

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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January 22, 2020

The Honorable Dr. Stephen M. Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn:

The Subcommittee is requesting information about the plans of the Food and Drug Administration (FDA) to enforce the Trump Administration's recently announced partial ban on flavored vaping pods.

On September 11, 2019, President Trump and his top health officials publicly vowed to protect America's youth by clearing the market of all flavored vaping products, including menthol.¹ The President pledged that the FDA would take action within a "couple of weeks."² The President's urgent vow to ban menthol was based on National Youth Tobacco Survey data showing that 64% of kids who vape use menthol or mint flavors.³

Despite these promises, the President went back on his commitment. Guidance was not finalized for 113 days, and when it emerged from FDA on January 2, 2020, special interests had secured an exemption for menthol.⁴ FDA justified its reversal on menthol on the Monitoring the Future (MTF) survey, which FDA claimed indicated "that youth use of menthol-flavored products is not as high as that for mint- and fruit-flavored products."⁵

However, now that children cannot get mint, they will use menthol. Chemically, mint

¹ The White House, *Remarks by President Trump in Meeting on E-Cigarettes* (Sept. 11, 2019) (online at www.whitehouse.gov/briefings-statements/remarks-president-trump-meeting-e-cigarettes/).

² *Id.*

³ Food and Drug Administration, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019) (online at www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non).

⁴ Food and Drug Administration, *Enforcement Priorities for Electronic Nicotine Delivery System (ENDS) and Other Deemed Products on the Market Without Premarket Authorization* (Jan. 2020) (online at www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-priorities-electronic-nicotine-delivery-system-ends-and-other-deemed-products-market).

⁵ *Id.*

and menthol share similar flavor profiles.⁶ Menthol is derived from mint plants.⁷ At a hearing before the Subcommittee last month, FDA Director of the Center for Tobacco Products, Mitch Zeller, acknowledged that literature supported the fact that children cannot differentiate between mint and menthol.⁸ The two flavors even make up a single category on FDA's own National Youth Tobacco Survey.⁹

Flavor migrations have been documented between less similar flavors. Mango was the most popular flavor until JUUL was forced to stop selling it, and mint went from unfavored by children to the most popular flavor. The Centers for Disease Control and Prevention (CDC) recognizes the reality of flavor migration. Dr. Ann Schuchat recently testified that "we believe that kids are likely to use whatever flavor is left."¹⁰

JUUL knows that too—its former Chief Executive Officer, Kevin Burns, is quoted as saying, "you need to have an IQ of 5 to know that when customers don't find mango, they buy mint."¹¹ With both mango and mint now banned, it is even more obvious that kids will choose menthol.

FDA's reliance on the MTF survey results for exempting menthol was inappropriate. The bulk of data collection for the MTF survey was conducted between March and May 2019, when JUUL still sold mint- and fruit-flavored pods—JUUL no longer sells them. Due to public pressure, JUUL has not sold mint-flavored pods since November 7, 2019 and has not sold fruit-flavored pods in stores since November 2018 or online since October 17, 2019.¹²

⁶ Food and Drug Administration, *Trump Administration Combating Epidemic of Youth E-Cigarette Use with Plan to Clear Market of Unauthorized, Non-Tobacco-Flavored E-Cigarette Products* (Sept. 11, 2019) (online at www.fda.gov/news-events/press-announcements/trump-administration-combating-epidemic-youth-e-cigarette-use-plan-clear-market-unauthorized-non).

⁷ *Menthol: Facts, Stats, and Regulations*, Truth Initiative (Aug. 31, 2018) (online at <https://truthinitiative.org/research-resources/traditional-tobacco-products/menthol-facts-stats-and-regulations>).

⁸ Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, Testimony of Mitch Zeller, Director of the Center for Tobacco Products, *Hearing on The Federal Response to the Epidemic of E-Cigarette Use, Especially Among Children, and the Food and Drug Administration's Compliance Policy* (Dec. 4, 2019) (online at <https://oversight.house.gov/legislation/hearings/broken-promises-examining-the-administration-s-retreat-on-banning-vaping>).

⁹ Centers for Disease Control and Prevention, *National Youth Tobacco Survey 2019 Questionnaire* (online at www.cdc.gov/tobacco/data_statistics/surveys/nyts/data/index.html).

¹⁰ Senate Committee on Health, Education, Labor and Pensions, Testimony of Dr. Anne Schuchat, Principal Deputy Director, Centers for Disease Control and Prevention, *Hearing on Examining the Response to Lung Illnesses and Rising Youth Electronic Cigarette Use* (Nov. 13, 2019) (online at www.help.senate.gov/hearings/examining-the-response-to-lung-illnesses-and-rising-youth-electronic-cigarette-use).

¹¹ *Former JUUL Executive Sues Over Retaliation, Claims Company Knowingly Sold Tainted Nicotine Pods*, CNBC (Oct. 30, 2019) (online at www.cnbc.com/2019/10/30/former-juul-executive-sues-over-retaliation-claims-company-knowingly-sold-tainted-pods.html).

¹² *JUUL Stops Selling Mint Ahead of Anticipated Federal Ban on Most E-Cigarette Flavors*, NBC News (Nov. 7, 2019) (online at www.nbcnews.com/health/vaping/juul-stops-selling-mint-ahead-anticipated-federal-ban-most-e-n1077211); *JUUL to Stop Selling Most E-Cigarette Flavors in Retail Shops in Effort to Curb 'Epidemic' Levels of Teen Vaping*, CNBC (Nov. 9, 2018) (online at www.cnbc.com/2018/11/09/juul-to-stop-selling-mango-other-e-cigarette-flavors-in-stores.html); *JUUL Has Stopped Selling All Fruity Flavors*, NBC News (Oct. 17, 2019)

FDA's decision to rely solely on the MTF survey for exempting menthol was deficient because the survey asked children only "which JUUL flavor do you use most often?"¹³ For example, according to the MTF survey, 5.9% of the 12th graders surveyed most often used menthol-flavored JUUL. However, the survey failed to determine the degree to which children used menthol when their preferred flavor was not available. In other words, FDA failed to take into consideration that exempting menthol will cause a migration of additional youth users to menthol.

The day after the guidance was announced, Mr. Zeller appeared on CNBC's *Squawk Box* to preempt criticism of the menthol exemption. During that appearance, he stated:

What we said in the guidance, and what we said in our announcement yesterday, is we have the ability to monitor and surveil what's going on and what the patterns of use are. And we've made it clear that if kids migrate to the menthol then we will have to revisit this and revisit the requirement that those products would have to get their applications in before flavors like that could be marketed.¹⁴

To fulfill the agency's promise to the country, FDA needs to be able to rapidly detect whether children are migrating to menthol. If they do, FDA needs to immediately clear the market of menthol. The Subcommittee is deeply concerned that FDA's tools to monitor youth use of flavors may not be capable of detecting youth migration to menthol without considerable delay. FDA may not be able to determine for months after-the-fact if children migrated to menthol-flavored e-cigarettes, as experts have predicted. In that case, the Administration's policy to exempt menthol from the vaping flavor ban will have done too much damage.

In order to evaluate this matter, the Subcommittee requests the following information by February 4, 2020:

1. Identify all tools that FDA plans to utilize to monitor youth use of menthol-flavored e-cigarettes, including for each such tool:
 - a. when FDA will implement use of the tool;
 - b. how information will be gathered;
 - c. over what time period will information be gathered (e.g., the dates in 2020 when surveys will begin and end); and
 - d. when FDA expects to receive youth menthol-flavored e-cigarettes use data from that tool;

(online at www.nbcnews.com/health/vaping/juul-has-stopped-selling-all-fruity-flavors-n1068211).

¹³ National Institutes of Health, *NIH-Funded Study Finds Teens Prefer Mint and Mango Vaping Flavors* (Nov. 5, 2019) (online at www.nih.gov/news-events/news-releases/nih-funded-study-finds-teens-prefer-mint-mango-vaping-flavors).

¹⁴ *Food and Drug Administration's Mitch Zeller on Why the Proposed Ban on E-Cigs Doesn't Include Menthol*, CNBC (Jan. 3, 2020) (online at www.cnbc.com/video/2020/01/03/proposed-flavored-e-cig-ban-menthol-fda-squawk-box.html).

2. If none of the tools identified above will provide FDA with data on youth use of menthol-flavored e-cigarettes within one month of being deployed, will FDA commit to developing and immediately implementing a tool that will do so and to continuing to use the tool to monitor youth menthol-flavored e-cigarette use each month?
3. Will FDA commit to immediately clearing the market of menthol-flavored e-cigarettes if it discovers that the percentage of youth users who most often use menthol increases to 10%, 20%, 30%, 40%, or even 50%? Is there any specific percentage at which FDA will commit to acting?
4. Provide monthly reports on youth menthol e-cigarette use.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee’s request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi
Chairman

Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Michael Cloud, Ranking Member