NATO

July 5, 2024

Delivered Via E-mail to: Record@judiciary-dem.senate.gov

Chairman Dick Durbin
U.S. Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Durbin and Members of the Committee on the Judiciary:

This letter and attachments respond to a question from the Committee and supplement my testimony on behalf of the National Association of Tobacco Outlets (NATO), a national retail trade association that represents more than 66,000 retail stores throughout the country, at the June 12, 2024, hearing of the Senate Committee on the Judiciary entitled "Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes."

In particular, on June 24, 2024, U.S. Senator Charles Grassley submitted the following question to NATO:

1. *Do any of your association's members sell vapor products that are not authorized for sale by the FDA, and if so, does your organization condone this practice?*

NATO understands that some of its members may sell vapor products that are not authorized for sale by the FDA pursuant to a marketing granted order. However, as referenced in NATO's written testimony, the association also understands that the FDA does not currently prioritize enforcement against vapor products subject to premarket tobacco product applications (PMTAs) that their manufacturers submitted by the applicable deadlines and remain pending before the agency or that is otherwise subject to an applicable court order stay. In some cases, the FDA has not acted on these PMTAs for over four years since their timely submission well beyond the 180-day statutory deadline for the FDA to issue an order from the date of receipt of the application.

As discussed in greater detail in NATO's written testimony, responsible retailers need greater clarity on this subject from the agency. NATO and its members affirm our support for a well-functioning regulatory system in which FDA oversight leads to accelerated reduction in underage use and tobacco-related harm. An effective regulatory system requires a more coherent compliance framework that clearly communicates the FDA's enforcement priorities, what categories of products the agency wants immediately removed from the marketplace and what categories can remain on the market pending review of timely filed applications.

The need for clarity is especially high right now, given FDA's own inconsistent statements over time. The history here is important. Since FDA asserted authority over vapor products in 2016, and per subsequently issued guidance documents and an order from the U.S. District Court for the District of Maryland, certain vapor products have been *specifically allowed* to remain on the market (i) up until

a deadline for filing marketing applications and, thereafter, (ii) during review of timely filed PMTAs for them. The regulated community –manufacturers, wholesalers, and retailers – relied on these policy decisions and continued to make and sell these products within the legal, regulated system, assuming FDA would follow through on its statutory obligation to rule on PMTAs within 180 days of their submission. However, while manufacturers of these products met their obligation under the court's order, nearly four years since the application deadline, FDA still has not completed reviews of these timely filed applications. It has also not ordered manufacturers of products covered by timely filed PMTAs to remove them from the market pending long-delayed decisions, but of late the agency has contributed to the confusion by pointing to the list of 27 authorized vapor products as the only ones the trade may sell without enforcement risk.

In the meantime, of course, the market has been flooded with new products made by manufacturers in flagrant violation of the Federal Food, Drug, and Cosmetic Act. But rather than say the agency is prioritizing enforcement against these rule-breakers (as it has in the past), FDA now seems reluctant to say one way or the other whether it is actively enforcing the premarket authorization requirements *against products FDA has previously and specifically said could remain on the market pending PMTA review*.

The sensible answer here is for FDA to clearly communicate to regulated industry – the industry members committed to helping federal regulation succeed – that products with timely filed, still-pending PMTAs may continue to be sold. It should focus its enforcement resources on the manufacturers, distributors, and retailers currently building an alternative, illegal, and unregulated marketplace in broad daylight. FDA should stand by the prudent decisions made first in 2016 and again in the years after to allow rule-followers to continue to sell products that met the requirements to remain on the market pending FDA review of timely filed applications – and just say so publicly. Not doing so just adds to the chaos of the current marketplace.

NATO has endeavored to keep its membership informed of FDA statements and actions in this area, and the association unequivocally does not condone the sale of illicit vapor products.

First, NATO has communicated to its members the vapor products that have received marketing authorization from the FDA, which, as of Friday, June 21, 2024, includes 4 menthol flavored vapor products:

- NATO News: "FDA Issues Marketing Granted Orders to NJOY Menthol Vapor Products," June 21, 2024.

Second, NATO regularly communicates to its members regulatory developments regarding vapor products, including FDA announcements of decisions on PMTAs and government enforcement actions involving illicit vapor products. As requested by U.S. Senator Thom Tillis during the hearing, NATO has enclosed the following examples of "NATO News" communications sent to the association's membership:

- "FDA Enforcement Actions Against Tobacco Retailers," February 2, 2024
- "FDA Enforcement Actions Against Tobacco Retailers," February 27, 2024
- "FDA Enforcement Actions Against Tobacco Retailers," April 24, 2024
- "FDA & DOJ Seizure of Illicit Vapor Products," April 30, 2024
- "FDA Expands Import Alert on Illegal Disposables," May 29, 2024

In these example communications, NATO provided updates on administrative and enforcement actions, and each included a comprehensive list of the vapor brands cited as unauthorized or illegally sold in FDA civil money penalty complaints, import alerts, and warning letters.

Thank you for the opportunity to provide testimony on the importance of effective enforcement, increased FDA transparency, and increased vapor product authorizations. NATO and its members support a well-regulated tobacco product market that prevents underage use and delivers on harm reduction, and we look forward to working with the FDA and the Senate Judiciary Committee to address these issues.

Sincerely,

David Spross

NATO Executive Director
david.spross@natocentral.org
845-430-5471

Attachments (6)