

# ACHIEVING STRATEGIC PRIORITIES WITH REGULATORY SCIENCE

Dana M. van Bemmelen, PhD, MPH  
Assistant Deputy Director for Research

Office of Science, Center for Tobacco Products, FDA  
December 2, 2015

*Disclaimer: The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy.*

# 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

# 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



# PURSuing STRATEGIC PRIORITIES BASED ON REGULATORY SCIENCE

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



# ACHIEVING STRATEGIC PRIORITIES

- As a regulatory agency, FDA can only go as far as the regulatory science can take us
- Developing a robust regulatory science program is critical to achieving programmatic success

# WHAT IS TOBACCO REGULATORY SCIENCE?

- Tobacco regulatory science involves the application of the best-available science to specific regulatory questions
- Tobacco regulatory research translates general scientific knowledge into the specific scientific findings that serve as the guide for regulatory decisions and actions
- To accomplish this, tobacco regulatory science evaluates distinct situations to determine which would most benefit public health

# HOW IS TOBACCO REGULATORY SCIENCE USED?

Regulatory science allows FDA to:

- Utilize the best science from a broad range of disciplines (e.g., product, nonclinical, health, and population sciences)
- Find new tools, information, and strategies for informed decision-making when taking regulatory actions
- Leverage opportunities for invention to quickly bridge the gap between scientific discovery and improving public health
- Bring together the best minds across academia, government, and private sector to advance science and its public health applications

# EXAMPLES OF TOBACCO REGULATORY ACTIONS

- Product Review
- Regulations and Guidance



# PRODUCT REVIEW

- Includes:
  - Investigational tobacco products
  - Pre-market tobacco applications (PMTA)
  - Substantial equivalence (SE)
  - Exemption from SE
  - Modified risk tobacco products (MRTPs)
- Applicant must provide adequate evidence for FDA to make a finding
- FDA uses scientific research to evaluate the evidence provided by the applicant



# PRODUCT REVIEW – STATUTORY QUESTIONS

- PMTA - Is the marketing of a new product appropriate for the protection of public health?
- SE - Do differences between a new product and a predicate product raise different questions of public health?
- MRTP - Will the product as it is actually used by consumers significantly reduce the harm and risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole?

# PRODUCT REVIEW – CONSIDERATIONS

## Information

- Materials
- Ingredients
- Design
- Composition
- Constituents
- Other features
- Marketing

## Impact

- Appeal
- Addictiveness
- Behavior/use
- Exposure
- Pharmacokinetics
- Toxicity
- Perception
- Initiation
- Cessation

## Public Health

- Morbidity
- Mortality

# PRODUCT STANDARDS – REGULATION AND GUIDANCE

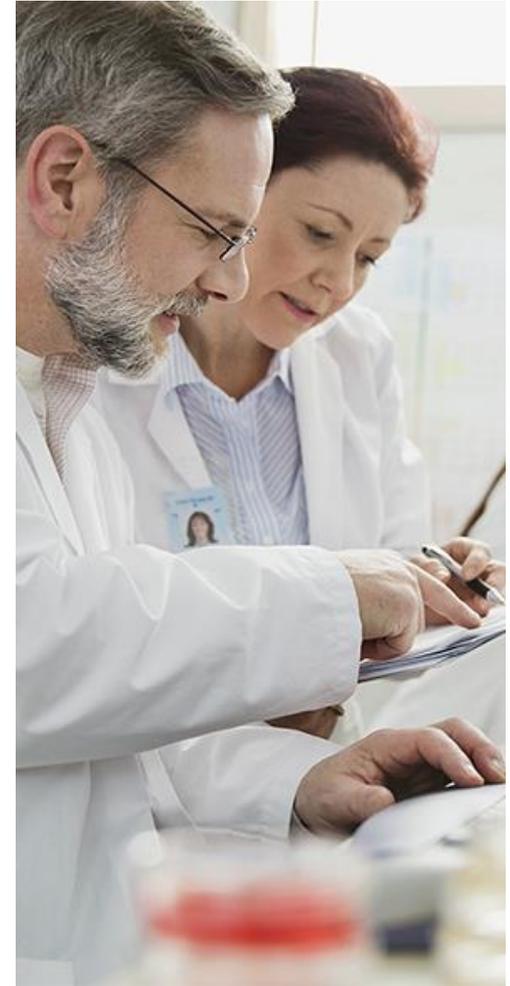
Through rulemaking, the Tobacco Control Act allows adoption of “...tobacco product standards... appropriate for the protection of public health.” (Sec 907)

- Nicotine yields
- Reduction or elimination of constituents, including smoke constituents
- Construction, components, ingredients, additives, constituents, and properties of the tobacco product
- Provisions for testing or measuring product characteristics
- Restrictions on sale and distribution
- Form and content of labeling

# PRODUCT STANDARDS – STATUTORY QUESTION

Is a product standard appropriate for the protection of public health, considering:

- The risks and benefits to the population as a whole
- The increased or decreased likelihood that existing users of tobacco products will stop using such products
- The increased or decreased likelihood that those who do not use tobacco products will start using such products



# PRODUCT STANDARDS – EXAMPLES OF USEFUL RESEARCH INFORMATION

- Data that describe the current situation
- The impact of the current situation on public health
- Data that describe an alternate situation
- The quantitative public health benefits of the alternate situation
- Secondary or unintended effects of the alternate situation
- The feasibility of achieving the alternate situation
- Whether other situations could accomplish the target health benefit at lower risk or cost

# IMPLEMENTING ONE OF THE LAW'S MOST POWERFUL TOOLS

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

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



# SETTING PRE- AND POST-MARKET POLICY

- Explore developing rules and guidances for:
  - Product review pathways (SE, PMTA, MRTP)
  - Tobacco Product Manufacturing Practices (TPMP)
  - Analytic test method validation
- Continue to establish and then meet performance standards for product reviews

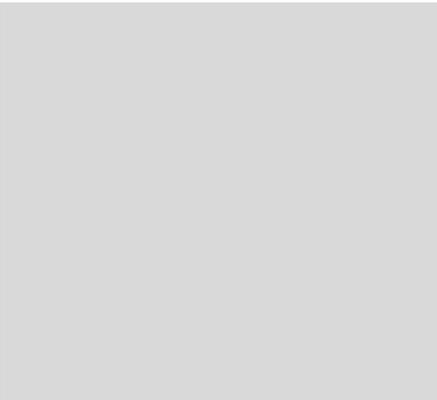
# PUBLIC EDUCATION



# EDUCATING AT RISK AUDIENCES ON THE DANGERS



Prevention  
among  
10 million  
youth



General Market  
Multicultural  
Rural  
American Indian/  
Alaska Native  
LGBT

# PUBLIC EDUCATION-EXAMPLES OF USEFUL RESEARCH INFORMATION

- Consumer Risk Perceptions of Tobacco Products
- Assessing Risk Perceptions of Flavored Small Cigars/Cigarillos Among Young Adults
- Communicating Harm of New Tobacco Products
- Communicating Smoking Risks Through Graphic Health Warnings
- Developing and Testing Warning Labels about E-cigarettes
- Framing Messages for Teen Smoking Prevention in Primary Care
- Optimizing Graphic Health Warning Labels to Promote Cessation among Young Adult Smokers
- Qualitative and Quantitative Studies of Consumer Perceptions Related to Different Ways of Presenting HPHCs
- Using Eye Tracking to Understand and Improve Graphic Health Warning Effectiveness

# 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



**THANK YOU**