

Regulating Tobacco Products: An International, Federal & State Level Perspective



Speakers



Dr. Brian King

Director, Food and Drug Administration's
Center for Tobacco Product



Mark Meaney

Director, Commercial Tobacco Control
Program at the Public Health Law Center



Moderator

Liz Furgurson

Chief Operating Officer, ASH



Dedicated to **ZERO** Tobacco Deaths

REGULATING TOBACCO PRODUCTS: AN INTERNATIONAL, FEDERAL, & STATE LEVEL PERSPECTIVE

*Brian King, PhD, MPH
Director, FDA Center for Tobacco Products*

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.

The FDA logo is displayed in the top right corner of the slide. It consists of the letters "FDA" in a bold, blue, sans-serif font, set against a white rectangular background.

September 14, 2023

CENTER FOR TOBACCO PRODUCTS

AGENDA



Current Tobacco Product Landscape

Overview of CTP

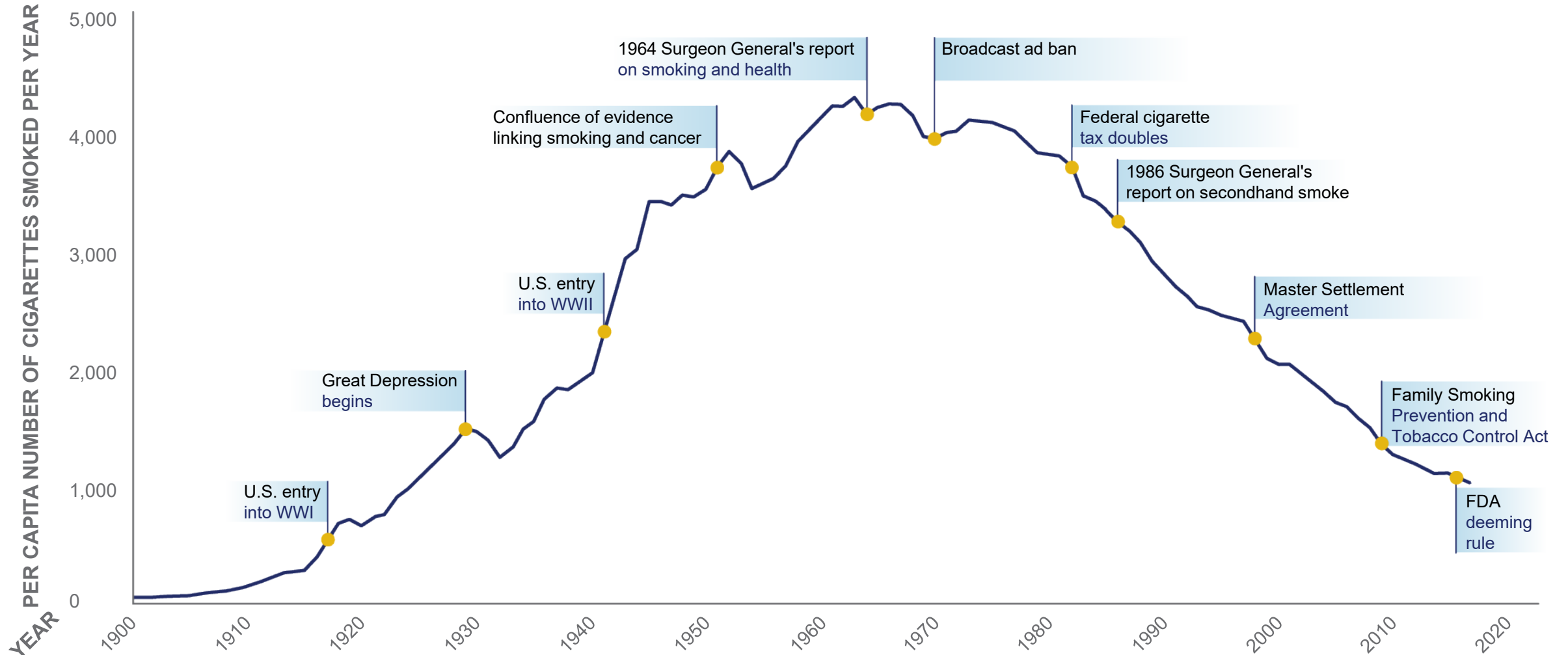
Programmatic Updates

Looking Ahead

CURRENT TOBACCO PRODUCT LANDSCAPE

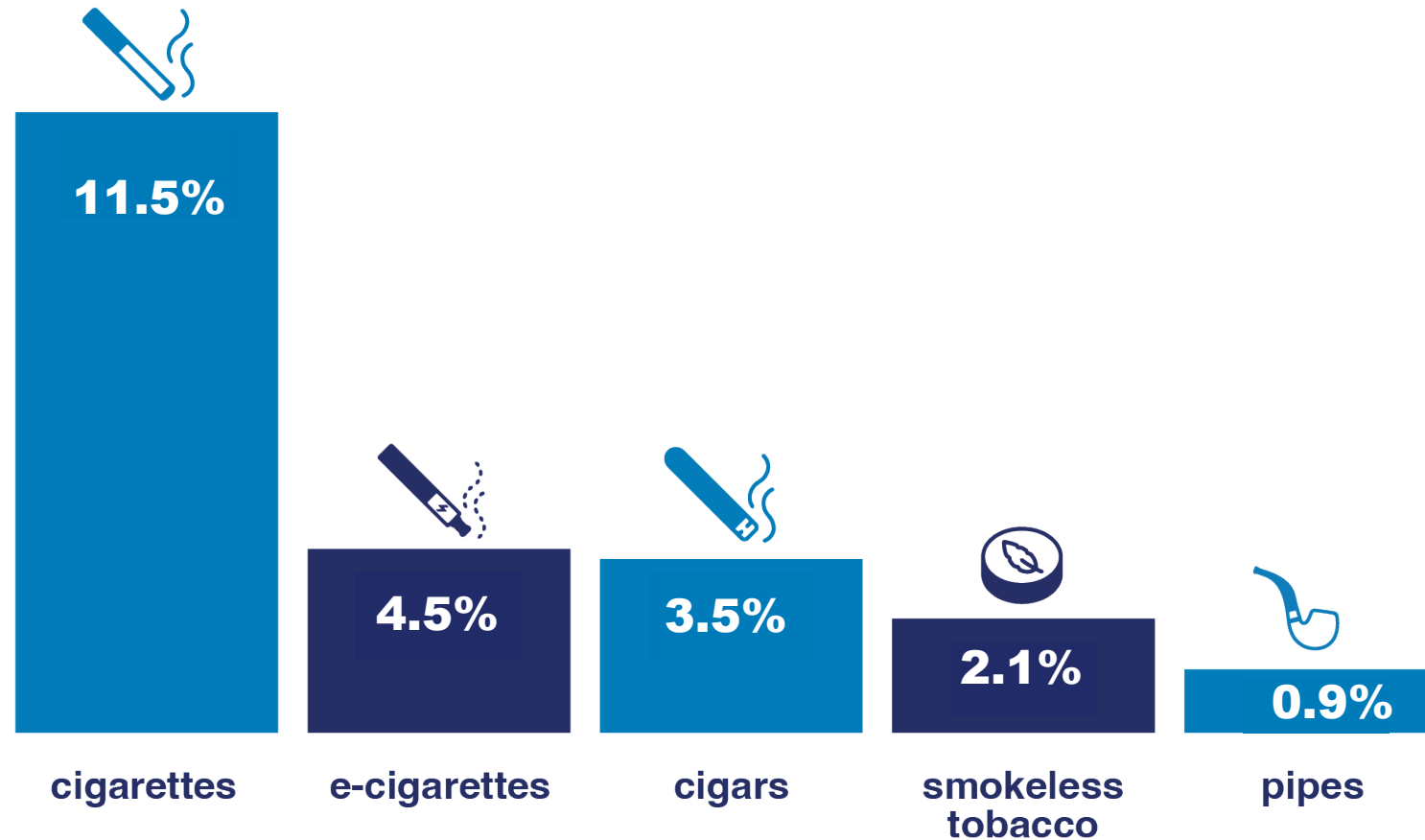


CIGARETTE CONSUMPTION 1900-2020



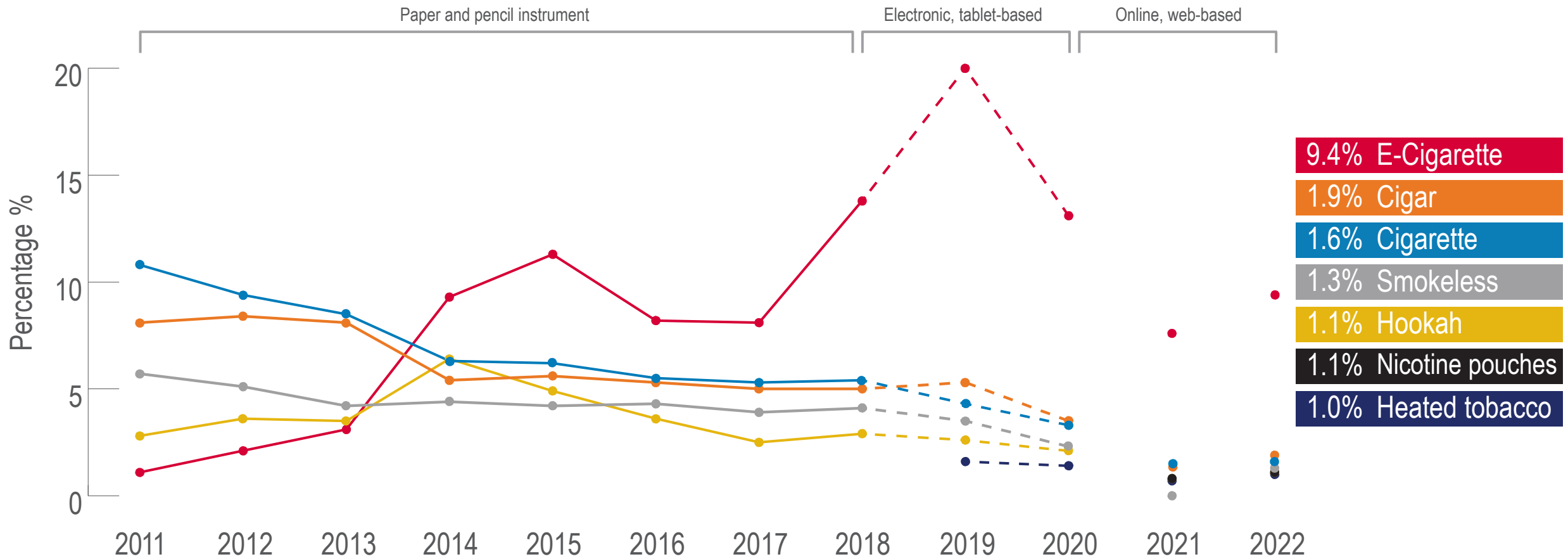
US Department of Health and Human Services. *Smoking Cessation: A Report of the Surgeon General*. Atlanta, GA: US Department of Health and Human Services, CDC; 2020.

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*.

CURRENT TOBACCO PRODUCT USE AMONG MIDDLE AND HIGH SCHOOL STUDENTS (2022)

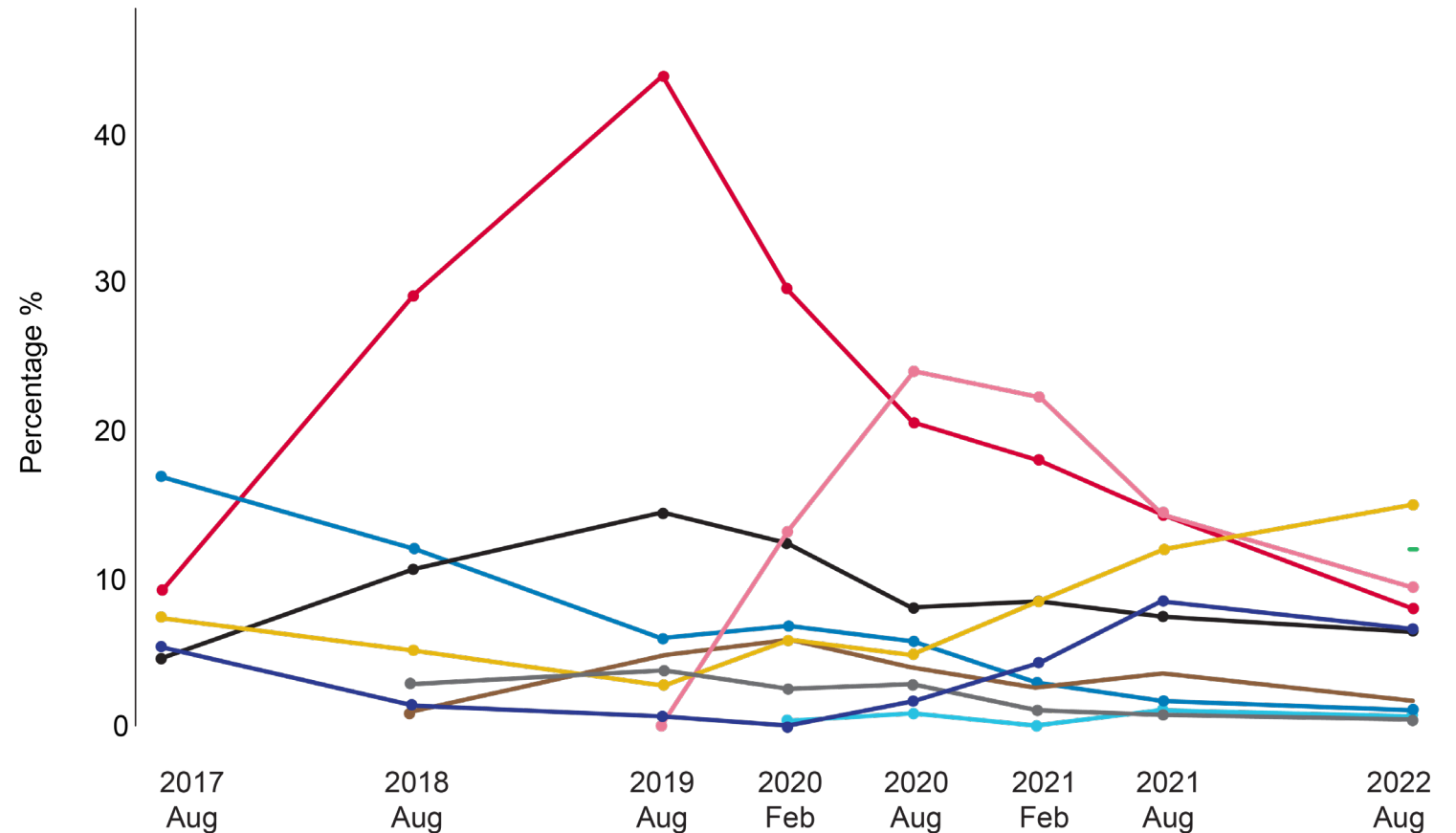


Dashed lines represent electronic data collection and solid lines represent data collection via paper and pencil instrument. The ability to compare results between 2022 and previous survey waves is limited because of methodological changes.

NOTE: Smokeless tobacco use is defined as use of chewing tobacco, snuff, dip, snus, or dissolvable tobacco product on ≥ 1 day during the past 30 days.

SOURCE: National Youth Tobacco Survey (NYTS), 2011-2022

Brands Use Among Current E-cigarette Users Aged 16-19, United States



Source: David Hammond. International Tobacco Control Survey.

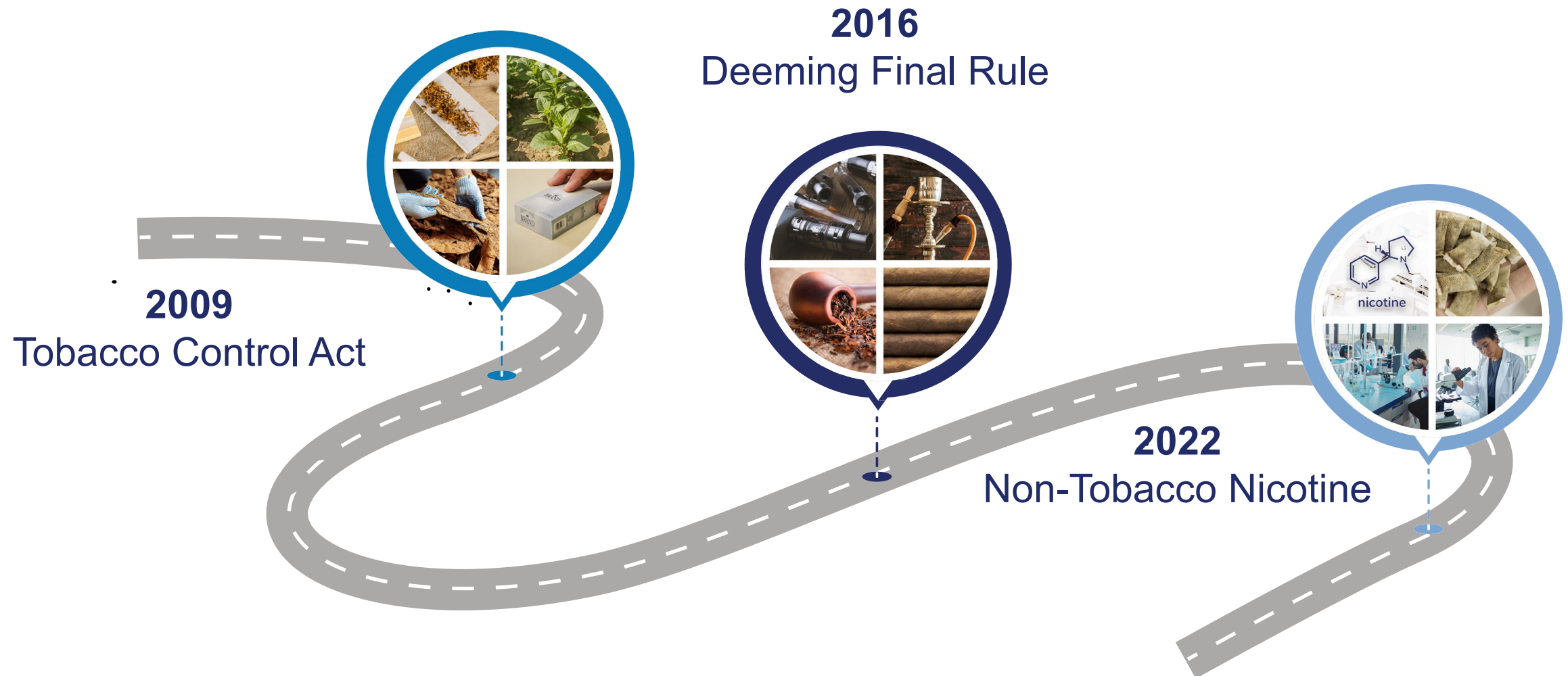
OVERVIEW OF CTP

mpower



- **Monitor tobacco use & prevention policies**
- **Protect people from tobacco smoke**
- **Offer help to quit tobacco use**
- **Warn about the dangers of tobacco**
- **Enforce bans on tobacco advertising, promotion, & sponsorship**
- **Raise taxes on tobacco**

TOBACCO CONTROL ACT



THE TOBACCO CONTROL ACT AUTHORITIES

CTP Authorities include:



Premarket review



Adverse event reporting



Post-market surveillance



New warning labels



Product standards



Advertising and promotion restrictions



Ingredients testing & reporting



User fees

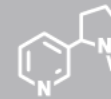


HPHC reporting

CTP Authorities generally DO NOT include:



Setting tobacco tax rates



Requiring the reduction of nicotine yields to zero

NRT

Regulating therapeutic products



Setting clean indoor air policies



Providing cessation services



Regulating tobacco growing



Banning all tobacco products



Changing the minimum age to purchase tobacco products

STATE/LOCAL PREEMPTION



The Tobacco Control Act does not limit state, local, and tribal governments from regulating tobacco products in many respects, such as:



Smokefree Indoor Laws



Restriction on Tobacco Products in Vending Machines and Tobacco Product Samples



Passing Laws More Restrictive than T21



Restricting Flavors in Tobacco Products



Impose Excise Tax on Tobacco Products

FDA'S TOBACCO REGULATORY ACTIVITIES



Review tobacco product applications

to ensure that new tobacco products meet public health standards

Ensure tobacco manufacturers and retailers follow the law through
surveillance, inspections and enforcement



FDA's Center for Tobacco Products



Educate

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

Implement the tobacco control laws through
rules & guidances



PROGRAMMATIC UPDATES



Rules & Guidances

Application Review

Compliance & Enforcement

Public Education

PROPOSED MENTHOL & 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

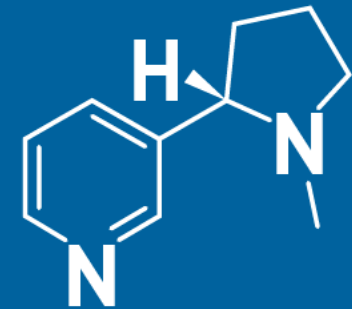


The FDA is committed to issuing the tobacco product standards for menthol in cigarettes and flavored cigars in the coming months.

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



PROGRAMMATIC UPDATES



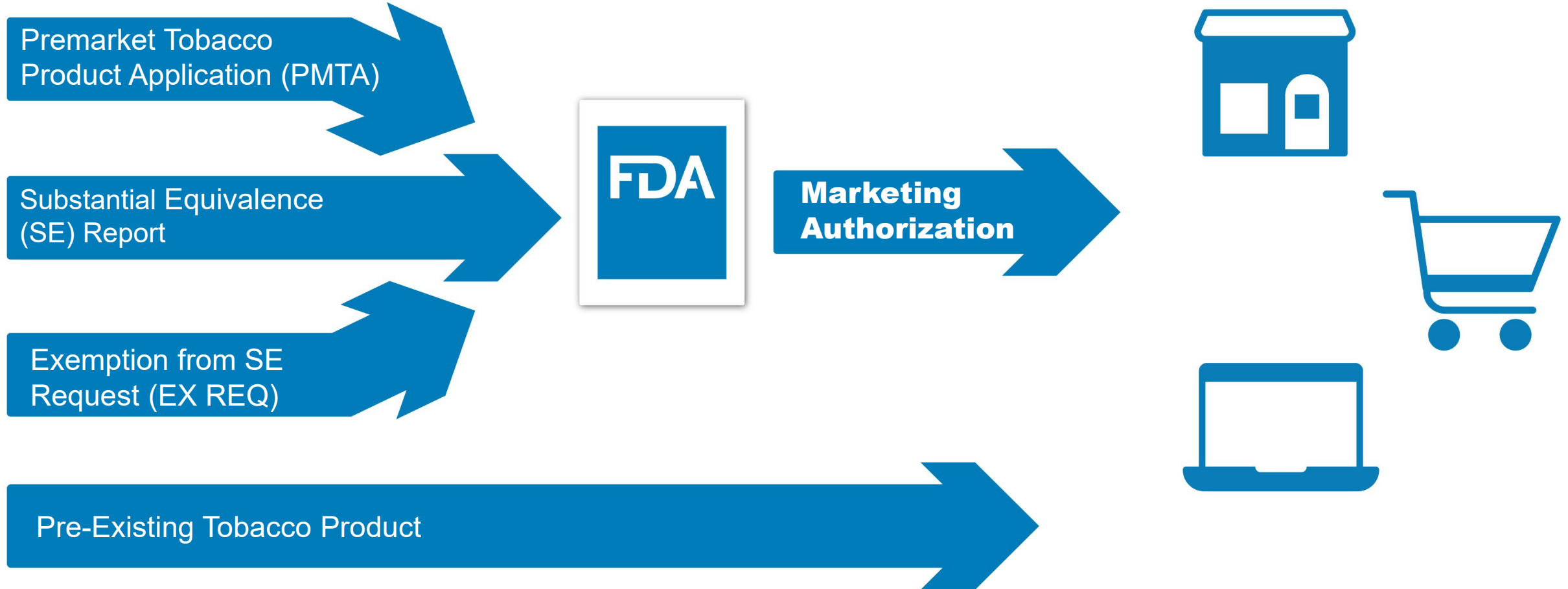
Rules & Guidances

Application Review

Compliance & Enforcement

Public Education

PATHWAYS TO MARKET



AUTHORIZATION VS APPROVAL

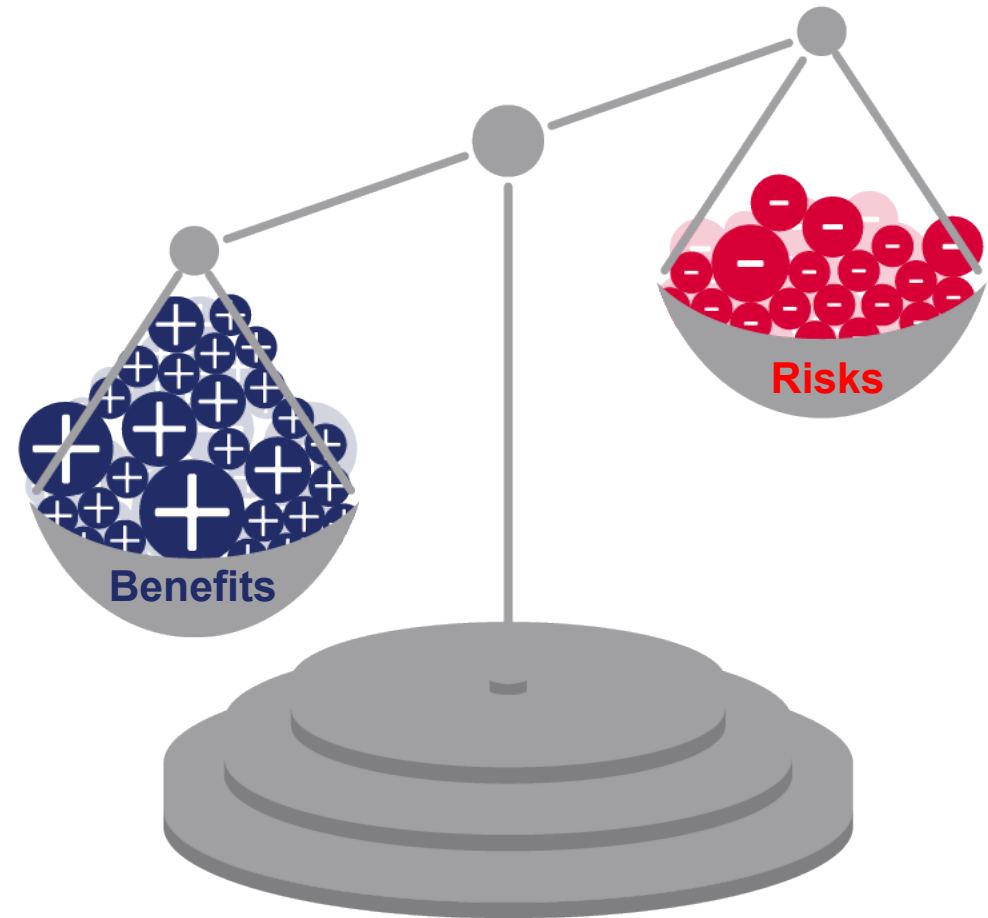


FDA “Authorizes”
Tobacco Products



FDA “Approves”
Drugs & Devices

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

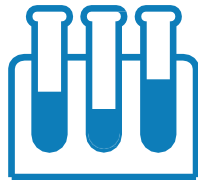


MULTI-DISCIPLINARY REVIEW

SOCIAL SCIENCE



CHEMISTRY



INDIVIDUAL
HEALTH IMPACT



POPULATION
HEALTH IMPACT

MEDICAL



ENVIRONMENTAL
SCIENCE



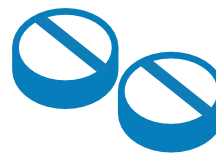
ENGINEERING



TOXICOLOGY



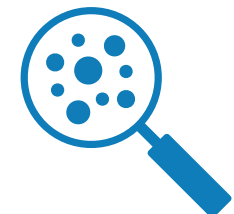
BEHAVIORAL AND
CLINICAL
PHARMACOLOGY



MICROBIOLOGY



EPIDEMIOLOGY



APPLICATION REVIEW STATUS TOTAL: PMTA FY20-23

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



PROGRAMMATIC UPDATES



Rules & Guidances

Application Review

Compliance & Enforcement

Public Education

CTP COMPLIANCE AND ENFORCEMENT ACTIVITIES



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



**Surveillance, Inspections,
and Investigations**



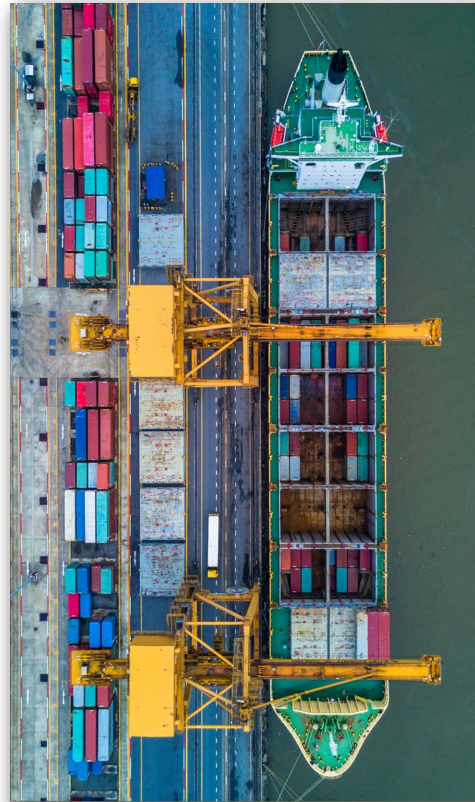
Enforcement Actions

Industry Compliance

ENSURING COMPLIANCE THROUGHOUT THE SUPPLY CHAIN



Manufacturer



Importer



Distributor



Retailer

COMPLIANCE & ENFORCEMENT ACTIONS



**Online
Investigations**

Through **August 11, 2023,**

>1,200 Warning Letters

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



Manufacturer

**~800 WARNING
LETTERS
(OVER 750 FOR ENDS)**

**25 CIVIL MONEY
PENALTIES
(ALL ENDS)**

**6 INJUNCTIONS
(ALL ENDS)**



Retailers

**OVER 128,000
WARNING LETTERS
(OVER 20,000 FOR ENDS)**

**OVER 30,000 CIVIL
MONEY PENALTIES
(OVER 3,300 FOR ENDS)**

**221 NO-TOBACCO-
SALE ORDERS**

PROGRAMMATIC UPDATES



Rules & Guidances

Application Review

Compliance & Enforcement

Public Education

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



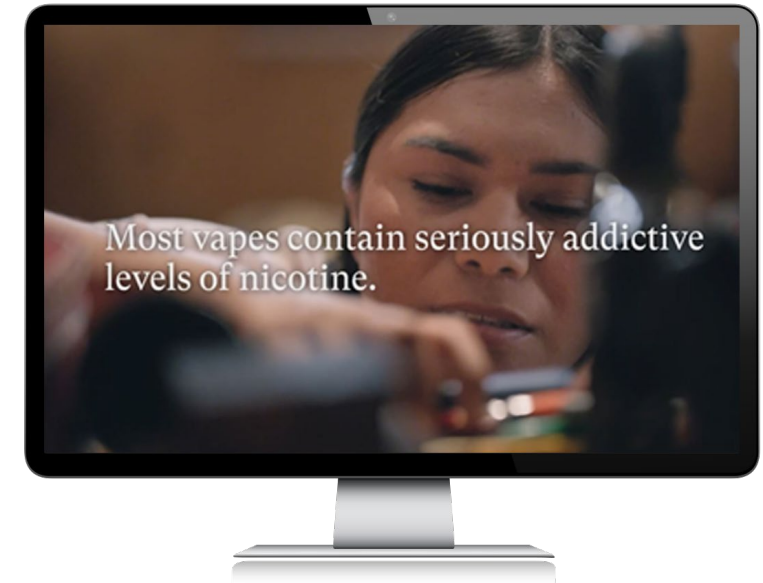
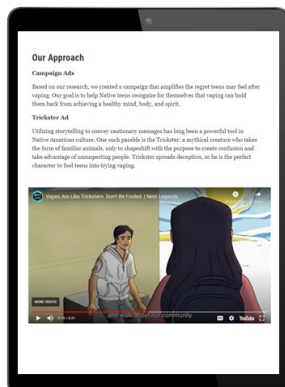
THE REAL COST E-CIGARETTE PREVENTION CAMPAIGN



- Started in 2018 as an extension of FDA's **The Real Cost** smoking prevention campaign
- Addresses the “**cost-free**” **mentality** among youth with messages about the **health consequences** and **risk of addiction** from using e-cigarettes



TOBACCO PREVENTION CAMPAIGNS



LOOKING AHEAD



EXTERNAL EVALUATION PLANNED ACTIONS



Cross-Cutting



**Science &
Application
Review**



**Regulation &
Guidance**



Compliance & Enforcement



Public Education Campaigns



Resources

HOW CAN YOU HELP?



- **Participate in Rulemaking**

- Make your voice heard. Submit your comments on rules and guidances at [Regulations.gov](https://www.regulations.gov)

- **Report Violations and Adverse Experiences**

- Tobacco product violations: 877-287-1373 or CTPCompliance@FDA.hhs.gov
- Tobacco-related health, quality problems, & adverse events: <https://www.safetyreporting.hhs.gov>

- **Expand FDA's Education Efforts**

- Visit <https://digitalmedia.hhs.gov/tobacco> to download or order **FREE** print materials, syndicate web content, and download social media content

- **Collect Data to Inform Efforts**

- Conduct research and publish local/state studies to help inform FDA's efforts

QUESTIONS?

FDA



Call Us

(877) CTP-1373



Email Us

AskCTP@fda.hhs.gov



Follow Us

@FDATobacco

**Additional platforms
to interact with FDA**



@FDA



@FDA



@FDA



@US_FDA



COMMERCIAL TOBACCO CONTROL: STATE AND LOCAL AUTHORITY



**PUBLIC HEALTH
LAW CENTER**
at Mitchell Hamline School of Law







THE PUBLIC HEALTH LAW CENTER



COMMERCIAL TOBACCO CONTROL TEAM



LEGAL TECHNICAL ASSISTANCE

-  Legal Research
-  Policy Development, Implementation, Defense
-  Publications
-  Trainings
-  Direct Representation
-  Lobby

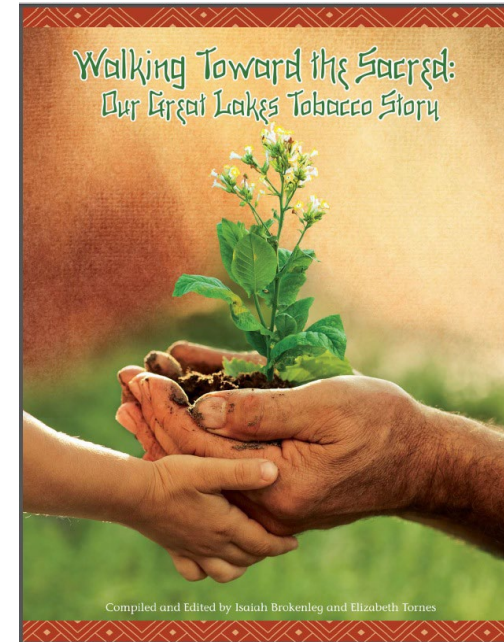


based on work for First Nations Health Authority at Gathering Wisdom VI

Drawing
change

Photo credit: Sam Bradd <https://drawingchange.com/gathering-wisdom-visuals-for-a-healthy-future/>

COMMERCIAL VS. TRADITIONAL



Source:

[http://www.glitc.org/
forms/Tabacco/
tabacco-booklet-web-.pdf](http://www.glitc.org/forms/Tabacco/tabacco-booklet-web-.pdf)

TOBACCO CONTROL ACT OF 2009

STATE AND LOCAL AUTHORITY



Preservation of State/Local Authority

Nothing in the Act limits state/local authority to enact a law “prohibiting the sale . . . of tobacco products.”

Preemption of State/Local Laws

No state/locality may establish “any requirement which is different from . . . any requirement under [the Act] relating to tobacco product standards.”

Saving Clause

The preemption restriction above “does not apply to [state or local] requirements relating to the sale” of tobacco products.

Federal v. State/Local Authority

The FDA

YES: Product standards

- Nicotine yields
- Ingredients, constituents
- How constructed
- Internet sales

NO:

- Smoke-free
- Tax
- Ban a class of products (e.g., all cigars)



States/Locals

NO: Product standards

YES:

- Smoke-free
- Youth access
- Taxes and pricing
- Sales & distribution

SMOKE-FREE POLICIES



SMOKE-FREE
HOUSING

November 2020



SMOKE-FREE MULTI-UNIT HOUSING

Equitable Enforcement Strategies



There is no safe level of secondhand smoke exposure, whether that exposure happens at work, in public spaces, or within the home.¹ The health problems associated with secondhand smoke exposure in multi-unit housing have been well documented for decades.²

Nonetheless, it is only recently that comprehensive public policy measures to address secondhand smoke exposure in multi-unit housing have been adopted through government policies. These policies include the smoke-free rule³ for public housing adopted by the U.S. Department of Housing and Urban Development (HUD) and a growing number of local jurisdictions that have adopted similar protections for residents of multi-unit housing.⁴



WHO CAN SELL TOBACCO PRODUCTS?

WHO CAN THEY SELL THEM TO?

- Overall structure for point-of-sale policies
- Can include minimum legal sale age
- Sets the rules and enforcement provisions

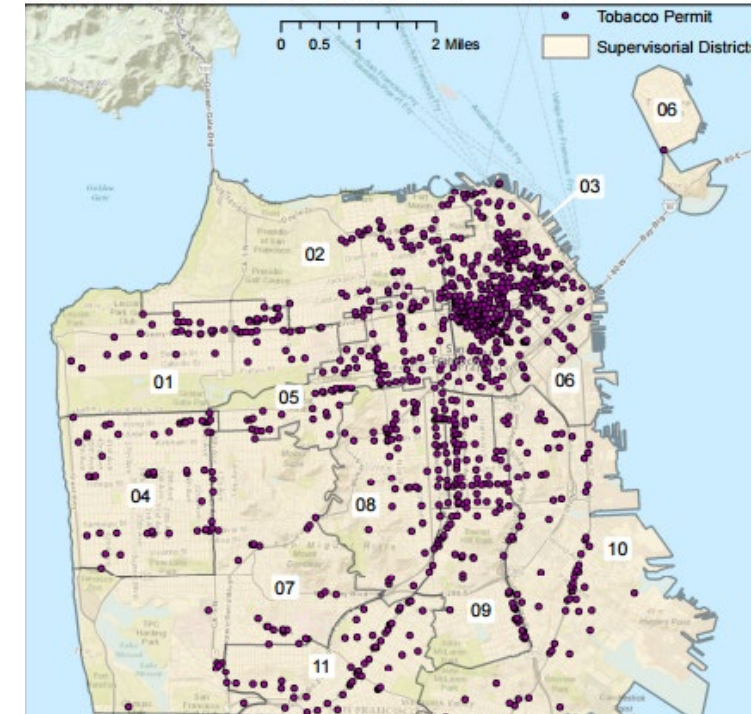


WHERE TOBACCO PRODUCTS CAN BE SOLD

PROXIMITY AND DENSITY

- Proximity to residential areas, schools, retailers
- Internet sales
- Pharmacies
- Cap and reduce the number of licenses

San Francisco Tobacco Permits - 2014



JCH

The New York Times

BUSINESS DAY

CVS Stores Stop Selling All Tobacco Products

By RACHEL ABRAMS SEPT. 3, 2014



Antismoking signs are posted where cigarettes once were displayed at a CVS in Manhattan that no longer sells tobacco products. Andrew Rensen/The New York Times

9/14/2023

11

WHICH PRODUCTS CAN BE SOLD?

ENDING THE SALE OF FLAVORS – ESPECIALLY MENTHOL

81% of youth initiate tobacco use with flavored products.

- Source: Truth Initiative

Menthol increases initiation, decreases cessation, exacerbates disparities.

- Source: Campaign for Tobacco Free Kids



FLAVORED TOBACCO RESTRICTIONS

THE EVOLUTION



TAX AND PRICING POLICIES

- 10% increase in cigarette tax results in a 3-5% decrease in use.
- Youth are 2-3 times more sensitive to price increases.
- Increased quit attempts – especially among lower income users.

Sources: Truth Initiative and
Tobacconomics.org

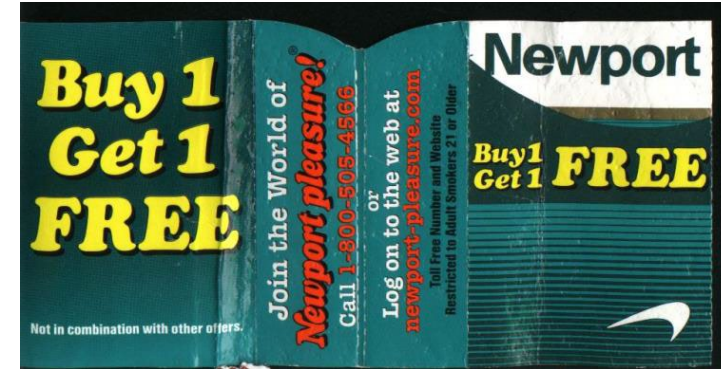


“Young people are very price sensitive.”

R. J. Reynolds Marketing Report, 1982

NON-TAX PRICING POLICIES

- Tobacco is often the cheapest in lowest income communities.
- Restricting redemption of coupons.
 - No “sale” prices.
- Price floors – often combined with minimum pack size.
- Part of strong retailer licensing structure.



MOVING TO THE END NICOTINE-FREE GENERATION



Brookline, MA Tobacco-Free Generation policy.

Phases out the sale of tobacco products by prohibiting the sale of tobacco to anyone born after January 1, 2000.



ENDGAME POLICIES

ENDING THE SALE



- Beverly Hills, CA passed ordinance prohibiting the sale of all tobacco products except in cigar lounges and by hotel concierges to registered hotel guests.



- Manhattan Beach, CA passed ordinance prohibiting the sale of all tobacco products everywhere in the jurisdiction.

STATE PREEMPTION – THE DANGER WITHIN A FUNDAMENTAL HEALTH EQUITY ISSUE

- Locally tailored policies are the best policies for addressing health disparities.
- Preemption locks in the status quo and inhibits policy innovation.
- Community involvement helps to develop more thoughtful policies.



grassrootschange.net

WHY ARE STATE AND LOCAL POLICIES IMPORTANT?

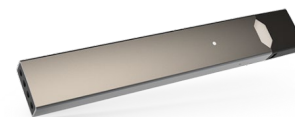
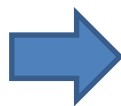
PRECISION AND FLEXIBILITY

- The tobacco industry is always ready to pivot.
- “Future-proof” policies.
- Tailored implementation and enforcement.



EVOLUTION OF E-CIGARETTES

ENSURING THAT TAX POLICY KEEPS UP



OFFICE 4



Office 4 - Tropical Peach



Office 4 - Lush Ice

SYNTHETIC NICOTINE PRODUCTS

Our Mission

We believe that innovation is the key to creating unforgettable experiences. And innovation is at the heart of what we do. PuffBar provides adult vapers with premium products to elevate life's greatest moments. For us, offering consumers the best choice on the market isn't just a mission — it's a requirement. As America's leading innovator in vape devices, we pride ourselves in setting the bar. And we're committed to raising that bar, one puff at a time.



Tobacco Free

Better Flavor, Better Experience

As a demonstrated pledge to premium quality, Puffs nicotine-based products are created with tobacco-free nicotine. Our nicotine-based products are crafted from a patented manufacturing process, not from tobacco. The result? A virtually tasteless, odorless nicotine without the residual impurities of tobacco-derived nicotine. This dramatically improves flavor while still maintaining the same satisfaction smokers are seeking from their nicotine.

Experience

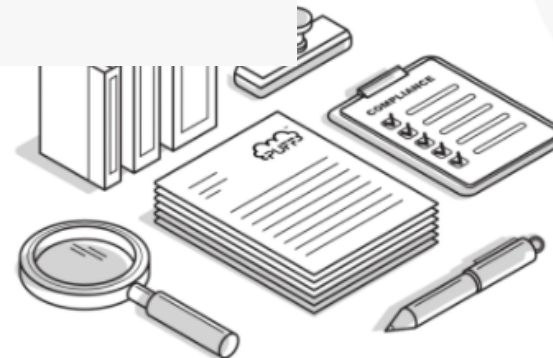
Our nicotine-based products are crafted from a patented manufacturing process, not from tobacco. The result? A virtually tasteless, odorless nicotine without the residual impurities of tobacco-derived nicotine. This dramatically improves flavor while still maintaining the same satisfaction smokers are seeking from their nicotine.



Fully Licensed & Compliant

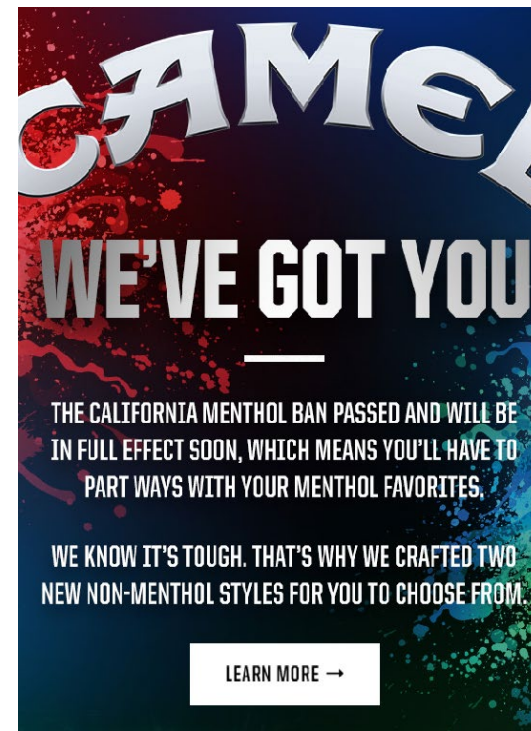
The Puff Difference

Puff Bar is fully licensed and compliant with current tobacco regulations in the United States. Puff Bar is proud to be working directly with state and federal policy makers to create fair rules & regulation as well as assisting in stopping counterfeits from entering the US market.



NEXT PHASE INTENTIONAL AMBIGUITY

- “Non-menthol” products – cooling sensations.
- Introduced immediately after California’s flavored tobacco referendum passed.
- These appear to be flavored products and are marketed to indicate that they’re flavored.



CONTACT US



651.290.7506



publichealthlawcenter@mitchellhamline.edu



www.publichealthlawcenter.org



[@phealthlawctr](https://twitter.com/phealthlawctr)



facebook.com/publichealthlawcenter

Stay Involved



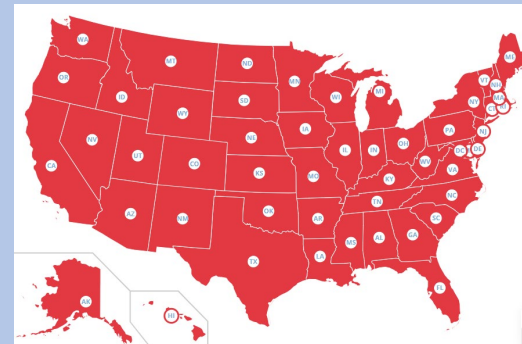
Please complete our survey after the webinar ends. Thank you!

NEXT WEBINAR:

Thursday, October 5, 2023

2023 U.S. Tobacco Industry
Interference Report Launch

Resource to Use



*U.S. Tobacco
Lobbyist & Lobbying
Firm Registration
Tracker 2023*

ash.org/tobacco-money