FDA’S CENTER FOR TOBACCO PRODUCTS: AN UPDATE ON REGULATORY ACTIVITIES AND PRIORITIES

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AGENDA

- Opening Remarks
- Comprehensive Regulatory Plan
- Programmatic Updates
  - Science
  - Public Education
  - Regulatory
  - Compliance and Enforcement
- Questions
LOOKING BACK SINCE LAST YEAR’S SRNT

- Many significant events, actions and progress since last year’s annual meeting, including:
  - New FDA Commissioner Scott Gottlieb, M.D.
  - New CTP Office of Science Director Matt Holman, Ph.D.
  - Continued peer-reviewed analysis of PATH, increased availability of data for the public
  - Expansion and launch of new public education efforts

- And the roadmap that guides us moving forward – our new comprehensive regulatory plan for tobacco and nicotine
FDA’S NEW COMPREHENSIVE REGULATORY PLAN
“We truly find ourselves at a crossroads when it comes to efforts to reduce tobacco use. But if we’re going to meaningfully improve the public health, we need to be willing to take a hard look at our entire approach.”

FDA Commissioner Dr. Scott Gottlieb
July 28, 2017
FDA’S COMPREHENSIVE REGULATORY PLAN

- New approach places nicotine – and the issue of addiction – at the center of regulatory efforts

- Acknowledging that while highly addictive, nicotine is delivered through products on a continuum of risk and cigarettes are the most harmful

- Strikes an appropriate balance between smart regulation and encouraging innovation of satisfying, less harmful products

- Continue to base all actions on regulatory and scientific foundation
“Nicotine, while highly addictive, is delivered through products on a continuum of risk...[and] the combustible cigarette is where nicotine's delivery vehicle leads to incredible amounts of disease and death.”

FDA Commissioner Dr. Scott Gottlieb
October 19, 2017
• FDA will issue an Advance Notice of Proposed Rulemaking (ANPRM) to seek input on many topics including, but not limited to:
  – How manufacturers could comply with a nicotine product standard for cigarettes
  – Questions about potential unintended effects, such as compensation and illicit trade
  – Implementation and enforcement
SEEKING COMMENT ON ISSUES IN AN EVOLVING TOBACCO MARKETPLACE

- Tobacco marketplace continues to evolve – and FDA is seeking additional information to inform other potential regulatory actions
- Future ANPRMs seeking comment on:
  - Role that flavors (including menthol) may play in 1) attracting youth and 2) helping some smokers switch to potentially less harmful forms of nicotine delivery
  - Scientific data on patterns of use and resulting public health impacts of premium cigars
- Potential product standards to reduce harms of non-combustible products
  - Reviewing comments on proposed product standard for N-nitrosonornicotine (NNN) levels in smokeless products
Revised deadlines, only for products marketed as of August 8, 2016, for manufacturers to submit applications for deemed products

- We are committed to encouraging innovations with potential to make notable public health differences
- Ultimately, informing policies and efforts to best protect kids and help smokers quit
- In interim, allows FDA to explore measures to make tobacco products less toxic, appealing and addictive. For example:
  - Product standard to address ENDS battery issues
  - Product standard to address accidental child exposure to liquid nicotine
Revised application deadlines:

- would be required to meet any product standards issued in interim
- will enable manufacturers to submit higher quality, more complete applications (informed by additional FDA rules and guidances)

<table>
<thead>
<tr>
<th>Type</th>
<th>Example</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combustible</td>
<td>Cigars, pipe tobacco, hookah tobacco</td>
<td>Aug. 8, 2021</td>
</tr>
<tr>
<td>Non-combustible</td>
<td>E-cigarettes and other ENDS, gels, certain dissolvables</td>
<td>Aug. 8, 2022</td>
</tr>
</tbody>
</table>
Importantly, as part of the comprehensive plan, compliance dates for all other provisions in the FD&C Act that generally apply to “tobacco products” still apply to deemed products:

- Registering manufacturing establishments and providing product listings to FDA*
- Reporting ingredients and harmful and potentially harmful constituents to FDA*
- Not selling modified risk tobacco products (including “light,” “low,” or “mild”) unless authorized by FDA

*The compliance dates for these deadlines were extended to account for technical difficulties
The following restrictions also still apply:

- No in person or online sales to minors under the age of 18
- Age verification by photo ID required for anyone under 27
- No sale in vending machines where anyone under age 18 has access at any time
- No free samples of deemed tobacco products
ISSUING ADDITIONAL FOUNDATIONAL RULES AND GUIDANCES

Additional time will allow FDA to issue foundational rules and guidances, including:

- Premarket Tobacco Application (PMTA) rule
- Substantial Equivalence (SE) rule
- Modified Risk Tobacco Product Application (MRTP) rule
- Tobacco Product Manufacturing Practice (TPMP) rule
- PMTA for ENDS Final Guidance

Will make the review process more efficient, predictable and transparent while upholding our public health mission.

FDA will continue to assist manufacturers through online information, meetings, webinars and additional guidances.
FDA ANNOUNCES COMPREHENSIVE REGULATORY PLAN

“Addressing the addictive levels of nicotine in combustible cigarettes must be part of the FDA’s strategy for addressing the devastating addiction crisis that is threatening American families.”

FDA COMMISSIONER Scott Gottlieb, M.D.
PROGRAMMATIC UPDATES
INTRODUCING DR. MATT HOLMAN

Introducing
CTP Office of Science Director
Dr. Matt Holman
ACTIVE CTP PROJECTS BY FISCAL YEAR

Total Number of Research Projects = 398

Some projects captured in multiple years.
PATH STUDY TIMELINE

- 2011: Award Contract
- 2012: Field Test
- 2013: Wave 1
- 2014: Wave 2
- 2015: Wave 3
- 2016: Wave 4
- 2017: Wave 1 Biomarker Restricted Use File

**Sample Replenishment**
- Wave 1 Qx Public Use File
- Wave 2 Qx Restricted Use File

**Timeline Events**
- Wave 1 Qx Public Use File
- Wave 2 Qx Restricted Use File
TCORS 2.0

• RFA-OD-17-006 invited new & renewal applications
• Cooperative Agreements
• Limited to $4M annual total costs
• Goal is to build capacity through
  – Research programs
  – Time-sensitive research
  – Investigators’ career enhancement
• Funding Timeline
  – Applications Received: July 2017
  – NIH Peer Review: January 2018
  – NIH Council: May/June 2018
  – Earliest Start: July 2018
• Proposed product standard for NNN levels in smokeless tobacco products
  – Issued Jan 2017
  – Chewing tobacco, moist snuff, & snus

• Proposed average level is \( \leq 1.0 \ \mu g/g \) (dry weight basis)

• Estimate reducing oral cancer risk by 65%

• Comment period closed in July
  – Reviewing more than 7,500 comments
Philip Morris Products S.A. submitted MRTPAs for Heat-Not-Burn (HNB) products:
- iQOS system with Marlboro Heatsticks
- iQOS system with Marlboro Smooth Menthol Heatsticks
- iQOS system with Marlboro Fresh Menthol Heatsticks

Jan 2018: TPSAC meeting held

Posted for public comment
IQOS MRTPAs

Modified Risk Claims:

• The IQOS system heats tobacco but does not burn it

• This significantly reduces the production of harmful and potentially harmful chemicals

• Scientific studies have shown that switching completely from cigarettes to the IQOS system can reduce the risks of tobacco-related diseases
• R.J. Reynolds Tobacco Company submitted MRTPAs for smokeless tobacco products:
  – Camel Snus Frost
  – Camel Snus Frost Large
  – Camel Snus Mellow
  – Camel Snus Mint
  – Camel Snus Robust
  – Camel Snus Winterchill

• Posted for public comment

• TPSAC meeting not yet scheduled
“The Real Cost,” has prevented nearly 350,000 youth aged 11 to 18 nationwide from smoking from 2014 to 2016

- Almost 9 in 10 youth reported seeing “The Real Cost” ads within 7 months of the launch
- Positively influenced tobacco-related risk perceptions and beliefs specific to tobacco only 15 months after launch
- High levels of exposure to campaign messaging were associated with a 30 percent decrease in the risk of smoking initiation among youth aged 11 to 18

1 1/20/2017 MMWR
• Expanded *The Real Cost* to include messaging on electronic nicotine delivery systems (ENDS)
  – FDA’s first e-cigarette ad launched in Oct.
  – Full-scale effort in Fall 2018

• Launched Retailer Education: Providing free materials to retailers to help prevent and reduce tobacco sales to minors

• Launched Point-of-Sale: Helping smokers try quitting again by reframing what it means to quit and trying to quit more often by practicing
EVERY TRY COUNTS

ADULT SMOKING CESSATION CAMPAIGN AT POINT-OF-SALE
Drive an increase in motivation to quit among smokers 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**
Established smokers report that the point-of-sale environment can discourage their quit attempts:

- Customers spend 3-4 minutes in a convenience store per visit
- Tobacco companies spend over $9 billion annually on point-of-sale advertising and promotions
- When they’re trying to quit smoking the retail environment can generate a strong urge to smoke, prompting a slip or a relapse
- The point-of-sale environment can elicit an increase in unplanned purchases of tobacco products

“And you go into a store and make a purchase or something, when you look up, what do you see? Cigarettes. Even when I wanted to quit, they were coming at me.” – Research Participant
DEFINING THE TARGET AUDIENCE

Of the people who visit convenience stores, our target audience is the 5.8 million adults that have tried to quit smoking but were unsuccessful.

Data Source: SIMMONS 2016 Fall NCS/NHCS Adults Full Year – SM6HF
STRATEGIC APPROACH

• **Research identified key barriers to their success:**
  – No one’s celebrating them as they try
  – They’ve “heard it all” before
  – Smokers don’t feel “ready” to attempt again

• **Where the opportunity lies:**
  – Celebrate smoker’s attempts to quit smoking
  – Reframe past failures as an important part of the quit journey
  – Encourage belief that smokers are more ready than they know
  – Work in synergy with messaging from CDC’s *Tips from Former Smokers* to encourage trying again
Paid Media Objective:
- Reach smokers who want to quit with messaging of encouragement and support in an environment that can trigger unplanned tobacco purchases

Paid Media Budget
- The cost to run the Every Try Counts campaign in **35 markets for 24 months** is roughly $60 million
- Markets selected have high smoking prevalence, a smoking population of 20K+, and have available paid media opportunities in and around convenience stores

Retailer Receptivity
- Ad vendors saw no concerns with this type of campaign messaging in ads and placing advertising in local convenience stores.
Similar to all of the other CTP campaigns, an outcome evaluation study will be conducted.
• Continue working on the ANPRMs, proposed rules and guidances announced in the comprehensive plan

• In 2017, issued or revised guidances on several topics, including:
  – Registration and Product Listing
  – Listing of Ingredients in Tobacco Products
  – Health Document Submission Requirements
  – Prohibition of Distributing Free Samples of Tobacco Products
  – Compliance Policy for Required Warning Statements on Small-Packaged Cigars
  – Applicability of Certain Requirements to Vape Shops
COMPLIANCE AND ENFORCEMENT UPDATE
In 2017:

- Inspected more than 45 tobacco manufacturing facilities and conducted 18 investigations of free sample and brand sponsorship events.
- Conducted more than 200 inspections of vape shops engaged in manufacturing activities.
- Conducted more than 150,000 compliance check inspections of tobacco retailers and issued more than 13,500 Warning Letters, 5,500 Civil Money Penalties, and 50 No-Tobacco-Sale-Order complaints.
  - Includes issuing more than 10,000 Warning Letters to brick and mortar and online retailers for selling newly-regulated tobacco products (e-cigarettes, e-liquids and cigars) to minors from August 8, 2016 through the end of 2017.
QUESTIONS?

THANK YOU

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