



# STUDY ON THE PATTERNS OF USE AND HEALTH EFFECTS OF “PREMIUM” CIGARS AND PRIORITY RESEARCH

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# AGENDA

The logo for the U.S. Food and Drug Administration (FDA), consisting of the letters "FDA" in white on a blue square background.

- 1. HHS Personnel**
- 2. Background on Cigar Use in the United States**
- 3. FDA/CTP Regulatory Authority**
- 4. Task Objectives & Deliverables**
- 5. Discussion and Questions**



# HHS Personnel



# INTRODUCTION OF HHS PERSONNEL



FDA & NIH are co-sponsoring this project

**NIH** is the contractual lead sponsor *responsible for all deliverable & communication between the parties*

**Shari Feirman, PhD**

*NIH Task Leader and primary Point of Contact with NASEM*

*Public Health Analyst, Clinical and Healthcare Research Policy Division, Office of Science*

**Stuart Nightingale, MD**

*Alternate NIH Task Leader*

*Consultant/contractor, Clinical and Healthcare Research Policy Division, Office of Science Policy*

**FDA** requested & funded this study *requirements & outcomes of the project are based on FDA's needs*

**Lisa Lagasse, PhD**

*FDA Point of Contact*

*Social Scientist, Center for Tobacco Products, Office of Science*



# Background on Cigar Use in the United States



# YOUTH CIGAR USE IN THE UNITED STATES

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- In 2020, cigars were most common combustible product among youth
  - 3.5% (960,000) of U.S. middle school & high school youth used cigars<sup>1</sup>
- Current cigar smoking by non-Hispanic blacks
  - 9.2% high school students
  - 3.1% middle school students
- Trends in youth smoking 2011-2018
  - Significant declines in cigar use<sup>2</sup>
  - Flavors continue to be an important factor in cigar use<sup>3</sup>

1. Gentzke AS, Wang TW, Jamal A, et al. Tobacco Product Use Among Middle and High School Students — United States, 2020. MMWR Morb Mortal Wkly Rep 2020; 69:1881–1888

2. Gentzke AS, Creamer M, Cullen KA, et al. Vital Signs: Tobacco Product Use Among Middle and High School Students — United States, 2011–2018. MMWR Morb Mortal Wkly Rep 2019;68:157–164.

3. Rostron BL, Cheng YC, Gardner LD, Ambrose BK. Prevalence and Reasons for Use of Flavored Cigars and ENDS among US Youth and Adults: Estimates from Wave 4 of the PATH Study, 2016-2017. Am J Health Behav. 2020 Jan 1;44(1):76-81.

# ADULT CIGAR USE AND POPULATION HEALTH BURDEN IN THE UNITED STATES



- 3.6% of U.S. adults used cigars in 2019 (8.7 million)<sup>4</sup>
  - Majority of users are male
  - 2000-2015: Cigar use increased among female & non-Hispanic blacks<sup>5</sup>
- Cigar use is associated with various forms of cancer (including lung & oral), coronary heart disease, & all-cause mortality<sup>5,7</sup>
- Overall population health burden of regular cigar smoking among U.S. adults ages ≥35 estimated to be ~9,000 deaths per year<sup>8</sup>

4. U.S. Centers for Disease Control and Prevention (2019) Tobacco Product Use among Adults – United States, 2019 [Tobacco Product Use Among Adults—United States, 2019 \(cdc.gov\)](https://www.cdc.gov/tobacco/data_trends/2019).

5. Rostron BL, Corey CG, Gindi RM. Cigar smoking prevalence and morbidity among US adults, 2000-2015. *Prev Med Rep.* 2019 Feb 11;14:100821.

6. National Cancer Institute. Cigars: Health Effects and Trends. Tobacco Control Monograph No. 9. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute. NIH Pub. No. 98-4302, February 1998.

7. Chang, C.M., Corey, C.G., Rostron, B.L. et al. Systematic review of cigar smoking and all cause and smoking related mortality. *BMC Public Health* 2015; 15: 390.

8. Nonnemaker J, Rostron B, MacMonegle A et al. Mortality and Economic Costs From Regular Cigar Use in the United States, 2010 *Am J Pub Health* 2014; 104: e86\_e91.



# FDA/CTP Regulatory Authority





# TOBACCO CONTROL ACT GIVES FDA/CTP REGULATORY AUTHORITY

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Passed June 2009, recognizes FDA as “primary federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products”

Originally applied to all cigarettes, cigarette tobacco, roll-your-own tobacco, & smokeless tobacco

August 2016: FDA’s authority was extended to regulate all products meeting the definition of a tobacco product, including cigars



# CIGAR SUBTYPES

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- “Cigar” means a tobacco product that:
  - Is not a cigarette and
  - Is a roll of tobacco wrapped in leaf tobacco or any substance containing tobacco<sup>5</sup>
- Four general subtypes of cigars marketed in the U.S., which are generally defined as follows:
  - *“Premium” cigars*: studies have not used a single, consistent definition
  - *Filtered cigar/little cigar*: cigars that are usually brown & have a filter like a cigarette
  - *Cigarillo*: medium-sized cigars & sometimes come with plastic or wood tips
  - *Other traditional cigars*: Large cigars that do not fall into one of the other categories



5. Food and Drug Administration. Regulation of flavors in tobacco products (21 CFR Parts 1100, 1140, and 1143). Fed Regist 2018;83  
<https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products>



# Task Objectives & Deliverables



# PROJECT OBJECTIVE & APPLICATION

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## Objective

Conduct comprehensive & systematic assessment of the public health issues related to “premium” cigars as well as the health effects of “premium” cigars compared to other tobacco products

## Application

FDA will use the results in building the evidence base to inform the development of policy options & to evaluate the impact of FDA regulatory efforts



# LITERATURE REVIEW

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Describe patterns of use for “premium” cigars & how patterns may differ

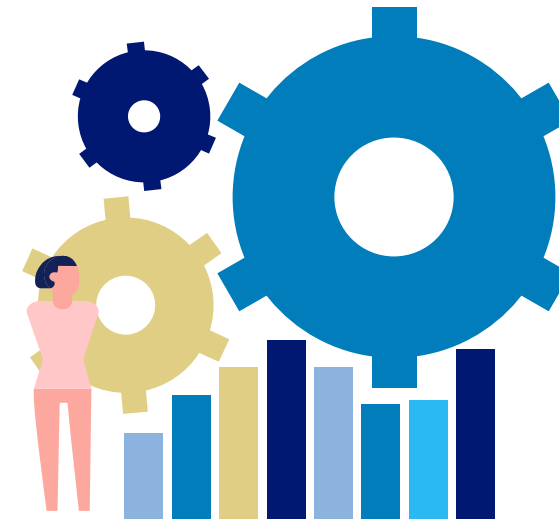
- Among cigar subtypes and other tobacco products
- By different populations (e.g., types of tobacco users, age, & other demographics)

Analyze data on both short- & long-term health effects of “premium” cigars, including but not limited to:

- Health effects associated with the use of “premium” cigars
- Comparison of other cigar subtypes and other tobacco products
- Explanation of how health effects may vary by population
- Explanation of how variations in the patterns of use for “premium” cigars & other cigar subtypes may impact health outcomes
- Exposure to harmful and potentially harmful constituents in the tobacco & smoke & associated toxicity, among cigar users & non-users

Provide description of populations who use “premium” cigars versus those who use:

- Other cigar subtypes
- Other tobacco products (including demographic characteristics, tobacco use status, & factors that influence potential use)



# RESEARCH QUESTIONS MAY INCLUDE



## Patterns of Use

- What is known about the characteristics of “premium” cigars that cause people to start using them & continue using them?
- How are those characteristics similar to or different from characteristics of other tobacco products?

## Health Effects among Users

- What are the short- & long-term health effects of “premium” cigar?

## Health Effects in Non-Users

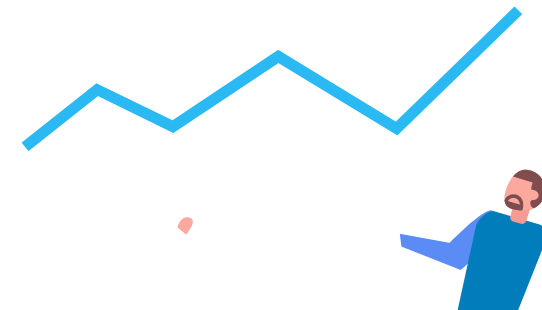
- What are the short- & long-term health effects (cancer and noncancer) of secondary and tertiary exposure to “premium” cigar smoke?

## Abuse Liability

- What is known about the pharmacokinetics of plasma nicotine in “premium” cigar smokers in prescribed & ad libitum smoking regimens?

## Measurement

- Due to the varying sizes of cigars, what is the most accurate way to measure exposure?



# SOME GUIDELINES

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The committee should identify:

- Research, data, & other evidence used to inform its analysis & conclusions
- Key research gaps
- References or other information considered by the Committee that were provided by, or funded by, any parties that would be directly affected by a change to the regulation of “premium” cigars





# Discussion and Questions

