NATO

April 17, 2023

Senator Joseph Baldacci, Co-Chair
Representative Michele Meyer, Co-Chair
Members of the Maine Joint Committee on Health and Human Services

RE: LD1215 (Flavored Tobacco Product Sales Ban)

Dear Co-Chairs Baldacci and Meyers and Members of the Joint Health and Human Services Committee:

The National Association of Tobacco Outlets (NATO) is a national trade association that represents hundreds of retail store members across Maine. On behalf of its Maine retail member stores, NATO is providing the following testimony in opposition to LD1215 with regards to the U.S. Food and Drug Administration's tobacco product regulatory actions that have had and will have a significant and direct impact on the sale of flavored tobacco products.

FDA Authority to Regulate Tobacco Products: In 2009, the federal Family Smoking Prevention and Tobacco Control Act was signed into law. This federal law authorized the FDA to regulate the manufacture, distribution, and sale of tobacco products. Under this authority, the agency regulates all tobacco products, including cigarettes, cigars, smokeless tobacco, pipe tobacco, electronic cigarettes and vapor products, oral nicotine products, and hookah tobacco.

Pre-Market Tobacco Applications Required: The law requires that a manufacturer which introduces a tobacco product into the marketplace after February 15, 2007, must file a pre-market tobacco application (referred to as a PMTA) with the FDA and receive a marketing authorization order from the agency before the product can be lawfully sold in the U.S. market. For tobacco products containing nicotine derived from the tobacco plant, the FDA received PMTAs covering almost 9 million tobacco products, the vast majority being electronic cigarettes and nicotine vapor products.

Then, in March of 2022, Congress passed, and President Biden signed into law, new legislation that extended the FDA's authority to products that contain non-tobacco nicotine, or synthetic nicotine. In response to this new law, PMTAs for another 1,000,000 products were submitted to the FDA by May14, 2022.

Products Refused and Denied by the FDA: In response to the PMTAs filed for products that have either tobacco-derived nicotine or synthetic nicotine, to date the FDA has refused to accept PMTAs or issued marketing denial orders for more than 8.6 million tobacco products with tobacco-

derived nicotine and more than 925,000 tobacco products with synthetic nicotine. The remaining products under PMTAs continue to be reviewed by the agency and future decisions will be issued either authorizing or denying the marketing of the products.

To date, and out of nearly 10 million tobacco-derived and synthetic nicotine products, the FDA has only issued marketing authorization orders for 45 products for which PMTAs were filed. To issue a marketing authorization order, the FDA must find that the product "is appropriate for the protection of the public health." The 45 tobacco products receiving marketing authorization orders have met that standard. Some of these products, and some of the products still under review, are "flavored tobacco products" as defined by LD1215.

FDA Enforcement Actions: In recent public statements, the FDA has stated that "All new tobacco products on the market without the statutorily required premarket authorization are marketed unlawfully and are subject to enforcement action at FDA's discretion." As a part of its regulatory function, and to remove unlawful tobacco products from the market, the agency continues to undertake additional enforcement actions including issuing warning letters and filing lawsuits seeking fines against companies that do not remove their products from the market. In fact, the FDA has issued civil money penalty complaints seeking fines against several electronic cigarette companies for continuing to sell their unlawful products. Also, the FDA has the authority to seize unlawful products and seek court injunctions as well as criminal prosecutions.

With the FDA taking action to remove more than 90% of unlawful tobacco products from the market through the PMTA process and working to finalize the review of PMTAs on the remaining products, enforcement by the agency is a key component of its regulatory authority. In fact, on February 24, 2023, the FDA announced its intention to work with senior officials from the Department of Health and Human Services and the Department of Justice in pursuing enforcement.

FDA Regulations to Ban Menthol in Cigarettes and Flavors in Cigars: In April of 2022, the FDA published a proposed regulation that would ban the sale of menthol cigarettes, menthol roll-your-own cigarette tobacco, and all flavored cigars. On January 4, 2023, the agency announced that it plans to finalize these new regulations banning menthol cigarettes and flavored cigars by August of 2023, just four months from now.

FDA Occupying the Field of Flavored Tobacco Regulation: From all these actions being taken, it is clear that the FDA is occupying the field of flavored tobacco product regulation and utilizing a scientific approach through an application and review process to determine whether flavored tobacco products may remain on the market or are unlawful to sell.

Given this scope of regulatory action, I urge the Joint Committee on Health and Human Services to not proceed with LD1215, but rather allow the FDA to regulate flavored tobacco products not only in Maine, but nationwide. Thank you for your consideration.

Sincerely,

Thomas A. Briant

NATO Executive Director