

# United States Senate

WASHINGTON, DC 20510-1304

September 9, 2022

The Honorable Xavier Becerra  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, Southwest  
Washington, DC 20201

The Honorable Robert M. Califf, MD  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Secretary Becerra and Commissioner Califf:

One year.

Earlier this week, JUUL Labs—arguably the company most responsible for what one former Food and Drug Administration (FDA) Commissioner dubbed our nation’s “youth vaping epidemic”—tentatively agreed to pay nearly \$440 million to nearly three dozen states suing over the company’s marketing and sales practices, which targeted children nationwide. Attorneys General in those states did not cower to JUUL’s legal prowess or its cadre of former FDA officials now on payroll. Instead, they saw a company that was preying on children, and they acted decisively—an approach that seems foreign to the FDA.

As of today, the FDA is exactly one year overdue in fulfilling a court order to complete its premarket review of e-cigarette products, including JUUL. I am deeply concerned that FDA has not taken the steps necessary to complete these premarket reviews and to remove unauthorized products from the market. Youth e-cigarette use remains a serious public health problem, and FDA’s inadequate response is leaving our kids at risk.

In 2019, the U.S. District Court for the District of Maryland found that FDA had acted without legal authority by suspending operation of the premarket review requirements of the *Family Smoking Prevention and Tobacco Control Act* and set a deadline of September 9, 2020, for manufacturers to submit premarket applications. Under the court’s order, products for which applications were filed timely could remain on the market for up to one additional year during FDA’s review. FDA is now one year past the court-ordered deadline to complete its premarket reviews.

One year.

Further, the agency has continued to state in court filings that it does not expect to complete review of the most popular e-cigarette products until the end of June 2023—nearly three years after the court-ordered deadline for manufacturers to submit applications, and nearly two years after the deadline established by the court for FDA to have completed those reviews. As a result of these harmful delays—and FDA’s refusal to use its authority to remove e-cigarette

products from the market until reviews are complete—many unauthorized e-cigarettes that are attractive to kids remain on the market. Of note, FDA has only completed reviews of about half of those e-cigarettes with submitted applications that represent a large share of the market. This inaction has real life consequences—with the Truth Initiative estimating that nearly two and a half million children and young adults have begun using vaping products over the past year.

It is bad enough that FDA is now one year delinquent in finalizing review of e-cigarette applications, but it appears as though—even when FDA has actually completed review of a product and denied an application—many vaping companies regularly flout the agency’s orders. And FDA does nothing to stop them. A recent STAT News investigation reviewed 120 denial letters that FDA sent to vaping companies between August 2021 and May 2022, ordering their products off the market. The investigation found that at least 139 of these products—more than 50 percent of the products named in those warning letters—are still being sold in the United States. The FDA has sweeping legal authority—granted to it by Congress—to crack down on e-cigarette companies that ignore denial orders, including the ability to impose seven-figure fines and physically remove products from the market. Yet, inexplicably, FDA has never used those powers against illegally marketed e-cigarettes.

The agency has further refused to use its power and authority—and legal mandate—to regulate the synthetic nicotine marketplace. Many companies, such as PuffBar, developed kid-friendly flavored synthetic nicotine products in an attempt to evade FDA regulation. When Congress became aware of this problem, and at FDA’s request, we acted—passing a law that requires synthetic nicotine products to receive FDA authorization in order to remain on the market. The deadline for FDA to complete review of synthetic nicotine products came and went on July 13, nearly two months ago. To my knowledge, not a single synthetic nicotine product has been authorized, and yet these illegally marketed products remain widely available in a plethora of flavors on store shelves nationwide.

The FDA continues to fail our children with its missed deadlines, failure to enforce orders, and general lack of urgency with respect to e-cigarettes and synthetic nicotine products. For years, a bipartisan chorus of Senators and Representatives have been sounding the alarm about the dangers of these products to our children, while FDA action has been too slow or, in many instances, completely non-existent. If the FDA cannot, or will not, do its job, then it is time for the Department of Health and Human Services (HHS) to step in. Millions of children nationwide are now addicted to nicotine because of e-cigarettes and synthetic nicotine products. How many millions more must become addicted before our public health agencies act?

Sincerely,



Richard J. Durbin  
United States Senator