United States Senate
WASHINGTON, DC 20510

March 1, 2022

The Honorable Chuck Schumer
Senate Majority Leader
United States Senate
Washington, DC 20510

The Honorable Mitch McConnell
Senate Minority Leader
United States Senate
Washington, DC 20510

The Honorable Patrick Leahy
Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

The Honorable Richard Shelby
Vice Chairman
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Leader Schumer, Leader McConnell, Chairman Leahy, and Vice Chairman Shelby:

We write to respectfully request that the omnibus appropriations bill currently under negotiation include a bipartisan technical clarification to the definition of "tobacco product" within the Federal Food, Drug, and Cosmetic Act. Specifically, we ask that Congress remove any ambiguity around the Food and Drug Administration (FDA)'s ability to regulate products containing synthetic nicotine as tobacco products. Without prompt action, flavored e-cigarette manufacturers may continue to use legal loopholes to sidestep the FDA, which has the potential to erase progress we have made toward curbing the nationwide youth vaping epidemic.

Congress and multiple Administrations have enacted a series of bipartisan actions to reduce the number of children and teens addicted to harmful e-cigarettes. This includes bipartisan legislation blocking online sales to children, as well as actions by the FDA to prioritize enforcement against certain flavored e-cigarette products that appeal to kids and the FDA's implementation of the premarket review requirement for new electronic nicotine delivery systems. Despite this progress, youth e-cigarette use remains an ongoing concern as the most recent National Youth Tobacco Survey (NYTS) found that more than two million U.S. middle school and high school students used e-cigarettes in 2021. Almost 85 percent of youths using e-cigarettes used flavored products.[i]

The most recent NYTS also alarmingly confirmed that Puff Bar, the primary company still selling kid-friendly, fruit-flavored nicotine products in the United States, has gained significant traction in the youth market. Puff Bar is now used by 26.8 percent of students who vape, making it by far the most popular product amongst American youth.[ii] Though the FDA ordered Puff Bar to stop selling its tobacco-derived flavored products in 2020, the company pivoted and is now publicly selling synthetic, or "tobacco-free," flavored products in order to evade FDA regulation.[iii]

According to Puff Bar and a number of other brands, current law only authorizes the FDA to regulate tobacco-derived nicotine. They state their products contain synthetic nicotine and therefore do not fall under the agency's oversight. One chief executive explicitly called the ingredient change "a forced innovation" resulting from the need to continue to give consumers "the product that they want," and stated that the FDA gave them "no choice."[iv] Clearly, ambiguity in tobacco law facilitates deceitful behavior in the e-cigarette industry intended to evade public health oversight.

Continued confusion in the FDA's regulatory authority has the potential to sideline the meaningful progress finally being made to regulate the e-cigarette industry. This issue could grow: FDA recently rejected premarket tobacco product application paperwork for the vast majority of e-cigarette products due to failure to demonstrate that they protect the public health. Because these products may not legally be marketed, companies may reevaluate their business strategy.[v] The idea that these companies would follow Puff Bar's example and reformulate their products to leverage the synthetic nicotine loophole is troubling, but seems likely.[vi]

We have worked with bipartisan leadership of the Senate Health, Education, Labor, and Pensions (HELP) Committee, FDA, and other stakeholders on commonsense legislation that would close any loopholes. Given the seriousness and urgency of this issue, we respectfully ask that you include this language to clarify the FDA's authority to regulate synthetic nicotine as a tobacco product in the omnibus appropriations bill currently under negotiation. Thank you for your consideration of this important matter.

Sincerely,

Richard J. Durbin
United States Senator

Susan M. Collins
United States Senator

Jeffrey A. Merkley
United States Senator

Mitt Romney
United States Senator

Tim Kaine
United States Senator

Lisa Murkowski
United States Senator

Elizabeth Warren
United States Senator

John Cornyn
United States Senator

[i] Park-Lee E, Ren C, Sawdey MD, et al. Notes from the Field: E-Cigarette Use Among Middle and High School Students — National Youth Tobacco Survey, United States, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1387–1389. DOI: http://dx.doi.org/10.15585/mmwr.mm7039a4..

[ii] *Id.*

[iii] FDA WARNING LETTER Cool Clouds Distribution, Inc. d/b/a Puff Bar MARCS-CMS 608526 — JULY 20, 2020

[iv] Maloney, J. (2021, October 11). The 27-Year-Old Friends Behind Puff Bar—Teens' Favorite E-Cigarette. *The Wall Street Journal*, https://www.wsj.com/articles/the-27-year-old-friends-behind-puff-barteens-favorite-e-cigarette-11633978700.

[v] Zeller, M, (2021, September 9) Perspective: FDA's Progress on Tobacco Product Application Review and Related Enforcement, https://www.fda.gov/tobacco-products/ctp-newsroom/perspective-fdas-progress-tobacco-product-application-review-and-related-enforcement

[vi] Norcia, Alex. "Denied FDA Authorization, Vaping Companies Start to Explore Loopholes." *Filter*, 30 Aug. 2021, https://filtermag.org/fda-vaping-marketing-synthetic-nicotine/.