NATIONAL TOBACCO REFORM INITIATIVE

Ending Cigarette Use by Adults in a Decade is Possible

October 19, 2021

Mitch Zeller, JD
Director, Center for Tobacco Products
U.S.S. Food and Drug Administration
Building WO75, Room # 6418
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: FDA/CTP should request that the NASEM conduct a follow -up review of the landmark **Clearing the Smoke -Assessing the Science Base for Tobacco Harm Reduction**

Dear Director Zeller,

The National Tobacco Reform Initiative (hereafter referred to as the NTRI) is an informal organization led by a small group of distinguished, seasoned and independent 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 evidenced based discussions about the most effective ways to accelerate a reduction in the current number of adult smokers and associated diseases and premature deaths caused by smoking. One of NTRI's major priority areas is to establish a more rational tobacco and nicotine products regulatory framework based on their relative risks and that is adaptable to the increased speed of innovation in new technology of products that have the potential to displace deadly and addictive combustible tobacco products.

It has been over 20 years since the Institute of Medicine (now the National Academy of Medicine which issues reports as part of the National Academy of Science, Engineering and Medicine - NASEM) issued the 600-page landmark report **'Clearing the Smoke—Assessing the Science Base for Tobacco Harm Reduction'**. The report had been done at the request of the Food and Drug Administration as it considered how best to regulate the growing tobacco and nicotine marketplace - including what at the time were being referred to as PREPS (Potential Reduced Exposure Products). If we recall correctly, you had the foresight, even before FDA gained regulatory oversight over tobacco, to begin a process by which new tobacco and nicotine products coming into the marketplace could be evaluated, especially in comparison to the deadly cigarette- hence the name of the report 'Clearing the Smoke'.

Twenty years later while much has changed in the tobacco and nicotine marketplace many of the same issues and challenges that were addressed in the Report are still very relevant today. In spite of some progress over the last 20 years there are still 34 million cigarette smokers in the country. And equally shocking is that there are approximately 480,000 annual preventable deaths due to the combustible cigarette. Simply put, smoking remains the country's leading cause of preventable disease and death.

There is an urgent need for the Clearing the Smoke report to be updated, including an overarching need to look at how to improve the regulatory framework, to make it more efficient, flexible, and adaptable to meeting consumer and public health needs in a rapidly changing environment. The first paragraph of the Executive Summary of the original Clearing the Smoke report noted that:

> *Tobacco smoke is the cause of the most deadly epidemic of modern times. Smoking causes cancer (e.g. lung, oral cavity, esophagus, larynx, pancreas, bladder, kidney), chronic obstructive pulmonary disease (COPD), myocardial infarction and stroke. The continuing toll of tobacco use has prompted the search for means of harm reduction for those who cannot or will not stop using tobacco. Numerous products that allow continued nicotine consumption are now entering the market. This report is concerned with the evaluation of these products.*

Those words are as relevant today as they were 20 years ago.

The Report is rich with information on a spectrum of issues and can assist in beginning the needed discussions about where we need to be going in the future. Below are the **Principal Recommendations that were developed 20 years ago**:

> **The Committee believes that harm reduction is a feasible and justifiable public health policy – but only if it is implemented carefully to achieve the following objectives:**
>
> - Manufacturers have the necessary ***incentive*** to develop and market products that reduce exposure to tobacco toxicants and that have a reasonable prospect of reducing the risk of tobacco related disease;
> - Consumers are fully and accurately ***informed*** of all known, likely and potential consequences of using these products;
> - Promotion, advertising, and labeling of these products are firmly ***regulated*** to prevent false or misleading claims, explicit or implicit;
> - Health and behavioral effects of using PREPs are ***monitored*** on a continuing basis;
> - Basic, clinical and epidemiological ***research*** is conducted to establish their potential for harm reductions for individuals and populations;
> - Harm reduction is implemented as a ***component*** of a comprehensive national tobacco control program that emphasizes abstinence-oriented prevention and treatment.

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 environment. Recognizing that things were rapidly changing, you, and then FDA Commissioner Scott Gottlieb announced and outlined a new visionary plan in July of 2017, now over four (4) years ago. Unfortunately, the substance of that 'vision' has not been fully and openly discussed let alone implemented, in part due to an overwhelming workload that the Center for Tobacco Products is having to deal with. We recognize that, but we believe that the CTP should take a more proactive leadership role in providing or finding a 'neutral forum' where stakeholders could engage in civil dialogue and talk about the future, not unlike it did 20 plus years ago. The current environment is almost toxic.

In announcing the visionary nicotine policy, the FDA called for increased engagement and dialogue among stakeholders. The agency has used such terms as 'crossroads', the need to 'encourage innovation'; the need to regulate products based on the 'continuum of risk'; the need to ensure that children and adolescents are not targeted or encouraged or have access to or use any tobacco or nicotine product; the need to provide adult smokers with lower risk affordable alternatives; and the need to reduce nicotine levels *in cigarettes* to nonaddictive levels. In its July 2017 press release the agency said:

"Envisioning a world where cigarettes would no longer create or sustain addiction and where adults who need or want nicotine could get it from less harmful alternative sources, needs to be the cornerstone of our efforts- and we believe it is vital that we pursue common ground."

Commissioner Gottlieb then went on to say:

"To succeed, FDA must be strategic about how to use its tobacco and drug authorities. To succeed, participants from all sectors in the ongoing harm reduction debate need to take a step back and work together to reach greater common ground."

We are writing to request that the FDA undertake a thorough and urgently needed update to the Clearing the Smoke report. This can be accomplished either within the agency itself or more preferably by requesting that the prestigious National Academies of Science, Engineering and Medicine (NASEM) undertake this needed review. The original Clearing the Smoke report was requested by the FDA and conducted by what was then called the Institute of Medicine (IoM). Such a review would include and consider but not be limited to such topics and issues as:

- **Science, technology and innovation have dramatically advanced**

Over the last 20 years novel new nicotine delivery products have been developed so that we now have what is referred to as a science- based 'continuum of risk' with products that range from the deadly combustible cigarette at one end to noncombustible products on the other that includes snus, e-cigarettes, heat- not- burn products, nicotine products without tobacco and nicotine replacement therapy (NRT) products. In spite of the development of these products, and important advances in innovation and technologies, we have not 'cleared the smoke'. This is in part due to the slowness in which these products are being reviewed and approved and aren't being made available to the smoking public and because little has been done to better educate the public.

- **The issue of 'nicotine'- what it is and what it is not- its risks and benefits needs to be better defined**

In spite of the fact that nicotine has long been available to smokers in the form of NRT (Nicotine Replacement Therapies) without serious adverse effects, there has been an effort over the last several years to raise concerns about the effects of nicotine. A review of the science is urgently needed as more and more products are being developed and so that the public can understand the risks and relative risks of various nicotine-containing products including nicotine derived from tobacco as well as synthetically made.

- **Consumer preferences and choices have changed drastically**

Users of tobacco and nicotine product should be entitled to full, complete, truthful and accurate information about the risks and relative risks of the growing spectrum of products. Information should be presented in such a way that someone using any tobacco and nicotine product can understand those risks, and relative risks. This is something that a spectrum of stakeholders need to be a part of so that there is consistency and continuity in the messages being given to consumers and the general public. It is unfortunate that confusion continues to reign. A good example has been and continues to be that over 70 percent of the public and users of tobacco believe that nicotine is a major cause of cancer and many erroneously believe that all tobacco products are equally harmful.

- **The regulatory framework needs to be modernized**

The Food and Drug Administration has often sought to ***modernize*** and update its authorities to meet the changing environment in the drug, food, and medical device arenas, but has not done so in the tobacco and nicotine space. Consideration should be given to what more the Agency can do within the existing

statute but equally what changes could/should be made in the Tobacco Control Act enacted more than ten years ago. An assessment of what is working and what needs improvement or updating should be undertaken. A full, independent review is urgently needed particularly in terms of the harm reduction provisions of the act. A review of the statute would enable Congress to consider suggestions for amendment. Consideration should also include reviewing what other countries are doing in the area of tobacco harm reduction and the regulatory frameworks they are using.

- **The public health and tobacco control communities remain divided in how best to move forward**

In this dynamically changing environment, the public health community and the tobacco control community have become increasing divided about how best to deal with and manage change – particularly in terms of harm reduction. Some continue to rely on more traditional tobacco control policies while others see significant opportunities that need to be considered and implemented. Both argue that their positions are solidly based on advancing the long held public health goal of 'reducing disease and death' from the use of tobacco.

The CTP and NASEM are in a unique position to bring stakeholders together and to engage in civil dialogue that will provide all parties (including policy makers) with new suggestions and ideas. It is unfortunate that the discussions are currently being undertaken in an environment that often lacks a scientific base and which are debated in the media, often with misleading and false statements. This needs to change.

THEREFORE we the undersigned, many of whom have long standing histories of involvement with tobacco control, respectfully call on the Food and Drug Administration Center for Tobacco Products to initiate a review and updating of the **Clearing the Smoke** report that can put all stakeholders on a track that will collectively advance public health objectives. We believe that the NASEM, having produced the earlier report is the most appropriate body to undertake such a review on behalf of the FDA/CTP. The FDA/CTP can and should provide the necessary leadership to help move things forward, not only in terms of the US policies but globally as well.

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

Scott D. Ballin, J.D
Retired; Former VP and Legislative Counsel, American Heart Association; Advisor to the University of Virginia 'Morven Dialogues' on tobacco harm reduction: Health Policy
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

Sincerely,

On behalf of the other members of the leadership committee of the National Tobacco Reform Initiative and other co-signers of this request:

David Abrams, PhD – Professor, Department of Social and Behavioral Science, College of Global Health, New York University

Aaron Biebert- Former President and CEO, Clear Medical Solutions; Sociologist and Director of 'A Billion Lives' & 'You Don't Know Nicotine'

Allan C. Erickson – Retired, Former Vice President for Public Education and Tobacco Control, American Cancer Society, Former Staff Director, Latin American Coordinating Committee on Tobacco Control

Ray Niaura, PhD -Professor School of Public Health Global Studies, New York University; and

John R. Seffrin, PhD –Retired

Additional Supporters of this request from the United States:

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
Associate Director (Populations Sciences)
Brown University Cancer Center

Anthony J. Alberg, PhD, MPH
Professor and Chair
Department of Epidemiology and Biostatistics
Arnold School of Public Health
University of South Carolina

Neal L. Benowitz, MD
Professor of Medicine Emeritus (Active)
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

Cristine Delnevo, PhD, MPH
Professor of Health Behavior, Policy & Society
Rutgers University, School of Public Health
Director, Rutgers Center for Tobacco Studies
Senior Advisor for Tobacco Control,
Rutgers Cancer Institute of New Jersey

Clifford E. Douglas, JD
Adjunct Professor and Director, Tobacco Research Network, University of Michigan School of Public Health
Former Vice President for Tobacco Control and Founding Director, Center for Tobacco Control, American Cancer Society

Michael Eriksen, Sc.D.
Regents' Professor
School of Public Health
Georgia State University
Atlanta, Georgia

Jonathan Foulds, PhD
Professor of Public Health Science and Psychiatry
Penn State College of Medicine

Thomas J. Glynn, PhD
Adjunct Lecturer
Prevention Research Center
School of Medicine, Stanford University and,
National Cancer Institute (Ret.)
American Cancer Society (Ret.)

Maciej L. Goniewicz, PharmD, PhD
Professor of Oncology, Department of Health Behavior, Division of Cancer Prevention and Population Sciences
Roswell Park Comprehensive Cancer Center

Dorothy K. Hatsukami, PhD
Professor, Department of Psychiatry and Behavioral Sciences
University of Minnesota

Cheryl G. Healton, Dr.PH
Dean and Director; Professor of Public Health
School of Global Public Health
New York University

Stephen S. Hecht, PhD
Wallin Professor of Cancer Prevention
American Cancer Society Professor
American Chemical Society Fellow
Masonic Cancer Center
University of Minnesota

Lynn T. Kozlowski, PhD
Former Dean
Professor of Community Health and Health Behavior
School of Public Health & Health Professions
University at Buffalo, SUNY

Scott J. Leischow, PhD
Professor of Population Health and
Executive Director, Clinical and Community Translational Science
Arizona State University

David T. Levy, PhD
Professor, Cancer Prevention and Control
Lombardi Comprehensive Cancer Center
Georgetown University

David Méndez, PhD
Associate Professor of Health Management and Policy, School of Public Health
University of Michigan

Robin Mermelstein, PhD
Distinguished Professor, Liberal Arts and Sciences, Psychology Department
Director, Institute for Health Research and Policy
Co-Director, Center for Clinical and Translational Science, University of Illinois at Chicago

Thomas J. Miller, JD
Attorney General of Iowa

Jeff Nesbit
Former Associate Commissioner
Food and Drug Administration

Joel L. Nitzkin, MD, MPH, DPA
Principle Consultant, JLN,MD Associates, LLC
Past President American Association of Public Health Physicians (AAPHP)
Past President National Association of County & City Health Officials (NACCHO)

Michael F. Pesko, PhD
Associate Professor
Department of Economics/Andrew Young School of Policy Studies
Georgia State University

Brad Rodu, DDS
Professor of Medicine
Endowed Chair, Tobacco Harm Reduction Research
University of Louisville

Jed E. Rose, PhD
Professor, Department of Psychiatry and Behavioral Sciences, Director of the Duke Center for Smoking Cessation
Duke University Medical Center
President and CEO, Rose Research Center, LLC
Raleigh, North Carolina

Sally Satel, MD
Senior Fellow, American Enterprise Institute
Visiting Professor of Psychiatry, Columbia University's
Vagelos College of Physicians and Surgeons

Steven Schroeder, MD
Distinguished Professor of Health and Health Care, Department of Medicine, Director of the Smoking Cessation Leadership Center,
University of California at San Francisco
Former president and CEO, The Robert Wood Johnson Foundation

Peter G. Shields, M.D.
Deputy Director, Comprehensive Cancer Center
Professor, College of Medicine
Julius F. Stone Chair in Cancer Research
James Cancer Hospital
Ohio State University

Kenneth E. Warner, PhD
Avedis Donabedian Distinguished University
Professor Emeritus
Dean Emeritus
University of Michigan School of Public Health

Additional Supporters of this request from outside the United States:

Ron Borland PhD, FASSA |
Deputy Director, Melbourne Center for Behaviour Change,
Professor of Psychology – Health Behaviour,
Melbourne School of Psychological Sciences
The University of Melbourne, Australia

Karl Fagerstrom, PhD
Professor Emeritus
President, Fagerstrom Consulting
Sweden

Martin Jarvis DSc OBE
Emeritus Professor of Health Psychology
Department of Behavioural Science & Health
University College London

Colin Mendelsohn, MB BS (Hons)
Tobacco Treatment Specialist
Founding Chairman of the Australian Tobacco Harm Reduction Association,
Sydney, Australia

Ann McNeill
Professor of Tobacco Addiction
Institute of Psychiatry, Psychology & Neuroscience
King's College London

Prof. Gerry Stimson
Emeritus Professor Imperial College London
and Director Knowledge-Action-Change, United Kingdom

David Sweanor, JD
Chair of the Advisory Board of the
Center for Health, Law, Policy and Ethics
University of Ottawa, Canada

cc: Janet Woodcock, MD, Acting Commissioner, U.S. Food and Drug Administration (FDA)
Matthew R. Holman PhD, Director of the Office of Science at FDA's Center for Tobacco Products