NATIONAL TOBACCO REFORM INITIATIVE

Ending Cigarette Use by Adults in a Decade is Possible

April 15, 2025

Martin A. Makary, MD, MPH
Commissioner United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-000

CC: Robert F. Kennedy Jr.
Secretary of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Reducing the burden of chronic disease in America

Dear Commissioner Makary,

The National Tobacco Reform Initiative (hereafter referred to as the NTRI) is an informal organization led by a small group of tobacco control leaders with decades of service fighting the tobacco epidemic. NTRI is a voluntary organization and receives no financial assistance from any organization or outside entities. We advocate for civil engagement with all interested stakeholders and for open evidence based discussions about the most effective ways to accelerate a reduction in the number of adult smokers and associated diseases and premature deaths caused by smoking. One of NTRI's objectives has been to establish a more rational and flexible tobacco and nicotine products regulatory framework based on products' relative risks, that is adaptable to the increased speed of innovation in products that have the potential to displace deadly and addictive combustible tobacco products.

We are writing because we want the current administration to take advantage of the historic opportunity that exists through the FDA's Center for Tobacco Products (CTP) to accelerate a reduction in cigarette smoking. We support the administration's renewed focus on reducing the toll of chronic disease in America and we commend you for making this goal a high priority. We lament the fact that it has been 25 years since the Institute of Medicine (now the National Academy of Medicine) issued its landmark report 'Clearing the Smoke—Assessing the Science Base for Tobacco Harm Reduction'. Prior administrations have failed to fully act on the recommendations of this report which discussed how best to regulate the growing tobacco and nicotine marketplace to reduce the burden of chronic disease in Americans. Regulation, science and technology, innovation, changes in consumer preferences, new entrants into the marketplace and competition are all playing a role in reshaping a rapidly changing tobacco product landscape. There was some hope by many in July of 2017 when FDA Commissioner Gottlieb announced and outlined a visionary comprehensive plan. Unfortunately, the substance of that vision was not fully and openly discussed, let alone implemented. Thus, in spite of some progress over

the last 25 years there are still over 28 million adult cigarette smokers in the country. It is estimated that smoking costs the United States approximately $600 billion dollars each year in health care costs and lost productivity. Simply put, smoking remains the country's leading cause of preventable disease and death.

There have been some concerns raised by many in the public health community about the impact that staffing cuts at the Center for Tobacco Products may have on the ability of the Center to carry out its important public health mission. The health, safety and well-being of millions of Americans depends on an FDA that they have confidence in and can trust. This means having the most qualified, professional, competent and dedicated staff available. While recognizing that staffing cuts are inevitable we suggest that it needs to be done with a careful assessment and review in order to ensure that the best people are retained and hired to carry out the goals and objectives of the agency's mission. During your Senate confirmation hearing the issue of staffing cuts was raised. You indicated that you would a take a careful look at the issue and would take a 'surgical approach' when deciding where cuts would need to be made. We support that approach. It is also important to take into consideration that the operations of the CTP are not funded by taxpayer monies but via a 'user fee' paid by the tobacco industry.

As you will have noted throughout this letter, we fully accept that the CTP desperately needs reforms in how it regulates tobacco and nicotine products, including novel nicotine products. It needs to be able to adapt to a rapidly changing tobacco and nicotine environment quickly and efficiently and that means having the most qualified staff to do the work. Now the question is what comes next? CTP cannot be allowed to sink into paralysis since the stakes are so high. Far too many Americans struggle to get off cigarettes and we simply cannot accept losing nearly half a million Americans every year to premature death caused by smoking. CTP's core mission is as relevant today as ever. We think there are enormous opportunities under your leadership to finally end the epidemic of smoking related diseases that have plagued Americans for more than a century. Here are a few suggestions of things that could be done.

1. Hire a new Director of CTP who has a clear vision of how he or she will quickly streamline the PMTA and MRTP processes so that all applicants get an answer within 180 days.
2. FDA-CTP should prioritize adjudicating PMTA applications for products that were submitted and accepted for review years ago, and for which no evidence of serious ongoing concerns have been raised.
3. Within a year, the new director should announce new and clear requirements for PMTA applications, that will facilitate evaluation by FDA staff within the 180 day window.
4. As recommended by the Reagan-Udall committee, FDA-CTP and all tobacco control policies should clearly and firmly recognize the continuum of risk among nicotine products, and the urgent need to shift the US population away from the most dangerous (smoked) products towards far less harmful products and abstinence.
5. In tandem with the development of a regulatory framework that prioritizes authorization of significantly reduced risk products, ensure that FDA-CTP (with DoJ and other federal and local partners) implements a much more robust enforcement policy.
6. The enforcement policy should prioritize stopping the sale in the United States of unauthorized, illegal products that are largely imported illegally from other countries (primarily China). This will require multi-agency coordination and should work hand-in-hand with efforts to ensure the safety of our pharmaceutical supply and to collect tariffs on imported goods.
7. Once these steps are under way, FDA-CTP should move quickly to implement the Low Nicotine Standard for combustible tobacco, which was first proposed under the first Trump administration, and is currently awaiting comments from interested parties. Implementation of this product standard will transform the nicotine market in USA and result in enormous public health benefits. Successful implementation will require availability of alternative legal, low-risk nicotine products, and control of illegal importation of unauthorized products.

There are also some important areas of tobacco control that have been operating outside of CTP that we think need to be retained somewhere in government and coordinated with the CTPs mission. The Office of Smoking and Health (OSH) has existed as a government entity dating back to the mid-1960s when the National Clearinghouse on Smoking and Health was established to provide annual updates on the harms of tobacco use. These reports became known as Surgeon General's reports on smoking and health. There remains a need, perhaps even greater today given the rapidly evolving marketplace of tobacco and nicotine products, to produce comprehensive reviews of the scientific evidence of how tobacco products exist on a continuum of risk. OSH has also supported a world class tobacco and nicotine product testing laboratory at CDC which needs to be maintained in order to allow science-based regulation of tobacco products. Continuation of these functions are needed to understand the health risks of different tobacco and nicotine products being consumed by Americans. Finally, and perhaps most critically, OSH has been the primary sponsor of the national TIPS for smokers media campaign reaching millions of Americans with a message to stop smoking and providing information on how people who struggle to stop smoking can get help. During 2012–2018, the Tips From Former Smokers campaign was associated with an estimated $7.3 billion in healthcare sector cost savings and 129,100 premature deaths avoided.

In summary, there is an urgency to 'modernize' the CTP that will allow the Center to implement cost effective programs and strategies that we believe are consistent with your goals of reducing chronic disease in the country. We also wish to bring to your attention the NTRI's filing of a Citizens Petition with the FDA in March 2020 asking the agency to undertake initiatives to modernize and streamline the CTP's efforts (https://www.tobaccoreform.org/).

THEREFORE, we the undersigned who have dedicated their careers to reducing disease and death from tobacco products respectfully hope that you will follow the principles that you mentioned in your Senate confirmation hearing. In your written remarks you concluded by saying, " If I am confirmed I hope to ensure that the FDA holds to the gold standard of trusted science, transparency and common sense to rebuild public trust and Make America Healthy Again.' The NTRI and those who have added their names to this letter want to be seen as a supportive part of the solution and not be seen as part of the problem. We look forward to learning of your plans to address these opportunities and stand ready to offer our support and input on how best to accomplish our shared goal of reducing the burden of chronic diseases in America.

If you have any questions about this request, please direct them to:

Scott D. Ballin, J.D
Former VP and Legislative Counsel, American Heart Association; Advisor to the University of Virginia 'Morven Dialogues' on tobacco harm reduction
540 939-4624 (office)
202 258-2419 (mobile)
E-mail: scdba@aol.com

K. Michael Cummings, PhD, MPH
Professor, Department of Psychiatry & Behavioral Sciences
Medical University of South Carolina
843-876-2429 (office)
716-868-8579 (mobile)
E-mail: cummingk@musc.edu

Additional supporters of this request

Jasjit S Ahluwalia, MD, MPH, MS Professor, Behavioral and Social Sciences and Professor, Medicine Center for Alcohol and Addiction Studies Brown University School of Public Health and Alpert School of Medicine	Neal L. Benowitz MD Professor of Medicine Emeritus University of California San Francisco Zuckerberg San Francisco General Hospital
Richard J. Bonnie, LL.B Harrison Foundation Professor of Medicine and Law and Professor of Psychiatry and Neurobehavioral Sciences Director, Institute of Law, Psychiatry and Public Policy and Professor of Public Policy, Frank Batten School of Leadership and Public Policy University of Virginia	Matthew Carpenter, PhD Associate Director of Cancer Prevention and Control Hollings Cancer Center Medical University of South Carolina
Eric C. Donny, Ph.D. Expert in addiction to nicotine and strategies to reduce the harm cause by tobacco through regulation	Clifford E. Douglas, J.D. President and Chief Executive Officer Global Action to End Smoking
Michael P. Eriksen, Sc.D. Former Director, OSH Editor-in-Chief, Health Education Research	Jonathan Foulds PhD Professor of Public Health Sciences & Psychiatry Penn State College of Medicine
Thomas J. Glynn, MA, MS, PhD Adjunct Lecturer Prevention Research Center School of Medicine Stanford University National Cancer Institute (Retired) American Cancer Society (Retired)	Jamie Hartmann-Boyce, MA, DPhil (she/her) Assistant Professor of Health Policy and Management Department of Health Policy and Promotion University of Massachusetts Amherst
Cheryl Healton Professor, Public Health Policy and Management New York University	Stephen S. Hecht, Ph.D Wallin Professor of Cancer Prevention University of Minnesota.
Scott J. Leischow, PhD Research Professor Arizona State University	Robin Mermelstein, Ph.D. Distinguished Professor, Psychology Department University of Illinois at Chicago
Ray Niaura, PhD Professor School of Public Health Global Studies New York University	Michael F. Pesko J. Rhoads Foster Professor Department of Economics University of Missouri
Vaughan W. Rees, PhD Senior Lecturer on Social and Behavioral Sciences Director, Center for Global Tobacco Control Department of Social and Behavioral Sciences Harvard T.H. Chan School of Public Health	Nancy Rigotti, MD Professor of Medicine, Harvard Medical School. Director, Tobacco Research and Treatment Center, Massachusetts General Hospital
Jed E. Rose, Ph.D. President and CEO Rose Research Center Raleigh, NC	Steven A. Schroeder, MD Professor Emeritus, Department of Medicine University of California, San Francisco

John R Seffrin PhD Former chief executive officer of the American cancer society, Retired	Peter G. Shields, M.D., EMT-P Emeritus Professor Medical Oncology, Cancer Prevention Department of Internal Medicine Member, Ohio State University Comprehensive Cancer Center The Ohio State University
Donald R. Shopland, Sr. Ringgold, GA US Public Health Service (Retired)	Tracy Smith, PhD Associate Professor Addiction Sciences Division, Department of Psychiatry and Behavioral Sciences Co-Leader, Cancer Prevention and Control Hollings Cancer Center Medical University of South Carolina
Theodore L. Wagener, PhD Leonard J. Immke, Jr. and Charlotte L. Immke Chair in Cancer Research, Professor of Internal Medicine, Wexner Medical Center The Ohio State University Comprehensive Cancer Center	Kenneth E. Warner, PhD Avedis Donabedian Distinguished University Professor Emeritus Dean Emeritus University of Michigan School of Public Health
Jeffrey Willett, Ph.D. Vice President, Strategic Engagement Global Action to End Smoking Former National Vice President, Integrated Strategies with American Heart Association	Derek Yach Global Health Strategies Independent global health consultant Connecticut, USA