

President Joseph R. Biden Jr.
The White House
1600 Pennsylvania Avenue NW Washington, D.C. 20500

Copy to: Office of Management and Budget, Office of Information and Regulatory Affairs
Via email at OIRA-submissions@omb.eop.gov.

Subject: Urgent Appeal to Reconsider Proposed FDA Rule on Menthol in Cigarettes, Docket No. FDA-2021-N-1349 (“Tobacco Product Standard for Menthol in Cigarettes”)

Dear President Biden,

I hope this message finds you well. I am writing to urgently bring to your attention a recent development concerning the Food and Drug Administration's (FDA) submission of a proposed rule - Docket No. FDA-2021-N-1349 (“Tobacco Product Standard for Menthol in Cigarettes”) (“Menthol Proposed Rule”) to the Office of Management and Budget (OMB) for final review.

The undersigned represent themselves and also small and medium size distribution and retail businesses engaged in, among other, sales of nicotine products, including cigarettes.

In these difficult times, when citizens and small businesses are uncertain about their economic future, gravely impacted by inflation and their purchasing power, by domestic polarization and international unrest, and by the ever-increasing burden of taxes and regulation, it is imperative that the Administration listen to, and represent, its constituencies to continue to enjoy the trust and support received so far.

In brief, we submit to you that **FDA did not meet the legal criteria to adopt the Menthol Proposed Rule** - meaning the rule must be “appropriate for the protection of the public health”—a standard which requires FDA to consider both the rule’s benefits and its harms. Concretely, as required by the Family Smoking prevention and Tobacco Control Act (the “Statute”), before finalizing the rule FDA must consider:

- Scientific evidence concerning the risks and benefits to the population as a whole, which includes both users and non-users of tobacco products.
- The increased or decreased likelihood that tobacco users will stop using the products at issue and that non-users will start using the products at issue; and
- All other information submitted in connection with a proposed tobacco product standard, including countervailing effects on the health of users and non-users, such as the creation of a significant demand for contraband. (FDCA §§ 907(a)(3)(B)(i), 907(b)(2), 21 U.S.C. §§ 387g(a)(3)(B)(i), 387g(b)(2).)

Further, we believe that **FDA has not evaluated fully and accurately the costs and benefits of the rule**, in particular in light of the effects on menthol bans in domestic and foreign jurisdictions (e.g., California, Canada, and the European Union member states); has not evaluated the potential interactions and significance to Indian Tribal Governments; has taken 12 years to draft a rule that, in its relevant part, is a total of merely three lines long, without describing the mechanism of implementation, timing of compliance, and any other elements necessary for the rule’s effectiveness, and generally has rushed this rule to OMB only a few months after receiving 175, 557 comments to the Menthol proposed Rule docket, which FDA could not have reasonably evaluated and investigated in such a short period of time. Among other, various comments submitted to the Menthol Proposed Rule docket point out to the arbitrary and capricious nature of the ban under the Menthol Proposed Rule, and violations of the Constitution, which comments we urge your Administration, as protectors of our Constitution, to examine carefully.

Respectfully, we are therefore requesting that your Administration consider sending this rule back to the FDA for further review, rewrite and thoughtful analysis of stakeholders' comments received by FDA to date, which may require commissioning additional effectiveness studies and reopening the docket for comments.

Background

We appreciate that the balance between protecting public health and safeguarding individual freedoms and economic interests is a delicate one.

Cigarette smoking and menthol cigarette smoking is at an all-times low in the United States and has steadily declined since 2001, with youth smoking seeing the steepest declines ever. At the same time, a multitude of other health perils, such as obesity, alcoholism, and opioid addiction, are on dramatic rise, while healthcare is beyond affordability for many citizens, unacceptably so when compared to other developed nations. While smoking remains an important concern, the urgency to promulgate a rule on menthol cigarettes without careful consideration of all factors may result in novel burdens on our society's existing challenges and may escalate unwanted consequences.

The proposed rule aims to ban the sale of menthol cigarettes, which is a matter that requires thoughtful regulatory action given the likelihood of significant impact of this rule throughout the small business community, on state and federal tax revenue, and on the security and safety of the citizens due to the distinct probability of increased black market criminal activity following a menthol ban.

The rule, in relevant part, is merely three lines:

“Subpart B—Product Standard for Menthol in Cigarettes

§ 1162.5 Prohibition on use of menthol as a characterizing flavor in cigarettes.

A cigarette or any of its components or parts (including the tobacco, filter, wrapper, or paper, as applicable) shall not contain, as a constituent (including a smoke constituent) or additive, menthol that is a characterizing flavor of the tobacco product or tobacco smoke.”

These three lines of the Menthol Proposed Rule lack any clear direction as to how exactly would the “absence of menthol” be quantified and enforced, and do not even define “menthol”. Further, the Menthol Proposed Rule relies on a subjective determination of what is a “characterizing flavor” - a concept not measurable by any known method, a term *not even defined* in the Statute, and therefore placing the entire Menthol Proposed Rule, as currently drafted, *outside of the scope of the authority granted to FDA by Congress* for rulemaking in connection with tobacco products.

These are grave flaws in the Menthol Proposed Rule, which will give opportunities to creative ways to circumvent the rule's intended outcome; will render the rule, when finalized, vulnerable to legal challenges, and will create a situation of uncertainty that can last for many years. This situation will primarily hurt retailers, distributors, and consumers.

Beyond the lack of clarity and completeness of the Menthol Proposed Rule, we respectfully submit that OMB is best positioned to urge FDA to carefully and holistically consider at a minimum the following factors, which, in our humble opinion, were likely to be disregarded or subjectively and insufficiently addressed in FDA's review of the state of the market, of the docket comments it received in 2013 as a result of the Advanced Notice of Proposed Rulemaking (Docket No FDA-2013-N-0521-0079):

1. **Complex Nature of the Use and Trade Patterns of Various Types of Tobacco Products:** The patterns of use and trade in tobacco products are complex and subject to numerous factors. The correlation among various patterns of nicotine products use, consumer behaviors when faced with a ban (such as at-home mentholation, switch to flavored cannabis products with the afferent health and behavioral consequences, and mental health impact) as well as illicit market dynamics, price elasticity, substitution, , and the impact on the supply chain, must be carefully and holistically examined

before engaging in sweeping rulemaking that will affect roughly 37% of the entire US market and the underlying supply chain.

2. **Harm Reduction Strategies:** The ongoing debate about the role of harm reduction strategies in reducing the health risks associated with tobacco use should be fully explored. Harm reduction alternatives offer viable options to those unable or unwilling to quit nicotine, and accelerate the demise of smoking altogether, as we have seen happening both domestically and internationally with the introduction of vaping products and oral nicotine products, to the point where Sweden has become this year the first smoke-free country on account of use of oral tobacco and nicotine products. Conversely, jurisdictions impacted by flavor bans such as San Francisco seem to have seen an increase in smoking combustibles by youth.
3. **Economic Impact Analysis:** A robust economic impact analysis has not been conducted. Such analysis should involve: modeling of impact on jobs, tax revenues, government programs; trust in government; impact on licensed and regulated retail businesses; escalating law enforcement costs; impact on mental health costs; illicit market increase; revenue growth for the criminal organizations which fund, among other, human and weapons trafficking; a thorough review of the case studies in jurisdictions where menthol products have been banned, with mixed results - such as California, Canada, and the European Union member states.
4. **Prohibition Lessons:** The lessons of history, particularly the era of alcohol prohibition in the United States, show that outright bans will inevitably lead to dramatic unintended consequences.
5. **Social Justice Considerations:** A ban on menthol tobacco products is likely to disproportionately affect minorities, some of which prefer menthol products, marginalized communities, and small and medium enterprises, potentially deepening existing social and economic disparities and fueling social unrest.
6. **Measuring the Real Reasons Behind Increase in Healthcare Costs.**
7. **FDA's Premarket Review of New Tobacco Products Applications.** FDA reviews every new tobacco product application and makes a product-by-product determination regarding the marketing of the respective product under the "appropriate for the protection of public health" standard. Thus, FDA has ample opportunity to evaluate risks and benefits of each menthol-flavored products before allowing new market entries, and should accelerate and prioritize the review of products with vastly reduced risk profiles compared to cigarettes, in order to provide consumers incentives to move away from all combustible cigarettes,
8. **Current Enforcement Failure against Illicit Tobacco Products.** FDA itself acknowledged that it does not have the resources to fight the illicit market in tobacco products, which currently feeds the US market with products worth billions of dollars - all untaxed, unregulated and potentially unsafe products, most of which are preferred by youth. We urge that the seeming health benefits of removing regulated menthol products out of the legal economy be weighed against the eventual realistic consequence of ultimately finding unregulated menthol products offered through illicit trade channels, benefiting crime and allowing unregulated products and sales practices as a consequence of weak or lacking FDA enforcement. If we have already lost that battle, how can we hope to win against the illicit trade that will ensue as a natural consequence of a menthol ban?
9. **Wise Regulation Over Prohibition:** It is essential to explore regulatory alternatives that emphasize enforceable regulatory measures, such as better age verification tools, more aggressive enforcement, consumer, school, and parental education, incorporating harm reduction alternatives into smoking cessation programs, as it was successfully done in the United Kingdom by the UK government, and providing consumers with a clear understating of the continuum of risk of various nicotine products so that cigarettes become a relic of the past.

To support these arguments, we have enclosed as Exhibit A a list of relevant studies and documents, with hyperlinks, for your consideration.

Again, it is in the spirit of creating an enforceable, sustainable, and effective regulatory framework that we respectfully request your administration to instruct OMB to send the Menthol Proposed Rule to the FDA for holistic reconsideration, to carefully assess the consequences of a proposed menthol ban and consider alternative regulatory approaches that properly balance public health concerns while respecting individual rights and minimizing unintended repercussions.

I understand the gravity of the decisions facing your administration, and I am grateful for your dedication to public health and well-being. However, given the colossal ramifications the Menthol proposed Rule would have on small businesses and citizens across the United States, I kindly request your prompt attention to this matter, as it holds profound implications for public health, constitutionally protected individual freedoms, and economic survival.

Thank you for your time and consideration.

Sincerely,

Hamid Rezaeepour

Sr Director Retail Strategy

United Pacific

Enclosure: Exhibit A

EXHIBIT A

Relevant Studies

Center for Regulatory Effectiveness -An Inquiry into the Nature, Causes and Impacts of Contraband Cigarettes, 2011 chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.thecre.com/ccsf/wp-content/uploads/2011/06/AnInquiryIntoContrabandCigarettes.pdf

KPMG Report - A study of the illicit cigarette market in the European Union, Norway and Switzerland chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://assets.kpmg.com/content/dam/kpmg/pdf/2016/06/project-sun-report.pdf

Liber, Alex C. and Stoklosa, Michal J. and Levy, David and Sánchez-Romero, Luz María and Cadham, Christopher J. and Pesko, Michael, A Bite-Style Model to Evaluate Poland's Menthol Cigarette Ban. Available at SSRN: <https://ssrn.com/abstract=3946277>

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Convenience Industry Council of Canada <https://www.newswire.ca/news-releases/covid-19-shutdown-of-illegal-tobacco-manufacturing-and-sale-leads-to-spike-in-legal-cigarette-sales-805424084.html>

Neill Franklin, Executive Director of LEAP, Opinion: Ban on Menthol Cigarettes Would Have Unintended Consequences, City Limits (Dec. 2, 2019), <https://tinyurl.com/rdezamds>

Christopher S. Carpenter & Hai V. Nguyen, Intended and Unintended Effects of Banning Menthol Cigarettes, 64 J.L. & Econ. 629, 629 (2021) ("Carpenter & Nguyen, Intended and Unintended Effects of Banning Menthol Cigarettes"), <https://tinyurl.com/48v82m6b>

Ulrik Boesen, Massachusetts Flavored Tobacco Ban: No Impact on New England Sales, Tax Foundation (Feb. 3, 2022) ("Boesen, Massachusetts Flavored Tobacco Ban"), <https://tinyurl.com/2p8jw2t6>

Ulrik Boesen, Cigarette Taxes and Cigarette Smuggling by State, 2019, TAX FOUND. FISCAL FACT 782, 7 (Nov. 2021), <https://files.taxfoundation.org/20211201101747/Cigarette-Taxes-and-Cigarette-Smuggling-by-State-2019.pdf>.

FDA, Draft Concept Paper: Illicit Trade in Tobacco Products after Implementation of an FDA Product Standard 13 (Mar. 15, 2018), <https://tinyurl.com/fz7yhpui>

FDA "there is uncertainty in precisely quantifying the [ban's] effects." 87 Fed. Reg. at 26,482

U.S. State Dep't, The Global Illicit Trade in Tobacco: A Threat to National Security 12 (Dec. 2015), <https://tinyurl.com/650w2ytw>

Kahnawake Men on Trial for Organized Crime Charges From SQ's Largest Tobacco Smuggling Bust, CBC (Apr. 26, 2019), <https://tinyurl.com/3rdxzeod>

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