OVERVIEW OF THE CENTER FOR TOBACCO PRODUCTS (CTP)

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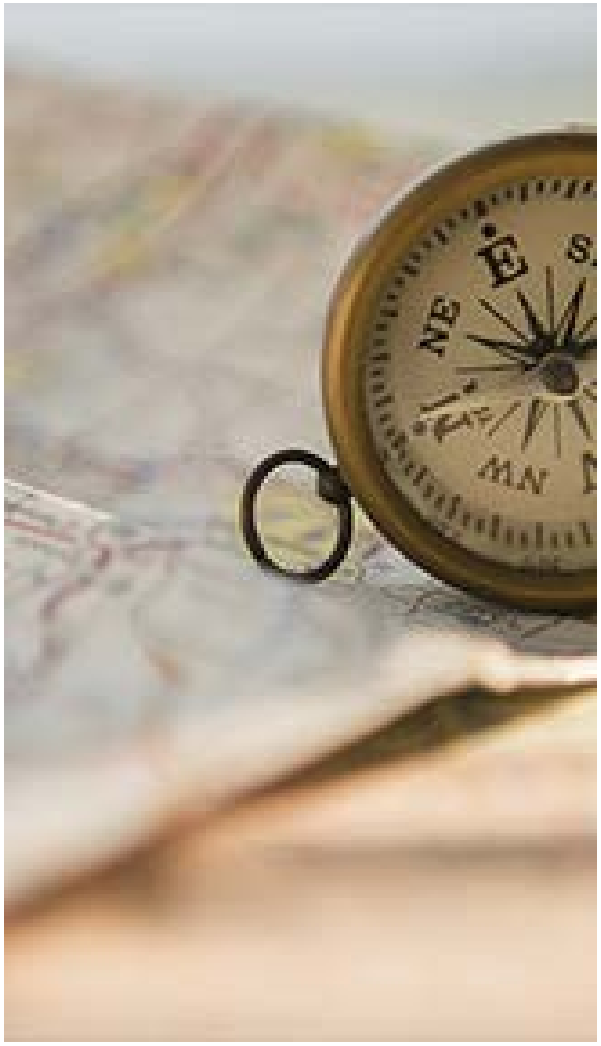
March 2019

AGENDA

- The Public Health Reality
- FDA's Tobacco Authorities
- CTP's Programmatic Efforts
- Comprehensive Plan for Tobacco & Nicotine Regulation
- CTP Small Business Initiative



THE PUBLIC HEALTH REALITY

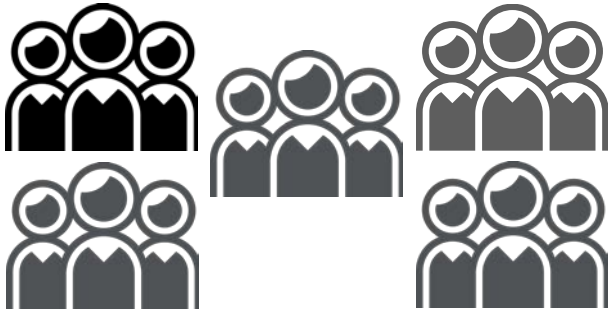
AN UPHILL BATTLE AGAINST DISEASE AND DEATH

1900

100 Million Worldwide
PREMATURE DEATHS

2000

1 Billion Worldwide
PREMATURE DEATHS



2100

THE BURDEN OF CIGARETTE SMOKING IN THE U.S.

For Adults:

- Tobacco use is still the leading cause of preventable death – over 480,000 Americans die each year
- Nearly 70% of current adult smokers want to stop smoking completely

For Teens:

- For youth under age 18, every day, about 2,000 smoke their first cigarette, more than 300 become daily smokers, nearly 2,000 smoke their first cigar, nearly 1,300 use smokeless tobacco for the first time
- Almost 90 percent of adult smokers started smoking before the age of 18
- Nationwide, over 3 million high school students, and over .5 million middle school students, currently smoke e-cigarettes

FDA'S TOBACCO AUTHORITIES

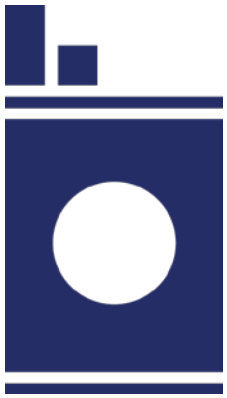
THE TOBACCO CONTROL ACT BECAME LAW ON JUNE 22, 2009

- To protect the public and create a healthier future for all Americans – particularly youth – a bipartisan Congress passed the Tobacco Control Act (TCA)
- FDA's goal is to reduce the harm from all regulated tobacco products across the entire U.S. population:
  - Reducing the number of people who start using tobacco products
  - Encouraging more people to stop using these products
  - Reducing the adverse health impact for those who continue to use these products

THE TOBACCO CONTROL ACT BECAME LAW ON JUNE 22, 2009

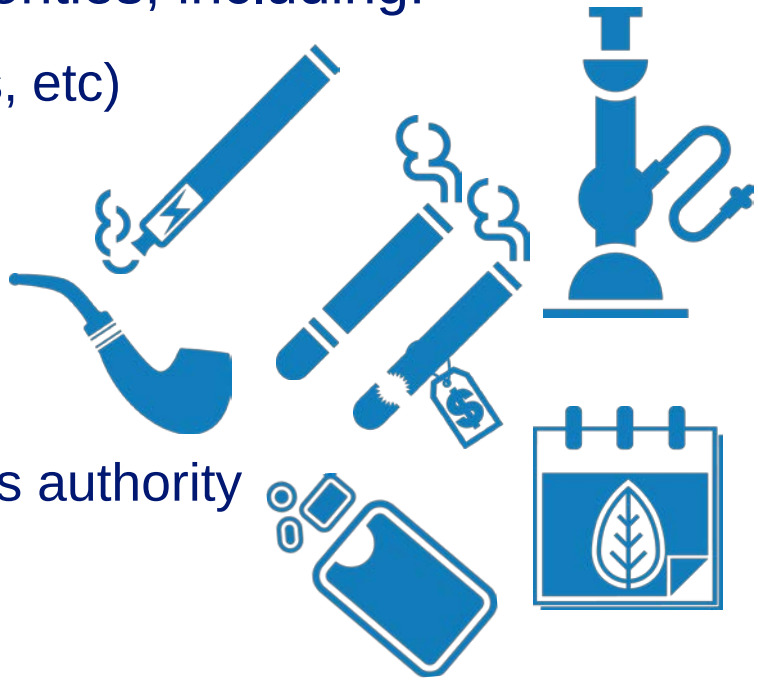
Since 2009, FDA had authority to regulate tobacco products intended for human consumption to reduce harm across the population

- Immediate authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless
- The law also permitted FDA to "deem" products meeting the statutory definition of tobacco product by issuing a regulation



FINAL DEEMING REGULATION

- On August 8, 2016, a final rule went into effect that “deems” all products meeting the statutory definition of tobacco product, including components or parts (but excluding accessories), to be subject to FDA’s tobacco product authorities, including:
  - ✓ ENDS (e-cigarettes, e-cigars, vape pens, etc)
  - ✓ All cigars
  - ✓ Pipe tobacco
  - ✓ Nicotine gels
  - ✓ Waterpipe (hookah)
  - ✓ Dissolvables not already under the FDA’s authority
  - ✓ Future tobacco products



EMPLOYING A PUBLIC HEALTH STANDARD

- Pursue a “public health” standard as tobacco cannot be regulated using FDA’s traditional “safe and effective” standard
- Take into account the effects on both users and non-users of tobacco products
- Assess the “net” population-level health impacts of tobacco products

UTILIZING USER FEES EXCLUSIVELY

- Entirely funded through industry-paid user fees based on market share (not applications)
- User fees are the sole allowable source for FDA tobacco program spending, and the FDA tobacco program is the sole allowable use of the funds
- Funding levels started at $85M in 2009, grow to $712M in 2019, and remain at that level

THE TOBACCO CONTROL ACT'S AUTHORITIES

The Tobacco Control Act amended the Food, Drug, and Cosmetic Act to provide FDA authority for:

- Premarket review of new and modified risk tobacco products
- Post-market surveillance
- Product standards
- Reporting of ingredients
- Testing and reporting of harmful and potentially harmful constituents
- Adverse event reporting
- New health warnings
- Advertising and promotion restrictions
- User fees

CTP'S REGULATORY AUTHORITIES

In general, CTP's regulatory authorities do not extend to:

- Setting tax rates for tobacco products
- Regulating therapeutic products, such as those marketed to treat tobacco dependence (regulated by other parts of FDA)
- Setting clean indoor air policies
- Regulating tobacco growing
- Requiring the reduction of nicotine yields to zero
- Providing cessation services
- Banning all cigarettes, smokeless tobacco products, little cigars, other cigars, pipe tobacco, or roll-your-own tobacco products
- Changing the minimum age to purchase tobacco products

HOW FDA IS USING ITS TOBACCO AUTHORITIES

- Understand the regulated products
- Review new products before they can be marketed
- Review proposed modified risk products that state/imply reduced exposure or risk before they can be marketed
- Restrict marketing and distribution to protect public health
- Decrease the harms of tobacco products
- Ensure industry compliance with FDA regulation through education, inspections, and enforcement
- Educate the public about FDA's regulatory actions
- Expand the science base for regulatory action and evaluation

CTP'S PROGRAMMATIC EFFORTS

CTP OFFICES

Office of Management

Office of Regulations

Office of Science

Office of Compliance and Enforcement

Office of Health Communication and Education

UNDERSTANDING THE REGULATED PRODUCTS

- **Registration and listing**
  - Companies must register manufacturing facilities and provide a list of all their regulated products.
- **Ingredient reporting**
  - Companies must provide a list of ingredients for regulated products.
- **Submission of health information**
  - All documents related to health, toxicology, behavioral, physiologic effects that are developed after enactment of the statute.
  - Upon request, all documents related to research on health toxicology, behavioral, physiologic, and marketing research.
- **Harmful and potentially harmful constituents (HPHC)**
  - Manufacturers must report levels by brand and sub-brand.
  - Guidance issued defining HPHC as constituents that cause harm or have the potential to cause direct harm (toxicity, addictiveness) or indirect harm (increase initiation or decrease cessation).
  - FDA established a list of 93 HPHC.
  - FDA issued draft guidance on initial reporting of 20 HPHC.

REVIEW NEW PRODUCTS BEFORE THEY CAN BE MARKETED

The FD&C Act requires that, before a *new* tobacco product may be introduced into interstate commerce for commercial distribution in the U.S., the new tobacco product must undergo premarket review by FDA and receive marketing authorization through one of the following pathways—

- **Premarket tobacco product applications** (an application for a new tobacco product that includes comprehensive product information and samples of the product);
- **Substantial equivalence applications** (an application that compares a new tobacco product to a "predicate" or comparison product);
- **Exemption requests** (a request submitted for a minor modification to a product involving only a change to an additive)

REVIEW PROPOSED MODIFIED RISK PRODUCTS BEFORE THEY CAN BE MARKETED

- Premarket review is required for modified risk tobacco products
- FDA will allow reduced risk claims when scientifically proven and an order is issued by FDA.
- Pre-market review required if the label, labeling, or advertising represents explicitly or implicitly that:
  - The tobacco product presents a lower risk of disease or is less harmful than one or more marketed products.
  - The tobacco product or its smoke contains a reduced level or presents a reduced exposure to a substance or is free of a substance.
  - The label, labeling, or advertising uses the descriptors “light,” “mild,” “low,” or similar descriptors.

EXPAND SCIENCE BASE FOR REGULATORY ACTION & EVALUATION

To expand the scientific foundation for FDA tobacco product regulation

- Fund research that is then administered by the National Institutes of Health Tobacco Regulatory Science Program
  - Investigator initiated awards
  - Supplements to existing grants or cooperative agreements
  - Tobacco Centers of Regulatory Science (TCORS) in areas of importance to FDA (14 TCORS awarded in 2013; 9 TCORS 2.0 awarded in 2018)
  - Population Assessment of Tobacco and Health (PATH) Study (tobacco longitudinal cohort study)
- Support for national surveys (e.g. NYTS)
- Laboratory analyses (FDA, CDC, NCTR)

RESTRICT MARKETING AND DISTRIBUTION

To reduce youth initiation, FDA restricts access and marketing of tobacco products by prohibiting:

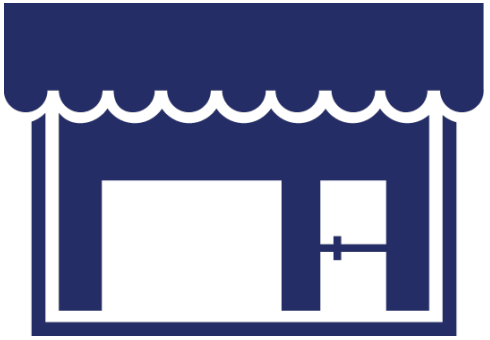
- Sales to people younger than 18; proof of age for purchase <27 years of age required
- Sales in vending machines or self-service displays, except in facilities where children under 18 are never present or permitted at any time
- Distribution of free samples; restricts the distribution of free samples of smokeless tobacco products to “qualified adult-only facilities”

FDA also restricts access and marketing by prohibiting:

- Brand name sponsorship of athletic, musical, or other social events, teams
- Hats and tee shirts, etc., with brand names or logos
- Sales of cigarette packs with fewer than 20 cigarettes

ENSURE INDUSTRY COMPLIANCE – RETAILERS AND MANUFACTURERS

- Retailers:
  - Contracts with states, territories, and tribes to conduct tobacco retailer inspections to ensure compliance with FDA regulations
  - FDA also inspects in jurisdictions without contracts using FDA inspectors



- Manufacturers:
  - FDA inspects each registered domestic establishment engaged in the manufacture, preparation, compounding, or processing of tobacco products (biennial)

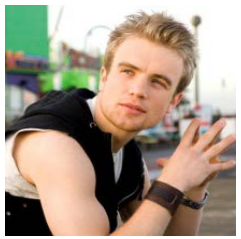
EDUCATE THE PUBLIC

- Public education efforts related to statutory authorities and regulatory actions
- Publish list of harmful and potentially harmful constituents by brand and sub-brand in a way that is understandable and not misleading

PUBLIC EDUCATION CAMPAIGNS

- Public education campaigns are a proven strategy in preventing and reducing population-level tobacco use
- Campaigns have contributed to significant declines in tobacco use over the past several decades. FDA has efforts targeting discrete audiences:
  - ✓ *The Real Cost:* General market teens at risk of smoking (February 2014)
  - ✓ *Fresh Empire:* Multicultural teens at risk of smoking (October 2015)
  - ✓ *The Real Cost Smokeless:* Rural male teens at risk of using smokeless (April 2016)
  - ✓ *This Free Life*: Lesbian, Gay, Bisexual, Transgender (LGBT) young adults at risk of becoming regular smokers (May 2016)
  - ✓ *Every Try Counts*: Smokers who have tried to quit in the last year but were unsuccessful (December 2017)
  - ✓ *The Real Cost Youth E-Cigarette Prevention*: General market teens on the dangers of e-cigarette use (September 2018)



CTP's Small Business Initiative

SUPPORT THE SMALL BUSINESS PROGRAM GOALS

Small Business Outreach

1:1 Small Business Briefing Sessions

Internal Training Presentations/Newsletter

Small Business Database

CTP Small Business Initiative Team

SMALL BUSINESS OUTREACH

- Collaborate with the FDAs Small Business Specialist (OAGS) periodically on developing strategies to foster and support the Small Business Program.

- Attend both internal and external FDA sponsored Small Business Meetings, Small Business Outreach Fairs and Conferences in conjunction with the Small Business Specialist periodically throughout the year.

1:1 SMALL BUSINESS BRIEFING SESSIONS

- Conduct periodic in person 1:1 briefing sessions with Small Businesses at CTP, in conjunction with the FDA assigned Small Business Specialist.

- Briefing sessions are held will small businesses in each of the socioeconomic programs (Small Businesses, Small Disadvantaged Businesses, SDVOB, Women-owned Small Businesses, and Hub Zone Businesses) and 8(a)s allowing them the opportunity to present their capabilities and relevant experiences.

1:1 SMALL BUSINESS BRIEFING SESSIONS

Benefits:

- CTPs ability to present a brief summary/overview of potential “real” fiscal year requirements.
- Small Business’ ability to present their capabilities/relevant experiences based on the same or similar requirements.
- Q&A session allowing both CTP and the Small Businesses to get questions answered on the spot as it relates to CTPs requirement; and the small businesses capabilities and relevant experience.
- Assists with CTPs required Acquisition Strategy, Acquisition Planning, and Market Research goals.

INTERNAL TRAINING PRESENTATIONS AND NEWSLETTER TO THE CORS AND PM STAFF

- Conduct internal presentations through the Acquisition Assistance Team's (AAT) "Ask the Experts" forum to inform and educate CORs, Program Managers, and Subject Matter Experts on the Small Business Programs, throughout the year.

- Publish articles in our COR Newsletter on various informative topics.

SMALL BUSINESS DATABASE

- Created and maintain a CTP Small Business database search tool that lists Small Businesses, to include their pertinent company data, within each of the socioeconomic programs to share with CTP CORs/PMs/SMEs for these purposes:
  - Acquisition Strategy
  - Acquisition Planning
  - Market Research
  - Fact Finding and Information Gathering

CTP SMALL BUSINESS INITIATIVE TEAM

- Conduct AAT Small Business Initiative Group monthly meetings to organize, coordinate, and accomplish each of the mission goals.

- Team Members/Supporters:
  - Patricia Pemberton, AAT Director and Small Business Coordinator
  - George Gonzalez, AAT Deputy Director
  - Jill Staton, Team Member/Newsletter Writer/Editor
  - Kathleen Marsden, Team Lead
  - Noah Pomato, Team Lead
  - Keith Austin, Team Lead

QUESTIONS?

THANK YOU

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