

ONE HUNDRED FIFTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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March 8, 2018

The Honorable Scott Gottlieb, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

I am writing to reiterate my concerns regarding the delays to the May 2016 final deeming rule, particularly in light of products like JUUL gaining widespread popularity among our nation's youth. The rule extends the Food and Drug Administration's (FDA) authority to all tobacco products, including e-cigarettes and other electronic nicotine delivery systems (ENDS). Finalizing the 2016 deeming rule was a critical step in strengthening FDA's ability to regulate these products, but full implementation of the rule is needed in order to achieve the goals of the Family Smoking Prevention and Tobacco Control Act as passed by Congress in 2009.

FDA's decision in July 2017 to delay important compliance deadlines for the final deeming rule will permit some newly deemed products to stay on the market until 2022 without premarket review by FDA. Prior to the delay, manufacturers would have been obligated to begin submitting certain categories of applications this year. This compliance extension means that for over four more years these products will lack needed public health oversight and will risk continued exposure to a new generation of youth.

The need for FDA oversight has become all the more critical as press reports note that JUUL has become widely available to minors and its usage among teens is rampant.<sup>1</sup> JUUL resembles a USB flash drive, can be charged in a computer, and comes in kid-friendly flavors like "creme brulee," "fruit medley," and "cool cucumber." Nicotine containing products such as JUUL can be highly addictive and JUUL even advertises on its website that the device's liquid-nicotine cartridge contains the same amount of nicotine as a pack of cigarettes.

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<sup>1</sup> See CBS News, Concerns Over Health Effects of Vaping – And Rising Use Among Teens, Feb. 26, 2018 (<https://www.cbsnews.com/news/vaping-health-effects-rising-use-among-teens/>).

The availability of JUUL and e-cigarettes to youth is extremely troubling, and I am deeply concerned that FDA's delay of the final deeming rule will lead to more kids and teens using these harmful products and getting addicted to nicotine.

According to the National Youth Tobacco Survey, 11.3 percent of high school students and 4.3 percent of middle school students were current e-cigarette users in 2016.<sup>2</sup> However, a recent study identified that a quarter of youth and young adult JUUL users refer to JUUL use as "JUULing" and not "vaping."<sup>3</sup> As a result, CDC e-cigarette data may not be fully capturing the extent of JUUL usage.

However, since JUUL entered the market in 2015 – after the grandfathered date of February 15, 2007 for newly deemed products, but prior to the finalization of the deeming rule in 2016 – the manufacturers of this product are not required to submit a premarket tobacco product application to FDA until August 8, 2022.<sup>4</sup> It is concerning to me that these products will continue to be disseminated, marketed, and utilized for several more years without FDA having all necessary information to evaluate the health risks and potential health implications for these products. There is simply no reason for FDA to not begin reviewing these products immediately.

I am particularly concerned about the impact of these delays on youth access to e-cigarettes and other ENDS products. The Centers for Disease Control and Prevention (CDC) and the Surgeon General have reported that e-cigarettes are now the most commonly used form of tobacco by youth in the United States and that young people are trying these products based on curiosity, taste, and the belief that e-cigarettes are less harmful than other tobacco products.<sup>5</sup>

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<sup>2</sup> Centers for Disease Control and Prevention, "Tobacco Use Among Middle and High School Students – United States, 2011-2016," Morbidity and Mortality Weekly Report, 66(23):597-603, June 16, 2017 (<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6623a1.pdf>).

<sup>3</sup> Truth Initiative, "Monitoring the future reveals good and bad news underscoring need for education and regulation," Dec. 14, 2017 (<https://truthinitiative.org/sites/default/files/Latest-Monitoring-the-Future-Survey-Reveals-Good-and-Bad-News-Underscoring-Need-For-Education-and-Regulation.pdf>).

<sup>4</sup> See Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule, Guidance for Industry (Revised) (Nov. 2017), <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf>.

<sup>5</sup> Centers for Disease Control and Prevention, "Tobacco Use Among Middle and High School Students – United States, 2011-2016," Morbidity and Mortality Weekly Report, 66(23):597-603, June 16, 2017 (<https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6623a1.pdf>). Dep't Health & Human Services, Office of the Surgeon General, E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General, 2016 ([https://e-cigarettes.surgeongeneral.gov/documents/2016\\_sgr\\_full\\_report\\_non-508.pdf](https://e-cigarettes.surgeongeneral.gov/documents/2016_sgr_full_report_non-508.pdf)).

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Additionally, just this past January the National Academies of Sciences, Engineering, and Medicine released a comprehensive report on the public health consequences of e-cigarettes, finding that there is substantial evidence that e-cigarette use increases the risk of ever using combustible tobacco cigarettes among youth and young adults.<sup>6</sup>

Even more concerning, new research released this month has shown that adolescents who use e-cigarettes are exposed to at least five different dangerous chemicals and that fruit-flavored products – that are often the most appealing to youth users – produced significantly higher levels of certain cancer-causing chemicals.<sup>7</sup> This research confirms what we have already known: that kids and teens face serious health risks from these products.

I am encouraged by FDA's intentions for a new comprehensive plan for tobacco and nicotine regulation and believe these efforts have the potential to significantly reduce nicotine addiction and tobacco-related disease and death in the future. However, these actions should not come at the expense of important oversight for newly deemed tobacco products like e-cigarettes and ENDS.

I urge you to reconsider the lengthy compliance extensions to the deeming rule that will leave potentially risky products on the market for several more years. By exercising your authority under the Tobacco Control Act to review new tobacco products like JUUL, the agency would be able to expeditiously remove products that are harmful to public health from the market when necessary. FDA must exercise its authority to the fullest extent without delay in order to protect the American public, and most especially American youth, from the harmful effects of tobacco usage.

Sincerely,

A handwritten signature in blue ink, reading "Frank Pallone, Jr." with a stylized flourish at the end.

Frank Pallone, Jr.  
Ranking Member

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<sup>6</sup> The National Academies of Sciences, Engineering, and Medicine, Consensus Study Report, Public Health Consequences of E-Cigarettes, Jan. 2018.

<sup>7</sup> Rubinstein, Mark L., et al. *Adolescent Exposure to Toxic Volatile Organic Chemicals From E-Cigarettes*, Pediatrics, Vol. 141, No. 4 (April 2018), (<https://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=AAP&Entity=PRAsset&AttachmentType=F&EntityID=121686&AttachmentID=3b026982-97a7-4e43-8713-fef7106071c7>).