AN UPDATE ON FDA'S COMPREHENSIVE PLAN ON TOBACCO AND NICOTINE

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Director, FDA Center for Tobacco Products

October 25, 2018

AGENDA

- FDA's Comprehensive Plan for Tobacco and Nicotine Regulation
- Regulatory Policies on Addiction, Appeal & Cessation
- Youth Tobacco Prevention Plan
- Science-Based Review of Potential Modified Risk Tobacco Products
- Closing Thoughts
- Questions

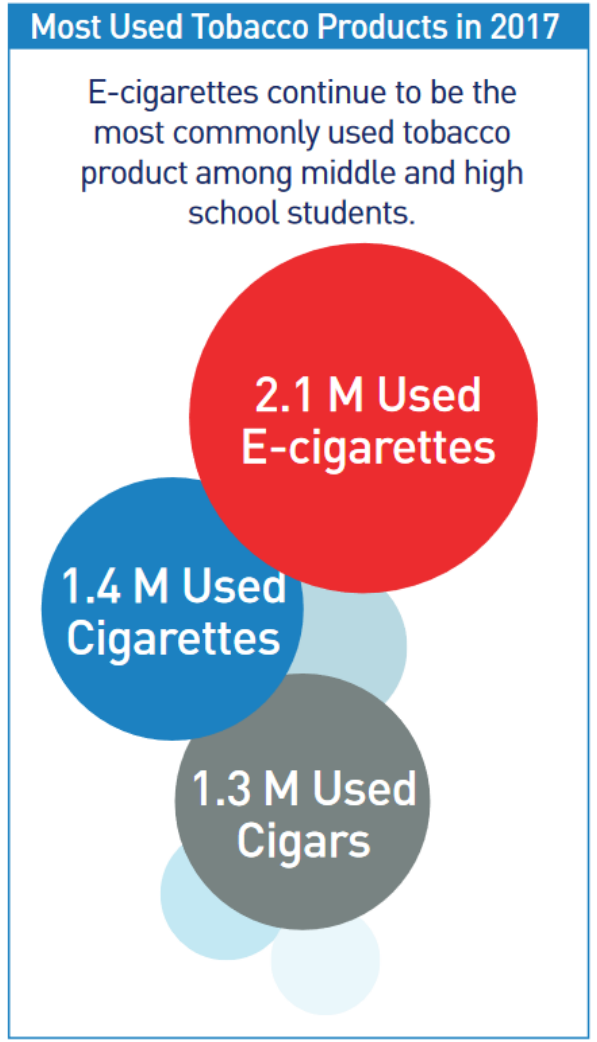
FINDINGS FROM NASEM E-CIGARETTE REPORT

- National Academies of Sciences, Engineering, and Medicine (NASEM) published *Public Health Consequences of E-Cigarettes* in January
  - The report was commissioned by FDA at the direction of Congress

- Evaluates the available scientific evidence of the short- and long-term effects related to use of electronic nicotine delivery systems (ENDS). Key findings:
  - Substantial evidence that completely switching from regular cigarettes to e-cigarettes results in reduced short-term adverse health outcomes
  - Conclusive evidence that completely switching from combustible cigarettes to e-cigs reduces an individual user's exposure to numerous toxicants and carcinogens
  - Substantial evidence to suggest youth and young adults who use e-cigs are more likely to transition to combustible cigarettes

FINDINGS FROM THE 2017 NATIONAL YOUTH TOBACCO SURVEY (NYTS)

- NYTS is the only nationally representative survey of middle and high school students that focuses exclusively on tobacco use
- Over the past several years, e-cigarettes were the most commonly used tobacco product by youth
- More than 2 million middle and high school students were current users of e-cigarettes in 2017
- All of these factors are taken into consideration in the public health standard



HOW CAN WE MAKE THE GREATEST IMPACT?

"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 NEW COMPREHENSIVE REGULATORY PLAN

ADDICTIVE NICOTINE IN COMBUSTIBLE CIGARETTES

"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'S VISION FOR ADDRESSING NICOTINE

FDA envisions a world where **cigarettes would no longer create or sustain addiction**, and where **adults** who still seek nicotine could **get it** from alternative and **less harmful sources**

- Decrease the likelihood that future generations will become addicted to cigarettes
- Allow more addicted smokers to quit
- Encourage innovation of less harmful products for adults who need them
- Support innovations to medicinal nicotine and other therapeutic cessation products

FDA'S COMPREHENSIVE REGULATORY PLAN

These efforts fall under several categories:

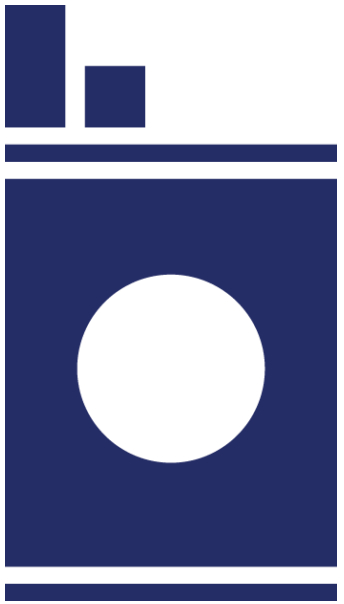
1) Regulatory Policies on Addiction, Appeal & Cessation

2) Youth Tobacco Prevention Plan
   - Access
   - Marketing
   - Education

3) Science-Based Review of Potential Modified Risk Tobacco Products

REGULATORY POLICIES ON ADDICTION, APPEAL & CESSATION

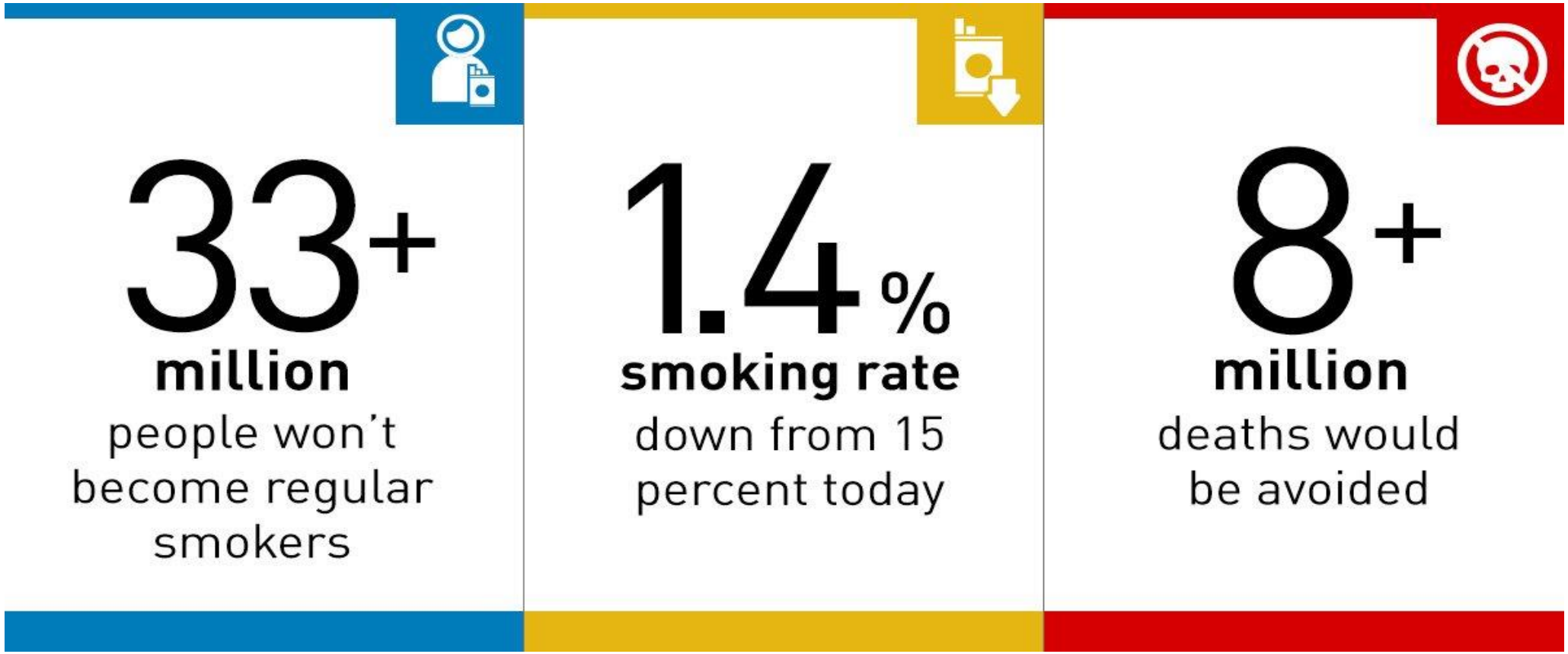
NICOTINE PRODUCT STANDARD ANPRM



- On March 15, FDA issued the *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes*, an Advance Notice of Proposed Rulemaking (ANPRM)
- Sought public comment for consideration in developing a potential product standard to lower nicotine to a minimally or non-addictive level in cigarettes
  - What potential maximum nicotine level would be appropriate for the protection of the public health;
  - How a maximum nicotine level should be measured;
  - Whether such a product standard should be implemented all at once or gradually;
  - Whether a nicotine product standard should also cover additional combustible tobacco products; and
  - What unintended consequences might occur as a result of such a standard
- Comment period closed on July 16, 2018

ESTIMATES FROM ONE POSSIBLE NICOTINE PRODUCT STANDARD POLICY

Includes newly published estimates of one possible policy scenario to be realized by 2100:



FDA NICOTINE STEERING COMMITTEE

- FDA Nicotine Steering Committee formed in September 2017
- Charged with re-evaluating and modernizing FDA's approach to the development and regulation of nicotine replacement therapy (NRT) products
  - Ensures alignment of FDA's centers and facilitates consensus and development of unified positions on cross-cutting issues
- Public hearing held in January 2018 to solicit comments on a variety of issues including:
  - New indications such as "Reduce to quit" for therapeutic product evaluation
  - Investigational New Drug Application vs Investigational Tobacco Product
  - Broadening NRT indications and flexibility on labeling
- In August, issued "Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products" Draft Guidance – focuses on data recommended to evaluate potential toxicities associated with orally inhaled nicotine-containing drug products, including ENDS
- Additional guidance coming on new potential clinically relevant outcomes for cessation products

FLAVORS IN TOBACCO PRODUCTS ANPRM

- On March 20, FDA issued *Regulation of Flavors in Tobacco Products*, an Advance Notice of Proposed Rulemaking (ANPRM)
- Sought comments, research and data on:
  - Role flavors play in initiation & patterns of tobacco use, particularly among youth & young adults;
  - Role flavors may play in helping some adult smokers reduce cigarette use and/or switch to potentially less harmful tobacco products;
  - Consumer perceptions of health risks and addictiveness of flavored products;
  - Whether certain flavors used in tobacco products present potential adverse health effects to users or others
- Comment period closed on July 19, 2018

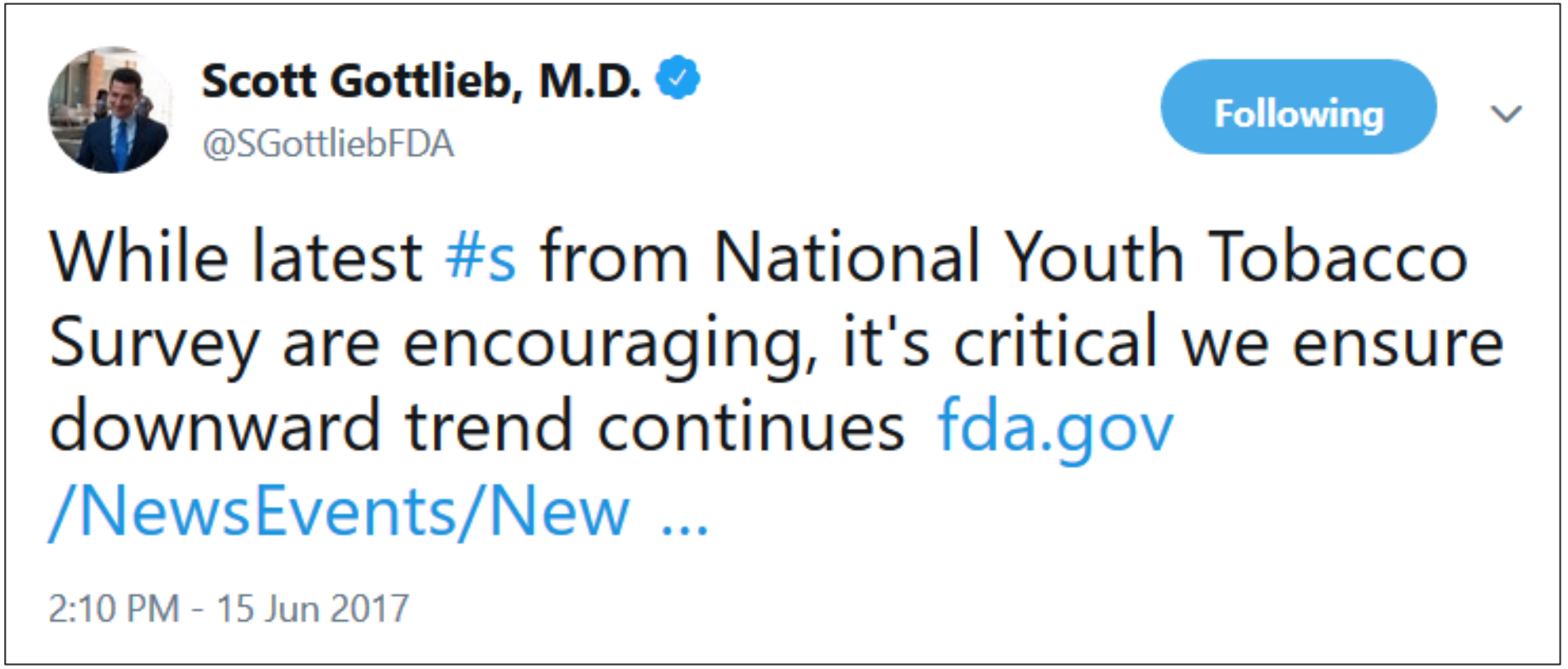
YOUTH TOBACCO PREVENTION PLAN

A TIMELINE OF ESCALATING CONCERN AND ACTIONS

- The last few months have seen FDA take a series of actions amid growing concerns of youth use of, and access to, e-cigarettes

- These actions should not come as a surprise – Dr. Gottlieb has consistently made our concerns known for well over a year

JUNE 2017

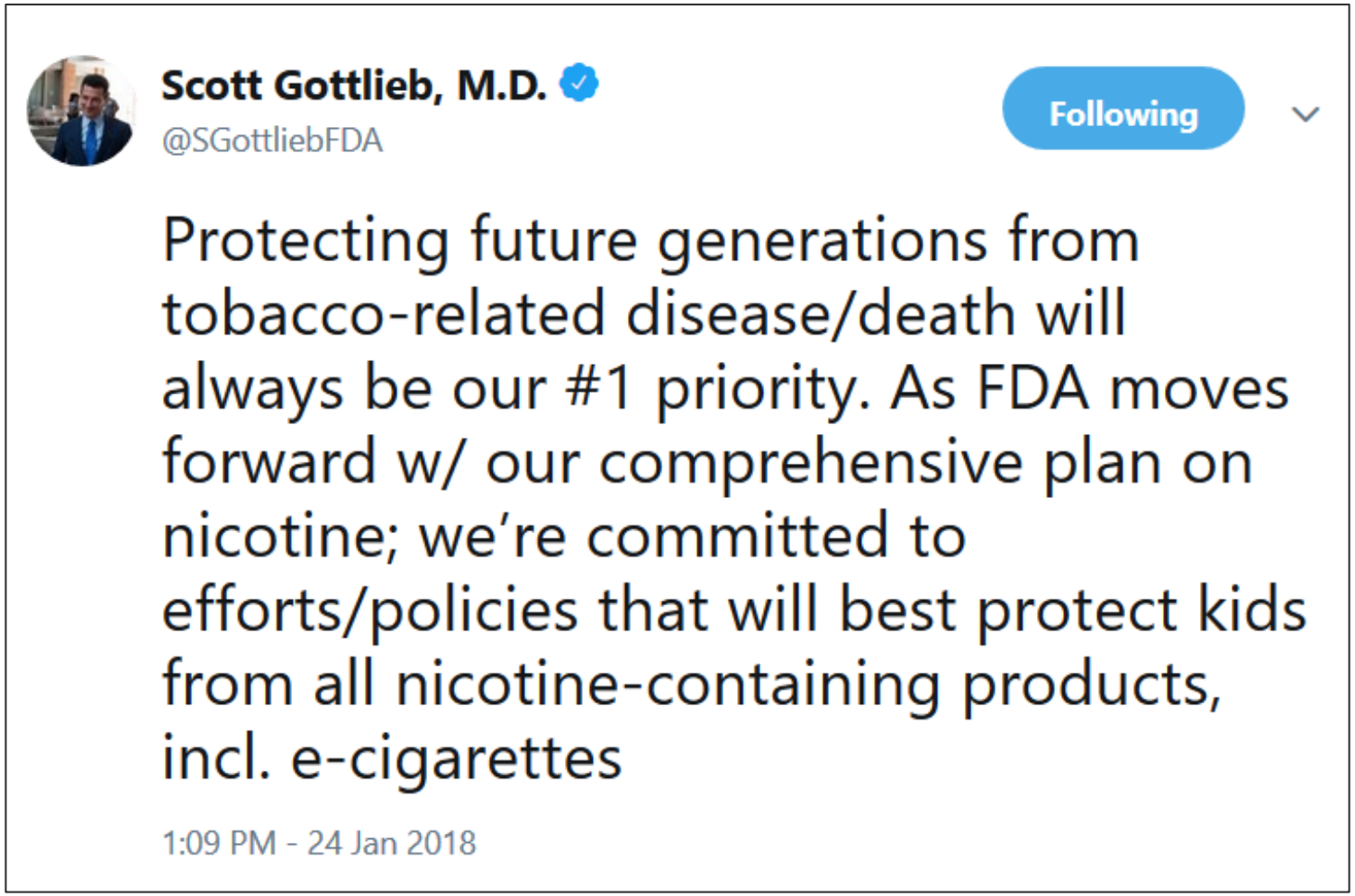

Scott Gottlieb, M.D.
@SGottliebFDA
Following
While latest #s from National Youth Tobacco Survey are encouraging, it's critical we ensure downward trend continues fda.gov /NewsEvents/New ...
2:10 PM - 15 Jun 2017

JULY 2017

"I have real concerns about kids' use of e-cigarettes, and I know many others share those concerns, especially those products marketed with obviously kid-appealing flavors."

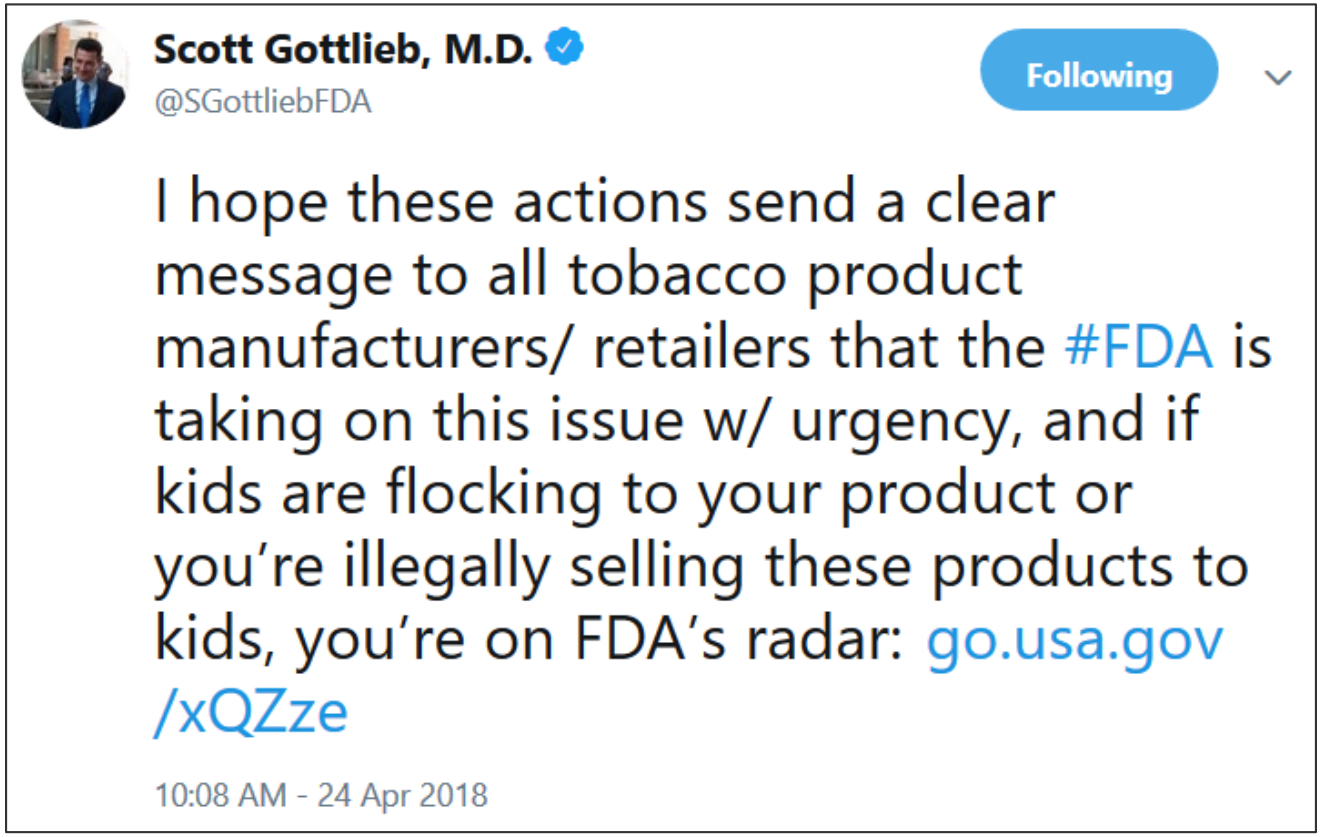
- Commissioner Gottlieb, July 28, 2017

JANUARY 2018



APRIL 2018: YOUTH TOBACCO PREVENTION PLAN

On April 24, Commissioner Gottlieb announced a new segment of the Comprehensive Plan to reduce access to – and use of – tobacco products, particularly e-cigarettes



YOUTH TOBACCO PREVENTION PLAN

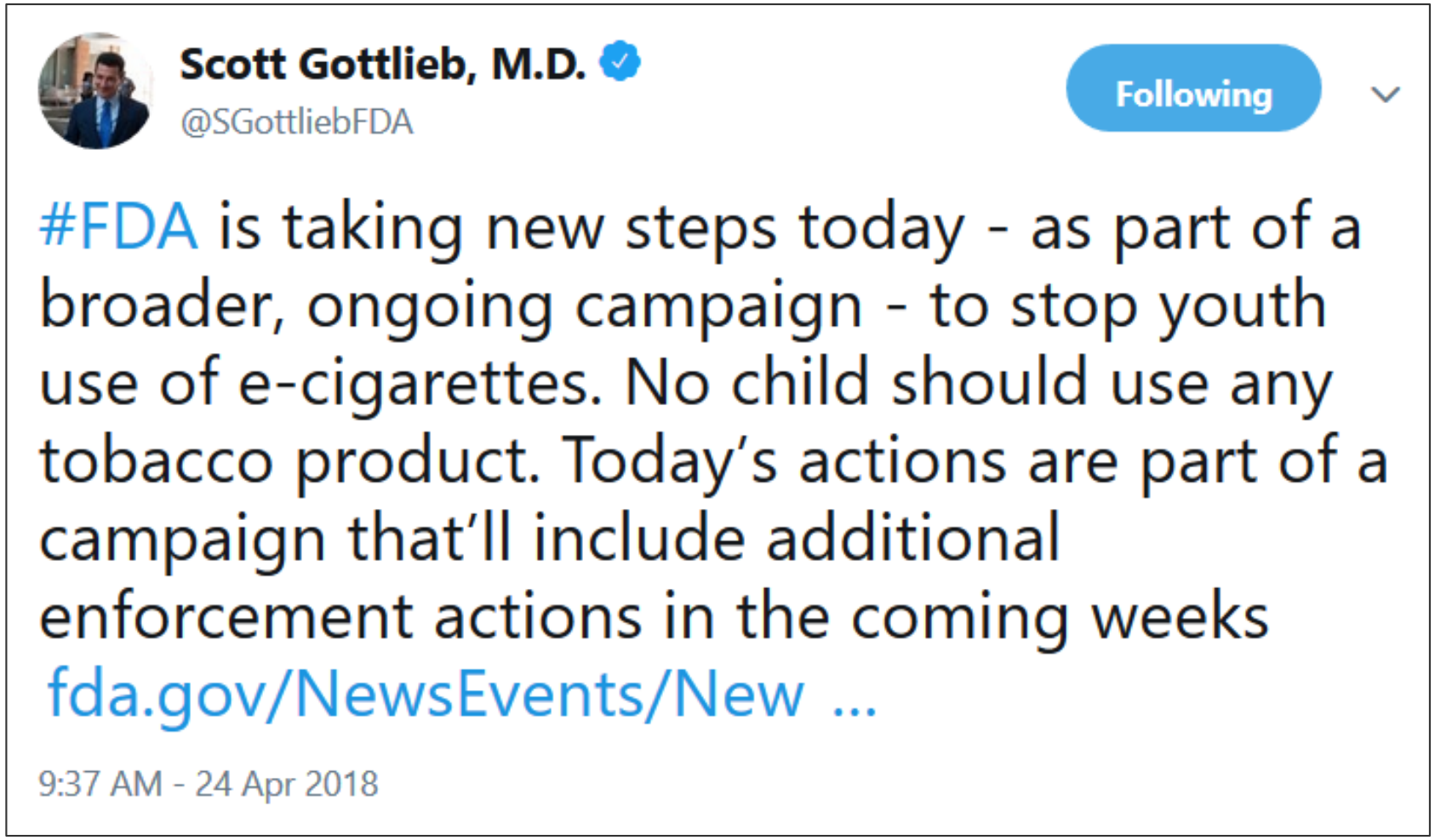
- The Youth Tobacco Prevention plan has three main strategies:
  - *Preventing youth access*
  - *Curbing the marketing of products*
  - *Educating teens and their families*

- One major concern is the popularity of products that closely resemble a USB flash drive, have high levels of nicotine, and have emissions that are hard to see
  - These characteristics may facilitate youth use by making products more attractive to youth
  - Several of these products fall under the JUUL brand, but other brands with similar characteristics are emerging
  - Kids may be trying these products and liking them without knowing they contain nicotine

APRIL: YOUTH TOBACCO PREVENTION PLAN INITIAL ACTIONS

- Conducted a large-scale, undercover nationwide “blitz” of brick-and-mortar & online retailers for selling JUUL to underage youth
  - Issued 56 warning letters and filed 6 CMPs from March-June
- Worked with eBay to remove listings for JUUL on its website and voluntarily implement new measures to prevent new listings
- Sent 904(b) letters to JUUL and others requiring them to submit important documents on product marketing and research on health, toxicological, behavioral or physiological effects of the product, including:
  - Youth initiation and use
  - Whether certain design features, ingredients, or specifications appeal to different age groups
  - Youth-related adverse events and consumer complaints

APRIL 2018


Scott Gottlieb, M.D.
@SGottliebFDA
Following
#FDA is taking new steps today - as part of a broader, ongoing campaign - to stop youth use of e-cigarettes. No child should use any tobacco product. Today's actions are part of a campaign that'll include additional enforcement actions in the coming weeks
fda.gov/NewsEvents/New ...
9:37 AM - 24 Apr 2018

MAY: YOUTH TOBACCO PREVENTION PLAN ACTIONS

- On May 1, issued 17 warning letters to manufacturers, distributors, and retailers for selling e-liquids used in e-cigarettes with labeling and/or advertising that cause them to resemble kid-friendly food products such as juice boxes, candy, cookies, and some included cartoon-like imagery
  - FTC jointly-issued 13 of the letters because Section 5 of the Federal Trade Commission Act prohibits unfair or deceptive advertising

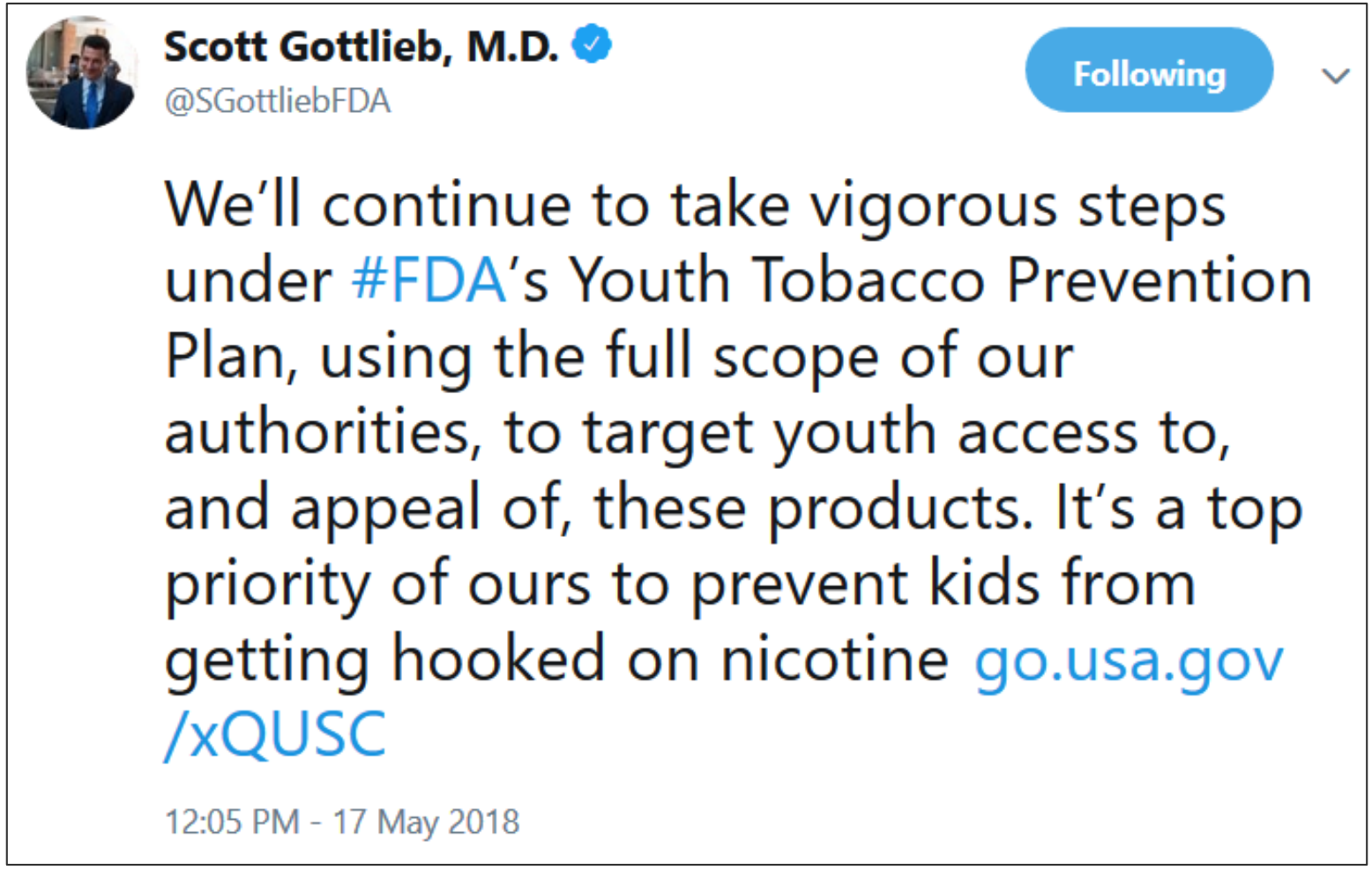
- All 17 companies have stopped selling these products
  - Several of the companies were also cited for illegally selling the products to minors

MAY: YOUTH TOBACCO PREVENTION PLAN ACTIONS

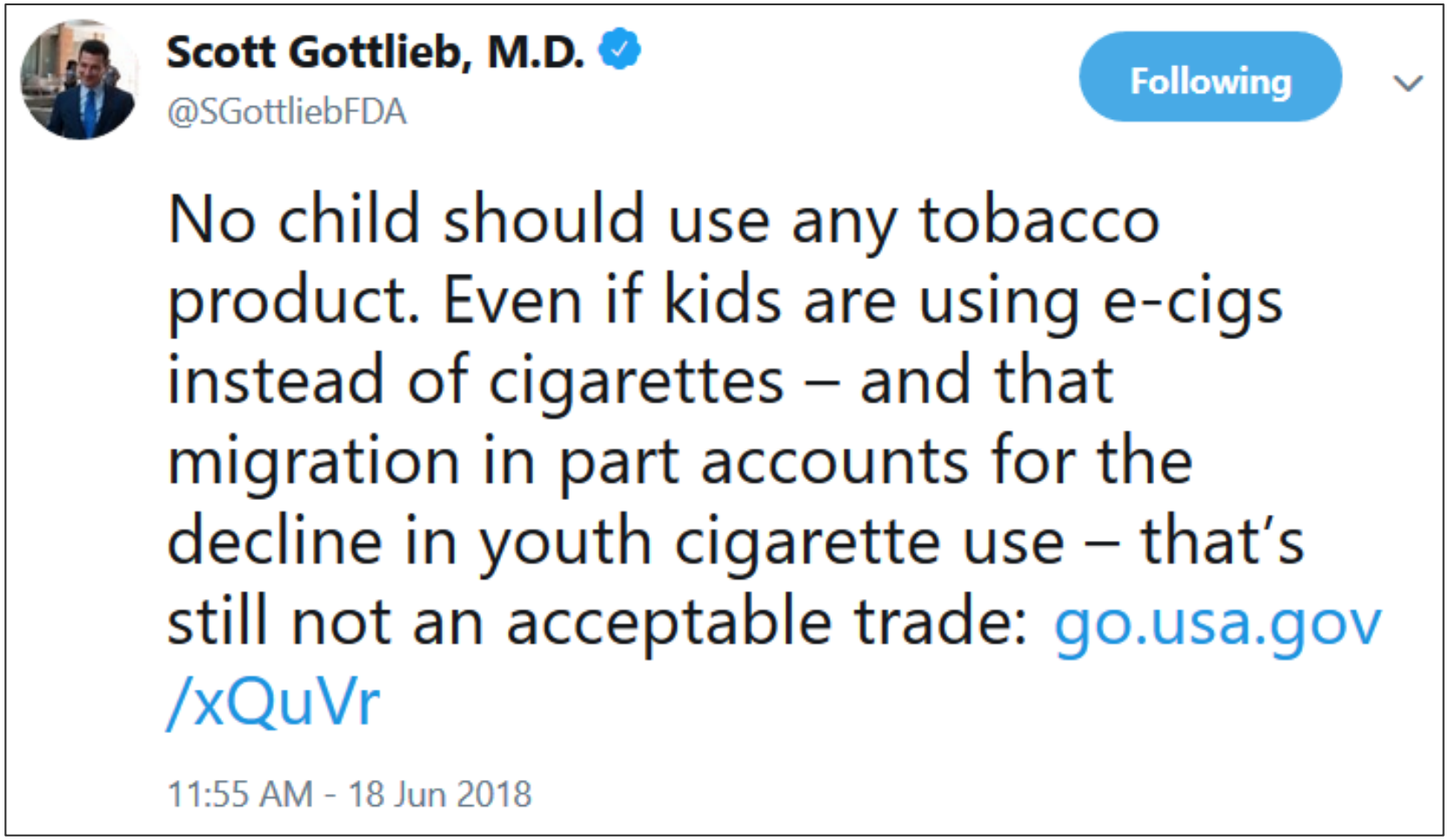
- On May 17, issued additional 904(b) letters to companies and manufacturers regarding the following four e-cigarette products:
  - Bo Starter Kit
  - Zoor Kit
  - Myle Products
  - SMPO Kit

- Products were selected based on attributes that overlap with JUUL, including:
  - The use of e-liquids that contain nicotine salts with corresponding high nicotine concentration
  - A small size which makes these products easily concealable
  - Product design features that are intuitive, even for novice users

MAY 2018


Scott Gottlieb, M.D.
@SGottliebFDA
Following
We'll continue to take vigorous steps under #FDA's Youth Tobacco Prevention Plan, using the full scope of our authorities, to target youth access to, and appeal of, these products. It's a top priority of ours to prevent kids from getting hooked on nicotine go.usa.gov/xQUSC
12:05 PM - 17 May 2018

JUNE 2018


Scott Gottlieb, M.D.
@SGottliebFDA
Following
No child should use any tobacco product. Even if kids are using e-cigs instead of cigarettes – and that migration in part accounts for the decline in youth cigarette use – that's still not an acceptable trade: go.usa.gov/xQuVr
11:55 AM - 18 Jun 2018

SEPTEMBER 12: YOUTH TOBACCO PREVENTION PLAN NEXT STEPS

Despite these actions and clear signals from the Commissioner to industry, the youth issues persist

Preliminary data from the 2018 National Youth Tobacco Survey show a disturbingly sharp rise in the number of teens using e-cigarettes. From 2017 to 2018:

- The number of high-school-age children reporting use of e-cigarettes ***rose by more than 75%***
- Use among middle-schoolers ***increased nearly 50%***

On Sept. 12, FDA announced a series of new steps in the three strategies of its Youth Tobacco Prevention Plan

SEPTEMBER: YOUTH TOBACCO PREVENTION PLAN ACTIONS

- In the largest coordinated enforcement effort in FDA's history, issued more than 1,100 warning letters and 131 civil money penalty complaints to retailers who illegally sold e-cigarette to minors
  - Issued 12 additional warning letters to online retailers for selling misleadingly labeled and/or advertised e-liquids resembling kid-friendly products
- Issued letters to the makers of JUUL, Vuse, MarkTen XL, blu e-cigs and Logic asking the companies to submit plans describing how they will address the widespread youth access and use of their products
  - Letters laid out a few examples of actions the companies could take, including eliminating online sales, removing flavored products from the market until they are reviewed by FDA, and revising current marketing practices to help prevent use by those under the age of 18
- FDA made clear that all options are on the table, including revisiting the current policy that provides manufacturers of certain deemed products more time to submit a premarket application (until 2022)

OCTOBER: YOUTH TOBACCO PREVENTION PLAN ACTIONS

- On October 11, issued warning letter to HelloCig Electronic Technology Co. Ltd for various violations, including selling two e-liquids that contain prescription drugs, leading the FDA to determine that the products are unapproved new drugs

- On October 12, sent letters to 21 companies as part of investigation of whether 40+ currently marketed e-cigarettes may be subject to enforcement actions because they were not on the market as of August 8, 2016 nor have they received premarket authorizations

YOUTH TOBACCO PREVENTION PLAN: EDUCATION

- "The Real Cost" Youth E-Cigarette Prevention Campaign is targeted to youth aged 12-17 who have used e-cigarettes or are open to trying them; launched last month
- Ads are running online and include location-targeted advertising around high schools nationwide, as well as posters in school bathrooms
- Campaign messages focus on educating youth that using e-cigarettes, just like cigarettes, puts them at risk for addiction and other health consequences
- To ensure these messages are reaching the intended youth audience, the ads will run on age-verified digital platforms

FDA LAUNCHED “EPIDEMIC” ON SEPTEMBER 17, 2018

“THE REAL COST” YOUTH E-CIGARETTE PREVENTION CAMPAIGN

Learn more about “The Real Cost” Youth E-Cigarette Prevention Campaign:

Preventing Teen Tobacco Use

Kathleen Crosby

Director of Office of Health Communication & Education at FDA CTP

3:45 - 5:00 pm

SCIENCE-BASED REVIEW OF POTENTIAL MODIFIED RISK TOBACCO PRODUCTS

REVIEWING PRODUCTS IN EVOLVING TOBACCO MARKETPLACE: MODIFIED RISK APPLICATIONS

- *iQOS*: In May 2017, FDA filed three MRTP applications for scientific review from PMI for its *iQOS* system and three *HeatStick* products
  - TPSAC meeting held Jan. 24-25, comment period is open-ended
- *Camel Snus*: In Dec. 2017, FDA filed MRTP applications for scientific review from R.J. Reynolds Tobacco Company for six *Camel Snus* smokeless tobacco products
  - TPSAC meeting held Sept. 13-14, comment period remains open
- *Copenhagen Snuff Fine Cut*: In Sept. 2018, FDA filed MRTP applications for scientific review from U.S. Smokeless Tobacco Company for one moist snuff tobacco product
- *General Snus*: In Dec. 2016, FDA denied one request in Swedish Match North America's MRTP applications for eight smokeless tobacco products and deferred on two other requests
  - In October 2018, FDA posted an amendment submitted by the company

IMPROVING EFFICIENCY AND TRANSPARENCY

- FDA continues working on foundational rules and guidances to clarify the “rules of the road”, including but not limited to:
  - Rules for pathway submissions (SE, PMTA, MRTP)
  - Guidance for industry (PMTA for ENDS Final Guidance)

- Rolling out updates to make the review process more efficient, predictable and transparent while upholding our public health mission
  - For example, companies previously needed to file FOIA requests to obtain certain review documents, but copies of these documents are now available to companies following an adverse decision

- Earlier this week, held Tobacco Product Application Review public meeting to solicit practical feedback and suggestions to improve our processes

CLOSING THOUGHTS

- Our responsibility is to assess the "net" impact on the population
  - Impact on initiation is a mandatory consideration – but *how much weight* should be placed it?
- FDA is committed to pursuing our comprehensive plan but concerns about teens and nicotine in any form remain
- The alarming increase in youth e-cigarette use should cause us all to pause; especially after you see other 2018 NYTS results
- We still believe that a world where kids cannot become addicted to cigarettes, and addicted adults have access to less harmful forms of nicotine and improved medicinal products, is an achievable vision that will save countless lives
- But FDA has been very clear going back to June of last year about the need to protect kids
- ***The stakes just got higher***

QUESTIONS?

THANK YOU

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