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Durbin presses FDA to protect children from addictive vaping products

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WASHINGTON – Senate Democratic Whip Dick Durbin (D-IL), along with 13 of his Senate colleagues, sent a letter to the U.S. Food and Drug Administration (FDA) about JUUL e-cigarette vaping products, and other e-cigarettes with flavors like gummy bear, cotton candy, peanut butter cup, and cookies ‘n cream, urging the agency to take swift action against these products that are clearly being marketed to children and teens. The Senators urged the FDA to reconsider its decision to delay a review of these products that have entered the market in recent years, and requested additional information from FDA on its current oversight of e-cigarette products. 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. E-cigarettes remain the most popular form of tobacco use among youth, with more than 2.1 million teens using these tobacco products.

“We write today to once again urge you to reconsider your decision to delay a meaningful review of cigars, e-cigarettes, and nicotine e-liquids that entered the market in recent years, particularly given the effect that flavors are having on youth use of these products. Further, we are requesting additional information regarding your agency’s enforcement—or lack thereof—of current tobacco regulations,” Durbin and the senators wrote. **“Today, more than two million young people are using e-cigarettes and 1.3 million youth are smoking cigars, and millions more could be using these tobacco products by the year 2022 if these dangerous and addictive products are allowed to proliferate without an FDA review for three to four more years.”**

In April, Durbin and his colleagues sent a letter to the FDA pressing them for swift action on e-cigarette regulations and urging 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. As a result, new products which are popular with children – like JUUL Labs, Inc.'s e-cigarette vaping device – are now able to remain on the market without FDA review for many years to come. The senators urged FDA to end the delay and begin regulation and review of e-cigarette products now.

Joining Durbin on the letter include U.S. Senators Sherrod Brown (D-OH), Richard Blumenthal (D-CT), Patty Murray (D-WA), Ed Markey (D-MA), Jeff Merkley (D-OR), Dianne Feinstein (D-CA), Jack Reed (D-RI), Elizabeth Warren (D-MA), Chris Van Hollen (D-MD), Sheldon Whitehouse (D-RI), Tammy Duckworth (D-IL), Tom Udall (D-NM), and Maggie Hassan (D-NH).

Full text of the letter to the FDA can be found below:

June 27, 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:

As we have raised with you many times, there has been an alarming increase in electronic cigarette (e-cigarette) use among middle and high school students nationwide over the past few years. While we have successfully reduced youth cigarette smoking rates through public health policies, the failure of the Food and Drug Administration (FDA) to take swift and decisive action against tobacco products that clearly appeal to children—including flavored cigars, JUUL, and other e-cigarettes with flavors, including those with flavors like gummy bear, cotton candy, peanut butter cup, and cookies 'n cream—is jeopardizing this progress and fueling an emerging public health crisis. We write today to once again urge you to reconsider your decision to delay a meaningful review of cigars, e-cigarettes, and nicotine e-liquids that entered the market in recent years, particularly given the effect that flavors are having on youth use of these products. Further, we are requesting additional information regarding your agency's enforcement—or lack thereof—of current tobacco regulations.

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 dipped to 11.7 percent in 2017, 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. Use of cigars by youth is also a significant public health concern. Sales of flavored cigars have increased 50 percent since 2008, accounting for half of the U.S. cigar market, and more high school students now smoke cigars than cigarettes. 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.

In May 2016, after years of deliberation and scientific examination, the FDA issued a rule (the "deeming rule") establishing the agency's authority under the *Family Smoking Prevention and Tobacco Control Act* to regulate e-cigarettes and cigars—including their flavorings—in order to protect the public health and prevent youth use of these products. The deeming rule required manufacturers to submit information on all e-cigarettes and cigars that entered the market between February 15, 2007 and August 8, 2016 (the effective date of the deeming rule), to allow the FDA to assess their risks to public health. However, much to our dismay, instead of requiring manufacturers to submit this information by August 8, 2018 (as required by the deeming rule), you made the decision last year to suspend this commonsense review until at least 2021 for cigars and 2022 for e-cigarettes, and possibly longer. Today, more than two million young people are using e-cigarettes and 1.3 million youth are smoking cigars, and millions more could be using these tobacco products by the year 2022 if these dangerous and addictive products are allowed to proliferate without an FDA review for three to four more years.

Despite FDA's ill-advised decision to suspend commonsense regulation of tobacco products that were already on the market as of August 2016, there are still tools in place today to ensure FDA review of products before they enter the market after that date. The deeming rule provided that any "deemed tobacco products" coming to market after August 8, 2016, must first go through FDA review before they can be sold. In order to better understand whether the FDA is enforcing this aspect of the rule, we request answers to the following questions as soon as possible, but no later than July 20, 2018:

- Please provide a complete list of all deemed tobacco products that were on the market prior to August 8, 2016, and, following your July 2017 announcement, are unfortunately allowed to remain on the market for several years without an FDA review.

1. Has FDA made this information publicly available on its website? Will the agency consider doing so? If not, why not?

- Given the ongoing introduction of new tobacco products to the market without FDA review, there appears to be confusion about what criteria a deemed tobacco product must meet to be considered "on the market" prior to August 8, 2016. What criteria does FDA use to determine if a product was "on the market"?

1. Would a product that was distributed only via free samples before August 8, 2016, satisfy FDA's definition of "on the market"?

1. Would a tobacco product available for purchase in only a very limited number of retail outlets or for a very limited duration of time be considered "on the market"?

1. Has FDA set a minimum number of sales that is necessary to demonstrate that a product was "on the market"?

- Are there any flavored cigars, e-cigarette devices, or flavored e-liquids currently available for purchase in the U.S. that were not on the market prior to August 8, 2016, and have not gone through FDA review?

1. Please provide a complete list of all deemed tobacco products that FDA has identified as being on the market in violation of existing regulations.

1. Has FDA ordered the removal of any such deemed tobacco products?

- As you know, JUUL and accompanying mango-flavored JUULpods are incredibly popular with children. According to JUUL's own social media posts, the mango flavor did not come to market until 2017, well after the August 8, 2016, effective date of the deeming rule. Did JUUL's mango-flavored pod go through FDA review, or is this product on the market in violation of FDA's rules? If the former, please provide information on the timeline for JUUL's submission and FDA's review of application materials for the mango-flavored pod. If the latter, when will FDA order the removal of this kid-appealing flavor?

- Does FDA have in place a process for identifying products that entered the market after August 8, 2016, without receiving a marketing order from FDA? If yes, please explain that process.

1. Does FDA require all manufacturers with products on the market without a marketing order to submit information to FDA to demonstrate that their products were on the market prior to August 8, 2016?

1. Has FDA ever investigated whether a product is on the market without a required marketing order? How many? What were the outcomes?

- The compliance policy in the 2016 deeming rule permitted manufacturers to keep products on the market for an additional year after submission of an application to provide a limited amount of time for FDA to review the application. But the July 2017 suspension of product review appears to permit manufacturers to keep products on the market while FDA reviews applications, no matter how long FDA's review may take. Is that an accurate reading of your current policy? If so, has FDA taken steps to ensure that it reviews applications in a timely way?

- On March 21, 2018, FDA issued an Advance Notice of Proposed Rulemaking (ANPRM) regarding the regulation of flavors in tobacco products. Thankfully, as FDA acknowledged in the ANPRM, much is already known about this issue—especially regarding the popularity of these products with children.

1. Has FDA ever advanced a tobacco-related ANPRM through to a final rule? If so, please identify such rules.

1. FDA has already once delayed the deadline for this comment period. When does FDA plan to issue a proposed rule and final rule for the regulation of flavors in tobacco products?

It has not gone without notice that FDA has taken some modest steps to address e-cigarette use in children—including requesting detailed information from a few e-cigarette manufacturers about the marketing and development of their products; ordering the removal of certain e-cigarette flavorings that resemble foods; attempting to reduce third-party sales of these products; issuing warning letters to a couple dozen brick-and-mortar storefronts that have been selling tobacco products to children; and incorporating e-cigarettes into The Real Cost campaign.

However, the horse is already out of the barn and considerably more must be done to address this looming wave of youth tobacco addiction aided, in part, by FDA inaction. If companies want to use flavors in their tobacco products, they should be required to demonstrate to the FDA that use of flavors will benefit public health—today, not four years from now. We look forward to receiving your responses. Thank you for your immediate attention to this important issue.

Sincerely,