RESEARCH TO INFORM FDA REGULATORY ACTIONS

R21 WEBINAR
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NATIONAL INSTITUTES OF HEALTH

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IMPLEMENTING THE TOBACCO CONTROL ACT

• Since 2009, CTP had authority to regulate tobacco products intended for human consumption to reduce harm across the population
  - Reducing the number of people who start to use tobacco products
  - Encouraging more people to stop using these products
  - Reducing the adverse health impact for those who continue to use these products
• Initially regulated the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless
NEW REGULATION

- FDA finalized a rule effective August 8, 2016 to regulate all tobacco products, including components or parts (but excluding accessories), 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
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
  - Reporting of harmful and potentially harmful constituents
  - Adverse event reporting
  - Health warnings
  - Advertising and promotion restrictions
  - User fees
NOT WITHIN CTP AUTHORITY

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
POPULATION HEALTH STANDARD

- FDA/CTP regulates tobacco based on a population health model
  - Tobacco **cannot** be regulated using FDA’s traditional “safe and effective” standard

- Regulatory actions are based on the risks and benefits to the population as a whole, including both users and nonusers of the product
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
TOBACCO REGULATORY SCIENCE

REGULATORY SCIENCE

• Scientific discipline with independent goals and measures not found in either the basic or applied sciences
• Ensures that scientifically valid techniques, tools, and models are available to evaluate products
• Informs regulatory actions that promote optimal public health outcomes

TOBACCO REGULATORY SCIENCE

• Informs FDA’s regulatory authority
• Recognizes that tobacco products cannot be regulated using FDA’s traditional “safe and effective” standard
• Enables FDA to best assess the “net” population-level health impacts

THE SCIENCE OF TOBACCO REGULATION

• Product
  – Chemistry
  – Engineering
  – Microbiology

• Tobacco Product User
  – Toxicology
  – Pharmacology
  – Clinical medicine
  – Addiction
  – Product use behavior

• Population as a Whole
  – Environmental assessment
  – Epidemiology
  – Consumer perception
  – Statistical analysis
  – Evaluation
SELECT CTP REGULATORY ACTIVITIES

- Product standards
- Product review
- Public education
PRODUCT STANDARDS
• Product standards are one example of tobacco product regulation
• Through rulemaking, the Tobacco Control Act allows adoption of “…tobacco product standards… appropriate for the protection of public health.” Sec 907.
• Examples of Potential Product Standards
  – 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 for the proper use of the tobacco product
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?
EXAMPLES OF PRODUCT STANDARD ACTIVITIES

Notice of Proposed Rule Making (Published January 2017)

- Tobacco Product Standard for N-Nitrosonornicotine Level in Finished Smokeless Tobacco Products
  - Proposing a tobacco product standard that would establish a limit of N-nitrosonornicotine (NNN) in finished smokeless tobacco products

Advance Notices of Proposed Rule Making (Published March 2019)

- Tobacco Product Standards for Nicotine Level of Combusted Cigarettes
  - To obtain information for consideration in developing a tobacco product standard to set the maximum nicotine level for cigarettes.

- Regulation of Flavors in Tobacco Products
  - To obtain information related to the role that flavors play in tobacco products.

- Regulation of Premium Cigars
  - To obtain scientific data related to the patterns of use and resulting public health impacts from premium cigars.

PRODUCT REVIEW
PRODUCT REVIEW

- Includes:
  - Investigational tobacco products
  - New product review
  - Substantial equivalence (SE)
  - Exemption from SE
  - Modified risk tobacco products

- 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

• Premarket Tobacco Applications (PMTA) - Is the marketing of a new product appropriate for the protection of public health?

• Substantial Equivalence (SE) - Do differences between a new product and a predicate product raise different questions of public health?

• Modified Risk Tobacco Products (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 – RESEARCH

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Impact:

- Appeal
- Addictiveness
- Behavior/use
- Exposure
- Pharmacokinetics
- Toxicity
- Perception
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Public health:

- Morbidity
- Mortality
PUBLIC EDUCATION
FDA maximizes its impact on public health by focusing public education efforts on at-risk audiences such as:
- general market youth who are already experimenting with cigarettes or open to it,
- multicultural including African American, Hispanic, Asian/Pacific Islander, and American Indian/Alaska Native youth,
- rural youth, and
- lesbian, gay, bisexual, and transgender (LGBT) young adults.
• *Every Try Counts* launched in January 2018

• Campaign Objective: Drive an *increase in motivation to quit among adult smokers* (ages 25-54) who want to quit but were recently unsuccessful, utilizing paid media tactics in and around where tobacco is sold to:
  – Get smokers to try again by *reframing what it means to quit*
  – Get smokers to try quitting more often by *practicing the quit*
As outlined in the RFAs*

- Toxicity
- Addiction
- Health Effects
- Behavior
- Communication
- Marketing Influences
- Impact Analysis

*RFA-OD-19-021, -022
• Scientific research can:
  – understand the impact of changes in tobacco product characteristics (such as flavors or product design) on dependence
  – develop innovative methods and measures to assess tobacco use behaviors, including perceptions, susceptibility, experimentation, adoption, switching, and use (including dual use)
  – understand how product design characteristics (and changes in those characteristics) impact constituent exposure and toxicity from tobacco products
  – develop biomarkers to assess exposure, as well as biomarkers to assess harm or toxicity of non-cigarette tobacco products, including ENDS
  – help identify misperceptions among users and non-users of tobacco products
  – demonstrate new approaches to communication which would promote greater public understanding of the risks associated with the use of tobacco products
Thank You