



June 12, 2024

The Honorable Dick Durbin  
Chairman  
Committee on the Judiciary  
United States Senate  
Washington, DC 20510

The Honorable Lindsey Graham  
Ranking Member  
Committee on the Judiciary  
United States Senate  
Washington, DC 20510

**RE: June 12, 2024 Hearing: “Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes”**

Dear Chairman Durbin and Ranking Member Graham:

The American Lung Association thanks the Committee on the Judiciary for holding this hearing. One of the Lung Association’s strategic imperatives is to create a tobacco-free future. The Lung Association has worked for three decades to first, get the U.S. Food and Drug Administration (FDA) authority to regulate tobacco products with the passage of the Family Smoking Prevention and Tobacco Control Act (TCA), and now, for FDA to use its full authority to implement the TCA in order to protect the public health.

As it stands, there are only [23 e-cigarette products authorized and therefore legal to be sold in the United States](#). These products were submitted through the pre-market tobacco applications (PMTA) process and received a marketing grant order (MGO) from the FDA. This means that virtually the entire e-cigarette market consists of unauthorized, illegal products, including many flavored products (largely disposables) that FDA has found to be highly appealing to children. The illegal products on the market tend to fall in two major buckets:

1. Products for which a PMTA has been submitted and a marketing denial order (MDO) was issued; or those applications for which a decision on an application is still pending; and
2. Products that have never submitted a PMTA and are flagrantly disregarding U.S. law.

Even though FDA has denied marketing authorizations for millions of flavored e-cigarette products, several studies indicate that the e-cigarette market has expanded in the U.S. These products are getting larger in volume of liquid they contain, stronger in nicotine strength and cheaper to purchase. None of these products have been authorized to be sold in the U.S. Meanwhile, the prevalence of youth e-cigarette use remains too high, with 2.1 million high school and middle school students currently using e-cigarettes.

The tobacco industry is unlike any other industry FDA oversees, and, consequently, the relationship between FDA’s Center for Tobacco Products (CTP) and industry needs to be different than other FDA centers. The tobacco industry does not share CTP’s mission of protecting the public health – or the health of any individual. The industry is committed to maintaining sales and addiction to products that are the number one cause of preventable death and disease in this country. They do this in flagrant disregard for federal law.

The proliferation of e-cigarettes and other tobacco products prior to the deeming rule taking effect – and then the failure to stop new products from coming onto the marketplace once it did take effect – make CTP’s enforcement of the Tobacco Control Act against an industry that does

not want to be regulated at all even more difficult. The Lung Association calls on CTP to order all products off the market unless they have been granted a marketing order by the FDA.

However, without more robust enforcement, companies have no reason to do anything other than drag their feet, target kids, rack up profits and continue to defy the law. Now is the time for a comprehensive strategy – including actions that must be taken by FDA, and increased involvement from the U.S. Department of Justice (DOJ) and U.S. Customs and Border Protection (CBP). That is why the Lung Association applauds the announcement on Monday, June 10 from DOJ and FDA for their new multi-agency taskforce to address the illegal distribution and sale of e-cigarettes. We are hopeful that bringing together multiple law enforcement partners, the U.S. Postal Inspection Services and Federal Trade Commission will be a powerful step in combatting the youth vaping epidemic. It will be imperative for the protection for the public health that this taskforce coordinate and streamline efforts to utilize all enforcement tools necessary to remove illegal and addictive tobacco products from the market.

Below, you will find the American Lung Association's recommendations for action.

### **FDA Must Finish Long Overdue Review of Pre-Market Tobacco Product Applications**

A federal court required that all premarket tobacco product applications received by September 9, 2020, be reviewed within one year (by September 9, 2021). Now, more than two years past the deadline, we are still waiting for FDA to complete this work. FDA has made progress in reducing the backlog over the past year, including several decisions on menthol e-cigarette products. There are important decisions on e-cigarette products with high market share remaining.

Last week the FDA rescinded its marketing denial order on JUUL Labs's products. While this rescission is not an authorization – it is deeply concerning that any JUUL product is still available for sale. As you know, JUUL bears the largest responsibility for the youth e-cigarette epidemic from 2017-2019. FDA must swiftly review their applications. FDA must follow the law and not permit any JUUL product or other tobacco product to be sold in the U.S. prior to it receiving a premarket authorization.

It is imperative that CTP not delay beyond the forthcoming June deadline to finish the review of all pending tobacco product applications. The Lung Association continues to recognize that no flavored tobacco product can meet the standard for protecting the public health.

FDA must also finish its long overdue review of PMTA applications for products made with synthetic nicotine. Congress made clear and [FDA has acknowledged](#) that any tobacco product made with synthetic nicotine that had not receive a marketing authorization order by July 13, 2022 must be removed from the marketplace. Greater enforcement against these illegal products is also overdue and greatly needed.

### **Federal Law Enforcement Must Significantly Increase Their Engagement with FDA Against Illegal Tobacco Products**

Despite some actions taken by CTP and DOJ, too many illegal (primarily flavored) e-cigarette products remain on the market. The focus of enforcement must be at the manufacturer, distributor, retailer and importer level. Although we appreciate that FDA has issued over 1100 warning letters to such entities, we urge that FDA make much greater use of its stronger enforcement tools, including civil monetary penalties (CMPs) and no-tobacco-sale orders.

Federal law enforcement must be involved to conduct product seizures, import restrictions, injunctive actions and criminal prosecutions. The Lung Association urges that all these steps be undertaken. It is imperative that the DOJ seek injunctive relief from courts against the marketing of unauthorized products. As it stands, the DOJ has only sought injunctions against seven manufacturers of unauthorized e-cigarettes. Additionally, the first set of these actions were brought between 13 to 18 months after FDA sent a warning letter. Both agencies must work together to bring forward injunctions against more manufacturers of unauthorized e-cigarettes and streamline the process. By waiting between 13 to 18 months, the U.S. government enables and encourages the tobacco industry's profits from the sale of their illegal products. The DOJ must prioritize tobacco product enforcement and protect more children from becoming addicted to these dangerous products.

It is also evident that the illegal importation of unauthorized e-cigarette products manufactured in China, specifically flavored disposable e-cigarettes, has increased in recent years. While FDA has placed certain e-cigarette companies on its import alert red list, FDA and CBP have only recently announced the first large-scale seizure of unauthorized products. The detection and seizure of imported un-authorized e-cigarette products must be a joint priority between FDA and CBP.

### **Congress Must Pass the Bipartisan Resources to Prevent Youth Vaping Act**

The Lung Association also calls on Congress to pass S. 3653, Resources to Prevent Youth Vaping Act, the bipartisan legislation sponsored by Senators Shaheen and Murkowski. While all of CTP's activities are funded by user fees assessed against each class of product, e-cigarette manufacturers are not subject to any use fee – despite the significant amount of resource needed by FDA to enforce the law against them. Congress must take up this legislation to increase the FDA's ability to protect the public health from e-cigarettes.

FDA must act and finalize all pending applications. The FDA also urgently needs greater support and resources for the newly announcement task force plus CBP to protect the next generation of kids from illegal tobacco products. These agencies must use all enforcement tools at their disposal against manufacturers, distributors, importers 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.

The American Lung Association thanks the Committee for discussing this critical public health issue.

Thank you.

Sincerely,



Harold P. Wimmer  
President and CEO

Cc: Senate Committee on the Judiciary