



NATIONAL TOBACCO REFORM INITIATIVE

Ending Cigarette Use by Adults in a Decade is Possible

December 7, 2018

Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20857

RE: Recent FDA actions to reduce adolescent tobacco use

Dear Commissioner Gottlieb

We are writing on behalf of the National Tobacco Reform Initiative (NTRI) that was established by a small group of experienced, seasoned public health tobacco control leaders with a goal of reducing the use of cigarettes and other combustible tobacco products. As you know, NTRI strongly endorses the tobacco product regulatory framework you and Director Zeller have previously articulated that focuses on nicotine and supports innovations to promote tobacco harm reduction based upon the continuum of risk for nicotine-containing products. However, we also share your widely reported concern about the recent (2017 to 2018) apparent increase in e-cigarette use by adolescents. NTRI supports the deliberate and measured actions that FDA has announced to try to curb both access and the appeal of tobacco products to adolescents never smokers, while also preserving access to less harmful nicotine vaping products for addicted smokers.

There is plenty of evidence showing that characterizing flavors do generate interest in product trial by non-smokers, primarily youth. All one needs to do is look within the cigarette industry's own internal business records where they describe ways to design cigarettes to appeal the "beginning" smoker market where *"the cigarette would be low in irritation and possibly contain an added flavor to make it easier for those who have never smoked before to acquire the taste for it more quickly....This cigarette could possibly be menthol (RJ Reynolds Bates No: 501186367-6369; ...teenagers like sweet products. Honey might be considered...Apples connote goodness and freshness and we see many possibilities for our youth oriented cigarette with this flavor (B&W Bates No: 170042014).* Needless to say the cigarette companies have a long history of going after the youth market as *"replacement smokers"* for adults who either quit or die each year (see: Marketing to America's youth: evidence from corporate documents. Tobacco Control, 2002; 11[Supple 1]:i5-i17).

Thus, we applaud your effort to focus attention on the continuing marketing of menthol flavored cigarettes as well as flavors used in the marketing of cigars, many of which are also manufactured by cigarette companies. On the other hand, flavor additives in non-combustible nicotine alternative products such as e-cigarettes may actually be a good thing since it appears that the flavors encourage smokers to use these products as alternatives to smoking. We have no argument with FDA prohibiting obviously kid

friendly flavors (e.g., bubble gum, cotton candy, etc.) and those that are known or suspected to be toxic, however, we feel flavors help make lower risk noncombustible products attractive alternatives to combustible tobacco.

NTRI's overarching goal is to promote policies, programs and products that will effectively accelerate a more rapid reduction in the harms caused by tobacco use which as we all know stem primarily from the use of deadly and addictive cigarettes and cigars. We support efforts to discourage nonsmokers, especially youth from initiating any tobacco use, but recognize the need to have regulatory policies that balance the need to protect nonsmokers and youth while also supporting opportunities for addicted smokers to have access to less harmful nicotine delivery products.

We were disheartened to see the reaction of some public health groups which appeared to us to be pressuring FDA to take more aggressive actions to restrict the use of flavors in e-cigarettes under the guise of the need to protect youth. First, we do not feel that the evidence warrants such an approach at this time and appreciated FDA more measured and thoughtful plan to encourage stronger age verification for the sale of tobacco product to minors and policies that incentivized product manufacturers to limit their marketing and product sales to adult only venues (e.g., vape shops). Vape shops are the primary source used by adult smokers for purchasing vaping products and supplies and should be supported since most do not sell cigarettes and thus have an economic incentive to assist cigarette smokers to transition away from smoking to noncombustible nicotine delivery products.

Second, we do not think it is realistic nor good public policy to favor one group, in this case youth, over others, such as adult smokers. Some public health officials have said that any youth use of e-cigarettes is unacceptable, no matters what. While we agree that youth should not use e-cigarettes, however, we don't think a zero tolerance policy is realistic and certainly should not be the sole basis for policy decisions. Unfortunately, youth are attracted to take up many adult behaviors, which we all wish they would not do. However, it should not be surprising to anyone that youth will be the first to take up new product innovations. This was true with cell phones and social media, and historically even with tobacco products with the introduction of the modern American blend cigarette and later filters, and flavored cigarettes. Of course, the cigarette innovations proved to be disasters for public health. However, the fact that vaping has attracted a younger audience should come as no surprise to FDA or anyone who thinks about how consumer products actually gain favor in a marketplace. In fact, the growth of e-cigarettes among younger adults may help to partially explain the more rapid reduction in cigarette use seen in those 18-40 years of age. There is even evidence among adolescents showing that the growing popularity of vaping may be displacing combustible cigarettes. If true, that could be a positive thing, although admittedly we do not know the long term consequences of nicotine vaping, although the consequences of cigarettes are well known and is clearly something we wish to avoid.

A recent paper by Levy et al. (see: Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check, *Tobacco Control*, 2018, Epub ahead of print: doi:10.1136/tobaccocontrol-2018-054446) observed an inverse relationship between vaping and smoking across several different national data sets for both youth and young adults, suggesting that the growing popularity of e-cigarettes by young people may in fact be displacing cigarettes, rather than automatically leading youth into smoking as some have claimed. It is probably too early to know what the trends are telling us for sure, and the recent marked uptick in vaping driven by the popularity of pod-based vaping products such as Juul among adolescents is certainly a trend worth worrying about, tracking closely, and intervening upon if needed. However, the Family Smoking Prevention and Tobacco Control Act mandates that FDA use its regulatory authority to benefit population health broadly, not just to address the needs of specific subgroup (i.e., youth or adult smokers).

Again, NTRI appreciates the leadership you have shown on this important public health issue and supports the deliberate and measured actions that FDA has announced to try to curb both access and the appeal of tobacco products to adolescents never smokers, while also preserving access to less harmful nicotine vaping products for addicted smokers.

Sincerely,



K. Michael Cummings, MPH, PhD, on behalf of the undersigned members of the National Tobacco Reform Leadership Team

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cc: Mitch Zeller, Director, Center for Tobacco Products