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VIA ELECTRONIC DELIVERY

Joint Standing Committee on Health and Human Services
The 130th Legislature
State of Maine
2 & 3 State House Station
Augusta, ME 04333-0003

Re: Hearing Before the Joint Standing Committee on Health and Human Services, February 9, 2022, 10:00 a.m.; H.P. 1258/L.D. 1693, An Act to Advance Health Equity, Improve the Well-being of All Maine People and Create a Health Trust; Written Testimony of RAI Services Company

Chair Claxton, Chair Meyer, and Distinguished Committee Members:

Thank you for the opportunity to submit this written testimony. RAI Services Company ("RAIS") and its affiliated tobacco companies hope that the following will be informative to the Committee as it considers public comment and testimony on H.P. 1258/L.D. 1693, "An Act to Advance Health Equity, Improve the Well-being of All Maine People and Create a Health Trust" (the "Bill").[1]

In our testimony below, we share the State's interest in tobacco harm reduction. We also share the State's interests in keeping tobacco products out of the hands of youth. Rather than through the current categorical ban of all flavored tobacco products, these interests can be better addressed by incorporating FDA's regulatory oversight of tobacco products. We urge this Committee to include an exemption in the flavor ban to permit products that FDA has allowed to be marketed in the United States. This would include products subject to an FDA Marketing Granted Order after the Agency's review of premarket tobacco product applications ("PMTAs") under 21 U.S.C. § 387j and modified risk tobacco product applications ("MRTPAs") under 21 U.S.C. § 387k, as well as products subject to an FDA Marketing Order after the Agency's review of a Substantial Equivalence Report ("SE Reports") under 21 U.S.C. § 387e(j). *See also id.* § 387j(a)(3) (defining "substantially equivalent").

BACKGROUND

In 2009, the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") amended the Federal Food, Drug & Cosmetic Act ("FD&C Act") to give FDA broad authority to regulate the manufacture, sale, and distribution of tobacco products. Generally, the

[1] RAI Services Company coordinates regulatory compliance for Reynolds American Inc's subsidiary companies, including R.J. Reynolds Tobacco Company, American Snuff Company, LLC, Santa Fe Natural Tobacco Company, Inc., R.J. Reynolds Vapor Company, and Modoral Brands, Inc. References to "RAIS" or "Reynolds" in this letter include itself and its affiliated subsidiaries as applicable.

Tobacco Control Act deemed any product not commercially marketed in the United States as of February 15, 2007, to be a "new tobacco product." *See* 21 U.S.C. § 387j(a). "New tobacco product" also applies to the modification of a tobacco product where the modified product was commercially marketed in the U.S. after February 15, 2007. *See id.*

The Tobacco Control Act established three pathways to market for new tobacco products: (1) substantial equivalence, (2) an exemption from demonstrating substantial equivalence, and (3) premarket tobacco product applications. First, for substantial equivalence, FDA must find that a new tobacco product is "substantially equivalent" to a "predicate" product if the new product has the same characteristics as that predicate product, or if the product has different characteristics, by demonstrating that the new product does not raise different questions of public health than the predicate product. *See id.* § 387j(a)(3). For this pathway, a manufacturer must submit an SE Report, and if the Agency agrees that the Report satisfies the Tobacco Control Act, the Agency will issue an SE marketing order.[2]

An SE Report requires the submission of extensive scientific information. The Tobacco Control Act explains that, under the SE pathway, an applicant must submit a report describing "the basis for such person's determination that . . . the tobacco product is substantially equivalent" to a predicate product, 21 U.S.C. § 387e(j)(1)(A)(i), along with "an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person." *Id*. § 387j(a)(4)(A). Manufacturers must also provide "detailed information regarding data concerning adverse health effects." *Id.* § 387j(a)(4)(B). More specifically, FDA requires a detailed comparison of the characteristics of the new tobacco product to the predicate tobacco product, including a comparison of product design (with detailed specifications that vary on the product type), a comparison of product composition (including materials, tobacco ingredients, and ingredients other than tobacco), and comparisons of other features (including harmful and potentially harmful constituents (HPHCs), and shelf life and stability information—among others. *See* 21 C.F.R. § 1107.19. For these requirements, FDA expects sufficient scientific test data to substantiate these comparisons, including test protocols, quantitative acceptance criteria, and test results (including means and variances, data sets, and a summary of the results) on a sufficient sample size and on test samples that reflect the finished tobacco product and design. *See id.*

Second, substantial equivalence exemptions may apply to a tobacco product that is modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of a tobacco additive. *See id.* § 387e(j)(3). Manufacturers may submit an exemption request, *see, e.g.*, 21 C.F.R. § 1107.1, and if the Agency agrees that the exemption applies, FDA will issue an exempt order.[3] Among other things, FDA requires: a detailed explanation of the purpose of a product modification; a detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the

[2] FDA publishes products subject to these orders on its website. *See* FDA, Marketing Orders for SE, https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se (last accessed Feb. 3, 2022).

[3] FDA also publishes products subject to these orders on its website. *See* FDA, Marketing Orders for Exemption from SE, https://www.fda.gov/tobacco-products/exemption-substantial-equivalence/marketing-orders-exemption-se (last accessed Feb. 3, 2022).

quantity of an existing tobacco additive; a detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the Federal Food, Drug, and Cosmetic Act; a detailed explanation as to why an SE Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health; and a certification summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability. *See* 21 C.F.R. § 1107.1(b).

Finally, a premarket tobacco product application may be submitted when seeking marketing authorization for any new tobacco product. After a manufacturer submits a PMTA, if FDA agrees that the marketing for the product is appropriate for the protection of the public health, *see* 21 U.S.C. § 387j(c)(2), FDA will issue a marketing granted order.[4] PMTAs are voluminous submissions and can span hundreds of thousands of pages of information. The Tobacco Control Act requires an applicant to submit far more data in support of a PMTA, including: "full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products," "a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product," and numerous other requirements. 21 U.S.C. § 387j(b)(1)(A) – (B).

A PMTA must also include: "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;" "an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;" "such samples of such tobacco product and of components thereof as the Secretary may reasonably require;" "specimens of the labeling proposed to be used for such tobacco product;" and "such other information relevant to the subject matter of the application as the Secretary may require." 21 U.S.C. § 387j(b)(1)(C) – (G). To meet the Tobacco Control Act's "appropriate for the protection of the public health standard," PMTAs must also provide scientific substantiation of the effects on youth, young adults, and other relevant vulnerable populations, including: the health risks of the tobacco products to both users and nonusers of the product, the impact the product and its marketing will have on the likelihood of changes in tobacco use behavior, as well as the likelihood of tobacco use initiation by tobacco product nonusers; how users and nonusers perceive the risk of the tobacco product's label, labeling, and advertising; and the impact of human factors on the health risks to product users and nonusers. 21 C.F.R. § 1114.7(h).

[4] FDA also publishes products subject to these orders on its website. *See* FDA, Premarket Tobacco Product Marketing Granted Orders, https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders (last accessed Feb. 3, 2022).

DISCUSSION

Providing for an exemption in the Bill to permit products that FDA has allowed to be marketed in the United States makes sense from a public health perspective.

FDA's Rigorous Requirements for Tobacco Product Applications

As set forth above, the Tobacco Control Act, and FDA by regulation, has set forth significant requirements for PMTAs, SE Reports, and SE Exemption Requests before the Agency permits these tobacco products to be marketed. And these determinations are made only after the Agency's review of voluminous submissions with large amounts of scientific data.

For example, a marketing granted order for a PMTA means that FDA has determined that the marketing for the product is appropriate for the protection of public health. *See id.* § 387j(c)(2). FDA requires PMTAs to include extensive design data, information about constituents, information about manufacturing processes, marketing plan information, and rigorous scientific analyses. As part of FDA's review of PMTAs, Congress directed FDA to weigh certain factors, including the following public-health effects:

- Risks and benefits to the population as a whole, including people who would use the proposed new tobacco product, as well as nonusers;
- Whether people who currently use any tobacco product would be more or less likely to stop using such products if the proposed new tobacco product were available; and
- Whether people who currently do not use any tobacco products would be more or less likely to begin using tobacco products if the new product were available.

See 21 U.S.C. § 387j(c)(4).

In weighing these factors and ultimately issuing a marketing order, FDA must find that a PMTA provides "scientific evidence" and "clinical data" that demonstrate that marketing of a product is "appropriate for the protection of the public health." *Id.* § 387j(c)(5). In other words, any decision by FDA to grant a marketing order for a PMTA means that the federal government will have decided based on its technical and scientific expertise that the marketing of the product is "appropriate for the protection of the public health." *See id.* §§ 387j(c)(1)(A), (c)(4), (c)(5). Conversely, FDA must deny a PMTA if it finds that marketing of a specific product—including flavored products—is not "appropriate for the protection of public health." *See id.* § 387j(c)(2)(A).

And even after FDA issues a marketing granted order for a PMTA, it maintains extensive regulatory authority, including the power to require postmarket reporting and surveillance, to restrict marketing and promotional efforts that may appeal to youth, and to take enforcement actions against retailers that sell to minors. *See id.* §§ 387j(c)(1)(A)(i), (B); 387f(d); 387d. Congress entrusted FDA with making judgments on PMTAs about new tobacco products because of FDA's expertise in evaluating the scientific evidence and making appropriate product-based determinations.

Those public-health determinations made on a product-by-product basis by FDA should be incorporated by state and local governments into law. Incorporating a PMTA exemption would not only recognize the importance of FDA's premarket review and clearance of new tobacco products, but it would also allow the State to achieve its public health goals of tobacco harm reduction among adult users while also limiting access and use of flavored products among youth.

Any Blanket Restrictions or Bans on ENDS Products May Detract From Public Health

FDA and other leading public health authorities have acknowledged that ENDS products may provide smokers with a less risky alternative to traditional cigarettes. Thus, any blanket restrictions or bans on ENDS products may detract from public health rather than improve it. FDA's Director of the Center for Tobacco Products, in fact, has declared in court that "[d]ramatically and precipitously reducing availability of [ENDS] could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products." *Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-883, Dkt. 120-1, at ¶ 15 (D. Md. filed June 12, 2019) (Decl. of Director of FDA's Center for Tobacco Products Mitchell Zeller). In January 2020, FDA Commissioner Stephen Hahn recognized "the potential role that e-cigarettes may play in helping smokers transition completely away from combustible tobacco to a potentially less risky form of nicotine delivery." FDA, *FDA finalizes enforcement policy on authorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint* (Jan. 2, 2020), https://tinyurl.com/uncmdhp.

Notably, there is significant evidence that ENDS products have increased the rate of decline in smoking prevalence. According to the Centers for Disease Control and Prevention's ("CDC") National Center for Health Statistics, in 2018, "adults who quit smoking cigarettes within the past year were the most likely to have ever used (57.3%) and to be current (25.2%) e-cigarette users." NCHS Data Brief, No. 365, at 1 (Apr. 2020), https://tinyurl.com/2hjgsp7p. Additional scientific studies have confirmed that ENDS products have a positive impact on smoking prevalence, including as compared to traditional nicotine-replacement therapies, as well as no treatment:

- Hartman-Boyce et al., Electronic cigarettes for smoking cessation, Cochrane Database of Sys. Revs. (2020) ("[Q]uit rates were higher in people randomized to nicotine EC than in those randomized to nicotine replacement therapy"; "There is moderate-certainty evidence that ECs with nicotine increase quit rates compared to ECs without nicotine and compared to NRT.");

- Oberndorfer et al., Effectiveness of Electronic Cigarettes in Smoking Cessation: a Systematic Review and Meta-Analysis, pending publication, Soc. Res. on Nicotine & Tob. (2020) ("Our results suggest that nicotine-ECs may be more effective in smoking cessation when compared to placebo ECs or NRT.");

- Eisenberg, Efficacy and Safety of E-Cigarettes for Smoking Cessation - E3, Am. Coll. Cardio. (2020) ("The E3 trial showed that nicotine e-cigarettes plus counseling were superior to counseling alone at smoking cessation.");

- Hajek et al., A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy, NEJM (2020) ("E-cigarettes were more effective for smoking cessation than nicotine-replacement therapy, when both products were accompanied by behavioral support.").

These findings are consistent with data from the FDA's longitudinal study, Population Assessment of Tobacco and Health. *See* Glasser et al., *Patterns of e-cigarette use and subsequent cigarette smoking cessation over two years (2013/2014 to 2015/2016) in the Population Assessment of Tobacco and Health (PATH) Study*, Soc. Res. on Nicotine & Tob. (2020) ("Smoking cessation was more likely among frequent e-cigarette users, users of e-cigarettes in last quit attempt, and users of flavored and rechargeable devices.").

While FDA has not yet issued a Marketing Granted Order for a non-tobacco-flavored ENDS product, the findings of numerous public health experts and studies show that flavored ENDS products are an integral component of consumer acceptability to provide smokers with a less risky alternative to traditional cigarettes:

- Landry, et al. (2019): "retaining tobacco, mint, and menthol flavors may facilitate the maintenance of vaping in adults who may be attracted to e-cigarettes as an alternative to cigarettes or cessation strategy."

- Takett, et al. (2015): non-tobacco/non-menthol flavored e-cigarettes appear to be associated with higher rates of smoking cessation.

- Farsalinos, et al. (2013): "[E-cigarette] liquid flavourings play a major role in the overall experience of dedicated users and support the hypothesis that they are important contributors in reducing or eliminating smoking consumption."

- U.K. Action on Smoking and Health (2015): "Nonusers should understand that flavours are an important aspect of vaping and integral to the experience. They are also part of a migration away from tobacco."

A flavor ban may further impair public health by leading to the development of a robust illicit market for ENDS products. The U.S. government has long recognized the existence of a large illicit market for combustible cigarettes. For instance, in 2015, the National Academies of Science, Engineering, and Medicine estimated that between 8.5% and 21% of the U.S. market for cigarettes was supplied by contraband products. *See* National Academies of Science, Engineering, and Medicine, Understanding the U.S. Illicit Tobacco Market: Characteristics, Policy Context, and Lessons from International Experiences 4 (2015). As the United States recognized in a filing to the World Trade Organization, "[b]anning all cigarettes—or any type of cigarette favored by a large portion of U.S. smokers—could significantly increase the existing black market for cigarettes and all the attendant contraband trafficking and other illegal activity." *Id.* (quoting United States, Measures Affecting the Production and Sale of Clove Cigarettes (2010)). It stands to reason that similar underground markets for ENDS products would emerge with a categorical ban on all flavored products.

Unregulated tobacco products potentially pose more risks than FDA-regulated tobacco products produced by licensed manufacturers because they are, by definition, unregulated and are also more likely to be adulterated and misbranded. In the case of cigarettes, for example, the Bureau of Alcohol, Tobacco, Firearms and Explosives ("ATF") recognized that "[w]hile all cigarettes are dangerous and cause disease, counterfeit cigarettes contain higher levels of tar, nicotine and carbon monoxide than genuine cigarettes." Bureau of Alcohol, Tobacco, Firearms and Explosives, Fact Sheet—Tobacco Enforcement (2018), *available at* https://tinyurl.com/r7uyccvh. The ATF has even reported finding contaminants such as sand, packing materials, and bits of plastic in unregulated cigarettes. *See id.*

The illicit market for vapor products has already had serious consequences. In the wake of numerous hospitalizations and several deaths attributed to vaping-related lung illness, FDA announced to Congress on September 25, 2019, that it was partnering with the Centers for Disease Control and Prevention ("CDC") to test the products associated with these illnesses. The CDC found that vitamin E acetate, an additive in some THC-containing e-cigarette products, was the primary cause of the EVALI outbreak. *See* CDC, Outbreak of Lung Injury Associated with E-cigarette use, or Vaping, "What We Know," *available at* https://tinyurl.com/dkaewwdh. This misuse of vitamin E acetate was linked to a vibrant market for bootlegged, illicit products. *See* D. Grady, *Vaping Illnesses Are Linked to Vitamin E Acetate, C.D.C. Says*, The New York Times (Nov. 8, 2019) ("The outbreak has revealed the existence of a vast, unregulated, shadowy marketplace of illicit or bootleg vaping products that are essentially a stew of unknown chemicals concocted, packed, and sold by unknown manufacturers and sellers."). Accordingly, the CDC warned the public about illicit ENDS products, saying "not [to] use THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, or family, or in-person or online dealers." *Id.*

<u>An Exemption Would Not Compromise the Bill's Public Health Goals</u>

Importantly, however, the Bill's public health goals can be achieved while also limiting access and use of flavored products among youth. At the federal level, the FDA has acted in response to concerns about youth vaping. In 2020, FDA effectively banned the sale of flavored, cartridge-based, electronic nicotine delivery system ("ENDS") products (other than tobacco- or menthol-flavored, cartridge-based ENDS products). *See* FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised*), 19 (Apr. 2020), https://tinyurl.com/bn498hfc ("Enforcement Priorities"). By way of background, when FDA promulgated its Deeming Rule, it brought ENDS products within its regulatory umbrella—meaning before the products were sold, they needed FDA authorization. *See* FDA, 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. 28,973 (May 2016) ("Deeming Rule"). At the time, FDA said it would use its enforcement discretion and allow the products to stay on the market for some time even if they had not received FDA authorization. *Id.* at 28,977–78. FDA changed course as to flavored, cartridge-based ENDS products (other than those that are tobacco- or menthol-flavored). FDA, *Enforcement Priorities*, 19. The upshot of the new policy is that flavored, cartridge-based ENDS products (other than those that are tobacco- or menthol-flavored) can no longer be sold, unless and until FDA grants a marketing order for such products, which includes the regulatory authority FDA maintains after the marketing order is granted, including the power to require

postmarket reporting and surveillance, to restrict marketing and promotional efforts that may appeal to youth, and to take enforcement actions against retailers that sell to minors.

Reynolds also shares the State's goal of keeping tobacco products (including ENDS products) out of the hands of youth. Reynolds is an original sponsor and lead participant in the *We Card* program. Since 1995, *We Card* has trained nearly half a million store owners, managers, and frontline employees to help prevent youth access to tobacco products. Reynolds has further expanded those efforts, including through the use of *We Card*'s "mystery shopper" program, which also will provide additional retailers with further education and training on verifying the legal age of purchasers.

Reynolds has instituted additional measures to ensure youth are not obtaining its ENDS products. For example, Reynolds adheres to rigorous standards to ensure its marketing is accurate and responsibly directed to adult tobacco consumers aged 21 and over. Reynolds also imposes strict compliance policies on retailers who sell its products in order to prevent youth from purchasing tobacco products, and Reynolds supports programs that train retailers to comply with age restrictions. Reynolds has instituted a contract-based, tiered compliance program, which involves penalties for retailers that are found to have illegally sold its VUSE products to youth. This is in conjunction with Reynolds directing its trade marketing representatives to discuss the issue of underage youth access with each of Reynolds' contracted retailers on an ongoing basis.

Importantly, providing this exemption in the Bill will not result in a loophole. For example, since fiscal year 2020, FDA has accepted over 6.5 million PMTAs and has issued only three Marketing Granted Orders for ENDS products. *See* FDA, *PMTA Review and Action Metrics*, *available at* https://www.fda.gov/media/155458/download (data as of Dec. 14, 2021); *see also* FDA, Tobacco Product Applications: Metrics & Reporting, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting.[5] FDA has issued marketing denial orders for 1.2 million ENDS products, and has issued over 5 million refuse to file (RTF) determinations.[6] Products that are still under FDA review are not allowed to be marketed.

In conclusion, for the reasons set forth above, RAIS urges this Committee to include an exemption in the flavor ban to permit products that FDA has allowed to be marketed.

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Thank you again for the opportunity to present this testimony. RAIS looks forward to answering any questions the Committee may have or providing additional information as requested.

REYNOLDS
A BETTER TOMORROW

Testimony by RAI Services Company

[5] FDA also issued Marketing Granted Orders for seven other product categories, including cigarettes and heated tobacco products.

[6] FDA makes a refuse to file (RTF) determination upon a finding that a PMTA is missing one or more items required by the Federal Food, Drug, and Cosmetic Act. After the Agency issues an RTF determination for a PMTA, the applicable products are not permitted to be marketed.