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IOWA DEPARTMENT OF JUSTICE
OFFICE OF THE ATTORNEY GENERAL

June 14, 2017

Dr. Scott Gottlieb, MD
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20857

Re: Reform of tobacco and nicotine regulation at FDA

Dear Dr. Gottlieb:

May we offer our sincere congratulations on your confirmation.

As specialists in the field of tobacco and nicotine science and policy, we were pleased to see your commitment to tobacco control reflected in your opening remarks to FDA staff: "*there's probably no single intervention, or product we're likely to create in the near future that can have as profound an impact on reducing illness and death from disease as our ability to increase the rate of decline in smoking."* We fully agree.

We also warmly welcome your openness to the concept of tobacco harm reduction: "*we need to have the science base to explore the potential to move current smokers – unable or unwilling to quit – to less harmful products, if they can't quit altogether.*"

There is already a considerable body of science and experience suggesting that a harm reduction approach, working together with the established evidence-based prevention and cessation tools of tobacco control, could yield substantial and highly cost-effective public health benefits. However, this will only be achieved if the right regulatory framework for less harmful products is adopted. We support FDA jurisdiction for these products, but at this time we do not believe that the current regulatory framework for the low-risk nicotine products such as e-cigarettes and smokeless tobacco is appropriate or will deliver the substantial public health benefits we hope and expect FDA's oversight will bring.

We hope that you and your colleagues will use the recently-announced three-month pause in enforcement deadlines to reconsider and improve the regulatory framework introduced in 2016 via the deeming rule and through the interpretation of the 2009 Tobacco Control Act. To that end, we would like to outline a potential change of approach and to draw your attention to two more detailed submissions.

Adopt sound regulatory principles

We believe that FDA's approach should be based on sound, principled foundations:

- **Regulation should be proportionate.** The burdens should be related to the relative risk of the products and regulation should not favor more harmful products over less harmful. The current regime for low-risk products is burdensome and opaque, and far more onerous than for cigarettes. The FDA's own estimates show application costs of between $286,000 and $2.6 million for electronic nicotine delivery devices and between $182,000 and $2.0 million for e-liquids. In addition, the criteria by which products will be assessed and approved as beneficial for public health are extremely broad and open to interpretation, so companies cannot judge if their applications will be successful before they spend the money. However, the more risky cigarette products have been 'grandfathered' and thousands of cigarette brands are on widespread sale without ever having faced an approval process.
- **Recognize potential benefits as well as risks and be wary of unintended consequences**. It is clear beyond reasonable doubt that vapor products present lower risks to nicotine users than smoking. FDA has rightly acknowledged a 'continuum of risk' in tobacco and nicotine products. It follows that regulators should recognize the potential unintended consequences of making uptake of lower-risk products more difficult or less attractive to smokers. Though we cannot be certain until the process is complete, we are concerned that the impact of the deeming rule will eliminate almost all of the vapor products that form the market. That may drive vapers back to smoking or reduce the rate of switching from smoking to vaping. Because the health and welfare costs of smoking are so high and the risks from vaping very much lower, this negative effect only needs to be small to exceed any conceivable benefits the deeming rule may bring.
- **Promote innovation.** Regulation should encourage pro-health innovation in low-risk alternatives to smoking. The current framework puts a hard brake on innovation by requiring a burdensome approval process for any changes, including safety and usability improvements.
- **Support informed choice through truthful communication of risk**. Risk communication should be truthful, plain-speaking, and focused on helping consumers make informed choices. The barriers to truthful communication are too high and leave consumers without important information that could be highly beneficial to their health.
- **Protection of young people**. Regulators should act to protect young people from use of any tobacco or nicotine product, while being mindful of positive and negative public health impacts arising from changes in cessation, uptake or use of other tobacco products that may arise as consequence of regulatory intervention.

Take action to avoid unnecessary damage to the market for innovative and disruptive technology

The costs and burdens of FDA's approach threaten to heavily contract and constrain the emerging market in vaping and other low-risk technologies, and some action is required in the short term to stabilize the market. Administrative options to do this include delaying enforcement dates for the Pre-

Market Tobacco Product (PMTA) authorization requirement for non-combustible products for at least an additional four years beyond the current dates. All the other protective measures that apply through the deeming rule, such as age restrictions, vending machine bans, and ingredients disclosures would remain. This will allow time to introduce a new standards-based regime, which addresses the problem more fundamentally (see below).

Move to a standards-based regime

The emergency interventions above, while necessary, do not provide an adequate long-term regulatory framework. This framework should be based on clear and transparent standards made through an open and consultative process. If vendors know what they are required to do, then the supply chain can adjust to be compliant. Consumers will know what they are buying. FDA can use its scientific resources efficiently. Standards can address, for example: chemical, electrical, battery, thermal and mechanical risks and related testing methods for devices, liquids and other consumables; manufacturing standards and quality control; and labelling and consumer information.

Useful standards have already been developed in the United States and are under development in other jurisdictions (e.g. France, UK). The approach taken in the European Union is to use standards and a notification regime for e-cigarettes.

Communicate useful information about risk to help consumers make informed choices

To improve communication of risk, federal entities such as FDA, CDC and the Surgeon General should embrace an objective to bring public perception closer to reality. FDA could, for example, approve standardized evidence-based and non-misleading statements that vendors of low-risk products could use in packaging and advertising, and exempt these from enforcement under the misbranding provisions of the Tobacco Control Act.

More detailed material

In addition to the general points made above, we invite you to consider two further documents.

1. *Liberating Nicotine from Smoke to Save Lives Now: Facing and Answering 7 Core Questions to Guide Regulation, Policy, and Communications*. The Director of the Center for Tobacco Products, Mitch Zeller, proposed seven questions about the place of nicotine in society. Several experts have responded to his challenge by writing the attached paper.
2. *Rethinking tobacco and nicotine policy*. This builds on the paper above and provides a more detailed discussion of the case for reforming FDA's approach to regulating tobacco and nicotine products, recognizing the constraints and flexibilities of the Tobacco Control Act.

Many issues have been raised about the FDA's regulatory approach to tobacco and nicotine in lawsuits and more generally. We hope that you find this letter and attachments to be a useful contribution to your consideration of these issues and how FDA might respond.

We would welcome your views on these points and the opportunity to meet you to discuss them.

Yours sincerely,

David B. Abrams, Ph.D.*

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* Drs. Abrams' and Niaura's signatures are solely in their personal capacity.