United States Senate

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U.S. Food and Drug Administration
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Dear Mr. Rao and Dr. King:

Thank you for testifying before the Senate Judiciary Committee on June 12. Your testimony helped Committee members and the public better understand your agencies' efforts to enforce federal law against the unlawful distribution and sale of unauthorized e-cigarettes, which are currently fueling alarming and unacceptable levels of youth vaping.

We appreciate the recent announcement that a federal task force has been established to enhance enforcement against these illegal and dangerous products through collaboration among the Food and Drug Administration (FDA); Department of Justice (DOJ); Bureau of Alcohol, Tobacco, Firearms and Explosives; U.S. Marshals Service; U.S. Postal Inspection Service; and Federal Trade Commission.

We remain deeply concerned about the inconsistency between FDA and DOJ's public statements that there are only 27 FDA-authorized e-cigarettes and the reality that thousands of unauthorized e-cigarettes in kid-friendly flavors, such as Blue Razz Ice, Strawberry Watermelon Bubble Gum, and Red Bull Strawberry, are readily available for purchase.

During the June 12 hearing, you each confirmed that, under the *Family Smoking Prevention and Tobacco Control Act* (TCA), the burden of proof is on manufacturers to demonstrate, prior to market entry, that an e-cigarette is "appropriate for the protection of public health." You each further confirmed that there is no safe harbor for e-cigarettes with pending premarket tobacco product applications (PMTAs), meaning unauthorized vapes with pending PMTAs are subject to enforcement actions.

In 2019, the U.S. District Court for the District of Maryland found that FDA had violated the TCA and "decided not to enforce the premarket review provisions at all." The federal court ordered FDA to complete its review of e-cigarette PMTAs by September 9, 2021. While FDA has now missed this deadline by more than 33 months, the agency represented to the court that it would complete its reviews for the products with the largest market share by June 30, 2024. This is the fourth deadline by which FDA has committed to complete this review. FDA and DOJ now have the opportunity to correct course after failures to regulate the e-cigarette market.

It is clear that the very first order of business for the task force should be to restore the law's premarket regime and enforce the removal of all unauthorized e-cigarettes from the

market. To help inform our understanding of the interagency task force, we request responses to the following questions by July 26, 2024:

1. How will the task force prioritize enforcement actions between and among manufacturers, distributors, and retailers?

2. Will the unlawful sale or distribution of unauthorized e-cigarettes, including those with pending PMTAs, be within the scope of enforcement for the task force?

3. How will the task force augment FDA's issuance of warning letters and civil monetary penalties? Specifically, will the task force provide resources to increase the number of inspections or shorten the timeline for re-inspections to assess compliance?

4. There have been a very limited number of injunctions or seizures related to the unlawful distribution and sale of unauthorized e-cigarettes. How will the task force enhance the use of these enforcement actions?

5. What new civil and criminal authorities, aside from violations of Sections 902 and 903 of the *Federal Food, Drug, and Cosmetic Act*, does the task force anticipate using? Do you plan to request additional authorities from Congress for this purpose?

Thank you for your attention to this pressing public health matter. We look forward to your response.

Sincerely,

Richard J. Durbin
United States Senator

Mitt Romney
United States Senator

Richard Blumenthal
United States Senator

Susan M. Collins
United States Senator

Jeffrey A. Merkley
United States Senator

Thom Tillis
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Mazie K. Hirono
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Ron Wyden
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cc: The Honorable Merrick Garland, Attorney General; U.S. Department of Justice
The Honorable Robert Califf, M.D., Commissioner; U.S. Food and Drug Administration