OVERVIEW OF THE CENTER FOR TOBACCO PRODUCTS

Office of Management

January 2017

CENTER FOR TOBACCO PRODUCTS

AGENDA

- About the FDA Center for Tobacco Products (CTP)

- CTP Small Business Initiative

CTP PROGRAM OFFICES

FDA
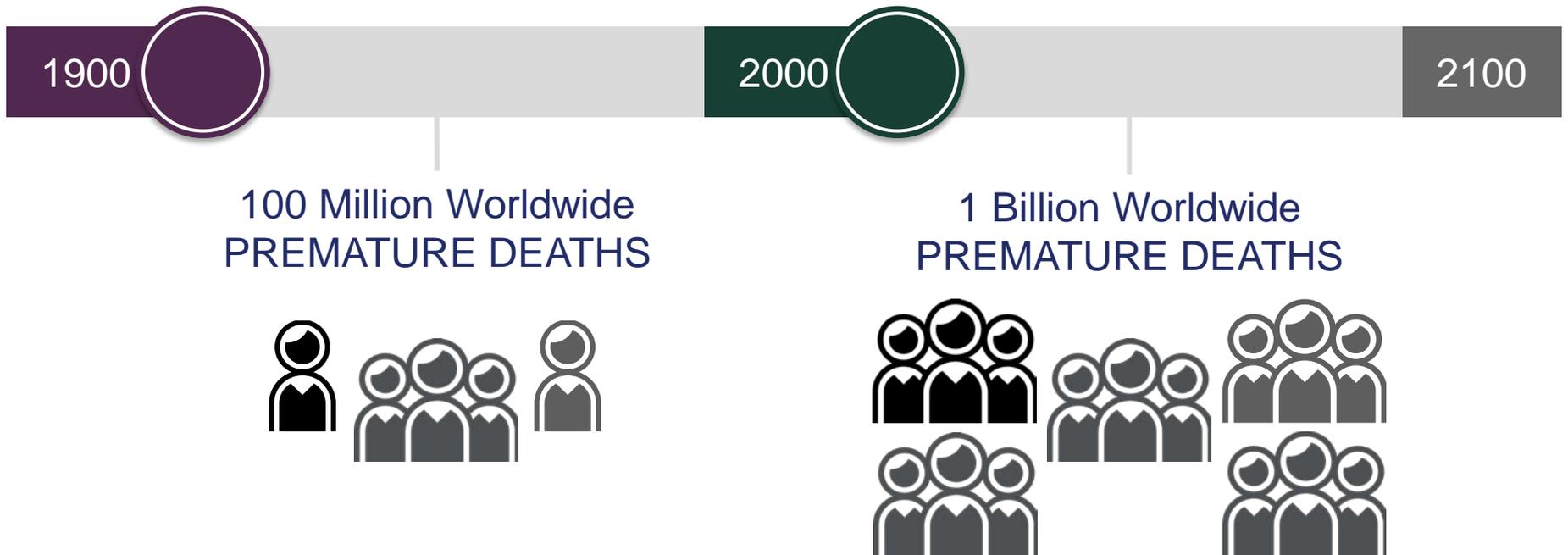
- Office of Regulations

- Office of Science

- Office of Health Communication and Education

- Office of Compliance and Enforcement

Center for Tobacco Products

PREVENTING THE PREVENTABLE IN THE US

FDA

- Progress since first Surgeon General's Report – despite huge strides, 36.5 million adults still smoke

- Still the leading cause of preventable disease and death – over 480,000 Americans die each year

- Every day nearly 2,500 youth under age 18 smoke their first cigarette

- More than 400 youth become daily smokers

- Every day more than 2,100 youth under age 18 smoke their first cigar

- Every day about 1,300 youth under age 18 use smokeless tobacco for the first time

FDA

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

- Regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless
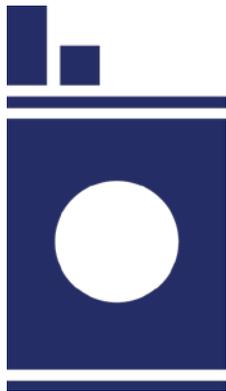
PROTECTING AMERICANS THROUGH NEW REGULATION

FDA

- Effective Aug. 8, 2016, FDA finalized a rule 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

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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

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CTP'S STRATEGIC PRIORITIES

PURSUING STRATEGIC PRIORITIES
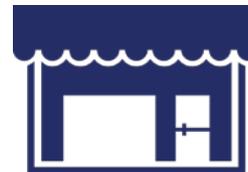
Product Standards

Comprehensive Nicotine Regulatory Policy

Pre- & Post-Market Controls: Regulations & Product Reviews

Compliance and Enforcement

Public Education

COMPLIANCE AND ENFORCEMENT

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MEASURING COMPLIANCE ACCOMPLISHMENTS

FDA

- Conducted over 714,000 retailer inspections covering 56 states and territories

- Issued more than 53,100 warning letters

- Issued over 10,180 civil money-penalty (CMP) actions against tobacco retailers

- Since Aug. 8, provisions for newly-deemed products are included in brick and mortar and online compliance checks

  - Sept. 2016: Issued first 55 Warning Letters to retailers for violations related to newly-regulated products, such as selling ENDS and cigars to minors

- July 2016: Retailer received a second No-Tobacco-Sale-Order (NTSO) for violation of certain restrictions, including sales to minors

Data as of 1/1/17

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PUBLIC EDUCATION

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PUBLIC EDUCATION EFFORTS

FDA

Multiple efforts over several years targeting discrete audiences:

- General market at-risk youth – February 2014 ("The Real Cost")

- Multicultural (African-American, Hispanic, Asian / Pacific Islander) at-risk youth – October 2015 ("Fresh Empire")

- Rural male youth at-risk of using smokeless tobacco – April 2016 ("The Real Cost" Smokeless Tobacco Prevention Campaign)

- LGBT young adults – May 2016 ("This Free Life")

- Adult smokers who want to quit (implemented at point-of-sale locations) [Campaign currently under development]

- American Indian / Alaska Native at-risk youth [Campaign currently under development]

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CTP'S SMALL BUSINESS INITIATIVE

SUPPORT THE SMALL BUSINESS PROGRAM GOALS

FDA

Small Business Outreach

1:1 Small Business Briefing Sessions

Internal Training Presentations/Newsletter

Small Business Database

SMALL BUSINESS OUTREACH

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SMALL BUSINESS OUTREACH

CTP Small Business Initiative Team

- 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

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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, CONT'D

FDA

Benefits:

- CTPs ability to present a brief summary/overview of potential 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.

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INTERNAL TRAINING PRESENTATIONS AND NEWSLETTER

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INTERNAL TRAINING PRESENTATIONS AND NEWSLETTER TO THE CORS AND PM STAFF

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

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

Small Business Database

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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

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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
    - George Gonzalez, AAT Deputy Director
    - Doreen Robinson, Team Lead/Small Business Coordinator
    - Jill Staton, Team Member/Newsletter Writer/Editor
    - Kathleen Marsden, Team Lead
    - Noah Pomato, Team Lead
    - Keith Austin, Team Lead

THANK YOU