

Congress of the United States

Washington, DC 20515

April 10, 2024

Brian Boynton
Consumer Protection Branch
U.S. Department of Justice
Civil Division
950 Pennsylvania Avenue, N.W.
Washington, D.C. 20530

Dear Principal Deputy Assistant Attorney General Boynton:

As Members of the Bipartisan Congressional Caucus to End the Youth Vaping Epidemic, we write to express our concern regarding the lack of enforcement in prosecuting illegal flavored vaping products. We ask you to respond to our questions no later than May 30, 2024.

FDA, to date, has not authorized a flavored vaping product. Yet unauthorized vaping products, the majority of which come from the People’s Republic of China (PRC), have flooded the market and continue to contribute significantly to underage vaping rates. According to the latest data available, among young people who reported e-cigarette use, more than one in four used e-cigarettes daily in 2023, and over a third reported using e-cigarettes at least 20 days in a month.¹ Flavors attract kids to tobacco products and nine out of ten youth e-cigarette users preferred flavored e-cigarettes,² with 56 percent of users using the most popular reported brand, Elf Bar,³ which has not been authorized by FDA.

Dozens of distributors and wholesalers in the United States carry illicit flavored vaping products without any consequences, while making thousands of dollars in profit.⁴ In one instance, 25 to 35 percent of one company’s profit came from sales of a single brand of illicit vapes.⁵

Safety and health are another area of major concern. There are alarming reports of electronic nicotine disposables and other vape products exploding and causing serious injury and death dating back to as early as 2018.⁶ In one case, a child sustained injury to his jaw after a vape pen exploded in his mouth. The pediatric surgeon treating the cracked jaw and shattered bone described the injury as “kind of like a close-range gunshot wound.”⁷ Just earlier this month, a vaping storage facility caused an intense explosion and fire, killing one person in Michigan.⁸ According to a 2018 Surgeon General’s Advisory, e-cigarettes are not harmless. Most contain nicotine, which can be harmful to the developing adolescent brain and can impact learning, memory,

¹ FDA. “Results from the Annual National Youth Tobacco Survey.” (November 2023) (Online at <https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey>)

² *Id.*

³ *Id.*

⁴ *Reuters*. “China e-cigarette titan behind ‘Elf Bar’ floods the U.S. with illegal vapes.” (December 6, 2023) (Online at <https://www.reuters.com/world/china/china-e-cigarette-titan-behind-elf-bar-floods-us-with-illegal-vapes-2023-12-06/>)

⁵ Transcript of Preliminary Injunction Hearing Before the Honorable Aileen Cannon, Case 9:22-cv-81576-Cannon

⁶ *The Florida Times Union*. “Autopsy report: Exploding vape pen killed Florida man.” (May 16, 2018) (Online at <https://www.jacksonville.com/story/news/state/2018/05/16/autopsy-report-exploding-vape-pen-killed-florida-man/12223913007/>)

⁷ *The Washington Post*. “A teen’s injuries looked like he was in a ‘high-speed’ crash. Instead, a vape pen exploded in his mouth.” (June 20, 2019) (Online at <https://www.washingtonpost.com/nation/2019/06/20/teens-injuries-looked-like-he-was-high-speed-crash-instead-vape-pen-exploded-his-mouth/>)

⁸ *Associated Press*. “Explosive fire at site housing vaping supplies kills 1 outside Detroit, sends debris a mile away.” (March 5, 2024) (Online at <https://apnews.com/article/industrial-fire-explosions-detroit-3f13867de5df191b4a34118e796a7d4d>)

and attention. E-cigarettes can also emit other harmful substances, including heavy metals, volatile organic compounds, and ultrafine particles.⁹

These facts are deeply troublesome to us, and we look forward to learning about your approach to addressing these concerns. We ask you respond to the questions below by May 30, 2024:

- (1) How many vapor or vapor-related cases has the Food and Drug Administration (FDA) referred to DOJ? How many vapor or vapor-related cases have the DOJ investigated or prosecuted in the last three years? How many, if any, such referrals are currently pending with the DOJ?
- (2) What is the referral or investigation process from the FDA to the DOJ? Has DOJ provided FDA with guidance regarding the type(s) of vapor cases that are appropriate for referral to DOJ? Separate from referrals from the FDA, has the DOJ initiated any investigations relating to vapor, or vapor-related products during the last three years?
- (3) What is the DOJ's internal review process or procedure once a referral has been received from the FDA? What factors are considered in declining or proceeding with a vapor, or vapor-related case? For each referral, please indicate whether DOJ took action and the amount of time that occurred between the referral and DOJ taking action.
- (4) Is there a unit within the DOJ focusing on prosecuting vapor or vapor-related crimes? Would such a unit be helpful? Does the DOJ have sufficient resources or expertise to litigate vapor-related referrals from the FDA?
- (5) Does the DOJ have plans to initiate further civil or criminal proceedings for egregious violations by manufacturers, wholesalers, or distributors, including injunctions and criminal prosecution? What constraints or obstacles prevent the DOJ from taking action?

Sincerely,



Raja Krishnamoorthi
Member of Congress



Celeste Maloy
Member of Congress

CC: Robert M. Califf, M.D., MACC, Commissioner of Food and Drugs – Food and Drug Administration

⁹ CDC. “Surgeon General’s Advisory on E-Cigarette Use Among Youth.” (December 2018) (Online at https://www.cdc.gov/tobacco/basic_information/e-cigarettes/surgeon-general-advisory/index.html)



Larry Bucshon, M.D.
Member of Congress



Diana DeGette
Member of Congress



Rosa L. DeLauro
Member of Congress



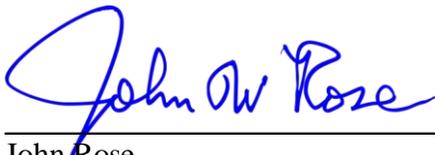
Mark DeSaulnier
Member of Congress



Josh Gottheimer
Member of Congress



Debbie Wasserman Schultz
Member of Congress



John Rose
Member of Congress



David J. Trone
Member of Congress



Raúl M. Grijalva
Member of Congress



Mikie Sherrill
Member of Congress