NATIONAL TOBACCO REFORM INITIATIVE

Ending Cigarette Use by Adults in a Decade is Possible

October 25, 2022

Independent Panel, FDA Center for Tobacco Products (CTP)

Good morning, my name is Mike Cummings, I'm a Professor and Division Director of Tobacco Policy Research in the Department of Psychiatry and Behavioral Sciences at the Medical University of South Carolina. Today, I'm speaking on behalf of the National Tobacco Reform Initiative an informal completely independent and voluntary organization that was created about 8 years ago to try and push FDA and other public health organizations to focus more attention on helping adult smokers get off cigarettes. My comments this morning will focus broadly on compliance and enforcement challenges and related tobacco regulatory issues.

FDA has authority to monitor and enforce federal laws and regulations that apply to tobacco retailers, manufacturers, importers, and distributors. Most of what FDA has done in the area of compliance and enforcement applies to the illegal sale of tobacco products to minors. This work has involved funding states to do compliance checks of retailers and issuing warning letters, and in some cases issuing fines for violations of federal law prohibiting the sale of tobacco products to minors. While continued effort to monitor and enforce laws governing the sales of tobacco products to minors has value, its contribution to improving overall population health is limited relative to other things FDA can be doing.

Less transparent but perhaps more challenging and important for the protection of public health has been Center for Tobacco Products (CTPs) effort to enforce federal rules that are intended to prevent the illicit marketing and distribution of tobacco products. Just last week FDA took enforcement action against 6 manufacturers who blatantly ignored the requirement to submit premarket

applications for their e-cigarette products. Such actions are justified by FDA, but the fact that companies feel empowered to market tobacco products outside the regulatory structure of the Tobacco Control Act suggests a more systemic problem exists. Former CTP Director Mitch Zeller often described his frustration with what he termed *whack-a-mole* enforcement where product manufacturers operating outside the rules would be issued ceased and desist orders by CTP only to discover that the product in question would reappear on a new website under a different company name.

While many will argue we need more enforcement resources to rein in rouge companies operating outside federal rules, one might ask why some companies feel emboldened to break the rules and market products without FDA authorization in the first place. The unfortunate reality is that the current regulatory structure governing tobacco products makes it easier to get marketing authorization for a new cigarette product than for a lower risk noncombustible alternative product.

I have four suggestions to improve compliance and enforcement with tobacco product regulations governing the marketing of tobacco products all of which are intended to incentivize companies to work within the legal framework of tobacco product regulations.

1) The first thing CTP needs to do is streamline the review and approval of new products using a product standards approach, whereby different product categories are identified based on risks and relative risks. **(slide 1)** A guiding principle should be that less harmful products have a competitive advantage. One simple approach would be to bucket products based on characteristics that contribute to toxicity and addictiveness. To some extent FDA has already done this by granting of marketing authorizations for new products including a very low nicotine combusted cigarette product, a heated tobacco product, and various types of e-cigarettes. By virtue of these approvals FDA has already signaled that these product categories are appropriate for the protection of public health, meaning that the anticipated public health benefits outweigh the costs based on the evidence available. Regular evidence reviews including the use of post-marketing surveillance data would allow FDA to continually update product standards as new information emerges.

2) Second, companies should be able to build upon prior product authorization which would reduce the current barriers, costs, and uncertainty which now serves to discourage companies and investors from seeking FDA marketing authorization for new potentially lower risk products. The focus of product reviews could be made to be similar to substantial equivalence process applied to cigarettes where product modifications are evaluated in relationship to an existing predicate product already on the market.
3) **(Slide 2)** Third, because clear and truthful communications about product risks and benefits are essential to consumer understanding of product risks, CTP should develop standardized product communications for different product categories based on risks and relative risks. Companies would be able to utilize these standardized risk messages once products are authorized for sale. This would incentivize companies to seek marketing authorizations from FDA for lower risk tobacco products since they would gain a marketing advantage once their product was authorized for sale.
4) Fourth, there has to be trust that the regulatory process adopted by CTP is evidence based, fair, and free of political interference. Building trust in the process requires a more transparent process than has occurred to date. Multiple stakeholders need to be more actively involved in the process **(slide 3)** than has been the case in the past. This can be accomplished through workshops, conferences, and advisory groups involving both public and private sector entities.

Finally, I would point out to members of the expert committee that the National Tobacco Reform Initiative filed a citizens petition with CTP in March 2020 discussing ways that the agency could accomplish its 2017 vision where cigarettes would not create and sustain addiction and where adults who need or want nicotine could get it from less harmful alternative sources. We share that vision and urge the panel to refer to our petition which provides some specific ways that vision can be achieved. Thank you for your time an attention.

Sincerely,

On behalf of the other members of the leadership committee of the National Tobacco Reform Initiative

Slide #1

Guiding Principles

Less harmful products should have a competitive advantage.

vs.

Slide #2

Guiding Principles

Clear and truthful communication about tobacco products risks and relative risks should be shared with public

Slide # 3

Guiding Principles

Multiple stakeholders need to be involved in finding solutions that will work

Government

Health care providers

Product users

Industry

Public health groups