NATO

June 11, 2024

Chairman Dick Durbin
Members of the Senate Judiciary Committee

Mr. Chairman and members of the Committee, I appreciate the opportunity to join you today. I am David Spross and serve as the Executive Director of the National Association of Tobacco Outlets (NATO), a national retail trade association that represents more than 66,000 retail stores throughout the country. We are very grateful to the Committee for focusing attention on the need to enhance enforcement against illicit vapor products.

At the outset, I want to clearly affirm our strong support for a well-functioning regulatory system in which FDA oversight leads to accelerated reductions in underage use and in tobacco-related harm. NATO and our members are invested in this system and in these goals, which Congress set forth when it enacted the Family Smoking Prevention and Tobacco Control Act of 2009. In short, all tobacco and nicotine products should be made, marketed, and sold in full compliance with FDA laws and regulations. Illicit markets are a major threat to that goal, and thus a threat to the responsible retail community committed to operating within – not outside – the legal system.

NATO members take responsible retailing seriously. Our members include licensed retailers who age-verify their customers to prevent sales to minors. We have partnered with the *We Card* Program, a national non-profit organization providing individual retail establishments as well as large retail chains with educational and training services. We have also been regularly informing our membership of the brands FDA has targeted in its warning letters and other enforcement actions, to ensure our members know in detail what products FDA is taking action against. These services are intended to help our members align their practices with FDA's enforcement priorities, and, most importantly, ensure they are selling only to adult customers twenty-one and older.

Today's hearing addresses a very important topic for the members of NATO as well as for our country. As you have heard today, the legal vapor market is being overrun by illicit and unregulated products—the vast majority of which are flavored vapor products made in China.

In September of last year, we alerted FDA to this illicit market crisis, and I know several NATO members have also independently shared their concerns with FDA. Since then, the crisis has only intensified. By our estimate, flagrantly illicit vapor products – all made, marketed, and sold without any FDA oversight – now make up more than 50% of the market, having grown by double digits since our September letter to FDA. Earlier this year, in a letter to Senator Durbin and others, NATO again shared our concern that the current market is characterized by a large number of illicit products, particularly flavored disposable products from China, and sought greater FDA focus on this burgeoning crisis.

We were heartened by Monday's announcement that the Department of Justice and FDA are creating a federal multi-agency task force that will focus on combatting the illicit distribution and sale of vapor products. To be successful, FDA and the members of the Task Force must use the full range of enforcement tools such as injunctions, civil money penalties, seizures, and import refusals against the largest manufacturers and distributors of these illicit products.

To date, we have seen piecemeal enforcement that often ignores the most egregious actors. When FDA does act, the agency's warning letters often go ignored, and it appears ignoring these letters results in few serious consequences. We need FDA to utilize its injunctive authorities and the enhanced civil penalties that Congress authorized—which can reach in the tens of millions of dollars in fines—to address this issue. Companies in open defiance of the law must be held accountable, and we believe that means FDA must immediately employ its most powerful enforcement tools against the worst offenders. With more aggressive action against these companies that are ignoring FDA requirements altogether, we believe order can be restored to this marketplace.

NATO and our members desire to be part of the solution and want FDA regulation to succeed. To this end, in September of last year, we requested that FDA host a stakeholder meeting to discuss how to enhance enforcement activities. Ideally, this meeting will bring together all stakeholders (*e.g.*, industry, FDA, other state and federal government agencies, and public health organizations) to have an open dialogue to drive solutions on enforcement. The time is now to convene such a meeting.

An effective regulatory system also requires a more coherent compliance framework that clearly communicates FDA's enforcement priorities – what categories of products it wants immediately removed from the marketplace and what categories can remain on the market. That information is critical to helping address the marketplace chaos we see every day.

FDA has been clear that only 23 authorized vapor products are legal. But we also understand that FDA is not currently prioritizing enforcement against vapor products that have fully complied with its 2016 Deeming Rule[i] and that have timely filed PMTAs which remain pending before the agency. FDA has repeatedly acknowledged that the removal of products pending PMTA review would stimulate illicit market activity and take potentially reduced harm products away from smokers. Simply put, NATO members—who are seeking to abide by the law—need greater clarity from FDA.

In addition to enforcement and transparency, we believe FDA should make more progress in reforming its PMTA process. We believe this illicit market has arisen in part because FDA's PMTA process has fallen short of its intended purpose. For example, FDA continues to review applications on products filed in some cases more than four years ago.

To date, FDA has authorized only a small handful of smoke-free products despite millions of adult consumers seeking better alternatives to smoking. This growing adult demand for smoke-free products should be seen as a positive, given the science that such products are substantially less harmful than combustible cigarettes. But with so few FDA-authorized vapor products available to adult smokers, scores of Chinese companies have exploited this vacuum and flooded the market with products that ignore FDA requirements altogether. Authorizing more products will help build a well-regulated market that delivers on harm reduction.

In closing, we believe the solution to the current crisis of illicit products is to urgently address all three needs: enforcement, transparency, and authorizations. NATO and its members support a well-regulated tobacco product market that reduces underage use and delivers on harm reduction for adult smokers. We look forward to working with FDA and the Task Force as it addresses these issues.

Sincerely,

David Spross

NATO Executive Director

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[i] Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products. (81 Fed. Reg. 28974, May 10, 2016).