juul.com/2019/06/06/cigarette-sales-reach-largest-ever-year-over-year-decline>.

mission to reduce the number of tobacco smokers is working and that JUUL's product presents a viable alternative to combustible tobacco products.

JUUL conducts all of its research and development efforts in the US with an aim of continuously improving the technological innovation of its products. Among the technological innovations achieved by JUUL is the portable charging case that is the subject of these comments. This article is comprised of a rechargeable lithium polymer (LiCoO₂) battery, a USB port, and a plastic housing that allows the user to charge the JUUL vaping device while providing a means to protect the device from damage during storage or transport. The portable charging case recharges by connecting to a power source through the USB port. When the portable charging case is charged, the device provides power to the JUUL vaping device and functions to protect the device while in a user's pocket, hand bag, luggage, or any other location where the device could be damaged. Currently, the portable charging case is manufactured in China, and is subject to a general rate of duty of 3.4%.

Exemption request

For the several reasons set forth below, JUUL submits for the USTR's consideration that the HTSUS classification associated with JUUL's portable charging case should be exempted from the final Tranche Four List of Section 301 tariffs.

- 1. JUUL is not able to source the portable charging case outside of China.*

In the near term, without significant disruption to JUUL's supply chain, JUUL is unable to source the portable charging case outside of China. JUUL has previously determined that no

manufacturers outside of China are willing or able to supply the portable charging case at the volume and price required to sustain JUUL's growth and meet customer demands. In fact, most vaporizing components and devices sold by JUUL and its competitors are made in China to achieve price competitiveness. Because of this, there is no immediate ability for JUUL or a vendor in another country to ramp up manufacturing of JUUL's portable charging case. There are no US-based manufacturers for these products and JUUL is not aware of any company that is planning to launch production facilities in the US to manufacture them. Further, JUUL has already contracted for a substantial volume of portable charging cases to be produced by its Chinese vendor. As such, JUUL's ability to immediately change its current location of production is simply not feasible.

2. Imposing an additional 25% duty on JUUL's portable charging case will directly harm US consumers and indirectly increase the costs of health care.

Levying an additional duty of 25% on JUUL's portable charging case would cause undue harm to, and financially burden, American consumers who are hoping to improve their lives by reducing or eliminating their use of combustible tobacco products and who cannot afford a further increase in costs for JUUL's products. In this regard, it is important to note that several of JUUL's products are currently subject to additional tariffs of 25% under prior tranches of Section 301 tariffs. Increasing the cost of another of JUUL's products by 25% will impact consumers in the form of a direct price increase, which is likely to make the product less affordable to the average consumer. Making JUUL's product cost-prohibitive for such consumers may, in turn, lead them to revert to the use of combustible tobacco products, which may increase the costs of health care to those consumers as well as US health insurers.

3. Imposing an additional 25% duty on JUUL's portable charging case will not achieve the Administration's core objectives for imposing Section 301 tariffs.

While JUUL appreciates the Administration's ongoing efforts to protect American technology and intellectual property, levying an additional duty of 25% on JUUL's portable charging case would not likely advance the Administration's objectives of contesting China's theft of American technology and intellectual property. The imposition of additional duties on consumer goods, such as JUUL's devices and components, was not within the original intention of the investigation into China's trade and Intellectual Property policies or practices. On June 15, 2018, the USTR issued a public statement regarding the focus of the Section 301 investigation on China's industrial sectors that benefit from the "Made in China 2025" policy.³ The original list of goods was only intended to target industrial goods and refrain from impacting goods used by the American consumer, such as, "cellular telephones or televisions." JUUL's vaping products and accessories are not part of the "Made in China 2025" or the "Belt and Road Initiative" priorities. Therefore, imposing increased duties for lithium batteries (used in consumer goods) is irrelevant to the goal of eliminating China's acts, policies, and practices surrounding Intellectual Property that cause harm to US interests. Vaping products and accessories are not a consideration in the "Made in China 2025" policy, nor should these products or accessories be part of any additional duties imposed since these are "goods commonly purchased by American consumers".

³ USTR, USTR Issues Tariffs on Chinese Products in Response to Unfair Trade Practices (June 15, 2018), <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2018/june/ustr-issues-tariffs-chinese-products>

4. Imposing an additional 25% duty on an entire category of goods under HTS subheading 8507.60 is too broad an action.

HTS subheading 8507.60 is too broad to include in its entirety within the scope of Section 301 tariffs. A vast number of consumer goods (as opposed to industrial goods and applications) are operated with the use of a lithium battery. Unfortunately, the HTS subheading for lithium batteries for both consumer and industrial applications is the same: 8507.60. Therefore, the additional duties imposed on consumer products falling within HTS subheading 8507.60 creates an unintended consequence that can impact the American consumer and is contrary to the intent of the Section 301 investigation.

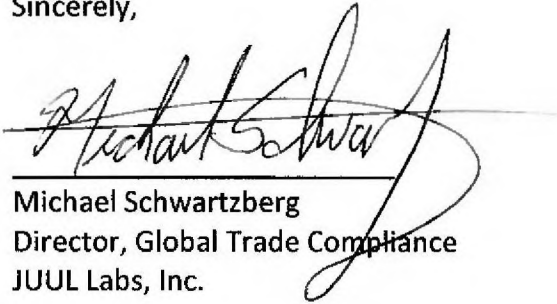
5. Imposing an additional 25% duty on JUUL's portable charging case will negatively impact US job growth.

Levying an additional duty of 25% on JUUL's portable charging case could contribute to a slowdown in a fast-growing industry that is already burdened by additional 25% tariffs on various other vaping products and components, and that has the potential to create a significant number of jobs in the US. As one of the fastest growing companies in the US, JUUL has directly and indirectly created, and has the potential to continue directly and indirectly creating, a plethora of new jobs here in the US. In addition, JUUL's growth has also created countless American jobs for JUUL's US business partners, such as contract manufacturers, logistics providers, etc. If the USTR increases the tariffs for JUUL's portable charging case by 25%, this will likely reduce the demand for JUUL's products, which will reduce JUUL's and its business partners' ability to create additional jobs in the US.

Conclusion

For the reasons set forth above, JUUL respectfully requests that the USTR consider the aforementioned impacts that imposing additional duties on JUUL's portable charging case—which is designed and produced as an accessory for a product that has the goal of reducing harm to US consumers—will place on products that were designed and produced with the goal of reducing harm in our society, and to exempt HTSUS 8507.60.0020 from the Tranche Four List of Section 301 tariffs.

Sincerely,



Michael Schwartzberg
Director, Global Trade Compliance
JUUL Labs, Inc.