May 22, 2024

Dr. Robert Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD. 20993-0002

The Honorable Merrick B. Garland
Attorney General
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, D.C. 20530-0001
c/o Brian A. Boynton

Troy A. Miller
Senior Official Performing the Duties of the Commissioner
U.S. Customs and Border Protection
1300 Pennsylvania Ave. NW
Washington, D.C. 20229

Sent by e-mail.

Re: Need for Stronger Enforcement Against Unauthorized E-Cigarettes

Dear Dr. Califf, Attorney General Garland and Senior Official Miller:

The undersigned public health, medical, education, community and other organizations write to urge the U.S. Food and Drug Administration (FDA), and its enforcement partners at the U.S. Department of Justice (DOJ) and the U.S. Customs and Border Protection (CBP), to use all the enforcement tools at their disposal against manufacturers, distributors, wholesalers and retailers to clear the market of unauthorized e-cigarette products, including flavored products that put young people at risk for nicotine addiction and other significant health harms. Because we believe that enforcement against illegal tobacco products is the responsibility of each of these federal agencies, we are transmitting this letter to FDA, DOJ and CBP.

The Tobacco Control Act gives FDA the explicit authority to charge a company with multiple violations, up to $1.2 million in a single proceeding.[7] While FDA repeatedly claims it is charging the statutory maximum in CMPs, it has never explained why it is not charging multiple violations. FDA has the authority to levy CMPs without the participation of other agencies like DOJ and CBP, but to create real incentives to comply with the law, FDA must be willing to levy more severe penalties.

The Department of Justice Must Prioritize Tobacco Product Enforcement and the Process for Bringing Actions for Injunctive Relief Must be Streamlined

Because FDA does not have its own litigation capability, it must involve the Department of Justice (DOJ) in seeking injunctive relief from courts against the marketing of unauthorized products. Yet injunctions have been sought by DOJ against only seven manufacturers of unauthorized e-cigarettes.[8] Moreover, in the first set of injunctive actions brought against companies selling unauthorized products (filed in October, 2022), between 13 to 18 months passed between the time FDA sent a warning letter to the companies and the commencement of injunction proceedings in court.[9] Similarly, for the most recent injunctive action brought (December 2023), more than 19 months passed between the time FDA first sent the company a warning letter and the commencement of injunction proceedings.[10] During this time, the companies profited from the sale of their illegal products, which included youth-appealing flavors. Therefore, tobacco product enforcement must be a priority for both FDA and DOJ and the agencies must find ways to streamline the process for seeking injunctions against unauthorized products, particularly those that constitute threats to young people.

U.S. Customs and Border Protection (CBP) Must Prioritize Efforrd Bd B[(a) (he)4 (c)4(or)3 (yoi Tw 4-20

Conclusion

The continuing deluge of unauthorized e-cigarettes into the U.S. market is undermining FDA's efforts to ensure that no e-cigarettes are marketed without being reviewed by FDA and found to have met the TCA standard of being "appropriate for the protection of the public health." Thus, despite the fact that FDA has denied marketing authorization for millions of flavored e-cigarette products,[16]