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.

FDA has authorized only 23 e-cigarette products and has made it clear that "[t]hese are the only e-cigarette products that currently may be lawfully sold in the U.S."[1] This means that virtually the entire e-cigarette market consists of unauthorized, illegal products, including a wide variety of flavored products (largely disposables) that FDA has found to be highly appealing to youth. This is a wholesale failure to enforce the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) by FDA and other government enforcement agencies. There must be an intensified and coordinated, multi-agency federal effort to enforce the law against these illegal products in an effective and equitable manner.

In this letter, we urge the adoption of several concrete changes in tobacco enforcement policies and activities to bring this problem under control.

FDA Should Make More Frequent Use of the Full Range of Available Enforcement Tools

Although FDA has issued over 600 warning letters to firms for manufacturing or selling new tobacco products without marketing authorization,[2] it has made sparing use of its stronger enforcement tools with respect to manufacturers, distributors, wholesalers and retailers, including civil monetary penalties (CMPs), no-tobacco-sale orders, product seizures, import restrictions, injunctive actions and criminal prosecutions. For example, as of the present time, FDA has filed CMP complaints against only 55 manufacturers and 108 retailers;[3] injunctions have been sought against only seven manufacturers[4] and there has been a single seizure pursuant to a civil forfeiture complaint.[5] This level of enforcement activity is far from adequate, given the unprecedented scope of illegal e-cigarette sales. Moreover, FDA has admitted that "there is no legal requirement that FDA send a warning letter before the agency can initiate an enforcement action."[6] Therefore, FDA and other federal enforcement agencies should make greater use of its most potent enforcement tools and should consider taking action without first sending a warning letter in appropriate cases.

FDA Must Seek Greater Penalties in CMP Actions

With respect to the CMPs it has issued, FDA has been consistently charging companies with only a *single* violation of the statute and thus has been seeking only the inflation-adjusted maximum penalty for a single violation – now only $20,678 – even where the company may be marketing hundreds or thousands of violative products. This is entirely insufficient to deter future illegal activity.

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[1] FDA, "Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products" (FDA Enforcement Actions), https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-enforcement-actions-against-industry-unauthorized-tobacco-products (last visited May 1, 2024).
[2] *Id*. at 3.
[3] *Id*. at 5.
[4] FDA, "FDA, DOJ Seek Permanent Injunction Against E-Cigarette Manufacturer" (Dec. 4, 2023), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-doj-seek-permanent-injunction-against-e-cigarette-manufacturer
[5] FDA, "FDA, DOJ Seize Over $700,000 Worth of Unauthorized E-Cigarettes" (Apr. 30, 2024), https://www.fda.gov/tobacco-products/ctp-newsroom/fda-doj-seize-over-700000-worth-unauthorized-e-cigarettes
[6] FDA Enforcement Actions, at 3.

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 Efforts to Stop Illegal Importation of Unauthorized Products

It is generally recognized that the illegal market has been largely supplied in recent years by the illegal importation of unauthorized products manufactured in China, particularly flavored disposable e-cigarettes that are appealing to youth. Although FDA has stated that it has placed

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[7] 21 USC § 333(f)(9)(A); *see generally*, https://assets.tobaccofreekids.org/content/what_we_do/federal_issues/fda/2023_06_30_Civil-Monetary-Penalties-Letter.pdf

[8] FDA Enforcement Actions.

[9] *See* Compl. ¶ 22, *U.S. v. Lucky's Convenience & Tobacco, LLC*, No. 22-cv-1237 (D. Kan. Oct. 18, 2022) (18 months between warning letter and complaint for permanent injunction); Compl. ¶ 21, *U.S. v. Morin Enterprises, Inc.*, No. 22-cv-02592 (D. Minn. Oct. 18, 2022) (18 months); Compl. ¶ 21, *U.S. v. Seditious Vapours LLC*, No. 22-cv-01777 (D. Ariz. Oct. 18, 2022) (13 months); Compl. ¶ 24, *U.S. v. Soul Vapor, LLC*, No. 22-cv-00458 (S.D.W. Va. Oct. 18, 2022) (16 months); Compl. ¶ 24, *U.S. v. Super Vape'z LLC*, No. 22-cv-05789 (W.D. Wash. Oct. 18, 2022) (18 months); Compl. ¶ 21, *U.S. v. Vapor Craft LLC*, No. 22-cv-00160 (M.D. Ga. Oct. 18, 2022) (13 months).

[10] *See* Compl. ¶ 27, *U.S. v. Fitzgerald*, No. 23-cv-01130 (M.D. Fla. Dec. 12, 2023). Moreover, a co-owner of the company that received the December 2023 complaint for a permanent injunction, herself a defendant in the injunction proceedings, first received a warning letter in October 20, 2016, when her business was registered under a different name, for selling to an underage person – more than 7 years before injunction proceedings were initiated. *Id.* ¶ 22.

certain e-cigarette companies on its import alert red list,[11] allowing the agency to detain products at the time of entry without a full inspection, FDA and CBP just recently announced the first large-scale seizure of unauthorized products.[12] The detection of unauthorized products must become a joint priority of FDA and CBP and the seizure authority must be more aggressively used, particularly for flavored products that appeal to young people.

Enforcement Actions Must be Brought Against All Parties in the Supply Chain

A federal enforcement strategy directed at unauthorized e-cigarette products must include enforcement actions against all parties in the e-cigarette supply chain, including manufacturers, distributors, importers and retailers. To date, FDA's actions, including warning letters, have mainly been targeted at retailers and manufacturers, with many involving products with minimal market shares. Heightened enforcement actions must also be directed at wholesalers and distributors, particularly those with large-scale operations. As the Reagan-Udall Report noted, "high profile [enforcement] actions against wholesalers and distributors who are handling illegally marketed products . . . could help clear the downstream distribution pathways of illegal products and deter those who might bring new products to the market without marketing authorization."[13]

FDA Must End the Broad Exercise of Enforcement Discretion

FDA has stated that it "has not adopted a broad policy of enforcement discretion regarding tobacco products without marketing authorization" and "[f]or the vast majority of unauthorized e-cigarettes on the market today, the pendency of an application does not create a legal safe harbor to sell that product."[14] But we know of no case where FDA or the Department of Justice has brought an enforcement action against – or even sent a warning letter to – a company with a pending application, even though such products are no more legal than products for which no application was ever filed. Some of the products proven to be most popular among youth – including JUUL – are still under review at FDA, long after the September, 2021 court-imposed deadline for FDA premarket determinations. As long as their applications are pending at FDA, those products appear to be protected by a de facto agency policy of enforcement discretion. Despite FDA's assurances that "[t]he decision whether to take enforcement action will be made on a case-by-case basis, taking into account youth use and other risk factors,"[15] that does not appear to be true as to products with pending applications. Certainly as to flavored products with great youth appeal, there should be no across-the-board policy of exercising enforcement discretion.

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[11] FDA News Release, "Joint Federal Operation Results in Seizure of More Than $18 Million in Illegal E-Cigarettes (December 14, 2023). https://www.fda.gov/news-events/press-announcements/joint-federal-operation-results-seizure-more-18-million-illegal-e-cigarettes

[12] *Id*.

[13] Operational Evaluation of Certain Components of FDA's Tobacco Program: A Report of the Tobacco Independent Expert Panel (Reagan-Udall Foundation, Dec. 2022), at 24. https://reaganudall.org/programs/operational-evaluation-fdas-human-foods-tobacco-programs

[14] FDA Enforcement Actions, at 2.

[15] *Id*.

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] several studies have shown that the number of e-cigarettes on the market has increased, and that these products have gotten larger in volume, stronger in nicotine strength and cheaper to buy.[17] None of these products have been authorized. Meanwhile, the prevalence of youth e-cigarette use remains unacceptably high, with 2.1 million high school and middle school students currently using e-cigarettes.[18] The failure to adequately enforce the law against unauthorized products plainly has real, and significant, public health consequences. As Commissioner Califf indicated in recent testimony before the House Agriculture, Rural Development, FDA and Related Agencies Appropriations Subcommittee, "we have had significant seizures and injunctions. But nowhere near the number that would stem the tide . . . ." of illegal products.[19] We urge FDA, DOJ and CBP to respond with an "all hands on deck" strategy that will use all enforcement tools at their disposal to protect the public health, and particularly the health of our young people, from the flood of illegal, unauthorized e-cigarettes.

Respectfully submitted,

Academic Pediatric Association
Academy of General Dentistry
Action on Smoking & Health
African American Tobacco Control Leadership Council
Allergy & Asthma Network
American Academy of Family Physicians
American Academy of Pediatrics
American Association for Dental, Oral, and Craniofacial Research
American Association for Respiratory Care
American Association of Child and Adolescent Psychiatry
American Cancer Society Cancer Action Network
American College Health Association (ACHA)
American College of Cardiology
American College of Chest Physicians (CHEST)
American College of Physicians
American Dental Association
American Heart Association
American Lung Association
American Medical Association
American Medical Women's Association
American Pediatric Society

[16] B. King, *A Year in Review: FDA's Progress on Tobacco Product Regulation in 2023* (February 22, 2024), at 3. https://www.fda.gov/tobacco-products/ctp-newsroom/year-review-fdas-progress-tobacco-product-regulation-2023#:~:text=CTP%20reached%20several%20important%20milestones,listening%20session%20held%20last%20summer.

[17] MC Diaz, et al., *Bigger, stronger and cheaper; growth in e-cigarette market driven by disposable devices with more e-liquid, higher nicotine concentration and declining prices*, Tobacco Control, Published Online First: 03 August 2023. Doi: 10.1136/tc-2023-058033.

[18] Jane Birdsey et al., *Tobacco Product Use Among U.S. Middle and High School Students – National Youth Tobacco Survey, 2023*, 72 MORBIDITY & MORTALITY WKLY. REP. 1173, 1173 (2023), https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7244a1-H.pdf.

[19] Hearing at 1:28:25, *Fiscal Year 2025 Budget Request for the Food and Drug Administration Before the Subcomm. on Agric., Rural Dev., Food & Drug Admin. of the H. Comm. on Appropriations*, 118th Cong. (2024) (statement of Robert Califf, Comm'r, Food & Drug Admin.), https://www.youtube.com/watch?v=MsfunubJ_Eo&t=5305s.

American Public Health Association
American Thoracic Society
Americans for Nonsmokers Rights
Association for the Treatment of Tobacco Use and Dependence
Association of American Indian Physicians
Association of Black Women Physicians
Association of Maternal & Child Health Programs
Association of Medical School Pediatric Department Chairs
Association of State and Territorial Health Officials
Big Cities Health Coalition
Black Women's Health Imperative
Breathe Southern California
CADCA
Campaign for Tobacco-Free Kids
Cancer Prevention and Treatment Fund
Center for Black Health & Equity
CenterLink: The Community of LGBTQ Centers
Community Wellness Alliance
COPD Foundation
DC Tobacco Free Coalition
Emphysema Foundation of America
First Focus on Children
For Future Lungs
GLMA: Health Professionals Advancing LGBTQ+ Equality
GO2 for Lung Cancer
Healthy Americas Foundation
IntelliQuit
Leadership Council for Healthy Communities
NAACP
National Alliance for Hispanic Health
National Association of Elementary School Principals
National Association of Hispanic Nurses
National Association of Pediatric Nurse Practitioners
National Association of School Nurses
National Association of Secondary School Principals
National Black Nurses Association, Inc
National Council of Negro Women (NCNW)
National Education Association
National Hispanic Medical Association
National LGBTQI+ Cancer Network
National Medical Association
National Network of Public Health Institutes
Oncology Nursing Society
Parents Against Vaping e-cigarettes (PAVe)
Pediatric Policy Council
Prevent Cancer Foundation
Preventing Tobacco Addiction Foundation / Tobacco 21
Preventive Cardiovascular Nurses Association
Respiratory Health Association
Save A Girl Save A World
Society for Cardiovascular Angiography and Interventions
Society for Pediatric Research
Society for Public Health Education
The African American Wellness Project
The National Alliance to Advance Adolescent Health
Truth Initiative
University of Wisconsin Center for Tobacco Research and Intervention

CC: Dr. Brian King, Director, FDA Center for Tobacco Products
Brian A. Boynton, Principal Deputy Assistant Attorney General