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United States Senate
WASHINGTON, DC 20510

April 8, 2019

Kevin Burns
Chief Executive Officer
JUUL Labs, Inc.
560 20th Street
San Francisco, California 94107

Dear Mr. Burns:

Nearly one year ago, many of us wrote to you urging that your company immediately take action to reduce youth use of the dangerous and addictive JUUL vaping device. One year later, JUUL is more popular than ever with children and your company has decided to team up with Big Tobacco giant Altria—the maker of Marlboro cigarettes, the most popular cigarette among children in the United States—in a partnership that the American Heart Association has called "a match made in tobacco heaven." The corporate marriage between two companies that have been the most prolific at marketing highly addictive nicotine products to children is alarming from a public health standpoint and demonstrates, yet again, that JUUL is more interested in padding its profit margins than protecting our nation's children. We write today seeking more information regarding JUUL's tactics to hook children on nicotine and to understand what your merger with Altria means for the public health.

Over the past year, the U.S. Surgeon General and the Food and Drug Administration (FDA) Commissioner have called youth use of e-cigarettes a "public health epidemic." According to the National Youth Tobacco Survey (NYTS), 20.8 percent of high-school students and 4.9 percent of middle-school students—more than 3.6 million children—currently use e-cigarettes. Over the past year alone, e-cigarette use among children increased by an alarming 78 percent in high-school students and 48 percent in middle-school students. And, according to the Centers for Disease Control and Prevention (CDC), JUUL is driving this epidemic.

In fact, CDC Director Robert Redfield recently stated, "The popularity of JUUL among kids threatens our progress in reducing youth e-cigarette use." The ever-increasing popularity of JUUL is clearly evident from your sales data—with JUUL sales increasing 641 percent between 2016 and 2017, from 2.2 million devices sold to 16.2 million devices sold. According to recent data from Wells Fargo, JUUL owns three-quarters of the e-cigarette market. While this may be good news for your investors, it is bad news for our children. It is no wonder that Altria identified JUUL as a perfect business partner with which to establish a lifelong customer base.

JUUL's decision to team up with Altria, the parent company of Philip Morris USA, is also bad news for children considering that Altria has a long and sordid history of spending billions to entice children to smoke through targeted campaigns that intentionally lied about the science and health effects from cigarettes. And their efforts have clearly paid off. According to

the CDC, Altria's Marlboro cigarette continues to be the most popular cigarette brand among children in the United States, with 48.8 percent of high school smokers preferring Marlboro cigarettes. Further, the proportion of high school smokers who smoked Marlboro cigarettes increased dramatically between 2012 and 2016, by a whopping 27 percent. While JUUL has promised to address youth vaping through its modest voluntary efforts, by accepting $12.8 billion from Altria—a tobacco giant with such a disturbing record of deceptive marketing to hook children onto cigarettes—JUUL has lost what little remaining credibility the company had when it claimed to care about the public health.

Given the fact that our public health agencies have identified JUUL as being largely responsible for fueling the e-cigarette epidemic among youth—and given the immense secrecy shrouding JUUL's business practices—we request documents and responses to the following questions, in writing, by April 25, 2019.

1. FDA Commissioner Gottlieb has said that approximately two-thirds of JUUL users are "new users of nicotine"—meaning, on an overwhelming basis, your products are not being used by adult smokers as a smoking cessation device. Has JUUL ever conducted a clinical trial in the United States proving that its products actually help smokers quit? If so, please provide that study. If not, why not?

2. The 2016 NYTS found that 78.2 percent of middle- and high-school students—20.5 million youth—had been exposed to e-cigarette advertisements from at least one source.

    a. Please provide a complete list of all of JUUL's advertising buys—including radio, TV, print, and social media.

    b. What steps has JUUL taken to ensure that these advertisements are not seen or heard by people under the age of 21?

    c. Altria, and other Big Tobacco companies, are prohibited from airing TV and radio advertisements for cigarettes and—under the Master Settlement Agreement—cannot run advertisements for cigarettes in publications with a substantial youth readership. Going forward, will JUUL commit to not airing any TV, radio, print, or social media e-cigarette advertisements that could be viewed by people under the age of 21?

3. According to the CDC, nearly 7 in 10 youths—17.7 million children—were exposed to e-cigarette advertising in retail stores in 2016. Will JUUL commit to not advertising in convenience stores and other retail stores, where advertisements can be widely viewed by children?

4. Has JUUL paid any "social media influencers" to promote its products? If so, please provide a complete list of influencers who have been paid by JUUL to promote its products. Has JUUL identified its connection with these influencers, in accordance with Federal Trade Commission (FTC) rules?

5. Please list all new contracting, purchasing order, and other financial arrangements with retailers, wholesalers, and distributors for JUUL products since the December 19, 2018, Altria announcement.

6. Please provide a copy of JUUL's response to the FDA's 904(b) letter on April 24, 2018.

7. In response to FDA's September 12, 2018, letter requesting a plan to address the epidemic of youth e-cigarette use, JUUL announced on November 13, 2018, that it will, among other actions: shut down its Facebook and Instagram accounts; stop accepting retail orders for Mango, Fruit, Creme, and Cucumber JUULpods in specialty vape shops and convenience stores; and enhance its online sales age-verification process and technology. In its own response, Altria committed to, among other policies and actions, discontinuing sales of its flavored e-cigarette products.

    a. Following the December 19, 2018, Altria merger announcement, please list any and all changes to JUUL's November 13, 2018, commitments and action plan.

    b. JUUL indicated that, in the future, it would "re-start accepting orders" for flavored JUULpods from stores that "comply with the criteria of our new 21+ Restricted Distribution Program."

        i. Which retail outlets would be eligible for participation in this new program and when would they be able to sell flavored JUULpods?

        ii. What criteria will JUUL use to determine the adequacy of age-verification technology implemented by retail outlets? Will JUUL use an independent third party to verify the adequacy of retail store actions? Will JUUL notify and/or work with the FDA to ensure the adequacy of this system?

        iii. What is the expected timeline for retail outlets to become compliant in such system?

    c. Ostensibly to prevent bulk shipments and youth access, JUUL announced it would limit online customers to two devices and fifteen JUUL pod packages per month, and no more than ten devices per year.

        i. Will JUUL notify and/or work with the FDA to ensure the adequacy of this system?

        ii. How did JUUL determine it would limit online purchases to 15 JUUL pods per month? Please provide pattern of use documentation to explain.

        iii. For products sold online, will JUUL require independent, third-party age and identity verification that compares customer information against third-party data sources, such as public records?

8. Did JUUL, or any of its employees or contractors, discuss with Altria, or any of its employees or contractors, either company's response to the FDA's September 12, 2018, inquiry on plans to address youth e-cigarette use?

9. Please provide a breakdown of sales—broken down by retail and online—between all of JUUL's flavored products—including year-over-year sales, aggregate sales, and percentage sales between flavored JUULpods.

10. Has JUUL collected information on the appeal of its flavored products among youth? Please provide information on youth use of each of JUUL's flavored products.

11. As you know, under the Tobacco Control Act, no new tobacco product can be legally marketed unless FDA has granted an order permitting such marketing. The FDA's 2016 deeming rule extended this authority to e-cigarettes and set an effective date of August 8, 2016—meaning a product that was not on the market as of that date may not be sold without an FDA marketing order.

    a. Has FDA issued a pre-market order to any JUUL product?

    b. When the FDA's Tobacco Product Listing database was accessed on August 27, 2018, there were 278 total JUUL products listed, including 57 distinct flavors in three distinct nicotine levels (0.5%, 3%, 5%) and categorized as both e-liquids and ENDS cartridges (5% 2.8mL/pk). These flavors included: Apple Cinnamon, Apple Cran, Apple Tart, Arctic Lime, Banana Creme, Berry, Berry Tart, Black Flag Risen Enriched, Blueberry Citrus, Bowden's Mate, Chamomile Tea, Chestnut Croissant, Chocolate Mint, Cinnamon Beignet, Cinnamon Spice, Cinnamon Tart, Citrus Medley, Coco Mint, Coconut Bourbon, Elderflower Fizz, Ginger Peach, Grapevine, Guava Lychee, Kiwi, Lemon Tart, Lemon Tea, Mimosa, Old Fashioned, Pear Tart, Spicy Watermelon, Strawberry, Strawberry Limoncello, Strawberry Rhubarb, Thai Tea, Tropical Melon, and Watermelon Limon.

        i. When did JUUL submit these 57 distinct flavors to FDA for registration and listing?

        ii. On what date did each of these 57 distinct flavors and three nicotine levels first appear on the market? Specifically, for each flavor and nicotine level combination, when did the first retail purchase order and online transaction occur?

        iii. Please provide the first date that free samples were distributed, if applicable, for each of the 57 flavors and three nicotine levels.

    c. When the FDA's Tobacco Product Listing database was accessed on January 16, 2019, there were only 52 total products listed.

i. When did JUUL de-register the previously listed products from the FDA database?

ii. When and why were the previously listed products removed from the market?

d. Among the 52 products described in (10)(c) are five e-liquid flavors—Classic Menthol, Cool Cucumber, Fruit Medley, Mango, and Mint, in "0.5 salt" concentrations. Additionally, there are "JUUL Compatible Private Blend Refill Kits" in multiple nicotine concentrations and sizes (0.0%, 1.7%, 3%, 5% and both 2.8mL/pk and 4mL/pk).

i. When did JUUL submit each of these distinct products to FDA for registration and listing?

ii. On what date did each of these products first appear on the market? Specifically, when did the first retail purchase order and online transaction occur for each of these distinct products?

iii. Please provide the first date that free samples were distributed, if applicable, for each of these distinct products.

e. On July 12, 2018, JUUL Labs announced that it would offer 3% nicotine pods in Mint and Virginia Tobacco flavor, noting these 3% nicotine pods would be available in "limited quantity" in August 2018 and "widely available" in October 2018. In March 2019, JUUL announced that it was making its Mango, Fruit, Crème, and Cucumber pods available in 3% strength as well. The announcements appear to indicate new products entering the market without pre-market orders from the FDA.

i. On what date did each of these 3% nicotine pods first appear on the market?

ii. Specifically, when did the first retail purchase order and online transaction occur for each of these products?

12. According to a recent report, JUUL has an "enterprise markets team" that is working to strike deals with health insurers, employers, health care providers, and the public sector to make JUUL available to employees and beneficiaries who want to stop smoking cigarettes.

a. What data and other information does JUUL communicate to health insurers, employers, health care providers, and the public sector about whether JUUL is effective at helping adult smokers stop smoking cigarettes?

b. Does JUUL clearly indicate that its products have not been found to be safe and effective by the FDA for the purpose of smoking cessation?

c. Please provide copies of materials that JUUL provides to health insurers, employers, health care providers, and the public sector.

d. Please provide all documents and other information reflecting communications with the FDA about whether any JUUL advertisements or proposed advertisements—or other actual or proposed promotional materials—make claims that JUUL helps smokers quit smoking (smoking cessation claims) or claims that JUUL is less hazardous than other tobacco products (modified risk claims).

13. On February 4, 2019, a coalition of 16 conservative-leaning and anti-regulation organizations wrote to President Trump, urging the White House to intervene with the FDA's public health oversight and "pump the brakes on its new regulatory efforts" regarding tobacco products, including e-cigarettes. It has been reported by *The New York Times* that JUUL has made financial contributions to signatories of this letter—including Americans for Tax Reform, the R Street Institute, and the American Legislative Exchange Council Action. Please confirm the amounts and dates of JUUL's contributions to these organizations, as well as the amounts and dates of JUUL's contributions to any other organizations that signed the February 4, 2019, letter.

Thank you for your immediate attention to this matter. While you and your investors may be perfectly content with hooking an entire new generation of children on your tobacco products in order to increase your profit margins, we will not rest until your dangerous products are out of the hands of our nation's children.

Sincerely,

Richard J. Durbin
United States Senator

Patty Murray
United States Senator

Ron Wyden
United States Senator

Sherrod Brown
United States Senator

Richard Blumenthal
United States Senator

Jack Reed
United States Senator

Elizabeth Warren
United States Senator

Tom Udall
United States Senator

Edward J. Markey
United States Senator

Jeffrey A. Merkley
United States Senator

Chris Van Hollen
United States Senator