

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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October 21, 2019

Dr. Ned Sharpless
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Sharpless:

In my September 5, 2019, letter to you, I laid out evidence that JUUL was illegally marketing its e-cigarettes by indicating that they were safer than cigarettes and were smoking cessation devices, despite not having received the required Food and Drug Administration (FDA) approvals. I concluded that letter by asking you to take appropriate action.¹

Your response was almost immediate. On September 9, 2019, you issued a warning letter to JUUL declaring that certain of its advertising practices were illegal.² I was heartened by your speedy response and your taking the first step in holding JUUL accountable for its role in the youth vaping epidemic.

Very shortly after your response to my letter, you took another very positive step. On September 11, you joined the President and U.S. Department of Health and Human Services (HHS) Secretary, Alex Azar, in announcing that FDA would issue a compliance policy designed to clear the market of all flavored e-cigarettes, including mint and menthol flavors. You stated that FDA “must act swiftly against flavored e-cigarette products that are especially attractive to children.”³ I wholeheartedly agree with you.

During your September 11 announcement, the President said that you and the Secretary Azar are “coming back over the next pretty short period of time, couple of weeks, with some

¹ Letter from Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform, to Dr. Ned Sharpless, Acting Commissioner, Food and Drug Administration (Sept. 5, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019-09-05.RK%20to%20Sharpless-%20FDA%20re%20JUUL.pdf>).

² Warning Letter from Director Ann Simoneau, Office of Compliance and Enforcement, Center for Tobacco Products, Food and Drug Administration, to Kevin Burns, Chief Executive Officer, JUUL Labs (Sept. 9, 2019) (online at www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/juul-labs-inc-590950-09092019).

³ *Id.*

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very strong recommendations.” Later in his remarks, the President reiterated that the action would occur within “the next couple of weeks.”⁴

It has now been six weeks, but FDA has not issued the compliance policy. Each day that flavors are on the market is another day for kids to pick up their first e-cigarette and start a lifetime of nicotine addiction. Delay in FDA’s action jeopardizes the health of children.

Last week, JUUL announced that, in anticipation of FDA’s flavor ban, it will stop selling some flavors, but it declared that it will continue to sell mint and menthol. They are not only JUUL’s most popular flavors, but are used by 64% of youth users.⁵ JUUL’s action underscores the need for strong action from you today. It also highlights how important it is to fulfill your promise that the flavor ban will “include mint and menthol” flavors.⁶

I urge you to put the flavor ban in place today before one more child gets hooked by flavored e-cigarettes. If you are unable to do that, then I request a briefing at your earliest convenience on the causes of the delay.

Sincerely,



Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Mike Cloud, Ranking Member

⁴ *Id.*

⁵ 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).

⁶ *Id.*