



Durbin and other Senators press JUUL Labs

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WASHINGTON – Today, Senate Democratic Whip Dick Durbin (D-IL), along with 10 of his Senate colleagues, sent two letters to JUUL Labs, Inc. and the U.S. Food and Drug Administration (FDA) about JUUL e-cigarette vaping products. In the letter to Juul Labs, Inc. Durbin and his colleagues ask a series of questions about how the product is marketed to children and teens, what ingredients are in the flavorings that accompany these devices, and requests that the company take a series of important steps to limit youth use of their product. A [recent article](#) in the New York Times describes in chilling detail how the JUUL vaping product—as well as the kid-friendly flavorings that accompany the device—has exploded in use among high school and middle school students across the United States, and how the product is being marketed to youth audiences nationwide.

“Your company’s popular vaping device (JUUL) and its accompanying flavored nicotine cartridges (JUULpods) are undermining our nation’s efforts to reduce tobacco use among youth and putting an entire new generation of children at risk of nicotine addiction and other health consequences,” Durbin and the senators write to JUUL Labs, Inc. CEO Kevin Burns. “Despite significant progress in reducing smoking, tobacco use is still the leading cause of preventable death in the United States, killing more than 480,000 people every year. Your company’s product purports to help people quit smoking cigarettes, yet we are concerned that JUUL—with its kid-appealing design and flavorings—will only lead to further nicotine addiction and adverse health consequences.”

In an additional letter to the FDA, Durbin and his colleagues urge the agency to take immediate steps to ban kid-friendly candy and fruit flavorings that are used with e-cigarettes and cigars. In August 2016, the FDA issued the “deeming rule” which deemed e-cigarettes, cigars, and hookahs “tobacco products” and asserted FDA’s ability to regulate them. However, the FDA made a decision last year to delay its regulation of e-cigarette products and flavorings from 2018 to 2022. New products targeted to youth –

like JUUL Labs, Inc.'s e-cigarette vaping product - have been able to slip by FDA review. The senators urged FDA to end the delay and begin regulation and review of e-cigarette products now.

“From aggressively marketing cigarettes and tobacco products near primary and secondary schools, to shamelessly using cartoon characters to shill their products to children, to making their tobacco products available in kid-friendly candy and fruit flavors, it is no secret that big tobacco companies will stop at nothing to hook young people on their addictive and dangerous products,” Durbin and the senators write to FDA Commissioner Scott Gottlieb. **“It is imperative that the FDA take immediate steps to remove kid-friendly e-cigarette and cigar flavorings from the market. If companies want to use flavors, they should be required to demonstrate to the FDA that use of flavors will benefit public health. If we wait four more years to act, we will have doomed countless more children to addiction and adverse health consequences at the hands of big tobacco companies.”**

Joining Durbin on the letter include U.S. Senators Sherrod Brown (D-OH), Richard Blumenthal (D-CT), Chuck Schumer (D-NY), Patty Murray (D-WA), Tom Udall (D-NM), Chris Van Hollen (D-MD), Jack Reed (D-RI), Ed Markey (D-MA), Elizabeth Warren (D-MA), and Tim Kaine (D-VA).

Full text of the letter to JUUL Labs, Inc can be found [here](#). Full text of the letter to the FDA can be found [here](#). Each letter is also copied and pasted below:

Letter to JUUL Labs, Inc.:

April 18, 2018

Kevin Burns

Chief Executive Officer

JUUL Labs, Inc.

560 20th Street

San Francisco, California 94107

Dear Mr. Burns:

Your company's popular vaping device (JUUL) and its accompanying flavored nicotine cartridges (JUULpods) are undermining our nation's efforts to reduce tobacco use among youth and putting an entire new generation of children at risk of nicotine addiction and other health consequences. We write today to request information regarding your product and to urge JUUL Labs, Inc. to immediately take action to reduce youth use of your dangerous and addictive device.

In recent decades, the United States has made enormous progress in reducing youth tobacco use. According to the Centers for Disease Control and Prevention (CDC), cigarette smoking among high school students is at record lows—dropping from 28 percent in 2000 to 8 percent in 2016. These reductions in youth cigarette use did not happen overnight—they occurred over time in large part thanks to a concerted national response. Recent reductions in youth smoking have been driven by state and federal actions, including a 62-cent increase in the federal cigarette tax in 2009; enactment of the 2009 law granting the Food and Drug Administration (FDA) authority over tobacco products; and the launch of a federally-funded mass media campaign to reduce tobacco use.

However, much to our dismay, these gains are being threatened because of non-cigarette tobacco products, especially electronic cigarettes (e-cigarettes) like JUUL. While there has been a steep drop in youth use of traditional cigarettes, youth use of e-cigarettes is skyrocketing. Between 2011 and 2015, the use of e-cigarettes among high school students increased more than ten-fold—from 1.5 percent to 16 percent. While e-cigarette use by high school students declined to 11.3 percent in 2016, e-cigarettes remain the most popular form of tobacco use among youth. According to the U.S. Surgeon General's Report on E-Cigarette Use Among Youth and Young Adults, much of the popularity associated with youth use of e-cigarettes can be attributed to the appealing candy and fruit flavorings that accompany these devices—flavors such as gummy bear, cotton candy, peanut butter cup, and cookies 'n cream. No one with a straight-face could ever argue that these flavorings are not meant to appeal to children.

An April 2, 2018, article in *The New York Times*, entitled “‘I Can’t Stop’: Schools Struggle With Vaping Explosion,” details the alarming explosion of vaping, and specifically JUUL use, among high school and middle school students across the country. E-cigarette use has become so prevalent in classrooms nationwide that many principals and teachers have amended school policy to address this scourge—in some cases, closing bathrooms, placing monitors by bathroom doors, or banning flash drives (which look like the JUUL device). While it remains an open question whether e-cigarettes can play a role in helping adult smokers to quit cigarettes, there is certainly no role for them to play in our nation's classrooms—especially considering the findings of the National Academies of Sciences, Engineering, and Medicine that there is “substantial evidence” that e-cigarette use increases the risk that youth will try

cigarettes, and “conclusive evidence” that most e-cigarettes contain and emit numerous potentially toxic substances.

Given our serious and ongoing concerns about the use of e-cigarette products among children and young adults—and given that your company owns 55 percent of the e-cigarette market share—please provide answers to the following questions no later than April 30, 2018:

- 1) Will your company commit to no longer selling JUULpods in flavors that clearly appeal to children and young people (including Fruit Medley, Crème Brulee, and Mango)?
- 2) Your company has introduced several new JUUL pods to the market since the FDA’s “deeming rule” took effect in August 2016. For example, your company’s own social media posts indicate that your popular mango-flavored product was not introduced until February 1, 2017. Did your company submit an application for pre-market review of these pods by the FDA, as required by the deeming rule? Did you receive a marketing order by the FDA? If not, how is your company legally marketing these new pods? Please provide the date when your company introduced each of your products to the market.
- 3) JUUL-branded products with clear appeal to kids are widely available for sale online, such as t-shirts, hoodies, and JUUL “wraps” or “skins” (brightly colored decals that wrap around the JUUL device and allow users to disguise their device in classrooms). Has JUUL authorized the use of its trademarks for use on these products? To demonstrate its seriousness in preventing marketing that appeal to kids, will JUUL undertake an aggressive effort to prevent the use of its trademarks on these products (as your spokeswoman told *The New York Times* in an April 8, 2018, article that you are committed to doing)?
- 4) According to data from Wells Fargo, JUUL’s unit sales increased more than 600 percent in 2017 and surpassed all other companies’ e-cigarette products. What proportion of these sales were to children under the age of 18? What proportion of these sales were to current or former adult cigarette smokers?
- 5) What specific ingredients (as well as nicotine levels) are in each of the different JUULpods? What constituents have you identified in the aerosol generated by your product?
- 6) Your company claims that the nicotine in JUUL is from “nicotine salts found in leaf tobacco,” rather than free-base nicotine. What is the health impact of this specific form of nicotine? Please provide any studies or evaluations conducted on the health

implications of this product, including the risk of addiction to youth, who are especially vulnerable to nicotine addiction.

7) The Truth Initiative found that 63 percent of 15-24 year old JUUL users do not know that the product always contains nicotine (all pods sold from JUUL include nicotine). What is your company doing to educate young people about the nicotine levels in your products and the harm of youth tobacco use?

8) While JUUL's Instagram account has age restrictions, its Twitter account does not. Will your company commit to imposing an above-21 age restriction for both your Instagram and Twitter accounts?

9) Aside from an easily circumvented age-verification pop-up window on your website, what steps does JUUL take on its website to verify a customer's age before purchase and does it use a delivery service that requires an adult signature upon delivery?

10) Your products are also sold on third party websites, such as eBay. These sites do not have reliable mechanisms to ensure that only individuals of legal age can purchase your products. What steps has your company taken to prevent the sale of JUUL on eBay or other third party websites?

11) Does your company support raising the federal tobacco age from 18 to 21?

12) Does your company support a federal tobacco tax on FDA-deemed tobacco products, including e-cigarettes, similar to what is done for cigarettes?

Despite significant progress in reducing smoking, tobacco use is still the leading cause of preventable death in the United States, killing more than 480,000 people every year. Your company's product purports to help people quit smoking cigarettes, yet we are concerned that JUUL—with its kid-appealing design and flavorings—will only lead to further nicotine addiction and adverse health consequences.

Letter to FDA:

April 18, 2018

The Honorable Scott Gottlieb, M.D.

Commissioner

United States Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, Maryland 20993

Dear Commissioner Gottlieb:

In 2009, Congress granted the Food and Drug Administration (FDA) the authority to regulate the manufacture, distribution, and marketing of tobacco products. In the years since, the FDA has taken a number of important steps to protect the public health and create a healthier future for all Americans by better educating the public about the risks of smoking, cracking down on deceptive practices of big tobacco companies, and considering lowering nicotine levels in cigarettes. We commend the FDA for initiating many of these efforts—including those commenced under your leadership—which have, and will, save lives. However, we write today to share our deep concern that the significant progress we have made in reducing tobacco use among our nation's youth is at serious risk of being reversed because of the FDA's failure to take swift action against specific products that clearly appeal to youth and threaten to hook a generation of children onto tobacco products.

From aggressively marketing cigarettes and tobacco products near primary and secondary schools, to shamelessly using cartoon characters to shill their products to children, to making their tobacco products available in kid-friendly candy and fruit flavors, it is no secret that big tobacco companies will stop at nothing to hook young people on their addictive and dangerous products. The good news is that, thanks to enhanced prevention and awareness policies, cigarette smoking among high school students is at record lows—dropping from 28 percent in 2000 to 8 percent in 2016. The bad news is that, much to our dismay, these gains are being jeopardized because of non-cigarette tobacco products—especially cigars and e-cigarettes with kid-appealing flavors, including the JUUL vaping device.

An April 2, 2018, article in *The New York Times*, entitled “‘I Can’t Stop’: Schools Struggle With Vaping Explosion,” details the alarming explosion of vaping, and specifically JUUL use, among high school and middle school students across the country. Between 2011 and 2015, the use of e-cigarettes among high school students increased more than ten-fold—from 1.5 percent to 16 percent. While e-cigarette use by high school students declined to 11.3 percent in 2016, e-cigarettes remain the most popular form of tobacco use among youth. According to the U.S. Surgeon General's Report on E-Cigarette Use Among Youth and Young Adults, much of the popularity associated with youth use of e-cigarettes can be attributed to the appealing candy and fruit flavorings that accompany these devices—flavors such as gummy bear, cotton candy, peanut butter cup, and cookies 'n cream. No one with a straight-face could ever argue that these flavorings are not meant to appeal to children.

The *Family Smoking Prevention and Tobacco Control Act of 2009* gave the FDA immediate authority over cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco and authorized the agency to expand its jurisdiction to other tobacco products. In May 2016, the FDA finally did so—issuing a rule (the “deeming rule”), which established the agency’s authority to regulate e-cigarettes and cigars in order to protect the public health and prevent use youth of these products. And yet—nearly a decade after this law was enacted and two years after the FDA asserted their ability to regulate e-cigarettes—these products and their kid-friendly flavorings are proliferating on the market without adequate FDA oversight.

While we were pleased that the FDA finally took an initial step to regulate flavorings in e-cigarettes and other tobacco products—issuing an advance notice of proposed rulemaking (ANPRM) on March 21, 2018—we remain very concerned that, by announcing in July 2017 a delay of critical, commonsense e-cigarette regulations until 2022, the FDA is not acting quickly enough to protect our nation’s youth from becoming addicted to these dangerous products. As the FDA has itself acknowledged, 81 percent of kids who have ever used tobacco products started with a flavored product, including 81 percent who have ever tried e-cigarettes and 65 percent who have ever tried cigars. Big tobacco companies are actively peddling e-cigarettes and kid-friendly flavorings in an attempt to hook an entirely new generation of children on nicotine and tobacco products, and yet the FDA has decided to suspend, for four more years, the requirement that these products undergo a scientific review by the FDA to determine their effect on kids and public health. This is unacceptable.

While it remains an open question whether e-cigarettes can play a role in helping adult smokers to quit cigarettes, there is certainly no role for them to play in our nation’s classrooms—and yet that is exactly where they are turning up. It is imperative that the FDA take immediate steps to remove kid-friendly e-cigarette and cigar flavorings from the market. If companies want to use flavors, they should be required to demonstrate to the FDA that use of flavors will benefit public health. If we wait four more years to act, we will have doomed countless more children to addiction and adverse health consequences at the hands of big tobacco companies.