FDA CENTER FOR TOBACCO PRODUCTS AND THE PUBLIC HEALTH STANDARD

Mitch Zeller, Director
FDA Center for Tobacco Products

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AGENDA

- Today’s Pre-Conference Workshop
- Background: FDA’s Authorities
- Employing a Public Health Standard
- Reviewing New Products Under the Public Health Standard
- CTP Presentations and Posters at SRNT
TODAY’S PRE-CONFERENCE WORKSHOP
Today’s Pre-Conference Workshop will address:

• Overview of the population health standard and recent FDA actions that highlight how science informs decision-making
• How scientific data can inform the population health standard using e-cigarettes as an example
• Panel to discuss perspectives on balancing risks and benefits of regulatory decision-making using the population health standard
BACKGROUND: FDA’S AUTHORITIES
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
FDA finalized a rule, effective August 8, 2016, 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
HOW FDA IS USING ITS REGULATORY AUTHORITY

• Understand the regulated products
• Review product changes to protect public health
• Prohibit modified risk claims that state/imply reduced exposure or risk without an order
• 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
EMPLOYING A PUBLIC HEALTH STANDARD
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• Pursue a “public health” standard as tobacco cannot be regulated using FDA’s traditional “safe and effective” standard
• Take into account the effects on both users and non-users of tobacco products
• Assess the “net” population-level health impacts of tobacco products
ASSESSING OVERALL IMPACT TO PUBLIC HEALTH

Net Impact to the Population

Patterns of Use

Product Toxicity

Former Smokers

At Risk Teens

- Teens start using tobacco
- Teens don't initiate

- Former smokers
  - Relapse
  - Don't relapse

- Net Impact
  - To the population
  - Patterns of use
  - Product toxicity
  - Former smokers
  - At risk teens

- Unable or unwilling to quit
- Smokers switch completely to non-combustibles
- Instead of quitting, smokers become dual users
MULTIDISCIPLINARY SCIENTIFIC APPROACH

Product Science
- Chemistry
- Engineering
- Microbiology

Nonclinical Science
- Toxicology
- Pharmacology
- Biology
- Environmental Science

Health Science
- Medicine
- Behavioral Pharmacology
- Psychology
- Neuroscience

Population Science
- Epidemiology
- Social science
- Statistics, modeling
- Evaluation
REVIEWING NEW PRODUCTS UNDER THE PUBLIC HEALTH STANDARD
• New products (those not marketed as of February 15, 2007, or products modified after that date) are subject to premarket review

• One pathway to market is the premarket tobacco product application or PMTA:
  – Permitting the product to be marketed would be “appropriate for the protection of the public health”

• By law, product review takes place on a case-by-case basis; authorizing or denying authorization for one product is not a referendum on the public health impact of all products in that class

REVIEWING NEW PRODUCTS TO PROTECT PUBLIC HEALTH
• ENDS products are a widely diverse and heterogeneous category
• FDA acknowledges the continuum of risk, is mindful of the principle of relative risk, and recognizes that different products will pose varying levels of individual-level risk and population-level harm
• But ultimately it is that net assessment under the public health standard, armed with sufficient regulatory science, that must drive regulatory action
• Right now, at a population level, we need to better characterize the risks and benefits associated with ENDS
• So we have questions
Questions about ENDS within the framework of the public health standard

- What are the known short and long-term health effects of for ENDS users
  - who have never used tobacco products before;
  - who also use other tobacco products; and
  - who have switched from only smoking combustible tobacco products?

- What other risks are associated with ENDS exposures in users (e.g., overheating or explosion resulting in burn injuries)?

- What populations of users may be at lower or higher risk of adverse effects related to ENDS use?

- What unique health effects may be of concern in youth users?

- Do ENDS help conventional cigarettes smokers quit smoking?

- Do cigarette smokers who use ENDS to quit smoking continue using ENDS, and if so, for how long?

- Does use of flavored ENDS products impact any of the above questions?
QUESTIONS ABOUT NICOTINE (MOSTLY RELATED TO THE PUBLIC HEALTH STANDARD)

- Can longer-term use for those who need it be accepted?
- What about recreational use for adults who may want it?
- Can a short transitional period of dual use be ok? Or a long period?
- How much youth initiation can we tolerate?
- How much weight should diminished interest in quitting play?
- Can we revise labeling and indications for medicinal nicotine to increase quitting?
- Where does the principle of harm reduction come in?
LOOKING FORWARD

• Bottom line: *This is highly complex and FDA needs more data to sufficiently understand the risks and benefits to the population as a whole*

• FDA *needs research* to help inform how we should think about these questions and their relation to the public health standard

• SRNT members have the opportunity to conduct research with the *public health standard in mind*
CTP PRESENTATIONS AND POSTERS AT SRNT
• Exploring Dimensions of Flavors: Toxicity, Preference and Use (Symposium 4, Podium Presentation 1 – March 9, 11:00 am)

• Health Communication for Non-Cigarette Tobacco Products (Symposium 1, Podium Presentation 1 – March 9, 11:00am)

• Dependence Behaviors and Nicotine Pharmacokinetics in Electronic Cigarette Users (Poster Session 1, Poster #73 – March 9, 12:30-2:00 pm)

• Dependence Behaviors and Nicotine Exposure in Large and Small Cigar Smokers (Poster Session 1, Poster #168 – March 9, 12:30-2:00 pm)
• Importance of Negative Results in Tobacco Regulatory Science: Negative Results with the Rat Micronucleus Assay for NNK and the Utility of the Comet Assay in Assessing NNK Genotoxicity (Poster Session 2, Poster #35 – March 9, 5:00-6:00 pm)

• Tobacco Use Transitions Among Youth and Youth Adults: Descriptive Longitudinal Data from Waves 1 and 2 of the PATH Study (Symposium 22, Podium Presentation 4 – March 10, 3:30 pm)

• Outcome Evaluation Results for FDA’s The Real Cost Campaign: Impact on Youth’s Risk Perceptions, Beliefs About Smoking and Smoking Behaviors (Podium Presentation 5, Paper Session 11 – March 11, 9:00 am)
THANK YOU

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