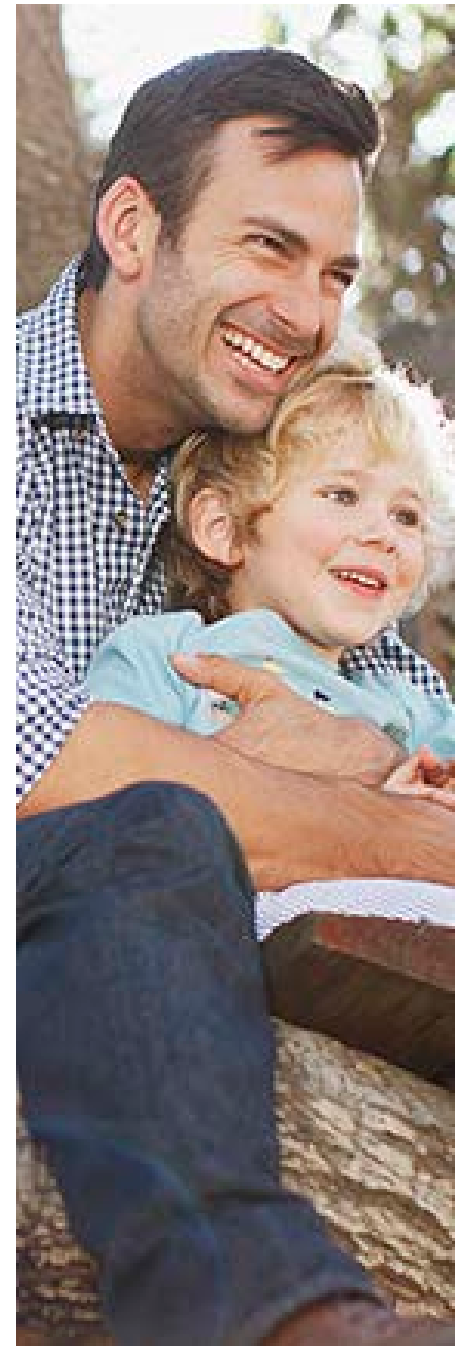


TRANSLATING FDA/CTP AUTHORITY INTO REGULATORY ACTION

#APHAtobacco



FDA

CENTER FOR
TOBACCO
PRODUCTS

Presented by
Mitch Zeller
Director

November 18, 2014

PRESENTER DISCLOSURE

Mitchell Zeller, JD
Center for Tobacco Products
US Food and Drug Administration

No relationships to disclose

OVERVIEW OF TODAY'S PRESENTATION

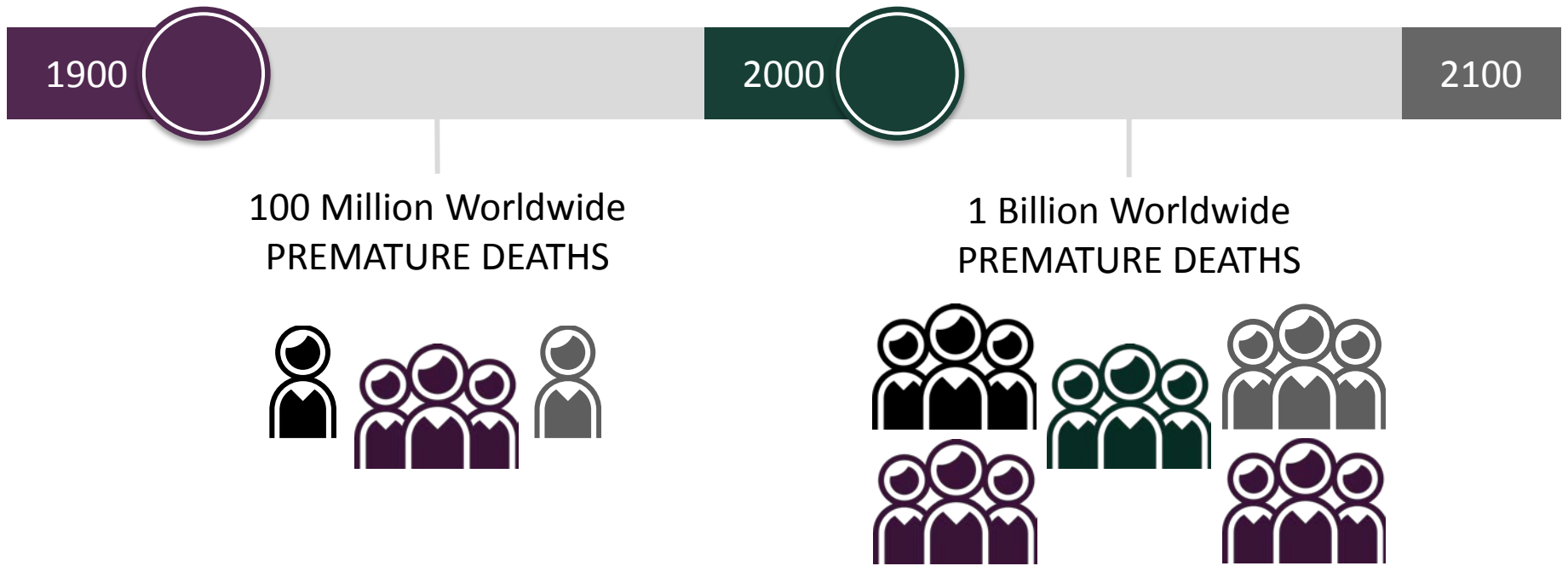
- The public health framework
- Building the foundation
- Pursuing strategic priorities



THE PUBLIC HEALTH FRAMEWORK

#APHAtobacco

FIGHTING AN UPHILL BATTLE AGAINST DISEASE AND DEATH



PREVENTING THE PREVENTABLE IN THE U.S.

- Progress since first SGR – despite huge strides, 42 million adults still smoke
- Still the leading cause of preventable disease and death – nearly 500,000 Americans die each year and 16 million more live with disease
- Every day over 3,200 teens smoke their first cigarette
- More than 700 youth become daily smokers



IMPLEMENTING THE TOBACCO CONTROL ACT

CTP has 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
- Assert jurisdiction over other products that meet the definition of a tobacco product, including e-cigarettes, cigars, and hookah



ACTING TO IMPROVE PUBLIC HEALTH

- Prevent youth tobacco initiation
- Encourage adults who use tobacco to quit
- Reduce product harms and addictiveness

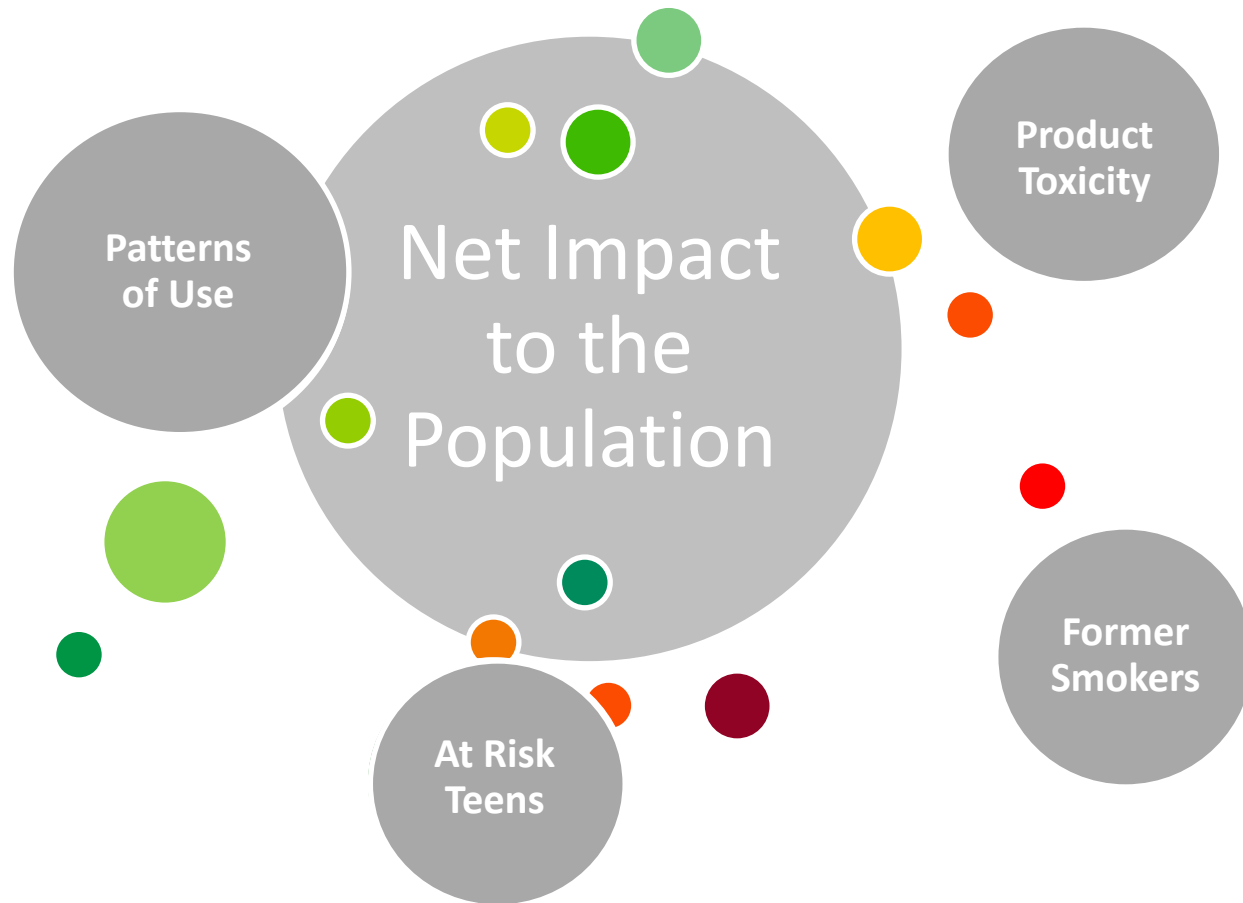


DEFINING A PUBLIC HEALTH STANDARD

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



ASSESSING OVERALL IMPACT TO PUBLIC HEALTH



DELVING INTO DEEMING

E-Cigarettes Face First Regulations

Fast-Selling Devices Would Need FDA Approval, Be Banned From Minors; Flavored Ones to Be Allowed

By THOMAS H. BURTON
AND MARK BYRNE

The Food and Drug Administration

is expected to issue regulations on e-cigarettes, eventually banning the popular devices from people under 18 and to gain FDA approval for flavored products. A ban on the sale of flavored e-cigarettes, along with other regulations, is expected to be proposed in the coming weeks, officials say.

have drawn huge investor interest while sparking debate over whether they attract new users or mostly divert cigarette buyers, and whether they lure children into nicotine addiction.

E-cigarettes are taxed less than regular cigarettes and typically cost less.

Under its new rules, the FDA will require manufacturers to provide scientific evidence to substantiate any claims they make that e-cigarettes are safer than standard ones.

The FDA plans a 75-day comment period before the regulations become final. Some provisions, such as requiring evidence of health benefits, will go into effect at that point. The agency then will allow two years for all other provisions to be effective.

One of the biggest new requirements is that e-cigarette makers will need to apply to the FDA within two years to keep existing products on the market. The agency then will rule on applications roughly as it does on

A randomized trial of 657 people in New Zealand published last year in the medical journal *Lancet* found e-cigarettes were "modestly effective" in smoking cessation, with a 7.3% abstinence rate after six months.

"We have not seen anything like this in 100 years that could make the combustible cigarette obsolete," said David Abrams, a professor at Johns Hopkins School of Public Health and research director at Legacy, an anti-tobacco group. He believes the devices could wean people from traditional cigarettes.

Smoking remains the leading cause of preventable death, killing 480,000 Americans annually, government estimates show.

FDA commissioner Margaret A. Hamburg said the regulations mark "an historic day for the FDA and for public health." She said the agency was stepping in to prevent children from smoking and suffering "a lifetime of nicotine addiction."

FDA officials stressed the new rules are just a first step and

Vapor Vendors

Top five e-cigarette sellers by market share in convenience stores

COMPANY/BRAND	MARKET SHARE
Lorillard/VO	42.8%
Wise/40y	23.2
Logic/Logic	16.9
CB Distributors/21st Century	12.7
Woods/Metro	2.3

Notes: For 52-week period ending March 23. Source: Mint Group/Market Watch Street Journal

don't target youth in their marketing.

Most researchers believe e-cigarettes are less harmful than regular ones, which release carbon monoxide and thousands of chemicals, including known carcinogens, through combustion.

The financial stakes are huge. Tobacco companies are plunging into e-cigarettes to try to offset sliding sales, rising taxes and widening bans on traditional smokes. Altria Group Inc., which has roughly half of the U.S. tobacco market, began testing its MarkTen e-cigarette brand last year and earlier this year signed a deal to acquire e-cigarette upstart Green Smoke Inc. for \$110 million.

Reynolds American Inc., maker of Camel cigarettes and the No. 2 tobacco player, plans to roll out its Vuse e-cigarettes nationally by midyear.

Both are racing to catch up: Lorillard Inc., the maker of Newport cigarettes and U.S. third-largest U.S. tobacco company. It has a nearly 60% e-ci-

FDA outlines plan to regulate e-cigarettes

BY BRADY DENNIS

The Food and Drug Administration will for the first time regulate the booming market of electronic cigarettes, as well as cigars, pipe tobacco and hookahs, under a proposal to be released Thursday.

The move would begin to place restrictions on e-cigarettes, a nearly \$2 billion industry that for years has operated outside the reach of federal regulators. If adopted, the government's plan would force manufacturers to curb sales to minors, stop handing out free samples, place health warning labels on their products and disclose the ingredients. Makers of e-cigarettes also would be banned from making health-related claims without scientific evidence.

The FDA's proposal stops short of broader restrictions sought by many tobacco-control advocates. Regulators at this point are not seeking to halt online sales of e-cigarettes, curb television advertising, or ban the use of flavorings such as watermelon, grape soda and pina colada — all tactics that critics say are aimed at attracting young smokers and that have

New U.S. Rules On E-Cigarettes To Be Proposed

Ban Sought on Selling to People Under 18

By SABRINA TAVERNISE

story for consumers will be required to be banned from free samples. New warnings will note that use they contain can be battery-powered devices in nicotine-laced water vapor are a fast-growing alternative to smoking, with sales



DELVING INTO DEEMING (CONT.)

- On April 24, FDA proposed a new rule that would extend CTP's authority to cover additional tobacco products
- Products that would be “deemed” to be subject to FDA regulation are those that meet the statutory definition of tobacco product, including:
 - Electronic Cigarettes (e-cigarettes)
 - Cigars
 - Pipe Tobacco
 - Nicotine Gels
 - Waterpipe (Hookah)
 - Tobacco Dissolvables not already under the FDA's authority

DEFINING AUTOMATIC PROVISIONS

- Prohibit adulteration and misbranding
- Requirement for ingredient listing
- Requirement for registration and product listing
- Review of Substantial Equivalence (SE) filings and premarket applications (PMTA) for newly deemed products
- Elimination of misleading descriptors and unproven modified risk claims
- Prohibition of free samples

ADDING ADDITIONAL RESTRICTIONS

- Prohibit sale to individuals under the age of 18 years and require age verification
- Prohibit sale using electronic or mechanical devices, e.g., vending machines, with limited exceptions



ADDING A HEALTH WARNING ABOUT ADDICTION

“WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical.”

- Required to be displayed on covered tobacco packages and in advertisements
- Product package:
 - ✓ 2 principal display panels (PDP);
 - ✓ Warning area shall comprise 30% of each PDP
- Advertisement:
 - ✓ Occupy at least 20% of the area of the ad
- Requirements the same as for smokeless tobacco

BUILDING THE FOUNDATION

#APHAtobacco

CREATING THE BUILDING BLOCKS

Building CTP to achieve programmatic goals

- Human resources, IT, acquisitions, logistics, budget
- Policy analysis
- External communications

Developing foundational rules and guidance

- “Deeming” proposed rule
- User fees proposed rule
- Investigational products
- Testing/reporting/disclosure

Setting and funding a research agenda



MEETING WHERE REGULATORS LIVE



PURSuing STRATEGIC PRIORITIES

- Product Standards
- Comprehensive FDA Nicotine Regulatory Policy
- Pre- & Post-Market Controls: Regulations & Product Reviews
- Compliance and Enforcement
- Public Education



PRODUCT STANDARDS

#APHAtobacco

IMPLEMENTING ONE OF THE LAW'S MOST POWERFUL TOOLS

- Advancing a product standard strategy that yields strong standards to improve public health and can withstand legal challenge
- Exploring potential standards for:
 - Addictiveness
 - Toxicity
 - Appeal



COMPREHENSIVE FDA NICOTINE REGULATORY POLICY

#APHAtobacco

LOOKING AT NICOTINE DIFFERENTLY

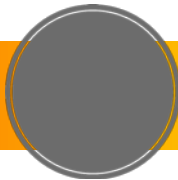
- Establish an integrated, FDA-wide policy on nicotine-containing products that is public-health based
- Implications for tobacco, drug, and device regulatory policy



LOOKING AT NICOTINE DIFFERENTLY

- Recognize that there is a continuum of nicotine-containing products
- Understand that people smoke for the nicotine but die from the tar
- Acknowledge public health opportunity

COMBUSTIBLES



NRT

LOOKING AT NICOTINE DIFFERENTLY

- Related actions include:
 - Finalizing Deeming regulation (Review of over 135,000 comments)
 - Developing jurisdiction policy on nicotine-containing products across FDA
 - Working with CDER and CDRH to determine how regulation of therapeutic nicotine products (Rx, OTC, drugs, devices) could evolve
 - Exploring options at CTP for an expedited premarket review policy based on principle of relative toxicity and risk



PRE- & POST-MARKET CONTROLS: REGULATIONS AND PRODUCT REVIEWS

#APHAtobacco

PROTECTING CONSUMERS



As the regulatory gatekeeper, CTP now stands between tobacco products and consumers

SETTING PRE- & POST-MARKET POLICY

- Explore developing rules and guidances for:
 - Product reviews
 - Investigational Tobacco Products (ITP)
 - Premarket Tobacco Application (PMTA)
 - Substantial Equivalence (SE)
 - Exemption from Substantial Equivalence
 - Modified Risk Tobacco Product (MRTP)
 - Tobacco Product Manufacturing Practices (TPMP)
 - Analytic test method validation

MEASURING PROGRESS IN MAKING SE DECISIONS

4,618 SE Submissions

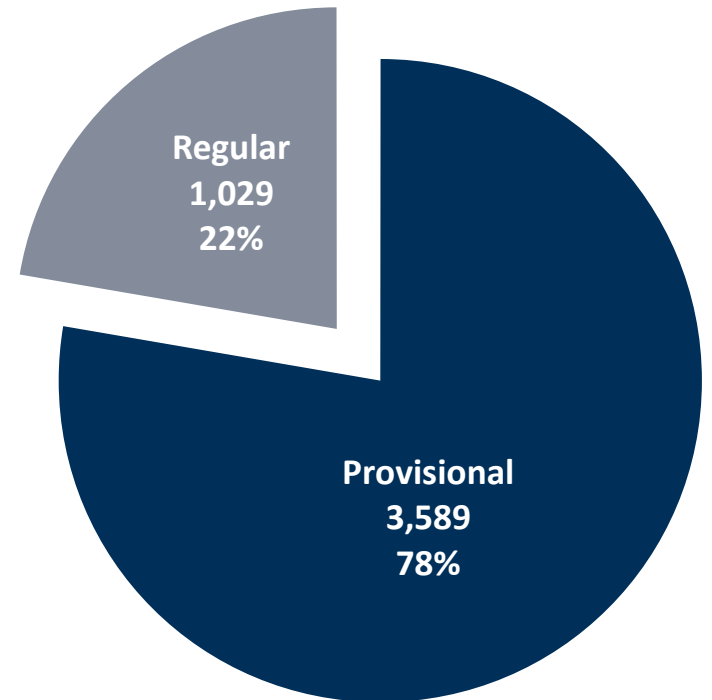
- 99% of acceptance reviews (jurisdiction and administrative) are complete

Regular Reports

- Resolved 45% via Order letter, Refuse-To-Accept letter or Withdrawal
- Review of new regular reports starts upon receipt as there is no backlog
- Established performance measures for review and action

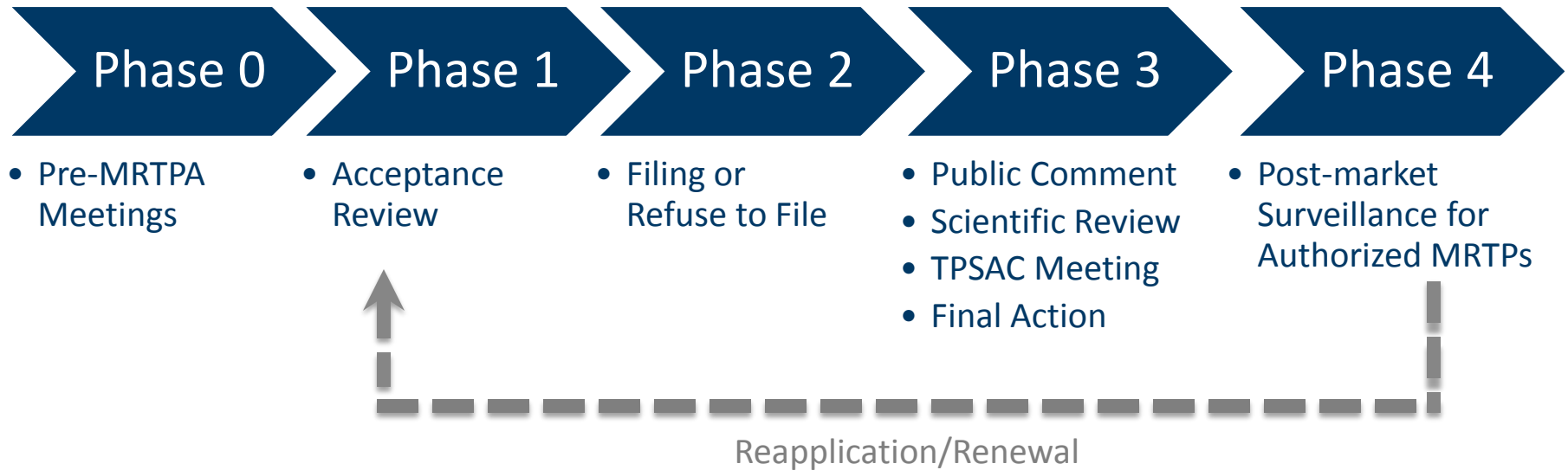
Provisional Reports

- Reviews have begun



Data as of 10/31/14

DEFINING THE MODIFIED RISK TOBACCO PRODUCT PROCESS



REVIEWING MODIFIED RISK TOBACCO PRODUCT APPLICATIONS

- Filed first MRTP applications in August 2014
- Made applications available for comment for 180 days
 - Current comment period closes Monday, February 23, 2015
 - Comments submitted in first 90 days (by Nov. 25) are more likely to be considered before referring applications to Tobacco Products Scientific Advisory Committee
- Published Draft Guidances
 - Draft Guidance for Industry and Staff: Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products
 - Draft Guidance for Industry: Modified Risk Tobacco Products Applications

COMPLIANCE AND ENFORCEMENT

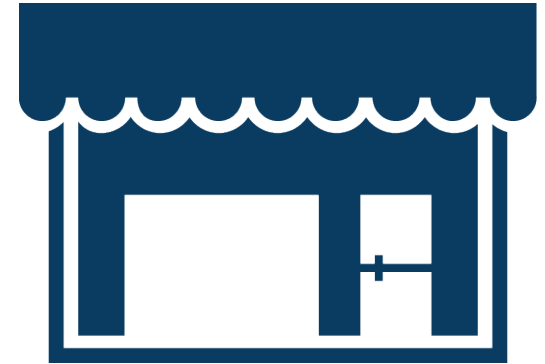
#APHAtobacco

ENFORCING THE LAW

- Inspect, investigate, monitor and review activities
- Initiate appropriate enforcement actions that are supported by evidence
 - Develop and document sufficient evidence to support enforcement actions for violations of the law
 - Expand state inspection program to remaining states and territories
 - Plan for implementation of compliance activities for newly deemed products
 - Implement compliance inspection, education, and enforcement activities on tribal lands

MEASURING COMPLIANCE PROGRESS TO DATE

- Conducted over 356,000 retailer inspections covering 54 states and territories
- Issued more than 20,300 warning letters
- Issued over 2,100 civil money-penalty actions against tobacco retailers
- Awarded FDA's first contracts to Tribal governments to conduct tobacco retail inspections within their jurisdictions



Data through 11/1/14

PUBLIC EDUCATION

#APHAtobacco

EDUCATING AT-RISK AUDIENCES ON THE DANGERS



**10
Million**



**General “At-Risk” Market
Multicultural
Rural
American Indian/
Alaska Native
LGBT**

Prevention



**Investing in
our Future**





New Ad: “The 7,000”



New Ad: “Contract”

MEASURING “THE REAL COST” SUCCESS TO DATE

Paid Media

- Reached more than 96% of our target audience over 20 times each quarter with advertising
- Generated 946 million impressions on youth-focused sites such as MTV.com, IGN.com and Hulu.com

Web and social media

- Engaged 1.8M unique visitors from all 50 states on the website
- Produced 910,325 unique conversations about the campaign via Social Media

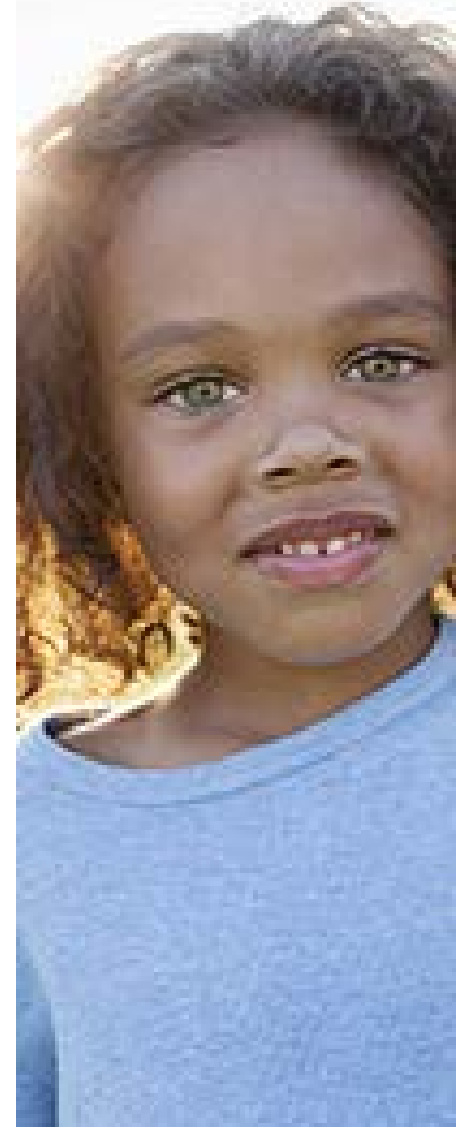
Comprehensive evaluation

- Multi-year, nationwide study consisting of in-person, nationally representative data
- Follow the same youth over 2 years to measure changes in tobacco-related attitudes and behaviors
- Ultimately, results will be used to determine if exposure to the campaign is associated with a decrease in smoking among youth ages 12-17

Data from 2/11/14 – 7/30/14

MAXIMIZING USE OF OUR AUTHORITY FOR A HEALTHIER TOMORROW

- Utilize the tools given to us by Congress to maximize their potential and positively impact public health...by reducing the death and disease caused by tobacco products



THANK YOU

#APHAto tobacco

#APHA14

www.fda.gov/tobaccoproducts



FDA

CENTER FOR
TOBACCO
PRODUCTS