

## **AGENDA**

### **Cigar Rights of America**

#### **12866 Meeting with the Office of Information and Regulatory Affairs**

**April 6, 2022**

#### **Re: HHS/FDA “Tobacco Product Standards for Characterizing Flavor in Cigars” (0910-AI28)**

- I. Introductions
- II. Background on Industry and Impacts (Cory Bappert)
  - A. Background on industry
  - B. Discussion of flavor in premium cigars
- III. Characterizing Flavor in Tobacco Products
  - A. Premium Cigars do not have characterizing flavor
  - B. Advertisements may discuss subtle notes of aroma and flavor, but the flavor is tobacco
  - C. FDA has always recognized this and we hope that will continue to be the case
  - D. In 2020, California law used an overbroad measure that included aroma
    - 1. Notably exempted premium cigars
  - E. Would essentially prohibit all cigar sales in current form
    - 1. \$1.5 billion industry
- IV. March 2022 NASEM Report
  - A. *Children do not smoke premium cigars.*
    - 1. Aligns with what we have seen in NYTS for years. Reasonable extrapolations show about 0.1% and the numbers have been falling for years
  - B. *Consumers typically smoke their first premium cigar at age 25.*
  - C. *Consumers smoke premium cigars in moderation, typically 1 cigar per month.*
  - D. *The health effects of premium cigars have not been fully studied.*
  - E. *Smoking one cigar per day does not significantly increase the risk of mortality.*
  - F. *“Premium cigar smokers and never-tobacco users had similar prevalence of cancer, heart condition, COPD, and asthma.”*
- V. Need for Clear Definition of Premium Cigars and Research (Drew Perraut)
  - A. Mehta Decision (2020)
    - 1. Enjoined aspects of deeming rule that included premium cigars
    - 2. Insufficient study of premium cigars as a category distinct from mass market cigars

3. FDA needed to consider them as an individual class to meet the requirements of the Administrative Procedures Act

B. NASEM Report (March 2022)

1. Handmade
2. Filler composed of at least 50 percent natural long-leaf filler tobacco
3. Wrapped in whole leaf tobacco (i.e., not reconstituted tobacco)
4. Weight of at least 6 pounds per 1,000 units (i.e., 2.72 g per stick)
5. No filters or tips
6. No characterizing flavor other than tobacco

- C. Need for OIRA to work with CDC and FDA for studies on premium cigars as a category in NYTS and other investigations

VI. Summary

- A. FDA should maintain its traditional definition of characterizing flavor
- B. Costs of including premium cigars in a characterizing flavor ban would be large and the benefits, for children or adults, would be vanishingly small
- C. OIRA should work with FDA and CDC to include study of premium cigars as a category

VII. Questions