June 17, 2021

Dr. Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD. 20903

Mr. Mitchell Zeller
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD. 20993

Re: Opposition to SBA Advocacy Office Request for Extension of Court-Ordered One-Year Limit on Compliance Period During FDA Premarket Review of Deemed Tobacco Products

Dear Acting Commissioner Woodcock and Director Zeller:

As plaintiffs in *American Academy of Pediatrics v. FDA*, 399 F.Supp.3d 479 (D. Md 2019) (*AAP* case), we write in strong opposition to the request of the Office of Advocacy of the U.S. Small Business Administration (Advocacy Office) that the U.S. Food and Drug Administration (FDA) seek an extension of the court-established one-year period of FDA review of premarket tobacco applications (PMTAs), during which deemed tobacco products may stay on the market without being subject to FDA enforcement actions.[1] The Advocacy Office letter is based entirely on the claimed impact of enforcing the court's order on small businesses in the vaping industry, with no regard for the impact of unregulated e-cigarettes on the public health, and particularly on youth – the very considerations that informed the court's order and that support its enforcement now.

The Advocacy Office argument is based on the prospect that FDA will not be able to make decisions on many of the pending applications filed by vape shops by the September 9, 2021 deadline, requiring many small businesses to take their products off the market or risk FDA enforcement actions. The letter entirely ignores the public health importance of premarket

[1] We do not take a position on the Advocacy Office request that FDA reverse its policy of prioritizing review of the products with the largest market share, given FDA's stated commitment "to providing an opportunity for review to all companies regardless of size, prior to Sept. 9, 2021 . . . ." Mitch Zeller, CTP Director, "Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline," Feb. 16, 2021, https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline.

review of tobacco products and the adverse consequences of continuing to allow e-cigarette products to remain on the market without having met the public health standard governing that review.

First, the letter fails to recognize that virtually every e-cigarette and e-liquid product on the market now, whether sold by vape shops or not, has been illegally on the market as of the date (August 8, 2016) they were first subject to FDA jurisdiction through issuance of the final deeming rule because they lack the required premarket orders. As the court found in the AAP case, these companies have, since 2016, enjoyed "a holiday from meeting the obligations of the law," largely as a result of the FDA's prior enforcement policy which the court found to be inconsistent with the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). *American Academy of Pediatrics v. FDA*, 379 F.Supp.3d 461 (D.Md. 2019). Now the Advocacy Office asks FDA to seek to extend this regulatory "holiday" yet another year.

Second, the Advocacy Office ignores the public health consequences of continuing to allow e-cigarette products to remain on the market without the required FDA review. The Maryland court found a direct connection between the failure to enforce premarket review and the epidemic of e-cigarette use among young people that has plagued our nation for the last several years, finding that it "has allowed the manufacturers enough time to attract new, young users and get them addicted to nicotine before any of their products, labels, or flavors are pulled from the market . . . .". 379 F.Supp. at 493. Yet now the Advocacy Office seeks another year of allowing these products to remain on the market without FDA marketing orders, at a time when an alarming 3.6 million high school and middle school students are e-cigarette users[2] – about the same number as when the U.S. Surgeon General first called youth e-cigarette use an "epidemic" in 2018.[3]

Third, the vape shops and other small businesses that the Advocacy Office seeks to protect have been an important source of e-cigarettes for youth. According to the 2020 National Youth Tobacco Survey (NYTS), 22% of high school e-cigarette users report obtaining e-cigarettes from a gas station or convenience store in the past month and 17.5% from a vape shop.[4] A study in *JAMA Pediatrics* found that in California, illegal e-cigarette sales to minors are significantly higher in tobacco and vape shops than in any other type of retailer, with 44.7% selling to underage buyers.[5] An assessment of vape shops in six cities across the U.S. found that one-third of vape shops were within two blocks of schools.[6] Of these vape shops, 29% had

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[2] Andrea S. Gentzke et al., *Tobacco Product Use Among Middle and High School Students – United States, 2020,* 69(50) Morbidity & Mortality Wkly Rep. 1881, 1884 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6950a1.htm#:~:text=Tobacco%20use%20is%20the%20leading,during%20youth%20and%20young%20adulthood.&text=In%202020%2C%2023.6%25%20(3.65,use%20of%20any%20tobacco%20product.

[3] OSG, HHS, *Surgeon General's Advisory on E-Cigarette Use Among Youth* 2 (2018), https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf.

[4] TW Wang, et al., "Characteristics of e-Cigarette Use Behaviors Among US Youth, 2020," *Jama Network Open,* published online June 7, 2021, https://pubmed.ncbi.nlm.nih.gov/34097049/.

[5] April Roeseler, et al., "Assessment of Underage Sales Violations in Tobacco Stores and Vape Shops," *JAMA Pediatrics,* published online June 24, 2019, https://pubmed.ncbi.nlm.nih.gov/31233124/.

[6] Carla Berg, et al., "Exploring the Point-of Sale Among Vape Shops Across the United States: Audits Integrating a Mystery Shopper Approach," *Nicotine and Tobacco Research,* published online February 28, 2020,

signage indicating health claims prohibited by the Tobacco Control Act, 16.3% offered free e-liquid samples and 27.4% had signage with cartoon imagery.[7] Moreover, vape shops sell a multitude of the more than 15,000 discrete flavors of e-liquids, many of which are sweet fruit and candy-flavored products that obviously appeal to kids.[8]

In addition, FDA should deny the Advocacy Office request because, to the extent that FDA may be unable to make decisions on all the PMTAs now pending by September 9, that result will be due, in large part, to the abject failure of e-cigarette companies, including vape shops that manufacture e-liquids, to take seriously their obligation to seek premarket review of their products and to file their PMTAs long before the applicable deadlines. Had they done so, it would have allowed FDA to make decisions on those applications long ago. FDA has indicated that "the majority of the PMTAs timely filed "came in very close to the Sept. 9 deadline."[9] As the history of FDA premarket review shows, this bunching of applications near the deadline was the result of the industry's own recalcitrance.

FDA first stated its intention to deem all tobacco products, including e-cigarettes, subject to its jurisdiction, in March 2011.[10] This was likely before many vape shops had even entered the market. Thus, from the beginning of their business activity, vape shops functioning as product manufacturers have known that they would, at some point, have to demonstrate to FDA that their products were "appropriate for the protection of the public health," the statutory standard to enter the market as a new tobacco product.[11] Moreover, every e-cigarette manufacturer, has known, since May, 2016, when the Deeming Rule was published in final form, that the products it had on the market as of the effective date of the Rule (August 8, 2016) would be required to submit a PMTA. As of May 2016, e-cigarette companies knew that PMTAs must be filed by the end of the two-year "compliance period" set out in the Deeming Rule, or August 8, 2018.

Thus, by the time FDA published its August 2017 Guidance extending the e-cigarette application deadline until 2022 (the Guidance later vacated by the court in the *AAP* case), e-cigarette companies should have made substantial progress in preparing their applications. Even after FDA published its August 2017 Guidance, FDA repeatedly advised the industry that it should not wait to prepare and file its applications. After it became clear that there had been a dramatic increase in youth usage of e-cigarettes, in September 2018, FDA Commissioner

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https://pubmed.ncbi.nlm.nih.gov/32149340/#:~:text=All%20shops%20sold%20open-system,for%20product%20and%20price%20promotions.

[7] *Id.*

[8] Greta Hsu, et al., "Evolution of Electronic Cigarette Brands from 2013-14 to 2016-2017: Analysis of Brand Websites, 20 *J. Med. Internet. Res.* E80 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5869180/.

[9] Mitch Zeller, CTP Director, "Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline," Feb. 16, 2021, https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-review-tobacco-product-applications-submitted-sept-9-2020-deadline.

[10] FDA, Letter to Stakeholders from Lawrence R. Deyton, Director, Center for Tobacco Products and Dr. Janet Woodcock, M.D., "Regulation of E-Cigarettes and Other Tobacco Products," April 25, 2011, http://web.archive.org/web/20110513154450/http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm.

[11] 21 U.S.C. §387j(c)(2)(A).

Gottlieb indicated the agency's intent to "revisit" the 2022 deadline.[12] In that same statement, the Commissioner made it clear that "there's no excuse for manufacturers not to file applications with the FDA because the agency hasn't told them what they are expected to do. If any manufacturer wants to get direct, precise guidance on a specific product application, just call us."[13] Thus, at most there was a one-year period (August 2017-September 2018) when e-cigarette manufacturers had any reason to assume that they had until 2022 to file their PMTAs. Moreover, during all relevant times, FDA urged companies to prepare and file their applications.

As the Maryland federal court observed, "…manufacturers long have been on notice that they will have to file premarket approval applications, substantial equivalence reports, and exemption requests, and if they have chosen to delay their preparations to do so, then any hardship occasioned by their now having to comply is of their own making." *AAP v. FDA*, 379 F.Supp.3d at 498. Indeed, the industry's failure to engage with the regulatory process was a central reason for the Maryland federal court to issue its Remedial Order in July 2019 establishing the original May 2020 application deadline. According to the court, "the record before me shows a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so, and it establishes a shockingly low rate of filings." *AAP v. FDA*, 399 F. Supp. at 485. The court continued: "Thus, the record offers little assurance that, in the absence of a deadline for filing, the industry will do anything other than raise every roadblock it can and take every available dilatory measure to keep its products on the market without approval." *Id.* As new data emerged in the Fall of 2019 showing a continued dramatic increase in youth usage of e-cigarettes, Acting Commissioner Sharpless again urged companies to file their applications: "And as I've said before, responsible manufacturers certainly don't need to wait to act. We encourage industry to use available FDA resources as a guide for their submissions to the agency."[14]

Far too many companies simply ignored FDA's advice and acted as if the time they would have to adhere to the law and file their PMTAs would never come. Had companies taken their legal obligations seriously long ago, the review process would have been completed for many products long before the approaching September 2021 deadline. FDA should not reward the recalcitrance of these companies by seeking, on their behalf, additional time for them to remain on the market without an FDA marketing order, in defiance of the law.

As challenging as FDA's task is in the remaining months before the September 2021 deadline, in his June 11 presentation on the premarket review process, CTP Office of Science

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[12] FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use, September 11, 2018, https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use#:~:text=Press%20Announcements-,Statement%20from%20FDA%20Commissioner%20Scott%20Gottlieb%2C%20M.D.%2C%20on%20new%20steps,of%20youth%20e-cigarette%20use&text=Statement%20From%3A,and%20disease%20caused%20by%20smoking. Case: 5

[13] *Id.*

[14] FDA, FDA issues proposed rule for premarket tobacco product applications as part of commitment to continuing strong oversight of e-cigarettes and other tobacco products, News Release, September 20, 2019, https://www.fda.gov/news-events/press-announcements/fda-issues-proposed-rule-premarket-tobacco-product-applications-part-commitment-continuing-strong.

Director Matt Holman indicated that his office was "on pace" to meet its ambitious internal goals for processing PMTAs, due to various steps taken in preparation for intensive product review, including the hiring of significant numbers of additional staff. Certainly these reassuring statements undercut the need for any request by FDA to the court for across-the-board relief from the one-year period of review.

In the final analysis, as FDA considers the possibility that some e-cigarette products may not receive PMTA determinations by September 9, the real question is: Who should bear the burden of FDA's inability to resolve those applications? The Advocacy Office would have that burden borne by the children who will continue to be vulnerable to the availability of appealing and highly-addictive e-cigarettes permitted to remain on the market without a decision by FDA on whether they improve public health, as legally required for any new tobacco product. Consistent with the objectives of the Tobacco Control Act, and the public health mission of FDA, the burden should rather be placed on the companies whose obstinate refusal to engage the regulatory process long before the absolute deadline created the risk that products will be removed from the market until they receive marketing orders.

At a White House Summit on e-cigarettes during the Trump Administration, Senator Mitt Romney (R-Utah) juxtaposed the dimensions of the youth e-cigarette epidemic with the economic interests of the vape shops feeding that epidemic: "100 kids addicted for every one [vape shop] employee," he estimated. He added: "I put the kids first." https://www.pscp.tv/w/1OwxWdMwrMZKQ

We urge FDA to "put the kids first" as well. It should deny the request of the Advocacy Office.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative