



NATIONAL TOBACCO REFORM INITIATIVE

Ending Cigarette Use by Adults in a Decade is Possible

March 1, 2023

Robert M. Califf M.D., MACC
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Subject: Reagan-Udall Report on CTP Operations --- Next Steps/Considerations

Dear Commissioner Califf:

We are writing to thank you for taking the initiative in requesting that the Reagan-Udall Foundation undertake a review of the operations of the Center for Tobacco Products (CTP). In our opinion such a review was urgently needed. Since the enactment of the Tobacco Control Act over ten years ago, much has changed in the tobacco and nicotine space. Scientific developments, long overdue in the tobacco and nicotine space, have allowed for rapid product innovations coupled with the internet which has allowed new entrants into the marketplace. Additionally, changing consumer preferences and desires for lower-risk products all have had an impact on changing tobacco and nicotine marketplace. The Center for Tobacco Products has had to confront these changes and challenges but unfortunately has fallen behind in its regulatory responsibilities.

While you had requested a seemingly narrower focus of issues in assessing the operations of the CTP, it is clear to us, after reading the Reagan-Udall report, that there are numerous direct and indirect interrelated issues needing to be addressed. As an example, at the recent Biopharma Congress meeting, you recently highlighted the need for *FDA Advisory Committee reforms* as well as '*combatting misinformation*'. On both issues we concur and believe this applies to things CTP could be doing better, along with many other issues addressed in the Reagan-Udall Foundation report. The CTP's Tobacco Products Scientific Advisory Committee (TPSAC) has done very little over the last 5 years when it should be more actively engaged in providing leadership in terms of science. Equally of concern has been the CTP's inability to educate and provide truthful, accurate and non-misleading information to the public and users of tobacco and nicotine products about the risks and relative risks of a growing spectrum of products.

The National Tobacco Reform Initiative (hereafter referred to as the NTRI) is an informal organization that was created about 9 years ago to try and push FDA and other public health organizations to focus more attention on helping adult smokers get off cigarettes, something that we were pleased to see you addressing in recent JAMA commentary - The Need for a Smoking Cessation "Care Package" (<https://pubmed.ncbi.nlm.nih.gov/36580350/>). Over the past several years NTRI has corresponded with the CTP and the Commissioner's office advocating for 'modernization and operational' reforms. Rather than reiterate our ideas in this letter we are including both hard copies and links of earlier correspondence

we believe you and CTP Director Brian King and newly appointed CTP Director of Office of Science, Matthew Farrelly can take into consideration.

The NTRI believes that in spite of the quick turnaround that the Reagan-Udall Foundation had to meet, it did an excellent job in hearing from a wide spectrum of stakeholders and in putting together an important assessment and report. We were pleased to see just last week that CTP has announced a number of steps responding to the Reagan-Udall report.

I. Letter signed by 42 public health experts to Mitch Zeller (October 2023)

As you may know, 2021 was the 20th Anniversary of the release of the landmark Institute of Medicine (IoM) report, **Clearing the Smoke-Assessing the Science Base for Tobacco Harm Reduction**. To us it was very clear that the CTP needed being ‘modernized’ to keep up with the rapidly evolving landscape of tobacco/nicotine products, product manufacturers and distributors, and consumer issues. It was falling behind in many areas something which has continued to this day. In our letter to Director Zeller, we suggested that the CTP consider asking NASEM to undertake a review and update of that report or if not NASEM then for CTP to take on the task itself. This type of effort would provide greater transparency and broader stakeholder engagement in addressing challenges and opportunities for **modernizing** the Tobacco Control Act. The full text of the letter can be found at: <https://www.tobaccoreform.org>

II. Letter signed by 24 public health experts to Susan C. Winckler, CEO, Reagan-Udall Foundation (August 22, 2022)

Upon hearing that you as Commissioner had asked the Reagan-Udall Foundation to do a review of the operations on the Center for Tobacco Products (CTP), the National Tobacco Reform Initiative sent a letter to CEO Winckler with our thoughts and with what some have referred to as a roadmap for change. The letter lays out nine (9) items that the Foundation consider as it undertook its work. In brief summary, it included such things as:

- Streamlining the review and approval processes for products;
- Regulating product categories and products based on good science and the ‘continuum of risk’;
- Eliminating excessive regulatory barriers;
- Undertaking an evidence-based truthful public education campaign on nicotine that coordinates efforts with the public and private sectors;
- Developing and implementing a broader based public education campaign about the risks and relative risks of products that would employ product labeling, marketing, social media etc.;
- Reducing nicotine in *combustible* products but done in parallel with providing users of tobacco with lower risk consumer acceptable alternatives;
- Avoiding the excessive risk aversion interpretation in applying the ‘Appropriate for the Protection of the Public Health’ standard;
- Working with all stakeholders in developing coordinated and cooperative surveillance, educational and enforcement activities particularly as they relate to youth;
- Doing more to bring together and engage with stakeholders through the use of conferences, summits, workshops, and advisory groups, which involve both the public and private sectors. For example, given the legitimate concerns about adolescent tobacco use, especially vaping, CTP should be bringing together a broad spectrum of stakeholder groups as soon as possible to discuss and work together on science based solutions to mitigate the problem more effectively.

The full text of this letter to the Reagan-Udall Foundation can be found at <https://www.tobaccoreform.org/>

III. NTRI Citizens Petition pending at the FDA/CTP (Filed March 2020)

Concerned about the inability of the CTP to move forward with its work in what has been a rapidly changing environment, including the visionary comprehensive plan released in July of 2017, the NTRI filed a petition with the FDA/CTP raising the same kind of issues noted in items I and II above. Many groups have provided comments on the Petition, although as of this date the NTRI has not heard anything back from the CTP about the Petition other than acknowledging its receipt. As was noted in the cover letter with the filing:

This petition is intended to make recommendations to the agency for carrying out its responsibilities pursuant to provisions of the Food Drug and Cosmetic Act and specifically under the Family Smoking Prevention and control Act and to consider ways of modernizing how it chooses to regulate a growing number of diverse tobacco and nicotine products. Specifically, we are urging FDA/CTP to establish a more flexible and workable regulatory framework that recognizes the opportunities associated with a rapidly evolving nicotine delivery market place, and to support stakeholder engagement and dialogue, which can better serve public health goals and objectives consistent with science-based comprehensive nicotine tobacco product regulatory strategies the agency outlined in 2017.

The full petition can be accessed on the NTRI website at: https://www.tobaccoreform.org/wp-content/uploads/2020/03/FDAPETITION2020_3-6-2020.pdf

We commend you for your leadership in taking the important initiative to have the Reagan-Udall Foundation review the operational deficiencies and needs of the CTP. But more importantly we are looking to you to provide further leadership that is needed to ensure that the CTP not only implements ‘operational’ reforms but also plans for the ‘modernizing’ of its regulatory framework to meet the challenges and opportunities in a rapidly changing environment. With smoking remaining this nation’s single most preventable cause of disease and death, we need to address not only issues pertaining to youth prevention which of course is important, but also address more urgently the problem of smoking related harms that face the more than 30 million people who continue persist in using cigarettes.

The NTRI and others stand ready to be available to you and your staff. Please feel free to call on us. If you have any questions about this request, please direct them to:

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Sincerely,

Scott D. Ballin

K. Michael Cummings

cc: CTP Director, Brian King, PhD; CTP Office of Science Director, Matthew Farrelly, PhD ; Susan Winckler, CEO Reagan-Udall Foundation

Key committees in Congress (House Energy and Commerce Committee- Subcommittee on Health, Subcommittee on Oversight) Senate Health, Education, Labor and Pensions Committee (HELP)