Congress of the United States
Washington, DC 20515

March 10, 2022

Dr. Robert Califf
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

We write today to reiterate our concern about high rates of youth tobacco use, and our disappointment that the FDA has failed to complete its review of pending Premarket Tobacco Product Applications (PMTA), allowing the e-cigarette products that are most popular with kids to remain on the market. We remain very frustrated that FDA has been slow to complete required premarket reviews, especially given the September 9, 2021 court-ordered deadline for the FDA to act on all PMTAs. As such, we urge you to quickly complete your review of pending applications and again ask that you deny applications for all non-tobacco flavored e-cigarettes, including menthol-flavored e-cigarettes.

Even as many schools were closed for in-person instruction for part of the year due to the COVID-19 pandemic, youth e-cigarette use remained concerningly high during 2021. The FDA and CDC's National Youth Tobacco Survey (NYTS) found that more than 2 million middle and high school students were current e-cigarette users last year.[1] In 2021, 44% of high school e-cigarette users reported vaping more than 20 days a month and 28% reported daily use, suggesting severe nicotine addiction.[2] And eighty-six percent (86%) of high school e-cigarette users reported using flavored products in the 2021 NYTS study.

Flavored e-cigarettes continue to put our youth at risk of nicotine addiction and the serious health harms that result from tobacco use. As you know, a primary driver of youth vaping continues to be the addition of flavorings to e-cigarettes, which make e-cigarettes more appealing to American youth. Now, 6 months past the court-ordered deadline for e-cigarettes to be reviewed by the FDA, products from the most popular e-cigarette brands among youth – including Vuse Alto, SMOK, JUUL, and Suorin – remain on the market and widely available without FDA authorization. Given the role flavors play in attracting youth to e-cigarettes, FDA should deny premarket applications for all non-tobacco flavored e-cigarettes.

[1] Park-Lee E, Ren C, Sawdey MD, et al. "*Notes from the Field*: E-Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021." Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR). October 1, 2021, 70(39);1387–1389. https://www.cdc.gov/mmwr/volumes/70/wr/mm7039a4.htm

[2] Wang TW, Neff LJ, Park-Lee E, Ren C, Cullen KA, King BA. "E-cigarette Use Among Middle and High School Students — United States, 2020." Centers for Disease Control and Prevention (CDC) Morbidity and Mortality Weekly Report (MMWR). September 18, 2020, 69(37);1310–1312. https://www.cdc.gov/mmwr/volumes/69/wr/mm6937e1.htm

We are pleased that, so far, the FDA has not authorized any non-tobacco flavored e-cigarettes. But we are concerned that FDA has not yet completed its review of many flavored e-cigarettes, including menthol e-cigarettes. If FDA were to authorize any flavored e-cigarettes, youth would simply migrate to those flavored e-cigarette products that remained on the market. Unfortunately, that is what happened following FDA's February 2020 guidance prohibiting all flavored cartridge-based e-cigarettes other than menthol. The market share for menthol-flavored e-cigarettes more than doubled in the eight weeks following the release of FDA's guidance.[3] Disposable e-cigarettes – which were similarly exempted from FDA's guidance – have also spiked in popularity, with 56% of high school e-cigarette users in the 2021 NYTS reporting the use of disposable products.

Given these realities, we strongly urge the FDA to (1) expeditiously complete review of remaining e-cigarette PMTAs and prioritize review of those products most popular among youth; (2) adhere to the overwhelming balance of unbiased medical and scientific evidence and deny PMTAs for all non-tobacco flavored e-cigarettes, including menthol flavored products; and (3) prioritize enforcement actions against flavored products that continue to be sold without a marketing order, especially if they are products with a significant market share or products that are most popular with youth.

Time is of the essence. While we appreciate that the FDA has issued marketing denial orders for over one million flavored products,[4] FDA has allowed many flavored products to continue to be sold. As FDA deliberates and delays action, flavored e-cigarettes and other e-cigarette products used by youth continue to be readily available on the market, and more and more kids will become addicted to nicotine, leading to lifelong health complications. Given the role flavors play in encouraging youth vaping, we advise the FDA to deny PMTAs for *all* non-tobacco flavored e-cigarettes, including menthol-flavored products.

Thank you for your attention to this urgent matter.

Sincerely,

Debbie Wasserman Schultz
Member of Congress

Diana DeGette
Member of Congress

CC: Mitchell Zeller, Director, FDA Center for Tobacco Products

[3] Diaz MC, Donovan EM, Schillo BA, Vallone D. "Menthol e-cigarette sales rise following 2020 FDA guidance." *Tobacco Control*. November 2021. 30(6):700-703. https://pubmed.ncbi.nlm.nih.gov/32967985/

[4] FDA News Release. "FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency." October 12, 2021. https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency

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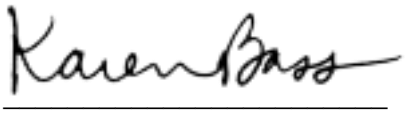

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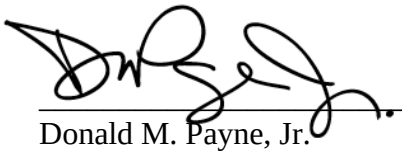

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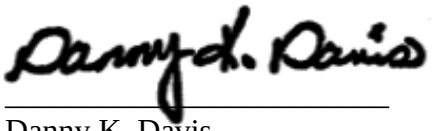

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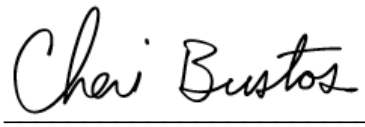

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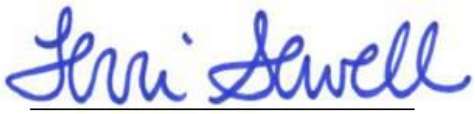

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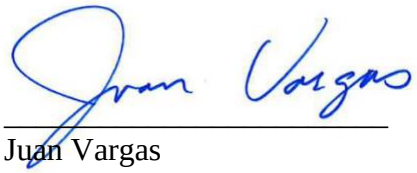

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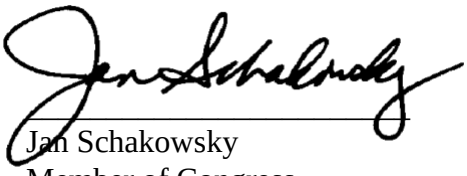

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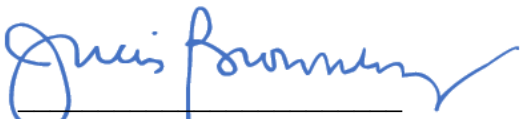

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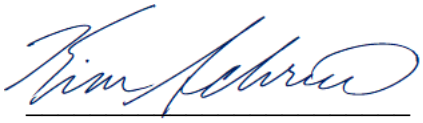

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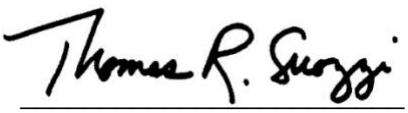

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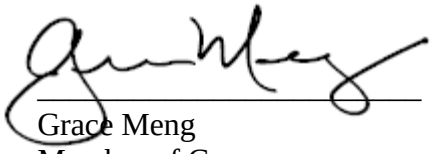

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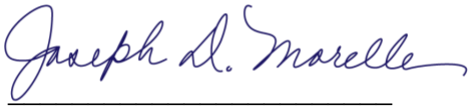

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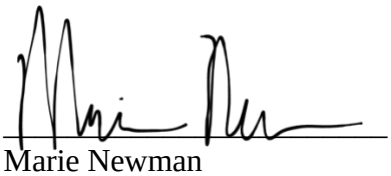

Marie Newman
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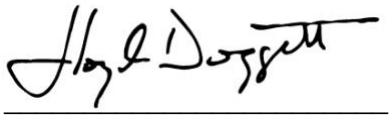

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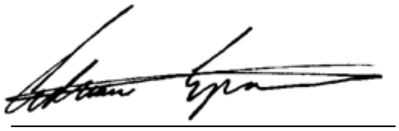

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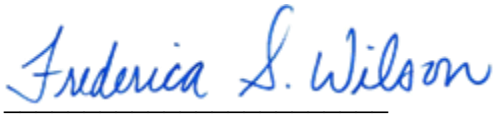

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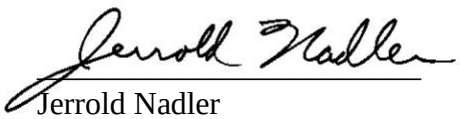

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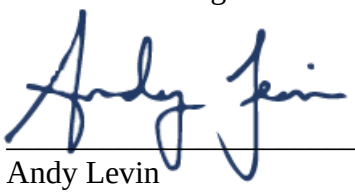

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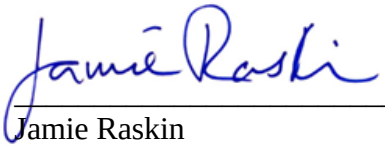

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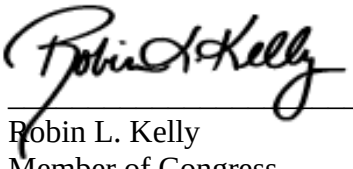

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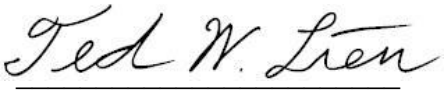

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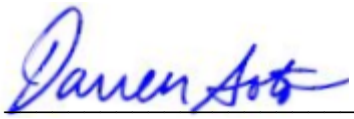

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