

# United States Senate

WASHINGTON, DC 20510

March 6, 2019

Dr. Scott Gottlieb, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

Dear Commissioner Gottlieb,

As we have noted previously, the rapid increase in youth use of e-cigarettes is unprecedented and troubling. We remain concerned that insufficient action by the Food and Drug Administration (FDA) is creating a new generation of youth addicted to nicotine. With the news of your resignation, we urge you and your successor at FDA to move immediately and aggressively to review these products and take action to protect children and public health.

As you know, electronic cigarettes or e-cigarettes are the most commonly used tobacco product among youth. The 2018 National Youth Tobacco Survey (NYTS) found that current (past 30 days) use of e-cigarettes increased by 78 percent among high school students and by 48 percent among middle school students between 2017 and 2018. The 2018 NYTS found that 4.9 million middle and high school students reported current use of any tobacco product in 2018, an increase of 38 percent among high school students and 29 percent among middle school students – and that this increase was clearly driven by e-cigarette use.<sup>1</sup> U.S. Surgeon General Vice Adm. Jerome M. Adams and Health and Human Services Secretary Alex Azar have recognized the epidemic of youth e-cigarette use, which threatens to reverse decades of progress in stopping youth use of tobacco.<sup>23</sup>

Juul is the most popular e-cigarette sold in the U.S. and is largely responsible for the increase in the number of youth using and becoming addicted to nicotine. It resembles a flash drive, is easy for kids to hide, and comes in a variety of flavors popular with kids. We have called on FDA to take action to prohibit the use of flavors in Juul and other e-cigarettes until or unless they have undergone a thorough FDA review that shows they are of benefit to the public health, because we believe flavors are contributing to the rapid rise in the use of these products by kids.

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<sup>1</sup> CDC, “Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018,” *MMWR*, 67(45):1276-1277, November 16, 2018, [https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s\\_cid=mm6745a5\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w).

<sup>2</sup> (2018) “Surgeon General releases advisory on E-cigarette epidemic among youth.” U.S. Department of Health and Human Services. Retrieved from <https://www.hhs.gov/about/news/2018/12/18/surgeon-general-releases-advisory-e-cigarette-epidemic-among-youth.html>

<sup>3</sup> (2018) “Secretary Azar Comments on Data Showing Rising E-Cigarette Use Among Youth.” U.S. Department of Health and Human Services. Retrieved from <https://www.hhs.gov/about/news/2018/11/15/secretary-azar-comments-on-data-showing-rising-ecigarette-use-among-youth.html>

Flavors are added to make the products more appealing to and tolerable for youth, and data show that that strategy works – FDA’s Population Assessment of Tobacco and Health (PATH) study shows that 81.5 percent of youth using e-cigarettes do so “because they come in flavors [they] like.”<sup>4</sup> The 2018 NYTS also found that more than two-thirds of high school e-cigarette users had used a flavored e-cigarette in the past month, and more than half use mint or menthol e-cigarettes flavors – underscoring the need for FDA to take action against all flavors, including mint and menthol.<sup>5</sup>

Another alarming aspect of Juul’s products that has not received sufficient attention is their high levels of nicotine. Juul released its original nicotine pods for e-cigarettes in 2015 with a nicotine concentration of 5 percent. Juul claims that each pod has the equivalent amount of nicotine as an entire pack of cigarettes.<sup>6</sup> The majority of competing products on the market at that time Juul released its nicotine pod had 1 percent to 2 percent nicotine concentration.<sup>7</sup> Today, many e-cigarettes and e-liquids reach the 5 percent to 7 percent nicotine content range. Juul’s competitors, seeking to emulate the company’s financial success, have flooded the U.S. market with e-cigarettes and e-liquid with these higher nicotine levels, resulting in what some researchers have referred to as a “nicotine arms race.”<sup>8</sup> Even more worrisome is that among youth Juul users, only about one-third are aware that these products contain any nicotine.<sup>9</sup>

The use of nicotine salts – first by Juul and then by its competitors – has facilitated this escalation in nicotine levels. In a recent advisory on youth use of e-cigarettes, the Surgeon General noted that nicotine salts “allow particularly high levels of nicotine to be inhaled more easily and with less irritation” than other forms of nicotine traditionally used in e-cigarettes and other tobacco products.<sup>10</sup> Consequently, the use of nicotine salts could make it easier for youth to start using nicotine and become addicted. The 2018 NYTS found that more than one in four youth (27.7%) are using e-cigarettes frequently – more than 20 days in the past 30 days, but no significant change in frequent use was observed for other tobacco products. This is an increase from 2017, which raises the concern that more youth are becoming addicted to high-nicotine concentrated e-cigarettes. As you acknowledged in your November 2018 statement, kids, their families, and their pediatricians are now struggling with how to end their addiction to nicotine.<sup>11</sup>

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<sup>4</sup> Ambrose, BK, et al., “Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014,” *Journal of the American Medical Association*, published online October 26, 2015.

<sup>5</sup> CDC, “Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students—United States, 2011-2018,” *MMWR*, 67(45):1276-1277, November 16, 2018, [https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s\\_cid=mm6745a5\\_w](https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w).

<sup>6</sup> (2018) “6 important facts about Juul.” Truth Initiative. Retrieved from <https://truthinitiative.org/news/6-important-facts-about-juul>

<sup>7</sup> Jackler, RK, Ramamurthi, D, “Nicotine arms race: JUUL and the high-nicotine product market” *Tobacco Control*, 2019 Feb 6. pii: tobaccocontrol-2018-054796. doi: 10.1136/tobaccocontrol-2018-054796. [Epub ahead of print]

<sup>8</sup> Ibid.

<sup>9</sup> (2018) “6 important facts about Juul.” Truth Initiative. Retrieved from <https://truthinitiative.org/news/6-important-facts-about-juul>

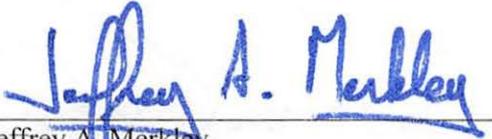
<sup>10</sup> Office of the Surgeon General. *Surgeon General’s Advisory on E-Cigarette Use Among Youth*. Washington, D.C. U.S. Department of Health and Human Services; 2018. <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

<sup>11</sup> Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency’s continued efforts to address growing epidemic of youth e-cigarette use, including potential new therapies to support cessation, November 2, 2018, <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624927.htm>.

While FDA recently held a workshop that recognized the lack of data on how to effectively treat kids addicted to nicotine, we urge FDA do more to prevent kids from becoming addicted in the first place. FDA's decision to delay compliance deadlines for the review of products that entered the market between February 15, 2007 and August 8, 2016 until 2022 has resulted in e-cigarette products remaining on the market without a review of their impact on public health. We again ask FDA to revisit that decision in light of the increases in e-cigarette use by children.

We also remain concerned that some products – including products imitating Juul's design and use of nicotine salts – illegally came onto the market after August 8, 2016 without undergoing a premarket review by FDA. The failure of FDA to adequately review all aspects of e-cigarettes, including the nicotine levels, use of nicotine salts, and the role of device characteristics that affect nicotine delivery, is exposing youth to products that are highly addictive. It is time for FDA to end the ability of Juul and other companies to design their products to maximize profits without regard to the impact of their products on the health of our nation's children.

Sincerely,



Jeffrey A. Merkley  
United States Senator



Richard Blumenthal  
United States Senator



Patty Murray  
United States Senator



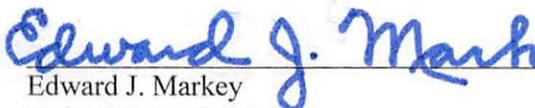
Kirsten Gillibrand  
United States Senator



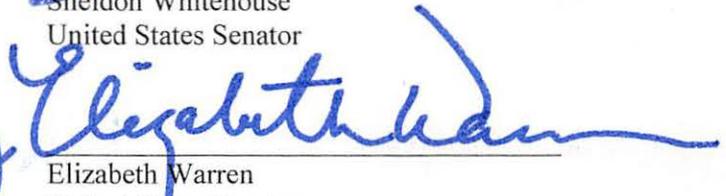
Jack Reed  
United States Senator



Sheldon Whitehouse  
United States Senator



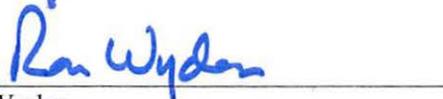
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United States Senator



Richard J. Durbin  
United States Senator