Congress of the United States

Washington, DC 20515

February 1, 2024

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

Dear Doctor Califf:

We are writing to follow up on our attached November 13th, 2023 letter regarding the extreme proliferation of illicit vaping products from the People's Republic of China. Because we have not received a response, we ask that you answer the questions posed in the November 13th letter, and those listed below by March 1, 2024.

While we appreciate the recent joint federal operation resulting in the seizure of more than 1.4 million units of illegal e-cigarettes in December 2023, much more needs to be done. Illegal vaping products from the PRC now make up more than half of all vaping products sold in the United States and contribute significantly to underage vaping rates.[i] According to the latest data from the Agency, among youth 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.[ii] In addition, nine out of ten users preferred flavored e-cigarettes,[iii] with 56 percent of users using the most popular reported brand, Elf Bar,[iv] which is made and illegally imported from the PRC.[v] These trends are deeply concerning and require the Agency to address the problem now.

We also learned from the Customs and Border Protection Agency (CBP) that many illegal vaping products shipped from the PRC are intentionally declared or manifested incorrectly. The packages are often mislabeled as consumer electronic goods such as flashlights, LED lights, or alarm clocks, making it difficult for CBP to efficiently find and seize illegal vaping products. For that reason, we encourage you to keep the interagency "red list" of illegal vaping products subject to seizure as up to date as possible.

Please respond to the questions below by March 1, 2024:

1. What is FDA's position on a comprehensive approach to reduce the proliferation of illicit vapes, including those from the PRC, including reforms outlined in the bipartisan letter[vi] from 33 Attorneys General?

2. Does FDA have plans to initiate further civil or criminal proceedings for egregious violations by manufacturers, wherever located, including injunctions, civil monetary penalties, and criminal prosecution? What constraints are preventing FDA, in conjunction with DOJ, from taking more aggressive action?

3. What steps is FDA taking to more aggressively prevent the importation of illegal vapor products?

4. Please provide a detailed explanation of why the Agency has not issued a rule requiring foreign manufacturing registration, as contemplated in the Tobacco Control Act. Does the Agency plan on issuing such a rule? Can the Agency address this regulatory gap with an interim final rule? If not, why not? If so, why hasn't the Agency done so?

5. The Agency appears to have missed its December 2023 deadline for finalizing review of large market share Electronic Nicotine Delivery Systems (ENDS) product applications. When will FDA come into compliance with the court order and finalize review of these applications? What is the cause of further delay?

Sincerely,

Raja Krishnamoorthi
Member of Congress

Rob Wittman
Member of Congress

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[i] https://www.cnbc.com/2023/06/22/flavored-e-cigarette-sales-usage-up-among-youths-.html
[ii] https://www.fda.gov/tobacco-products/youth-and-tobacco/results-annual-national-youth-tobacco-survey
[iii] Id.
[iv] Id.
[v] https://www.reuters.com/world/china/china-e-cigarette-titan-behind-elf-bar-floods-us-with-illegal-vapes-2023-12-06/
[vi] https://oag.ca.gov/system/files/attachments/press-docs/FDA%20Center%20for%20Tobacco%20Products%20Comment%20Letter%20-%20FINAL.pdf