



April 18, 2018

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

Re: Need for immediate FDA action to protect young people from Juul electronic cigarettes

Dear Dr. Gottlieb:

The Campaign for Tobacco-Free Kids, Truth Initiative, American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association and American Lung Association urge you to take immediate action to protect the nation's young people, and the public health, from the dramatic rise in teen usage of Juul electronic cigarettes.

According to widespread news reports, Juul electronic cigarettes have skyrocketed in popularity with teens across the United States. Educators and students report an alarming level of Juul use in middle and high schools, making this an urgent public health problem. Recent news coverage includes stories by [The New York Times](#), [Wall Street Journal](#) and [NBC Today Show](#).

Several factors have contributed to Juul's rising popularity with teens:

- Juul e-cigarettes are sleek, high tech and easy to hide. They look just like USB flash drives and can be charged in the USB port of a computer. They don't look anything like a traditional tobacco product. A Juul is also small enough to fit in a closed hand.
- Juul comes in sweet flavors that appeal to youth, including mango, fruit medley, crème brulee, cool mint and cool cucumber. The evidence is clear that flavors play a key role in youth use of tobacco products, including e-cigarettes. FDA's own Population Assessment of Tobacco and Health (PATH) study found that 85 percent of current e-cigarette users aged 12-17 had used a flavored product in the past month and 81.5 percent of those young users cited flavors as the reason for their use of the product.
- Juul appears to deliver nicotine more quickly, more effectively and at higher doses than other e-cigarettes, increasing users' risk of addiction. The manufacturer claims each Juul cartridge of nicotine liquid (called a "Juul pod") contains as much nicotine as a pack of cigarettes (about 200 puffs). The manufacturer also claims that Juul "delivers a nicotine experience truly akin to a cigarette, with two times the nicotine strength ... of leading competitive products" (April 21, 2015, press release). However, research conducted by Truth Initiative and newly published in *Tobacco Control* found that 63 percent of Juul

users aged 15-24 did not know that the product always contains nicotine. This finding may in part be explained by the fact that the same research also found that a significant portion of those who recognized Juul (25 percent) reported that use of the product is called “juuling,” indicating they may not realize it is an e-cigarette or tobacco product.

Juul sales have grown dramatically and now make up more than half the e-cigarette market. A 2018 report by the National Academies of Sciences, Engineering and Medicine, *Public Health Consequences of E-Cigarettes*, concluded that there is “substantial evidence” that e-cigarette use increases the risk of ever using combustible tobacco cigarettes among youth and young adults. Juul is putting kids at risk of nicotine addiction and threatens to undermine decades of progress in reducing youth tobacco use.

The alarming increase in youth use of Juul makes this an urgent public health problem that requires strong and immediate action by the Food and Drug Administration to protect kids. The FDA is responsible for regulating tobacco products, including e-cigarettes, and it is unacceptable that the FDA has yet to take action to address the skyrocketing youth use of Juul.

The FDA should take immediate steps to protect kids including, but not limited to, the following:

- The FDA should immediately order the removal of any Juul flavors, including the highly popular “mango” and “cool cucumber” flavors, which were introduced after August 8, 2016, without first seeking the required FDA authorization. Such flavors violate FDA’s Deeming Rule that extended the agency’s regulatory authority to additional tobacco products, including e-cigarettes, and prohibits the introduction of new or changed e-cigarettes after the August 8, 2016 effective date of the Rule, without prior FDA review and authorization. According to Juul’s own social media posts, the “mango” and “cool cucumber” flavors were not introduced until 2017.
- As Juul’s popularity has grown, new products that look and are alleged to perform like Juul have been introduced without first seeking FDA review. FDA should order the removal of these products unless and until they comply with the law by going through FDA review.
- The FDA should suspend internet sales of Juul until adequate rules are established to prevent those sales to kids by requiring effective age verification both at the time of sale and delivery. At the same time, FDA should dramatically step up its enforcement of the ban on underage sales of Juul by brick-and-mortar retailers.
- The FDA should reverse its unlawful 2017 decision that allows e-cigarettes that were already on the market as of August 8, 2016, to stay on the market until at least 2022 without filing applications and undergoing a public health review by the FDA. The rapid growth in Juul’s popularity with kids underscores the public health importance of requiring manufacturers of these products to undergo agency review and to demonstrate that the sale of these products is appropriate for the protection of public health, including specifying the safeguards being implemented to protect kids. The FDA should be reviewing these products and taking action to protect kids now, not waiting until 2022.

- Merchandise with the Juul name and using Juul trademarks, including t-shirts, hoodies and Juul “wraps” or “skins,” are being sold on the internet and have helped fuel the brand’s popularity with kids. FDA rules prohibit cigarette brand names from being used on other products because of the impact on kids. FDA should apply the same rule to Juul.

The rapid growth in Juul use by high school students demonstrates that the FDA and Juul’s manufacturer must do more to prevent the marketing and sale of the product to kids and ensure it is marketed and sold responsibly, consistent with the company’s own stated mission of providing “an alternative to smoking” for adults. If Juul fails to take the steps necessary to curtail youth use before the start of the next school year in fall 2018, the FDA should take strong, additional enforcement action, up to and including suspension of Juul sales until it does so.

Thank you for your attention to this urgent threat to public health.

Campaign for Tobacco-Free Kids

Truth Initiative

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association