# WRITTEN TESTIMONY OF MICHAEL A. MADDEN, MD

# REGARDING PROPOSED RHODE ISLAND FLAVOR BAN

# HOUSE BILL 6396

# OPPOSED

# JUNE 28, 2021

## I. Introduction

My name is Dr. Michael Madden, and I have been a family physician for 36 years. I write in opposition to Rhode Island's proposed flavored tobacco ban. House Bill 6396 would result in a complete ban of all flavors in all tobacco products, including smokeless tobacco products, electronic nicotine delivery systems (ENDS) and other alternative tobacco and nicotine products. I urge you to consider and reflect science-backed tobacco harm reduction in Rhode Island's tobacco control policies and to vote against this bill.

Non-combustible tobacco products present an enormous opportunity for tobacco harm reduction, and a complete prohibition of flavors in these products disincentivizes their use among Rhode Island's adult cigarette smoking population. Many policy makers who are not smokers do not understand the negative impact tobacco 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.

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. 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 thing" for their health.

Importantly, you should know that, while RAI Services Company (Reynolds) 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 public-health professionals employ to mitigate deadly health risks. An article published just this year in the New England Journal of Medicine strongly endorsed harm reduction, including tobacco harm reduction, as national health policy.[1]

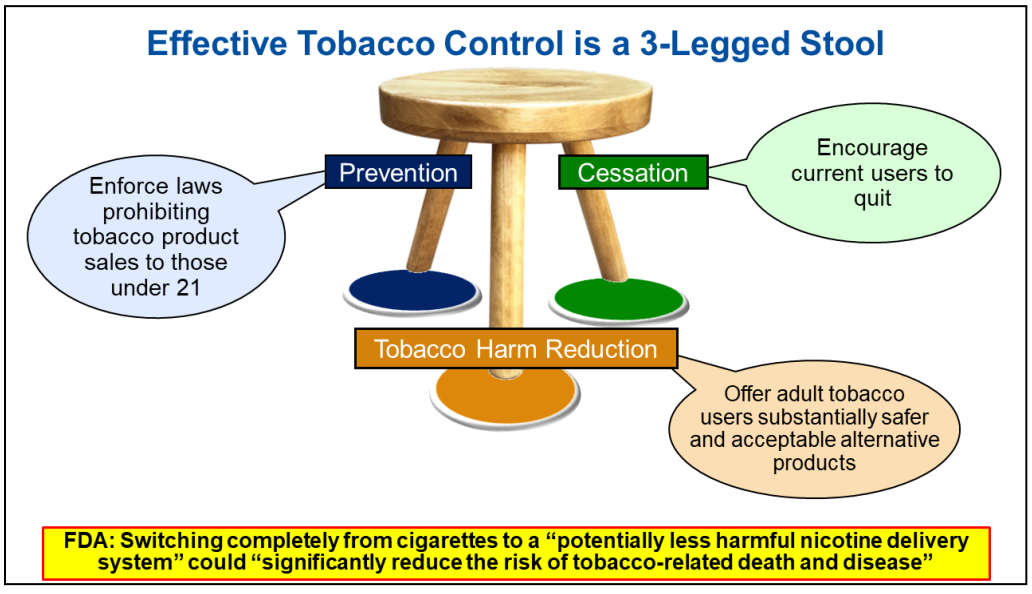
You are, no doubt, familiar with harm-reduction methods used to address a variety of public health ills, such as methadone, needle-exchange programs, and naloxone for people addicted to opioids. Additionally, condoms and PrEP (preexposure prophylaxis) are harm reduction tools used to decrease the chance 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.

However, Rhode Island's proposed flavored tobacco ban turns that science on its head by making tobacco harm reduction less acceptable to smokers of traditional, combustible cigarettes.

## III. What is Tobacco Harm Reduction?

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.




[1] Sue KL, Fiellin DA. Bringing Harm Reduction into Health Policy - Combating the Overdose Crisis. N Engl J Med. 2021 May 13;384(19):1781-1783. doi: 10.1056/NEJMp2103274.

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."[2] 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."[3]

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."[4] In fact, a study 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 as those who used traditional nicotine replacement therapies or quit cold turkey:[5] 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.

## IV. What Role Do Flavors 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. Industry data demonstrate that nationally more than 53 percent of adults chose flavored products when making the switch from cigarettes to ENDS.[6] And in Rhode Island, 83 percent of adult users of moist snuff products use flavored products.

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"[7] and may be marketed as safer

[2] 83 Fed. Reg. at 11824.
[3] http://nationalacademies.org/hmd/reports/2018/public-health-consequences-of-e-cigarettes.aspx
[4] https://publichealthmatters.blog.gov.uk/2019/10/29/vaping-and-lung-disease-in-the-us-phes-advice/
[5] Hajek, et al., "A Randomized Trial of E-cigarettes versus Nicotine-Replacement Therapy," NEJM, 380:7, Feb. 14, 2019.
[6] https://www.fda.gov/tobacco-products/products-ingredients-components/flavors-tobacco-products-what-are-potential-risks-and-benefits-public-health
[7] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders

alternatives to cigarettes. Twelve smokeless tobacco products have received this authorization, and many of them are on Rhode Island store shelves today.[8]

Additionally, manufacturers of "new" tobacco products, including all vapor products on the market today, 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 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. Those authorizations are expected by September 9 – just more than two months from now.

Thousands of PMTA applications were filed in September 2020 and the majority were for flavored products. The FDA will balance the science on improving the health of current smokers who might switch to a safer tobacco product with the health of non-tobacco users who might start. This will be a decision based on a detailed scientific analysis of the products and even their manufacturers' marketing plans for those products.

To be clear, none of these tobacco products, either in the MRTP or PMTA processes, 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.

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 we can and should "meet them where they are." Rhode Island's tobacco control policies can be leveraged to encourage these tobacco users to make safer choices for their own health grounded in thorough, individualized scientific review of each product.

## 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

[8] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products; https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information

experimentation with vapor products among teens (any use of vapor products in the last thirty days) was cut by over 30% percent in 2020.[9]

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. If you want to protect Rhode Island youth, pass a similar law and use your tobacco settlement dollars and other tax revenue to aggressively enforce that law. These strategies, which directly target youth access to tobacco products, are the right tools for the right goal.

## 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 other alternative tobacco products 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 Rhode Island residents of implementing a robust tobacco control strategy and to reject this proposal to ban all flavored tobacco products.

[9] Journal of the American Medical Association, December 3, 2020 (JAMA Network Open), 2020; 3(12):e2027572.