



American Heart Association.



October 23, 2020

Dr. Stephen M. Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Enforcement Priorities and Premarket Review of E-Cigarettes

Dear Commissioner Hahn:

In response to new data showing that youth e-cigarette use had reached record levels, the Trump Administration announced on September 11, 2019, that it planned to “clear the market” of flavored e-cigarettes,¹ a promise that it broke in the Food and Drug Administration’s (FDA) January 2020 Enforcement Guidance that exempted several categories of flavored e-cigarette products from prioritized enforcement.² Health and Human Services (HHS) Secretary Alex Azar recognized the evolving nature of the “[e-cigarette] crisis among America’s youth” in the HHS announcement of the January 2020 enforcement policy, and together, you made clear that FDA would “closely monitor the use rates of all e-cigarette products and take additional steps to address youth use as necessary.”³ More specifically, you stated, “should the FDA become aware of an increase of youth using any other flavored products (both cartridge-based or otherwise), the agency will take additional steps to address youth use of those products if necessary.”⁴

That concerning data is now in front of the agency. As FDA’s recent statement, “Next Steps on the Sept. 9 Premarket Submissions,” makes clear, “[n]ew data, such as that from the 2020 National Youth Tobacco Survey (NYTS) will . . . inform the FDA’s enforcement and other actions”⁵ We write to urge FDA to

¹ *President Trump Oval Office Remarks* (C-SPAN television broadcast Sept. 11, 2019), <https://www.c-span.org/video/?464219-1/president-trump-meets-advisers-vaping-products>.

² FDA, *Guidance for Industry, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*; 85 Fed. Reg. 23973 (Apr. 30, 2020) (first issued in January 2020 and re-issued in April 2020 “to reflect the court’s order in *American Academy of Pediatrics v. Food and Drug Administration*, Civil Action No. 8:18-cv-883-PWG (D. Md. Apr. 22, 2020), ECF No. 182 (granting a motion for a 120-day extension (until September 9, 2020) in light of the global outbreak of respiratory illness caused by a new coronavirus).

³ Press Release, HHS, *FDA Finalizes Enforcement Policy on Unauthorized Flavored Cartridge-Based E-Cigarettes That Appeal to Children, Including Fruit and Mint* (Jan. 2, 2020), <https://www.hhs.gov/about/news/2020/01/02/fda-finalizes-enforcement-policy-unauthorized-flavored-cartridge-based-e-cigarettes.html>.

⁴ *Id.*

⁵ FDA, *Next Steps on the Sept. 9 Premarket Submissions* (Sept. 21, 2020), <https://www.fda.gov/tobacco-products/ctp-newsroom/next-steps-sept-9-premarket-submissions>.

take two concrete actions in light of the new 2020 NYTS data⁶ and the e-cigarette sales data that were published in that same Morbidity and Mortality Weekly Report (MMWR) Early Release⁷: (1) revise the Agency’s current Enforcement Guidance describing enforcement priorities for e-cigarettes to remove the exemptions for both menthol and disposable e-cigarettes,⁸ and (2) consistent with the Principles to Guide FDA Premarket Review of E-cigarettes and Other Deemed Products submitted to FDA by organizations that have signed on to this letter,⁹ swiftly deny premarket review applications for flavored e-cigarettes and other flavored tobacco products subject to the deeming rule and highly addictive e-cigarettes that pose an increased risk of abuse among youth.

The NYTS data show that 3.6 million young people used e-cigarettes in 2020¹⁰—the same number that led FDA and the U.S. Surgeon General to first declare youth e-cigarette use an “epidemic” in 2018.¹¹ As you acknowledged in your statement issued on September 9, “[y]outh use of e-cigarettes remains a public health crisis.”¹² Youth e-cigarette use remains at epidemic levels in the U.S. largely due to a dramatic increase in the use and sale of menthol e-cigarettes and disposable e-cigarettes. These two categories of products were exempted from the FDA’s policy on flavored e-cigarettes reflected in the current Enforcement Guidance.¹³ The new 2020 NYTS data demonstrate that despite meaningful progress, the FDA missed an opportunity to drive down youth e-cigarette use to a far lower level and set our nation on a course to permanently reverse the youth e-cigarette epidemic. Thus, we call on you to make good on your commitment to “do everything possible to stop [this public health crisis].”¹⁴

⁶ Teresa W. Wang et al., *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69(37) MORBIDITY & MORTALITY WKLY. REP. 1310 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6937e1.htm?s_cid=mm6937e1_w.

⁷ Fatma Romeh M. Ali et al., *E-cigarette Unit Sales, by Product and Flavor Type – United States, 2014-2020*, 69(37) MORBIDITY & MORTALITY WKLY. REP. 1313 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6937e2.htm?s_cid=mm6937e2_w.

⁸ Although FDA recently has indicated that flavored disposable e-cigarettes will be an enforcement priority for the agency, Press Release, Commissioner of Food and Drugs - Food and Drug Administration Stephen M. Hahn M.D., National Survey Shows Encouraging Decline in Overall Youth E-Cigarette Use, Concerning Uptick in Use of Disposable Products (Sept. 9, 2020), <https://www.fda.gov/news-events/press-announcements/national-survey-shows-encouraging-decline-overall-youth-e-cigarette-use-concerning-uptick-use>; FDA, *supra* note 5, this new priority is at odds with the current Enforcement Guidance and does not make clear whether all flavored disposables, including menthol-flavored products, are now an enforcement priority.

⁹ American Academy of Pediatrics et al., Principles to Guide FDA Premarket Review of E-Cigarettes and other Deemed Tobacco Products, Aug. 10, 2020, https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2020_08_10_Premarket-Principles.pdf

¹⁰ Wang et al., *supra* note 6.

¹¹ FDA, *Think E-Cigs Can’t Harm Teens’ Health?*, (Apr. 30, 2020), <https://www.fda.gov/tobacco-products/public-health-education/think-e-cigs-cant-harm-teens-health>; Office of the Surgeon General, HHS, *Surgeon General’s Advisory on E-Cigarette Use Among Youth*, (2018), <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

¹² Press Release, Commissioner of Food and Drugs - Food and Drug Administration Stephen M. Hahn M.D., National Survey Shows Encouraging Decline in Overall Youth E-Cigarette Use, Concerning Uptick in Use of Disposable Products (Sept. 9, 2020), <https://www.fda.gov/news-events/press-announcements/national-survey-shows-encouraging-decline-overall-youth-e-cigarette-use-concerning-uptick-use>.

¹³ FDA, *supra* note 2.

¹⁴ Hahn, *supra* note 12.

I. **The FDA should end its enforcement exemptions for both menthol and disposable e-cigarettes.**

The FDA’s current Enforcement Guidance describing enforcement priorities for e-cigarettes has proven to be an inadequate response to the youth e-cigarette epidemic. The exemption for menthol and disposable products from prioritized enforcement against flavored e-cigarettes left thousands of flavored e-cigarettes widely available, and the new 2020 NYTS data show that kids migrated to these products.

The FDA’s Enforcement Guidance set the stage for kids to shift to disposable e-cigarettes, which remain on the market in every imaginable flavor, including cotton candy, pink lemonade, and banana ice. Given their sleek and easily concealable design, wide variety of flavors, and low price point, disposable e-cigarettes provide an easy substitute for users whose preferred cartridge-based products exited the market as a result of the Enforcement Guidance. In fact, as the example images show, many

manufacturers were already using the same flavors in disposable and cartridge-based products. Thus, it is no surprise that the new MMWR data found that between 2019 and 2020, disposable e-cigarette use increased approximately 1,000% (from 2.4% to 26.5%)



among high school current e-cigarette users and by 400% (from 3.0% to 15.2%) among middle school current e-cigarette users.¹⁵ Now, 870,000 youth are current users of disposable e-cigarettes.¹⁶ Moreover, the flavors prioritized for enforcement for cartridge-based products are now the same ones that are most popular among disposable users—among current youth users of disposable e-cigarettes, the most commonly used flavor type is fruit (82.7%), followed by mint (51.9%).¹⁷ Sales data published in the same MMWR illustrate a similar pattern. Between August 2019 and May 2020, the market share for disposable e-cigarettes nearly doubled, from 10.3% to 19.8%.¹⁸

The MMWR findings also show how quickly users migrated to menthol-flavored e-cigarettes that were exempt from the Enforcement Guidance. As expected, from August 2019 to May 2020, the proportion of pre-filled cartridge sales that were mint-flavored fell from 47.6% to 0.3%.¹⁹ At the same time, the proportion of pre-filled cartridge sales that were menthol increased dramatically from 10.7% to 61.8%.²⁰ As Figure 1 below from the MMWR shows, by May 2020, menthol-flavored products accounted for more than half (51.6%) of total e-cigarette sales, up from 11.4% in August 2019.²¹

¹⁵ Wang et al., *supra* note 6.

¹⁶ *Id.*

¹⁷ *Id.*

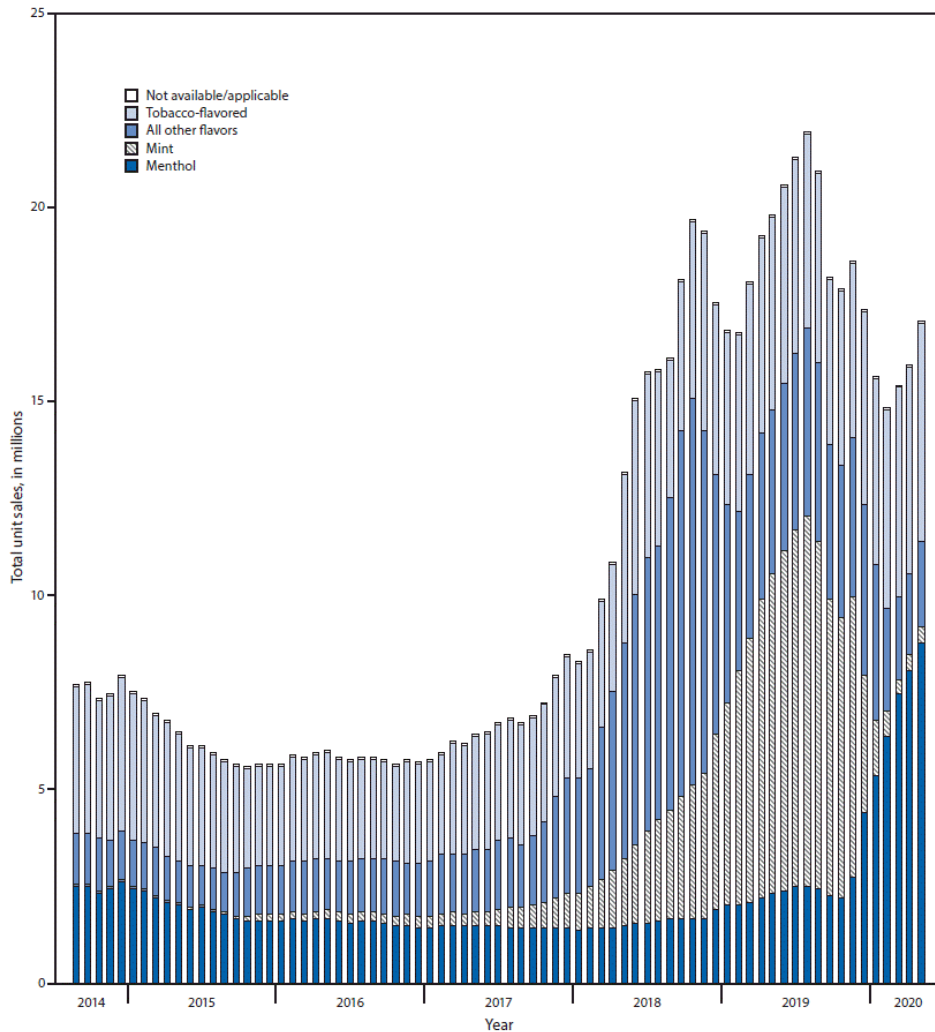
¹⁸ Ali et al., *supra* note 7.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

FIGURE 1. Total e-cigarette unit sales,* by flavor[†] — United States, September 14, 2014–May 17, 2020[§]



The NYTS data show that menthol flavors are popular among youth e-cigarette users. Among high school students who currently used any type of flavored e-cigarettes, 37% used menthol flavors.²² Use of menthol flavors was highest (44.5%) among high school e-cigarette users who primarily used e-cigarettes with prefilled pods or cartridges, like Juul.²³ The Enforcement Guidance’s exemptions provided a pathway for the industry to continue to hook over one million youth with menthol-flavored products alone.²⁴

Thus, recent data confirm that the exemptions for menthol and disposable e-cigarettes from FDA’s prioritized enforcement have led to a greater market presence of menthol and disposable products as well as an explosion of youth use of disposable e-cigarettes. The data also demonstrate the widespread youth use of menthol-flavored e-cigarettes. As noted previously, 870,000 youth are now using disposable e-cigarettes, and over one million youth are using menthol-flavored e-cigarettes. Therefore,

²² Wang et al., *supra* note 6.

²³ *Id.*

²⁴ *Id.*

the 2020 NYTS data and recent e-cigarette sales data support the urgent need for FDA to strengthen its enforcement policy by revising the current Enforcement Guidance to prioritize enforcement of the premarket review requirements against both disposable and menthol-flavored e-cigarettes.

In addition, FDA must take strong enforcement actions against non-compliant products. Any changes the agency makes to its compliance policy regarding flavored e-cigarette products must follow with swift and strong enforcement measures against those products that violate the policy. While FDA has taken some actions against products that either were introduced to the market after August 8, 2016, or that have blatantly marketed their products to youth, these measures have been sporadic and have not succeeded in removing non-compliant products from the market. Our groups have sent FDA several letters regarding products that did not appear to be on the market before August 8, 2016, yet action has not been taken on the myriad of products that fall into that category. Even when FDA sends warning letters, it is unclear when those products actually come off the market. For example, on July 20, 2020, FDA issued a warning letter to Puff Bar ordering it to remove its products from the market because they were not on the market before August 8, 2016 and did not have the required premarket authorization.²⁵ Around the same time, Puff Bar also claimed that it would suspend all its U.S. sales.²⁶ However, today the company's website states that it has only ceased all online sales.²⁷ In spite of these statements and FDA's warning letter, the company's products continue to be available on various websites online²⁸ and Nielsen data through September 5, 2020 show that Puff Bar remains the number one disposable e-cigarette brand.²⁹ These products are addicting our youth and FDA must take action to ensure that companies are compliant. Furthermore, FDA must ensure that companies take the appropriate action in response to FDA warning letters and apply the full force of the law against violators.

II. No premarket review application for any flavored e-cigarette should be authorized by FDA.

The court-ordered premarket review submission deadline of September 9, 2020 marked an important milestone for public health. As you highlighted in your statement that same day, “[s]cientific review of new products is a critical part of how [the FDA carries out its] mission to protect the public—especially kids—from the harms associated with tobacco use.”³⁰ The new 2020 NYTS and e-cigarette sales data published in the same MMWR constitute additional and significant evidence supporting the conclusion

²⁵ FDA, News Release, *FDA Notifies Companies, Including Puff Bar, to Remove Flavored Disposable E-Cigarettes and Youth-Appealing E-Liquids from Market for Not Having Required Authorization*, July 20, 2020, <https://www.fda.gov/news-events/press-announcements/fda-notifies-companies-including-puff-bar-remove-flavored-disposable-e-cigarettes-and-youth>.

²⁶ Eli Wolfe, *Controversial E-Cigarette Company Puff Bar Says It's Suspending U.S. Sales*, FAIR WARNING, July 13, 2020, <https://www.fairwarning.org/2020/07/e-cigarette-company-suspends-sales/#:~:text=Controversial%20E-Cigarette%20Company%20Puff%20Bar%20says%20it's%20suspending%20U.S.%20sales,-By%20Eli%20Wolfe&text=Puff%20Bar,%20a%20California-based,suspension%20Monday%20on%20its%20website>.

²⁷ Puff, <https://puffbar.com/> (last visited Oct. 23, 2020).

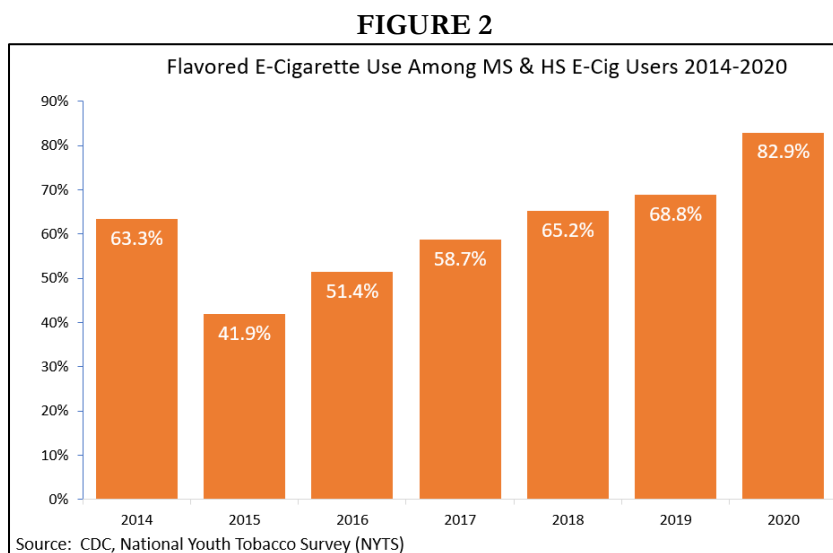
²⁸ See, e.g., Vapor4Life, <https://www.vapor4life.com/disposable-vapes/> (showing availability of Puff Bar, Puff Bar Plus and Puff Flow products for purchase) (last visited Oct. 23, 2020).

²⁹ Goldman Sachs Equity Research, *Americas Tobacco: Nielsen Data thru 9/5 – Total nicotine volumes continue to decelerate*, Ex. 19: Disposable E-Cig Market & Players, Sept. 15, 2020, at 8.

³⁰ Hahn, *supra* note 12.

that no non-tobacco flavored e-cigarette can be found appropriate for the protection of the public health.

The 2020 NYTS data published in the MMWR add to the overwhelming body of evidence that flavored e-cigarettes appeal to kids. Despite the Enforcement Guidance’s restriction on some flavored e-cigarettes, the 2020 NYTS found that the proportion of youth e-cigarette users using flavored products has steadily increased, from 41.9% in 2015 to 82.9% in 2020; this includes an increase from 68.8% in 2019 (see Figure 2 below).³¹



The data also confirm that all flavors—including menthol—appeal to kids. Among high school students who currently used any type of flavored e-cigarette, the most commonly used flavor types were fruit (73.1%), mint (55.8%), menthol (37%), and candy, desserts, or other sweets (36.4%).³² As long as any flavored e-cigarettes are left on the market, kids will get them and this public health crisis will not end. Thus, based on the available evidence to date, no premarket review application for any flavored e-cigarette or other flavored tobacco product subject to the deeming rule should be authorized by FDA.

III. The FDA should not authorize the marketing of any e-cigarette that poses an increased risk of abuse among youth.

The 2020 NYTS data also highlight the urgency of FDA action to address the youth addiction crisis. The MMWR data found that the proportion of youth who use e-cigarettes frequently is growing, an indicator of serious addiction. In 2020, 38.9% of high school users (up from 34.2% in 2019 and 15.5% in 2014) and 20% of middle school users (up from 18% in 2019) were frequent users of e-cigarettes, reporting use on at least 20 of the preceding 30 days (see Figure 3 below).³³ Alarming, 22.5% of high school users and

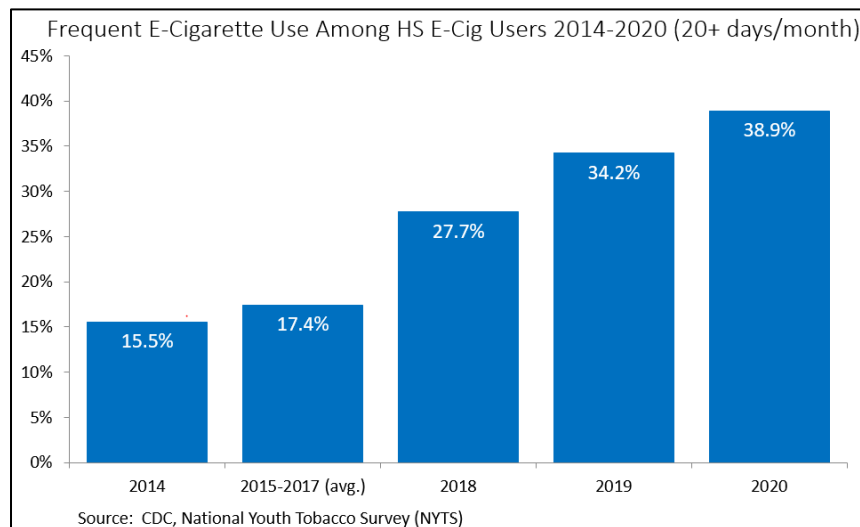
³¹ Wang et al., *supra* note 6.

³² *Id.*

³³ *Id.*

9.4% of middle school users reported daily use.³⁴ This amounts to 1.3 million middle and high school students who were frequent users of e-cigarettes, including over 730,000 daily users.³⁵

FIGURE 3



This escalating youth addiction data reflects the growing market share of products, like Juul, that have a high abuse liability, due to their high nicotine content and use of nicotine salt technology.³⁶ According to a 2018 Surgeon General advisory on e-cigarette use among youth, nicotine salts allow users to inhale high levels of nicotine more easily and with less irritation than e-cigarettes that use free-base nicotine.³⁷ As a result, the nicotine salt technology popularized by Juul makes it easier for young people to initiate use and become addicted. One study estimated that youth could meet the threshold for nicotine addiction by consuming just one quarter of a Juul pod per day.³⁸ A small study of users of Juul and other Juul-like devices (including Bo, Phix and Sourin) ages 13-21 found that their urinary cotinine levels far exceeded that of youth cigarette smokers.³⁹

Juul's competitors, seeking to emulate the company's success, have since flooded the U.S. market with high nicotine products, some delivering an even higher nicotine hit than Juul, resulting in what some researchers have referred to as a "nicotine arms race." The 5% nicotine pods sold by Juul and its competitors far exceed nicotine level limits set by many other countries, and are three or more times as powerful as most e-cigarettes on the market prior to 2015.⁴⁰ In addition to cartridge-based devices like

³⁴ *Id.*

³⁵ *Id.*

³⁶ See, e.g., Julia Belluz, *Scott Gottlieb's last word as FDA chief: Juul drove a youth addiction crisis*, *Vox*, Apr. 5, 2019, <https://www.vox.com/science-and-health/2019/4/5/18287073/vaping-juul-fda-scott-gottlieb>.

³⁷ Office of the Surgeon General, *Surgeon General's Advisory on E-Cigarette Use Among Youth*, Dec. 18, 2018, <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>.

³⁸ Robert K. Jackler & Divya Ramamurthi, *Nicotine arms race: JUUL and the high-nicotine product market*, 28(6) *TOBACCO CONTROL* 623 (2019).

³⁹ Maciej L. Goniewicz et al., *High exposure to nicotine among adolescents who use Juul and other vape pod systems ('pods')*, 28(6) *TOBACCO CONTROL* 676 (2019).

⁴⁰ Jackler & Ramamurthi, *supra* note 38.

Juul, disposable e-cigarettes and e-liquids for refillable devices are also now using nicotine salt technology. An analysis of e-cigarette sales in Nielsen-tracked channels⁴¹ found that products with 5% nicotine or higher increased from 0% of dollar sales in 2013 to 31.8% in 2017, and then doubled to 66.4% in 2018.⁴²

Teachers, parents and pediatricians across the country confirm that the youth e-cigarette epidemic is an epidemic of youth addiction.⁴³ FDA's premarket review process should therefore require manufacturers to provide convincing evidence that their products do not deliver nicotine at levels and in ways that increase the risk of abuse and addiction among youth. Products, like Juul, that quickly addict new users and then sustain addiction rather than making it easier to quit⁴⁴ should not be allowed to stay on, or enter, the market.

The new data published in the MMWR confirm that e-cigarette makers have lured kids with appealing flavors and hooked them with massive doses of nicotine. This stark reality must guide FDA in implementing premarket review and should preclude the authorization of any e-cigarettes likely to contribute to the current crisis.

Respectfully,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Parents Against Vaping e-cigarettes (PAVe)

Truth Initiative

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

⁴¹ Tracked data includes mass channel and convenience stores but does not include online sales or sales from tobacco and vape shops.

⁴² Alexa R. Romberg et al., *Patterns of nicotine concentrations in electronic cigarettes sold in the United States, 2013-2018*, 203 DRUG AND ALCOHOL DEPENDENCE 1 (2019).

⁴³ See e.g., Campaign for Tobacco-Free Kids, *Juul and Other High Nicotine E-Cigarettes Are Addicting a New Generation of Youth*, Sept. 16, 2020, <https://www.tobaccofreekids.org/assets/factsheets/0405.pdf>.

⁴⁴ Recent reviews of the scientific evidence by the U.S. Surgeon General and U.S. Preventive Services Task Force (USPSTF) confirm the 2018 finding by the National Academies of Sciences, Engineering, and Medicine (NASEM) that "there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation." Office of the Surgeon General, *Smoking Cessation: A Report of the Surgeon General*, 2020, <https://www.hhs.gov/sites/default/files/2020-cessation-sgr-full-report.pdf>; USPSTF, *Tobacco Smoking Cessation in Adults, Including Pregnant Persons: Interventions, Draft Recommendation Statement*, June 2, 2020, <https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/tobacco-smoking-cessation-in-adults-including-pregnant-women-interventions>; NASEM, PUBLIC HEALTH CONSEQUENCES OF E-CIGARETTES 584 (The National Academies Press, 2018), <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.