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

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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.
CURRENT TOBACCO PRODUCT LANDSCAPE
CIGARETTE CONSUMPTION 1900-2020

CURRENT ADULT USE OF TOBACCO PRODUCTS (2021)

- Cigarettes: 11.5%
- E-cigarettes: 4.5%
- Cigars: 3.5%
- Smokeless tobacco: 2.1%
- Pipes: 0.9%

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.


9.4% E-Cigarette
1.9% Cigar
1.6% Cigarette
1.3% Smokeless
1.1% Hookah
1.1% Nicotine pouches
1.0% Heated tobacco
Brands Use Among Current E-cigarette Users Aged 16-19, United States

Source: David Hammond. International Tobacco Control Survey.
OVERVIEW OF CTP
TOBACCO PRODUCT REGULATION GLOBALLY

- 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

2009
Tobacco Control Act

2016
Deeming Final Rule

2022
Non-Tobacco Nicotine
THE TOBACCO CONTROL ACT AUTHORITIES

CTP Authorities include:
- Premarket review
- Post-market surveillance
- Product standards
- Ingredients testing & reporting
- HPHC reporting
- Adverse event reporting
- New warning labels
- Advertising and promotion restrictions
- User fees

CTP Authorities generally DO NOT include:
- Setting tobacco tax rates
- Requiring the reduction of nicotine yields to zero
- Regulating therapeutic products
- Providing cessation services
- Setting clean indoor air policies
- Banning all tobacco products
- Regulating tobacco growing
- Changing the minimum age to purchase tobacco products
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
- Educate the public, especially youth, about the dangers of using tobacco products
- Implement the tobacco control laws through rules & guidances

FDA's Center for Tobacco Products
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.
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.
PROGRAMMATIC UPDATES

Rules & Guidances

Application Review

Compliance & Enforcement

Public Education
PATHWAYS TO MARKET

Premarket Tobacco Product Application (PMTA)

Substantial Equivalence (SE) Report

Exemption from SE Request (EX REQ)

Pre-Existing Tobacco Product

Marketing Authorization
AUTHORIZATION VS APPROVAL

FDA “Authorizes” Tobacco Products

FDA “Approves” Drugs & Devices
"Appropriate for the Protection of the Public Health"
MULTI-DISCIPLINARY REVIEW

INDIVIDUAL HEALTH IMPACT

POPULATION HEALTH IMPACT

ENGINEERING
CHEMISTRY
TOXICOLOGY
BEHAVIORAL AND CLINICAL PHARMACOLOGY
MICROBIOLOGY
SOCIAL SCIENCE
ENVIRONMENTAL SCIENCE
MEDICAL
EPIDEMIOLOGY

INDIVIDUAL HEALTH IMPACT

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SOCIAL SCIENCE
ENVIRONMENTAL SCIENCE
MEDICAL
EPIDEMIOLOGY
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

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

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<thead>
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<th>Online Investigations</th>
<th>Manufacturer</th>
<th>Retailers</th>
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| ~800 WARNING LETTERS 
(OVER 750 FOR ENDS) | 25 CIVIL MONEY PENALTIES 
(ALL ENDS) | 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 |   |
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

SOURCE: US Census 2017; YRBS 2017

Most vapes contain seriously addictive levels of nicotine.
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](http://Regulations.gov)

- **Report Violations and Adverse Experiences**
  - Tobacco product violations: 877-287-1373 or [CTPCompliance@FDA.hhs.gov](mailto:CTPCompliance@FDA.hhs.gov)
  - Tobacco-related health, quality problems, & adverse events: [https://www.safetyreporting.hhs.gov](https://www.safetyreporting.hhs.gov)

- **Expand FDA’s Education Efforts**
  - Visit [https://digitalmedia.hhs.gov/tobacco](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
COMMERCIAL TOBACCO CONTROL:
STATE AND LOCAL AUTHORITY
COMMERCIAL TOBACCO CONTROL TEAM

PUBLIC HEALTH LAW CENTER
at Mitchell Hamline School of Law
LEGAL TECHNICAL ASSISTANCE

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

9/14/2023
SOCIAL DETERMINANTS OF HEALTH

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
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 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. The health problems associated with secondhand smoke exposure in multi-unit housing have been well documented for decades. 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 rule 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.
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
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.
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

Source: Campaign for Tobacco-Free Kids

9/14/2023
SYNTHETIC NICOTINE PRODUCTS

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.

Our Mission

We believe that innovation is the key to creating a genuine experience. And innovation is at the heart of what we do. Puffbar is committed to providing products that are innovative, and we strive to be the best in our field.

Fully Licensed & Compliant

Puffbar is fully licensed and compliant with current tobacco regulations in the United States. Puffbar is proud to be working closely with state and federal policy makers to create a safer environment for consumers as well as addressing the growing need for compliant products that are safe and effective.
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.
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NEXT WEBINAR:

Thursday, October 5, 2023
2023 U.S. Tobacco Industry Interference Report Launch

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

Resource to Use

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

ash.org/tobacco-money