February 27, 2020

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-D-0661: Enforcement Priorities for Electronic Nicotine Delivery Systems ("ENDS") and Other Deemed Products on the Market Without Premarket Authorization

The undersigned State Attorneys General submit these comments in response to the Guidance for Industry "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization" (the "Guidance").[1]

For many years, State Attorneys General have fought, and continue to fight against the dangers caused by tobacco products. Collectively, we have gained considerable experience and success in combating the harms caused by the tobacco industry even as new products emerge, the latest of which are ENDS. The danger of ENDS to the public, and youth in particular, is significant, and the FDA's latest Guidance detailing how it plans to deal with this danger is inadequate. We urge the FDA to reconsider the Guidance and join state Attorneys General in effectively addressing the harms caused by ENDS.

Though we are disappointed by the Guidance's various shortcomings, we are encouraged that the FDA has committed to "continuously evaluating new information and adjusting its enforcement priorities in light of the best available data."[2] We urge the FDA to amend its Guidance to 1) include menthol flavors in its enforcement priorities for ENDS; and 2) expand its enforcement priorities of ENDS products beyond cartridge based systems. Enhancing the FDA's enforcement guidance will better defend the public health from the dangers of ENDS products.

I. The FDA Should Include Menthol Flavoring In Its Enforcement Priorities

Flavored ENDS present one of the primary risks to, and entry points for, underage users of tobacco products. So, while we are encouraged to see the Guidance include mint flavored ENDS in the FDA's enforcement priorities, it is essential that the FDA also include menthol flavoring. Failure to do so threatens to undermine a key component of the Guidance.

As the FDA is undoubtedly aware, menthol flavoring is derived from mint. Because menthol is a derivative and the two flavors share common characteristics, there are two likely consequences

[1] Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization, Guidance for Industry (Jan. 7, 2020), *available at*: https://www.fda.gov/regulatory-information/search-fda- guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed- products-market [hereinafter "Guidance"].
[2] *See* Guidance at 31.

from the Guidance: first, an increase in menthol use; second, ENDS manufacturers will easily be able to evade the Guidance by characterizing mint flavoring as menthol. Both of these consequences should be deeply troubling to the FDA.

A. Usage Of Menthol Flavored ENDS Will Increase As Users Transition Away From Mint Flavored ENDS.

The FDA has noted in the Guidance that youth use of mint and menthol flavorings by high school exclusive e-cigarette users have dramatically increased, from 16% in 2016 to 57.3% in 2019.[3] Indeed, JUUL's sale of mint pods increased over 200% during this time.[4] This increase occurred after JUUL had removed from retail stores all flavors other than mint, tobacco, and menthol, calling into question the assumption that youth were choosing their flavor preferences based on appeal alone, rather than availability. As the FDA admitted in its draft guidance "[h]istorical evidence suggests that flavored tobacco product users might be willing to move to other flavored tobacco products if their preferred product is no longer available."[5] This was true of mint flavoring, and we expect it to be true of menthol, especially with regards to youth usage.

B. ENDS Manufacturers Will Be Able To Rename Mint as Menthol

The FDA's decision to permit menthol flavors is problematic because the Guidance does not detail how the Agency will determine the flavor of a product.[6] Menthol flavoring is a derivative of mint, and the Guidance is silent on how it will distinguish between the two flavors. This causes us concern that the FDA will be relying on packaging descriptions of the flavor to determine whether or not to enforce premarket authorization of these products. Since changes to packaging and labeling are outside of the FDA's premarketing review authority, leaving menthol flavoring out of the Guidance's enforcement priorities creates the possibility that mint flavoring will remain on the market, labeled as menthol.[7] Indeed, former FDA commissioner Scott Gottlieb raised precisely this concern in his commentary on the Guidance, asking "will a manufacturer seek to re-name a flavor to 'menthol' or 'tobacco' to evade the new restrictions?"[8] By allowing menthol flavoring to remain on the market, the FDA has created a loophole that the tobacco industry can exploit.

C. Youth Initiation Through Flavored ENDS Far Exceeds Rates of Adult Smoking Cessation.

The FDA's stated basis for the more lenient treatment of menthol e-cigarette products is "to avoid foreclosing one potential means by which some adult smokers might seek to transition

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[3] *See* Guidance, at 15. (citing Cullen et al., "E-cigarette use among youth in the United States, 2019," JAMA, vol.322(21) (Nov.5, 2019.))

[4] Richard Morgan, *Juul's mint-flavored e-cig sales skyrocketed after other flavors pulled*, N.Y. POST (Sept. 11, 2019), *available at* https://nypost.com/2019/09/11/juuls-mint-flavored-e-cig-sales-soared-after-other-flavors-pulled/.

[5] Modifications to Compliance Policy for Certain Deemed Tobacco Products, Draft Guidance for Industry, 9 (Mar. 2019), *available at* https://www.fda.gov/media/121384/download.

[6] *See* Guidance, at 10

[7] *See Philip Morris USA Inc. v. U.S. Food & Drug Admin.*, 202 F. Supp. 3d 31, 50 (D.D.C. 2016) (finding FDA did not have statutory authority under the Tobacco Control Act with respect to label changes).

[8] Scott Gottlieb (@ScottGottliebMD), TWITTER (Jan. 1, 2020), *available at* https://twitter.com/ScottGottliebMD/status/1212434401881137152.

completely away from combusted tobacco products to potentially less harmful tobacco products."[9] The evidence that e-cigarettes of any sort serves as a smoking cessation product or safer alternative to combustible cigarettes is presently lacking. As the Surgeon General's 2020 report on smoking cessation said, "there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation."[10] Indeed, studies have shown that adult e-cigarette users are actually more likely to be using both e-cigarettes and combustible cigarettes.[11] The evidence that flavored e-cigarettes in particular assist in quitting smoking is similarly lacking at present[12] and the FDA admits as much in the Guidance, saying that "no ENDS product has been approved by FDA as a drug for smoking cessation."[13]

The FDA's determination that menthol flavoring may contribute to adult smoking cessation appears to be based on public comments from industry participants with an ongoing interest in the sale of flavored e-cigarette products rather than research or its own pre-market review.[14] Moreover, the tenuous evidence of any possible benefit of menthol flavoring for adult smokers is far outweighed by the risk of youth initiation and use. The FDA's default to, essentially, allowing menthol flavored ENDS as a possible smoking cessation device or alternative to combustible cigarettes for adult smokers is flawed, pending better evidence, and should be abandoned. The default should be in relying upon the evidence of exploding youth usage and in upholding the public health of our youth, certainly, at least, unless or until other evidence comes forth to alter that default position.

II. Limiting the Guidance To Cartridge Based ENDS Establishes A Loophole That Will Benefit Certain Manufacturers.

The Guidance details the FDA's intention to focus on flavored cartridge-based products, excluding tobacco and menthol flavorings.[15] The Attorneys General are concerned that this loophole establishes an exception for popular non-cartridge products. Sealed disposables, like Puffbar and Eonsmoke, have gained in popularity amongst youth, come in many flavors with high nicotine strength up to 7%, and are competitors to cartridge-based products.

The Guidance defines cartridge-based ENDS products as an "ENDS product that consists of, includes, or involves a cartridge or pod that holds liquids that is to be aerosolized through products

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[9] *See* Guidance, at 19.

[10] U.S. Dep't of Health & Human Servs., Office of the Surgeon General, E-Cigarette Use Among Youth & Young Adults: A Report of the Surgeon General, 124 (2016), *available at* https://e-cigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf.

[11] *See*, *e.g.*, Allison Inserro, *Who Uses E-Cigarettes More: Current Smokers or Former Smokers?*, AJMC (July 20, 2018), *available at* https://www.ajmc.com/newsroom/who-uses-ecigarettes-more-current-smokers-or-former-smokers--; Ctrs. for Disease Control & Prevention, Ralph S. Caraballo et al., *Quit Methods Used by US Adult Cigarette Smokers, 2014–2016*, PREVENTING CHRONIC DISEASES, vol. 14 (Apr. 13, 2017), *available at* https://www.cdc.gov/pcd/issues/2017/16_0600.htm.

[12] Nat'l Inst. of Health, U.S. Nat'l Library of Med., Samane Zare et al., A systematic review of consumer preference for e-cigarette attributes: Flavor, nicotine strength, and type, PLoS ONE, vol. 13(3) (Mar. 15, 2018), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5854347/.

[13] *See* Guidance at 24 fn. 80.

[14] *See* Guidance at 20.

[15] *See* Guidance at 10 (discussing enforcement priorities)

use."[16] Furthermore, a footnote giving an example of a product that is not captured by this definition "include completely self-contained, disposable products."[17] This is particularly troubling because it excludes several ENDS products popular with youth. These include refillable cartridge systems such as Suorin, or sealed disposables such as Puffbar and Eonsmoke disposables.

Creating a loophole that allows refillable cartridge systems and sealed disposables undermines the goals of the Guidance. The articulated rationale for prioritizing cartridge-based systems similarly applies to refillable cartridges and sealed disposables. Both categories of products can be concealed, used surreptitiously in schools, and easily disposed of. By providing different treatment to refillable cartridge systems and sealed disposables, the Guidance will continue to allow products with flavors such as Mango, O.M.G., Blue Razz, and Sour Apple.

The Guidance's focus on cartridge-based systems will continue to allow the two most popular e-cigarette devices among high school students (after JUUL) to operate outside the Guidance.[18] The Guidance's narrow focus on cartridge-based systems is not sufficient to fulfill its goal of restricting youth access to ENDS product. Indeed, all the Guidance will do is move the youth market to these refillable cartridge systems, with no gain to the public health as a result.

III. Conclusion

The Attorneys General urge the FDA to amend its guidance to 1) include menthol flavors in its enforcement priorities; 2) expand it enforcement priorities to include refillable cartridge ENDS and sealed disposable ENDS products. Enhanced enforcement priorities in these areas will benefit the public health.

Respectfully submitted by:

Lawrence Wasden
Idaho Attorney General

Kwame Raoul
Illinois Attorney General

Sean Reyes
Utah Attorney General

Kevin G. Clarkson
Alaska Attorney General

[16] *See* Guidance at 9.
[17] *See* Guidance at 9 fn. 20.
[18] *See* K.A. Cullen et al., "E-cigarette use among youth in the United States, 2019," JAMA, vol. 322(21) (Nov. 5, 2019), *available at* https://jamanetwork.com/journals/jama/article-abstract/2755265 (finding 7.8% of high school e-cigarette users reported using Suorin, and 3.1% reported using Smok). Because neither of these devices were included in the questionnaire, but based on write-in responses, the results are likely higher. As refillable open pod systems, neither would be covered by the current guidance priorities.

Xavier Becerra
California Attorney General

Phil Weiser
Colorado Attorney General

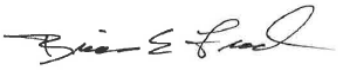
William Tong
Connecticut Attorney General

Kathleen Jennings
Delaware Attorney General

Karl A. Racine
District of Columbia Attorney General

Clare E. Connors
Hawaii Attorney General

Aaron M. Frey
Maine Attorney General



Brian Frosh
Maryland Attorney General

Maura Healey
Massachusetts Attorney General

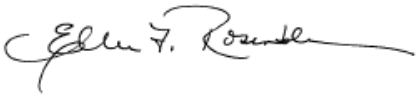
Aaron D. Ford
Nevada Attorney General

Hector Balderas
New Mexico Attorney General

Letitia James
New York Attorney General

Josh Stein
North Carolina Attorney General

Mike Hunter
Oklahoma Attorney General



Ellen F. Rosenblum
Oregon Attorney General

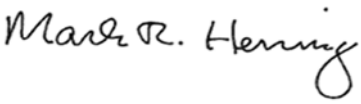
Josh Shapiro
Pennsylvania Attorney General

Dennise N. Longo Quiñones
Puerto Rico Attorney General

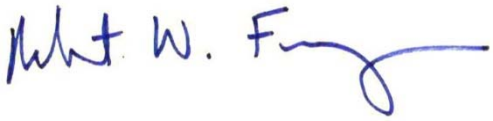
Peter F. Neronha
Rhode Island Attorney General

Ken Paxton
Texas Attorney General

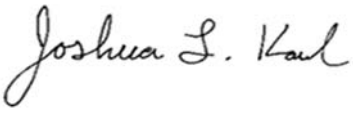
T.J. Donovan
Vermont Attorney General



Mark R. Herring
Virginia Attorney General



Robert W. Ferguson
Washington Attorney General



Joshua L. Kaul
Wisconsin Attorney General