



August 29, 2023

Dockets Management Staff (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2023-N-2873, Public Meeting and Listening Session for Developing the Food and Drug Administration’s Center for Tobacco Products’ Strategic Plan; Request for Comments**

The undersigned State Attorneys General submit these comments in response to the Food and Drug Administration’s (“FDA”) request for comments on the proposed five-year strategic plan for the Center for Tobacco Products (“CTP”). We urge FDA and CTP to swiftly formulate and implement a strategic plan that adequately protects public health from the glut of child-friendly flavored disposable Electronic Nicotine Delivery Systems (“ENDS”) currently on the market.

Youth ENDS use remains troublingly high, fueled largely by the widespread use of flavored disposable ENDS. Last year, 14.1% of high school students and 3.3% of middle school students reported current ENDS use.<sup>1</sup> Over 2.2 million of these students used fruit, candy, or dessert flavored ENDS; nearly 1.4 million used disposable products.<sup>2</sup>

There is a clear reason for these troubling statistics: despite lacking federally required marketing authorization, flavored disposable ENDS are ubiquitous. By the end of last year, disposable ENDS accounted for a majority of ENDS sales.<sup>3</sup> Hundreds of brands in a variety of child-friendly flavors and designs are readily available at

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<sup>1</sup> Maria Cooper et al., *Notes from the Field: E-cigarette Use Among Middle and High School Students — United States, 2022*, 71 *Morbidity and Mortality Weekly Report* 1283, 1283 (2022), <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7140a3-H.pdf>.

<sup>2</sup> *Id.* at 1284.

<sup>3</sup> Fatma Romeh M. Ali et al., *E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020-2022*, 72 *Morbidity and Mortality Weekly Report* 672, 672 (2023), <https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7225a1-H.pdf>.

convenience stores, vape shops, and online outlets nationwide. As the Associated Press recently reported, “[m]ore than 5,800 unique disposable products are now being sold in numerous flavors and formulations,” representing a 1500% increase from early 2020.<sup>4</sup>

Two of the proposed goal areas for the strategic plan—developing comprehensive and impactful tobacco regulations and ensuring compliance of regulated industry and tobacco products—must account for the risk that flavored and disposable ENDS pose to youth.

## **I. Comprehensive Tobacco Regulations Must Protect Youth From Flavored and Disposable ENDS Products.**

The strategic plan’s first goal area is to “develop, advance, and communicate comprehensive and impactful tobacco regulations and guidance.”<sup>5</sup> Comprehensive regulations and guidance must effectively protect youth from flavored and disposable ENDS products. To do so, FDA should (a) prohibit all non-tobacco flavors, including menthol, from ENDS products; (b) regulate the concentration and quantity of nicotine in ENDS products; (c) restrict marketing of ENDS products that is intended to appeal to youth, and (d) close the disposables loophole.

### **A. FDA Should Prohibit All Non-Tobacco Flavors in ENDS Products**

Several years of experience demonstrate that flavors make ENDS more attractive to youth.<sup>6</sup> “Youths report that flavors are a primary reason they use e-cigarettes, and most youth e-cigarette users first initiate use with flavored products.”<sup>7</sup> Youth are more likely to use flavored products than adults.<sup>8</sup> Flavored products—particularly those that are fruit, candy, or dessert flavored—account for the vast majority of youth ENDS use.<sup>9</sup> Last year, almost 85% of youth ENDS users reported using a flavored product.<sup>10</sup>

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<sup>4</sup> Matthew Perrone, *Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors*, Associated Press (June 26, 2023), <https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f>.

<sup>5</sup> Public Meeting and Listening Session for Developing the Food and Drug Administration’s Center for Tobacco Products’ Strategic Plan; Request for Comments, 88 Fed. Reg. 47509, 47510 (July 24, 2023) (capitalization omitted).

<sup>6</sup> Brian A. King, *Flavors Are a Major Driver of the Youth E-Cigarette Epidemic*, 110 Am. J. Pub. Health 773 (2020) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7204467/>; Nicholas I. Goldenson et al., *A Review of the Use and Appeal of Flavored Electronic Cigarettes*, 6 Current Addiction Reports 98 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6709993/>.

<sup>7</sup> King, *supra* note 6.

<sup>8</sup> Liane M. Schneller et al., *Use of Flavored E-Cigarettes and the Type of E-Cigarette Devices Used among Adults and Youth in the US*, 16 Int’l J. Env’tl. Res. & Pub. Health 2991 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6720922/pdf/ijerph-16-02991.pdf>.

<sup>9</sup> Cooper et al., *supra* note 1.

<sup>10</sup> *Id.*

To eliminate the heightened risk of youth use posed by flavors, FDA should ban all non-tobacco flavors in ENDS products.

## **B. FDA Should Regulate the Concentration and Quantity of Addictive Nicotine in ENDS Products**

In the last five years, we have witnessed a “nicotine arms race” in ENDS products.<sup>11</sup> Now, disposable ENDS commonly contain highly potent concentrations of nicotine, in some instances concentrations that exceed those of traditional combustible cigarettes and cartridge-based ENDS.<sup>12</sup> Where ENDS with nicotine concentrations above 5% were once rare, they now account for over 80% of sales.<sup>13</sup> And many brands now promise users hundreds or thousands of puffs in a single device,<sup>14</sup> easily delivering far greater cumulative quantities of nicotine than traditional cigarettes or cartridge-based ENDS.

Adolescent nicotine consumption is associated with numerous adverse physical outcomes like nicotine poisoning and toxicity, as well as mental health and behavioral problems like major depressive disorder, academic problems, and addiction to other substances.<sup>15</sup> Moreover, use of nicotine products is associated with higher susceptibility to later use of combustible cigarettes.<sup>16</sup>

FDA must stop the upward creep of nicotine in ENDS products, as many other countries have already done. Canada, for instance, limits nicotine concentration to

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<sup>11</sup> Robert K. Jackler and Divya Ramamurthi, *Nicotine Arms Race: JUUL and the high nicotine product market*, 28 *Tobacco Control* 623 (2019), <https://tobaccocontrol.bmj.com/content/28/6/623>.

<sup>12</sup> E.g. Fatma Romeh M. Ali et al., *Trends in US E-cigarette Sales and Prices by Nicotine Strength, Overall and by Product and Flavor Type, 2017-2022*, 25 *Nicotine Tobacco Res.* 1052, 1054 (2023), <https://academic.oup.com/ntr/article/25/5/1052/6965257>; U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease, Prevention and Health Promotion, Office on Smoking and Health, *E-Cigarette Use Among Youth And Young Adults: A Report of the Surgeon General* 100 (2016), [https://www.cdc.gov/tobacco/data\\_statistics/sgr/e-cigarettes/pdfs/2016\\_sgr\\_entire\\_report\\_508.pdf](https://www.cdc.gov/tobacco/data_statistics/sgr/e-cigarettes/pdfs/2016_sgr_entire_report_508.pdf).

<sup>13</sup> Romeh, *supra* note 12, at 1053.

<sup>14</sup> See, e.g., ELFBAR Pi7000 Disposable Pod Device, ELFBAR (last accessed July 17, 2023), <https://www.elfbar.com/product/ELFBAR-Pi7000-Disposable-Pod-Device.html> [<http://web.archive.org/web/20230613204130/https://www.elfbar.com/product/ELFBAR-Pi7000-Disposable-Pod-Device.html>].

<sup>15</sup> Brenda Douglass et al., *The Harmful Consequences of Vaping: A Public Health Threat*, 31 *J. Addictions Nursing* 79 (2020); Shivani Mathur Gaiha and Bonnie Halpern-Felsher, *Escalating Safety Concerns Are Not Changing Adolescent E-Cigarette Use Patterns: The Possible Role of Adolescent Mental Health*. 66 *J. Adolescent Health* 3 (2020); Shivani Mathur Gaiha and Bonnie Halpern-Felsher, *Public Health Considerations for Adolescent Initiation of Electronic Cigarettes*, 145 *Pediatrics* S175 (2020); Olufunmilayo H. Obisesan et al., *Association Between e-Cigarette Use and Depression in the Behavioral Risk Factor Surveillance System, 2016-2017*. *JAMA Netw. Open.* 2019;2(12):e1916800.

<sup>16</sup> Kaitlyn M. Berry et al. *Association of Electronic Cigarette Use with Subsequent Initiation of Tobacco Cigarettes in US Youths*. *JAMA Netw. Open.* 2019;2(2):e187794-e.

20mg/ml.<sup>17</sup> FDA should follow suit and impose evidence-based limits on nicotine in ENDS products.

### **C. FDA Should Restrict Marketing that Attracts Youth**

Marketing influences young people’s decision-making process and is a significant reason they use ENDS.<sup>18</sup> Youth are particularly susceptible to marketing and advertising, and exposure to ENDS marketing is associated with lower perceptions of related risks, including risk of addiction.<sup>19</sup>

Internet and social media marketing has been particularly problematic, increasing ENDS manufacturers’ opportunities to interact with young consumers.<sup>20</sup> And the use of social media and influencers can be especially pernicious for youth, given that tobacco marketing messages are more effective when they appear to come from peers rather than the manufacturer.<sup>21</sup>

FDA should adopt regulations that ensure marketing materials are not attractive to youth and that youth are not bombarded with messages encouraging them to use these products. As part of this work, FDA should closely examine the digital marketing landscape, including website advertising and the use of social media platforms like Snapchat, TikTok, Instagram, and Facebook, which deliver ENDS marketing directly to youth.

### **D. FDA Must Close the “Disposables Loophole”**

The surge of flavored disposable ENDS is partly a product of the “disposables loophole” in FDA’s 2020 Enforcement Priorities for Electronic Nicotine Delivery

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<sup>17</sup> *Vaping Products Regulation*, Canada.ca (August 8, 2023), <https://www.canada.ca/en/health-canada/services/smoking-tobacco/vaping/product-safety-regulation.html>.

<sup>18</sup> Kristy Marynak et al., *Exposure to Electronic Cigarette Advertising Among Middle and High School Students — United States, 2014–2016*, 67 *Morbidity and Mortality Weekly Report* 294 (2018), <https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6710a3-H.pdf>.

<sup>19</sup> Lauren Collins et al., *E-Cigarette Marketing and Communication: How E-Cigarette Companies Market E-Cigarettes and the Public Engages with E-cigarette Information*, 21 *Nicotine Tobacco Res.* 14 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6610165/pdf/ntx284.pdf>; Pallav Pokhrel et al., *Receptivity to E-cigarette Marketing, Harm Perceptions, and E-cigarette Use*, 39 *Am. J. Health Behav.* 121 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4877176/pdf/nihms-781339.pdf>; Karma McKelvey et al., *Youth say ads for flavored e-liquids are for them*, 91 *Addictive Behav.* 164 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6663555/pdf/nihms-994716.pdf>; Erin A. Vogel et al., *Effects of Social Media on Adolescents’ Willingness and Intention to Use E-Cigarettes: An Experimental Investigation*, 23 *Nicotine Tobacco Res.* 694 (2021).

<sup>20</sup> Nathan A. Silver et al., *Examining influencer compliance with advertising regulations in branded vaping content on Instagram*, *Frontiers Pub. Health* 10:1001115 (Jan. 9, 2023), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9869128/pdf/fpubh-10-1001115.pdf>; Robert K. Jackler et al., *Promotion of Tobacco Products on Facebook: Policy versus Practice*, 28 *Tobacco Control* 67 (2019).

<sup>21</sup> Edward Sepe et al., *Smooth Moves: Bar and Nightclub Tobacco Promotions that Target Young Adults*, 92 *Am. J. Pub. Health* 414 (2002), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447091/pdf/0920414.pdf>.

Systems. The Enforcement Priorities indicated that FDA’s top priority in 2020 was enforcement against cartridge-based products, such as JUUL. The Enforcement Priorities entirely omitted disposable flavored products, noting that—at the time—they were less popular among youth than cartridge-based products.<sup>22</sup> This is no longer the case. In 2022, more than half of youth ENDS users reported using disposables, while just a quarter reported using pod or cartridge-based products.<sup>23</sup>

New regulations and updated enforcement guidance must eliminate the disposables loophole. FDA should clearly communicate to the entire supply chain that federal authorities will not tolerate the unlawful sale of unauthorized flavored disposable ENDS. Going forward, we also urge FDA to take care to avoid introducing similar opportunities for unscrupulous companies to catapult emerging classes of ENDS products to popularity among youth.

## II. Enforcement Must Meaningfully Target the Entire Supply Chain

The strategic plan’s third proposed goal area is to “ensure compliance of regulated industry and tobacco products utilizing all available tools, including robust enforcement actions.”<sup>24</sup>

We appreciate that FDA has recently taken some steps to protect youth from flavored disposable ENDS. FDA has denied marketing authorization for ENDS that the agency has concluded do not demonstrate a benefit to adult users adequate to outweigh the risks to youth.<sup>25</sup> In recent months, FDA has also issued warning letters and import alerts aimed at stopping sales of Hyde, Esco Bar, Elf Bar, and Puff branded flavored disposable ENDS, which are currently among the most popular with youth.<sup>26</sup>

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<sup>22</sup> Food and Drug Administration, Center for Tobacco Products, Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised) 9, 11 (2020), <https://www.fda.gov/media/133880/download>.

<sup>23</sup> Cooper et al., *supra* note 1, at 1283.

<sup>24</sup> 88 Fed. Reg. at 47510 (capitalization omitted).

<sup>25</sup> *Tobacco Products Marketing Orders*, Food & Drug Administration (July 10, 2023), <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Marketing%20Denial>.

<sup>26</sup> FDA Puts Distributors on Notice for Illegal E-Cigarettes Popular with Youth, Including Elf Bar/EB Design and Esco Bars, U.S. Food & Drug Administration (July 27, 2023), <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-puts-distributors-notice-illegal-e-cigarettes-popular-youth-including-elf-bareb-design-and-esco>; FDA Conducts Retailer Inspection Blitz, Cracks Down on Illegal Sales of Popular Disposable E-cigarettes, U.S. Food & Drug Administration (May 31, 2023), <https://www.fda.gov/news-events/press-announcements/fda-conducts-retailer-inspection-blitz-cracks-down-illegal-sales-popular-disposable-e-cigarettes>; FDA Inspection Blitz Leads to More Than 180 Warning Letters to Retailers for the Illegal Sale of Youth-Appealing Elf Bar and Esco Bars E-Cigarettes, U.S. Food & Drug Administration (June 22, 2023), <https://www.fda.gov/news-events/press-announcements/fda-inspection-blitz-leads-more-180-warning-letters-retailers-illegal-sale-youth-appealing-elf-bar>.

While these are positive steps, they are not sufficient to stem the tide of flavored disposable ENDS products.<sup>27</sup> We urge FDA and its federal partners to initiate and follow through with enforcement actions against manufacturers, distributors, and retailers who are saturating the market with these products. We understand that FDA's recent retailer warning letters require recipients' responses within 15 working days. FDA should promptly pursue appropriate penalties against any recipients who refuse to remedy the relevant violations. Allowing violations to go unanswered undermines the deterrent effect the warning letters would otherwise have and risks further harm to children.

\* \* \*

We appreciate the FDA's attention to this important matter and stand ready to provide any support necessary to protect our kids from addiction to these dangerous products.

Sincerely,



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<sup>27</sup> Barbara A. Schillo et al., *Analysis of e-cigarette warning letters issued by the Food and Drug Administration in 2020 and 2021*, *Tobacco Control* (Oct. 13, 2022), <https://tobaccocontrol.bmj.com/content/early/2022/08/29/tc-2022-057359>.



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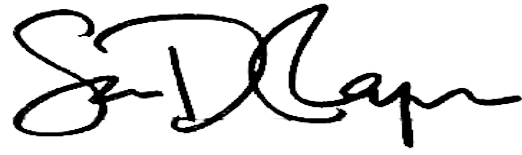
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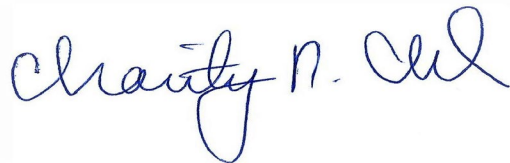




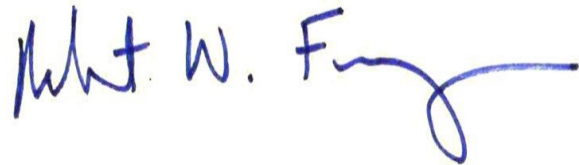
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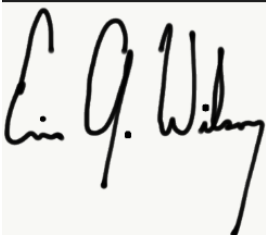
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