

NTRI Nat'l Tobacco Reform Initiative

Reducing Adult Smoking Rates to 5% by 2030

October 24, 2018

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

c.c. Mitch Zeller, Director, Center for Tobacco Products

Subject: National Dialogue on adolescent use of tobacco and nicotine products, and giving priority to providing adult smokers with lower risk tobacco and nicotine products

Dear Commissioner Gottlieb --

We are writing on behalf of the National Tobacco Reform Initiative (NTRI) which was established by a small group of experienced, seasoned, public health/ tobacco control leaders with the goal of making adult smoking of combustible cigarette products obsolete in the next decade. As you know from our letter to you in late July of 2018 (see <http://www.tobaccoreform.org>), our priorities mirror much of the FDA's vision that you and Director Zeller laid out in July 2017, and are now in the process of implementing. One of the overarching goals of the NTRI (like yours) is to look for opportunities to encourage dialogue and engagement between stakeholders and to serve as a 'catalyst' for change. This includes, but is not limited to public health organizations, the research community, health care professionals, governmental agencies, policy makers, tobacco and nicotine manufacturers, consumers, the general public, and the media.

Over the last few months, the FDA/CTP has raised concerns about the rising use of e-cigarettes by adolescents, something that all stakeholders should be concerned about. You have issued numerous enforcement letters and put many in industry on notice about the consequences for failing to comply with FDA laws. You have indicated that there will be more actions coming out of the FDA in the coming months. To fully address the situation will require the involvement and support of not only FDA, but other stakeholders as well. **We therefore wish to recommend that the FDA/CTP sponsor a national dialogue related to youth use of tobacco and nicotine products as well as the need to provide the 30 million adult smokers in this country with lower risk alternative tobacco and nicotine products, to be held sometime in early 2019.**

We propose the following title for such a Summit -- **National Dialogue on Advancing the FDA Vision to Reduce Adolescent Use of Tobacco and Nicotine Products and Providing Adult Smokers with Lower Risk Alternatives**

This summit would allow stakeholders to be engaged in such a way that a more unified and coordinated effort could be developed to address both challenges and opportunities, and it would obviously include much of what the FDA is currently **committed** to doing in these areas. But it would encompass much more.

In addition to the adolescent related issues, it would also be a way to give serious attention to the other important priority that you have laid out, and that is providing the 30 million current adult smokers in the U.S. with consumer acceptable lower-risk products, that include but is not limited to e-cigarettes. We cannot forget that there are 480,000 American deaths each year caused by cigarette smoking.

In our letter to you this past July, we raised concerns that this second priority is seemingly taking a back seat as the agency shifted resources to dealing with the e-cigarette and adolescent issue. We believe that the issue of youth use of e-cigarettes as well as addressing the needs of the 30 million smokers can and should go forward in tandem.

The spectrum of stakeholders that might attend this dialogue, in addition to the FDA and other governmental agencies, might include:

- Tobacco Control and Public Health Organizations (including organizations and individuals providing differing view and perspectives)
- Researchers and other academics
- Tobacco and nicotine manufacturers (and trade associations)
- Health care professionals
- Parent/ Teacher associations
- Wholesaler and retailer distributors and their trade associations
- Organizations representing *consumer* interests
- Vaping stores
- Federal, State and local policy makers and health officials
- Attorney's General
- Law enforcement
- Grocer manufacturers, pharmacies, convenience stores, etc. and their trade associations
- Media

This dialogue should be open and transparent and made available to others to view via a webcast. It would serve as an educational forum and a way to build relationships between stakeholders that would continue into the future. Your efforts need the support and involvement of other stakeholders. We need your continued visionary leadership. We offer our support in any way we can to help make the agency's vision become a reality.

Sincerely,

Allan C. Erickson, Coordinator

National Tobacco Reform Network

Following is a listing of the current members of the NTRI Leadership Team and their email addresses; also listed are the Advisory Group members:

Leadership Team

David Abrams, Ph.D. – Professor, Department of Social and Behavioral Sciences, College of Global Public Health, New York University (David.B.Abrams@nyu.edu);

Scott Ballin, JD – Health Policy Consultant, Former Vice President and Legislative Counsel to the American Health Association (ScDBa@aol.com);

Aaron Biebert – Former President and CEO, Clear Medical Solutions; Director, Attention Era Media Film Production Company – produced “A Billion Lives” documentary seen by millions worldwide (aaron@attentionera.com);

K. Michael Cummings, Ph.D. – Professor, Department of Psychiatry and Behavioral Sciences, Medical University of South Carolina; Co-leader, Tobacco Research Program, Hollings Cancer Center (cummingk@musc.edu);

Allan C. Erickson – Former Vice President for Public Education and Tobacco Control, American Cancer Society; staff director, Latin American Coordinating Committee for Tobacco Control; Provided ACS staff leadership for tobacco control at the local, district, state, regional, continent and global levels, the latter with the International Union Against Cancer in Geneva (Phone number – 404-531-4109);

Ray Niaura, Ph.D. – Professor, School of Public Health Global Studies, New York University (Niaura@nyu.edu);

John R. Seffrin, Ph.D. – Professor of Practice, School of Public Health, Indiana University at Bloomington (JohnSeffrin@gmail.com);

Daniel Wikler, Ph.D. – Mary B Saltonstall Professor of Ethics and Population Health, Department of Global Health and Populations, Harvard T.H. Chan School of Public Health (wikler@hsph.harvard.edu).

Advisory Group

Clive Bates, M.A., Sc. – Director, Counterfactual Consulting, London, U.K. and Harare, Zimbabwe;

Lawrence (Larry) Green, Ph.D. – Professor Emeritus, Former Professor, Department of Epidemiology and Biostatistics, School of Medicine, University of California at San Francisco;

Michael McGinnis, M.D. – Senior Scholar and Executive Director, National Academy of Medicine (NAM);

Thomas Miller – Iowa’s Attorney General;

Michael Terry – Former Corporate Executive; Son of Luther G. Terry, M.D., former U.S. Surgeon General.