

Congress of the United States

Washington, DC 20515

December 7, 2023

Robert Califf, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

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

Dear Doctor Califf and Principal Deputy Assistant Attorney General Boynton:

We are writing to draw your attention to the extreme proliferation of illicit vaping products from the People's Republic of China (PRC). Once imported illegally from the PRC, these unregulated products can be easily bought online and in brick-and-mortar stores across the United States. We ask you to work with the Customs and Border Protection (CBP) agency to address this urgent problem with all due speed.

The 2009 Tobacco Control Act (TCA) strictly prohibits manufacturers from introducing new products in the U.S. without going through the Pre-Market Authorization process.^[1] However, an estimated 90 percent of illicit vaping products without pre-market authorization arrive in the United States from manufacturers in the PRC,^{[2][3]} where flavored vaping products have been banned since 2022 for the Chinese domestic market.^[4] The vaping products often have custom designs, kid-friendly flavors, and can be quickly delivered to the United States. According to one news source, vaping products have been able to avoid detection and seizure at the border by changing a banned product's name to a similar sounding one, while using the same QR code as the one used in the banned product, and the same licensing code assigned to the manufacturer by the Chinese tobacco authorities.^[5]

These vaping products from the PRC are now more than half of all vaping products sold in the U.S.^[6] and are contributing significantly to underage vaping rates. According to data from the CDC Foundation, flavored vape sales have surged 64 percent over the past three and half years, to 18.4 million vaping products per month in September 2023.^[7] By September 2023,

^[1] 21 U.S. Code § 387j

^[2] <https://www.cbsnews.com/news/illegal-vaping-devices-mostly-china-us-fda-crackdown/>

^[3] <https://www.npr.org/2023/07/12/1187354558/flavored-vapes-are-supposed-to-be-illegal-but-theyre-still-widely-available>

^[4] <https://www.theguardian.com/society/2022/oct/16/china-bans-fruity-vapes-export-disposable-brand-britain>

^[5] <https://fortune.com/2023/10/13/chinese-ecigarette-elf-bar-us-vape-import-ban-name-change/>

^[6] <https://www.cnn.com/2023/06/22/flavored-e-cigarette-sales-usage-up-among-youths-.html>

^[7] *Id.*

disposable vapes made up 57.2 percent of e-cigarette sales in retail-tracked channels (which does not include online or vape shops). According to an article in the *New York Times*, there were more than 5,800 disposable vaping products being sold in kid-friendly flavors as of June 2023, which is a 1,500 percent increase from 2020.^[8]

Deeply concerning to us, in 2023, 10 percent of high schoolers and 4.6 percent of middle schoolers, or 2.1 million youth, used e-cigarettes.^[9] While we were encouraged to see that FDA in May 2023 issued an import alert for disposable Elf Bar e-cigarettes,^[10] which are now the most popular e-cigarettes with youth, recent news reports suggest that Elf Bar is successfully evading this import ban.^[11]

FDA is now more than two years past a court-ordered deadline to complete its review of timely-filed pre-market tobacco product applications (“PMTA”) from e-cigarette manufacturers. In its most recent filing with the court, FDA has indicated that it may not meet its most recent estimate to complete its review of large market share products by the end of this year. It is imperative that FDA complete these reviews without further delay.

Further, we are especially concerned with the finding that recent unlawful vaping imports are dominated by high-volume products containing approximately as much nicotine as in several cartons of cigarettes.^[12] Many brands promise users thousands of puffs in a single device, delivering more cumulative quantities of nicotine than traditional cigarettes.^[13] According to one news report, one brightly colored, fruit-flavored vaping product from the PRC, designed as a highlighter for youth to easily conceal, delivered as much as 50 milligrams of nicotine, or the equivalent of 50 cigarettes, in a single device.^[14]

These recent developments threaten to derail the gains made in helping young people stay free from nicotine addiction and carry serious public health implications for decades to come. To address these serious concerns, we respectfully ask you to address the following questions:

1. Is FDA on track for completing its review of all large market share PMTAs by December 2023?
2. What is FDA’s position on a comprehensive approach to combat the proliferation of illicit vapes, including those from the PRC, including reforms outlined in the bipartisan letter^[15] from 33 Attorneys General?

^[8] <https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-5e45cf57dc78f6b94213047c97b10f7e>

^[9] Id.

^[10] <https://www.fda.gov/news-events/press-announcements/fda-roundup-may-19-2023>

^[11] <https://apnews.com/article/ecigarettes-elf-bar-fda-disposable-vaping-5245aed253ca9cddf119483bd9cee1f1>

^[12] BMJ Journal, Bigger, Stronger and Cheaper: Growth in e-cigarette market driven by disposable devices with more e-liquid, higher nicotine concentration and declining prices, July 2023.

<https://tobaccocontrol.bmj.com/content/early/2023/08/02/tc-2023-058033>

^[13] New York Times, Illicit e-Cigarettes Flood Stores as F.D.A. Struggle to Combat Imports, October 10, 2023.

^[14] <https://www.dailymail.co.uk/health/article-12433029/Teachers-warned-new-Chinese-vapes-highlighter-disguised.html>

^[15] [https://oag.ca.gov/system/files/attachments/press-](https://oag.ca.gov/system/files/attachments/press-docs/FDA%20Center%20for%20Tobacco%20Products%20Comment%20Letter%20-%20FINAL.pdf)

[docs/FDA%20Center%20for%20Tobacco%20Products%20Comment%20Letter%20-%20FINAL.pdf](https://oag.ca.gov/system/files/attachments/press-docs/FDA%20Center%20for%20Tobacco%20Products%20Comment%20Letter%20-%20FINAL.pdf)

3. Does the FDA or the DOJ have plans to initiate further civil or criminal proceedings against egregious violations by manufacturers, wherever located, including injunctions, civil monetary penalties, and criminal prosecution?
4. What steps is FDA taking to more aggressively prevent the importation of illegal vapor products? Specifically:
 - a. Does the FDA plan to issue additional import alerts to address all known illegal products and their manufacturers?
 - b. Has the FDA provided CBP a complete list of vapor products that (a) have received a Marketing Granted Order, and (b) have PMTAs pending since September 9, 2020?
5. How many vapor or vapor-related cases have been referred to DOJ from FDA in the preceding 12-month period? How many, if any, referrals are currently pending with DOJ?
6. Has DOJ provided FDA with guidance regarding the type(s) of vapor cases that are appropriate for referral to DOJ?
7. What is DOJ's internal review process or procedure once a referral has been received from FDA?
8. Does DOJ have sufficient resources or expertise to litigate vapor-related referrals from FDA?

Sincerely,



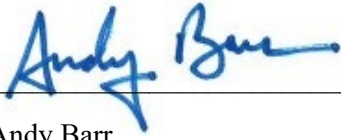
Raja Krishnamoorthi
Member of Congress



Rob Wittman
Member of Congress



Mike Gallagher
Member of Congress



Andy Barr
Member of Congress



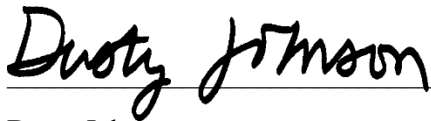
André Carson
Member of Congress



Neal P. Dunn, M.D.
Member of Congress



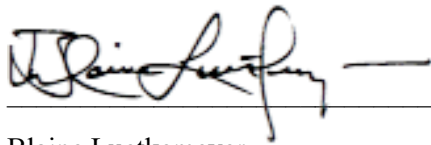
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