ACHIEVING STRATEGIC PRIORITIES WITH REGULATORY SCIENCE

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Disclaimer: The information in these materials is not a formal dissemination of information by FDA and does not represent agency position or policy.
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
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
COMPREHENSIVE FDA NICOTINE REGULATORY POLICY
LOOKING AT NICOTINE DIFFERENTLY

• Establish an integrated, FDA-wide policy on nicotine-containing products that is public-health based

• Recognize that there is a continuum of nicotine-containing products...and the reality that people smoke for the nicotine but die from the toxins in tobacco

• Evaluate the implications for tobacco, drug, and device regulatory policy
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
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
Waterpipe Funding Opportunity Announcement (FOA)

Anticipating the final deeming rule that includes waterpipe tobacco, this FOA is focused on the following CTP priorities related to waterpipe tobacco:

- Harmful and potentially harmful constituents (HPHCs) present in waterpipe tobacco smoke
- Types of in vitro and/or in vivo assays that can be used to distinguish toxicity of waterpipe tobacco smoke
- Impact of constituents, compounds, design features, and tobacco use behaviors on the toxicity of waterpipe tobacco products and smoke
- Impact of waterpipe tobacco characteristics and experimentation