

# United States Senate

WASHINGTON, DC 20510

November 16, 2021

The Honorable Janet Woodcock  
Acting Commissioner  
United States Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

Dear Acting Commissioner Woodcock:

We write to express great concern over the public health challenge presented by synthetic nicotine products, including their role in prolonging the youth vaping epidemic. As the Food and Drug Administration (FDA) continues to process pre-market tobacco product applications (PMTAs) for deemed new tobacco products, we are deeply alarmed by reports that manufacturers are switching to synthetic nicotine in order to skirt required pre-market reviews and continue marketing their nicotine-containing products. We write to urge your agency to act without delay to ensure that these products do not evade regulatory oversight by using the authority granted by Congress through the Federal Food, Drug, and Cosmetic Act (FDCA) to regulate synthetic nicotine products as drugs. We also write to ask what additional authorities or resources would be helpful for the FDA to regulate synthetic nicotine as a tobacco product.

The FDA is aware<sup>1</sup> that manufacturers of synthetic nicotine products allege that their nicotine is not derived from tobacco plants. Manufacturers producing synthetic nicotine products—such as the e-cigarette brand Puff Bar—make unsubstantiated claims that the nicotine is crafted from a “patented manufacturing process” that results in synthetic nicotine “without the residual impurities of tobacco-derived nicotine.”<sup>2</sup> Many other companies also market synthetic nicotine with assertions about their products’ purity, despite the fact that these claims are not verified, are potentially misleading, and fail to acknowledge nicotine’s well-established addictive properties<sup>3</sup> and potential harm to adolescent brain development.<sup>4</sup>

We are particularly concerned that manufacturers’ use of synthetic nicotine will undermine efforts to reduce the continued popularity of youth vaping. For example, Puff Bar markets Lychee Ice, Banana Ice, Blue Razz, Strawberry Banana, and other fruit flavors<sup>5</sup> which have been shown to attract youth to vaping.<sup>6</sup> The original Puff Bar devices are also priced as low as \$12.00 per e-cigarette device and come in colorful designs, making these products even more appealing

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<sup>1</sup> “Urgent Public Health Imperative to Regulate Synthetic Nicotine E-Cigarette Products as Drugs,” September 2, 2021, [https://www.tobaccofreekids.org/assets/content/what\\_we\\_do/federal\\_issues/fda/regulatory/2021\\_09\\_02\\_Letter-to-FDA-Synthetic-Nicotine.pdf](https://www.tobaccofreekids.org/assets/content/what_we_do/federal_issues/fda/regulatory/2021_09_02_Letter-to-FDA-Synthetic-Nicotine.pdf).

<sup>2</sup> “About-Puff-Bar,” Puff Bar, accessed September 30, 2021, <https://puffbar.com/pages/about-puff-bar>.

<sup>3</sup> “Nicotine and Tobacco as Substances of Abuse in Children and Adolescents | American Academy of Pediatrics,” accessed September 30, 2021, <https://pediatrics.aappublications.org/content/139/1/e20163436>.

<sup>4</sup> “Know the Risks of E-Cigarettes for Young People | Know the Risks: E-Cigarettes & Young People | U.S. Surgeon General’s Report,” Know the Risks: E-Cigarettes and Young People | U.S. Surgeon General’s Report, accessed September 30, 2021, <https://e-cigarettes.surgeongeneral.gov/knowtherisks.html>.

<sup>5</sup> “Puff Bar,” Puff Bar, accessed September 30, 2021, <https://puffbar.com/collections/puff-bar>.

to youth and young adults. Similarly, oral nicotine products containing synthetic nicotine also are marketed in fruit and candy flavors that appeal to youth and are marketed as “convenient” and “discreet” alternatives.

Data released from your agency in September indicate that more than 2 million middle and high school students reported current e-cigarette use in 2021. Of these, over 8 in 10 of youth favor flavored products, and fruit-flavored e-cigarettes remain the most popular on the market. These data also show that Puff Bar, a synthetic nicotine product, was reported as the most commonly used brand among high school e-cigarette users. As such, these products present a grave concern for sustaining this public health crisis.<sup>7</sup>

We understand that manufacturers of synthetic nicotine, and manufacturers of products that contain synthetic nicotine, have asserted that these products are not subject to FDA regulation as a tobacco product. These manufacturers cite the statutory definition of “tobacco product” under the Family Smoking Prevention and Tobacco Control Act (TCA, Pub.L 111-31), which defines a tobacco product as any product “made or derived from tobacco,” and argue that synthetic nicotine-containing products are therefore exempt from required pre-market authorization.

However, leading public health groups have written to the FDA three times, in November 2018<sup>8</sup>, March 2021<sup>9</sup>, and September 2021<sup>10</sup> asserting in detail that synthetic nicotine meets the definition of a “drug” as defined by the FDCA because these products are intended to affect the structure or function of the human body (21 U.S.C. §321(g)(1)). The FDA itself has recognized the effects of nicotine on the human body, by explicitly stating that nicotine “produces significant pharmacological effects in consumers, including satisfaction of addiction, stimulation, sedation, and weight control.”<sup>11</sup>

We implore you to use all available authority granted by Congress through the FDCA to regulate synthetic nicotine products as drugs, absent FDA authority to regulate synthetic nicotine as a tobacco product. The agency’s failure to assert its jurisdiction over these products threatens to undermine and negate the agency’s continued review of PMTAs. The FDA cannot allow manufacturers whose PMTA was denied to immediately pivot—or not submit a PMTA altogether—to market a host of new “synthetic nicotine” products that will prolong or even worsen the youth vaping crisis.

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<sup>6</sup> Liane M. Schneller et al., “Use of Flavored Electronic Cigarette Refill Liquids among Adults and Youth in the US—Results from Wave 2 of the Population Assessment of Tobacco and Health Study (2014–2015),” *PLOS ONE* 13, no. 8 (August 23, 2018): e0202744, <https://doi.org/10.1371/journal.pone.0202744>.

<sup>7</sup> Office of the Commissioner, “Youth E-Cigarette Use Remains Serious Public Health Concern Amid COVID-19 Pandemic,” FDA (FDA, September 30, 2021), <https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-remains-serious-public-health-concern-amid-covid-19-pandemic>.

<sup>8</sup> “Regulation of Synthetic Nicotine,” November 6, 2018.

<sup>9</sup> “Synthetic Nicotine and Puff Bar,” March 18, 2021, <https://www.lung.org/getmedia/4748ba27-73ba-4271-997d-a363edba78ba/fda-letter-re-puff-bar-synthetic-nicotine-final.pdf>.

<sup>10</sup> “Urgent Public Health Imperative to Regulate Synthetic Nicotine E-Cigarette Products as Drugs,” September 2, 2021.


<sup>11</sup> “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents,” Federal Register, August 28, 1996, <https://www.federalregister.gov/documents/1996/08/28/X96-10828/regulations-restricting-the-sale-and-distribution-of-cigarettes-and-smokeless-tobacco-to-protect>.

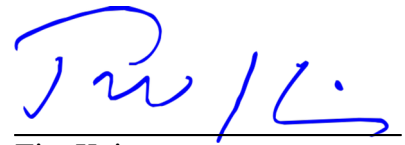
Given the urgency presented by these products, we request a response to this letter and the following questions within 30 days of receipt:


1. What steps is the FDA taking to ensure that manufacturers of tobacco products do not claim to have switched to use synthetic nicotine as a means to stay on the market after receiving a marketing denial order (MDO) from your agency?
2. On March 2, 2021, an FDA spokesperson said the FDA was aware of Puff Bar's transition to synthetic nicotine and noted an ongoing investigation.<sup>12</sup> In the more than seven months since that statement, what actions has FDA taken to investigate whether Puff Bar products are in violation of the drug or tobacco product provisions of the FDCA?
3. What additional authorities or resources would be helpful for FDA to regulate synthetic nicotine as a tobacco product?

Thank you for your attention to this critical public health concern.

Sincerely,

  
Jeffrey A. Merkley  
United States Senator

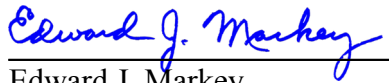
  
Tim Kaine  
United States Senator

  
Elizabeth Warren  
United States Senator

  
Sherrod Brown  
United States Senator

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<sup>12</sup> Jennifer Maloney, "Puff Bar Defies FDA Crackdown on Fruity E-Cigarettes By Ditching the Tobacco," Wall Street Journal, March 2, 2021.



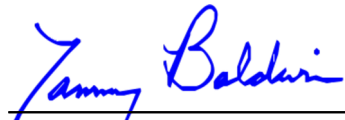
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Edward J. Markey  
United States Senator



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Richard Blumenthal  
United States Senator



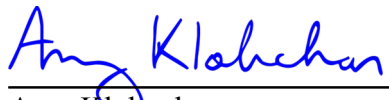
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Tammy Baldwin  
United States Senator



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Tina Smith  
United States Senator



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Amy Klobuchar  
United States Senator