United States Senate
WASHINGTON, DC 20510

June 20, 2019

Norman E. Sharpless, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Acting Commissioner Sharpless:

We write to recognize the 10-year anniversary of the Family Smoking Prevention and Tobacco Control Act and to urge proactive and expedient action to protect kids from dangerous tobacco products. This anniversary offers an important reminder of the serious threat posed to public health by tobacco and the need for strong action to make sure we protect kids from a dangerous new generation of tobacco products.

The landmark Family Smoking Prevention and Tobacco Control Act was passed on June 22, 2009 with the goals of reducing youth smoking rates and lessening the harm caused by tobacco products. Our commitment to reducing smoking rates and the disastrous public health impacts of such use led Congress to provide the Food and Drug Administration (FDA) with new authority to regulate the manufacturing, distribution, and marketing of all tobacco products. Congress believed in 2009, as we do today, that the federal government has a critical role in protecting the public health from this known, deadly, and widespread threat. The FDA can and must better use the authority granted to the agency under this important law.

Tobacco use is the leading preventable cause of premature death in the United States. In recent years, we have seen particularly alarming trends in youth tobacco use, stemming from pervasive and aggressive marketing of tobacco products, including e-cigarettes, to kids. More than one in four high school students report use of tobacco products.[1] Especially concerning is the uptick in e-cigarette consumption: from 2017 to 2018 alone, the amount of e-cigarette use reported in the past 30 days among high school students increased from 11.7 percent to 20.8 percent.[2] Data shows that these young smokers prefer flavored products: of high school students who reported current tobacco use, 65 percent used a flavored tobacco product.[3] Among high school e-cigarette users, more than half used a mint or menthol product.[4]

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[1] https://www.cdc.gov/media/releases/2019/p0211-youth-tobacco-use-increased.html
[2] https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm?s_cid=osh-vs-mmwr-full-001
[3] https://jamanetwork.com/journals/jamapediatrics/article-abstract/2720081
[4] https://www.cdc.gov/mmwr/volumes/67/wr/mm6745a5.htm?s_cid=mm6745a5_w

Nearly nine out of ten adults who smoke cigarettes first tried smoking before the age of 18, indicating adolescence is a critical period to prevent youth from nicotine addiction and tobacco-caused disease.[5] Curbing the availability of flavored products will be imperative in any prevention effort.

Changes in public policy, research, education, and treatment have saved the lives of millions of people in the last 30 years who may otherwise have died from tobacco-related causes, but the current trends in youth tobacco use threaten to reverse these decades of progress.

Unfortunately, despite the delegation of authority in 2009 for FDA to oversee tobacco products, the agency has not acted with the speed and proactivity necessary to prevent and respond to the public health crisis of rising youth tobacco use. In recent years, FDA has delayed asserting jurisdiction over e-cigarettes and then delayed enforcing the required public health reviews of these products. On the 10-year anniversary of this landmark law, we again call on FDA to protect youth from nicotine addiction and prevent tobacco-caused disease by using the full authority that Congress has given it to oversee tobacco products.

In order to better understand the agency's direction and plans, we request your response to the following questions by no later than July 22, 2019:

1. In July 2017, FDA announced they would postpone the product review requirements for newly-deemed tobacco products, allowing youth-appealing products to stay on the market with minimal oversight and preceding an unprecedented increase in youth e-cigarette use.[6] After a federal judge ruled last month that FDA's delay in tobacco product review violated the Family Smoking Prevention and Tobacco Control Act, FDA submitted a brief opposing the 120-day timeline proposed by public health advocates. The agency requested a deadline of no sooner than 10 months away, with products allowed to remain on the market for an additional year while FDA reviews their applications. Public health advocates have proposed that 120 days is ample time for manufacturers, which for years have been aware of the upcoming requirements, to submit applications.
    a. Prior to issuing its August 2017 guidance postponing the product review requirements, did FDA conduct any analysis of the likely public health consequences – including increases in youth initiation – of postponing these product reviews?
    b. Based on FDA and CDC data, how many young people will initiate tobacco use in the 22 months FDA's proposal would allow products to stay on the market without further review?

2. The evidence is clear that flavored e-cigarettes pose a major threat to young people in this country. While then-Commissioner Gottlieb committed to limit the sale of some flavored e-cigarettes to age-restricted retail settings and websites with "heightened age verification," we remain deeply concerned this proposal falls short of what is needed:

[5] https://www.cdc.gov/tobacco/data_statistics/sgr/50th-anniversary/pdfs/fs_smoking_youth_508.pdf
[6] https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death

removing all flavored tobacco products from the market unless or until FDA conducts a thorough product-by-product public health review demonstrating these products benefit public health.[7]

a. What is the evidence, if any, that supports flavors are necessary to help adults cease use of tobacco products?
b. How is the continued marketing of flavored e-cigarettes consistent with FDA's public health mission?
c. FDA sent letters to tobacco manufacturers in October 2018 and February 2019 asking for information to help FDA determine whether their products were on the market illegally without a required product review. Have these manufacturers provided this information to FDA? Which products have been removed from the market?
d. What is FDA doing to ensure that any product that was not on the market as of August 8, 2016 is not being sold?

3. In November 2018, then-Commissioner Gottlieb made a commitment to ban menthol cigarettes, which, according to FDA's own research, lead to greater initiation of youth smoking, greater addiction, and more trouble quitting.[8] We were deeply disappointed to see this long-overdue measure was not included in the 2019 Spring Unified Agenda.
   a. What progress have you made since November 2018 toward banning menthol cigarettes, and when will FDA issue a proposed rule?

4. FDA must act quickly to remove flavored cigars from the market. Nearly 1.3 million middle and high school students smoked cigars in 2018.[9]Cigars are available in hundreds of kid-friendly flavors, and nearly three quarters of current youth cigar smokers said they smoked cigars "because they come in the flavors I like." Banning flavored cigars will help prevent cigar initiation by young people and save lives.
   a. When will FDA issue a proposed rule to ban flavored cigars?

5. Reducing the level of nicotine in cigarettes has the potential to save countless lives and would be a major public health success. In 2017, then-Commissioner Gottlieb announced a plan for FDA to use its authority under the Family Smoking Prevention and Tobacco Control Act to do just that.
   a. What progress has FDA made toward establishing product standards to lower the nicotine level in cigarettes?
   b. Will you continue agency efforts toward achieving this important goal?

6. Under the Family Smoking Prevention and Tobacco Control Act, FDA has the critical responsibility for regulating retailers to ensure tobacco products are not sold to minors. FDA has provided nearly $315 million to states, tribes, and other entities to conduct retailer inspections to ensure compliance with the law.
   a. How does FDA work with states to protect kids from tobacco?

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[7] https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access

[8] https://www.fda.gov/media/86497/download; https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm?s_cid=mm6806e1_w

[9] https://www.cdc.gov/mmwr/volumes/68/wr/mm6806e1.htm?s_cid=osh-vs-mmwr-full-001

b. When compliance checks are conducted, are inspectors also looking for other violations of the Family Smoking Prevention and Tobacco Control Act? If so, what other potential violations are investigated?

We remain committed to fulfilling the promise of the Family Smoking Prevention and Tobacco Control Act and hope you will work with us to reduce tobacco use and the devastating harm these products cause. If you have any questions regarding this letter, please contact Andi Lipstein Fristedt with the HELP Committee Staff at (202) 224-7675.

Sincerely,

Patty Murray
United States Senator

Sherrod Brown
United States Senator

Jeffrey A. Merkley
United States Senator

Chris Van Hollen
United States Senator

Jack Reed
United States Senator

Richard Blumenthal
United States Senator

Edward J. Markey
United States Senator

Brian Schatz
United States Senator

Kirsten Gillibrand
United States Senator

Jeanne Shaheen
United States Senator

Sheldon Whitehouse
United States Senator

Christopher A. Coons
United States Senator

Elizabeth Warren
United States Senator

Amy Klobuchar
United States Senator

Richard J. Durbin
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Catherine Cortez Masto
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Ron Wyden
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