

August 29, 2023

Brian King, MPH, PhD
Director, Center for Tobacco Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: American Lung Association Comments on the U.S. Food and Drug Administration Center for Tobacco Products' Strategic Plan

Dear Dr. King:

The American Lung Association is pleased to submit these comments on the U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP)'s Strategic Plan.

The American Lung Association is the oldest, voluntary public health organization in the United States. One of our four strategic imperatives is to create a tobacco-free future, and tobacco cessation is vital to that effort. Tobacco use¹ is the leading cause of preventable death and disease in the United States, responsible for the deaths of 480,000 Americans annually.¹ An additional 16 million Americans live with a disease caused by tobacco.²

The Lung Association is pleased to see CTP's initiation of this strategic planning process. Over the 14 years FDA has had authority over tobacco products, its efforts have often had a lack of focus on the regulations and activities that would have the greatest impact on improving the public health. Therefore, the Lung Association hopes this strategic plan will result in a roadmap that CTP can follow to better regulate the manufacturing, marketing and sale of tobacco products, and ultimately reduce the death and disease caused by them.

Overall Comments on the Strategic Plan

The Lung Association believes the five proposed strategic goal areas generally capture the work CTP should engage in, and reflect the mandate given to them by Congress under the Family Smoking Prevention and Tobacco Control Act. However, the Lung Association strongly urges reconsideration of and revision to part of goal four, notably any promotion of the so-called "relative risk" of tobacco products. CTP should have no part in the industry's efforts to sustain addiction through the failed and flawed notion that adult smokers should switch to e-cigarettes. "Appropriate for the protection of the public health" does not include CTP promoting a tobacco product that has initiated and maintained the addiction of millions of people. We also recommend that CTP use a broad definition of "encourage cessation" when implementing this goal to encourage people of all ages, including youth and young adults to entirely end their addiction.

We are pleased to see the four cross cutting themes for these goals, and the transparency and health equity cross-cutting themes in particular. Health equity should be incorporated into all

¹ All references to tobacco use, tobacco control or tobacco products in this document refers specifically to the use of manufactured, commercial tobacco products and not to the sacred or traditional use of tobacco by American Indians and other communities.

aspects of what CTP does but should especially factor into the product standards that CTP chooses to pursue.

CTP has shown a disturbing lack of transparency in some of the regulatory actions it has taken over the years especially concerning its decisions on product applications. It is imperative that this strategic plan outline how CTP plans to increase its transparency.

The strategic plan should not create easier pathways for authorization of products that do not meet the appropriate for the protection of public health standard. Any product authorized for sale or granted modified risk tobacco product status should have the strongest science supporting such a decision, including impacts on youth use. Making authorization less robust will likely be a goal of the tobacco industry and its allies and we urge CTP to explicitly reject it.

Strategic Goal #1 - Develop, Advance, and Communicate Comprehensive and Impactful Tobacco Regulations and Guidance.

Finalize Rules Prohibiting Sale of Menthol Cigarettes and Flavored Cigars

The most important priority for CTP in this goal area is to finalize its proposed rules that would eliminate menthol cigarettes and flavored cigars from the marketplace. Menthol flavoring has been marketed and falsely perceived as a healthier alternative to non-menthol tobacco products.³ For generations, the tobacco industry has intentionally targeted Black, Brown, youth, LGBTQIA+ and other communities with its marketing of menthol cigarettes. This false perception of less risk and relentless marketing has resulted in increased initiation with menthol cigarettes and high usage of menthol cigarettes, contributing to more tobacco-related death and disease as well as tobacco-related health disparities. Over 80% of Black Americans who smoke use menthol cigarettes.⁴ Menthol cigarette use is also elevated among lesbian, gay and bisexual² individuals, 51% of LGB individuals who smoke use menthol cigarettes compared to 40% of heterosexual individuals who smoke.⁵ A recent study quantified the disproportionate harms from menthol cigarettes to Black Americans, finding that menthol cigarettes were responsible for 1.5 million new smokers, 157,000 smoking-related premature deaths and 1.5 million life-years lost among Black Americans from 1980-2018.⁶

Menthol cigarettes have been found to increase both the likelihood of becoming addicted to cigarettes and the degree of addiction.⁷ Research also indicates that menthol smokers are less likely than non-menthol smokers to successfully quit smoking despite having a higher urge to end their tobacco dependence.⁸ This is seen in the available data around interest and success in quitting. Black persons who smoke report a greater interest in quitting and more past year quit attempts than their white counterparts. However, Black individuals have been less successful in quitting due in large part to their disproportionate use of menthol cigarettes, which are more difficult to quit.⁹

As would be expected, the proportion of smokers who say they would quit in response to a menthol cigarette prohibition is higher among Black people who smoke than other demographic groups. In the first 13-17 months of removing menthol cigarettes from the marketplace, one study estimates 923,000 people who smoke would quit, including 230,000 Black Americans.¹⁰ This study, which evaluated Canada's law prohibiting the sale of menthol cigarettes, also concluded that removing menthol cigarettes from the marketplace was significantly associated

² National data is not available for transgender individuals.

with higher rates of quit attempts and quit success among menthol smokers compared to non-menthol smokers and may have helped to prevent relapse among menthol smokers who had quit smoking before the prohibition.

The American Lung Association submitted comments on the proposed rules ending the sale of [menthol cigarettes](#) and [flavored cigars](#) that contained additional information about the harms of menthol cigarettes and why these rules should be finalized.

Implement a Track and Trace System for Tobacco Products

FDA was required in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) to implement a track and trace system for tobacco products, a statutory obligation that has yet to be implemented by CTP. Setting up such a system should be among FDA's immediate regulatory priorities, as it would be supportive for its many other agenda items. Under this system, FDA and other enforcement authorities would be able to identify the source and distribution history of product packages and increase the effectiveness of the enforcement of the Tobacco Control Act.

There is an outstanding [citizen petition](#) that the Lung Association and several partners filed in 2013 to which FDA has yet to respond. Setting up a track and trace system for all tobacco products would be an excellent complementary step for when the proposed rules on menthol cigarettes and flavored cigars are implemented. It would also help with enforcing compliance with product standards and premarket tobacco product applications.

Finalize Federal Tobacco 21 Implementation Rules

Legislation increasing the tobacco sales age to 21 was passed and signed into law in December 2019 with FDA required to issue implementing rules six months later in June 2020. It is now August 2023, making these rules more than three years overdue. There is significant confusion amongst state governments especially in states that have yet to raise their own state minimum sales ages to 21 about how to harmonize state and federal enforcement efforts and what penalties states might be subject to if they do not enforce the federal sales age of 21. The finalization of these rules must be prioritized.

Defend Rule Requiring Graphic Warning Labels for Cigarettes

The Lung Association is deeply disappointed in the U.S. District Court ruling in the 5th Circuit that has vacated FDA's rule requiring graphic warning labels on cigarettes. We urge CTP and the Department of Justice to continue to defend the rule and educate about the benefits that would come from implementing it.

Issue a Rule Reducing Nicotine Levels in All Tobacco Products

The Lung Association was glad to see the inclusion of a proposed rule to reduce nicotine levels in cigarettes to non-addictive or minimally-addictive levels in the most recent Unified Federal agenda, and this should be a priority for CTP. However, we recognize that to be most effective, the proposal needs to be broadened to encompass all tobacco products. We are especially concerned about the potential impact reduced nicotine levels in just cigarettes or combusted tobacco products could have on youth tobacco product initiation with e-cigarettes. The Lung Association is also concerned about potential switching in lieu of cessation to other tobacco products with higher nicotine levels. In 2022, the Lung Association and the American Thoracic Society sent [a joint letter](#) to FDA Commissioner Robert Califf outlining our concerns with limiting a nicotine reduction standard to just cigarettes.

Ensure FDA Has Authority over All Cigars

We were deeply disappointed with the recent court ruling that leaves some premium cigars outside CTP's authority. We urge FDA to consider all possible actions in response. No tobacco product should be outside CTP's authority to issue basic health and safety regulations.

Finalize the Proposed Rule on N-nitrosornicotine in Smokeless Tobacco and Consider Issuing Additional Product Standards to Protect Health

In January 2017, FDA proposed a rule that would put a cap on the level of N-nitrosornicotine (NNN) in finished smokeless tobacco products. NNN is a potent carcinogen and epidemiological evidence shows that the use of smokeless tobacco products marketed in the U.S. increases the risk of oral cancer. Reducing the level of NNN in smokeless tobacco products would reduce the risk of oral cancer for users of such products. The Lung Association and other public health partners [commented on](#) the proposed rule and supported finalizing it at the time. We urge CTP to revisit this proposed rule and finalize it.

We also urge CTP to start conducting research and build evidence for additional similar product standards that could make tobacco products less hazardous, attractive or addictive. CTP's product standard authority has been underutilized by the agency in its first 14 years of existence, and we encourage CTP to use the authority in more robust fashion going forward.

Strategic Goal #2 - Ensure Timely, Clear, and Consistent Product Application Review to Protect Public Health

Finish Review of Pre-Market Tobacco Product Applications Received September 9, 2020

A federal court required that all premarket tobacco product applications received by September 9, 2020, be reviewed one-year later by September 9, 2021. Now, nearly two years past the deadline, we are still waiting for FDA to complete this work. While FDA has made progress in reducing the backlog over the past year, including several decisions on menthol e-cigarette products, important decisions on e-cigarette products with high market share remain outstanding. It is imperative that CTP not delay beyond 2023 to finish the review of these applications, and re-direct resources to accomplish this overdue task. The Lung Association continues to believe that no flavored tobacco product can meet the public health standard.

Increase Transparency in the Product Application and Review Process

As mentioned above, the Lung Association is pleased to see transparency as a cross cutting theme in this strategic plan. Transparency on the status of products that are legally allowed to be on the marketplace is most needed. CTP must make public an up-to-date list of products that have received marketing orders through the PMTA or substantial equivalence process. These up-to-date lists are crucial for compliance and enforcement by entities outside CTP.

One example of the problems the lack of an up-to-date list creates concerns the menthol replacement products that R.J. Reynolds and ITG Brands have introduced in states with flavored tobacco product laws. It is unclear if these products received substantial equivalence orders. It is also important to understand for all substantial equivalence orders what the predicate product was.

The Lung Association urges CTP to put a priority on transparency in its operations and ensure that critical information on CTP's website is kept up to date.

Strategic Goal #3 - Ensure Compliance of Regulated Industry and Tobacco Products Utilizing All Available Tools, Including Robust Enforcement Actions

CTP in Conjunction with Enforcement Agencies Must Step Up Enforcement Against Illegal Tobacco Products

While there have been some promising actions from CTP in conjunction with DOJ and other enforcement agencies over the past year, there remain too many illegal (primarily flavored) e-cigarette products on the market. The focus of enforcement must be at the manufacturer, distributor and importer level. While we are heartened to see warning letters finally being sent to such entities, CTP must swiftly pursue all available remedies, including civil penalties. In some cases, the companies appear to be openly defying marketing denial orders and/or court orders removing them from the marketplace.

The proliferation of e-cigarettes and other tobacco products prior to the deeming rule taking effect – and then the failure to stop new products from coming onto the marketplace once it did take effect – made CTP’s enforcement of the Tobacco Control Act against an industry that does not want to be regulated at all even more difficult. CTP must order all products off the market unless they have a marketing order that shows the product meets the public health standard. However, up to this point the exact opposite has been occurring. Without more robust enforcement, companies have no reason to do anything other than drag their feet, target kids, rack up profits and continue to defy the law.

Strategic Goal #4 - Improve Public Health by Enhancing Knowledge and Understanding of CTP Tobacco Product Regulation and the Risks Associated with Tobacco Product Use

Remove language from the description for this goal that references informing adults about the relative risk of tobacco products

As mentioned in our comments above, the description for this goal included language “and to inform adults who smoke about the relative risks of tobacco products.” The Lung Association strongly recommends this language be removed from the description.

What are measurable short- and long-term outcomes for the proposed goal areas over the next 2 to 5 years?

The Lung Association suggests the following short and long-term outcomes for CTP’s work over the next two to five years.

- CTP should issue and finalize product standards that make tobacco products less attractive, hazardous and addictive. This includes finalizing the menthol and flavored cigar product standards, the reduction in nicotine levels in all tobacco products product standard and the N-nitrosornicotine product standard.
- CTP should finish review of outstanding product applications and remove tobacco products that have not received marketing granted or other orders authorizing the product to be sold from CTP from the marketplace. No flavored product that does not otherwise meet substantial equivalence requirements should receive a marketing order as appropriate for the protection of public health. CTP’s work with enforcement agencies should also be reflected in the strategic plan regarding enforcement.
- CTP should ensure that the information related to which products are legally allowed to be on the marketplace is kept up to date. Public health officials, organizations and others

must be able to know which products are legally allowed for sale. This will allow outside stakeholders to assist with enforcement.

- The ultimate outcome should be reduced commercial tobacco use especially among youth and young adults. The Lung Association is very concerned with the percentage of young adults ages 18-24 who use e-cigarettes but did not smoke cigarettes previously. According to data from the 2021 National Health Interview Survey 61% of young adults who use e-cigarettes fall in this category.¹¹ Reducing initiation with e-cigarettes should be an outcome and removing flavored e-cigarette products from the marketplace will be helpful.

What are three specific actions CTP could take in the next 5 years that would have the most impact in significantly reducing tobacco-related death and disease?

The Lung Association believes these three actions by CTP would generate the most impact towards reducing tobacco-related death and disease, particularly within communities disproportionately impacted by tobacco.

- 1) CTP should finalize its products standards on menthol cigarettes and flavored cigars and move towards implementation.
- 2) CTP should not issue marketing orders for any flavored product subject to pre-market review requirements and should remove all illegal products that do not have an authorization from CTP from the marketplace.
- 3) CTP should implement a track and trace system for tobacco products to be able to track such products through their life cycle, and greatly ease enforcement.

Are there any important features, activities, or initiatives not encapsulated by these proposed goal areas that you believe CTP should consider as part of its strategic plan?

Redirect Resources to Finalize Product Review

Given the length of time past the court-ordered deadline CTP has taken to finalize pre-market tobacco application review from September 9, 2020, and recognizing CTP's finite resources, the Lung Association recommends re-directing resources from other efforts to finalize these reviews.

Work with FTC to Prevent E-cigarette Marketing to Kids on Social Media

The Lung Association has been pleased to see the Federal Trade Commission (FTC) focus its attention more on e-cigarette sales and marketing over the past several years, including issuing [several reports](#) on how the sales and marketing for e-cigarettes have evolved through 2020. We encourage CTP to work with FTC on monitoring and potentially regulating social media marketing to youth. The restrictions Juul agreed to in its recent set of settlement agreements with the states could offer a good model to examine for restrictions that could be applied more broadly.

Other Important Points to Consider

CTP's Mission Does not Align with the Goals of the Tobacco Industry

The tobacco industry is unlike any other industry FDA oversees, and, consequently, the relationship between CTP and industry needs to be different than other FDA centers. There are no shared goals or priorities between CTP and regulated industry – and if it appears there are, then that should be a red flag. The tobacco industry does not share CTP's mission of protecting the public health – or any individual's health. Instead, they are committed to maintaining sales

and addiction to products that are the number one cause of preventable death and disease in this country.

Other Countries' Experiences with Different Policy and Regulatory Environments Are Non-Comparable

The tobacco industry and e-cigarette companies in particular, often make comparisons between regulations in the U.S. and more permissive regulatory environments for their products in other countries such as the United Kingdom. We urge against such comparisons, recognizing there are key differences in policy environments between other countries and the U.S. that make the comparisons invalid. Advertising and marketing of tobacco products in the United Kingdom and other countries is often much more strictly regulated than the U.S. because of First Amendment protections. Tobacco products in other countries often carry larger graphic warning labels of the products effects as well.

Even with these different policy environments, recent data on youth vaping in the United Kingdom, compared to the U.S. and Canada showed some disturbing results. According to data released by the International Tobacco Control Policy Evaluation Project (ITC) from its Youth Tobacco and Vaping Survey in April 2023, vaping among high school students ages 16-19 rose dramatically from August 2021 to August 2022 in the U.K. to 24% from 16% previously, over 50% higher than Canada at 16% and the U.S. at 15%. During the same time period, cigarette smoking among 16–19-year-olds in the United Kingdom also increased from 15% to 21%.¹² This could be an indication that the permissive regulatory environment for e-cigarettes in the United Kingdom that encourages adults to use them is producing unintended consequences.

Conclusion

The American Lung Association appreciates the opportunity to submit comments on CTP's draft strategic plan. We hope this process results in a more focused CTP that moves forward on key regulations and activities that will improve the public health. More can be done and needs to be done to better regulate tobacco products and take products off the market that are not appropriate for the protection of public health.

The American Lung Association looks forward to partnering with CTP as it works on making this strategic plan a reality. Thank you.

Sincerely,



Harold P. Wimmer
National President and CEO

¹ U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

² U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years

of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

³ Anderson, Stacey J. "Marketing of menthol cigarettes and consumer perceptions: a review of tobacco industry documents." *Tobacco control* vol. 20 Suppl 2, Suppl_2 (2011): ii20-8. doi:10.1136/tc.2010.041939

⁴ Substance Abuse and Mental Health Services Administration's public online data analysis system (PDAS). National Survey on Drug Use and Health, 2021.

⁵ Ibid.

⁶ Mendes D, Le TTT. Consequences of a match made in hell: the harm caused by menthol smoking to the African American population over 1980-2018. *Tob Control*. 2021 Sep 16:tobaccocontrol-2021-056748.

⁷ Tobacco Products Scientific Advisory Committee, U.S. Food & Drug Administration, Menthol cigarettes and Public Health: Review of the Scientific Evidence and Recommendations (2011)

⁸ "Menthol and Other Flavors in Tobacco Products." U.S. Food & Drug Administration, April 29, 2021. <https://www.fda.gov/tobacco-products/products-ingredients-components/menthol-and-other-flavors-tobacco-products>

⁹ FDA. Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes (2013)

¹⁰ J. Chung-Hall, G.T. Fong, G. Meng, K.M. Cummings, A. Hyland, R.J. O'Connor, A.C.K. Quah, and L.V. Craig, "Evaluating the impact of menthol cigarette bans on cessation and smoking behaviors in Canada: longitudinal findings from the Canadian arm of the 2016-2018 ITC Four Country Smoking and Vaping Surveys," *Tobacco Control*, 31-Mar-2021. [Online]. Available: <https://tobaccocontrol.bmj.com/content/early/2021/03/31/tobaccocontrol-2020-056259>.

¹¹ [QuickStats: Percentage Distribution of Cigarette Smoking Status Among Current Adult E-Cigarette Users, by Age Group — National Health Interview Survey, United States, 2021](#). *MMWR Morb Mortal Wkly Rep* 2023;72:270.

¹² Hammond D, Reid JL, Burkhalter R, Hong D. Trends in Smoking and Vaping Among Young People: Findings from the ITC Youth Surveys. April 2023; University of Waterloo.