

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

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AGENDA

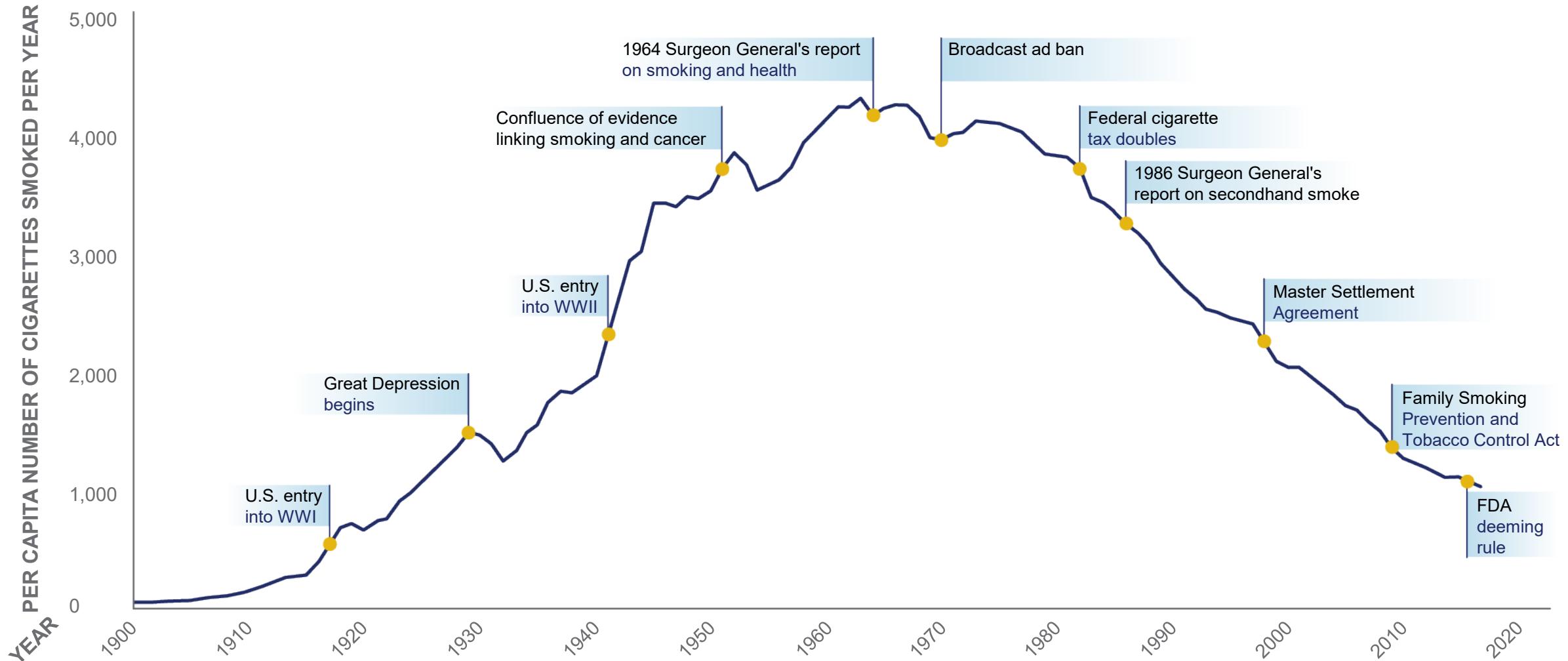
- Current State of Tobacco Use in the U.S.
- CTP Overview
- Programmatic Updates
- Resources

FDA



CIGARETTE CONSUMPTION, UNITED STATES, 1900-2020

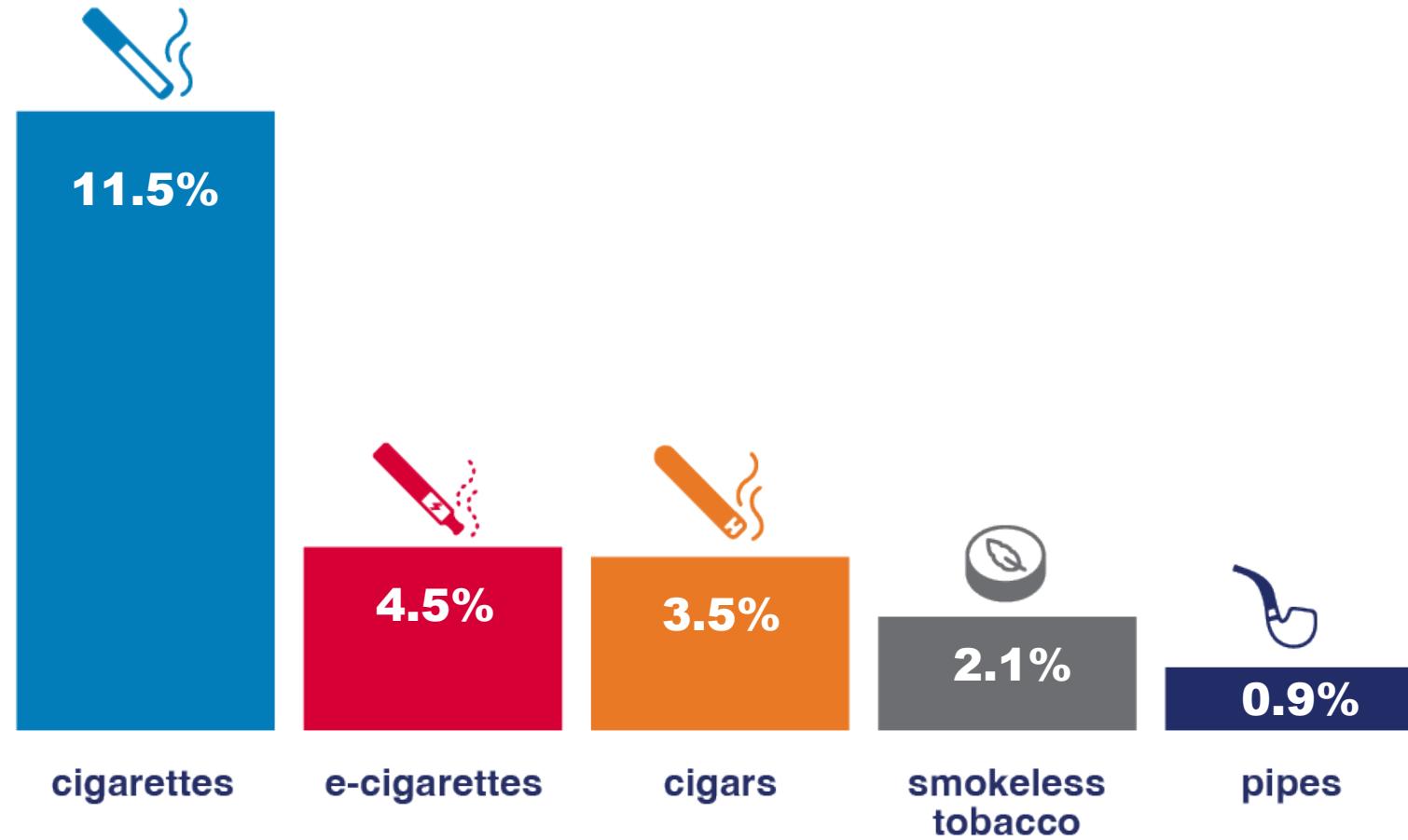
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US Department of Health and Human Services. *Smoking Cessation: A Report of the Surgeon General*. Atlanta, GA: US Department of Health and Human Services, CDC; 2020.

CURRENT ADULT USE OF TOBACCO PRODUCTS (2021)

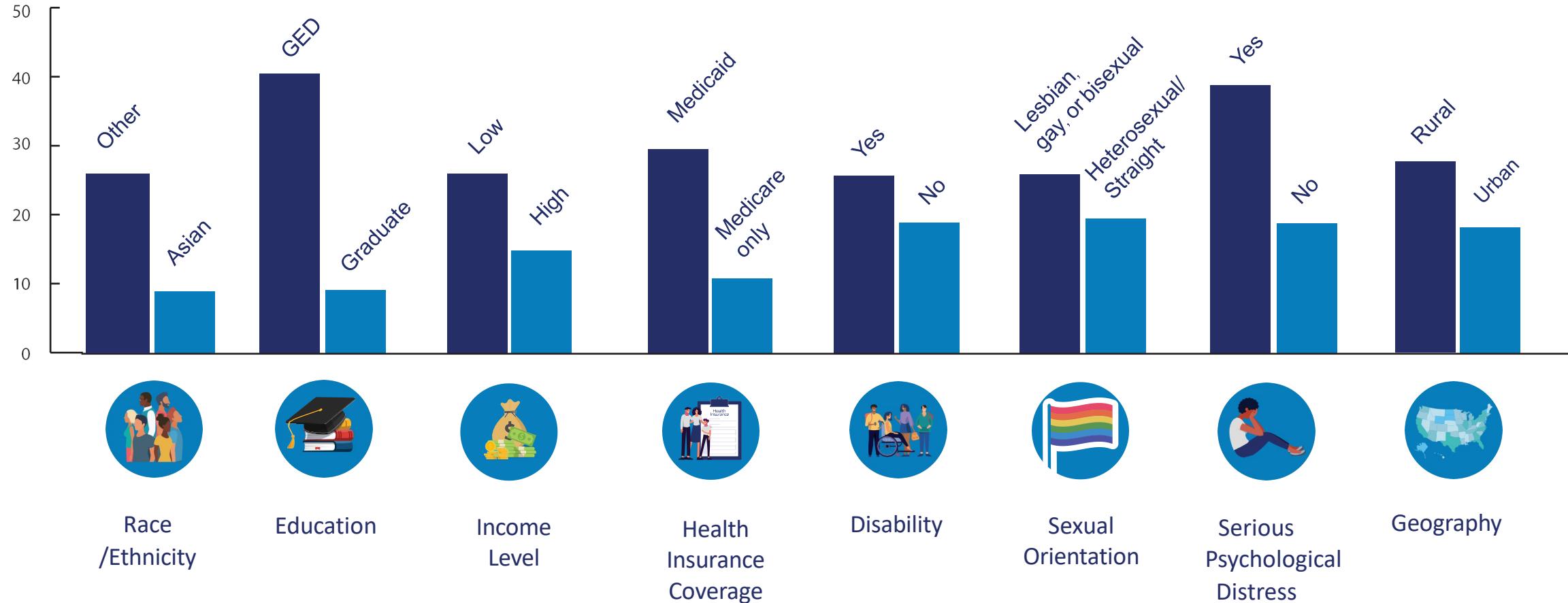
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Cornelius ME, et al. "Tobacco Product Use Among Adults - United States, 2021". Centers for Disease Control and Prevention (CDC). *MMWR*.

HEALTH DISPARITIES AND CURRENT TOBACCO USE AMONG ADULTS (2021)

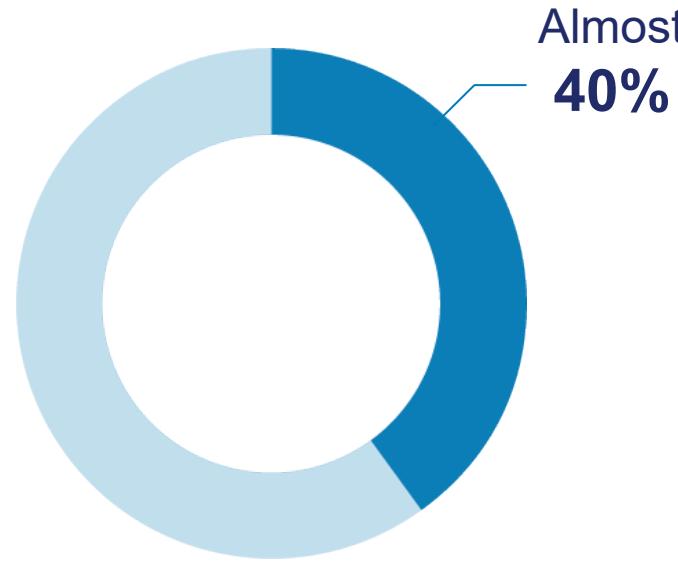
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Cornelius ME, et al. "Tobacco Product Use Among Adults - United States, 2021". Centers for Disease Control and Prevention (CDC). *MMWR*.



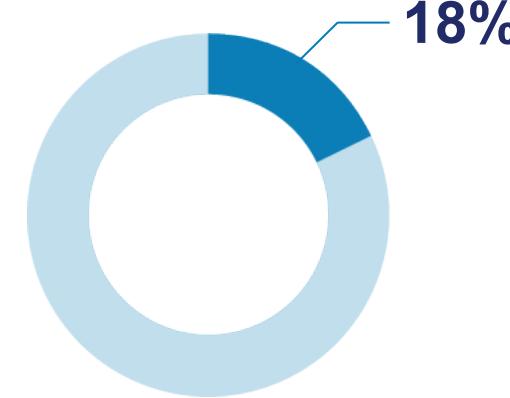
Individuals with behavioral health conditions, like depression or anxiety, account for:



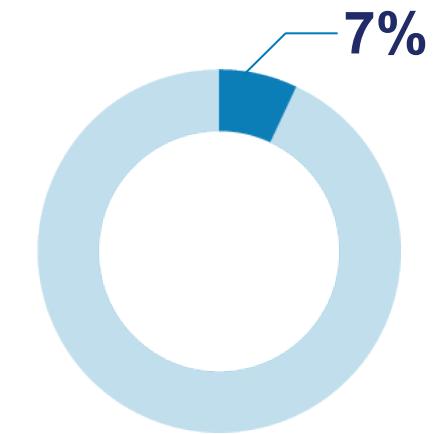
of all traditional cigarettes smoked by adults



Menthol use among adults who smoke (2019)



Those who report serious psychological stress

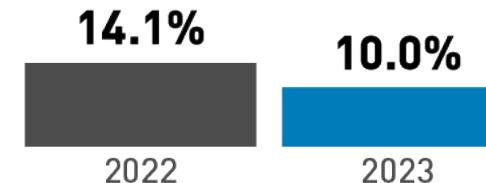


Those who do not report serious psychological stress

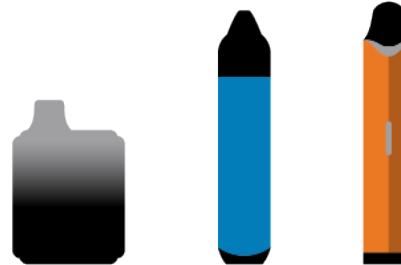
Similarly, young adults with serious mental health conditions use menthol tobacco products at disproportionately high rates

NYTS
2023

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

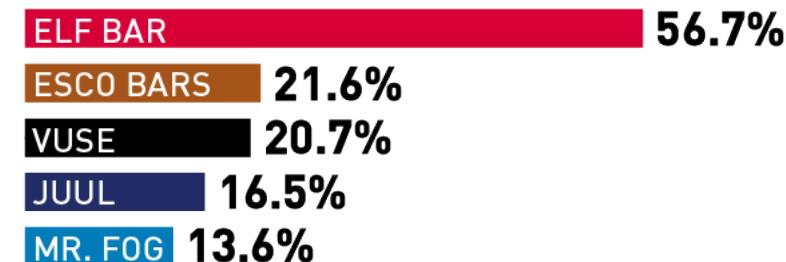


More than
2.1 million
youth currently use
e-cigarettes



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:

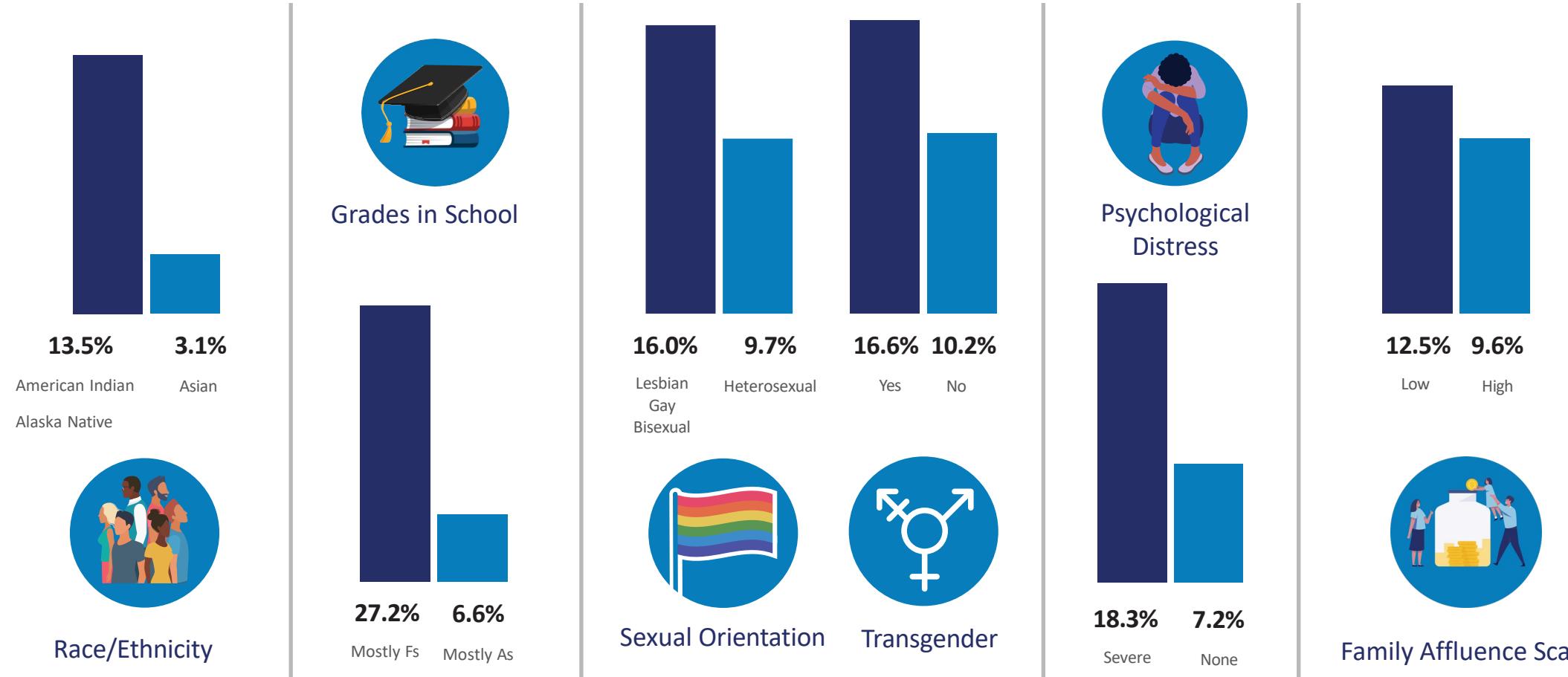


Almost
9 out of 10
use flavored e-cigarettes



TOBACCO USE DISPARITIES AMONG YOUTH (2022)

FDA



Centers for Disease Control and Prevention (CDC). Tobacco Product Use Among Middle and High School Students — United States, 2022. *MMWR Morb Mortal Weekly Rep.* 2022; 71(45):1429–1435

CTP OVERVIEW

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.



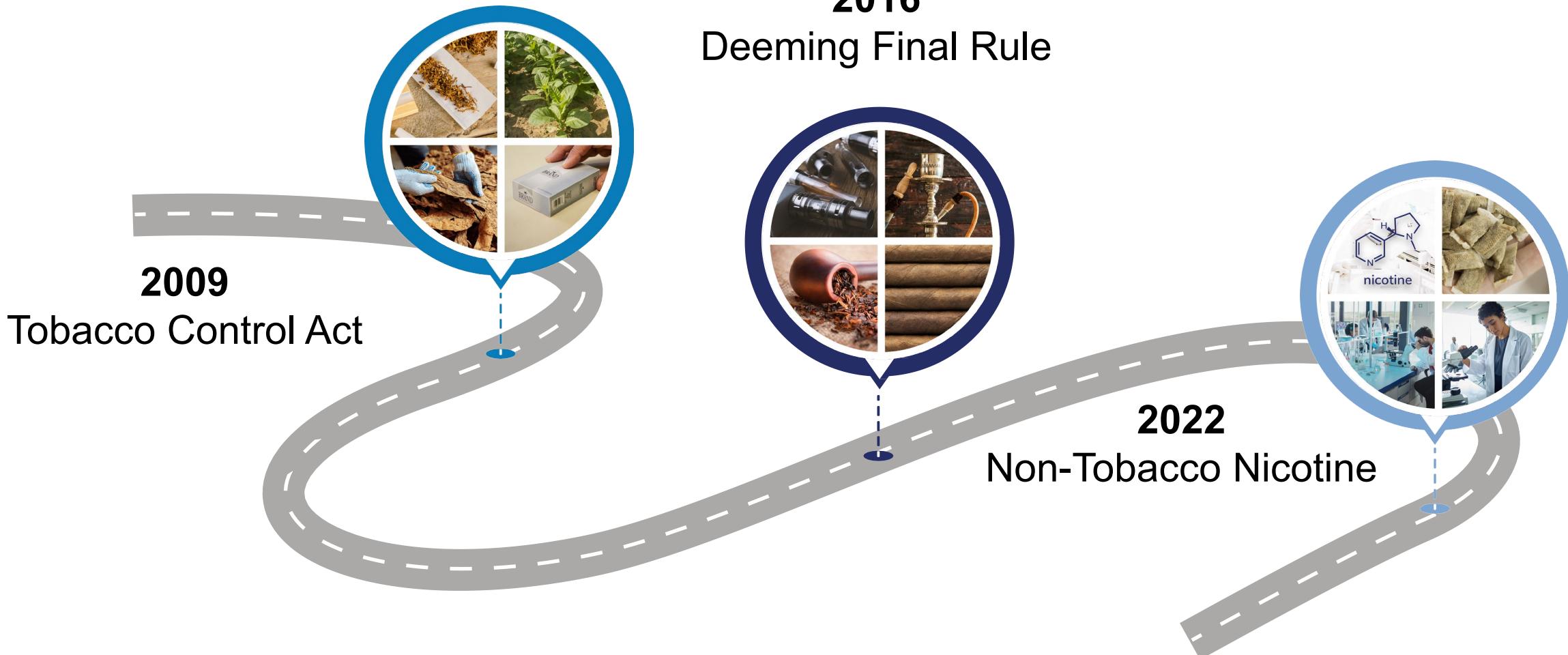
Mission

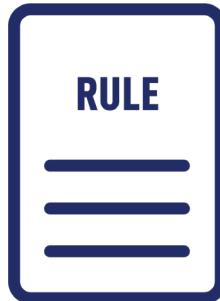
To protect the public health of the U.S. population from tobacco-related death and disease by comprehensively:

- 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





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





RULES & REGULATIONS



PREMARKET REVIEW



COMPLIANCE & ENFORCEMENT



PUBLIC EDUCATION

RULEMAKING PROCESS

FDA



**Rule/Regulation
Proposed**



**Public Comments
Considered**



**Final Rule
Issued**

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

FDA

FDA has **proposed product standards** to:

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



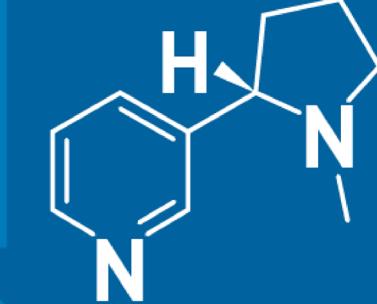
Menthol Cigarettes



Flavored Cigars

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

FDA



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:



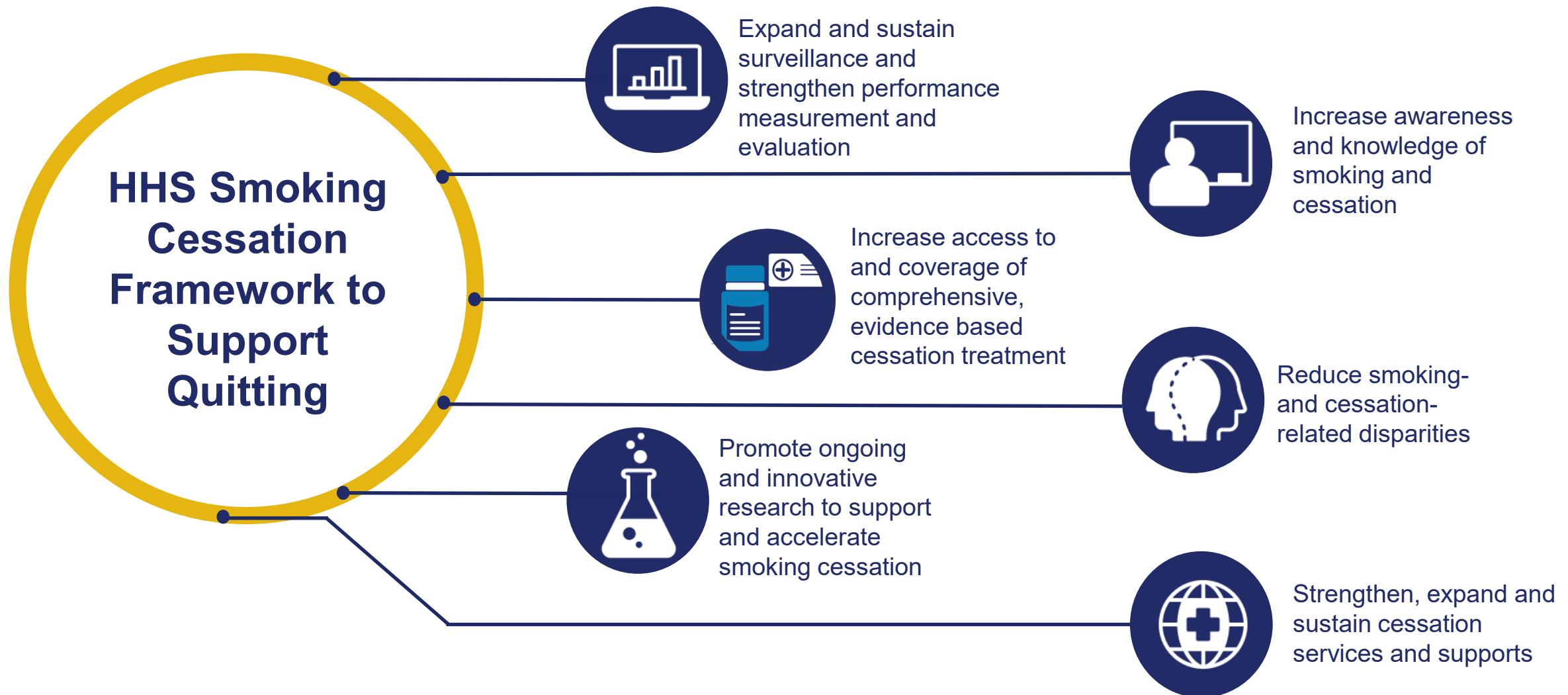
800 fewer deaths/year
due to increased cigar cessation among adults

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





**RULES &
REGULATIONS**



**PREMARKET
REVIEW**



**COMPLIANCE &
ENFORCEMENT**



**PUBLIC
EDUCATION**



Compliance, Training,
Education, and Outreach



Surveillance, Inspections,
and Investigations



Enforcement Actions

Industry Compliance



ONLINE INVESTIGATIONS



MANUFACTURERS



RETAILERS

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

~880 WARNING LETTERS (OVER 800 FOR ENDS)

54 CIVIL MONEY PENALTIES (ALL ENDS)

7 INJUNCTIONS (ALL ENDS)

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

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

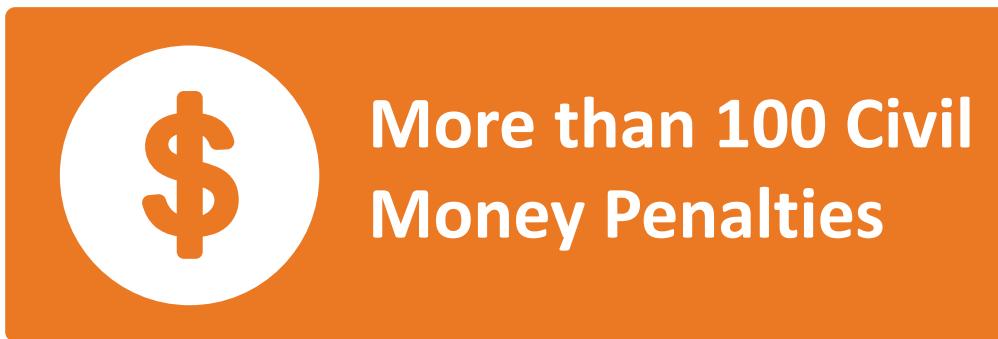
228 NO-TOBACCO-SALE ORDERS

RECENT ACTIONS AGAINST INDUSTRY FOR E-CIGARETTES THAT LACK AUTHORIZATION

FDA



Retailers



RECENT ACTIONS AGAINST INDUSTRY FOR E-CIGARETTES THAT LACK AUTHORIZATION

FDA



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

FDA



E-Cigarette



Cartoon



E-Cigarette



Cartoon



E-Cigarette



Toy



E-Cigarette



Alcohol Bottle



E-Cigarette



Toy



E-Cigarette



School Supplies



**RULES &
REGULATIONS**



**PREMARKET
REVIEW**

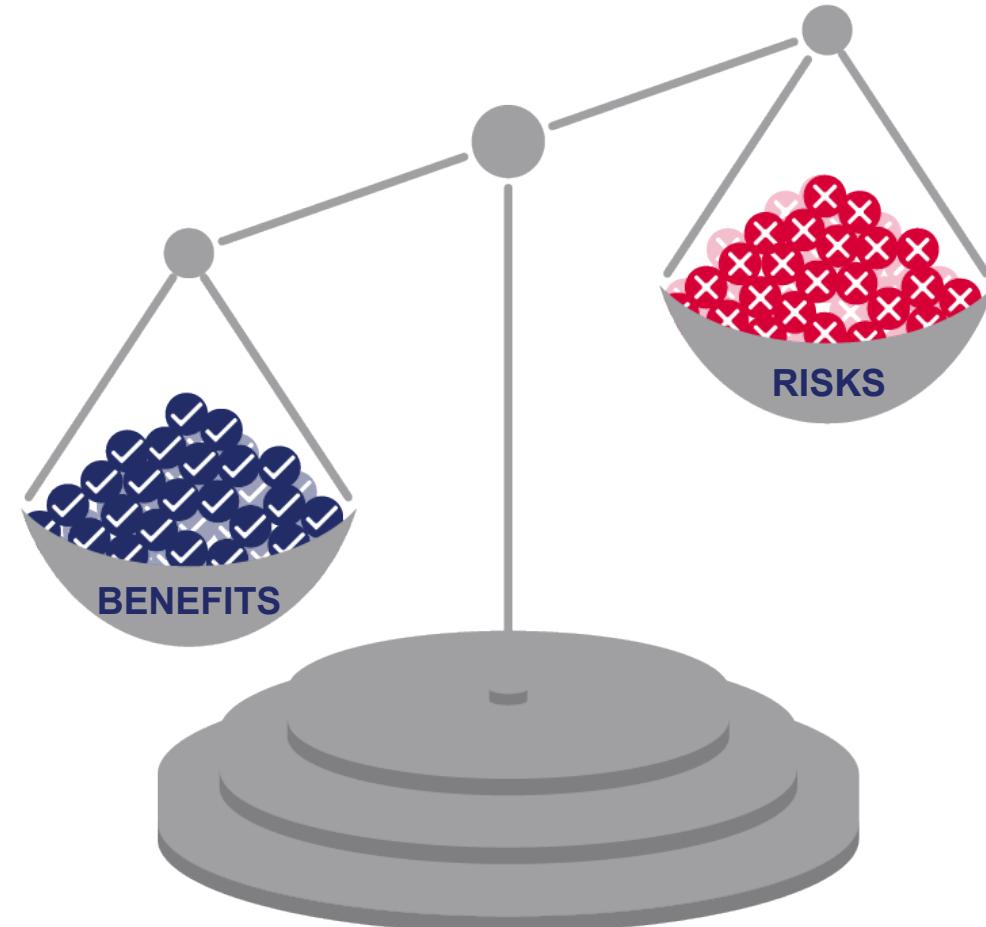


**COMPLIANCE &
ENFORCEMENT**



**PUBLIC
EDUCATION**

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



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

FDA

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





**RULES &
REGULATIONS**



**PREMARKET
REVIEW**



**COMPLIANCE &
ENFORCEMENT**



**PUBLIC
EDUCATION**

PUBLIC EDUCATION CAMPAIGN PROGRAM EVOLUTION

FDA



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.



"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.





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

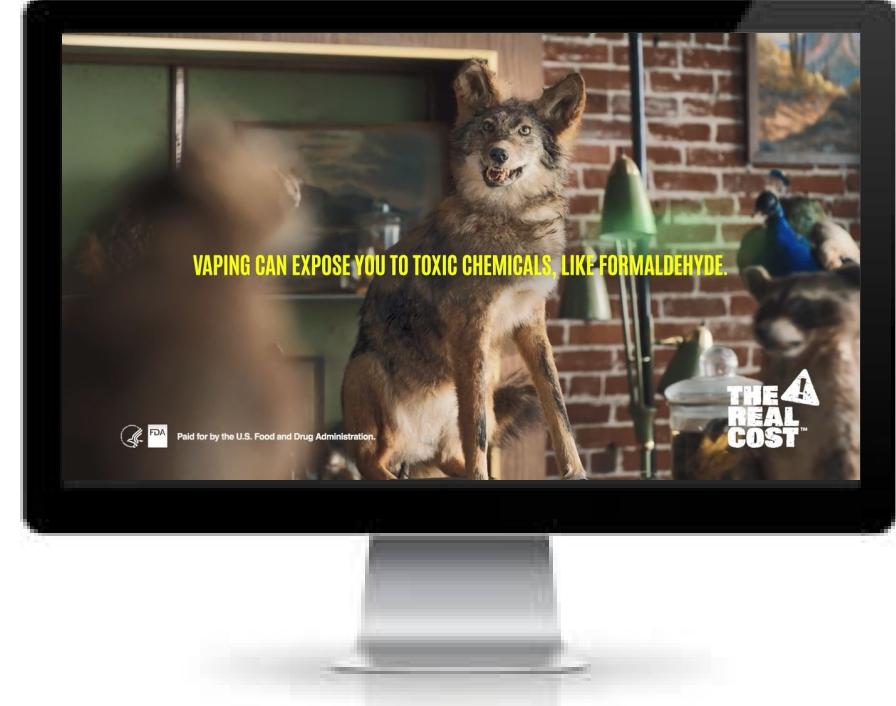


THE REAL COST: NEWEST ADS

FDA



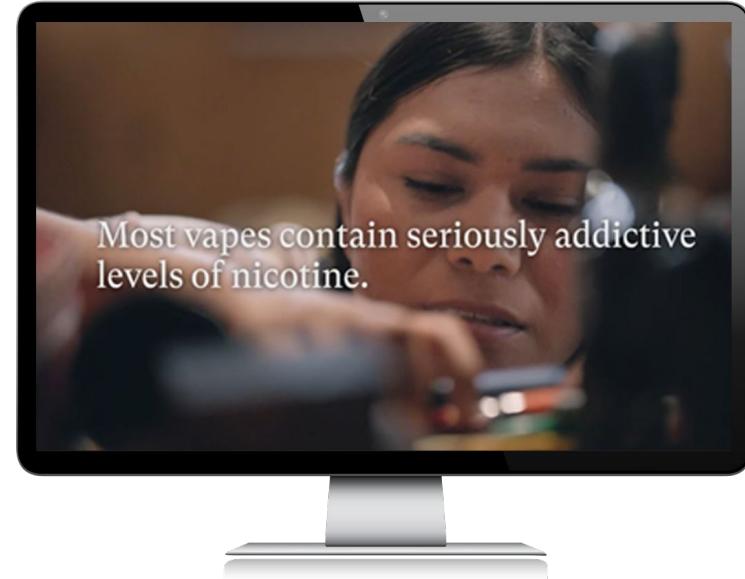
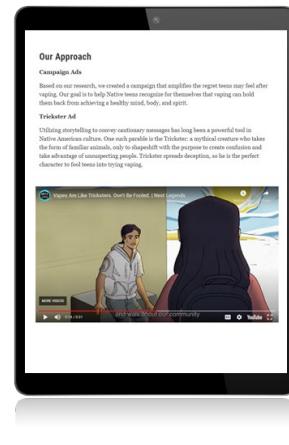
“Don’t Pollute Yourself”



“Toxic Taxidermy”

TOBACCO PREVENTION CAMPAIGNS

FDA



VAPING PREVENTION & EDUCATION RESOURCE CENTER

FDA

TEACHERS ▾

STUDENTS ▾

PARENTS ▾

ABOUT US

RESOURCES ▾



Resources for talking with students

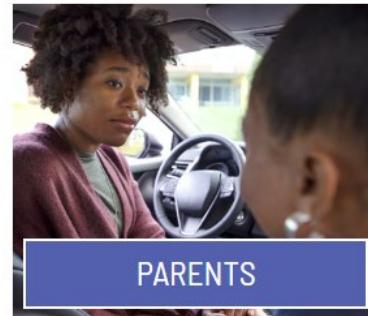
VAPING PREVENTION & EDUCATION



TEACHERS



STUDENTS



PARENTS

More than 2 million U.S. youth are using e-cigarettes

How much do you know about youth vaping?

DID YOU KNOW:

In 2021, approximately 1 in 9 high school students and 1 in 36 middle school students currently used e-cigarettes.

Small Device... A BIG PROBLEM

Most e-cigarettes contain nicotine, the same highly addictive drug in cigarettes. Some e-cigarettes may contain as much nicotine as a pack of 20 regular cigarettes.

FACTS FOR TOBACCO PRODUCTS

Source: Park-Lee, et al. MMWR 2021

www.fda.gov/tobacco [Facebook](https://www.facebook.com/FDA) [Twitter](https://www.twitter.com/FDA) [Instagram](https://www.instagram.com/FDA)

How to Talk to Kids About Vaping Risks

Use this guide to start an honest conversation at home about e-cigarettes and addiction.

Young vaping remains a public health crisis. Today, about 1 in 36 middle school students currently use e-cigarettes, and about 1 in 9 high school students used at school. Many kids think vaping is harmless, but it can have serious health consequences. Given the right tools and information, educators and other influential adults can make a profound difference in the lives of their children and students by sharing the facts and tips to help them stay safe.

Facts About Teen Vaping

Most e-cigarettes, including the popular heat-not-burn, contain nicotine, the same highly addictive chemical in regular cigarettes.

Nearly 80% of current middle school e-cigarette users are using a flavored product.

Teenagers are more susceptible to nicotine addiction than adults because their brains are still developing.

Kids who vape are more likely to start smoking cigarettes.

Many e-cigarettes are shaped like USB sticks, pens, or even watches, making them easy for students to hide at school.

Despite what some kids think, vaping is not safe. In fact, e-cigarettes contain as much nicotine as a whole pack of cigarettes.

A 2020 review of serious lung illnesses linked to vaping products, including e-cigarettes, affected thousands of people, including teens and young adults.

Some e-cigarette aerosols contain harmful chemicals such as formaldehyde, that can cause cancer.

THE RISKS OF VAPING

STORIES FROM REAL TEENS

DANGERS OF NICOTINE ADDICTION

SUPPORT FOR QUITTING

POSTER PROJECT

A poster project featuring a girl with long red hair. The text on the poster includes "THE RISKS OF VAPING", "STORIES FROM REAL TEENS", "DANGERS OF NICOTINE ADDICTION", "SUPPORT FOR QUITTING", and "POSTER PROJECT".

- 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.





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