

AN UPDATE ON PROGRAMMATIC ACTIVITIES FROM FDA'S CENTER FOR TOBACCO PRODUCTS

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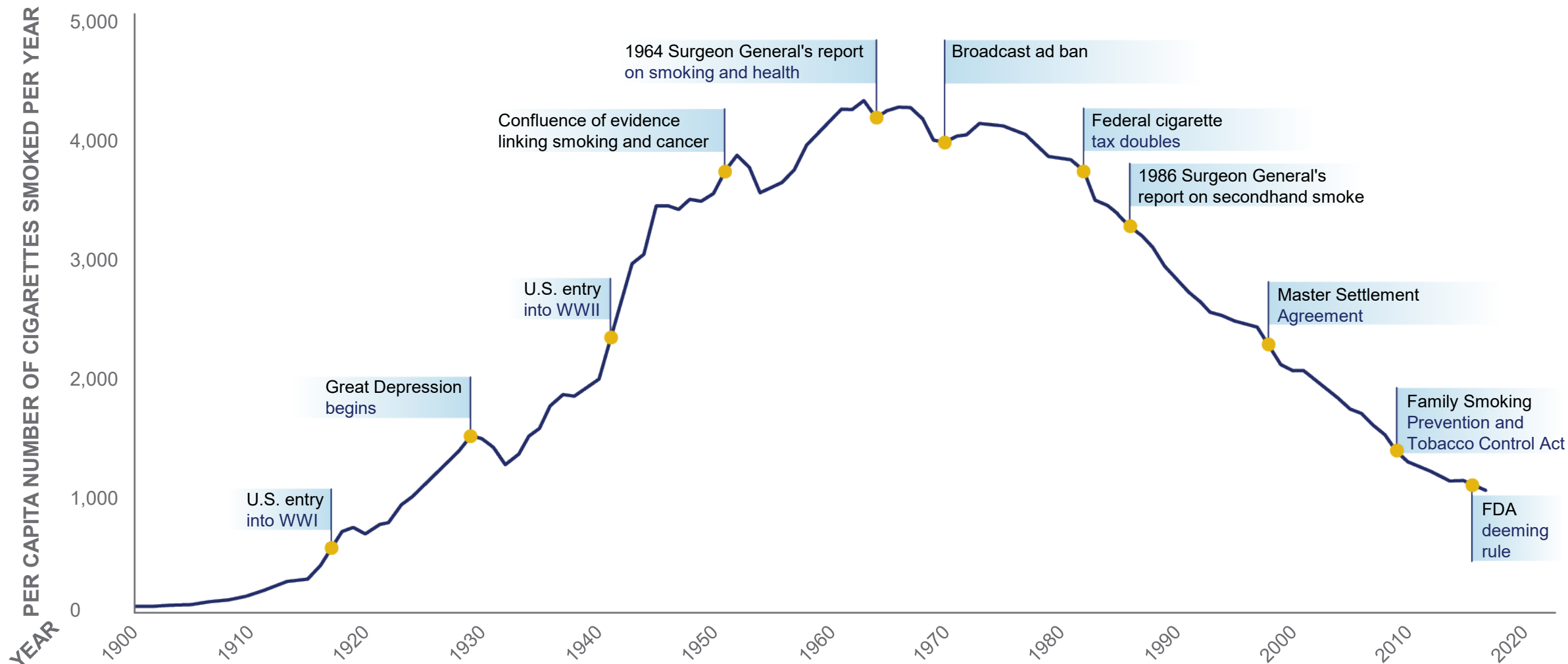


AGENDA

- Current State of Tobacco Use in the U.S.
- CTP Overview
- Programmatic Updates
- Resources

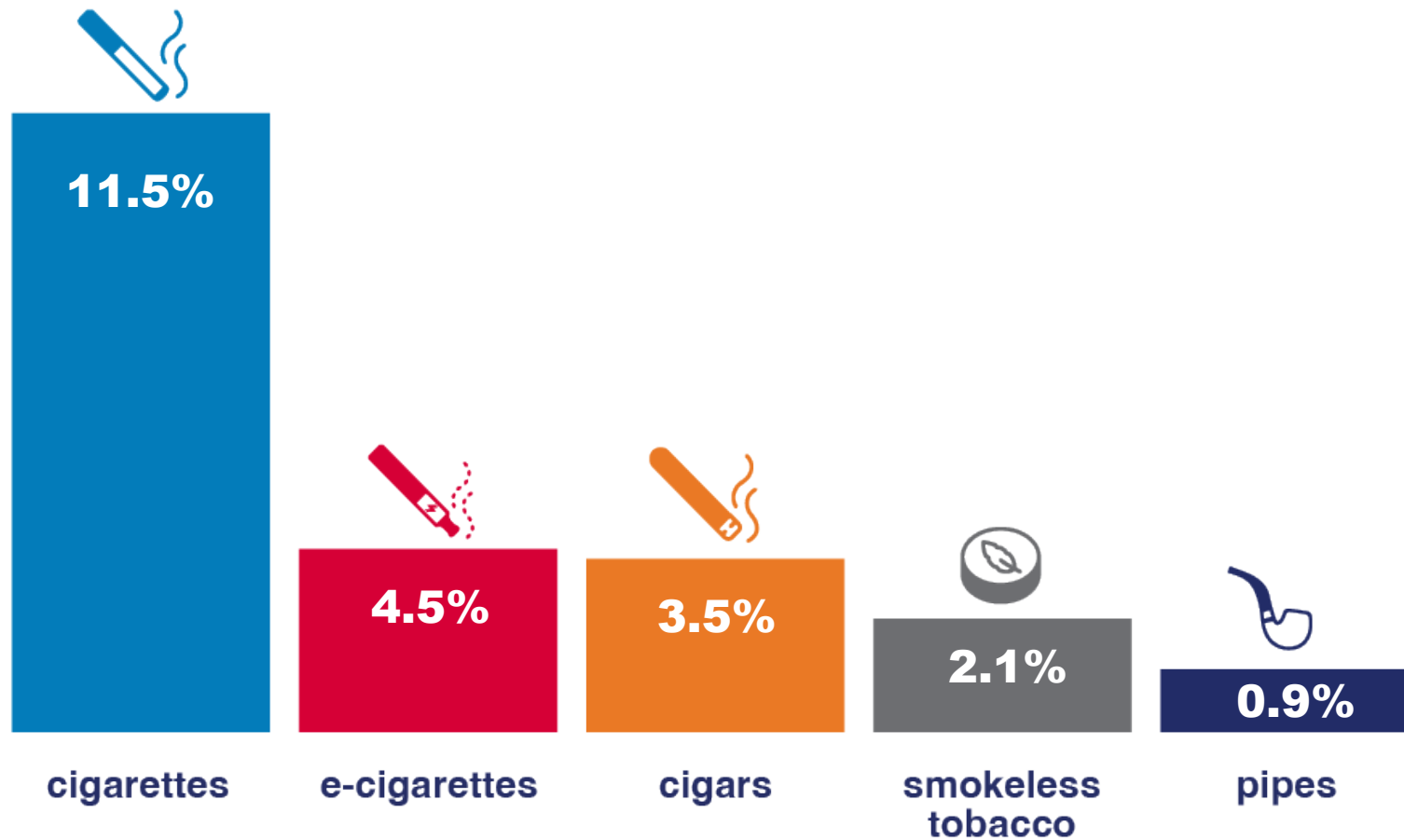


CIGARETTE CONSUMPTION, UNITED STATES, 1900-2020



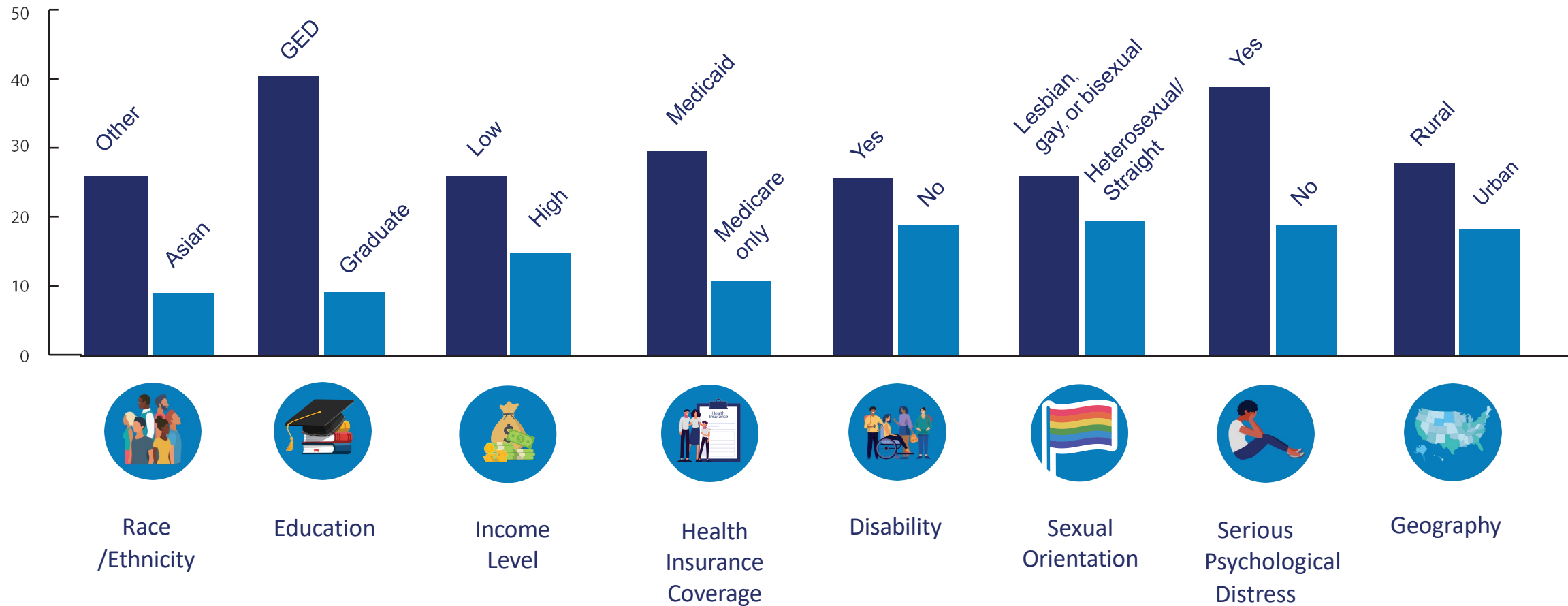
US Department of Health and Human Services. *Smoking Cessation: A Report of the Surgeon General*. Atlanta, GA: US Department of Health and Human Services, CDC; 2020.

CURRENT ADULT USE OF TOBACCO PRODUCTS (2021)



Cornelius ME, et al. "Tobacco Product Use Among Adults - United States, 2021". Centers for Disease Control and Prevention (CDC). *MMWR*.

HEALTH DISPARITIES AND CURRENT TOBACCO USE AMONG ADULTS (2021)

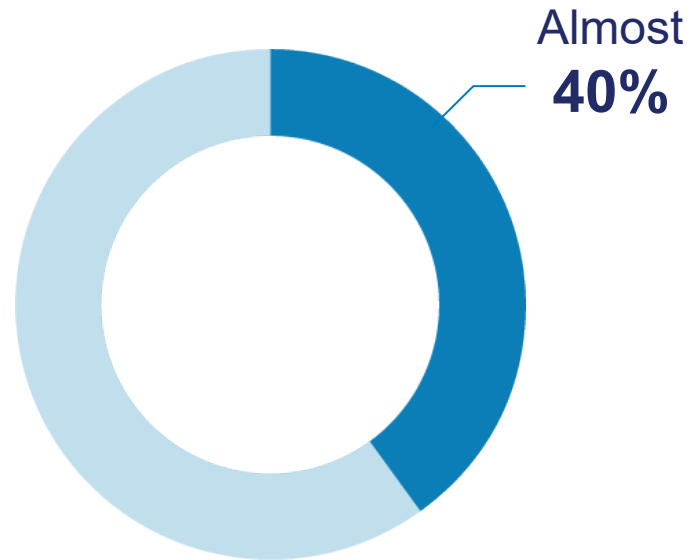


Cornelius ME, et al. "Tobacco Product Use Among Adults - United States, 2021". Centers for Disease Control and Prevention (CDC). *MMWR*.

TOBACCO AND BEHAVIORAL HEALTH



Individuals with behavioral health conditions, like depression or anxiety, account for:



of all traditional cigarettes smoked by adults



Menthol use among adults who smoke (2019)



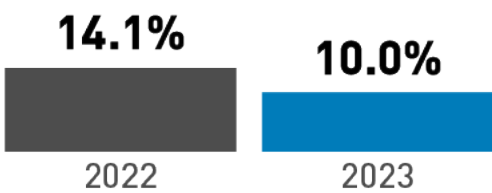
Similarly, young adults with serious mental health conditions use menthol tobacco products at disproportionately high rates

YOUTH E-CIGARETTE USE (2023)

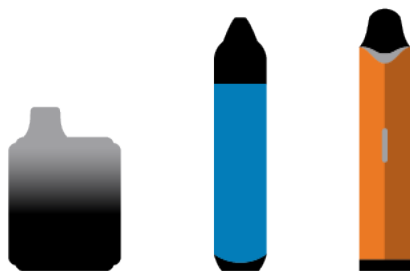
FDA

NYTS
2023

NYTS Shows Drop in E-Cigarette Use Among High School Students

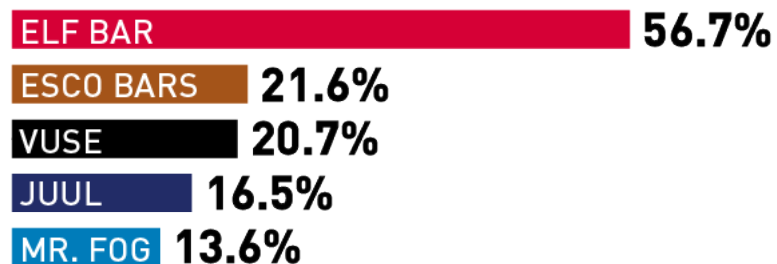


More than
2.1 million
youth currently use
e-cigarettes



Among youth who reported current use of e-cigarettes:

The most popular brands include disposable and cartridge-based products, and the most commonly reported products were:

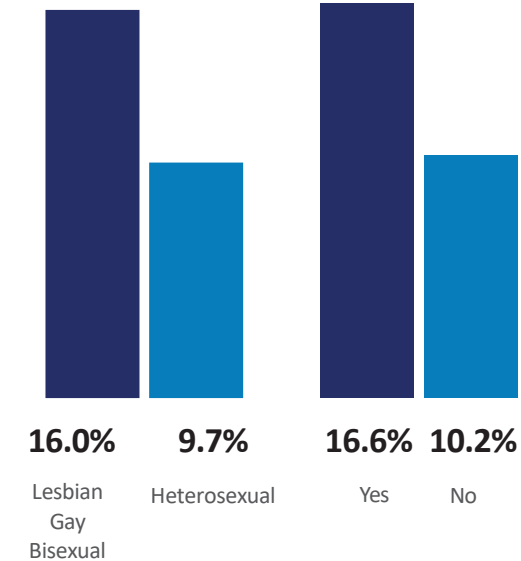
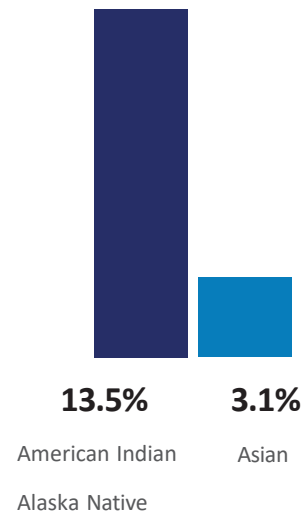


Almost
9 out of 10

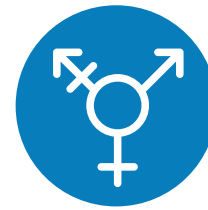


use flavored e-cigarettes

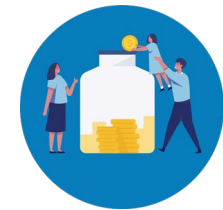
TOBACCO USE DISPARITIES AMONG YOUTH (2022)



Sexual Orientation



Transgender



Family Affluence Scale

CTP OVERVIEW

VISION AND MISSION



Vision

To make tobacco-related death and disease part of our nation's past by ensuring a healthier future and advancing health equity for those living in the United States.



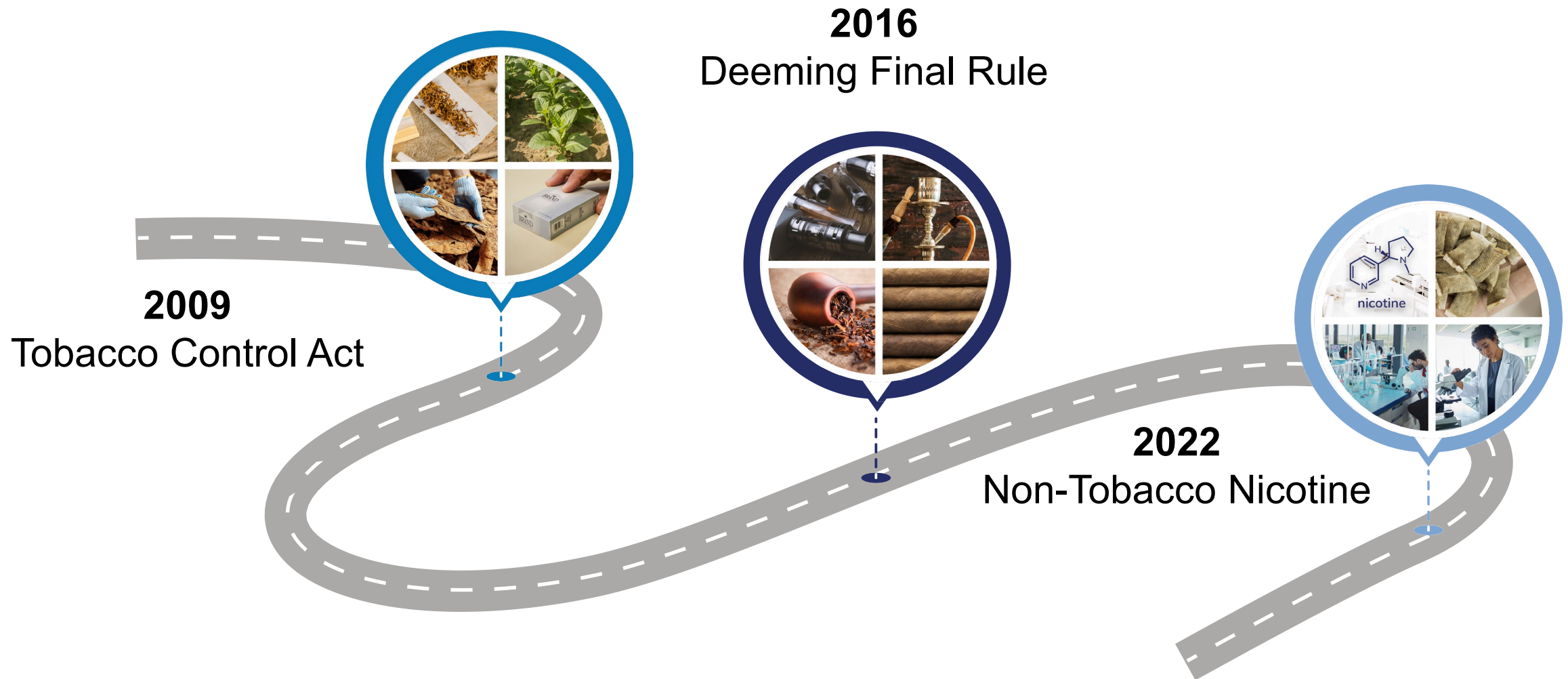
Mission

To protect the public health of the U.S. population from tobacco-related death and disease by comprehensively:

- Regulating the manufacture, distribution, and marketing of tobacco products
- Educating the public, especially youth, about the dangers of using tobacco products
- Promoting and supporting strategies that ensure an equitable chance at living a healthier life for everyone



TOBACCO REGULATION IN THE UNITED STATES



FDA'S TOBACCO REGULATORY ACTIVITIES



Implement the tobacco control laws through
RULES & GUIDANCES

REVIEW TOBACCO PRODUCT APPLICATIONS
to ensure that new tobacco products meet public health standards



FDA'S CENTER FOR TOBACCO PRODUCTS



Ensure tobacco manufacturers and retailers follow the law through
SURVEILLANCE, INSPECTIONS, AND ENFORCEMENT

EDUCATE
the public, especially youth, about the dangers of using tobacco products



PROGRAMMATIC UPDATES



RULEMAKING PROCESS



**Rule/Regulation
Proposed**



**Public Comments
Considered**



**Final Rule
Issued**

PROPOSED MENTHOL CIGARETTE & FLAVORED CIGAR PRODUCT STANDARDS (APRIL 2022)

FDA has **proposed product standards** to:

- Prohibit **menthol** as a characterizing flavor in cigarettes
- Prohibit all **characterizing flavors**, except tobacco, in cigars



Menthol Cigarettes

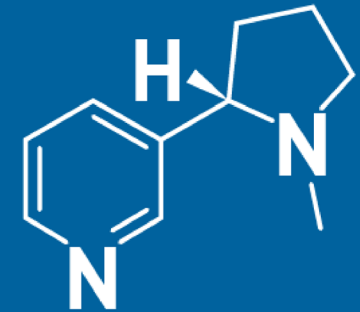


Flavored Cigars

NICOTINE PRODUCT STANDARD

FDA plans to develop a proposed product standard that would establish a **maximum nicotine level** to reduce the addictiveness of cigarettes and certain other combusted tobacco products

NICOTINE

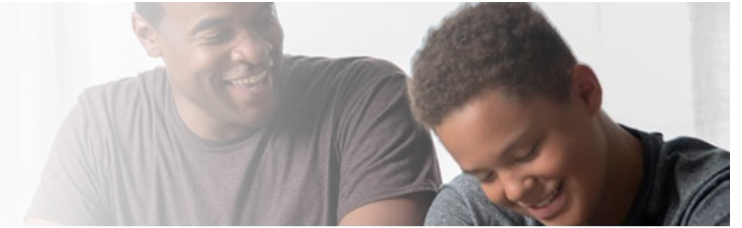


DISPARITIES IN MENTHOL CIGARETTE SMOKING



18.6 million
people currently smoke
menthol cigarettes

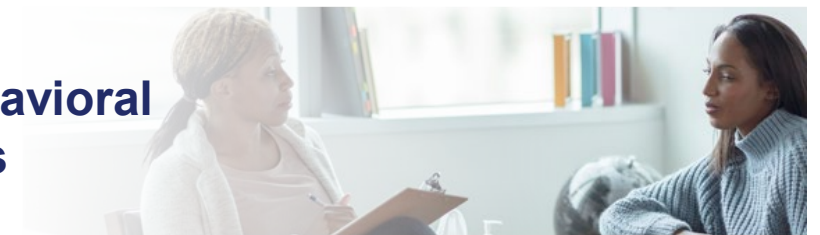
**Non-Hispanic Black
Persons**



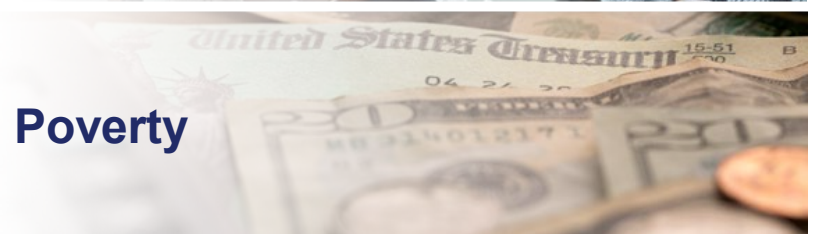
LGBTQ+



**Persons with Behavioral
Health Conditions**



Persons Living in Poverty



Published modeling studies have estimated that if menthol cigarettes were no longer available in the U.S.:



Up to 650,000 smoking and vaping attributable deaths avoided over 40 years

15%

A 15% reduction in smoking in 5 years

**Modeling estimated that prohibiting
characterizing flavors would result in:**



800 fewer deaths/year
due to increased cigar
cessation among adults

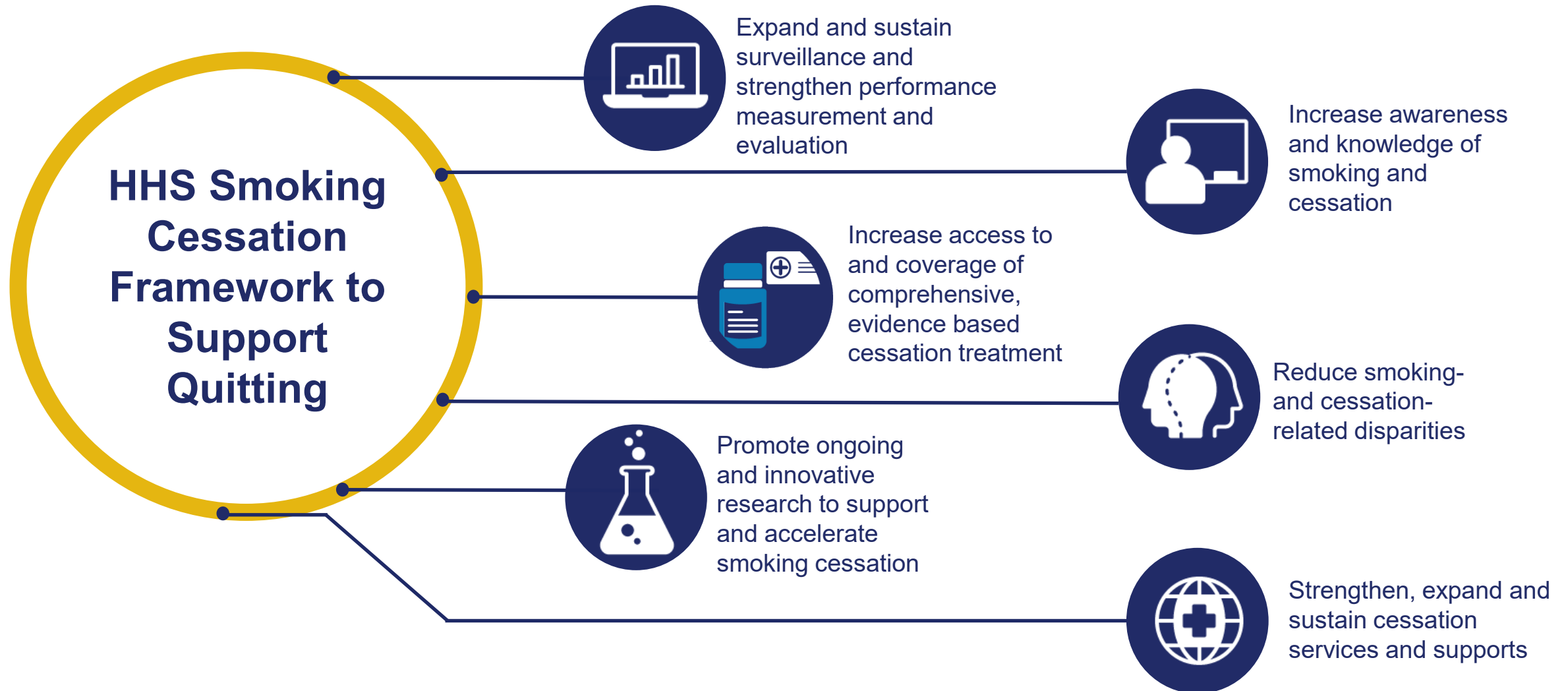
112,000

fewer cigar smokers
among each cohort
of 18-year-olds



FDA recognizes the importance of working with our federal partners to **ensure broad and equitable access** to effective and affordable tools and resources that can help smokers quit, particularly those who face the greatest health disparities and the greatest obstacles to cessation

HHS SMOKING CESSATION FRAMEWORK GOALS



PROGRAMMATIC UPDATES



**RULES &
REGULATIONS**



**PREMARKET
REVIEW**



**COMPLIANCE &
ENFORCEMENT**



**PUBLIC
EDUCATION**

CTP COMPLIANCE AND ENFORCEMENT ACTIVITIES



**Compliance, Training,
Education, and Outreach**



**Surveillance, Inspections,
and Investigations**



Enforcement Actions

Industry Compliance

COMPLIANCE & ENFORCEMENT ACTIONS



ONLINE INVESTIGATIONS

Through **March 31, 2024**,

>1,300 Warning Letters

issued through online investigations for various tobacco product violations of the Federal Food, Drug, and Cosmetic Act



MANUFACTURERS

~880 WARNING LETTERS
(OVER 800 FOR ENDS)

54 CIVIL MONEY PENALTIES
(ALL ENDS)

7 INJUNCTIONS
(ALL ENDS)



RETAILERS

OVER 136,000 WARNING LETTERS
(OVER 22,700 FOR ENDS)

OVER 32,800 CIVIL MONEY PENALTIES
(OVER 4,100 FOR ENDS)

228 NO-TOBACCO-SALE ORDERS

RECENT ACTIONS AGAINST INDUSTRY FOR E-CIGARETTES THAT LACK AUTHORIZATION



Retailers

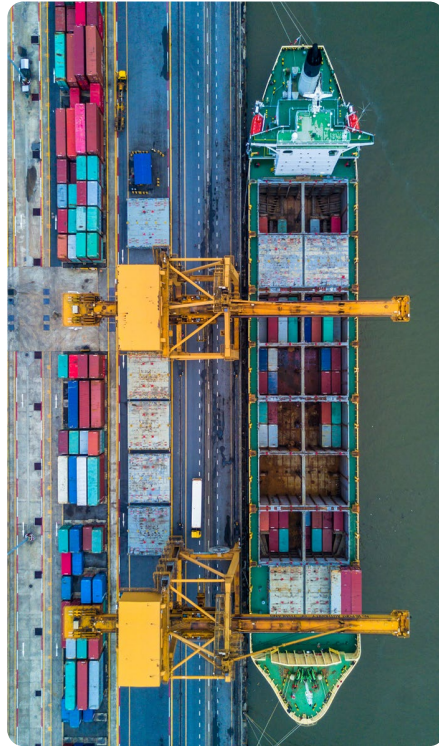


**More than 550
Warning Letters**



**More than 100 Civil
Money Penalties**

RECENT ACTIONS AGAINST INDUSTRY FOR E-CIGARETTES THAT LACK AUTHORIZATION



More than 660
Warning Letters



50 Civil Money
Penalties



7 Injunctions



45 Firms Listed on
2 Import Alerts

Manufacturers, Importers, and Distributors

EXAMPLE OF COMPLIANCE AND ENFORCEMENT ACTIVITY

E-CIGARETTES APPEALING TO YOUTH AND YOUNG PEOPLE



E-Cigarette



Cartoon



E-Cigarette



Cartoon



E-Cigarette



Toy



E-Cigarette



Alcohol Bottle



E-Cigarette



Toy



E-Cigarette



School Supplies

PROGRAMMATIC UPDATES



**RULES &
REGULATIONS**



**PREMARKET
REVIEW**

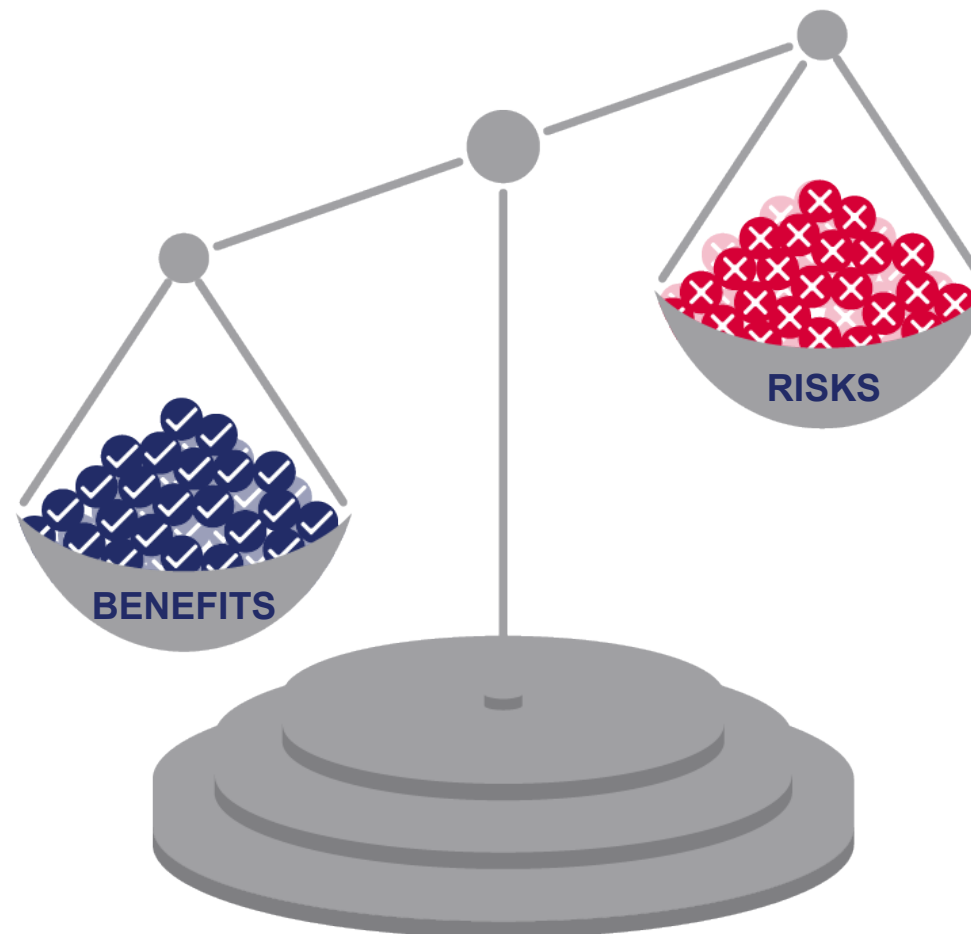


**COMPLIANCE &
ENFORCEMENT**



**PUBLIC
EDUCATION**

**“Appropriate for
the Protection of
the Public Health”**



PREMARKET TOBACCO PRODUCT APPLICATIONS (PMTA) FISCAL YEAR 2020 - TO DATE



Applications received for about
26 million
products, mostly e-cigarettes



Action taken on 99% of the applications, including



Marketing authorizations for
23
e-cigarette products

Refuse to accept letters,
Refuse to file letters, or
Marketing denial orders for
Millions
of products



PROGRAMMATIC UPDATES



PUBLIC EDUCATION CAMPAIGN PROGRAM EVOLUTION



2014 “The Real Cost” campaign launched with cigarette prevention messages to reach youth.



2015 The “Fresh Empire” cigarette prevention campaign launched to reach African American, Hispanic, and Asian American/Pacific Islander youth.



2016 “The Real Cost” campaign expanded to include smokeless tobacco prevention messages for rural male youth.



2017 The “This Free Life” campaign launched to prevent and reduce cigarette smoking among LGBTQ+ young adults.



2022 FDA launched the “Next Legends” campaign designed to reach American Indian and Alaska Native (AI/AN) youth.



2020 FDA phased out “The Real Cost” Smokeless, “Fresh Empire,” “This Free Life,” and “Every Try Counts” campaigns to focus on youth e-cigarette prevention.



2018 The “Every Try Counts” campaign launched to reach smokers in 35 U.S. counties with high adult smoking rates and encourage them to quit.



2018 FDA prioritized e-cigarette prevention messages due to high usage rates among youth and launched “The Real Cost” e-cigarette campaign.

2023 FDA continues to prioritize e-cigarette youth prevention through “The Real Cost” and “Next Legends” campaigns. FDA also develops adult cessation education resources.

2024 10th anniversary of “The Real Cost” campaign. FDA continues youth e-cigarette prevention and adult cessation education.



TOBACCO PREVENTION CAMPAIGNS



"The Real Cost" launched two ads in January 2023. For the first time, one of the ads focused on the negative mental health effects of smoking and withdrawal.



TOBACCO PREVENTION CAMPAIGNS



PREVENTED

UP TO

587,000

Youth ages 11-19 from **trying** cigarettes, half of whom may have become adult smokers



WILL SAVE

MORE THAN

\$180,000

for each of the up to 293,500 youth **prevented** from becoming established smokers



WILL SAVE

MORE THAN

\$53 BILLION

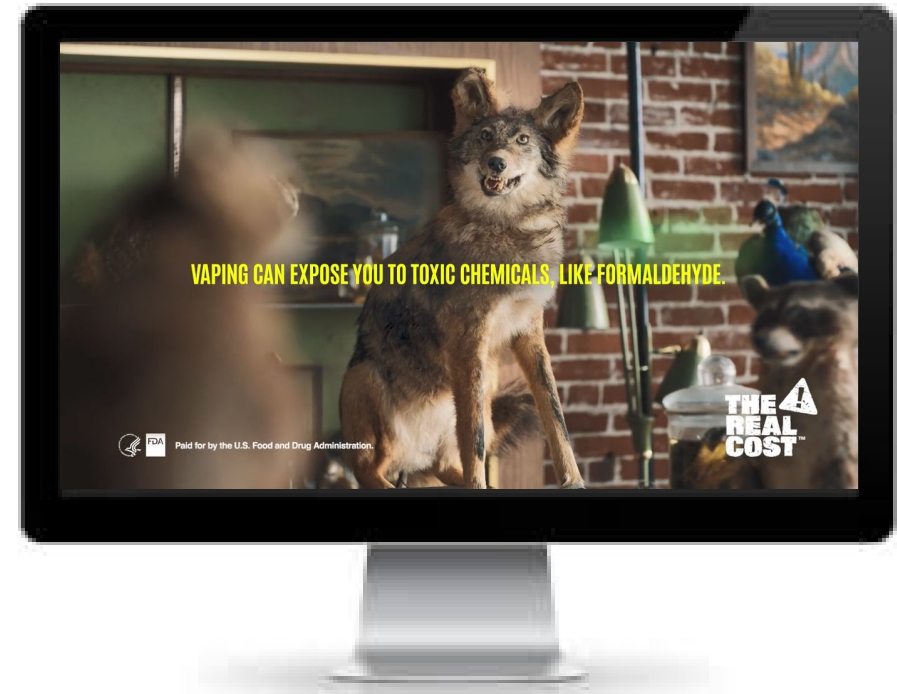
by **reducing** smoking-related costs like, medical care, lost wages, and increased disability



THE REAL COST: NEWEST ADS

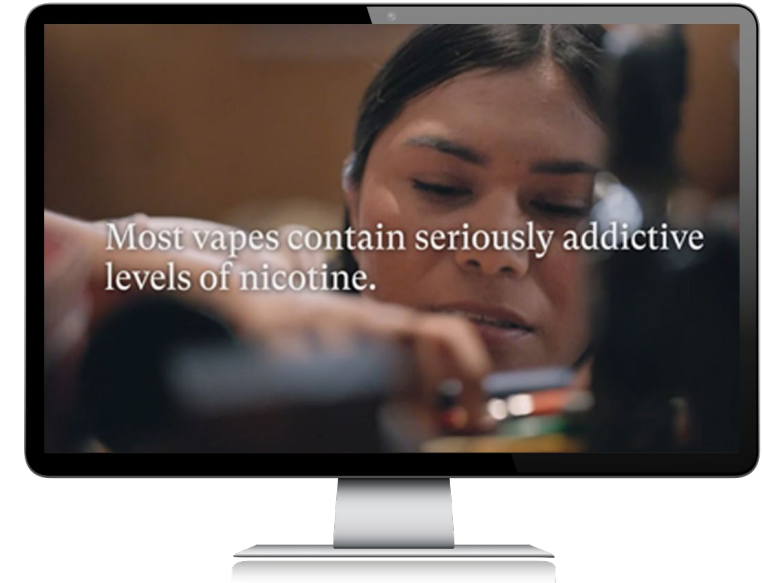
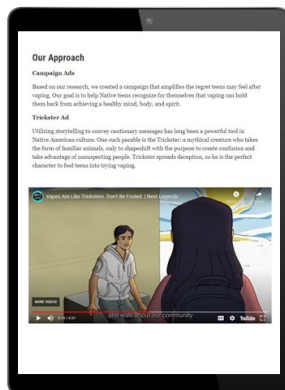


“Don’t Pollute Yourself”



“Toxic Taxidermy”

TOBACCO PREVENTION CAMPAIGNS



VAPING PREVENTION & EDUCATION RESOURCE CENTER



TEACHERS ▾

STUDENTS ▾

PARENTS ▾

ABOUT US

RESOURCES ▾



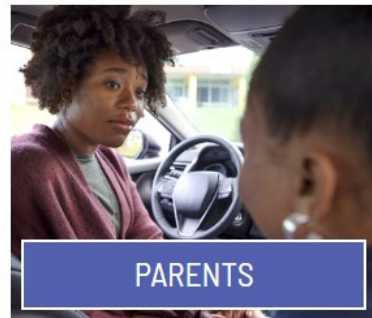
VAPING PREVENTION & EDUCATION



TEACHERS

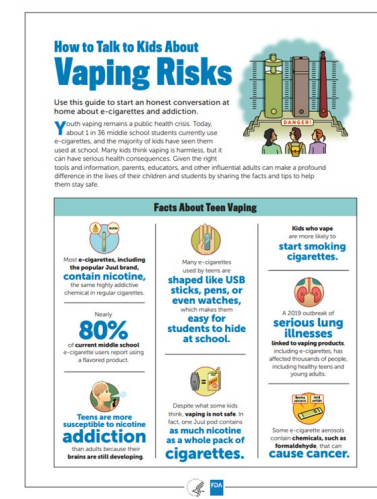
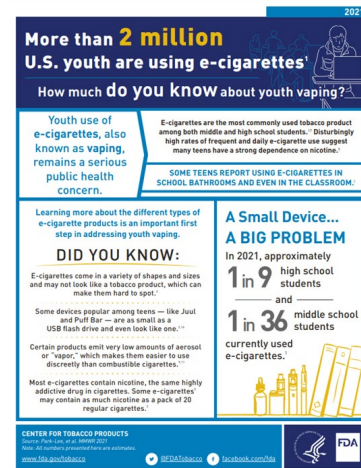


STUDENTS



PARENTS

www.fda.gov/youthvapingresources



SUMMARY

- Considerable progress has been made in lowering tobacco smoking in the United States over the past half decade.
- However, disparities persist, particularly with regard to menthol cigarette and flavor cigar smoking.
- Menthol leads to more initiation, progression to regular smoking, and difficulty quitting.
- FDA remains committed to using the full scope of its regulatory authorities to protect public health.



QUESTIONS?



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Email Us

AskCTP@fda.hhs.gov



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@FDATobacco



Report adverse experiences with tobacco products at:
<https://www.safetyreporting.hhs.gov>