



NATIONAL TAXPAYERS UNION

122 C Street N.W., Suite 700, Washington, DC 20001

June 20, 2024

Office of Science, Center for Tobacco Products
Food and Drug Administration
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Submitted via Email: TPSAC@fda.hhs.gov

Re: Written Comments to Accompany Oral Presentation 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

On behalf of National Taxpayers Union (NTU), I write with comments regarding Docket No. FDA-2024-N-0008, a public hearing of the Tobacco Products Scientific Advisory Committee concerning 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.” These comments are intended to accompany and provide additional background to NTU’s oral presentation at the June 26th public meeting.

I. Introduction

NTU is the nation’s oldest taxpayer advocacy organization, founded in 1969 to achieve favorable policy outcomes for taxpayers with Congress and the executive branch. Our experts and advocates engage federal policymakers on important matters affecting taxpayers in a variety of settings, including tax administration, trade, telecommunications and technology, transportation and infrastructure, financial services, health care, and product regulation. It is these latter two items which intersect and provide NTU with an opportunity to offer its views today.

We do not profess a specific expertise in the snus products that comprise the immediate topic of today’s hearing; however, in the past NTU has provided perspectives on Pre-Market Tobacco Product Applications (PMTA), MRTP, as well as other initiatives under FDA’s and the Center’s purview that are of keen interest to taxpayers. Examples include:

- Late last year, we filed comments with the Office of Information and Regulatory Affairs urging consideration of the fiscal problems associated with FDA’s Tobacco Product Standard for Menthol

in Cigarettes. We noted that state-level experience in Massachusetts showed a menthol ban drove a rise in illicit sales and a loss in tax revenue.¹

- In mid-2023 NTU led a coalition letter in support of Sections 768 and 769 of the House’s FY 2024 Agriculture, FDA and Related Agencies Appropriations bill to specify that none of the funds could be used to enact certain product bans or specify nicotine content levels in tobacco products, so as to “prevent overreach by regulators that would have significant negative impacts on taxpayers, farmers, retailers, consumers, manufacturers, state and local governments, and supply chains across the country.”²
- In 2022, we noted that despite creation of the PMTA process, at that time barely 20 product applications for e-cigarettes had been approved out of millions submitted. The result was a “gray market” in illicit products that could pressure states to raise taxes.³
- Throughout this time and into 2024, NTU has weighed in on numerous state-level tax and regulatory proposals affecting combustible tobacco and tobacco alternative products.⁴

The following comments will therefore focus on the “broader ... developments” mentioned in the Federal Register notice for Docket No. FDA-2024-N-0008.

II. Comments

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.

In order to connect the matters before the Committee to the fiscal policy concerns of taxpayers, some rather lengthy explanation is in order.

Research on the *gross* fiscal impact of combustible tobacco use on programs such as Medicaid, Medicare, veterans care, and government employee health programs is reasonably conclusive, if not unanimous on the exact amount of impact. Smoking and its various health outcomes – such as cancers, cardiovascular and pulmonary disease, and Type 2 diabetes – can increase hospital stays, surgeries, and other costly treatments and therapies.⁵

The *net* fiscal impact to taxpayers, considering health and non-health related government programs, is a more interpretative matter. For instance, because habitual smokers tend on average to have shorter lifespans, they can improve the overall actuarial position of government retirement systems. Counterfactuals could include diminished productivity in federal, state, and local government workforces which taxpayers fund, higher life insurance premiums, as well as the potential for increased disability benefit claims.⁶

¹ See comments at <https://www.ntu.org/publications/detail/ntu-submitted-comments-to-oira-on-ill-advised-menthol-ban>.

² See <https://www.ntu.org/publications/detail/coalition-supports-efforts-to-stop-tobacco-prohibitions-in-ag-approps-bill>.

³ See <https://www.ntu.org/publications/detail/fdas-lack-of-enforcement-continues-to-prop-up-gray-market-disposables>.

⁴ For just a few examples, see

<https://www.ntu.org/publications/detail/ntu-opposes-expansion-of-taxes-on-vapor-products-in-nebraska>; and <https://www.ntu.org/publications/detail/ntu-applauds-gov-scott-veto-of-flavor-ban>.

⁵ Gross estimates of smoking-related costs vary by definition, and types of government programs examined, but often run in the mid- to high- tens of billions annually. See, as a few examples, Xu, et al.,

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4603661/>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6052927/>; and testimony from Moody, <https://olis.oregonlegislature.gov/liz/2016R1/Downloads/CommitteeMeetingDocument/84458>.

⁶ A representative examination of this phenomenon is Tiihonen, et al., <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3533014/>.

On the revenue side, anti-smoking interest groups point out that taxes on tobacco products remain too low, whether the aim is to discourage use of the products or to cover their societal costs. But this point is also highly contentious. Roughly 30 years ago, some researchers began to suggest that smokers were more than “paying their way” for their decision to consume combustible tobacco. This connection was posited well before subsequent tax and regulatorily induced price hikes on the products have made that margin even greater.⁷

Additionally, there are political factors at work in tobacco tax increases, as NTU’s research arm (NTU Foundation) has well documented. As far back as 2013, our examination of budget and economic data determined that:

- States with low cigarette taxes have lower overall tax burdens;
- Tobacco tax increases are rarely used to offset other taxes;
- Tobacco taxes do not forestall other tax increases;
- Tobacco tax increases may encourage other subsequent tax increases; and
- Cigarette taxes do not spur economic growth.⁸

Other health innovations taking shape now will challenge the conventional “balance sheet” calculations of how smoking affects government-wide fiscal conditions and health care programs in particular. Newer prescription drugs to treat cardiovascular diseases (which can be exacerbated by smoking), have been estimated to significantly reduce per-capita Medicare expenditures. Recent trials with anti-obesity medications (AOMs) have likewise shown reductions in cardiovascular events. Other research has posited a longer-term contribution to program savings in Medicare and Medicaid by greater availability of AOMs, despite initially high costs of the medication.⁹ How would the outcomes from these medications interact with smoking-related treatments for traditionally associated comorbidities?

Moreover, if these increasingly encouraging signs of long-term fiscal benefits to health programs materialize, what will the net government-wide impact be? How could longevity increases impact not only retirement system benefits, but also decisions to delay retirement and keep contributing to the tax base? How would predilections for contributing toward self-funded plans like Individual Retirement Accounts change? Would disability programs see a moderation in claims? While those questions are obviously beyond the purview of this hearing, both TPSAC and FDA have a role in decisions that could move the body of research closer to finding more answers.

A final element in this discussion is whether and how the tobacco alternative products under CTP’s jurisdiction affect smoking uptake or cessation and subsequently, health.¹⁰ Here again, however, taxes play a role in calculations of costs and benefits. As one of my former colleagues Nicole Kaeding recounted in 2020, the “delicate balance” between tax rates and smoking could actually work against public health aims if policymakers choose excessive taxes on certain products. She provided analysis of a National Bureau of Economic Research Working Paper that explored Minnesota’s high taxes on vapor

⁷ One of the more seminal examples, from Viscusi, appears here:

<https://www.cato.org/sites/cato.org/files/serials/files/regulation/2005/12/v25n4-13.pdf>.

⁸ See <https://www.ntu.org/foundation/detail/tobacco-taxes-problems-not-solutions-for-taxpayers-and-budgets>.

⁹ For a comprehensive review of research on the value of prescription drug medication innovations in taxpayer-funded health settings, see <https://www.ntu.org/publications/detail/how-much-is-medicine-worth-to-the-american-taxpayer-a-cost-benefit-analysis>. See also Sepp, Pete, Comments to Centers for Medicare and Medicaid Services on 2025 Notice of Benefit and Payment Parameters (NBPP) Rule, January 8, 2024.

¹⁰ A very thorough treatment of this question appears in testimony from Stroud, Taxpayers Protection Alliance, https://www.house.mn.gov/comm/docs/WzWBOPyugkCmn5l7v_Alog.pdf.

products and scaled those results to national policy options, concluding that as many as 2.75 million individuals could be deterred from quitting smoking.¹¹

But this otherwise compelling research may still insufficiently stress a crucial point, as far as taxpayers are concerned. Some researchers lament the fact that too little independent research exists to verify the efficacy of alternatives to combustible tobacco for uptake and cessation. Yet, even a modest change to uptake or cessation from any of these products is useful feedback. And, the change can be tracked not only through scientific studies, *but also market data reflecting actual consumer preferences and purchases*. With the other factors described above, such as new health innovations, taxpayers can have a clearer idea of how public policy can be modulated to exert a salutary fiscal impact on health and non-health programs across government. *None of this 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.*

NTU believes the Committee’s role is to recognize the need for a stable policy climate that can add to the empirical collection of data. Denying, delaying, or deterring innovation in alternatives to traditional smoking – whether through a poorly functioning approval process, excessive taxes, overly burdensome regulations, or other ill-advised market interventions – will only thwart that goal.

2) The Application Process, in General, Needs Greater Certainty, Transparency, and Alacrity to Encourage the Development of and Investment in New Products. From PMTA to the Substantial Equivalence Pathway, to MRTP, both TPSAC and CTP can facilitate accumulation of better knowledge on the fiscal outcomes noted in 1).

CTP’s challenges with issues such as balancing workloads, embracing proactive instead of reactive management, and building trust in the community it serves are not unique to the federal government. NTU has observed them in numerous contexts as diverse as the Internal Revenue Service, the Surface Transportation Board, and the Federal Housing Finance Agency.

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 and conducted by a respected *external* party in consultation with numerous stakeholders. 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 whom NTU has partnered in the past.¹² The general recommendations were:

- “CTP must invest the time, now, with staff and public input, to create and implement a Strategic Plan that identifies the Center’s strategic objectives and plots an operational roadmap of the steps CTP will take over the next five years to achieve those objectives.” NTU has found that numerous government entities rise, or fall, based on the comprehensiveness of their strategic plans and the level of commitment that managers make toward their implementation. These two factors have, for example, proven remarkably predictive of the ebbs and flows that the IRS has experienced over the past 30 years.
- “CTP should increase its use of the Tobacco Products Scientific Advisory Committee (TPSAC) to obtain expert input on scientific issues and policy development, including regulations, guidance,

¹¹ See [Tax Rates and Smoking: A Delicate Balance - Foundation - National Taxpayers Union \(ntu.org\)](https://www.ntu.org/publications/tax-rates-and-smoking-a-delicate-balance-foundation-national-taxpayers-union-ntu.org).

¹² See the report at <https://reaganudall.org/operational-evaluation-fdas-tobacco-program>.

and data needs for effective product regulation.” Of direct pertinence to today’s meeting of TPSAC, this recommendation is second in importance only to the development of the strategic plan itself. The most successful agency transformations are undertaken with the assistance of an advisory or oversight body that stands sufficiently *apart* from that agency to render *candid* guidance, yet stands sufficiently *close* to that agency to render *relevant* guidance. Again, using the IRS as just one illustration, NTU has traced the decline of the IRS Oversight Board into dormancy in the early 2010s as a major cause of the tax agency’s persistent modernization problems.¹³

- Between hiring authorities under the 21st Century Cures Act and consultations with the Office of Personnel Management, TPC should pursue a workforce that can support the goals outlined above. Attracting new talent with fresh perspectives toward longstanding issues is often a catalyst for agency transformation.
- “The Agency should continue to pursue securing user fees from each sector regulated by the Center, including, for example, Electronic Nicotine Delivery Systems.” This topic, of special import for taxpayers, is discussed in greater detail in Comment #3.

Overall, stakeholders consulted for the Reagan-Udall report often voiced concern over the lack of transparency, clarity, and consistency on the part of CTP’s regulatory, guidance, and enforcement actions, especially in the PMTA and MRTP application submission and review stages. Certainly, the four recommendations elucidated above could help to address these shortfalls, but how could they be operationalized? In NTU’s opinion, it all begins with early, robust collaboration with the constituencies CTP and TPSAC are intended to serve.

Our experience tells us that there are several methods CTP and TPSAC could embrace that carry a better promise of success:

- *Adapt the “Job Aid” concept for tax guidance to CTP guidance.* Although they can vary somewhat in their composition and operation, Job Aids are generally initiated by the IRS for either members of their own staff or the practitioner community as “how-to” guides for ensuring best practices in carrying out the intent of tax administration. As one expert we cited in testimony to the IRS put it, Job Aids “provide clarity and understanding of the Service’s stance without creating significant disputes between taxpayers, their advisers, and the Service’s agents, saving the Service time and taxpayer money in attempting to pass and then properly enforce its regulations.”¹⁴ This is precisely the kind of synergy that could benefit CTP and TPSAC.
- *Create an Ombudsman/Advocate for individuals and companies that must interact with CTP application, review, and approval processes.* The Reagan-Udall report noted the explosion in litigation that has resulted from the millions of product determinations that CTP faces, and the perception among some applicants with fewer resources of barriers to entry in the review and approval process. Aside from reducing the workload through judicious reorientation of the review process, “early intervention” could prevent costly and time-consuming compliance activity for applicants and the government. One way this has occurred at other agencies is to provide stakeholders with a genuine opportunity to resolve administrative problems through a dedicated intermediary – one housed within that agency but nonetheless focused outward on those who interact with processes that can sometimes prove difficult to understand or even frustrating.

¹³ See testimony of Pete Sepp before the U.S. Senate Committee on Finance, May 16, 2023, at <https://www.ntu.org/publications/detail/compliance-should-be-irs-goal-not-enforcement>.

¹⁴ See <https://www.ntu.org/publications/detail/irs-considering-backdoor-death-tax-hike>.

Another is to staff an entity that serves as a convenor and articulator of stakeholder concerns. Two standout models here are the National Taxpayer Advocate at the IRS, which is directly empowered to assist taxpayers who are unable to resolve tax administration issues through the conventional IRS chain of customer interaction. Another is the Small Business Administration Office of Advocacy, which was created to serve as “the independent voice for small business within the federal government, the watchdog of the Regulatory Flexibility Act, and a source of small business statistics and research.”¹⁵

- *Utilize “Regulatory Sandboxes.”* This concept, in widespread practice abroad, was originally proven in the tech policy sphere. As Ryan Nabil, the Director of Technology Policy and Senior Fellow for NTU’s research arm (NTU Foundation) wrote prior to coming to our organization:

‘[R]egulatory sandbox’ programs allow companies to test innovative products and services under a modified and frequently lightened regulatory framework for a limited period. These programs allow companies to test new financial products and enable regulators to become more familiar with technological innovation and its impact on businesses. By allowing regulators to evaluate how different rules impact businesses, sandbox programs can provide crucial information to help regulators craft business- and innovation-friendly rules.¹⁶

Recently NTU Foundation proposed this framework to the Internal Revenue Service for developing tax regulations governing cryptocurrency. As NTU Foundation Attorney Lindsey Carpenter explained in comments to the IRS:

Under this sandbox method, the IRS would recruit cryptocurrency experts from outside the IRS. These experts should represent all areas of cryptocurrency: Regulatory, taxation, trading platforms, cybersecurity, investors, brokers, sellers, etc. Then, in a controlled environment, the IRS should foster allowing for the free flow of ideas about cryptocurrency and how to properly tax such.¹⁷

TPSAC would be an ideal candidate for adapting the regulatory sandbox method for entities interacting with CTP on a variety of highly technical aspects surrounding PMTAs and MRTPs.

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, and would recommend some additional principles for CTP, beyond Reagan-Udall’s findings:

- *Fees should be proportionate to the cost and level of service provided.* The Internal Revenue Service recently lost litigation brought by practitioners who argued that the government was collecting excessive charges to administer the Preparer Tax Identification Number (PTIN) program. The government is now in discussions with plaintiffs to arrive at a settlement for

¹⁵ For further introductory information on Office of Advocacy activities, see <https://advocacy.sba.gov/category/regulation/agency-roundtables/>, <https://advocacy.sba.gov/regulatory-reform/>, and <https://advocacy.sba.gov/category/research/economic-reports/>.

¹⁶ See <https://cei.org/studies/how-regulatory-sandbox-programs-can-promote-technological-innovation-and-consumer-welfare/> and [NTUF Comments to OMB on AI Governance - Foundation - National Taxpayers Union](#).

¹⁷ See [NTUF’s Comments On IRS Cryptocurrency Regulations - Foundation - National Taxpayers Union](#).

repaying excessive charges.¹⁸ Had the fees been properly calibrated in the first place, this costly and time-consuming process could have been avoided.

- *Fees should be carefully managed and safeguarded from attempts to divert them to other programmatic activities or causes.* The “Passenger Security Fee” levied by the Transportation Security Administration was statutorily increased so that the proceeds could be used to offset the deficit impact of spending increases in larger legislation, while multi-year extensions of customs user fees are often employed as an artifice to improve the budgetary “score” behind numerous bills.¹⁹
- *The fee system should be transparently managed and subject to regular oversight.* One of the best managerial success stories behind user fees is the model for air traffic control (ATC) systems in ubiquitous practice for most major U.S. trading partners. The typical structure is that ATC services are provided by a nonprofit entity governed and funded by users ranging from airlines to cargo carriers and overseen by a board of directors in which carriers, labor organizations, and passenger advocates participate.²⁰ A counterexample is the Environmental Protection Agency’s approval process for industry applications to bring new chemicals into commercial use, which has been plagued with delays and heavy additional regulatory costs for the private sector.²¹

Besides these positive – and cautionary – examples, CTP can also draw lessons from FDA’s User Fee Agreements (UFAs) that help to provide a reasonable level of certainty and continuity for applicants seeking permission to market branded and generic prescription drugs, biologics, and medical devices. The UFA program does not function perfectly, as NTU has pointed out on previous occasions. Yet, it does possess virtues worth CTP’s emulation, including early and frequent stakeholder engagement, and a proactive, businesslike approach to fee-setting that makes the process less susceptible to controversial interventions from elected officials.

III. Conclusion

NTU is grateful for your consideration, and I am hopeful that the fiscally based framing we have provided in these comments is useful to you. If you have any questions or concerns, please do not hesitate to contact us.

Sincerely,



Pete Sepp
President

¹⁸ See <https://www.forbes.com/sites/kellyphillipserb/2023/10/05/irs-lowers-ptin-fees-as-another-court-battle-breeds-over-regulating-tax-p-reparers/>.

¹⁹ See <https://www.ntu.org/publications/detail/bigger-government-burdens-on-air-travel-like-pfcs-wont-fly-with-taxpayers> and <https://www.ntu.org/foundation/detail/one-weird-trick-congress-uses-to-game-budget-numbers>.

²⁰ For a thorough archive on this issue, see <https://enotrans.org/faa-reform-reference-page/>.

²¹ See, for example, <https://www.ntu.org/publications/detail/ntu-led-coalition-writes-to-house-energy-and-commerce-committee-on-epa-regulatory-powers>.

