# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM 2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051 MINORITY (202) 225-5074

September 12, 2019

Mr. James Monsees Founder and Chief Product Officer JUUL Labs, Inc. 560 20th Street San Francisco, CA 94107

Ms. Ashley Gould Chief Administrative Officer JUUL Labs, Inc. 560 20th Street San Francisco, CA 94107

Dear Mr. Monsees and Ms. Gould:

Enclosed are post-hearing questions that have been directed to you and submitted to the official record for the hearing that was held on Thursday, July 25, 2019, titled "Examining JUUL's Role in the Youth Nicotine Epidemic: Part II."

In order to ensure a complete hearing record, please return your written response to the Committee on or before Thursday, September 26, 2019, including each question in full. Your response should be addressed to the Committee office at 2157 Rayburn House Office Building, Washington, D.C. 20515. Please also send an electronic version of your response by e-mail to Joshua Zucker, Assistant Clerk, at Joshua.Zucker@mail.house.gov.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Elisa LaNier, Chief Clerk, at (202) 225-5051.

Sincerely,

Chairman

Subcommittee on Economic and Consumer Policy

cc: The Honorable Mike Cloud, Ranking Member Subcommittee on Economic and Consumer Policy

#### Questions for Mr. James Monsees

Co-Founder, JUUL

And

#### **Ashley Gould**

Chief Administrative Officer JUUL

July 25, 2019 Hearing: "Examining JUUL's Role In The Youth Nicotine Epidemic"

### Questions from Chairman Raja Krishnamoorthi Subcommittee on Economic and Consumer Policy

- 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?
- 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.

- 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?
  - i. Identify any person or entity with which JUUL has shared the data?
  - k. Has JUUL's marketing team had access to the data?
- 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?

- 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 Baltimonre 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?
- 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 Isreal. 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?
- 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?

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

- 17. Provide the research basis for the "Moving Beyond" program.
- 18. What are the monthly sales amounts for each of JUUL's flavors, at each nicotine level, from January 1, 2017 to present?
- 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?
- 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.
- 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.
- 22. On August 30, 2019, the Center for Disease Control and Prevention posted an Investigation Notice entitled "Outbreak of Severe Pulmanary 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?
- 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 relied upon by JUUL that demonstrates the effectiveness of connected technology to curb the rapid increase in the U.S. of vaping among youth.
- 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. 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?
- 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 beter study youth usage? Privide all documentation FDA sent you on this topic.

- 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?
- 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?
- 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.
- 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?
- 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.
- 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 that cigarettes?
- 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?
- 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.
- 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 distributers/warehouses/wholesalers also stopped in Novermber 2018?
- c. In November 2018, what volume of flavored JUULpods were in the hands of retailers? Commercial distributers? Warehouses? Wholesalers?
- 35. Identify and describe all grants JUUL made in relation to youth prevention and/or wellness?
- 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.
- 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?
- 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.
- 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?
- 40. Identify any U.S. states in which you have not engaged lobbyists.
- 41. Will you agree to stop opposing state laws to ban flavors?
- 42. Will you agree not to challenge any federal action that bans flavors?
- 43. Is nicotine harmful to any users?
- 44. Is JUUL's 59 milligram-per-milliLiter nicotine formulation highly addictive?
- 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?
- 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.)

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  - 47. Describe all agreements between JUUL and any major tobacco company prior to Altria's investment in JUUL.
  - 48. Has Altria received any consumer information, research, or data from JUUL on JUUL's customers or market research? Please describe.
  - 49. Describe your relationship with Avail Vapor.
    - Were you aware when you entered into an agreement with Avail Vapor a. that Altria had recently invested in them?
    - What information did Altria collect from Avail Vapor about your b. products, marketing, and/or sales?
  - 50. List all third party market research affiliates that have conducted research, focus groups, or collected or analyzed consumer data for JUUL.
  - In November of 2018 JUUL removed and/or deleted social media accounts and 51. 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.
    - Did JUUL retain data analytics information (audience reach and b. demographics) for the social media posts that JUUL removed in November 2018? What information did JUUL retain? Provide all such retained information.
  - 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.
    - When did JUUL become aware that those accounts existed? a.
    - b. Did you track those accounts or hashtags related to those accounts?
    - Were you aware that those accounts were promoting and selling JUUL c. products to youth?
    - d. Provide all communications with social media platforms about the removal of those accounts in or around June 2018.
  - 53. Identify all current and former members of JUUL's Board of Directors, including the dates they joined and left the Board.
  - 54. What role do board members and investors play in decision-making in relation to JUUL's design, marketing, and sales?
  - Have you licensed your patented e-liquid formulation, or any of your flavors, to 55. third parties?

- 56. Have you ever partnered with any other manufacturers, distributors or sellers of eliquid or flavors to market JUUL or JUUL compatible products? Please list each company and briefly describe the relationship.
- 57. Describe your previous and current relationship with Cuttwood and other third party e-liquid makers.
- 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?
- 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 Foundaton not incorporated by the originally planned date of O1 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"?
- 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?