WRITTEN TESTIMONY OF MICHAEL A. MADDEN, MD

REGARDING MAINE FLAVOR BAN (HP 1155)

I. Introduction

My name is Dr. Michael Madden, and I have been a family physician for 39 years. I write in opposition to HP 1155, which would result in a complete ban of all flavors in all tobacco products, including smokeless tobacco products, electronic nicotine delivery systems (ENDS) and other nicotine vapor products. I urge you to consider and reflect science-backed tobacco harm reduction policy in Maine's tobacco control activities.

Non-combustible tobacco products present an enormous opportunity for tobacco harm reduction, and a complete prohibition of flavored ENDS by the state on these products disincentivizes their use among Maine's adult cigarette smoking population.

In my roles as a family physician, as President of the Board of Allies for Health + Wellbeing (Southwest Pennsylvania's largest provider of services and care for individuals with or at risk for HIV), and as former Chief Medical Officer of Gateway Health (a multi-state managed care company serving Medicare and Medicaid populations), I have worked in clinical and administrative settings to address harm reduction in a variety of public health crises, including the opioid epidemic, HIV/AIDS, and smoking. In these roles I learned how important it is to "meet the person where they are" and "make it easy for them to do the right (health) thing". Many policy makers who are not smokers do not understand the negative impact flavor bans can have on adults. Please put yourself in the shoes of a current adult smoker trying to improve their health before voting to limit their options. I have also taught evidence-based literature review extensively to physicians, residents, and medical students. Importantly, you should know that, while RAI Services Company has compensated me for my time in preparing this testimony, the opinions expressed are my own.

II. What is Harm Reduction?

Harm reduction is a key principle we public-health professionals employ to mitigate deadly health risks. You are, no doubt, familiar with harm-reduction methods used to address a variety of public health ills, such as methadone, needle-exchange programs, and naloxone for people addicted to opioids. Additionally, condoms and PrEP (preexposure prophylaxis) are harm reduction tools used to decrease the chance of HIV transmission in sexually active adults, while helmet and seatbelt laws have long been commonplace methods for reducing death and serious injury in motor vehicle accidents.

While neither methadone, nor condoms, nor seatbelts entirely reduce an individual's risk of death from drug overdose, HIV, or a car accident, respectively, all these harm reduction techniques are substantially safer than the conditions they address.

In the case of smoking, which claims 1,300 lives per day in the United State, tobacco harm reduction equals a broad array of non-combustible tobacco products (including vapor, SNUS, and moist tobacco) that are both available and acceptable to current cigarette smokers. A body of evidence from leading health authorities indicates that vapor products are 90 to 95 percent less harmful than combustible cigarettes, and decades of scientific research have established that oral tobacco products pose substantially fewer health risks to users than cigarettes.

However, the bill before you now turns that science on its head by banning these less harmful products and making tobacco harm reduction (THR) less acceptable to smokers of traditional, combustible cigarettes.

III. What is Tobacco Harm Reduction?

Smokers die prematurely not because they consume nicotine – which is not a carcinogen – but because of **how** they consume it: in the combustible form of a cigarette. According to the FDA, switching completely from cigarettes to a "potentially less harmful nicotine delivery system," could "significantly reduce the risk of tobacco-related death and disease."[1] Further, the National Academies of Sciences, Engineering, and Medicine has found that "[t]here is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."[2]

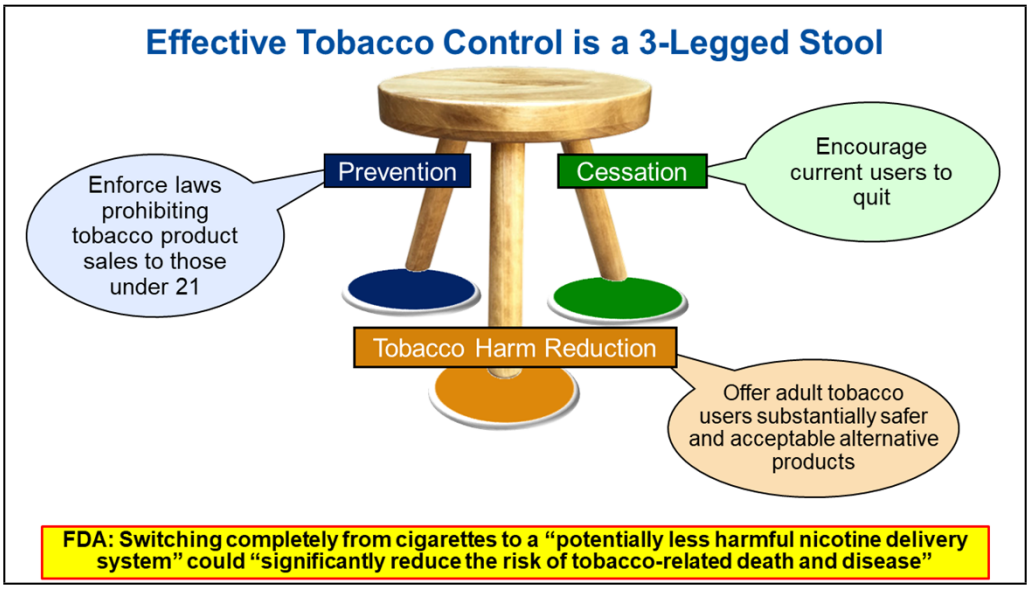
And beyond simple substitution of products, recent studies reveal that use of e-cigarettes may actually help adult smokers quit. According to Public Health England, a leading public health organization in the U.K., "vaping carries a small fraction of the risk of smoking" and "[u]sing a nicotine-containing e-cigarette makes it much more likely someone will quit successfully than relying on willpower alone."[3] And a study recently published in the New England Journal of Medicine found that cigarettes smokers who used e-cigarettes while quitting smoking were nearly twice as likely to be smoke free one year later.[4] While 9.9 percent of the smokers who did not use e-cigarettes were smoke free at the end of the year, 18 percent of the smokers using e-cigarettes were no longer smoking at the end of the study period.

[1] 83 Fed. Reg. at 11824.

[2] http://nationalacademies.org/hmd/reports/2018/public-health-consequences-of-e-cigarettes.aspx

[3] https://publichealthmatters.blog.gov.uk/2019/10/29/vaping-and-lung-disease-in-the-us-phes-advice/

[4] Hajek, et al., "A Randomized Trial of E-cigarettes versus Nicotine-Replacement Therapy," NEJM, 380:7, Feb. 14, 2019.



Successful, public health-focused tobacco control is a three-legged stool supported by prevention of initiation, education regarding tobacco cessation, and encouraging tobacco harm reduction for those adult smokers who choose to continue using tobacco or nicotine-containing products.

IV. What Action Has Already Been Taken on Tobacco Harm Reduction in the U.S.?

In 2009, when the FDA began regulating the tobacco industry, it established a procedure through which a tobacco product could be authorized for marketing as a "modified risk tobacco product," or MRTP. Products authorized for MRTP marketing have been determined by the FDA to be "appropriate for the protection of public health"[5] and can be marketed as a safer alternative to cigarettes.

Since that time, a dozen non-combustible tobacco products have been approved by the FDA as modified-risk tobacco products. Some of these products are on store shelves in Maine today. And at least one state, Connecticut, has altered its tobacco taxation structure to recognize this innovative policy. In Connecticut, products authorized by the FDA as MRTP products are taxed at *half* of the rate of other tobacco products.[6]

Along with the MRTP process, manufacturers of "new" tobacco products, including nicotine-vapor products, were required to submit safety and public health benefit data to the FDA by September 9, 2020, or have their products removed from the market. This process (referred to

[5] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders

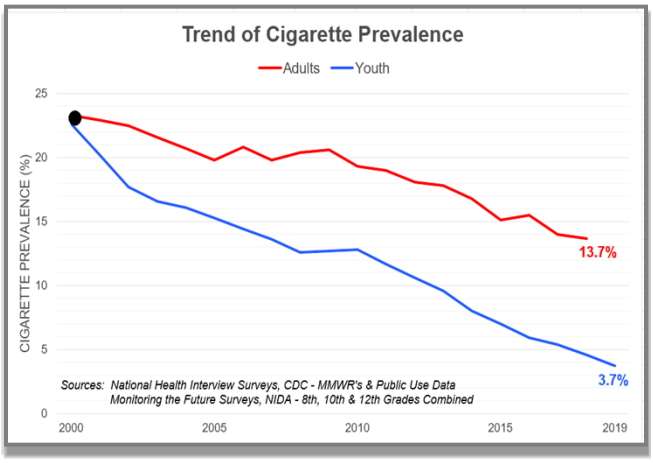
[6] https://vaporproductstax.com/connecticut-will-apply-a-discount-when-taxing-modified-risk-tobacco-products/#:~:text=Legislators%20in%20the%20State%20of,%E2%80%9Cmodified%20risk%20tobacco%20product%E2%80%9D

as a Pre-Market Tobacco Application or PMTA) requires manufacturers to provide extensive and persuasive evidence that their products will provide tobacco harm-reduction benefits for existing adult smokers, while limiting their appeal to and access by youth – the exact combination of policy objectives addressed in the MRTP process for traditional tobacco products. Only those products that meet the FDA's definition of "appropriate for the protection of public health" will be approved for continued sale in the United States. This definition means that the FDA will consider the balance of improving the health of current smokers who could switch to a safer product with the health of non-tobacco users who might start. This will be a decision based on a detailed scientific analysis. The Maine legislature would be wise to avoid making politically expedient public health policy that may contradict the FDA's thorough analysis. Even worse, passing laws that diminish the public health potential of THR is NOT in the best interest of the heath of Maine's citizens.

To be clear, none of these tobacco products, either in the MRTP or PMTA process, seek approval from the FDA as drug or medical devices for smoking cessation, like nicotine gum or patches or other smoking cessation aids. Those who argue that these products should be restricted because they have not been "approved" by the FDA for smoking cessation entirely miss the point of tobacco harm reduction. Tobacco harm reduction offers alternative, less dangerous products for current smokers who want to continue to use tobacco or nicotine products. An apt analogy would be nonalcoholic beer consumed by those who want to cut down or abstain from alcohol. No one is proposing bans on flavored "near beer". Although some smokers (as noted above) may find that ENDS are helpful to them in quitting smoking, they are not medical devices or reviewed as such by the FDA (nor is near beer). The reality is that some smokers want to quit combustible cigarettes, but otherwise enjoy the taste and feel and other social aspects they associate with cigarette smoking. They want to do it their way and as stated above, we should "meet them where they are". Maine's tobacco control policies can be leveraged to encourage these tobacco users to make safer choices for their own health.

V. What about Youth Use of Tobacco Products?

Prevention of youth initiation of tobacco use is a key aspect of the three-legged stool of tobacco control. Fortunately, there is encouraging news in surveys on teen use of tobacco products. Teen use of cigarettes is at the lowest level in history.



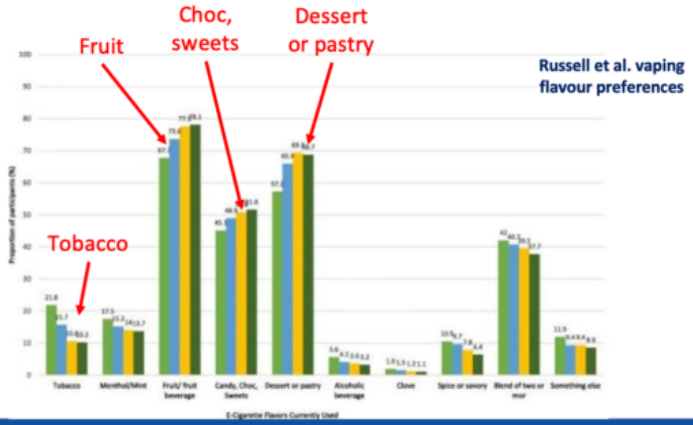
Despite a dramatic increase in teen use of vapor products in 2018-19, recent surveys show not only that fewer than 5 percent of teens are daily vapers but also that the rate of experimentation with vapor products among teens (any use in the last thirty days) was cut in half to 13 percent in 2020.[7]

That success may be due in large part to the December 2019 change to federal law that banned the sale of any tobacco products to those under age 21. Maine enacted a similar law in July 2018, and it is imperative that the state use its tobacco settlement dollars and other tax revenue to aggressively enforce these laws. Increasingly, youth are using disposable vapor products. To balance the competing goals of lower youth access but attractive tobacco harm reduction strategies for current smokers, consider targeting just disposable products.

These strategies (enhanced enforcement and a disposable vapor flavor ban), which directly target youth access to tobacco products, are the right tools for the right goal.

VI. What Role Do Flavored Products Play in Tobacco Harm Reduction?

In announcing in 2018 its Advanced Notice on Proposed Rulemaking on flavors in tobacco products, the FDA recognized that the availability of flavored tobacco products may, in fact, help smokers move away from combustible cigarettes to less harmful tobacco products.[8] Industry data demonstrate that nationally more than 53 percent of adults chose flavored products when making the switch from cigarettes to ENDS. And as the chart below demonstrates, adults OFTEN choose sweet or fruit flavors that are different from the tobacco taste in combustible cigarettes and part of the appeal of ENDS. This should not be surprising when you see the line of adults at a restaurant desert buffet.



Russell C, et al. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J.* BioMed Central; 2018

[7] Journal of the American Medical Association, December 3, 2020 (JAMA Network Open), 2020; 3(12):e2027572.
[8] https://www.fda.gov/tobacco-products/products-ingredients-components/flavors-tobacco-products-what-are-potential-risks-and-benefits-public-health

Of the first eight products approved for MRTP marketing claims of reduced health risk, fully half are flavored (mint or wintergreen) products.[9] And the likelihood that some flavored ENDS currently being considered for PMTA status will be approved for continued sale is high.

The bill before you now would prohibit the sale of some ENDS in Maine that the FDA has determined to be in the best interest of public health. At the very least, the bill also should include an exception for PMTA-approved products, along with its MRTP exception.

VII. Why is Menthol an Important Flavor?

Industry data indicate that 43 percent of cigarette sales in the State are menthol cigarettes. By banning the sale of mint/menthol ENDS along with all other flavors, you decrease the likelihood that menthol smokers may see less harmful ENDS as an acceptable substitute to menthol cigarettes.

Furthermore, assuming some former menthol smokers in Maine already have made the switch to ENDS (of any flavor), eliminating a flavor that is approved for sale in traditional, combustible cigarettes in Maine or nearby states may drive those former smokers back to illicitly obtained menthol cigarettes.

To avoid these incongruous and inconsistent results, any ENDS flavor ban passed in Maine should include an exception for mint/menthol ENDS and moist snuff.

VIII. Conclusion

Tobacco harm reduction offers adult consumers of combustible cigarettes a continuum of products from moist snuff to e-cigarettes, to nicotine lozenges, and others that allow them to continue use of tobacco and nicotine products that are substantially less hazardous to their health. That the majority of adults who make that choice also choose flavored versions of these non-combustible products must not be ignored.

I urge you to consider the public health benefits to all Maine residents of implementing a robust tobacco harm control strategy and to reject this proposal to ban all flavored ENDS. Alternatively, the flavor ban must include common-sense exceptions, including mint/menthol ENDS and moist snuff and ENDS approved through the FDA's MRTP and PMTA processes.

[9] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products