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For a Hearing on

Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes

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Chairman Durbin, Ranking Member Graham, Members of the Committee: Thank you for inviting me to testify today at this hearing on combatting the youth vaping epidemic. Addressing this epidemic can only be achieved by enhancing enforcement to remove unauthorized e-cigarettes that remain on the market illegally.

I am Yolonda Richardson, President and CEO of the Campaign for Tobacco-Free Kids. The Campaign is the leading advocacy organization working to reduce tobacco use and its deadly consequences in the United States and around the world. Through strategic communications and policy advocacy campaigns, we promote the adoption of proven solutions that are most effective at reducing tobacco use and saving the most lives. In addition to our work fighting tobacco use, our Global Health Advocacy Incubator applies our broad range of advocacy experience to supporting organizations working to address other critical public health challenges.

Premarket Review: A Cornerstone for Protecting Public Health

The Campaign has been a strong advocate for the Family Smoking Prevention and Tobacco Control Act, which was landmark legislation enacted in 2009 that gave FDA the authority to oversee tobacco products. Since its enactment, we have urged FDA to aggressively use this authority to protect kids and public health. Through effective regulation, we can reduce the 480,000 deaths and about $240 billion in health care costs attributable to tobacco use each year in the United States.[1]

Congress gave FDA the authority to oversee tobacco products in order to protect the public, and particularly young people, from an industry that aggressively markets harmful and addictive products. Each year, the tobacco industry spends more than $9.4 billion marketing and promoting products that addict our kids and others. One of the most important tools that Congress gave FDA was the authority to conduct premarket reviews of new tobacco products before they can be legally sold.

Prior to the Tobacco Control Act, when cigarette manufacturers were free to introduce new tobacco products without any oversight by FDA, the public's health suffered enormously. Manufacturers designed cigarettes to deliver precise doses of nicotine that would create and sustain addiction. They added ingredients to mask the harshness of tobacco smoke and make them easier to use, particularly for youth. They added features like filters to provide smokers with a false sense of security that they were reducing their risk of disease.

The Tobacco Control Act was intended to prevent the introduction of new tobacco products that are harmful and increase the possibility of attracting youth. With the Tobacco Control Act in place, decisions about which new tobacco products enter the market would no longer be made solely by tobacco manufacturers, based on economic considerations, such as sales and profits. Instead, these decisions would ultimately be made by FDA, based on a scientific assessment of a product's likely impact on public health that would involve consideration of the risk of the product, how it is likely to be used, and who is likely to use it.

Under the Tobacco Control Act, manufacturers of a new tobacco product must demonstrate that their product is "appropriate for the protection of the public health." This standard is intended to prevent tobacco manufacturers from introducing new products that may increase harm to the public, such as by expanding the number of people who use and become addicted to tobacco or by discouraging people who currently use tobacco products from quitting altogether.

Given the health risks of tobacco products, this is an appropriately high standard, and the burden is on the manufacturer to meet it. In order for a new product to be authorized for sale, manufacturers must demonstrate that the introduction of a new product will measurably enhance public health.

Problems Applying Premarket Review to E-Cigarettes

Unfortunately, premarket review has not been applied in a timely and effective way for e-cigarettes.

By the time FDA first exercised regulatory oversight over e-cigarettes in 2016, a substantial e-cigarette market had already formed, and e-cigarettes had already become the most popular tobacco product among youth. E-cigarettes were available in thousands of different flavors that increased their appeal and use by youth.[2] And manufacturers were increasing the amount of nicotine that e-cigarettes could deliver, which increased the likelihood that youth who experimented with these products would become long-time addicted e-cigarette users, with a risk that they may move on to smoking conventional cigarettes.[3] The e-cigarette market was a "wild, wild West" of unregulated, highly addictive, flavored products marketed to young people.

Not long after FDA finally began to apply its oversight authority to this existing marketplace, it suspended premarket review of e-cigarettes, issuing a guidance in 2017 that sought to extend the deadline for e-cigarette manufacturers to submit premarket applications by four additional years (from 2018 to 2022) and would have allowed those products to remain on the market for as long as it took for FDA to review them. As a result of a lawsuit brought by the Campaign for Tobacco-Free Kids and other public health groups, a Maryland federal court vacated FDA's guidance, characterizing it as a "holiday from meeting the obligations of the law." The court set September 9, 2020 as the new date by which companies had to file premarket applications and indicated that companies that submitted applications on time could keep those products on the market for only one additional year (until September 9, 2021) without being subject to FDA enforcement.

Because of this court order, FDA began reviewing e-cigarette applications and has completed its review of the vast majority of applications it has received. We commend FDA for appropriately applying the public health standard during its reviews, particularly as to flavored products. The agency has recognized that flavors increase the appeal and use of e-cigarettes by youth and, therefore, is requiring manufacturers to demonstrate that their flavored e-cigarettes provide an

offsetting public health benefit by helping adult smokers to quit. This is the population-wide assessment of public health that the Tobacco Control Act requires of FDA.

But FDA is still far from completing its review of e-cigarettes. Some of the e-cigarettes with the greatest impact on the market, like JUUL, are still under review. While FDA needs to thoroughly review each application it receives, it has had some of these applications for nearly four years. For e-cigarettes that use nicotine derived from tobacco and represent a significant share of the market, FDA must provide a quarterly status report on its progress to a federal court. Initially, FDA projected it would complete those reviews by the end of June 2023. Then it said the end of December 2023. Now FDA is projecting it will complete those reviews by the end of June 2024. Separately, FDA has reported that more than 9,500 synthetic nicotine products are also under review but has not projected when it expects to complete those reviews.

The delay in completing these reviews is particularly problematic because FDA appears to have an unstated policy of not taking enforcement action against products with pending applications. This unstated policy has allowed many unauthorized e-cigarettes to remain on the market, including flavored e-cigarettes that FDA has found present a particular risk to youth. We believe this across-the-board enforcement discretion is contrary to the Tobacco Control Act and the Maryland court decision that established September 9, 2021 as the date by which marketing orders must be issued in order for products to remain on the market without being subject to enforcement action.

E-Cigarette Companies Making a Difficult Situation Worse

FDA's job of implementing premarket review has been made much more difficult because of actions taken by the e-cigarette industry itself. Many e-cigarette companies are simply disregarding FDA requirements. The level of non-compliance for e-cigarettes far exceeds what FDA experiences with other products it regulates such as drugs and medical devices. As the Reagan-Udall Independent Expert Panel that examined FDA's regulation of tobacco products observed, "there are few incentives for industry to come into compliance and many incentives for industry to delay the process."[4]

E-cigarette companies flooded FDA with premarket applications for millions of products. The vast majority of applications did not contain basic required information and did not represent a serious effort to provide the evidence necessary to meet the public health standard. One company submitted applications for more than 4.5 million products, which FDA refused to file because they failed to meet certain requirements or denied.[5] In total, FDA received applications for more than 6.5 million products before the September 9, 2020 deadline, which bogged down the premarket review process.[6]

Many other e-cigarette companies sought to evade the premarket review requirement entirely by marketing e-cigarettes with synthetic nicotine rather than nicotine derived from tobacco. Puff Bar, a disposable e-cigarette that appeared on the US market in 2019, quickly became the fourth most popular brand among high school e-cigarette users.[7] In 2020, FDA issued a warning letter to Puff Bar to stop selling its flavored disposable e-cigarettes without FDA authorization.[8] In a clear effort to evade the law, in February 2021, Puff Bar announced that it was using synthetic nicotine in its products, and that year, Puff Bar became the most popular e-cigarette brand used by youth.[9] Many other companies similarly tried to evade premarket review by switching to synthetic nicotine.

Ultimately, Congress enacted legislation in 2022 to clarify FDA's authority to regulate synthetic nicotine products as tobacco products under the Tobacco Control Act.[10]

There continues to be widespread disregard for the premarket review requirement today. Some e-cigarette manufacturers are selling unauthorized e-cigarettes for which a premarket application was never submitted. Others are selling unauthorized e-cigarettes that have a pending application at FDA, with the expectation that FDA will not take enforcement action against them. Non-compliance permeates the entire supply chain: manufacturers, importers, distributors, wholesalers, and retailers.

The magnitude of the problem is remarkable. The e-cigarette market in the United States consists almost entirely of unauthorized, illegal products, including a wide variety of flavored products that FDA has found are highly appealing to youth. FDA has authorized 23 e-cigarette products – and no flavored e-cigarettes (only tobacco-flavored e-cigarettes). But thousands of e-cigarettes in a wide array of flavors are available for sale at convenience stores, vape shops, and online. According to retailer scanner data, more than 6,000 e-cigarette products are available for sale in the U.S. – and that does not even include sales at vape shops and online.[11]

Finding an unauthorized e-cigarette is not like looking for a needle in a haystack. This is not an "underground" illegal market; these illegal products are everywhere and in plain sight. Elf Bar was the most popular e-cigarette brand among youth last year, even though Elf Bar products are not authorized by FDA and are on the market illegally.[12]

This non-compliance with the premarket review requirement necessitates swift and strong enforcement action from FDA, the Department of Justice, and other agencies involved in enforcement.

Unauthorized E-Cigarettes are Creating a Public Health Risk

The large number of unauthorized e-cigarettes on the market present significant risks to public health. These products are highly addictive, can expose users to harmful substances, and have consistently been shown to appeal to youth.

While youth use of e-cigarettes is down from 2019, when it reached an all-time high, e-cigarettes remain the most commonly used tobacco product among middle and high school students in the U.S. In 2023, 2.1 million youth reported currently using e-cigarettes, including 10 percent of high school students.[13] Each day, more than 4,300 kids (under 18) try an e-cigarette for the first time.[14]

Youth are not just experimenting with e-cigarettes but are using them frequently. Last year, nearly 40 percent of high school e-cigarette users reported vaping on 20 or more days during the past month, which is a worrying sign that many are becoming addicted.[15] Because e-cigarettes can be used more discreetly than cigarettes, young people are able to use them easily throughout the day, even during class, exposing themselves to dose after dose of nicotine.

According to an advisory by the Surgeon General, the aerosol produced by an e-cigarette "is not harmless" and that "any e-cigarette use among young people is unsafe."[16] E-cigarettes expose users to nicotine and other harmful substances, including heavy metals, volatile organic compounds, and ultrafine particles.[17] Nicotine exposure during adolescence can harm the

developing brain and can impact learning, memory and attention.[18] In addition to the risks from e-cigarettes themselves, there is evidence that using e-cigarettes increases the risk that youth and young adults will try cigarette smoking.[19]

Adolescence is a particularly important time to prevent the initiation of e-cigarette use. Use of tobacco products almost always begins during adolescence, a time when youth are more vulnerable to nicotine addiction and less aware of the risks of tobacco use. Because nicotine is highly addictive, youth use of e-cigarettes may have lifelong implications. That is why preventing youth tobacco use is a critical consideration in FDA's determination of whether to authorize or deny marketing authorization for an e-cigarette.

Flavors are a key driver of high rates of youth e-cigarette use. E-cigarettes come in thousands of flavors, which make these products more attractive and easier for youth and young adults to use. Last year, nearly 90 percent of youth e-cigarette users used flavored products.[20] According to a 2016 Surgeon General report, flavors are among the most commonly cited reasons for using e-cigarettes among youth and young adults.[21]

Flavors are so appealing that young people gravitate to whatever e-cigarette device affords them the flavors they seek. When FDA changed its enforcement priorities in 2020 to prioritize enforcement against most flavored cartridge-based e-cigarettes, which at the time were the most popular e-cigarette products among youth, large numbers of youth switched to disposable e-cigarettes because they continued to be available in a wide variety of flavors.[22] It was the flavors that drove appeal and youth use, not the type of e-cigarette device.

Appealing flavors and addictive levels of nicotine is a dangerous combination. That is why FDA has rejected applications for millions of flavored e-cigarettes and has so far not authorized any flavored e-cigarettes, only tobacco-flavored ones.

Yet flavored e-cigarettes remain widely available because of widespread non-compliance with FDA's premarket review requirement. While FDA has not authorized any flavored e-cigarettes, about 80 percent of retail sales of e-cigarettes are for flavored products.[23] Premarket review was supposed to prevent products harmful to public health from being sold. But inadequate enforcement is undermining this important public health protection.

Stronger Enforcement Action is Needed

The Tobacco Control Act provides a number of enforcement tools to address unauthorized e-cigarettes on the market, including civil money penalties (CMPs), product seizures, import restrictions, injunctive actions, and criminal prosecutions. Some enforcement actions FDA can take on its own. For others, it needs to work with the Department of Justice and Customs and Border Protection.

Over the past year, FDA has taken some important enforcement actions. It has increased its use of CMPs, worked with the Department of Justice to seize more than 45,000 unauthorized products at a warehouse in California,[24] and worked with Customs and Border Protection to seize 1.4 million unauthorized e-cigarettes at a cargo examination site at Los Angeles International Airport.[25]

But despite these enforcement actions, unauthorized e-cigarettes continue to dominate the market. The current level of enforcement activity is insufficient to address the large number of unauthorized products on the market effectively.

We welcome the announcement by FDA and DOJ this week about the creation of a multi-agency task force to combat the illegal distribution and sale of e-cigarettes. This could be an important step forward, but it will only have an impact if it is immediately followed with concrete and comprehensive enforcement actions. Federal agencies should also coordinate closely with states and localities enforcing state and local laws against flavored e-cigarettes.

More and stronger enforcement action is needed. Without it, many companies will continue to calculate that the profits that can be made from making and selling unauthorized e-cigarettes are worth the risk.

The Campaign for Tobacco-Free Kids along with 77 other public health, medical, education, and community organizations recently sent a letter to FDA, DOJ, and CBP, calling on them to use all the enforcement tools at their disposal to clear the market of unauthorized e-cigarettes. In that letter, we urge these agencies to adopt several concrete changes in tobacco enforcement policies and activities to bring this problem under control.[26]

First, FDA should make more frequent use of the full range of its enforcement tools. While FDA has issued more than 1,100 warning letters to firms for manufacturing or selling unauthorized tobacco products, it has made sparing use of its stronger enforcement tools. For example, FDA has filed CMP complaints against only 55 manufacturers and 140 retailers; injunctions have been sought against only seven manufacturers; and there has been a single seizure pursuant to a civil forfeiture complaint.[27] 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.

Second, FDA must seek greater penalties in CMP actions. When FDA has issued a CMP, it has consistently charged companies with only a single violation of the statute and has been only seeking the maximum penalty for a single violation, which currently is only $20,678.[28] FDA is doing this even where a company may be marketing hundreds or thousands of unauthorized products. Such a small penalty cannot provide an effective deterrent to a company making money from illegal sales. The Tobacco Control Act gives FDA the authority to impose much higher penalties, and the agency should use it. FDA can charge a company with multiple violations, up to $1.2 million in a single proceeding.[29] Recently FDA has indicated that it is planning to issue new guidance regarding CMPs. We hope it is implemented quickly and will result in far more severe penalties.

Third, the Department of Justice must seek injunctive relief against retailers to prevent the illegal sale of e-cigarettes. Because FDA does not have its own litigation capability, it must involve the Department of Justice in seeking injunctive relief from courts against the selling of unauthorized products. Yet DOJ has sought injunctions against only seven manufacturers of unauthorized e-cigarettes.[30] Moreover, a significant amount of time – between 13 months and more than 19 months – passed between the time FDA first sent the companies a warning letter and the commencement of injunction proceedings. During this time, the companies were able to continue

to profit from the sale of illegal products, which included youth-appealing flavors. FDA and DOJ must find ways to streamline the process for seeking injunctions against unauthorized products.

Fourth, Customs and Border Protection must stop illegal importation of unauthorized products. Today's market of unauthorized e-cigarettes has been largely supplied by the illegal importation of unauthorized products manufactured in China, particularly flavored disposable e-cigarettes that are appealing to youth.[31] FDA has stated that it has placed certain e-cigarette companies on its import alert red list, allowing the agency to detain products at the time of entry without a full inspection.[32] But FDA and CBP announced the first large-scale seizure of unauthorized products only in December.[33] The detection of authorized 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.

Fifth, enforcement actions must be brought against all parties in the supply chain. 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 review 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."[34]

Sixth, 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."[35] 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. These products include ones that are popular with youth, such as JUUL. Certainly, as to flavored products with great youth appeal, there should be no across-the-board policy of exercising enforcement discretion.

Lastly, FDA must complete its review of all products, particularly products with large market shares and those used by youth. As noted earlier, thousands of e-cigarettes – products with tobacco-derived nicotine as well as products made with synthetic nicotine – are still under review by FDA. Two years ago, FDA announced a marketing denial order for JUUL, then it stayed its own order and last week it rescinded the order entirely, returning the JUUL application to scientific review.[36] This kind of delay and confusion is simply unacceptable, especially as these products stay on the market, particularly for a product with proven appeal to young people.

FDA needs to move as quickly as possible to a true premarket review process – whereby products are reviewed prior to entering the market, as the Tobacco Control Act intended – rather than the current process whereby products are being reviewed when they are already on the market and they stay on the market for years without marketing authorization.

Conclusion

Premarket review is an important requirement of the Tobacco Control Act. It is intended to protect youth and the public from new tobacco products that are harmful to public health. Yet unauthorized e-cigarettes remain widely available, despite the risks they present, especially to young people. Thousands of unauthorized flavored e-cigarettes are being sold despite the evidence that flavors increase the appeal and use of e-cigarettes by youth.

More and stronger enforcement action is needed. Otherwise, companies will continue to flout FDA requirements and put our young people at risk. We need an "all hands on deck" approach to enforcement. We urge FDA, DOJ and other agencies involved in enforcement to work together to address this urgent public health concern.

Premarket review has great potential to reduce youth use of e-cigarettes. We need to make sure that potential is realized and that e-cigarettes do not create a new generation of tobacco users.

Thank you for the opportunity to testify today.

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