

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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October 30, 2019

Mr. Paul Ray
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
Washington, D.C. 20503

Dear Mr. Ray:

Due to the epidemic of e-cigarette use by young people, on September 11, 2019, the President announced that the Trump Administration would ban all flavored e-cigarettes, which are strongly associated with industry efforts to market to youth.¹

On Friday, October 25, 2019, the Food and Drug Administration (FDA) sent your office that compliance policy, which is entitled “Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Tobacco Products on the Market Without Premarket Tobacco Authorization.”²

I am writing to urge you to immediately approve the Administration’s compliance policy, which is designed to clear the market of all flavored e-cigarettes, including mint and menthol flavors. I also request a briefing on these matters as soon as possible.

OIRA Should Conclude its Review by November 8, 2019

Recognizing the need for immediate action on flavored e-cigarettes to combat an ongoing public health crisis, FDA Acting Commissioner Sharpless declared that FDA “must act swiftly against flavored e-cigarette products that are especially attractive to children.”³

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 Office of Information and Regulatory Affairs, *Pending EO 12866 Regulatory Review* (Oct. 25, 2019) (online at www.reginfo.gov/public/do/eoDetails?rriid=129746).

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).

Each day flavors are on the market is another day for young people to pick up their first e-cigarettes and start a lifetime of nicotine addiction.

OIRA has shown its ability to act quickly. For example, in your effort to quickly roll out the Tax Cuts and Jobs Act of 2017, you agreed that tax regulatory actions “will be reviewed by OIRA for no more than 10 business days.”⁴ In addition, OIRA is required to act on advance notices of proposed rulemaking within ten days, which are akin to this compliance policy.⁵

This policy is straightforward because it concerns only how FDA will exercise its discretionary enforcement authority. It is not designated as “economically significant.”⁶ It does not require a cost benefit analysis, which, if included, could slow your review. It is a matter within FDA’s discretion, and FDA’s determination regarding the extent of a flavor ban should not be overturned by the OIRA review process.

For these reasons, I urge you to approve the FDA’s compliance policy within ten days, by November 8, 2019.

OIRA Should Not Exclude Any Flavors from the Ban, Particularly Mint and Menthol

Secretary of Health and Human Services Azar specifically stated that mint and menthol would be included in the ban—without them, the flavor ban will not be effective at keeping kids away from e-cigarettes.⁷ Before the Subcommittee, Dr. Anne Schuchat, Principal Deputy Director of the Centers for Disease Control and Prevention (CDC), agreed, testifying that for the flavor ban to be effective, mint and menthol must be included.⁸ Mint and menthol are the most popular flavors sold, by the most popular e-cigarette maker (JUUL), which is the most popular e-cigarette among youth. Mint and menthol are used by 64% of youth users.⁹

⁴ Department of the Treasury and Office of Management and Budget, *Memorandum of Understanding*, (Apr. 11, 2018) (online at <https://home.treasury.gov/sites/default/files/2018-04/04-11%20Signed%20Treasury%20OIRA%20MOA.pdf>).

⁵ Executive Order No. 12866 § 6(b)(2)(A), 58 Fed. Reg. 51735 (Oct. 4, 1993) (online at www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf).

⁶ Office of Information and Regulatory Affairs, *Pending EO 12866 Regulatory Review* (Oct. 25, 2019) (online at www.reginfo.gov/public/do/eoDetails?rrid=129746).

⁷ 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/).

⁸ Committee on Oversight and Reform, Subcommittee on Economic and Consumer Policy, Testimony of Dr. Anne Schuchat, Principal Deputy Secretary, Centers for Disease Control and Prevention, *Hearing on “Don’t Vape: Examining the Outbreak of Lung Disease and CDC’s Urgent Warning Not to Use E-Cigarettes”* (Sept. 24, 2019) (online <https://oversight.house.gov/legislation/hearings/don-t-vape-examining-the-outbreak-of-lung-disease-and-cdc-s-urgent-warning-not>).

⁹ 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).

On October 17, 2019, JUUL announced that, in anticipation of the FDA's flavor ban, it will stop selling some flavors, but it declared that it will continue to sell mint and menthol.¹⁰ The decision to keep mint and menthol on the market shows that JUUL is not demonstrating a serious commitment to curbing youth use. This conclusion is further supported by JUUL's decision to allow Altria, a tobacco company that owns 35% of JUUL, to lobby against the flavor ban's inclusion of mint and menthol, while misleadingly claiming that *it* will not lobby the Administration to do the same.¹¹

OIRA should not weaken or scuttle the flavor ban. In 2015, the FDA submitted a rule to OIRA that included an e-cigarette flavor ban. After OIRA accepted more than 100 meetings with industry lobbyists, the rule emerged from OIRA with the flavor ban glaringly removed. Since then, flavors have fueled a youth use epidemic. E-cigarette industry lobbyists argued that more evidence was needed that flavors attract kids to e-cigarettes.¹²

Unfortunately, we now have that evidence on mass scale. Youth e-cigarette use has surged to crisis levels. Preliminary numbers from CDC's National Youth Tobacco Survey indicate that youth use of e-cigarettes has risen to an all-time high, with 27.5% of high school students reporting e-cigarette use. That is a 32% increase in the past year, and a 135% increase over two years.¹³

Subcommittee Request

The health and safety of our nation's youth are at stake. I urge you to approve FDA's ban within the next ten days and reject any attempts to weaken FDA's flavor ban. No flavor exclusions serve the public interest. In connection with this letter, I also request a briefing from your office as soon as possible on OIRA's plans with respect to the e-cigarette flavor ban.

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

¹⁰ *JUUL Suspends Sales of Flavored Vapes and Signs Settlement to Stop Marketing to Youth*, National Public Radio (Oct. 17, 2019) (online at www.npr.org/sections/health-shots/2019/10/17/771098368/juul-suspends-sales-of-flavored-vapes-and-signs-settlement-to-stop-marketing-to-).

¹¹ *JUUL Halting Sales of Most Flavors 'Does Not Stop' Trump Administration's E-Cigarette Plans*, Azar Says, CNBC (Oct. 24, 2019) (online at www.cnbc.com/2019/10/24/juul-halting-sales-of-sweet-flavors-does-not-stop-trump-plans-hhs-secretary.html); *Trump Campaign Urges White House to Soften Proposed Flavored Vape Ban*, Washington Post (Oct. 25, 2019) (online at www.washingtonpost.com/politics/trump-campaign-urges-white-house-to-soften-proposed-flavored-vape-ban/2019/10/25/5d39dbae-f733-11e9-a285-882a8e386a96_story.html).

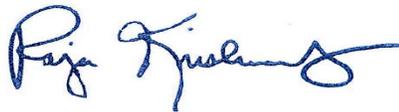
¹² *The FDA Tried to Ban Flavors Years Before the Vaping Outbreak. Top Obama Officials Rejected the Plan*, Los Angeles Times (Oct. 1, 2019) (online at www.latimes.com/politics/story/2019-10-01/vaping-flavors-obama-white-house-fda).

¹³ 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).

Mr. Paul Ray
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Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,

A handwritten signature in blue ink, appearing to read "Raja Krishnamoorthi", written in a cursive style.

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member