COALITION OF MANUFACTURERS OF SMOKING ALTERNATIVES (CMSA)

1/5/2024

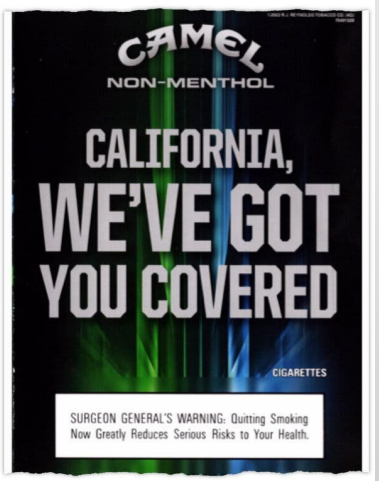
EO 12866 Meeting
re Tobacco Product Standard for Menthol in Cigarettes

FDA must consider the unintended consequences of banning menthol in cigarettes.

- While CMSA supports FDA's goal of shifting consumers away from combusted cigarettes, FDA's proposed regulation to ban menthol in cigarettes in the United States (the Product Standard) may have indirect impacts on companies trying to shift toward lower risk alternatives to combusted products.
- As proposed, the Product Standard is vague and unenforceable.
- FDA has failed to consider less burdensome alternatives – including access restrictions.
- FDA has underestimated the demand for an illegal market that will result from a prohibition of menthol cigarettes, and the associated public health and national security threats.
- FDA has underestimated the detrimental economic impact of the Product Standard, including the impacts of a black market and shifting tax burdens to lower risk products.

As Proposed, the Product Standard is Vague and Unenforceable

- The definition of a characterizing flavor fails to provide much needed clarity to manufacturers and law enforcement regarding what constitutes "menthol that is a characterizing flavor"
  - There is no discernable provision to **test** the products, there is no provision for **measurement** of what might constitute a characterizing flavor, and no testing requirement that would allow a manufacturer to **demonstrate** compliance – running counter to the basic tenants of a product standard as contemplated by the Tobacco Control Act
- The lived experience of California law enforcement officers enforcing local and state flavored product bans sheds light on the practical barriers FDA is likely to face in implementing such a vague standard*
  - Multisensory evaluation
  - Ambiguity in product naming, labeling, and marketing
    - Introduction of "non-menthol" alternatives
  - Migration to gray or black markets**
  - Resulting disputes and litigation re a product's classification



For CMSA, the adoption of this definition of characterizing flavor across product categories is concerning precedent for **new product development** – leaving manufacturers to guess whether their products will be considered to have a "characterizing flavor" and potentially subject to heightened regulatory scrutiny

*See "Challenges in Enforcing Local Flavored Tobacco Restrictions," California Department of Public Health (2019).

**Empty Packs Survey, WSPM Group or Altria (study shows that the flavor ban has had limited effect on the access or demand for flavored vapor products throughout the entire state. The results of the study include: Of the vapor packs found, almost all (97.9 percent) were flavored); Donaldson SI, Beard TA, Colonna R, et al. Online Purchase Attempts of Flavored E-Cigarettes to Minors in California Before and After Senate Bill 793. JAMA Netw Open. 2023;6(12):e2348749. doi:10.1001/jamanetworkopen.2023.48749.

FDA has Failed to Consider Less Burdensome Alternatives

- E.O.s 12866 and 13563 direct FDA to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits
- The Proposed Product Standard received over **175,000** comments on the record, many of which set forth less burdensome alternatives to address the *youth use* and *health equity* problems cited as drivers for implementation
  - Intensified efforts to enforce Tobacco-21*
  - Public education campaigns
  - Marketing and sales-based restrictions to limit youth access and appeal
- In fact, FDA itself has previously suggested that such alternatives help demonstrate that a menthol-flavored product is appropriate for the protection of public health. For example, in its reviews of premarket tobacco product applications (PMTAs) for electronic nicotine delivery system (ENDS) products, FDA says that it "considers the impact of marketing restrictions and other mitigation efforts", including:
  - Advertising and promotion restrictions
  - Sales access restrictions
  - Device access restrictions
- In line with this guidance, Juul Labs recently submitted PMTAs for next-generation menthol-flavored pods with product-level access controls** and other manufacturers have voluntarily committed to marketing and sales restrictions.***

*Agaku IT, Nkosi L, Agaku QD, Gwar J, Tsafa T. A Rapid Evaluation of the US Federal Tobacco 21 (T21) Law and Lessons From Statewide T21 Policies: Findings From Population-Level Surveys. Prev Chronic Dis 2022;19:210430. DOI: http://dx.doi.org/10.5888/pcd19.210430

**"Juul Labs Submits PMTA for Next-Generation Menthol-Flavored Pods with Device-Level Locking." available at: https://www.juullabs.com/ngp-pmta-menthol-locking/

***see, e.g., NJOY Marketing Granted Orders, available at: https://www.fda.gov/media/165233/download?attachment

The Underestimated Demand for an Illegal Market for Menthol Cigarettes

- In the Proposed Rulemaking, FDA states that it does not anticipate that there will be a large supply of illicit menthol cigarettes following implementation of the standard.
- Conversely, new empirical evidence on the likely impacts of the Proposed Product Standard demonstrates a much larger consumer demand from illegal menthol cigarette markets than estimates from research reviewed in FDA's regulatory impact assessment.
  - Dr. Kenkel and team* conducted a sophisticated discrete choice experiment (DCE) to address the key question of what current menthol smokers might do if a ban on menthol cigarettes was enacted in the U.S.;
  - The authors then ran an econometric model, informed by the DCE findings, which accounted for a range of policy scenarios;
  - The results indicate that consumer demand for illicit cigarettes will be from **48-97%** as large as the status quo demand, whereas estimates relied upon by FDA suggest that only **6.5%** of menthol smokers will purchase illegal menthol cigarettes;
  - The availability of menthol e-cigarettes also will impact consumer choices, with a prohibition of menthol e-cigarettes shifting consumers back towards menthol cigarettes. To date, FDA has not authorized any menthol e-cigarettes.

- In light of this evidence, the cost-benefit analyses should be reconsidered with re-estimation of the **likelihood that smokers would continue to seek out and use illicit menthol cigarettes** versus the **likelihood that smokers would quit or completely switch to another tobacco product**

*Yu-Chun Cheng, Donald S. Kenkel, Alan D. Mathios, Hua Wang, "Are Menthol Smokers Different? An Economic Perspective", National Bureau of Economic Research Working Paper Series (July 2022, rev. August 2023). available at: https://www.nber.org/system/files/working_papers/w30286/w30286.pdf

Heightened Illicit Tobacco Trafficking is a Public Health and National Security Threat

- Given the **18.5 million** current menthol smokers, substantial consumer demand raises the likelihood of active illegal market supply-side responses.
- FDA indicates that it can devote resources to enforcement to manage an illicit market. However, FDA has not demonstrated its ability to effectively enforce against banned products.
  - A large illicit tobacco trade already exists. An estimated **7%-21%** of cigarettes consumed in the United States are purchased illicitly.*
  - FDA has had little success in enforcement against flavored tobacco products to date.**
  - In states with menthol bans, including Massachusetts and California, robust markets for illicit cigarettes have formed.***
- The dangers posed by illicit markets are significant***
  - Illicit tobacco product operations **involve corruption**, **money laundering**, and **terrorism**.
  - Illicit tobacco product sales ***hurt consumers*****,** because the products fail to adhere to health standards.
  - Illicit tobacco product sales ***harm governments*****,** because of lost revenue.
  - Illicit tobacco product markets ***hurt legal businesses*****,** which are unable to complete with illicit products.
- Congress has expressed its concerns about the national security threat that the illicit trafficking of tobacco products continues to pose,**** and the Administration must consider the impacts of this rulemaking on the growing production and distribution of illegal cigarettes.

*National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, "Preventing and Reducing Illicit Tobacco Trade in the United States" available at: https://www.cdc.gov/tobacco/stateandcommunity/pdfs/illicit-trade-report-508.pdf

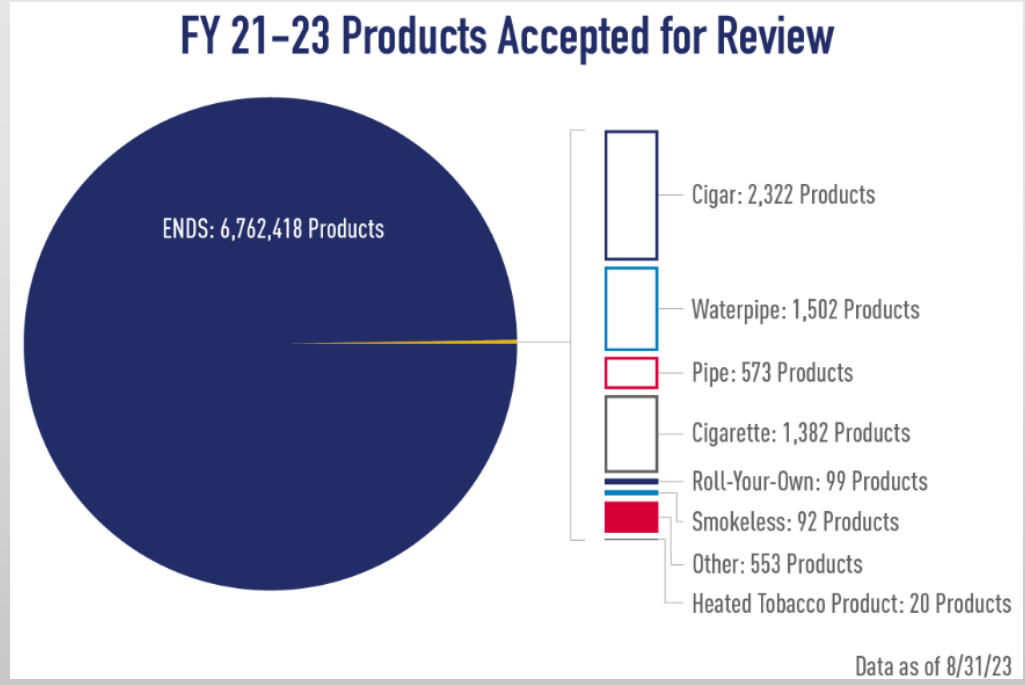
** CDC Foundation, "Monitoring US E-Cigarette Sales: National Trends" (June 2023) (showing that despite heightened enforcement efforts, flavored vape sales have surged 60% over the past 3 years)

***Adam Hoffer, "Taxes and Illicit Trade" Tax Foundation (August 10, 2023) available at: https://taxfoundation.org/blog/illicit-trade-taxes-counterfeit-cigarettes/

****Letter from US Senators Bill Cassidy, Mark Warner, Bob Casey, Marco Rubio, and Bill Hagerty to US Secretary of State Antony Blinken (August 4, 2023), available at: https://www.cassidy.senate.gov/wp-content/uploads/media/doc/illicit_tobacco_trafficking_letter.pdf

The Product Standard Would Further Burden Premarket Reviews

- FDA's Center for Tobacco Products (CTP) is overburdened with premarket review applications,* with a substantial backlog of both premarket tobacco product applications (PMTAs) and substantial equivalence applications (SEs), the majority of which have been pending review for several years
- The Proposed Product Standard contemplates the use of premarket review pathways for modifications to would-be banned products
- The failure of CTP to clearly set out basic elements of its premarket review process to date has resulted in confusion, inefficiency, litigation, and suspicions of political interference,** which will only be heightened by another bolus of applications resulting from this rulemaking
- While FDA estimates costs for "reallocation" of manufacturers' resources to other tobacco products, it does not consider that the ban may have the reverse effect of diverting time, attention, and funding away from new product review and development



Source: FDA Review Metrics

*See Report from Office of Inspector General, "The Food and Drug Administration Needs to Improve the Premarket Tobacco Application Review Process for Electronic Nicotine Delivery Systems to Protect Public Health" ;

**See Oversight Committee Letter to FDA, responding the Reagan-Udall Report, available at: https://oversight.house.gov/release/comer-probes-fdas-tobacco-and-nicotine-regulatory-programs-riddled-with-uncertainty/

Widespread, Detrimental Economic Impact

Excise Tax Base

If FDA bans menthol cigarettes, federal and state governments stand to lose more than **$6.6 billion** in the first full year following prohibition*

Shifting Tax Burden

Losses at the Federal and State level will trigger a shifting in tax burdens, with an **increased tax placed on products lower on the risk continuum** (e.g., smokeless products)

User Fees

The loss of user fees for menthol cigarettes and/or flavored cigars, compounding on lost user fees for premium cigars, will result in reallocation that has yet to be fully fleshed out and will likely result in a deficiency in funding in the interim. Yet, FDA has expressed a need to secure *additional* user fees in order to carry out its basic duties.

*Tax Foundation Comments on Tobacco Product Standard for Menthol Cigarettes), available at: https://taxfoundation.org/blog/fda-ban-menthol-cigarettes/