



TODD ROKITA
ATTORNEY GENERAL

August 29, 2023

The Honorable Robert Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

Dear Commissioner Califf:

As the Chief Legal Officer for the State of Indiana and as a parent to young children, I write to express my concerns about the proliferation of illegal disposable e-cigarettes inundating our communities and schools. Over 2.5 million middle and high school students nationwide have used an e-cigarette in the past 30 days, and 25% use e-cigarettes daily.¹ In Indiana, 1 in 10 high school students and 1 in 30 middle school students reported current tobacco product use with e-cigarettes being the most used.² I urge the Food and Drug Administration (“FDA”) to carefully consider these concerns when crafting the proposed strategic plan for the Center for Tobacco Products.

In late May, you added exporters of these dangerous devices to your import red list, which means the Agency can detain all future shipments of these products without warning.³ You also issued warning letters to producers of these youth-enticing

¹ Cooper M, Park-Lee E, Ren C, Cornelius M, Jamal A, Cullen KA. *Notes from the Field: E-cigarette Use Among Middle and High School Students — United States, 2022*. MMWR Morb Mortal Wkly Rep 2022;71:1283–1285, <http://dx.doi.org/10.15585/mmwr.mm7140a3>.

² Ind. Dep’t of Health, *Highlights from the Indiana Youth Tobacco Survey (2022)*, <https://www.in.gov/health/tpc/files/Highlights-from-the-2022-IYTS.pdf>.

³ Press Release, U.S. Food & Drug Admin., *FDA Puts Firms Responsible for Esco Bars and Breeze – Two Popular Disposable E-cigarette Brands – On Notice* (May 25, 2023), <https://www.fda.gov/tobacco-products/ctp-newsroom/fda-puts-firms-responsible-esco-bars-and-breeze-two-popular-disposable-e-cigarette-brands-notice>.

products demanding that producers begin complying with federal law.⁴ I appreciate the FDA’s recent actions to tamp down on these products, but the import alert and warning letters do not go far enough to protect our children. Indiana and its enforcement officers and agency’s need further and immediate clarity and enforcement actions to permanently remove these products from store shelves and extricate them from the hands of our kids.

In the United States, Puff, Elf Bar, and Breeze Smoke remain the most popular brands of illegal disposable e-cigarettes.⁵ These products come in “child-friendly” flavors such as Blue Razz Ice, Strawberry Cream, and Bubble Gang Sour Apple Berry—and they are highly obtainable to America’s youth at local convenience stores, via TikTok, and on various easily accessible websites.⁶

In fact, Chinese disposables e-cigarette manufacturers, such as Elf Bar, directly market their products to our youth on TikTok. The hashtag “#ElfBar” recently passed 2.1 billion views on the platform.⁷ Interestingly, last October, the Chinese government banned flavored vaping products for its own citizens.⁸ Much like the use of TikTok, what China considers too detrimental for its own youth, it allows for the unadulterated exportation of American consumers, especially its youth.⁹ The number of different types of e-cigarette devices sold in the U.S. has nearly tripled to over 9,000 since 2020.¹⁰ This rise is almost entirely driven by unauthorized disposable vapes from China.¹¹ New products launch from China by simply sending a logo and flavor to Chinese manufacturers, and in turn, those manufacturers can deliver tens of thousands of devices within weeks.¹²

Moreover, and very critically, the dangers of fentanyl are not confined to illicit pills. Several reports suggest that illegal, disposable, and flavored e-cigarettes made

⁴ Press Release, U.S. Food & Drug Admin., *FDA Conducts Retailer Inspection Blitz, Cracks Down on Illegal Sales of Popular Disposable E-Cigarettes* (May 31, 2023), <https://www.fda.gov/news-events/press-announcements/fda-conducts-retailer-inspection-blitz-cracks-down-illegal-sales-popular-disposable-e-cigarettes>.

⁵ CDC, Ali FR, Seidenberg AB, Crane E, Seaman E, Tynan MA, Marynak K. *E-cigarette Unit Sales by Product and Flavor Type, and Top-Selling Brands, United States, 2020–2022*. *MMWR Morb Mortal Wkly Rep* 2023;72:672–677, https://www.cdc.gov/mmwr/volumes/72/wr/mm7225a1.htm?s_cid=mm7225a1_w.

⁶ See Disposable Vapes, Made-in-China.com: <https://bit.ly/40GbxXs>.

⁷ Shant Shahrigan, *Feds should crack down on Elf Bar vaping products targeting kids, Sen. Schumer says*, *NEW YORK DAILY NEWS* (March 19, 2023), <https://www.yahoo.com/lifestyle/feds-crack-down-elf-bar-212000914.html>.

⁸ Jim McDonald, *China: Flavor Ban and Other Rules Take Effect Oct. 1st*, *VAPING360* (Sept. 27, 2022), <https://vaping360.com/vape-news/117762/china-flavor-ban-and-other-rules-take-effect-oct-1st/>.

⁹ Joe McDonald and Zen Soo, *Why does US see Chinese-owned TikTok as a security threat?*, *AP NEWS* (March 24, 2023), <https://apnews.com/article/tiktok-bytedance-shou-zi-chew-8d8a6a9694357040d484670b7f4833be>.

¹⁰ Thousands of types of illegal vaping devices, mostly from China, flooding US despite FDA crack-down, report says, *CBS NEWS* (June 27, 2023), <https://www.cbsnews.com/news/illegal-vaping-devices-mostly-china-us-fda-crackdown>.

¹¹ *Id.*

¹² *Id.*

in China and unlawfully sold to consumers in America may be laced with fentanyl.¹³ The rate of overdose deaths involving synthetic fentanyl increased over 56% from 2019 to 2020¹⁴ and another 26% from 2020 to 2021.¹⁵ In 2021, there were 67,325 deaths attributable to synthetic fentanyl.¹⁶ With the ability to vape any substance, including THC, children who obtain illegal e-cigarettes are at a heightened risk of unknowingly consuming fentanyl.

The FDA's warning letters serve as a first step but do not address all the illegal manufacturers and products in the marketplace or the fentanyl crisis.¹⁷ The warning letters and import alert provide inconsistent application of the Agency's enforcement, making such guidance confusing for State retailers. The alert and warnings touched on Elf Bar, Esco Bar, and Breeze, but left Air Bag, Mr. Fog, Fume, and Kang Vape unaddressed.¹⁸ By taking enforcement action on one product and not the other, the inconsistency could lead retailers and consumers to think that the FDA authorized certain products, such as Kang Vape.

As a champion of small businesses, I understand that operating in an unclear, inconsistent regulatory environment can negatively impact them. Many U.S. retail associations believe the FDA could rectify this situation by publicly identifying the disposable electronic nicotine delivery systems that may be sold subject to the Agency's enforcement discretion.¹⁹ Specifically, the FDA's Center for Tobacco Products could provide better assistance and clarity to states' enforcement agencies, wholesalers, and retailers by publishing a list of disposable e-cigarettes that may be sold.

The lack of enforcement allows bad actors to contaminate the American people with these addicting and potentially dangerous, illegal disposable e-cigarettes in

¹³ Greg Swan, *China is fueling America's fentanyl epidemic through illegal, disposable flavored vapes*, WASHINGTON TIMES (June 19, 2023), <https://www.washington-times.com/news/2023/jun/19/china-is-fueling-americas-fentanyl-epidemic-throug>; see also Brooke Steinberg, *My 13-year-old son will never be the same after fentanyl-laced vape*, NY POST (March 31, 2023), <https://nypost.com/2023/03/31/my-son-13-will-never-be-the-same-after-fentanyl-laced-vape/>; Jessica Moore, *In wake of scary incident at New Rochelle High School, expert offers advice how to keep kids who vape safe*, CBS NEW YORK (Jan. 11, 2023), <https://www.cbsnews.com/newyork/news/in-wake-of-scary-incident-at-new-rochelle-high-school-expert-offers-advice-how-to-keep-kids-who-vape-safe/>.

¹⁴ CDC, Fentanyl, <https://www.cdc.gov/opioids/basics/fentanyl.html> (last visited July 18, 2023).

¹⁵ *Id.*

¹⁶ National Safety Council, Drug Overdoses, <https://injuryfacts.nsc.org/home-and-community/safety-topics/drugoverdoses/data-details/> (last visited July 18, 2023).

¹⁷ News Release, FDA, *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* (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>.

¹⁸ Thousands of types of illegal vaping devices, mostly from China, flooding US despite FDA crackdown, report says, CBS NEWS (June 27, 2023), <https://www.cbsnews.com/news/illegal-vaping-devices-mostly-china-us-fda-crackdown>.

¹⁹ Taco Tuinstra, *Retailers Seek Clarity on Vapor Products*, TOBACCO REPORTER (June 2, 2023), <https://tobaccoreporter.com/2023/06/02/u-s-retailers-seek-clarity-on-vapor-products/>.

various youth-enticing flavors. Every day the FDA does not act places the public safety and health of our children and individuals who use these products at risk. Immediate enforcement against these hazardous products is needed for the sake of our children.

The Chinese Communist Party remains the most consequential threat to national security and the well-being of our country.²⁰ On behalf of my constituents, I ask the FDA to act quickly to provide increased on-the-ground enforcement efforts at brick-and-mortar retailers in collaboration with state and local law enforcement. Again, the FDA needs to provide more direction on which disposable electronic nicotine delivery systems may be lawfully sold subject to the Agency's enforcement discretion by publishing a list of products that may be lawfully sold.

Thank you for your attention to this matter.

Respectfully,

A handwritten signature in black ink, appearing to read "Todd Rokita". The signature is fluid and cursive, with a large, stylized initial "T".

TODD ROKITA
ATTORNEY GENERAL OF INDIANA

²⁰ Olivia Gazis, *China "most consequential threat" to US national security, top intelligence official says*, CBS NEWS (March 8, 2023), <https://www.cbsnews.com/news/china-worldwide-threats-hearing>.