United States Senate

WASHINGTON, DC 20510

April 23, 2019

Ned Sharpless, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless,

According to a recent report, e-cigarette use may be correlated to the occurrence of seizures, particularly in youth and young adults. This disturbing development highlights the urgent need for the Food and Drug Administration (FDA) to swiftly conduct a public health review of e-cigarettes and implement regulations to govern their manufacture and sale.

A recent Special Announcement from the FDA's Center for Tobacco Products publicized that, since 2010, nearly three dozen Americans have voluntarily reported seizures associated with e-cigarette use.[1] Given the self-identifying nature of these reports, it is possible that this number is severely underreported. This new information is particularly concerning given the continued rise of youth e-cigarette initiation and usage. According to the 2018 National Youth Tobacco Survey, e-cigarette use among high school students increased by 78 percent between 2017 and 2018, with one in five high school students reporting that they currently use e-cigarettes.[2] Similar trends are evident among middle school students, where current e-cigarette use increased by 48 percent over the same period of time.[2] Former FDA Commissioner Gottlieb has warned that these trends are likely to continue in 2019.[3]

The Centers for Disease Control and Prevention cited the popularity and availability of JUUL, an e-cigarette product that can be used covertly due to its shape, as largely responsible for the reported increase in e-cigarette use among youth.[2] Moreover, JUUL has a higher nicotine content than many other e-cigarettes,[4] and nicotine toxicity is a known cause of seizures.[1]

While former Commissioner Gottlieb took some action to address this skyrocketing epidemic hooking a new generation of kids on nicotine, the FDA has unfortunately squandered multiple opportunities to effectively regulate e-cigarettes. By the time the FDA proposed a rule in 2014 to extend to e-cigarettes its regulatory authority under the *Tobacco Control Act*,[5] e-cigarettes had already become the most

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[1] Special Announcement, Statement from the Food and Drug Administration that Some E-cigarette Users Are Having Seizures, Most Reports Involving Youth and Young Adults (Apr. 3, 2019), https://www.fda.gov/TobaccoProducts/NewsEvents/ucm635133.htm.

[2] Karen A. Cullen et al., *Notes from the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students — United States, 2011–2018*, Morbidity and Mortality Weekly Report (Nov. 15, 2018), http://dx.doi.org/10.15585/mmwr.mm6745a5.

[3] Press Announcement, Statement from FDA Commissioner Scott Gottlieb, M.D., on new data demonstrating rising youth use of tobacco products and the agency's ongoing actions to confront the epidemic of youth e-cigarette use (Feb. 11, 2019), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631112.htm.

[4] Truth Initiative, How *much nicotine is in juul?* (Feb. 26, 2019), https://truthinitiative.org/news/how-much-nicotine-juul.

[5] 21 U.S.C. § 387a (2009).

commonly used tobacco product among youth. Despite concerns about youth use of these products, FDA did not finalize the rule until 2016. In 2017, the Trump FDA decided to delay from 2018 until 2022 a requirement under that rule that e-cigarettes undergo a scientific review by FDA to assess their impact on public health.[6] Furthermore, the FDA has done little to finalize rules around e-cigarette flavors, including menthol, despite their appeal to youth.

Once the product review requirement takes effect, the FDA will receive detailed information about the health risks of their products from e-cigarette manufacturers. This information will provide the FDA with considerably more data to help identify and investigate the link between e-cigarette usage and seizures or other health risks. As part of the product review, manufacturers will also have to demonstrate that flavors — or other characteristics of their products — are not making them more appealing to youth. Unfortunately, the FDA's delay in implementing the product review requirement continues to put public health at risk.

In light of this new information, please answer the following questions by May 15, 2019:

1. How long will it take the FDA to thoroughly investigate a potential causal relationship between some e-cigarette usage and seizures?

2. Will the FDA consider moving up the compliance date for the product review requirement under the deeming rule for e-cigarettes if stronger evidence of causation is identified? If no, why not?

3. Is the FDA currently working with e-cigarette manufacturers to collect adverse event reporting related to e-cigarette use or other compliance data? If no, why not?

4. What other steps is the FDA taking to ensure there are no other adverse health outcomes related to e-cigarette use, particularly among youth, that are currently undetected or underreported? How is the FDA ensuring that any potential adverse health outcomes related to e-cigarette use are reported to the agency?

Please contact Nikki Hurt in Sen. Markey's office at nikki_hurt@markey.senate.gov or at 202-224-2742 with any questions. Thank you for your attention to this request.

Sincerely,

Edward J. Markey
United States Senator

Patty Murray
United States Senator

[6] Press Announcement, FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death (July 28, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm

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