NATIONAL TAXPAYERS UNION
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September 10, 2024

The Honorable Brett Guthrie, Chair
The Honorable Larry Bucshon, M.D., Vice Chair
The Honorable Anna Eshoo, Ranking Member
Subcommittee on Health, Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chair Guthrie, Vice Chair Bucshon, Ranking Member Eshoo, and Members of the Committee:

On behalf of National Taxpayers Union (NTU), America's oldest national-level taxpayer advocacy organization, I write to offer commendations as well as comments on the Subcommittee's hearing, "Evaluating FDA Human Foods and Tobacco Programs." Aside from NTU's abiding interest in the fiscally responsible and efficient administration of government programs, recent analysis that NTU provided to an executive branch entity may be of interest to Subcommittee members today.

On June 26, the Tobacco Products Advisory Committee (TPSAC) convened a public meeting to consider a renewal request of a risk modification order from Swedish Match, along with "[a]dditional discussion about broader Modified Risk Tobacco Products (MRTP) program developments related to the conceptualization and measurement of consumer understanding." It was toward these "broader developments" that NTU directed oral and written testimony at the TPSAC meeting.

For background purposes, I have attached to this communication a full copy of our TPSAC testimony. We humbly submit this in hopes that the contents and citations may prove useful both for this hearing and for Subcommittee members and staff going forward. To summarize our remarks:

1) **Taxpayer-funded Public Health Programs Could Fiscally Benefit over the Longer Term by More Products Entering the Market More Quickly; and the Overall Net Fiscal Picture, including Non-Health Care Programs, Can Become Clearer as a Result.** Research on the *gross* fiscal impact of combustible tobacco use on programs such as Medicaid and Medicare is reasonably conclusive, but the *net* fiscal impact to taxpayers, considering health and non-health related government programs (e.g., retirement), is a more interpretative matter. Little more can be known if products are

never given the time and space in the market to demonstrate whether they can control costs to the economy and the public fisc.

2) **The Application Process, in General, Needs Greater Certainty, Transparency, and Alacrity to Encourage the Development of and Investment in New Products. From PMTA (premarket tobacco product application) to the Substantial Equivalence Pathway, to MRTP, both TPSAC and CTP can facilitate accumulation of better knowledge on the fiscal outcomes noted in 1).** However, CTP does have an advantage over many other federal agencies facing transition, in the form of a detailed management assessment report sanctioned by cabinet-level leadership. In December 2022, the Reagan-Udall Foundation for the FDA published "Operational Evaluation of Certain Components of FDA's Tobacco Program," led by an independent expert panel that gathered views and input from numerous individuals and organizations—including two taxpayer organizations with which NTU has partnered in the past.
3) **Participants in the Process Deserve Value for the Considerable Regulatory Costs and Charges They Must Bear for Engaging in that Process.** The fourth recommendation in the Reagan-Udall report goes on at length to discuss expansion and revision of the regulatory user fee regime that CTP currently operates. NTU is quite familiar with the operation of government user charges in other contexts.

Given the scope of today's hearing, we respectfully suggest that our comments to TPSAC may elicit some questions for discussion with at least one of the hearing's witnesses, the Center for Tobacco Products (CTP) Director, Dr. Brian King. In NTU's view, among these items are:

1) Will CTP recommit to the administrative reforms recommended in the Reagan-Udall report, particularly in providing transparency, clarity, and consistency in regulatory, guidance, and enforcement actions, especially in the PMTA and MRTP application submission and review stages? If so, does CTP have a strategic plan with specific milestones and timetables to do so?
2) As CTP considers how to improve transparency, clarity, and consistency in fees charged to regulatory entities, what models from inside (e.g., prescription drug user fees) and outside FDA (e.g., air traffic control services outside the U.S.) will it emulate?
3) What are the sources of the slow pace of PMTA and MRTP application hearings and approvals, and how can the pace be improved for the benefit of both government and stakeholders? Since the publication of NTU's testimony, for example, the latest National Youth Tobacco Survey from FDA reports declining use of e-cigarettes to its "lowest level in a decade" and continued low usage of nicotine pouches (less than 2 percent).[1] If concern over youth consumption of these products is one reason for CTP's reluctance to clear massive PMTA and MRTP dockets, how can a more realistic approach toward risk be adopted?
4) How can more collaborative approaches between the government and regulated entities inform CTP's and TPSAC's own processes? Examples include ombudsman/advocate entities to facilitate problem resolution between stakeholders and the government, "regulatory sandboxes," or the Internal Revenue Service "Job Aid" concept to CTP's own

[1] See the FDA's News Release at https://www.fda.gov/news-events/press-announcements/youth-e-cigarette-use-drops-lowest-level-decade.

regulatory guidance. Has CTP considered these or other processes for constructive management of its relationships with stakeholders, and if not, why not?

The breadth of topics and limitations on time may require follow-up discussions between the Subcommittee and CTP well beyond this hearing. Nonetheless, NTU believes that in the best interests of taxpayers, it is vital for Subcommittee members to exercise robust oversight of CTP in the future, and to insist upon updates from CTP on its progress in resolving longstanding issues in the administration of PMTA, MRTP, and other initiatives under its purview.

I thank you for your consideration of NTU's views, and should you or your staff have any questions, we are at your service.

Appreciatively,

Pete Sepp
President

Enclosure: Written comments of NTU to the Center for Tobacco Products' (CTP) Tobacco Products Scientific Advisory Committee's (TPSAC) June 26, 2024 Public Meeting on Docket No. FDA-2024-N-0008