

National Tobacco Reform Initiative

“Ending Cigarette Use by Adults in a Generation is Possible”

July 7, 2017

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

SUBJECT: “Modernizing’ Tobacco and Nicotine Policies and Regulations

Dear Commissioner Gottlieb:

We would first like to congratulate you on your appointment as FDA Commissioner, and to wish you all of the best in your efforts in furthering the important mission of the Food and Drug Administration.

As you know, cigarette smoking remains this nation’s leading preventable cause of disease and death, accounting for approximately 480,000 deaths each year. It is costing our society approximately \$300 billion in health care costs and lost productivity. While much progress has been made in our collective efforts, much more clearly needs to be done. As you so succinctly put it in your comments before Congress and to the FDA staff upon assuming your new position,

“In areas where there is an inherent, obvious and seemingly unavoidable risk to consumer products, whether it is combustible tobacco or dangerously addictive opioid drugs, we have an opportunity to help consumers move to less risky alternatives”, and;

“We need to redouble efforts to help smokers become tobacco-free. And, we need to have the science base to explore the potential to move current smokers -- unable to quit – to less harmful products, if they can’t quit altogether. At all times, we must protect kids from the dangers of tobacco use.”

We are writing as individuals who have spent decades working on tobacco and public health issues inside and outside of government, and who have come together to form the ***National Tobacco Reform Initiative***. We believe that with some new thinking and new initiatives, we can end cigarette use by adults in a generation. Doing that has led us to focus on three (3) priority actions that are consistent with your call for ‘redoubling our efforts’. These priority actions can be found in a recent Report that we issued entitled, ***Ending Cigarette Use by Adults in a Generation is Possible*** (March 2017). We are enclosing a copy of the Report which can also be accessed at: www.tobaccoreform.org.

Of particular importance to the FDA is priority number #3, which calls for: **The establishment of a more rational tobacco, nicotine and alternative products regulatory framework based on their relative risks, and that is adaptable to the increased speed of innovation in new technology development.**

To address the challenge ahead, we need action on a short, medium and longer time scale.

In the short term, some decisive action is required to put the approaching authorization requirements for vapor technologies on hold, because it is threatening the demise of an entire class of potentially viable alternative nicotine products. While a few large companies may be able to meet the proposed deeming requirements, we would like to see more competition in the marketplace, in general, as this favors consumers.

In the medium term, we need to work within the existing Tobacco Control Act to engineer a rational and proportionate regulatory framework for these products. We support the proposals sent in the letter to you from Attorney General Miller's office on 14 June (enclosed).

Longer term, we need to consider reform of the TCA, either by amendment or reinterpretation, of its core provisions. It has been eight years since the Tobacco Control Act was signed into law. Much has changed in that period and we can expect more changes to take place. Increased research, technology and innovation, new product development, competition, and even consumer demands are all playing an important role. It is clear to us and many others that the time has come for a review of the TCA and for it to be brought up to date. This is work that can and should start now, and we would be happy to contribute to such an effort.

Over the past several years, CTP Director, Mitch Zeller, has spoken of the need for the kinds of reforms we are advocating. He has called for the establishment of a more rational tobacco and nicotine policy that is based on the 'continuum of risk'. Yet, the agency has been slow to incorporate this important approach into its regulatory decision-making. We believe that this is, in part, because the regulatory framework being used is outdated.

We encourage the FDA to take a leadership role in helping begin a discussion and dialogue about 'what is working and what is not' with respect to the TCA, and how it can be 'modernized' to better serve the public health interests of our society. This discussion should not only take place at the FDA, but also in other public and private sector venues as well. Last year, for example, the Food and Drug Law Institute focused its tobacco conference on 'tobacco and nicotine policies at a regulatory and legislative crossroads'. This year's conference, to be held in October in Washington, will continue those discussions. Earlier this year, the first U.S. E-Cigarette Summit was held in Washington, and another one is planned for next year.

We stand ready to do our part and look forward to continuing to work with you, Director Zeller and others in any way we can. If you can find time in your schedule, we would welcome a meeting to discuss our concerns and a constructive partnership with you as you take on this challenging role.

Please contact us through Scott Ballin who advises our team on issues relevant to FDA regulation of tobacco products. Scott's phone number is 202 258-2419; his e-mail address is ScDBa@aol.com.

With the best of wishes,

Allan C. Erickson
Former Vice President for Public Education and Tobacco Control, American Cancer Society,
on behalf of the NTRI team members listed below

Scott Ballin – Former Vice President for Public Policy and Legislative Counsel, American Heart Association;
Advisor to the 'Morven Dialogues', University of Virginia;
John R. Seffrin, Ph.D. – Professor of Practice, School of Public Health, Indiana University at Bloomington;
Thomas Miller – Attorney General, State of Iowa;
K. Michael Cummings, Ph.D. – Professor, Medical University of South Carolina;
Michael Terry – Corporate CEO and Son of Former U.S. Surgeon Luther Terry, M.D.
Tom Glynn, Ph.D. – Consultant Professor, Stanford University;
Derek Yach -Chief Health Officer, the Vitality Group; and,
Donald Shopland – Former Director, Office on Smoking and Health, US Public Health Service

Enclosure: [Executive Summary Report](#)
[Letter to Dr Gottlieb from AG Miller and others, 14 June 2017](#)