

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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MEMORANDUM

February 5, 2020

To: Democratic Members of the Subcommittee on Economic and Consumer Policy

Fr: Subcommittee Staff

Re: Update on the Subcommittee's E-Cigarette Investigation

The Subcommittee on Economic and Consumer Policy's investigation of the youth vaping epidemic has uncovered new facts about JUUL, the nation's leading e-cigarette company. In response to the Subcommittee's demand for internal company documents and answers to key questions, which Chairman Raja Krishnamoorthi sent on September 12, 2019, JUUL has admitted:

- JUUL's business strategy relies on keeping users addicted to nicotine;
- JUUL will not rule out re-introducing kid-friendly flavors in the United States, or introducing new ones in the future;
- JUUL's targeting of Native Americans was more pervasive than initially known, and the company has now identified eight of the tribes it targeted;
- JUUL may still be making claims about safety and efficacy without the legal authorization to do so;
- JUUL is lobbying in 48 states;
- JUUL continues to market to children outside of the United States; and
- JUUL's vaping products do not use American-grown tobacco, and its foreign tobacco is mostly processed outside of the United States.

Below is a summary of the Subcommittee's actions to date and new disclosures from JUUL's written responses to the Subcommittee's questions. The company's full responses are included as Attachment A to this memorandum.

I. SUBCOMMITTEE INVESTIGATION

The Subcommittee has led Congress' investigation of JUUL and the youth vaping epidemic, taking the following key actions:

- Chairman Krishnamoorthi launched this investigation on June 7, 2019, issuing extensive document requests to JUUL¹;
- The Subcommittee held the first Congressional hearings on vaping on July 24 and 25, 2019, obtaining testimony about JUUL's marketing strategies to youth²;
- Chairman Krishnamoorthi presented the Food and Drug Administration (FDA) with clear evidence of illegal safety claims made by JUUL³;
- On September 11, 2019, Chairman Krishnamoorthi praised the Administration's announcement that it would clear the market of all flavored e-cigarettes, including min- and menthol-flavored products⁴;
- On September 24, 2019, the Subcommittee held the first Congressional hearing examining the sudden outbreak of vaping-related lung injuries, and the Centers for Disease Control and Prevention (CDC) advised Americans not to use e-cigarettes⁵;
- On September 25, 2019, Chairman Krishnamoorthi sent letters to four of the leading e-cigarette manufacturers, calling on them to stop advertising on television, radio, and through social media influencers⁶;

¹ Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Kevin Burns, Chief Executive Officer, JUUL Labs, Inc. (June 7, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2019-06-07.RK%20to%20Burns-JUUL%20re%20E-Cigarette%20Epidemic.pdf>).

² Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Economic and Consumer Policy Subcommittee to Examine JUUL's Role in the Youth Vaping Epidemic* (July 23, 2019) (online at <https://oversight.house.gov/news/press-releases/economic-and-consumer-policy-subcommittee-to-examine-juul-s-role-in-youth>).

³ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Investigation Prompts FDA to Issue Warning Letter to JUUL* (Sept. 9, 2019) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-investigation-prompts-fda-to-issue-warning-letter-to-juul>).

⁴ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Chairman Krishnamoorthi Issues Statement on Administration's Plan to Ban Flavored E-Cigarettes Following Information Unveiled by Oversight Subcommittee* (Sept. 11, 2019) (online at <https://oversight.house.gov/news/press-releases/subcommittee-chairman-krishnamoorthi-issues-statement-on-administration-s-plan>).

⁵ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on Don't Vape: Examining the Outbreak of Lung Disease and CDC's Urgent Warning Not to Use E-Cigarettes* (Sept. 24, 2019) (online at <https://oversight.house.gov/legislation/hearings/don-t-vape-examining-the-outbreak-of-lung-disease-and-cdc-s-urgent-warning-not>).

⁶ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Chairman Krishnamoorthi Issues Statement Following Favorable Response to Call for E-Cigarette Companies to Stop Advertising* (Oct. 16, 2019) (<https://oversight.house.gov/news/press-releases/subcommittee-chairman-krishnamoorthi-issues-statement-following-favorable>); *See also* Email from Counsel for Blu to Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Oct. 15, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Fontem%20Blu%20Agreement%20Terms%2010.15.19_Redacted.pdf).

- On October 1, 2019, the Subcommittee urged the National Institutes of Health to allocate grant funding to research the long-term health effects of e-cigarettes⁷;
- On October 7, 2019, Chairman Krishnamoorthi introduced the END ENDS Act (H.R. 4624) to cap nicotine levels and make e-cigarettes less likely to addict new users⁸;
- On October 10, 2019, Chairman Krishnamoorthi sent a letter to Reynolds American, Inc., demanding documents regarding its then-pervasive advertising⁹;
- On October 22, 2019, Chairman Krishnamoorthi sent a letter calling on FDA to deliver on the Administration's promise to ban all e-cigarette flavors¹⁰;
- On October 30, 2019, after FDA finalized its flavor guidance, Chairman Krishnamoorthi called on the White House's Office of Information and Regulatory Affairs (OIRA) to finish its review of FDA's guidance within ten days and cancel its meeting with industry lobbyists so the guidance could quickly go into effect¹¹;
- On November 7, 2019, Chairman Krishnamoorthi demanded documents from JUUL and its contract manufacturer about allegations that it was knowingly selling contaminated JUUL pods¹²;
- On November 18, 2019, Chairman Krishnamoorthi sent letters calling on the Administration to issue its promised ban on e-cigarette flavors and requested information from FDA and OIRA regarding their delay in finalizing the ban¹³;

⁷ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Urges NIH to Allocate Grant Funding to Research Long-Term Health Effects of E-Cigarettes* (Oct. 1, 2019) (online at <https://oversight.house.gov/news/press-releases/subcommittee-urges-nih-to-allocate-grant-funding-to-research-long-term-health>).

⁸ *New Bill Aims to Cap Nicotine Levels in E-Cigarettes*, CNN (Oct. 7, 2019) (online at www.cnn.com/2019/10/07/health/vaping-nicotine-cap-krishnamoorthi-bn/index.html).

⁹ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Ramps Up Pressure on E-Cigarette Companies to End All Advertising* (Oct 10, 2019) (online at <https://oversight.house.gov/news/press-releases/subcommittee-ramps-up-pressure-on-e-cigarette-companies-to-end-all-advertising>).

¹⁰ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Pressures FDA to Publish Final E-Cigarette Flavor Ban* (Oct. 22, 2019) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-presses-fda-to-publish-final-e-cigarette-flavor-ban>).

¹¹ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Calls on OIRA to Complete Review of Administration's Vaping Flavor Ban in Ten Days* (Oct. 30, 2019) (online at <https://oversight.house.gov/news/press-releases/subcommittee-calls-on-oira-to-complete-review-of-administration-s-vaping-flavor>).

¹² Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Requests Documents from JUUL Labs on Product Contamination* (Nov. 7, 2019) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-requests-documents-from-juul-labs-on-product>).

¹³ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Chairman Krishnamoorthi Seeks Answers After News that President Trump May Abandon E-Cigarette Flavor Ban* (Nov. 18, 2019) (online at <https://oversight.house.gov/news/press-releases/subcommittee-chairman-krishnamoorthi-seeks-answers-after-news-that-president>).

- On December 4, 2019, the Subcommittee held a hearing with FDA to examine why the flavor guidance was being delayed and why FDA should not to include flavor exemptions as favors to industry¹⁴;
- On December 12, 2019, Chairman Krishnamoorthi introduced the PREVENT Act to establish e-cigarette user fees collected from e-cigarette manufactures to fund youth anti-vaping education¹⁵;
- On January 2, 2020, when FDA finally issued the flavor guidance with exemptions for menthol, open tank vapes, and disposable e-cigarettes, Chairman Krishnamoorthi requested information on how FDA planned to prevent youth from migrating to the menthol products it let stay on the market, and seeking FDA's commitment to act when it discovers rising youth use of menthol e-cigarettes¹⁶; and
- On January 30, 2020, Chairman Krishnamoorthi sent letters to NJOY and Blu, makers of disposable e-cigarettes, about their business plans after FDA exempted their products from its flavor guidance.¹⁷

The Subcommittee's oversight and investigation have forced major changes to the industry's troubling practices. In just eight months, the investigation has fundamentally altered the e-cigarette landscape for the better. Key accomplishments include:

- The Subcommittee exposed JUUL's pervasive targeting of children by obtaining testimony about JUUL: (1) presenting to kids in school and falsely claiming that JUUL was "totally safe"; (2) sponsoring summer camps for kids as young as eight; (3) targeting Native Americans as guinea pigs for its product; (4) targeting other vulnerable populations, including veterans and minority communities; and (5) implementing a vast and sophisticated network of social media influencers¹⁸;

¹⁴ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Hearing on The Federal Response to the Epidemic of E-Cigarette Use, Especially Among Children, and the Food and Drug Administration's Compliance Policy* (Dec. 4, 2019) (online at <https://oversight.house.gov/legislation/hearings/broken-promises-examining-the-administration-s-retreat-on-banning-vaping>).

¹⁵ *New Bill Would Make E-Cigarette Companies Pay for Teenage Anti-Vaping Campaign*, Washington Examiner (Dec. 13, 2019) (online at www.washingtonexaminer.com/policy/healthcare/new-bill-would-make-e-cigarette-companies-pay-for-teenage-anti-vaping-campaign).

¹⁶ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Presses FDA on Menthol Exemption from Ban on Flavored Vaping Products*, (Jan. 23, 2020) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-presses-fda-on-menthol-exception-from-ban-on-flavored-0>).

¹⁷ Congressman Raja Krishnamoorthi, *Press Release: Congressman Raja Krishnamoorthi Reaffirms Call to Ban All Flavored E-Cigarettes, Including Disposable E-Cigarettes* (Feb. 3, 2020) (online at <https://krishnamoorthi.house.gov/media/press-releases/congressman-krishnamoorthi-reaffirms-call-ban-all-flavored-e-cigarettes>).

¹⁸ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: New Documents Show JUUL Deliberately Targeted Children to Become the Nation's Largest Seller of E-Cigarettes* (July 25, 2019) (online at <https://oversight.house.gov/news/press-releases/new-documents-show-juul-deliberately-targeted-children-to-become-the-nation-s>).

- Immediately following Chairman Krishnamoorthi's letter to FDA, which explained that JUUL's marketing practices violated federal law, FDA issued a Warning Letter to JUUL, attributing the Subcommittee's letter just four days later¹⁹;
- Two days later, President Trump, FDA, and the Department of Health and Human Services (HHS) referred to the Subcommittee's investigative results when they promised to ban all e-cigarette flavors to curb youth use²⁰;
- JUUL announced on September 25, 2019, that it would stop all U.S. advertising and was removing its Chief Executive Officer, Kevin Burns;
- In September and October 2019, in response to letters from Chairman Krishnamoorthi, NJOY and Logic confirmed they would not advertise their e-cigarettes in the United States, and Blu discontinued its social media influencer program that included celebrities like Post Malone²¹;
- Congress passed legislation raising the age to purchase tobacco products to 21 years old (H.R. 1865).

II. KEY JUUL ADMISSIONS

Following testimony from JUUL's Co-Founder and Chief Product Officer, James Monsees, and JUUL's Chief Administrative Officer (CAO), Ashley Gould, at the Subcommittee's July 25, 2019, hearing, Chairman Krishnamoorthi sent the company additional questions. JUUL produced a response on January 12, 2020, in which the company made the following admissions:

A. **JUUL Relies on Keeping Users Addicted to Nicotine, and JUUL Has Not Conducted Clinical Studies to Show Efficacy on Smoking Cessation**

Publicly, JUUL has claimed that its product is intended to help smokers. In response to Chairman Krishnamoorthi's questions, JUUL admitted that its intent is to be the preferred means of nicotine delivery to nicotine addicts. JUUL stated that its product was **"intended to switch**

¹⁹ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Oversight Subcommittee Investigation Prompts FDA to Issue Warning Letter to JUUL* (Sept. 9, 2019) (online at <https://oversight.house.gov/news/press-releases/oversight-subcommittee-investigation-prompts-fda-to-issue-warning-letter-to-juul>).

²⁰ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Chairman Krishnamoorthi Issues Statement on Administration's Plan to Ban Flavored E-Cigarettes Following Information Unveiled by Oversight Subcommittee Investigation* (Sept. 11, 2019) (online at <https://oversight.house.gov/news/press-releases/subcommittee-chairman-krishnamoorthi-issues-statement-on-administration-s-plan>).

²¹ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, *Press Release: Subcommittee Chairman Krishnamoorthi Issues Statement Following Favorable Response to Call for E-Cigarette Companies to Stop Advertising* (Oct. 16, 2019) (<https://oversight.house.gov/news/press-releases/subcommittee-chairman-krishnamoorthi-issues-statement-following-favorable>); *See also* Email from Counsel for Blu to Staff, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Oct. 15, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Fontem%20Blu%20Agreement%20Terms%2010.15.19_Redacted.pdf).

adult smokers from one nicotine delivery system to another.” JUUL also stated: “Switching involves continuing to consume nicotine but from a different device.”

The Subcommittee asked JUUL:

Question 15. What does JUUL mean by the term “switch” in its advertising? In JUUL’s usage, would it be considered a “switch” if a cigarette smoker stops smoking cigarettes, starts using JUUL, and continues to use JUUL indefinitely?

JUUL provided the following response:

Response:

As part of our review of policies and practices, in September 2019, JLI suspended all broadcast (e.g., TV and radio), print, and digital product advertising in the U.S. Prior to this time, the Company ran a marketing campaign in 2019 with the tag line “Make the Switch” because the JUUL system was designed to help adult smokers switch from combustible cigarettes to an alternative nicotine delivery system and is not intended for the cure or treatment of nicotine addiction (e.g., cessation), prevention of nicotine addiction relapse, or relief of nicotine withdrawal symptoms. Switching is not another word for cessation; they mean two very different things. Switching involves continuing to consume nicotine but from a different device, while cessation is about getting users to eliminate their nicotine consumption altogether. Moreover, FDA defines the scope of smoking-cessation medications as treating dependence by reducing the symptoms of going without nicotine. JUUL products are switching products; JUULpods contain nicotine derived from tobacco and are intended to switch adult smokers from one nicotine delivery system to another. JUUL products are not cessation products and that is clear in our marketing and communications. Moreover, this is a distinction recognized in FDA guidance.³ Further, consistent with federal law, all of our “Make the Switch” advertisements contained the following language: “WARNING. This product contains nicotine. Nicotine is an addictive chemical.” That same warning also appeared on JUUL packaging, and the JUULpod packaging identifies the amount of nicotine in the product.

JUUL has led consumers to believe that its product is helpful for smoking cessation, despite the absence of evidence for that claim. JUUL has failed to conduct any clinical studies on the efficacy of its product on smoking cessation.

The Subcommittee asked JUUL:

Question 33. Why has JUUL never conducted a clinical trial to prove that its devices help adult smokers quit smoking cigarettes? Please provide all plans and documents related to any such proposed or planned clinical trial.

JUUL evaded providing a direct answer to this question:

Response:

As JLI works to fulfill its mission to eliminate combustible cigarettes among adult smokers, JLI is committed to both conducting and supporting well-designed nonclinical, clinical, and behavioral research examining the public health impact of its products. JLI understands that there are many questions about the health impact of ENDS products and is committed to contributing to the body of global public health research on these topics. To that end, JLI has built a robust scientific research program to assess the harm-reduction potential of JUUL products, including their impact on the individual user, their ability to switch adult smokers from combustible cigarettes, and the net-population impact on public health.

It is important to note that the Family Smoking Prevention and Tobacco Control Act was purposefully designed to ensure the quality and transparency of research relating to the health, dependency effects, and other potential risks of new forms of tobacco products like ours. For example, the Act established the PMTA process, which *requires* manufacturers like JLI to establish that their products are appropriate for the protection of public health, and to disclose to the agency the results of research examining the health risks of their products. As part of the PMTA process, FDA has recommended that manufacturers complete a number of nonclinical, clinical, and other studies, and JLI has structured its research program to meet this guidance. Through the PMTA process and broader regulatory framework for tobacco products, FDA is well positioned to assess the regulatory science underpinning all manufacturer submissions, and there are requirements in place to ensure FDA has access to data that are relevant to the public health.

As described in JLI's August 12, 2019 letter to the Subcommittee, we have conducted clinical trials of the health impacts of JUUL products, including *Changes in Biomarkers of Exposure Associated with Switching for 5 Days from Combusted Cigarettes to Nicotine Salt Pod System*¹⁴ and *An Open-Label Clinical Study to Evaluate Selected Constituents in Exhaled Breath and Room Air after the Use of Vapor Products and Conventional Cigarettes under Conditions of Residential, Office and Hospitality Environments*.¹⁵

B. JUUL Will Not Rule Out Re-Introducing Kid-Friendly Flavors in the United States, or Introducing New Flavors in the Future

The Subcommittee asked JUUL whether it plans to introduce new flavors through the PMTA process. JUUL confirmed that it may seek to introduce “non-tobacco flavors,” leaving the door open for introducing new flavors or re-introducing the flavors like mango and mint that are already proven to be popular with children.

Question 28. During the hearing Mr. Monsees testified that JUUL has “no intention of introducing any new flavors whatsoever until after PMTA takes place.” Does JUUL plan to introduce new flavors through the Premarket Tobacco Product Application (PMTA) process? Describe all plans for introducing new flavors, including the flavors under consideration.

Response:

JLI does not intend to re-introduce any previously marketed flavored JUUL products without prior authorization by FDA, if at all. Moreover, JLI will fully comply with the Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization issued by FDA on January 2, 2020 (the “FDA Flavors Guidance”). For its initial PMTA, which JLI will submit by the required deadline, JLI will include a limited number of JUUL products (tobacco and non-tobacco flavored) with data to support FDA’s determination of whether these products are appropriate for the protection of public health.

C. JUUL’s Targeting of Native American Tribes Was More Pervasive Than Initially Known, and JUUL Has Now Identified Eight Tribes it Targeted

During the Subcommittee’s July 25 hearing, testimony from Rae O’Leary exposed that JUUL was targeting Native Americans as guinea pigs for its product. JUUL tried to sell its product through tribal health agencies’ smoking cessation programs, despite not having FDA approval to do so. JUUL also made unfounded claims to the tribe that its product was healthy. Ms. O’Leary detailed JUUL’s presentation to the Cheyenne River Sioux Tribe (CRST):

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.²²

²² Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, Testimony of Rae O’Leary, Public Health Analyst, Missouri Breaks Industries Research, *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).

JUUL now admits that its targeting of Native American tribes was more widespread. In three months, between December 2018 and February 2019, JUUL admitted to making similar pitches to the leaders of at least eight Native American tribes:

- the Moapa Band of the Paiute Tribe;
- the Lummi Nation;
- the Nooksack Tribe;
- the Cheyenne River Sioux Tribe;
- the S'Klallam Tribe;
- the Chickasaw Nation;
- the Muckleshoot Tribe; and
- the Kalispel Tribe.

JUUL also admitted that it contacted an undisclosed additional number of tribes with similar pitches, but JUUL refused to identify those additional tribes or to state how many it contacted.

Question 24. Identify all Native American tribes JUUL approached with any offer. For each tribe:

- a. What did JUUL propose?**
- b. Did the proposal involve JUUL being used for smoking cessation?**
- c. Did the proposal involve tribal health professionals being involved in distribution of the product?**
- d. What is the status of the proposal (e.g., proposal rejected, contract formed, still under contract)?**
- e. How much did JUUL offer in money and other things of value?**
- f. How much did JUUL actually pay in money and other things of value?**
- g. What data was, or was to be, collected from participants? Was such data actually collected? For how many participants?**
- h. For what purposes does JUUL use the data?**
- i. Identify any person or entity with which JUUL has shared the data?**
- j. Has JUUL's marketing team had access to the data?**

Response:

Between December 2018 and February 2019, JLI met with leadership from five tribes (the Moapa Band of the Paiute Tribe, the Lummi Nation⁶, the Cheyenne River Sioux Tribe, the

⁶ JLI understands that Chairman Ross Cline of the Nooksack Tribe also attended this meeting.

S'Klallam Tribe, and the Chickasaw Nation) to discuss the concept of a switching program for individuals aged 21+ who were current smokers and sought to switch away from using combustible cigarettes. No switching programs were entered into; JLI terminated this initiative in Spring 2019 before any contracts for switching programs were presented to or signed by these Native American tribes. No data was collected from tribal members, and JLI did not pay any money to tribes to support switching programs.

During these introductory meetings, JLI described the general concept of a switching program, which would include the availability of discounted product to enrollees during the 90-day program period and the collection of participant data at certain intervals in the program. JLI ceased outreach to Native American tribes regarding the switching programs before there was a concrete proposal covering the data metrics that would be tracked for participants, the price of the discounted product, or what additional support JLI would provide.

JLI also had contact with representatives from other tribes, and JLI understands that the topic of switching programs arose in some of these conversations. To JLI's understanding, these preliminary discussions did not advance to organized meetings to present a switching program proposal.

In addition, JLI had conversations with other tribes to discuss sales of JUUL products in casinos or convenience stores owned by tribes. During in-person meetings to discuss casino sales with two of these tribes (the Muckleshoot Indian Tribe and the Kalispel Tribe), the topic of a possible switching program for casino employees or tribal members was also raised. No agreements were entered into.

D. JUUL May Still Be Making Claims About Safety and Efficacy Without Legal Authorization

Manufacturers of tobacco products may not claim that their products are healthier or safer than cigarettes (“modified risk claims”) unless they have marketing orders 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 Food Drug & Cosmetic Act.²³

JUUL employed an Enterprise Markets Team to pitch JUUL to companies and insurers to purportedly 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, a marketing claim that requires FDA authorization. However, FDA has not made that determination.²⁴

²³ 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.”).

²⁴ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, Testimony of James Monsees, Co-founder and Chief Product Officer, JUUL Labs, Inc., *Hearing on Examining JUUL's Role in*

JUUL has refused to provide the Subcommittee with documents and information about the Enterprise Markets Team. JUUL has indicated that, while the Team may be scaled back, JUUL's Enterprise Markets Team still exists.

Question 36. Describe the functions of JUUL's Enterprise Markets Team?

- a. When was the team formed?
- b. How many people are members of the team? Identify each person, their title, and brief description of their role?
- c. Identify all companies and organizations the team has approached with a proposal?
- d. For each company and organization identified in response to part (c) above, indicate the status of the proposal (e.g., proposal rejected, contract formed, still under contract)?
- e. Describe what the team proposes to the companies and organizations it approaches?
- f. What does the team say about JUUL and smoking cessation?
- g. What does the team say about JUUL's health implications?
- h. Provide all materials and presentations the team uses in communicating with companies and organizations.

Response:

Enterprise Markets was focused on identifying and reaching out to organizations and companies that might be interested in partnering with JLI. The team was led by Doug Roberts. Between October 2018 (when Enterprise Markets was established) and August 2019, the Enterprise Markets team reached out to a number of companies and organizations. Most of these outreach efforts were related to discussions with organizations and companies regarding potential switching programs for members or employees of the organization or company that desired to move away from combustible cigarette use. As proposed, the switching programs would include product discounts to enrollees during the 90-day program period and the collection of participant data at certain intervals in the program. In their discussions with third parties, Enterprise Markets presented JUUL as a product that could be used by current smokers to switch away from combustible cigarettes.

Portions of the Enterprise Markets team were dissolved in August 2019.

E. JUUL is Lobbying in 48 States

JUUL has lobbied in 48 states—every U.S. state except Vermont and Missouri. While JUUL's recent strategy at the federal level has been to try to avoid negative press attention, it has worked behind the scenes against public health initiatives at the state and local level. For

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>).

example, JUUL spent more than \$4.5 million fighting an e-cigarette sales ban in San Francisco and hundreds of thousands opposing a statewide flavor ban in California.²⁵

Question 40. Identify any U.S. states in which you have not engaged lobbyists.

Response:

JLI has not engaged lobbyists in Missouri or Vermont.

F. JUUL Continues to Market to Children Outside of the United States

When the tobacco industry faced restrictive laws in the United States, it stepped up marketing its products in countries without similar restrictions. JUUL appears to be following the same approach.

JUUL has been forced to make some changes to keep its products away from children in the United States. The Subcommittee asked whether JUUL has carried over those changes to countries where they were not required. JUUL indicated that it has not. Instead, JUUL indicated that it follows the purchasing age laws in those countries—the bare minimum.

Question 19. JUUL states that it is committed to combating youth use of vapor products and claims that it has taken a number of actions in the U.S. including restricting flavors in retail outlets, enhancing online controls on the sales, and exiting social media. Has JUUL implemented identical actions and policies to combat youth use in all countries in which it sells its products? If not, outline all differences in such policies in each country in which JUUL is sold and the rationale for the policy differences?

Response:

JLI has implemented policies to require that retailers in all countries in which JLI sells its products abide by the legal age to purchase e-cigarettes. In markets without a legal age to purchase e-cigarettes, JLI has implemented policies to require that retailers abide by the legal age to purchase combustible cigarettes.

G. JUUL's Vaping Products Do Not Use American-Grown Tobacco, and Its Foreign Tobacco is Also Mostly Processed Outside of the United States

None of the tobacco used in the creation of JUUL's e-liquids is grown in America. Instead, JUUL uses only tobacco grown overseas. Two thirds of the final nicotine production from the foreign tobacco occurs overseas—in Switzerland, Ireland, and India.

²⁵ *JUUL Threw Millions of Dollars at Washington. It Hasn't Bought Much*, Politico (Sept. 11, 2019) (online at www.politico.com/story/2019/09/11/juul-vaping-lobbying-washington-1491029).

Question 9. From what countries is the tobacco used for the nicotine for your JUULpods sourced? What percentage is U.S.-grown tobacco? From which states? What percentage of the U.S.-grown tobacco is from each state? Please provide invoices or other documentation.

Response:

The tobacco grown for nicotine JUULpods today is sourced 100% out of India. Final production of United States Pharmacopeia nicotine occurs in Switzerland, Ireland, India and the U.S. Roughly one-third of the final nicotine production occurs in North Carolina. JLI currently works with several different suppliers.

ATTACHMENT A

RESPONSES OF JUUL LABS, INC. TO QUESTIONS FOR THE RECORD

JULY 25, 2019 HEARING BEFORE
HOUSE COMMITTEE ON OVERSIGHT AND REFORM
SUBCOMMITTEE ON ECONOMIC AND CONSUMER POLICY
EXAMINING JUUL'S ROLE IN THE YOUTH NICOTINE EPIDEMIC: PART II

The Honorable Raja Krishnamoorthi

Question 1. JUUL's San Francisco ballot initiative, "An Act to Prevent Youth Use of Vapor Products," includes a provision (Section 19N.5-6A) that would preempt all laws related to vaping, including San Francisco's ban on all flavored nicotine products.

- a. Please answer yes or no. Does JUUL support a repeal of San Francisco's ban on flavored nicotine and tobacco products?**
- b. How much has JUUL paid to the Coalition for Reasonable Vaping, the Ballot Measure Committee responsible for including the preemption clause?**
- c. Would the ballot initiative repeal or undo any previous laws or regulations related to tobacco products?**
 - i. Which previous San Francisco laws or regulations related to tobacco products would it repeal or undo?**

Response:

No, JLI does not and did not support a repeal of San Francisco's ban on flavored nicotine and tobacco products. The initiative addressed only electronic nicotine delivery systems ("ENDS") products and would not have repealed any previous laws or regulations on tobacco products, other than San Francisco's 2019 ban on all ENDS products that require premarket review, but do not have a premarket review order under 21 U.S.C. § 387j(c)(1)(A)(i), while leaving combustible cigarettes available. In addition, as part of an ongoing review of the Company's policies and practices, we ceased active support of Prop C in September 2019. JLI believes FDA's PMTA process and its "appropriate for the protection of the public health" standard are the best ways to assess the role these products can play in helping adult smokers move away from combustible cigarettes while also being kept out of the hands of those underage.

Question 2. During the July 25th hearing, to the question of why JUUL needed student participant data from Baltimore's Freedom and Democracy School, Ms. Gould said that "I am not aware of the details of that so I would have to get back to you."

- a. Did JUUL request or receive student participant data or information from the Freedom and Democracy School?**
- b. What categories of data did JUUL request or receive from the Freedom and Democracy School?**
- c. For each category identified in item (b) above, for how many student participants was the category of data collected or received?**
- d. What are the ages of each student participant about whom JUUL collected or received data?**
- e. What is your retention policy on such data?**

- f. For what purposes does JUUL use the data?**
- g. Identify any person or entity with which JUUL has shared the data?**
- h. Has JUUL's marketing team had access to the data?**
- i. Pastor Cecil Gray led, or leads, Freedom and Democracy school. Did JUUL pay any other organization, church, school or camp associated with or led by Pastor Cecil Gray? Please provide all invoices, contracts, or financial transactions related to JUUL's partnership with any organization, church, or camp associated with or led by Pastor Cecil Gray.**

Response:

In late 2017, JLI embarked on an effort designed to work with and equip schools to educate students about the harms of nicotine use. To that end, JLI created its Education and Youth Prevention Department ("EYP") in order to combat underage use of ENDS products. Throughout its lifespan, the focus and intent of EYP never wavered from a commitment to preventing youth use, including by developing an anti-vaping curriculum and offering that curriculum to schools. JLI reached out to schools – not youth – working with them to develop effective youth prevention programs. While EYP did work with some schools, it failed to meet its initial expectations. EYP ended up partnering with only a few schools.

JLI entered into agreements with one school and two school districts, including Freedom & Democracy Charter School, for the purpose of supporting the implementation of a pilot program to educate, prevent and/or discourage students from using e-cigarettes and educate students about the dangers of nicotine. Under the agreements, the school would keep track of the number of students who attended each session and provide that information to the JLI consultants, along with evaluation and assessment forms that accompanied the curriculum. The purpose was to track the efficacy of the program. No personally identifiable data was to be collected. Because Freedom & Democracy School never implemented the proposed anti-vaping curriculum, no data was ever collected or shared with JLI. On August 21, 2018, each agreement was amended to make clear that the Company would not be providing any curriculum.

JLI significantly scaled back its youth prevention outreach programs in June 2018 after its efforts were criticized as mimicking Big Tobacco and after receiving requests that it scale back the programs. JLI stopped proactive outreach to schools for youth prevention efforts in June 2018. Between June and September, JLI was a passive resource, only responding to schools that affirmatively reached out to JLI for help combatting the youth vaping problem. EYP was fully dissolved in September 2018.

JLI continues to believe that educating youth is important in stopping youth usage of nicotine products. JLI has donated millions of dollars towards that effort and is currently evaluating what it can do to effectively support youth prevention efforts going forward.

Question 3. During the July 25th hearing, Ms. Gould said that JUUL had discontinued all school programs and educational initiatives. However, it appears that the Black Mental Health Alliance in Baltimore is still conducting its Youth Tobacco Initiative for teenagers.

- a. Is JUUL’s partnership with the Black Mental Health Alliance still active?**
- b. Did JUUL create, or participate in the development of the curriculum for Black Mental Health Alliance’s Youth Tobacco Initiative?**
- c. Is JUUL continuing to fund the Black Mental Health Alliance’s Youth Tobacco Initiative?**
- d. Did JUUL request or receive data or information from the Black Mental Health Alliance on the teenagers participating in this program?**
- e. What categories of data did JUUL request or receive from the Black Mental Health Alliance?**
- f. For each category identified in item (e) above, for how many participants was the category of data collected or received?**
- g. What are the ages of each participant about whom JUUL collected or received data?**
- h. What is your retention policy on such data?**
- i. For what purposes does JUUL use the data?**
- j. Identify any person or entity with which JUUL has shared the data?**
- k. Has JUUL’s marketing team had access to the data?**

Response:

JLI provided two grants to the Black Mental Health Alliance (“BMHA”) as part of its community engagement efforts. JLI did not create or participate in the development of the curriculum for BMHA’s Youth Tobacco Initiative. JLI neither requested nor received data from BMHA and its partnership with BMHA is no longer active.

Question 4. Did JUUL request or receive data or information from any other youth in connection with any of JUUL’s other youth-oriented programming?

- a. What categories of data did JUUL request or receive? From which sources?**
- b. For each category identified in item (a) above, for how many participants was the category of data collected or received?**
- c. What are the ages of each student participant about whom JUUL collected or received data?**
- d. What is your retention policy on such data?**
- e. For what purposes does JUUL use the data?**
- f. Identify any person or entity with which JUUL has shared the data?**
- g. Has JUUL’s marketing team had access to the data?**

Response:

JLI entered into agreements with one school and two school districts, including the Agua Fria Union High School District, for the purpose of supporting the implementation of a pilot program to educate, prevent, and/or discourage students from using e-cigarettes. Under the agreements, the schools were to keep track of the aggregate number of students who attended each session and provide that information to the JLI consultants, along with anonymous evaluation and

assessment forms that accompanied the curriculum. The purpose of this provision was to track the efficacy of the program, and no personally identifiable data was to be collected.

Agua Fria was the only school district to implement the proposed anti-vaping curriculum, in a “Transition to High School” summer pilot program for incoming freshmen. In doing so, the school collected the Course Evaluation & Feedback surveys that accompanied the three-hour lesson plan from 180 student participants. The evaluation included instructions at the top, stating: “Please do not put your name or any other personally identifiable information on this form. Your responses are completely anonymous.” The questions were designed to assess the effectiveness of the curriculum and the results were only shared internally within the Education and Youth Prevention team to inform the curriculum. The results were not shared with the Marketing department, nor were they used for marketing purposes.

JLI’s Education and Youth Prevention Department was dissolved in September 2018.

Question 5. During the July 25th hearing, questions about JUUL’s activities in Baltimore were raised three times, related specifically to a summer camp, school visits, and LifeSkills Inc.

- a. List all events, including policy and health events, focus groups, parties, marketing campaigns or meetings JUUL has held and/or funded in Baltimore.**
- b. Did JUUL conduct any focus groups in Baltimore that included participants under the age of 21?**
 - i. Provide all demographic information on the participants in such focus groups, including age and race.**
 - ii. Did JUUL pay or reward any such focus group participants with parties or BBQs?**
- c. Identify all groups JUUL has worked with in Baltimore outside of its core business functions of manufacturing, distribution, and sales, including any civic organization such as the NAACP or National Action Network.**
 - i. For each such group, provide documentation of all JUUL donations, gifts, invoices, and/or financial transactions.**
- d. Did JUUL attend any policy conventions or events hosted by organizations such as the National Action Network or any other organization that represent the interests of African Americans?**
 - i. Did JUUL request or receive any data or contact information on the individuals that participated in these conventions?**
 - ii. Did JUUL send any emails or make any contact with individuals listed in the data received?**
 - iii. Was the information shared or discussed with anyone on JUUL’s marketing team?**

Response:

JLI has held, funded, and participated in a variety of events in Baltimore in its efforts to significantly displace combustible cigarettes. For example, JLI employees and consultants met with public officials and community leaders to discuss a wide variety of issues; JLI has provided

grants and sponsorships to some Baltimore-based organizations; and the Company conducted focus groups.

JLI provided grants or other funding to four Baltimore-based organizations: Black Mental Health Alliance; LifeSkills, Inc.; the Northwood Appold Church; and the New Vision House of Hope.

JLI's Strategic Partnerships team has supported a diverse range of organizations across an ideological spectrum that are committed to helping the world's one billion adult smokers transition from combustible cigarettes. Strategic Partnerships does attend some JLI-sponsored events, but JLI does not collect information from attendees or share it with the marketing or sales teams.

Question 6. Reports indicate that JUUL has taken steps to change the wicks in certain of its products from silica to cotton in the UK, Switzerland, and Israel. Describe all contemplated changes to your product's wick, the reason(s) for such changes, the impact such changes would have on nicotine delivery, the geographic locations where JUUL has considered offering such products and/or will offer such products, and the status of the change including whether the altered product could be offered today and timelines for when it will be offered?

Response:

The wick is an important component of our pod system. It moves liquid from the reservoir portion of the pod into the atomizer (heated) area where vaporization occurs. We select materials that are non-toxic, inert, absorbent, resistant to heat and e-liquid, provide consistent liquid delivery, and are able to tolerate heating over the course of the pod's use. These properties are important to the consistent functioning of our product and go through extensive testing to ensure safety and consistent function.

We launched the J2 pod earlier this year in select foreign markets to help improve our ability to convert adult smokers. We have evaluated a number of materials for suitability to our wick application. These include stainless steel, hemp fiber, Kevlar, and Nomex. These are all high temperature wicking materials used in various related industries.

Our goal when evaluating a new wick material is to ensure a consistent product performance and experience by the user. Cotton, due to its material properties, conducts e-liquid differently than silica, and therefore—in general—results in more consistent vapor delivery from puff to puff. Neither material has any chemical interaction with the e-liquid or nicotine, but simply moves liquid to the heated area of the pod. In addition, J1 and J2 pods are used with the same device in European markets.

Question 7. Describe all changes to your product that JUUL has considered since January 1, 2017, specifying the reason for each considered change, the impact each change would have had on nicotine delivery, the geographic location where JUUL has considered offering the changed product or has offered the product, and the status of each change including whether the changed product could be offered today and timelines for when it will be offered?

Response:

Please see the responses to Questions 6 and 23. Information regarding contemplated changes to our product is competitively sensitive.

Question 8. Where are JUUL devices and JUULpods assembled, and where are each component part for them manufactured before being assembled? Please list the parts and countries.

Response:

JLI uses two suppliers for its e-liquid, both of which are based in the United States (“the e-liquid suppliers”). The e-liquid suppliers use facilities, labor, and equipment located in the United States to formulate the e-liquid in the United States. One operates out of North Carolina and the other operates in Maryland. The overall manufacturing processes are unique to the JUUL system, and the formulas and chemistries for the e-liquids for the JUUL system are proprietary to JLI.

JLI sources empty pods from third-party contract manufacturers in China. These suppliers use designs and manufacturing processes developed by JLI in the United States, and which are customized and proprietary to JLI. The contract manufacturers receive and inspect the pod materials, then install a wick and coil, electrical contacts, a gasket, an absorbent pad, a mouthpiece, and a cap. Then they package the empty pods and ship them to the United States.

To fill empty pods with e-liquid, JLI relies on three domestic contract manufacturers. These contract manufacturers use designs and manufacturing processes developed by JLI in the United States, and which are customized and proprietary to JLI. Each of these U.S. contract manufacturers receives the empty pods, e-liquid, and packaging material. As directed by JLI, the contract manufacturer then conducts quality control analysis on the empty pods and the e-liquid.

The rechargeable JUUL devices are manufactured by two suppliers in China. These suppliers use designs and manufacturing processes developed by JLI in the United States, and which are customized and proprietary to JLI. The JUUL devices are imported into the United States for packaging, along with a USB charger. Some of the JUUL devices are sent to U.S. based contract manufacturers to be combined with a variety of JUULpods to make a JUUL starter kit. The rest of the JUUL devices are sent to a logistics company for packaging and distribution to be sold as standalone devices (i.e., a “JUUL basic kit”).

Question 9. From what countries is the tobacco used for the nicotine for your JUULpods sourced? What percentage is U.S.-grown tobacco? From which states? What percentage of the U.S.-grown tobacco is from each state? Please provide invoices or other documentation.

Response:

The tobacco grown for nicotine JUULpods today is sourced 100% out of India. Final production of United States Pharmacopeia nicotine occurs in Switzerland, Ireland, India and the

U.S. Roughly one-third of the final nicotine production occurs in North Carolina. JLI currently works with several different suppliers.

Question 10. What is the country of origin for the nicotine used in the e-liquid in JUULpods? Please provide proportions if from multiple locations.

Response:

Please see the response to Question 9.

Question 11. Does JUUL flag inappropriate social media posts on the major platforms (Facebook, Twitter, Instagram, Snapchat) or others?

- a. If so, how does the company do so? Please provide documentation of these actions.
- b. When did JUUL start this process?
- c. A former JUUL senior manager was quoted in the New York Times saying that after the product launched in 2015, JUUL knew that teenagers were posting images of themselves using the products on social media. Why did JUUL wait years to take action, instead of doing so when it first noticed the posts in 2015?

Response:

JLI's Brand Protection department regularly monitors social media and other Internet sources for infringing content, including content that is youth oriented. Utilizing third-party monitoring services to identify illicit or underage promotion, JLI has reported thousands of listings and accounts for removal. In 2019 alone, JLI has provided information to social media companies that led to more than 45,000 social media posts and almost 2,000 accounts being removed, eliminating routes of improper messaging to more than 1,500,000 followers.

JLI began flagging inappropriate social media posts in September 2017 due to posters impersonating JLI, and/or selling or giving away JUUL products.

Question 12. How does JUUL enforce its policy to prohibit the sale of non-mint and non-menthol JUULpod flavors in retail stores? What penalties are imposed for the retailer? How many retailers have violated the policy, and what percentage of JUUL retailers does that represent?

Response:

JLI ceased distribution of non-tobacco and non-menthol-based flavors to distributors and retailers through its wholesale and retail distribution system in November 2018 and Mint JUULpods in November 2019. Counterfeit and illegal JUUL-compatible pods have tried to fill the gap in the market left by our products. JLI has taken aggressive steps against manufacturers of these counterfeit and illegal compatible pods, including defending its intellectual property by commencing actions in front of the International Trade Commission and providing information to FDA on these illegal products to support enforcement.

Question 13. If emails were exchanged as early as June 5, 2018 about the similarity between JUUL's "YP programs vs. those from Big Tobacco" and mentioning "current executive concerns & discussion re: discontinuing our work w/schools," why did it take until September 2018 to end such programs, as Ashley Gould testified in the hearing?

Response:

JLI significantly scaled back its youth prevention outreach programs in June 2018 after its efforts were criticized as mimicking Big Tobacco and after receiving requests that it scale back the programs. JLI stopped proactive outreach to schools for youth prevention efforts in June 2018. Between June and September, JLI was a passive resource, only responding to schools that affirmatively reached out to JLI for help combatting the youth vaping problem. EYP was fully dissolved in September 2018.

JLI continues to believe that educating youth is important in stopping youth usage of nicotine products. JLI has donated millions of dollars towards that effort and is currently evaluating what it can do to effectively support youth prevention efforts going forward.

Question 14. What evidence does JUUL have, for each of the flavors it sells, to show that the flavor is necessary to help smokers quit smoking cigarettes? What evidence does JUUL have, for each of the flavors that were rushed to the market leading up to the August 8, 2016 deadline, to show that the flavor is necessary to help smokers quit smoking cigarettes?

Response:

JLI is dedicated to conducting robust scientific research of its products. As JLI works to fulfill its mission to help convert adult smokers from combustible cigarettes, JLI is committed to both conducting and supporting well-designed nonclinical, clinical, and behavioral research examining the public health impact of its products. Under Section 910(b) of the Tobacco Control Act, FDA will evaluate whether the scientific data demonstrates that a product is appropriate for the protection of public health. Factors that it considers include risks and benefits to the population as a whole and whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available.

JLI understands that there are many questions about the health impact of ENDS products, and JLI is committed to contributing to the body of global public health research on these topics. To that end, JLI has built a scientific research program to assess the harm-reduction potential of JUUL products, including their impact on the individual user, their ability to switch adult smokers from combustible cigarettes, and the net population impact on public health as a whole.

JLI's behavioral research examines what adult smokers do in the real world when using JUUL products. JLI seeks to answer the following questions: What are the rates at which smokers switch completely from combustible cigarettes; who are the smokers that are most successfully able to switch and who are not; and what attributes drive switching? JLI collects this information through research surveys of JUUL product users, approved or authorized by

Institutional Review Boards that ensure the ethical conduct of the research, and JLI currently has over 100,000 participants enrolled in behavioral studies around the world. JLI believes this is the largest behavioral research program in the world dedicated to the study of ENDS products, and JLI plans to further grow the program with tens of thousands of more participants by year end. Results from JLI's most recent studies are promising and find that approximately half of all adult smokers demonstrate 30-day abstinence from combustible cigarettes at follow-up assessments after just three months of JUUL product use.

As described and included in JLI's August 12, 2019 letter to the Subcommittee, please find below a non-exhaustive list of relevant behavioral studies:

Factors Associated with Past 30-day Abstinence from Cigarette Smoking in a Non-Probabilistic Sample of 15,456 Adult Established Current Smokers in the United States Who Used JUUL Vapor Products for Three Months¹

A behavioral study published in the *Harm Reduction Journal* examined the impact of JUUL product use, the critical role of JUULpod flavors, and other factors in predicting abstinence from cigarette smoking among new users of JUUL products. The study examined past 30-day smoking abstinence rates among 15,456 adult smokers aged 21+ years after three months of using JUUL products. Abstinence was defined as “no smoking (not even a puff)” of a combustible cigarette in the past 30 days before the survey. Results showed that 47.1% of study participants who completed the three-month follow-up assessment had completely abstained from smoking for the previous 30 days. This is a remarkably high rate of conversion from the use of combustible cigarettes.

Factors Associated with Past 30-day Abstinence from Cigarette Smoking in a Non-Probabilistic Sample of 15,456 Adult Established Current Smokers in the United States Who Used JUUL Vapor Products for Six Months²

As a follow-up to the behavioral study published in the *Harm Reduction Journal*, this study examined past 30-day smoking abstinence rates among the 15,456 adult smokers aged 21+ years after six months of using JUUL products. Abstinence was defined as “no smoking (not even a puff)” of a combustible cigarette in the past 30 days before the survey.

Past 30-day smoking abstinence at six months was 54.0% among those who completed the six-month assessment, up approximately 7% from the three-month assessment. Similar to the findings among adult smokers at three months, more frequent use of the JUUL system and primary use of JUULpods in characterizing flavors, particularly Mint and Mango, appear to be important to new JUUL product users' chances of abstaining from cigarettes. Primary users of these flavors

¹ Russell, Christopher, et al., *Factors Associated with Past 30-day Abstinence from Cigarette Smoking in a Non-Probabilistic Sample of 15,456 Adult Established Current Smokers in the United States Who Used JUUL Vapor Products for Three Months*, Harm Reduction J., 2019.

² Russell, Christopher, et al., *Factors Associated with Past 30-day Abstinence from Cigarette Smoking in a Non-Probabilistic Sample of 15,456 Adult Established Current Smokers in the United States Who Used JUUL Vapor Products for Six Months*, Harm Reduction J., (In Press.)

had between 46–52% greater odds of abstaining from smoking at six months as compared to those using only tobacco flavors.

Question 15. What does JUUL mean by the term “switch” in its advertising? In JUUL’s usage, would it be considered a “switch” if a cigarette smoker stops smoking cigarettes, starts using JUUL, and continues to use JUUL indefinitely?

Response:

As part of our review of policies and practices, in September 2019, JLI suspended all broadcast (e.g., TV and radio), print, and digital product advertising in the U.S. Prior to this time, the Company ran a marketing campaign in 2019 with the tag line “Make the Switch” because the JUUL system was designed to help adult smokers switch from combustible cigarettes to an alternative nicotine delivery system and is not intended for the cure or treatment of nicotine addiction (e.g., cessation), prevention of nicotine addiction relapse, or relief of nicotine withdrawal symptoms. Switching is not another word for cessation; they mean two very different things. Switching involves continuing to consume nicotine but from a different device, while cessation is about getting users to eliminate their nicotine consumption altogether. Moreover, FDA defines the scope of smoking-cessation medications as treating dependence by reducing the symptoms of going without nicotine. JUUL products are switching products; JUULpods contain nicotine derived from tobacco and are intended to switch adult smokers from one nicotine delivery system to another. JUUL products are not cessation products and that is clear in our marketing and communications. Moreover, this is a distinction recognized in FDA guidance.³ Further, consistent with federal law, all of our “Make the Switch” advertisements contained the following language: “WARNING. This product contains nicotine. Nicotine is an addictive chemical.” That same warning also appeared on JUUL packaging, and the JUULpod packaging identifies the amount of nicotine in the product.

Question 16. Provide all documents and communications regarding the development, design and marketing of JUUL’s “switch” advertising strategy, including the ads using the phrase “make the switch” and featuring testimonials of smokers who have switched to JUUL.

Response:

Documents responsive to this request were produced to the Subcommittee on June 28, 2019.

Question 17. Provide the research basis for the “Moving Beyond” program.

³ See, e.g., 21 C.F.R. § 1100.5(a) (reflecting FDA’s conclusion that “smoking cessation” is tied to “cure or treatment of nicotine addiction”); 82 Fed. Reg. 2193, 2200 (Jan. 9, 2017) (“FDA does not consider claims suggesting that a tobacco product provides an alternative way of obtaining the effects of nicotine, or that a tobacco product will provide the same effects as another tobacco product ... to bring a tobacco product within its drug and device authority”); “Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry”, U.S. Dep’t of Health and Human Servs., Food and Drug Admin., Ctr. for Tobacco Products, June 2019, at 36 (distinguishing between “switching behavior,” “cessation” and other types of smoking-related behavior, such as “dual use” of both cigarettes and ENDS products).

Response:

The authors of the Moving Beyond curriculum were Bruce Harter and Wendell Greer, the former Superintendent and Associate Superintendent of the West Contra Costa Unified School District, respectively. Both Harter and Greer started their careers as educators in the classroom. They created the Moving Beyond curriculum from reputable, public online sources, including a tobacco prevention curriculum developed by Dr. Bonnie Halpern-Fischer, a developmental psychologist at Stanford University. Julie Henderson, JLI Director of Education and Youth Prevention, also assisted in the development of the curriculum.

Question 18. What are the monthly sales amounts for each of JUUL's flavors, at each nicotine level, from January 1, 2017 to present?

Response:

The information requested is competitively sensitive, but we are happy to discuss the question with Subcommittee staff in a confidential setting.

Question 19. JUUL states that it is committed to combating youth use of vapor products and claims that it has taken a number of actions in the U.S. including restricting flavors in retail outlets, enhancing online controls on the sales, and exiting social media. Has JUUL implemented identical actions and policies to combat youth use in all countries in which it sells its products? If not, outline all differences in such policies in each country in which JUUL is sold and the rationale for the policy differences?

Response:

JLI has implemented policies to require that retailers in all countries in which JLI sells its products abide by the legal age to purchase e-cigarettes. In markets without a legal age to purchase e-cigarettes, JLI has implemented policies to require that retailers abide by the legal age to purchase combustible cigarettes.

Question 20. Identify all legal proceedings in foreign jurisdictions in which JUUL is participating, or has participated since January 1, 2013. Provide copies of all complaints, pleadings, and documents filed by, or on behalf of, JUUL in any legal forum in any foreign jurisdiction where JUUL is challenging existing or proposed government policies, regulations or legislation.

Response:

JLI is not a party to a foreign judicial proceeding challenging existing or proposed government policies, regulations, or legislation.

Question 21. Provide copies of all contracts between JUUL and any third party for marketing and/or advertising work occurring outside of the United States and identify all payments

made in regard to these activities from January 1, 2013 to present. Marketing and/or advertising work includes, but is not limited to, event marketing, direct consumer engagement (e.g., use of brand ambassadors, pop-up “JUUL bars”), outdoor advertising, point of sale advertising, corporate social responsibility efforts, vaping prevention education, print media, and digital media.

Response:

JLI works in conformance with the legal requirements and cultural norms of all societies in which it operates. JLI partners principally with two marketing agencies for its international advertising: Gutenberg and OMD. Gutenberg adapts JLI’s United States creative for JLI’s international markets by translating the United States materials and ensuring that the translations accord with local laws and regulations. OMD is an international media buying agency, which JLI uses for purchasing creative in its international markets. OMD works with many local, third-party marketing vendors worldwide to purchase creative for JLI advertisements.

Question 22. On August 30, 2019, the Center for Disease Control and Prevention posted an Investigation Notice entitled “Outbreak of Severe Pulmonary Disease Associated with Using E-cigarette Products.” As of September 6, 2019, CDC had identified over 450 possible cases of lung illness associated with the use of e-cigarette products in 33 states and 1 U.S. territory.

- a. What has JUUL’s involvement been in the investigation?**
- b. How many of the 450 plus possible cases involve an individual who reported using a JUUL product and/or device?**

Response:

JLI has been closely monitoring this situation, while federal and state health authorities have conducted their comprehensive investigations into vaping-related lung illnesses. In August 2019, JLI submitted a letter to the CDC to express its support of the ongoing investigation and to offer assistance to the CDC in all efforts to better assess and address the adverse event profile of ENDS products. In December 2019, the CDC announced that its laboratory data shows that vitamin E acetate, an additive in some THC-containing vaping products, is closely associated with EVALI. The CDC identified Vitamin E acetate in bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) from 48 of the 51 EVALI patients, but not in the BAL fluid from the healthy comparison group.⁴

JUUL product ingredients do not include THC, any compound derived from cannabis, or vitamin E compounds like those found in cannabis-related products.⁵ JLI appreciates the work of the CDC, FDA, and other public health authorities in investigating this serious issue, as well as continuing to update the public on the status of their investigations.

⁴ *New Cases in Outbreak of E-cigarette, or Vaping, Product Use – Associated Lung Injury (EVALI) On the Decline*, Centers for Disease Control and Prevention, Dec. 20, 2019, <https://www.cdc.gov/media/releases/2019/p1220-cases-EVALI.html>.

⁵ *Consumer Update: 9/19*, Sept. 19, 2019, <https://newsroom.juul.com/consumer-update-9-19/>.

Question 23. JUUL is currently testing a connected device, the JUUL C1, in Canada.

- a. When did JUUL first have access to the technology in the JUUL C1?**
- b. How many JUUL C1 devices do you plan to sell in Canada, and over what time period?**
- c. How long will your JUUL C1 pilot last?**
- d. Describe all plans to offer the same, or similar, connected devices in the U.S. and elsewhere, and describe the scope and timing of those offerings?**
- e. JUUL CEO, Kevin Burns, has indicated that the connected devices being tested are a starting point for JUUL to have a much more intimate relationship with customers and to help coach them to manage their nicotine uptake.**
 - i. How does JUUL plan to use the connected devices to have “a much more intimate relationship” with customers? Provide all documents demonstrating these plans.**
 - ii. How does JUUL plan to help “coach” customers to manage their nicotine uptake? Provide all documents demonstrating these plans.**
- f. Provide any research or evidence**

Response:

The engineering development of the JUUL C1 began in September 2017, and the JUUL C1 pilot launched in July 2019. The C1 pilots ended in Canada and the UK on July 29, 2019, and September 23, 2019, respectively, and JLI currently is selling the JUUL C1 in Canada and the UK. The C1 offers features that allow people to monitor their usage, provide access restrictions at the user level to prevent unauthorized use, and find their JUUL device if it is lost.

Question 24. Identify all Native American tribes JUUL approached with any offer. For each tribe:

- a. What did JUUL propose?**
- b. Did the proposal involve JUUL being used for smoking cessation?**
- c. Did the proposal involve tribal health professionals being involved in distribution of the product?**
- d. What is the status of the proposal (e.g., proposal rejected, contract formed, still under contract)?**
- e. How much did JUUL offer in money and other things of value?**
- f. How much did JUUL actually pay in money and other things of value?**
- g. What data was, or was to be, collected from participants? Was such data actually collected? For how many participants?**
- h. For what purposes does JUUL use the data?**
- i. Identify any person or entity with which JUUL has shared the data?**
- j. Has JUUL’s marketing team had access to the data?**

Response:

Between December 2018 and February 2019, JLI met with leadership from five tribes (the Moapa Band of the Paiute Tribe, the Lummi Nation⁶, the Cheyenne River Sioux Tribe, the

⁶ JLI understands that Chairman Ross Cline of the Nooksack Tribe also attended this meeting.

S’Klallam Tribe, and the Chickasaw Nation) to discuss the concept of a switching program for individuals aged 21+ who were current smokers and sought to switch away from using combustible cigarettes. No switching programs were entered into; JLI terminated this initiative in Spring 2019 before any contracts for switching programs were presented to or signed by these Native American tribes. No data was collected from tribal members, and JLI did not pay any money to tribes to support switching programs.

During these introductory meetings, JLI described the general concept of a switching program, which would include the availability of discounted product to enrollees during the 90-day program period and the collection of participant data at certain intervals in the program. JLI ceased outreach to Native American tribes regarding the switching programs before there was a concrete proposal covering the data metrics that would be tracked for participants, the price of the discounted product, or what additional support JLI would provide.

JLI also had contact with representatives from other tribes, and JLI understands that the topic of switching programs arose in some of these conversations. To JLI’s understanding, these preliminary discussions did not advance to organized meetings to present a switching program proposal.

In addition, JLI had conversations with other tribes to discuss sales of JUUL products in casinos or convenience stores owned by tribes. During in-person meetings to discuss casino sales with two of these tribes (the Muckleshoot Indian Tribe and the Kalispel Tribe), the topic of a possible switching program for casino employees or tribal members was also raised. No agreements were entered into.

Question 25. During the hearing, Mr. Monsees stated:

“So there have been some conversations that the FDA has taken up with us, where they provided some guidance on, in particular, how to run surveys. Now understand, when we want to better understand the usage issue, it is very difficult for us to study youth directly. So one of the ways in which I think we have had the most valuable or positive relationship with the FDA thus far was just getting guidance from them on how we can better study youth usage.”

Describe all FDA guidance on how JUUL can better study youth usage? Provide all documentation FDA sent you on this topic.

Response:

Before conducting research with youth on the use of ENDS products, including JUUL products, JLI met with FDA’s Center for Tobacco Products (CTP), Office of Science, to discuss study design and approach and to solicit the Agency’s feedback on the appropriateness of conducting such research with a youth population. The goal was to better understand the scope and impact of youth use, including use of JUUL products, as part of our PMTA because FDA requires information regarding the appropriateness of the product for the protection of public health. At that time, JLI was not aware of any other manufacturer conducting research with youth

to support its PMTA. Since then, JLI believes that FDA has made it clear that such research is important to evaluate the net population impact of ENDS products.

As a result of the Agency's feedback and dialogue during the meeting, JLI bifurcated the research into two components: (i) youth prevalence (use of) and (ii) youth perception (e.g., intent to use). The engagement with FDA on youth research included: (1) JLI requesting a meeting with FDA to discuss potential studies; (2) FDA responding to JLI's questions; (3) JLI meeting in person with FDA; (4) JLI receiving the minutes from the meeting with FDA; and (5) JLI's research partner, CSUR, executing the research plan.

JLI presented its proposals to FDA, incorporated FDA's feedback, and then proceeded with the research. The research proposed by JLI was conducted by third parties; JLI did not, and currently does not, have access to the raw data.

Question 26. In JUUL's June 21, 2019 written response to the Subcommittee, you stated that JUUL "does not have a traditional celebrity or influencer program," and identified only 4 individuals that JUUL had engaged as influencers. Documents and testimony presented during the hearing demonstrated that JUUL's June 21 response was inaccurate and/or incomplete. Would you like to revise your answer?

Response:

JLI did not and does not have a traditional (meaning significant and designed as payment for marketing activities) influencer program. JLI has never paid celebrities conditioned on their endorsement of JUUL products. While celebrities and other high-profile individuals have been referred to as "influencers" in certain documents and/or have received free product or product discounts, these were not conditioned on the recipients posting images of JUUL products on social media. Only one celebrity, an actress named Nora Lum (a.k.a. Awkwafina), who was an existing JLI ecommerce customer who talked publicly about switching to JUUL products from combustible cigarettes, has appeared in a user testimonial on JLI's website.

JLI has paid a total of \$8,500 for four individuals to post content related to JUUL products on Instagram and blogs, as follows: (1) JLI paid a total of \$3,500 for two blog posts and four Instagram photographs featuring JUUL from fashion blogger Laura Ellner in November 2017; (2) JLI paid a total of \$2,500 for one blog post and one Instagram photograph from lifestyle and travel blogger Joe Miragliotta in November 2017; (3) JLI paid \$1,000 for one blog post and one Instagram photograph from lifestyle influencer Christina Zayas in November 2017; and (4) JLI paid \$1,500 for one Instagram photograph from lifestyle blogger Christian Bendek in October 2017. In February 2018, JLI paid an additional \$1,000 for Mr. Bendek to share a 2015 Wired Magazine article about JUUL in a link with a photograph on his Facebook page (which appears under his name). These payments represent the only direct compensation paid by the Company to any individuals to post their own JUUL-related content on social media or elsewhere to date.

Additionally, two professional photographers were offered product discounts in exchange for providing JLI with photographs that it could use on its own social media accounts and posting one JUUL-related photograph to Instagram. JLI provided these individuals with a two-page

document describing its content guidelines, including the requirement that any individuals appearing in a photograph with a JUUL device must be over 30 years old. The individuals also were informed that all content was required to comply with JLI's guidelines, and that all content had to be reviewed and approved by JLI before posting. One photographer, Moe Eldawi, thereafter posted three images of JUUL products on his Instagram account, "nikon_photo," (although only one had been requested by JLI). The image selected by JLI and most popular of the three received 31 likes. The other two images received 20 and 27 likes, respectively. Mr. Eldawi was provided discount codes allowing him to purchase one Starter Kit and 20 JUULpod 4-packs at \$1.00 each. The other photographer, Jacob Fischer, did not ultimately post JUUL-product-related content on his Instagram account, but provided the Company with ten photographs of JUUL devices for it to use in exchange for two codes to purchase JUUL Starter Kits for \$1.00 each, and five codes to purchase up to 10 JUULpod 4-pack for \$1.00 each.

Question 27. During the hearing, Congresswoman Pressley referenced a February 2, 2016 JUUL email from Sarah Richardson, the Communications Director to a group, including JUUL's Executive Director of Brand and Product Marketing and the Director of Global Customer Implementation. That email stated:

"Wanted to recap you on our chat this a.m. regarding JUUL's limited SKU messaging, i.e., various nicotine levels, new flavors, bottled juice. Guidelines: (1) For grandfathering purposes we don't want to frame these SKU launches as being a test or being a short-term SKU. Limited launch or limited locations is preferable. Don't want to imply that they are going away. (2) We also don't want to imply anything around timing for expanded availability to protect ourselves, as many may very well not be available by the end of this year."

- a. Why was it important that JUUL not "frame these SKU launches as being a test or being a short-term SKU?"**
- b. How many limited SKU launches did JUUL introduce after this email and how many are still available today?**

Response:

In August 2016, JLI expanded its portfolio to include additional JUULpod flavors, as well as JUULpods in different packaging configurations (e.g., 2-packs in addition to 4-packs). These JUULpod flavors included, among others, Classic Menthol (now Menthol), Classic Tobacco, Mango, and Cool Cucumber (now Cucumber). These four flavors were available in a nicotine strength of 5.0%. Virginia Tobacco and Cool Mint (now Mint) were available in nicotine strengths of 3.0% and 5.0%. These products were sold through a limited number of independent, specialty vape shops during this time period. All JUUL products currently available for purchase were on the market as of August 8, 2016.

During this time, JLI had trouble with its supply chain, leading to shortages in certain flavors. This email was directed at customer service agents who received requests from customers asking about the availability of certain flavors. The Company was unsure of the longevity of its release of these flavors and therefore was unable to give customers definitive answers.

Question 28. During the hearing Mr. Monsees testified that JUUL has “no intention of introducing any new flavors whatsoever until after PMTA takes place.” Does JUUL plan to introduce new flavors through the Premarket Tobacco Product Application (PMTA) process? Describe all plans for introducing new flavors, including the flavors under consideration.

Response:

JLI does not intend to re-introduce any previously marketed flavored JUUL products without prior authorization by FDA, if at all. Moreover, JLI will fully comply with the Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization issued by FDA on January 2, 2020 (the “FDA Flavors Guidance”). For its initial PMTA, which JLI will submit by the required deadline, JLI will include a limited number of JUUL products (tobacco and non-tobacco flavored) with data to support FDA’s determination of whether these products are appropriate for the protection of public health.

Question 29. During the hearing Mr. Monsees testified that the:

“Market has been backfilled by a number of... third-party manufacturers, mainly Chinese fly-by-night companies with little to no manufacturing practice to it. We have raided a number of these facilities proactively, in China....”

- a. Describe what you meant by “raided”?**
- b. Under what authority can JUUL raid another private company in China?**
- c. Describe any partnership with Chinese authorities?**
- d. How many such raids has JUUL conducted?**

Response:

JLI’s Brand Protection team initiated investigations of online sellers and distributors of counterfeit goods in China. Much like it does in the United States, JLI provides investigation results to law enforcement in China, who then conduct their own investigation into the information provided, validate that information, and, if appropriate, execute search warrants. While JLI does not have the authority to conduct raids on its own, JLI’s investigations resulted in Chinese law enforcement carrying out the raids.

JLI does not partner with Chinese authorities. Chinese law enforcement independently reviews cases and makes enforcement decisions.

In 2019, JLI investigations have led to 17 raid actions in China.

Question 30. Has JUUL taken any steps to develop changes to devices to be used in geographic locations that have capped nicotine concentrations in e-liquids (e.g. changes to voltage, wattage, temperature)? Describe all such steps and potential or actual changes.

Response:

Please see the response to Question 6.

Question 31. On July 14, 2019, JUUL sent a letter to the U.S. Trade Representative about the Administration’s tariffs on lithium batteries. That letter stated:

“Imposing a 25 percent duty on JUUL’s portable charging case will indirectly increase the cost 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 the use of tobacco products. Making JUUL’s product cost-prohibitive, may, in turn, lead them to revert to the use of tobacco products, which may increase the cost of health care to consumers as well as U.S. health insurers.”

- a. How is that statement not a claim that your product is a smoking cessation device?**
- b. How is that statement not a claim that your product is healthier than cigarettes?**

Response:

None of the statements in the letter constitutes a “claim” regarding JLI’s product due to the simple fact that the letter itself—sent to an executive agency of the United States government rather than consumers and addressing a matter of federal policy within that agency’s purview—is not a promotional communication. For example, the letter is not directed at consumers and is neither promotional “labeling” nor “advertising” over which FDA has authority, as those terms are defined by statute and interpreted by courts and FDA itself.⁷

Moreover, it is appropriate for JLI to make statements, even in promotional communications, about use of its tobacco product as an alternative source of nicotine, in lieu of one or more other tobacco products. Such statements do not render JLI’s product subject to regulation as a “smoking cessation” product, which is one intended for use to reduce or eliminate use of nicotine altogether. FDA has recognized as much, in explaining when it will regulate a product made or derived from tobacco and intended for human consumption as a drug, device, or combination product. The agency stated: “FDA does not consider claims suggesting that a tobacco product provides an alternative way of obtaining the effects of nicotine, or that a tobacco product will provide the same effects as another tobacco product . . . to bring a tobacco product within its drug and device authority.”⁸

This makes sense given that FDA’s authority to regulate products made from tobacco as drugs/devices is directed, in relevant part, to circumstances where they are intended for “cure, mitigation, treatment or prevention of disease.” Nicotine addiction is a disease, but smoking itself is not. Accordingly, FDA regulates a product made from tobacco as a drug/device only when

⁷ See, e.g., 21 U.S.C. §§ 321(m), 387c(a)(1), 387c(a)(7)(A); *Kordel v. United States*, 335 U.S. 345, 348-351 (1948); 21 C.F.R. § 1.3(a); 81 Fed. Reg. 28974, 29062 (May 10, 2016).

⁸ 82 Fed. Reg. 2193, 2200 (Jan. 9, 2017).

intended for uses tied to alleviating nicotine addiction—i.e., the “cure or treatment of nicotine addiction (e.g., smoking cessation), relapse prevention, or relief of nicotine withdrawal symptoms.”⁹

The letter was consistent with FDA’s policy in this regard, having clearly and explicitly referred to JLI’s product only as an alternative to combustible tobacco products, and not as a tool for reducing or eliminating use of tobacco products entirely. The letter referred to “consumers who are hoping to improve their lives by reducing or eliminating their use of *combustible* tobacco products” and the possibility that tariffs could “lead them to revert to the use of *combustible* tobacco products” (emphases added). This was exclusively focused on use of JLI’s product as an alternative to combustible tobacco products as way of obtaining the effects of nicotine, and neither stated nor implied any utility with respect to eliminating or reducing use of tobacco products as a general category, or with respect to the cure or treatment of nicotine addiction, relapse prevention, or relief of nicotine withdrawal symptoms.¹⁰

Finally, the letter does not constitute a type of communication in which statements about reduced harm or risk are prohibited. In addition to labels, labeling, and advertising, the statute applies to “any action directed to consumers through the media or otherwise, . . . respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.”¹¹ In other words, it applies only to “consumer-directed claims regarding a manufacturer’s specific products.”¹² That is not the case with the letter, which was directed to an executive agency of the United States government and related to a live policy issue of public importance. In view of significant constitutional issues in this kind of scenario, the Sixth Circuit has further made clear that the statute leaves “untouched” the ability of JLI and other tobacco product manufacturers to make “direct comments on public issues.”¹³ That is exactly what JLI did in sending the letter to the U.S. Trade Representative.

Question 32. Did Stanford University send JUUL a cease and desist letter regarding JUUL’s use of content from Dr. Bonnie Halpern-Felsher and/or Stanford University? After JUUL received that letter, what changes did it make to its presentation materials?

Response:

Yes. After receiving the letter, JLI consultants modified the Moving Beyond curriculum to remove all references to Stanford University.

⁹ 21 U.S.C. § 321(g)(1)(B), (h)(2), (rr)(2).

¹⁰ 21 C.F.R. § 1100.5(a).

¹¹ 21 U.S.C. § 387k(b)(2)(A)(iii).

¹² *Disc. Tobacco City & Lottery v. United States*, 674 F.3d 509, 533 (6th Cir. 2012).

¹³ *Id.*

Question 33. Why has JUUL never conducted a clinical trial to prove that its devices help adult smokers quit smoking cigarettes? Please provide all plans and documents related to any such proposed or planned clinical trial.

Response:

As JLI works to fulfill its mission to eliminate combustible cigarettes among adult smokers, JLI is committed to both conducting and supporting well-designed nonclinical, clinical, and behavioral research examining the public health impact of its products. JLI understands that there are many questions about the health impact of ENDS products and is committed to contributing to the body of global public health research on these topics. To that end, JLI has built a robust scientific research program to assess the harm-reduction potential of JUUL products, including their impact on the individual user, their ability to switch adult smokers from combustible cigarettes, and the net-population impact on public health.

It is important to note that the Family Smoking Prevention and Tobacco Control Act was purposefully designed to ensure the quality and transparency of research relating to the health, dependency effects, and other potential risks of new forms of tobacco products like ours. For example, the Act established the PMTA process, which *requires* manufacturers like JLI to establish that their products are appropriate for the protection of public health, and to disclose to the agency the results of research examining the health risks of their products. As part of the PMTA process, FDA has recommended that manufacturers complete a number of nonclinical, clinical, and other studies, and JLI has structured its research program to meet this guidance. Through the PMTA process and broader regulatory framework for tobacco products, FDA is well positioned to assess the regulatory science underpinning all manufacturer submissions, and there are requirements in place to ensure FDA has access to data that are relevant to the public health.

As described in JLI's August 12, 2019 letter to the Subcommittee, we have conducted clinical trials of the health impacts of JUUL products, including *Changes in Biomarkers of Exposure Associated with Switching for 5 Days from Combusted Cigarettes to Nicotine Salt Pod System*¹⁴ and *An Open-Label Clinical Study to Evaluate Selected Constituents in Exhaled Breath and Room Air after the Use of Vapor Products and Conventional Cigarettes under Conditions of Residential, Office and Hospitality Environments*.¹⁵

Question 34. During the hearing, Ms. Gould testified that JUUL stopped distributing certain flavored JUULpods to retail establishments in November of 2018. Yet, flavored JUULpods are still available in many retail stores.

a. How is that possible?

b. In addition to retailers, did JUUL also ensure that distributions of JUULpods to commercial distributors/warehouses/wholesalers also stopped in November 2018?

¹⁴ Jay, Joanna, *et al.*, *Changes in Biomarkers of Exposure Associate with Switching for 5 Days from Combusted Cigarettes to Nicotine Salt Pod System*, Poster presented at Society for Research on Nicotine and Tobacco, San Francisco, CA, Feb. 23, 2019.

¹⁵ Evans, Blair, *et al.*, *An Open-Label Clinical Study to Evaluate Selected Constituents in Exhaled Breath and Room Air after the Use of Vapor Products and Conventional Cigarettes under Conditions of Residential, Office and Hospitality Environments*, Poster presented at Global Forum on Nicotine, June 14, 2019.

c. In November 2018, what volume of flavored JUULpods were in the hands of retailers? Commercial distributors? Warehouses? Wholesalers?

Response:

JLI ceased distribution of its non-tobacco and non-menthol-based flavored JUUL products to all traditional retail outlets and commercial distributors through our wholesale and retail distribution system in November 2018. During the period following November 2018, retail outlets and commercial distributors sold their current stock of NTM-flavored JUULpods until depletion. Because retailers own the product that they previously purchased, and JLI has no contractual right to demand that retailers stop selling the product, retailers sold the product until their inventory depleted.

Since November 2018, counterfeit and illegal JUUL-compatible pods tried to fill the gap in the market left by our products. JLI has taken aggressive steps against manufacturers of these counterfeit and illegal compatible pods, including defending its intellectual property by commencing actions in front of the International Trade Commission and alerting FDA of these illegal products.

JLI has developed a significant and aggressive plan for brand protection. JLI's Brand Protection program consists of five teams: Customs Enforcement, Online Enforcement, Investigations, Intelligence, and Operations. As described below, these teams execute Brand Protection's mandate to investigate all leads related to counterfeit and diverted goods.

The Customs Enforcement team focuses on preventing counterfeit goods from entering countries. The Customs Enforcement team provides training to customs agencies around the world regarding JUUL's logistical footprint. The team acts as a subject matter expert to support customs agents in identification and authentication of goods that are detained. They also supply intelligence to investigators regarding importers and exporters of counterfeit goods.

The Online Enforcement team uses sophisticated third-party web scraping tools to identify potentially infringing listings on e-commerce sites as well as social media platforms. JLI currently monitors over 300 international e-commerce sites and 20 international social media platforms in 20 different languages. The team's key objective is rapid reporting for removal of infringing content or content that violates platform policy. Although e-commerce and social media platforms have the right to refuse requests for removal, JLI's online enforcement team has achieved an approximately 80%+ compliance rate related to content removal. The Online Enforcement team also identifies potential distribution and production operations, which are forwarded to the Investigations team for further review.

The Investigations team oversees all field investigation operations. All regional managers are former law enforcement officers from federal and local agencies. The team conducts regular proactive market surveys to identify retailers, distributors and manufacturers offering counterfeit or diverted goods. Once identified, specific action is taken depending upon whether or not law enforcement in a given region is interested in opening a criminal case. The Investigations team is also responsible for developing intelligence on upstream suppliers of offending retailers and

investigating information provided on importers of counterfeit or diverted goods. In 2019, JLI has conducted hundreds of investigations. JLI has provided hundreds of leads to law enforcement agencies in the U.S. related to sellers of counterfeit and diverted goods.

The Intelligence team aggregates all inbound information from the Investigations, Customs Enforcement and Online Enforcement teams in order to develop intelligence on the most significant players involved in the manufacture, distribution and/or sale of counterfeit and diverted goods. This information assists our investigation and interdiction efforts.

Finally, the Operations team focuses on legal actions, including sending cease and desist requests to individuals and companies found to be offering counterfeit or diverted goods. The Operations team works with JLI's IP litigation team if such individuals or companies are found not to be in compliance with cease and desist requests. The team is also responsible for retention and control of evidence acquired during the course of investigations in support of criminal or civil actions against infringers.

Question 35. Identify and describe all grants JUUL made in relation to youth prevention and/or wellness?

Response:

JLI granted funds to one high school and two high school districts, Freedom & Democracy Charter Schools, Agua Fria Union High School District, and Hinsdale Township High School District, and two other organizations, Richmond Police Activities League and Steve's Camp, in order for the organizations to implement the Moving Beyond curriculum. In August 2018, JLI amended these grant agreements to make clear that the funds were for youth prevention, but that the school or organization could no longer use *Moving Beyond*. Please see the response to Question 4 for additional information. JLI also granted funds to Impact Canine Solutions, the Black Mental Health Alliance, LifeSkills, and Discovery Education for each organization to develop and/or implement its own youth prevention or wellness program independently of JLI.

Question 36. Describe the functions of JUUL's Enterprise Markets Team?

- a. When was the team formed?
- b. How many people are members of the team? Identify each person, their title, and a brief description of their role?
- c. Identify all companies and organizations the team has approached with a proposal?
- d. For each company and organization identified in response to part (c) above, indicate the status of the proposal (e.g., proposal rejected, contract formed, still under contract)?
- e. Describe what the team proposes to the companies and organizations it approaches?
- f. What does the team say about JUUL and smoking cessation?
- g. What does the team say about JUUL's health implications?
- h. Provide all materials and presentations the team uses in communicating with companies and organizations.

Response:

Enterprise Markets was focused on identifying and reaching out to organizations and companies that might be interested in partnering with JLI. The team was led by Doug Roberts. Between October 2018 (when Enterprise Markets was established) and August 2019, the Enterprise Markets team reached out to a number of companies and organizations. Most of these outreach efforts were related to discussions with organizations and companies regarding potential switching programs for members or employees of the organization or company that desired to move away from combustible cigarette use. As proposed, the switching programs would include product discounts to enrollees during the 90-day program period and the collection of participant data at certain intervals in the program. In their discussions with third parties, Enterprise Markets presented JUUL as a product that could be used by current smokers to switch away from combustible cigarettes.

Portions of the Enterprise Markets team were dissolved in August 2019.

Question 37. Does JUUL believe that if it had never sold flavored products there would still be as many underage e-cigarette users as there are today?

Response:

While we are not comfortable speculating in response to hypotheticals, especially in light of the fact that there are numerous other e-cigarette manufacturers, many of which have and continue to sell products in flavors other than tobacco and menthol, JLI's policies, including our October 2019 decision to cease the sale of NTM flavors in the U.S. and our November 2019 decision to cease the sale of Mint JUULpods in the U.S., pending FDA review, reflect our seriousness about these issues and our commitment to earning the trust of our stakeholders. JLI believes FDA's PMTA process and its "appropriate for the protection of the public health" standard are the best ways to assess the role these products can play in helping adult smokers move away from combustible cigarettes while also being kept out of the hands of youth.

Question 38. JUUL told the Cheyenne River Sioux Tribe that its product was healthy, and healthier than cigarettes. Were those claims modified risk claims? If not, explain in detail why they do not constitute modified risk claims. JUUL also proposed that tribal medical professionals prescribe JUUL as a smoking cessation device. Was that a smoking cessation claim? If not, explain in detail why not.

Response:

On January 23, 2019, JLI representatives met with leadership from the Cheyenne River Sioux Tribe (CRST) Council, at a motel owned by the CRST on tribal land. JLI representatives presented a slide deck on a potential switching program for adult tribal members who were smokers. This presentation was not consumer facing; rather, it was directed to the CRST leadership who would have considered whether to adopt the proposed program.

On February 1, 2019, JLI representatives met with CRST leadership and CRST's Health Committee at the CRST Public Health Center on tribal land to discuss the potential switching

program in more detail. During the meeting, JLI representatives again presented a slide deck on a potential switching program for adult tribal members who were smokers.

JLI terminated this initiative in Spring 2019 before any contracts for switching programs were presented to or signed by these Native American tribes. No data was collected from tribal members, and JLI did not pay any money to tribes to support switching programs.

JLI's representatives' presentations do not run afoul of the Tobacco Control Act for several reasons: (1) the materials were presented to tribal leaders in their capacity as tribal decision-makers, not consumers, and therefore were neither labels, labeling, nor advertising of JUUL products; (2) the materials were non-promotional in nature and focused primarily on JUUL products as a switching device, which FDA explicitly allows, so long as the materials do not suggest use to help cure or treat nicotine addiction; and (3) the harm reduction information focused on ENDS products as a category and was not product-specific, which does not violate the Federal Food, Drug, and Cosmetic Act.

Question 39. Initially, JUUL distributed free samples of its product.

- a. Over what time period did JUUL distribute free samples?**
- b. Does JUUL still distribute free samples? For instance, to Native American tribal members?**
- c. How many free samples did JUUL distribute?**
- d. Why did JUUL cease distributing free samples?**
- e. Why did JUUL decide to provide \$1 products? How many \$1 products did JUUL distribute?**

Response:

In June 2015, JLI launched the JUUL device and four JUULpod flavors at 5% nicotine strength—Virginia Tobacco, Cool Mint (now Mint), Fruit Medley (now Fruit), and Creme Brulee (now Creme). These products were actively marketed and sold through various sales and distribution channels, including traditional convenience stores and independent outlets. JLI distributed free samples of its products for a limited period of time following the launch of the JUUL device.

JLI is unaware of any “free samples” relating to products from the December 2015 to January 2016 and August 2016 product expansions. Since the deeming rule’s effective date of August 8, 2016, JLI has implemented policies prohibiting free samples consistent with FDA regulations. Since FDA’s deeming regulations became effective, JLI has, at times, distributed coupons or discount codes through which adult consumers can purchase product at a discount on JLI’s age-gated e-commerce website.

Question 40. Identify any U.S. states in which you have not engaged lobbyists.

Response:

JLI has not engaged lobbyists in Missouri or Vermont.

Question 41. Will you agree to stop opposing state laws to ban flavors?

Response:

JLI is committed to working with public health authorities at all levels of government. JLI announced in September 2019 that it would refrain from lobbying the Administration on FDA's draft guidance relating to the sale of flavored ENDS products. JLI intends to fully comply with the FDA Flavors Guidance.¹⁶ While JLI believes flavors can play an important role in providing a satisfying alternative for adult smokers, JLI believes FDA's PMTA process and its "appropriate for the protection of the public health" standard are the best ways to assess the role these products can play in helping adult smokers move away from combustible cigarettes while also being kept out of the hands of youth.

Question 42. Will you agree not to challenge any federal action that bans flavors?

Response:

JLI announced in September 2019 that it would refrain from lobbying the Administration on FDA's guidance relating to the sale of flavored ENDS products. JLI intends to fully comply with the FDA Flavors Guidance. While JLI believes flavors can play an important role in providing a satisfying alternative for adult smokers, JLI believes FDA's PMTA process and its "appropriate for the protection of the public health" standard are the best ways to assess the role these products can play in helping adult smokers move away from combustible cigarettes while also being kept out of the hands of youth.

Question 43. Is nicotine harmful to any users?

Response:

Nicotine is an addictive chemical and should not be consumed by non-users, especially those underage. FDA research says nicotine is not carcinogenic; cancers related to combustible cigarettes are caused by the non-nicotine components of a cigarette. FDA and the U.S. Surgeon General have conducted more detailed analysis of this question.

Question 44. Is JUUL's 59 milligram-per-milliliter nicotine formulation highly addictive?

Response:

Nicotine is an addictive chemical. For additional information, please see the responses to questions 43 and 45.

¹⁶ *JUUL Labs Names New Leadership, Outlines Changes To Policy And Marketing Efforts*, JUUL Sept. 25, 2019, <https://newsroom.juul.com/juul-labs-names-new-leadership-outlines-changes-to-policy-and-marketing-efforts/>.

Question 45. Has JUUL ever had any indication that its nicotine salt formulation could be more potent or more addictive than cigarettes? If so, describe when and how?

Response:

The JUUL system and its nicotine-salt-based e-liquid formulation was designed to provide a physiological effect and experience more similar to the use of combustible cigarettes for adult smokers than other e-cigarettes on the market at that time. Using a nicotine-salt-based formulation, rather than a freebase nicotine (like earlier versions of e-cigarettes), in the e-liquid allows adult smokers to have a nicotine experience that more closely competes with cigarettes, thus more readily transitioning them from combustible use.

Use of JUUL products has consistently demonstrated a nicotine-absorption curve that is higher than nicotine replacement therapy products and lower than a combustible cigarette. Clinical studies have shown use of the JUULpod e-liquid formulation with a 5% nicotine strength results in both a lower maximum nicotine concentration in the blood (Cmax) and lower total nicotine concentration in the blood over time compared to use of a combustible cigarette (AUC, or area under the curve). Traditional measures of abuse liability also indicate that JUUL products lie between combustible cigarettes on one end and nicotine replacement therapy products on the other. These measures demonstrate that JUUL products have the potential to convert adult smokers, though not all smokers will find them a viable alternative to cigarettes. JLI continues to conduct and evaluate additional research, including clinical and behavioral studies, relating to the physiological impact and potential dependence of its products on users.

Further, given the ingredient composition of JUUL products and the fact that they do not rely on combustion, the JUUL system exposes users to aerosol with substantially lower levels of known carcinogens and other harmful and potentially harmful constituents than smoke from combustible cigarettes. In this respect, although JLI's nicotine-salt-based e-liquid formulation was designed to have acceptability and nicotine delivery more comparable to cigarettes among adult smokers, JLI believes that JUUL products are potentially less harmful than these combustible products.

Question 46. JUUL's US patent '895 shows that the JUUL formulation can achieve higher nicotine blood levels faster than a cigarette.

- a. Provide all documents associated with JUUL's US patent '895.
- b. List all individuals involved with the research and formulation related to the '895 patent.
- c. Describe the device and formula used for the 4% formulation in the '895 patent and how that differs from the 5% formulation and JUUL devices currently sold in stores.
- d. Describe in detail the pharmacokinetic research and information that supplied Fig 4 of the '895 patent.
- e. JUUL's internal clinical testing in 2014 had shown on some occasions that the 4% nicotine salt product could be more potent than a Pall Mall cigarette, correct?
- f. Did the pharmacokinetic studies in the '895 patent use the same 4% nicotine salt formula that was used in JUUL's early clinical testing?

- g. Describe all steps taken to ensure that JUUL devices did not exceed the pharmacokinetic curvature of a cigarette.
- h. Why did JUUL chose to describe its nicotine content with the “5% Strength” label?
 - i. Why did JUUL decide to calculate this nicotine content by weight instead of nicotine by volume?
 - ii. Explain the results of any market research that was conducted on ways to communicate JUUL’s nicotine content to consumers.
- i. List the names of all non-smokers who participated in trial, testing, and development of the formulation of JUULpods.
- j. Which JUUL employees and other individuals who personally tested JUUL’s nicotine formulation were smokers and which were non-smokers? (e.g., Gal Cohen, Ari Atkins, etc.)

Response:

The tests reflected in the ‘895 patent were not conducted on the JUUL device or on the e-liquid in the JUULpods that have been marketed for sale. Instead, they were conducted using third-party hardware and an e-liquid solution that differs from JLI’s commercial e-liquids.

What is relevant to JLI’s customers is how the JUUL device and JUULpods that are available on the market perform. Clinical studies consistently show that use of the JUULpod e-liquid formulation at 5% nicotine strength provides a physiological effect and experience less potent than the use of combustible cigarettes but more satisfying than nicotine replacement therapies on the market, but actually results in a lower maximum nicotine absorption in the blood compared to the use of a combustible cigarette.

JLI has always disclosed the nicotine strength of its products by weight and has also utilized weight-based measurements in its internal testing. Accordingly, for 5% strength JUUL e-liquids, 5% of the weight of the e-liquid is attributable to the weight of the nicotine contained therein. JLI believes that weight-based measurements and disclosures for nicotine strength are superior to volumetric alternatives for several reasons: weight-based measurements are less susceptible to variability in a laboratory setting (e.g., due to fluctuations in temperature, adhesion during titration, etc.); and the nicotine content of combustible cigarettes is best measured and described in weight-based terms, and JUUL products were designed as an alternative to combustible cigarettes. Other market-leading e-cigarette companies also disclose the nicotine strength of their products by weight.

Question 47. Describe all agreements between JUUL and any major tobacco company prior to Altria’s investment in JUUL.

Response:

The only agreement between JLI and any major tobacco company prior to Altria’s investment in JLI was a settlement agreement with Phillip Morris International regarding trademark litigation. Japan Tobacco International invested in PLOOM before it was renamed to PAX Labs, Inc. and then to JUUL Labs, Inc., but that relationship ended in 2015.

Question 48. Has Altria received any consumer information, research, or data from JUUL on JUUL's customers or market research? Please describe.

Response:

As part of the process that preceded Altria's investment in JLI, the Company made available to Altria materials to facilitate its due diligence efforts. The materials included a summary of behavioral research as well as select research on brand awareness and preference. These research materials were provided to Altria's clean team only.

Question 49. Describe your relationship with Avail Vapor.

- a. Were you aware when you entered into an agreement with Avail Vapor that Altria had recently invested in them?**
- b. What information did Altria collect from Avail Vapor about your products, marketing, and/or sales?**

Response:

Avail Vapor is a national chain vape shop retailer that sold JLI products. JLI first entered into a mutual nondisclosure agreement with Avail Vapor on October 28, 2017, and Avail Vapor purchased its first JUUL products on October 31, 2017. JLI was not aware of Altria's investment in Avail Vapor at that time.

On November 2, 2017, Altria announced it had invested in Avail Vapor. That same day, Avail Vapor alerted JLI about the investment, assuring JLI that Avail Vapor would continue to sell JUUL products and that JLI's data was not available to Altria. On November 21, 2017, JLI and Avail Vapor entered into a distribution agreement.

JLI renewed the distribution agreement with Avail Vapor on November 19, 2018, and again on January 8, 2019.

Question 50. List all third party market research affiliates that have conducted research, focus groups, or collected or analyzed consumer data for JUUL.

Response:

JLI seeks to understand the marketplace and to comply with the regulatory structure in place in each market in which it operates. Please see the responses above for various groups that have assisted in this effort for topics that were previously inquired about in these responses.

Question 51. In November of 2018 JUUL removed and/or deleted social media accounts and content.

- a. Identify and describe the roles of all individuals involved in the decision to remove and/or delete social media accounts and content, and all individuals who carried out the removal and/or deletions.**

- b. Did JUUL retain data analytics information (audience reach and demographics) for the social media posts that JUUL removed in November 2018? What information did JUUL retain? Provide all such retained information.**

Response:

JLI retained data analytics information, including some data analytics information regarding audience reach and demographics, for the social media posts that JLI removed in November 2018.

JLI uses a third-party vendor to support enforcement on social media. To be clear, JLI does not remove or delete third-party accounts because JLI does not have the access or authority to do so. Based on the policies of each platform, JLI submits (or causes to be submitted) requests for content removal based on IP infringing-content, violations of platform policy, and/or content that appears to be directed towards youth. Due to the sheer volume of content on social media, manual enforcement is impractical and ineffective, so JLI uses a third-party vendor called IncoPro. IncoPro's brand protection software is called Talisman.

The core of the online enforcement program is based on keyword searches. Keyword search lists are built over time, learning what words or grouping of words are used to direct traffic to listings. To search for content violations, Talisman scrapes information on listings that meet the word search criteria. The individuals responsible for social media takedowns then review the content aggregated by Talisman. Any content determined to be infringing or a violation of platform policy or appearing to be directed at youth use is submitted for removal to the social media platform. Decisions to remove these items are 100% at the discretion of the social media platforms; companies like JLI can only request removal. If a social media platform determines that the content does not violate its standards, it will not remove the content no matter how egregious it may be.

Question 52. In June 2018, JUUL worked with Instagram to remove certain accounts that were promoting to youth and selling products to youth, such as JUULnation and DoIt4JUUL.

- a. When did JUUL become aware that those accounts existed?**
- b. Did you track those accounts or hashtags related to those accounts?**
- c. Were you aware that those accounts were promoting and selling JUUL products to youth?**
- d. Provide all communications with social media platforms about the removal of those accounts in or around June 2018.**

Response:

JUULnation and DoIt4JUUL were third-party accounts unaffiliated with JLI. Their posts consisted of original, user-generated content. Around September 2017, these accounts began to hold giveaways and/or sweepstakes to win JUUL products. After the Brand Protection team became aware of this, it began reporting the posts promoting the giveaways/sweepstakes due to violations of the platforms' policies. The accounts escalated the activity by beginning to offer product for sale via their accounts. The Brand Protection team continued to report these listings to the platforms for removal based on continued violation of policy. On September 13, 2017, JLI sent

a cease-and-desist letter to JUULnation and on December 5, 2017, and December 20, 2017, JLI sent cease-and-desist letters to Doit4JUUL. From September 2017 until May 2018, JLI continued reporting various infringing posts and activity from both accounts to the platforms. Between April 2018 and May 2018, both JUULnation (Followers ~85,500) and Doit4JUUL (~110,000) were removed from Instagram.

Question 53. Identify all current and former members of JUUL’s Board of Directors, including the dates they joined and left the Board.

Response:

The current members of JLI’s Board of Directors are Adam Bowen, Zach Frankel, Hank Handelsman, James Monsees, Nick Pritzker, Riaz Valani and K.C. Crosthwaite. Ho Young Huh and Kevin Burns previously served on JLI’s Board of Directors.

Question 54. What role do board members and investors play in decision-making in relation to JUUL’s design, marketing, and sales?

Response:

The Board of Directors is not directly engaged in design, marketing or sales decisions beyond the typical role of a board of directors for a corporation that includes oversight of management and policy setting for the company. Certain individuals on the Board of Directors have also served in employment positions and have been involved in design, marketing and sales decisions. For example, the founders of JLI, James Monsees and Adam Bowen, are board members, as is JLI’s CEO.

Question 55. Have you licensed your patented e-liquid formulation, or any of your flavors, to third parties?

Response:

No.

Question 56. Have you ever partnered with any other manufacturers, distributors or sellers of e-liquid or flavors to market JUUL or JUUL compatible products? Please list each company and briefly describe the relationship.

Response:

In 2015 and 2016, JLI established relationships with several e-liquid companies to market JUUL products. In early 2018, JLI ended all but one of these relationships. Following FDA’s indicated intention to remove flavors from the market absent a PMTA, JLI ended the remaining relationship.

JLI endorses and authorizes only genuine JUUL products purchased from JUUL.com or licensed retailers; any other pod is either counterfeit or an illegal JUUL-compatible pod. JLI has taken aggressive steps against manufacturers of these counterfeit and illegal JUUL-compatible pods, including defending its intellectual property by commencing actions in front of the International Trade Commission and alerting FDA of these illegal products.

Question 57. Describe your previous and current relationship with Cuttwood and other third party e-liquid makers.

Response:

See response to Question No. 56.

Question 58. JUUL removed certain flavors from retail stores in November 2018, but continues to sell Mint in retail locations.

- a. When JUUL removed certain flavors, but left Mint in stores, was it aware that just weeks earlier, Altria had removed all flavors of its MarkTen product except Mint?
- b. Did JUUL coordinate its decision to leave Mint in retail stores with Altria? With any other e-cigarette companies?

Response:

JLI's decision to suspend the sale and distribution of NTM flavored JUUL products to traditional retail stores through its wholesale and retail distribution system was part of the Company's youth action plan and driven by a request from FDA in September 2018. JLI announced its youth action plan in November 2018. Although Altria removed all flavors of its MarkTen product except Mint in October 2018, and thus JLI was aware of such actions, JLI's decision to remove certain flavors from retail stores was made independent of Altria's actions relating to its since-discontinued MarkTen line.

As of November 2019, JLI has ceased the sale of Mint JUULpods in the U.S., as well as NTM flavored JUULpods, pending FDA review.

Question 59. What is the status of JUUL's Foundation?

- a. Please provide all communications that occurred in the development of the Foundation.
- b. What firm and/or consultants were used to form the governance structure of the Foundation?
- c. Why was the Foundation not incorporated by the originally planned date of Q1 FY '19?
- d. What organizations had JUUL considered for allocation grants and investments aligned with the Foundation vision to "understand and reduce access to and use of substances including nicotine by adolescents"?

Response:

JLI never incorporated a foundation. As such, no grants or investments were considered.

JLI did consider establishing a foundation to channel its corporate philanthropy, but no incorporation date was ever determined. JLI retained three consultants to assist in this effort: Farella Braun + Martel LLP, The Giving Practice, and The 360 Group.

Question 60. In JUUL’s 2018 Annual Operating Plan (AOP), the company references a potential FDA inspection of JUUL HQ.

- a. Why did JUUL suspect the FDA would inspect its facilities eight months before the inspection ever occurred?**
- b. Did strategies implemented in preparation for the inspection include intentional deletion or destruction of incriminating documents, data, or communications?**
- c. What “intelligence” did JUUL have prior to the FDA’s October, 2018 raid?**

Response:

FDA did not “raid” JLI’s facilities, but instead conducted a facilities inspection within its authority under the Federal Food, Drug, and Cosmetic Act. Several months after the inspection, FDA informed JLI that the inspection was “closed,” and JLI’s headquarters were classified as “No Action Indicated” – meaning that FDA had decided not to take any action based on the inspection.

Under FDA regulations, JLI is required to establish a robust Quality System to ensure products consistently meet applicable requirements and specifications. While FDA has not yet adopted “current good manufacturing practice” (“cGMP”) requirements for tobacco products, JLI nonetheless has sought to borrow cGMP concepts from other FDA-regulated industries, including medical devices and pharmaceutical products.

As part of its Quality System, JLI also must ensure it remains prepared for any potential inspection, by FDA or other regulators, of its facilities and manufacturing operations to ensure that inspectors receive ready access to documents and information. In early 2018, JLI had no reason to believe that it would be subject to an FDA inspection at any particular time; rather, JLI’s ordinary course of doing business as an FDA-regulated company involves ensuring it is prepared for any potential inspection or audit. JLI’s strategy for preparing for any potential inspection or audit does not include the intentional deletion or destruction of documents, data or communications. Quite the opposite; JLI’s approach is to be open and forthcoming with FDA.