

February 17, 2021

**ORAL TESTIMONY OF MICHAEL A. MADDEN, MD**

**BEFORE THE PREVENTIVE HEALTH POLICY DIVISION  
OF THE MINNESOTA HOUSE OF REPRESENTATIVES**

**REGARDING HOUSE BILL HF904**

My name is Michael Madden. I am a doctor and the former Chief Medical Officer of a multi-state managed care company serving Medicare and Medicaid populations. I've been practicing medicine for more than 36 years and have worked extensively on issues such as opioid addiction, HIV, and smoking.

While Reynolds has compensated me for my time in preparing my testimony, let me be clear that the opinions expressed are my own.

I speak today in opposition to HF904, and I urge you to consider the public-health need to balance limiting youth access to electronic nicotine delivery systems – ENDS or e-cigarettes – with the enormous opportunity non-combustible tobacco products present for tobacco harm reduction.

Harm reduction is a key public health principle employed to mitigate deadly health risks. Examples include methadone for opioid addiction and condom use to decrease HIV transmission. While not reducing risk to zero, harm reduction substantially improves safety and saves lives.

Smokers die prematurely not because they consume nicotine – which is not a carcinogen – but because of **how** they consume it: in a combustible form. For example, moist snuff users (the majority of whom use flavored products) experience significantly lower risk of disease than smokers. And leading health authorities have agreed that vapor products may

substantially reduce smoking's harms. Industry data show that 66 percent of adult moist snuff user and more than 53 percent of adults who make the switch to ENDS choose non-tobacco flavored products. That adults prefer flavored products when making the decision to switch cannot be ignored.

In the last 14 months, both the federal government and Minnesota have banned the sale of **all** tobacco products to those under 21. To now ban all flavored tobacco products without an assessment of the impact of those laws limits adult Minnesotans' access to products that are both substantially safer than combustible products and more appealing than non-flavored products.

True tobacco harm reduction requires a broad array of non-combustible tobacco products be accessible **and** appealing to current smokers.

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**WRITTEN TESTIMONY OF MICHAEL A. MADDEN, MD**  
**BEFORE THE PREVENTIVE HEALTH POLICY DIVISION**  
**OF THE MINNESOTA HOUSE OF REPRESENTATIVES**

**REGARDING HF904**

**I. Introduction**

My name is Dr. Michael Madden, and I've been a family physician for 39 years. I offer testimony today in opposition to HF 904, which would ban the sale of all flavored tobacco products in Minnesota. My goal is to provide you with a public-health context for the use of flavors in non-combustible tobacco products, such as electronic nicotine delivery systems – ENDS, e-cigarettes, or “vapor products” – moist snuff, and other alternative tobacco products. In particular, I urge your committee to balance the need to limit youth access to these products with the enormous opportunity non-combustible products present for tobacco harm reduction among the State's adult smoking population.

Importantly, you should know that, while Reynolds American, Inc., has compensated me for my time in preparing this testimony, the opinions expressed are my own.

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. I have also taught evidence-based literature review extensively to physicians, residents, and medical students.

To be clear, I fully share the concern about youth use of vapor products: Youth should **not** use tobacco products, including vapor products. Conversely, to achieve tobacco harm reduction among adults, products that present substantially less risk than combustible tobacco products – such as vapor products, moist snuff, and other alternative tobacco products – must be not only accessible but also appealing to adults. This is very important.

**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 or techniques 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 of 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 and is the country's leading cause of preventable death, tobacco harm reduction equals a broad array of non-combustible tobacco products and flavors. A body of evidence from leading health authorities indicates that ENDS – along with moist snuff and other alternative tobacco products, including nicotine pouches, lozenges, and gums – have the potential to substantially reduce smoking's harm.

### **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. For example, decades of epidemiology on moist snuff reveals a significantly reduced risk of health problems when compared to traditional cigarettes.<sup>1</sup> 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.”<sup>2</sup> 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.”<sup>3</sup>

And beyond simple substitution of products, recent studies reveal that use of e-cigarettes may actually help adult smokers quit using combustible tobacco products. 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.”<sup>4</sup>

In fact, 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 as those who did not to be smoke free one year later.<sup>5</sup> 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 utilizing e-cigarettes were no longer using combustible cigarettes at the end of the study period.

### **IV. What Role Do Flavored Products Play in Tobacco Harm Reduction?**

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<sup>1</sup> See, e.g., <https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-019-0294-6>.

<sup>2</sup> 83 Fed. Reg. at 11824.

<sup>3</sup> <http://nationalacademies.org/hmd/reports/2018/public-health-consequences-of-e-cigarettes.aspx>

<sup>4</sup> <https://publichealthmatters.blog.gov.uk/2019/10/29/vaping-and-lung-disease-in-the-us-phis-advice/>

<sup>5</sup> Hajek, et al., “A Randomized Trial of E-cigarettes versus Nicotine-Replacement Therapy,” *NEJM*, 380:7, Feb. 14, 2019.

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. Industry data demonstrate that nationally more than 53 percent of adults chose flavored products when making the switch from cigarettes to ENDS.<sup>6</sup> And 64 percent of adult users of moist snuff products use flavored products. That number is even higher in Minnesota, with 88 percent of moist snuff users purchasing a flavored product.

In 2009, when the FDA began regulating the tobacco industry, it established a procedure through which a tobacco product could be approved for marketing as a “modified risk tobacco product,” or MRTP. Products approved for MRTP marketing have been determined by the FDA to be “appropriate for the protection of public health.”<sup>7</sup> Of the eight original products approved for MRTP marketing, fully half are flavored (mint or wintergreen) products.<sup>8</sup>

Additionally, manufacturers of “new” tobacco products, including ENDS, 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 as a Pre-Market Tobacco Application or PMTA) requires manufacturers of these products 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 you hope to achieve here. Only those products that meet the FDA’s definition of “appropriate for the protection of public health” will be approved.

The bill before you now would prohibit the sale of products in Minnesota that the FDA has determined to be in the public’s interest. At the very least, the bill should include an exception for products marketed with FDA approval.

## **V. Can Youth Use of Tobacco Products Be Addressed through Other Means?**

Much of the interest in banning flavored tobacco products is driven by the intent to reduce youth use. But the issue is already being directly addressed by both Minnesota and federal law. In December 2019 – just fourteen months ago – the federal government banned the sale of **all** tobacco products to those younger than 21. And your legislature followed suit last summer, banning the sale of all tobacco products (flavored and unflavored) to those under 21 as of August 1, 2020 – just six months ago. Furthermore, data suggest that youth use of smokeless tobacco products like moist snuff is low and that youth are not using alternative nicotine products in any significant numbers.

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<sup>6</sup> <https://www.fda.gov/tobacco-products/products-ingredients-components/flavors-tobacco-products-what-are-potential-risks-and-benefits-public-health>

<sup>7</sup> <https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders>

<sup>8</sup> <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products>

A proper balancing of the need to protect youth and the need to save lives of current smokers requires that the impact of those new laws that directly address their intended target be assessed **before** new broader and more restrictive legislation is passed. There simply are no data suggesting that any jurisdiction that has banned the sale of flavored tobacco products has realized an actual decline in youth use of tobacco products. And adults cannot be encouraged to reduce use of combustible cigarettes if they cannot access less hazardous alternative products or if those alternatives are not acceptable to them.

## **VI. Conclusion**

Tobacco harm reduction recognizes that outright bans and prohibitions on products and flavors will not reduce adult tobacco consumers' demand for these products. Tobacco harm reduction offers adult consumers of combustible cigarettes – the most risky tobacco products on the market today – 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.