United States Senate
WASHINGTON, DC 20510

February 20, 2020

The Honorable Alex Azar II
Secretary
Department of Health of Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretary Azar:

We write to request clarification of your recent statements on a radio program indicating the U.S. Food and Drug Administration (FDA) may: (1) exclude certain vaping products from a federal court-ordered deadline of May 12, 2020 requiring manufacturers to submit premarket applications for all new tobacco products on the market as of August 8, 2016 that FDA deemed to be subject to the Tobacco Control Act (TCA); and (2) change the standard for obtaining authorization of a premarket tobacco application (PMTA) for certain small vape-shop products. It is incredibly alarming that while youth e-cigarette use is skyrocketing, the Trump Administration continues to focus on ideas that would delay and diminish long-overdue steps to hold tobacco companies accountable.

In July 2019, a federal judge issued an order requiring that manufacturers submit premarket applications to FDA for deemed new tobacco products by May 12, 2020.[1] In a January 21 interview on an Ohio radio program, you stated that "by May of this year, all e-cigarettes – *not all vaping products*, just e-cigarettes, which are nicotine delivery devices – are required by law to come in and seek FDA approval."[2] You also stated the Administration was working "to create pathways that would streamline approval for the open-tank, small vape shop-based products."[3]

These comments raise concerns FDA will inappropriately exclude certain tobacco products from the court-ordered deadline for premarket submissions and will not hold all PMTAs submitted by the deadline to the strict standards in the TCA. It is essential FDA abide by the court's order, as well as all appropriate statutory and regulatory premarket review requirements for all new tobacco products, including open-tank systems and e-liquids made in small vape shops.

In May 2016, FDA issued a final rule deeming all categories of products that meet the TCA's definition of "tobacco product" (except accessories) to be subject to the statute's requirements.[4] As FDA articulated in the deeming rule, the definition encompasses, among other things, *all* electronic nicotine delivery systems (ENDS) and their "components and parts," including "[e]-liquids; atomizers; batteries (with or without variable voltage); cartomizers (atomizer plus

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[1] *Am. Academy of Pediatrics v. FDA*, 399 F. Supp. 3d 479 (D. Md. 2019) ("the FDA shall require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule . . . , applications for marketing orders must be filed within 10 months of this Memorandum Opinion and Order").
[2] https://www.iheart.com/podcast/139-the-scott-show-27091419/episode/hhs-secretary-alex-azar-56131042/.
[3] *Ibid.*
[4] 81 FR 28973, 28975.

replaceable fluid-filled cartridge); digital display/lights to adjust settings; clearomisers, tank systems, flavors, vials that contain e-liquids, and programmable software."[5] Accordingly, manufacturers must make premarket submissions to FDA for these and all other products that are deemed new tobacco products by May 12, 2020.

The FDA may not authorize a PMTA unless it meets the statutory requirements of the TCA, including scientific data demonstrating the "tobacco product to be marketed would be appropriate for the protection of the public health."[6] A PMTA must also contain, among other things, reports of health risk investigations, a complete statement of product ingredients, a complete description of the manufacturing and processing methods, and proposed product labeling.[7] The TCA does not include exceptions for open-tank tobacco products or distinguish "vape shop-based products" from other deemed products. Vape shops that manufacture or modify open-tank ENDS or e-liquids, and thus make new tobacco products, are required to comply with same PMTA requirements as other manufacturers.[8]

We continue to implore the Administration to take serious, appropriate action to curb the youth vaping crisis and protect the public health. As the federal judge explained in his order, this deadline is crucial to addressing the "clear public health emergency" of youth e-cigarette use that is fueled in part by specifically targeted kid-friendly flavors and "a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so . . . ."[9] The Administration must ensure only new tobacco products for which manufactures have filed applications by the May 12, 2020 deadline remain on the market after that date, and FDA reviews those premarket applications consistent with the TCA.

Accordingly, please provide, by March 5, clarification of your January 21 comments and affirm that FDA will accept and appropriately review PMTAs and all other premarket submissions for deemed new tobacco products, including those that are "open-tank, small vape shop-based products." If you have any questions, please contact Andi Lipstein Fristedt with Senator Murray's HELP Committee Staff at 202-224-7675.

Sincerely,

Patty Murray
United States Senator

Sherrod Brown
United States Senator

[5] 21 U.S.C. 321(rr)(1); 81 FR 28973, 28975.
[6] 21 U.S.C. 387j(c)(2) and (c)(4).
[7] 21 U.S.C. 387j(b).
[8] FDA Guidance for Industry, Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops, March 2019. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/interpretation-and-compliance-policy-certain-label-requirement-applicability-certain-federal-food .
[9] 399 F. Supp. 3d at 485.

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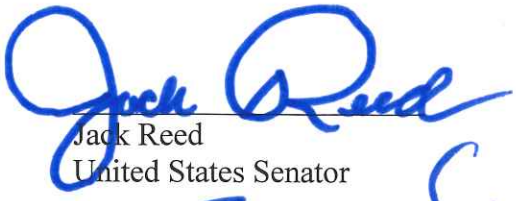

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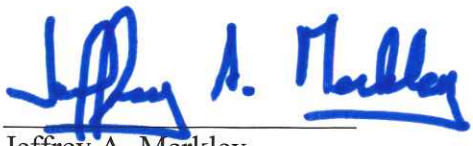

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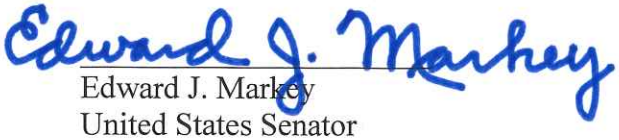

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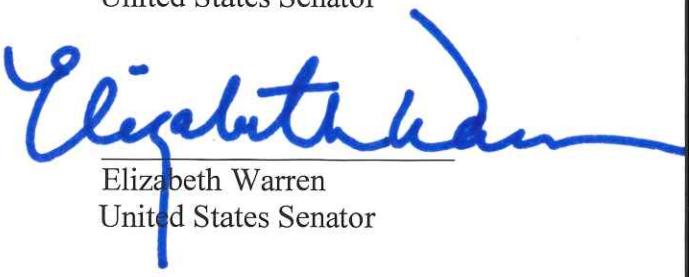

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