FDA'S COMPREHENSIVE PLAN FOR TOBACCO AND NICOTINE REGULATION

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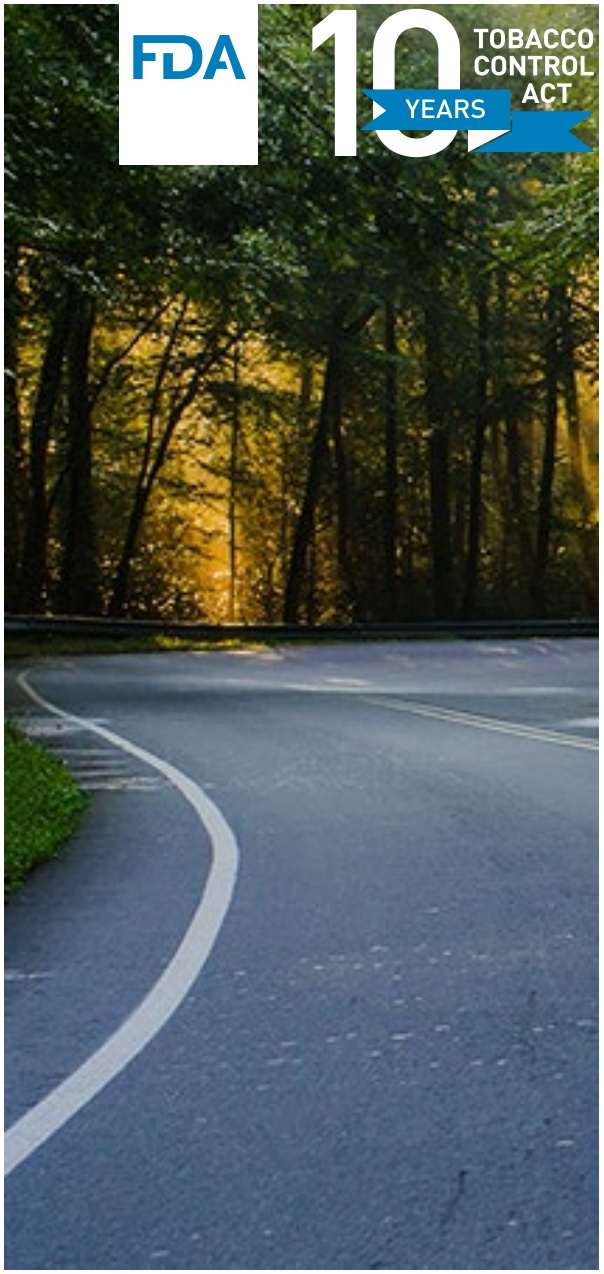
AGENDA

- Comprehensive Plan for Tobacco & Nicotine Regulation
  - Regulatory Policies on Addiction, Appeal & Cessation
  - Youth Tobacco Prevention Plan
  - Science-Based Review of Tobacco Products
- Investment in Regulatory Science
- Closing Thoughts
- Questions



COMPREHENSIVE PLAN FOR TOBACCO AND NICOTINE REGULATION

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, including:

1) Regulatory Policies on Addiction, Appeal & Cessation

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

3) Science-Based Review of Tobacco Products

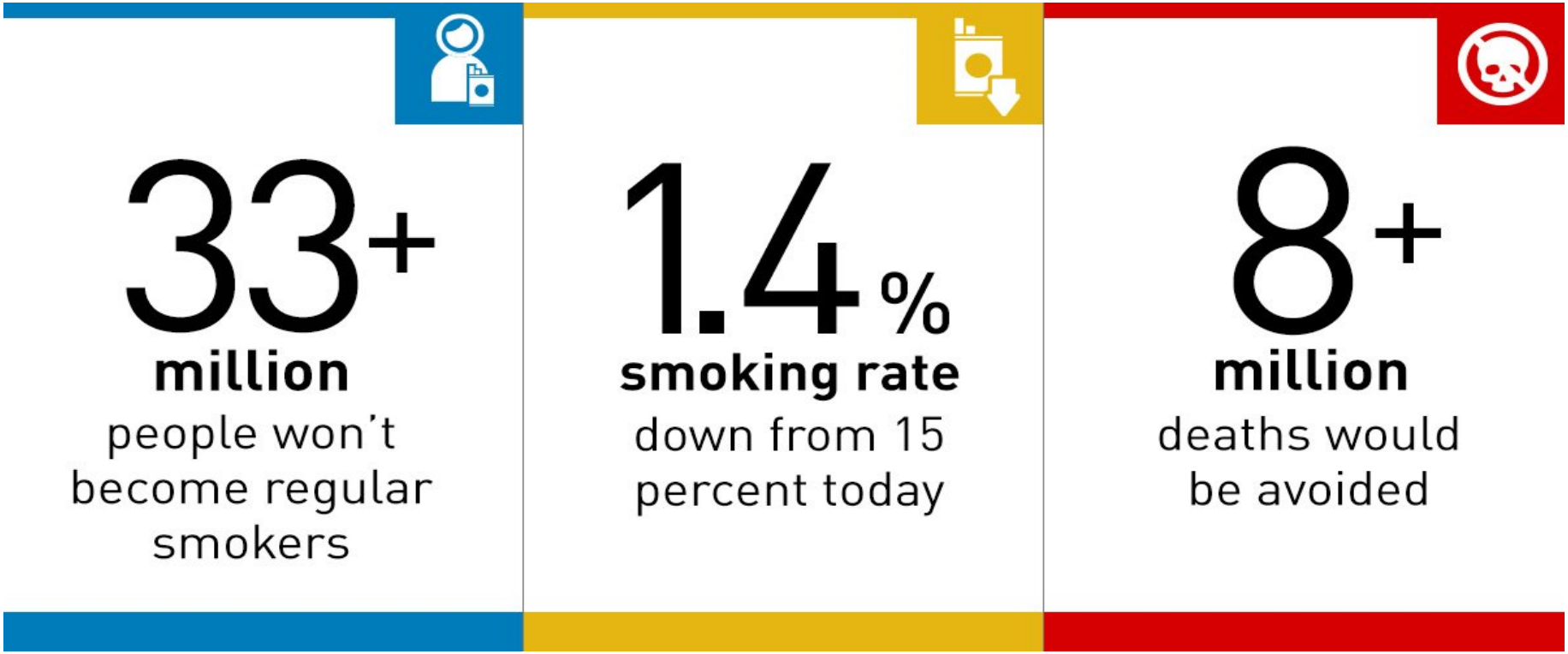
REGULATORY POLICIES ON ADDICTION, APPEAL & CESSATION

NICOTINE PRODUCT STANDARD ANPRM

- On March 15, 2018, FDA issued the *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes,* an 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

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



ENCOURAGING A NATIONAL NICOTINE DIALOGUE

- Discuss core of the problem – but also the solution to addiction
- Engage public to educate and discuss:
  - **Correct common misperceptions**: Mistaken beliefs about nicotine and cancer
  - **Nicotine's role in continuum of risk**: Can be highly addictive; combustible cigarette is the delivery vehicle responsible for most disease and death; safe and effective in medicinal nicotine
  - **Nicotine and youth**: Potential for nicotine to rewire a teen's brain and create cravings leading to addiction; potential for future generations to not get addicted
  - **Adult smokers and nicotine**: How those who still seek nicotine can get satisfying levels from other and less harmful sources
  - **Vulnerable populations**: Consider the impact on adult smokers with mental health disorders

FDA'S NICOTINE STEERING COMMITTEE

- September 2017: Nicotine Steering Committee formed and charged with re-evaluating and modernizing FDA's approach to the development and regulation of nicotine replacement therapy (NRT) products
- January 2018: Held public hearing 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 and broadening NRT indications and flexibility on labeling
- August 2018: Issued "Nonclinical Testing of Orally Inhaled Nicotine-Containing Drug Products" Draft Guidance that focuses on data recommended to evaluate potential toxicities associated with orally inhaled nicotine-containing drug products, including ENDS
- February 2019: Issued "Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products" Draft Guidance that helps lay out a framework for new potentially clinically relevant outcomes for smoking cessation, such as reducing the chance of a smoker going back to using cigarettes long term

PUBLIC MEETINGS ON YOUTH CESSATION

- On Jan. 18, 2019, FDA held a public hearing on "Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies"

- "Youth Tobacco Cessation: Science and Treatment Strategies" public scientific workshop being held today
  - Purpose is to discuss the challenges and latest science on youth tobacco use, addiction and cessation treatment strategies
  - Submit electronic or written comments by May 31, 2019

FLAVORS IN TOBACCO PRODUCTS ANPRM

- On March 20, 2018, FDA issued *Regulation of Flavors in Tobacco Products*, an 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

REGULATION OF PREMIUM CIGARS ANPRM

- On March 23, 2018, FDA issued Regulation of Premium Cigars, an Advance Notice of Proposed Rulemaking (ANPRM)
- Seeks scientific data on patterns of use and resulting public health impacts of “premium” cigars
  - The definition of “premium” cigars;
  - Use patterns of premium cigars generally and among youth and young adults specifically;
  - Public health considerations associated with premium cigars, including the health effects;
  - Studies or information regarding consumer perceptions of the health risks of premium cigars
- Comment period closed on July 25, 2018

YOUTH TOBACCO PREVENTION PLAN

YOUTH TOBACCO PREVENTION PLAN

- The Youth Tobacco Prevention plan has three main strategies:
  - *Preventing youth access*
  - *Curbing the marketing of tobacco products aimed at youth*
  - *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

ENFORCEMENT ACTIONS TO ADDRESS YOUTH ACCESS AND MARKETING TO YOUTH

YOUTH TOBACCO PREVENTION PLAN: ACCESS & MARKETING

- Conducted a large-scale, undercover nationwide "blitz" of brick-and-mortar & online retailers for selling JUUL to underage youth
- Worked with eBay to remove JUUL listings and implement measures to prevent new listings

- 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-cigarettes to minors
- Issued 17 warning letters for selling e-liquids with labeling and/or advertising causing them to resemble kid-friendly food products such as juice boxes, candy and cookies – some with cartoon imagery

YOUTH TOBACCO PREVENTION PLAN: ACCESS & MARKETING

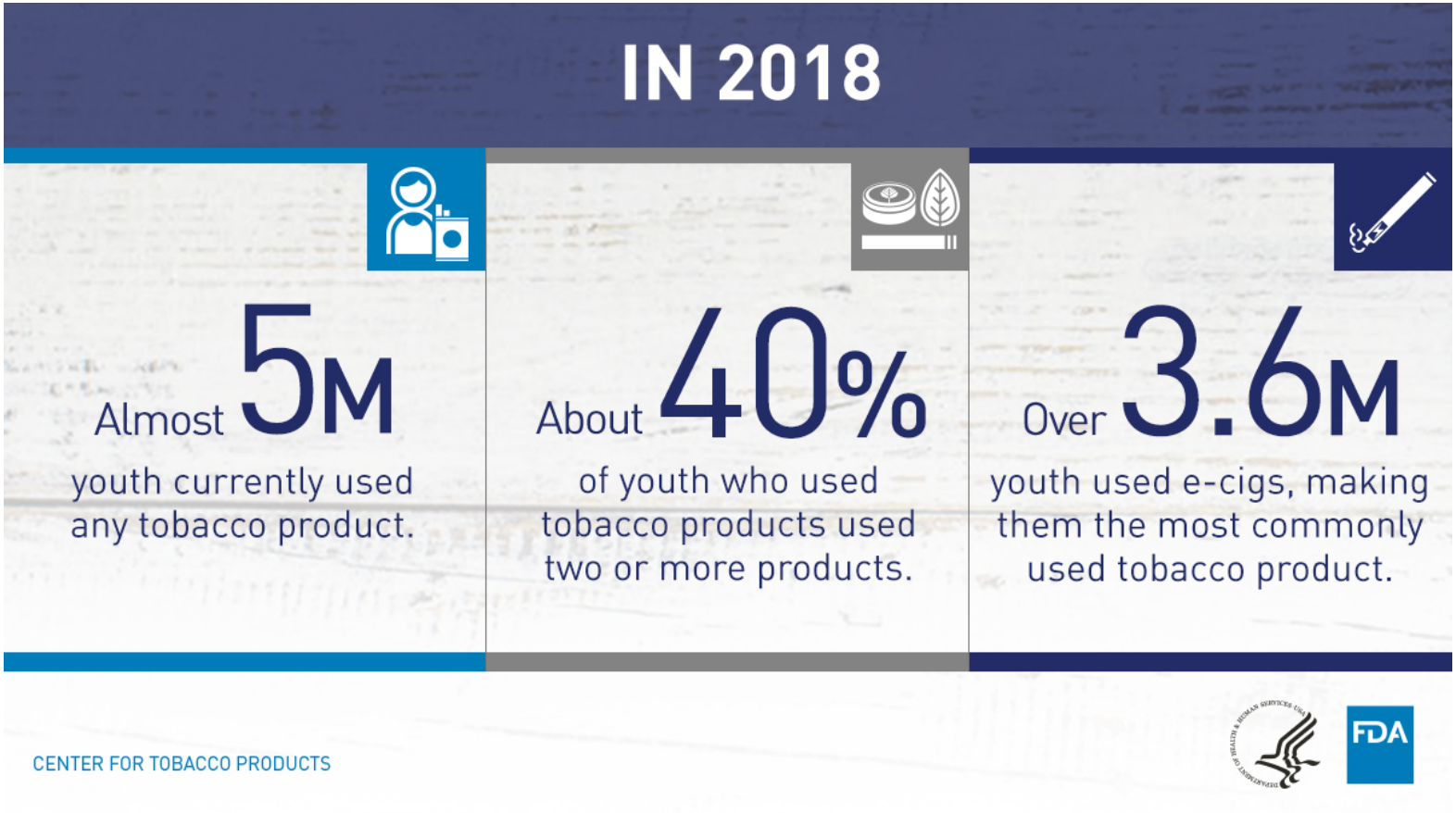
- Issued letters to makers of JUUL, Vuse, MarkTen XL, blu e-cigs and Logic asking them to submit plans on how they will address widespread youth access and use of their products

- Sent letters to 59 companies seeking information on over 75 brands of ENDS products to determine if those products are being illegally marketed outside FDA's compliance policy
- Initiated enforcement action against certain Walgreens & Circle K stores for repeated violations on the sale and distribution of tobacco products to minors
- Issued warning letters to two companies, Undisputed Worldwide and EZ Fumes, for manufacturing, selling, and/or distributing nicotine-containing e-liquids with misleading labeling and/or advertising that imitate prescription cough syrup

POLICY ACTION TO ADDRESS YOUTH ACCESS AND MARKETING TO YOUTH

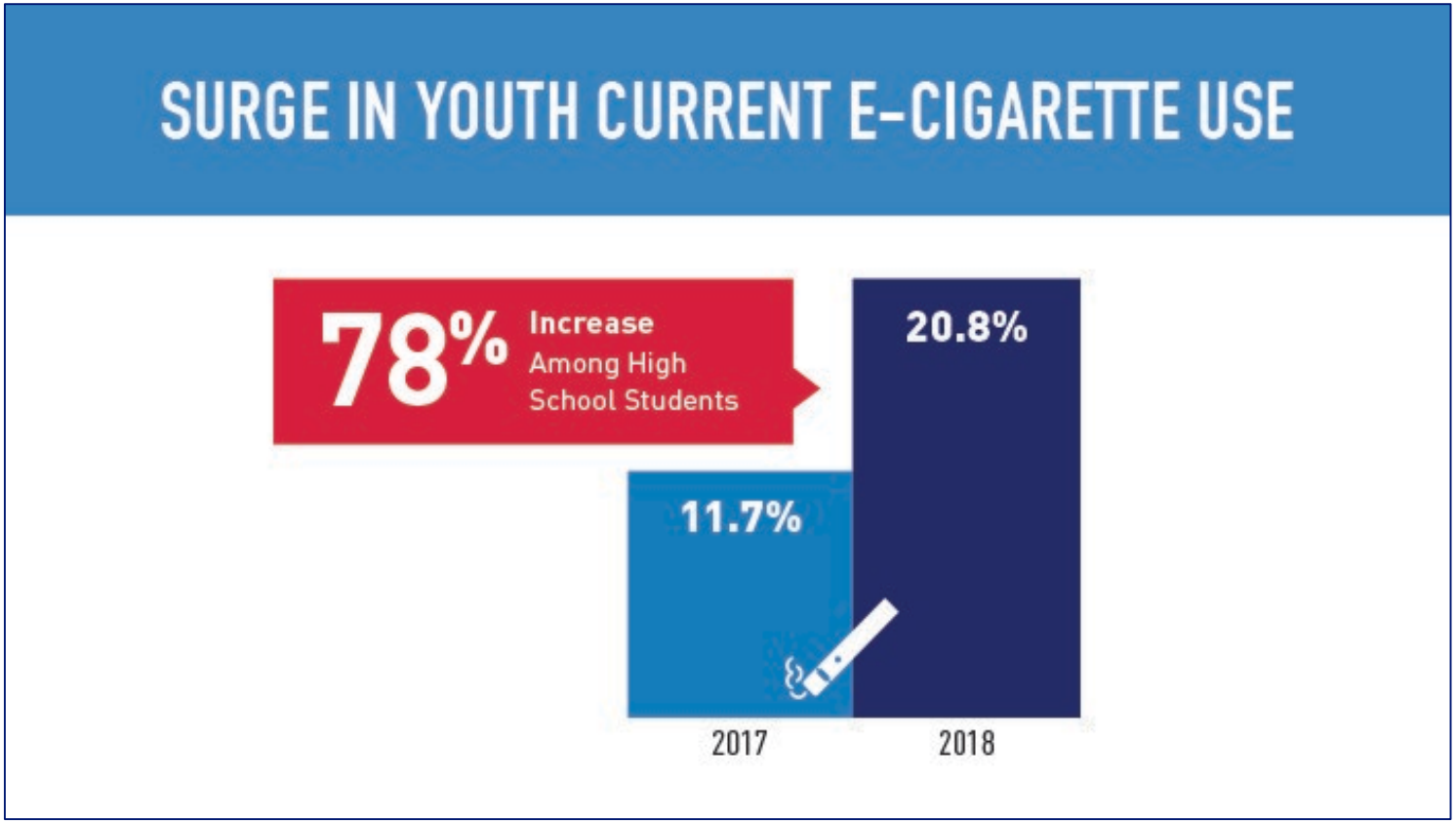
2018 NATIONAL YOUTH TOBACCO SURVEY RESULTS RELEASED

The 2018 National Youth Tobacco Survey data show an alarming surge in youth e-cigarette use



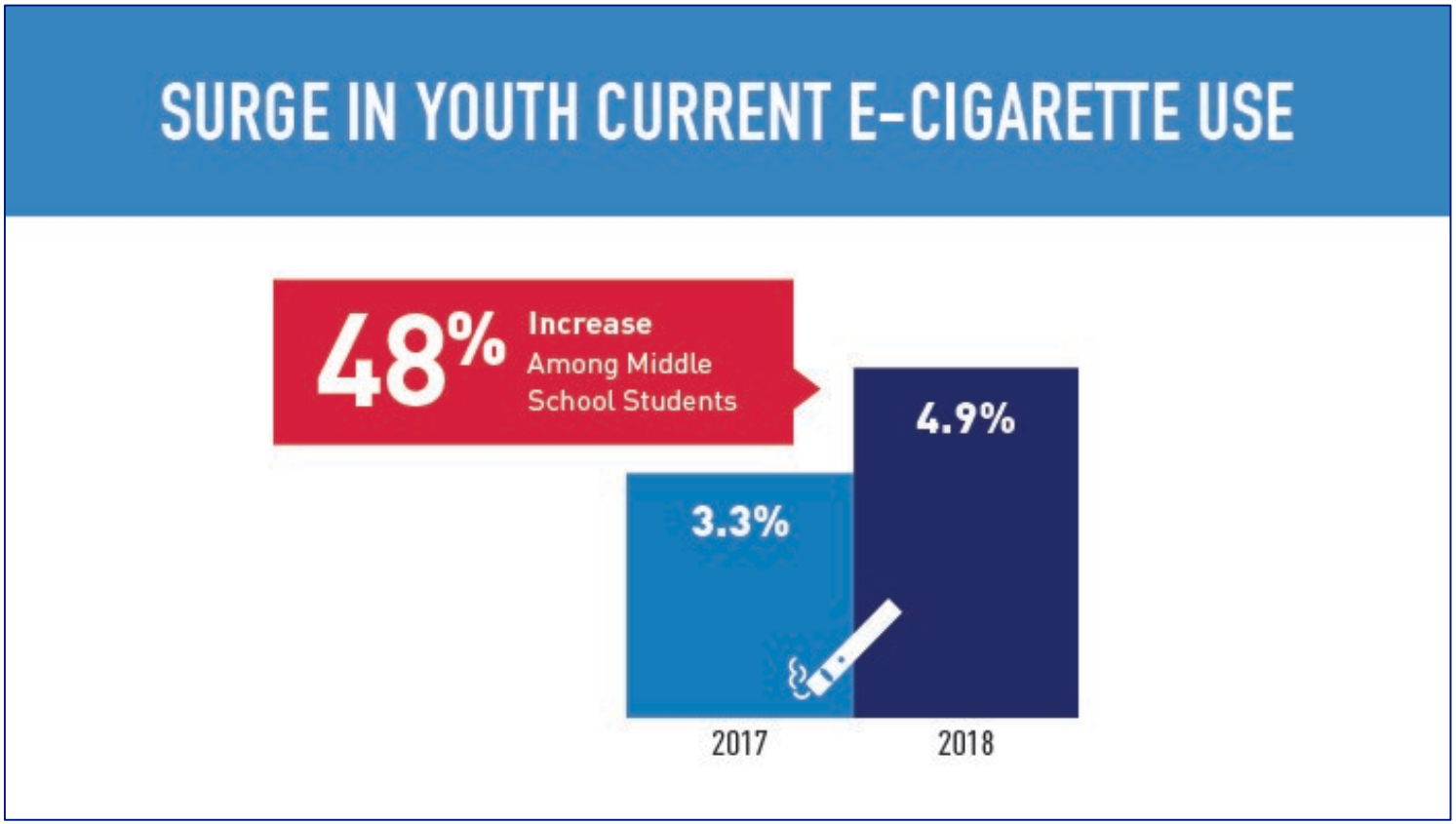
NOVEMBER: 2018 NATIONAL YOUTH TOBACCO SURVEY RESULTS RELEASED

From 2017 to 2018, there was a 78 percent increase in current e-cigarette use among high school students



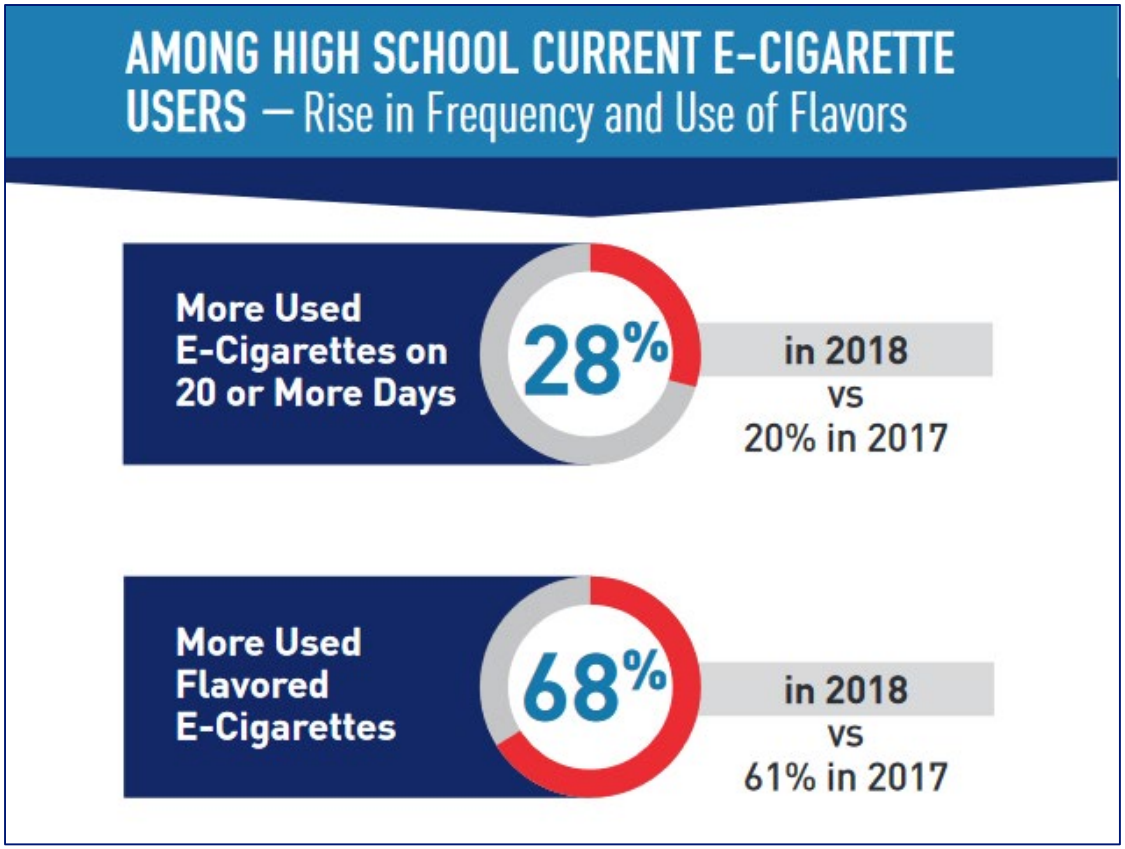
NOVEMBER: 2018 NATIONAL YOUTH TOBACCO SURVEY RESULTS RELEASED

From 2017 to 2018, there was a 48 percent increase in current e-cigarette use among middle school students



NOVEMBER: 2018 NATIONAL YOUTH TOBACCO SURVEY RESULTS RELEASED

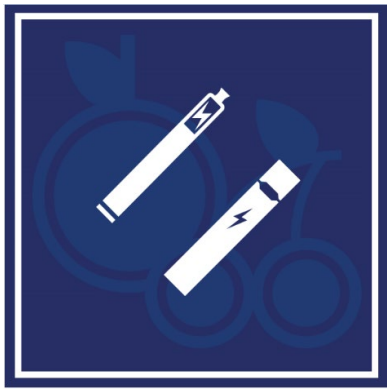
Among high school students who currently used e-cigarettes, frequency and use of flavored e-cigarettes products increased



POLICY RESPONSE TO THE SURGE IN YOUTH E-CIGARETTE USE

- In Sept. 2018, FDA announced the agency would be reconsidering all policy options with respect to deemed products to respond to the surge in youth e-cigarette use rates
- In Nov. 2018, FDA announced a framework aimed at preventing youth access to, and appeal of, flavored tobacco products – specifically, e-cigs and cigars
- In March 2019, FDA released draft guidance "Modifications to Compliance Policy for Certain Deemed Tobacco Products" that outlines policy changes and prioritization of enforcement resources
  - Guidance currently scheduled to take effect 30 days after it is finalized
  - Comment period closed April 30; comments being reviewed

DRAFT GUIDANCE: CHANGES TO COMPLIANCE POLICY – ENDS



- Previously, manufacturers of ENDS on the market as of Aug. 2016 had until 2022 to submit applications for premarket authorization
- **ENDS policy change**: Flavored ENDS products (other than tobacco-, mint-, and menthol-flavored ones), and ENDS products that are targeted to minors or likely to promote use of ENDS by minors, would be subject to enforcement beginning 30 days after guidance is finalized
- Enforcement of this policy will be prioritized by the following products:
  - Those that are offered for sale in ways that pose a greater risk for minors to access them
  - Those that are targeted to minors or likely to promote use of ENDS by minors
  - Those that are offered for sale in the US without the manufacturer submitting applications for premarket authorization by Aug. 8, 2021

DRAFT GUIDANCE: CHANGES TO COMPLIANCE POLICY – FLAVORED CIGARS

- Previously, manufacturers of new cigars on the market as of Aug. 2016 had until 2021 to submit applications for premarket authorization
- **Cigar policy change**: Any new flavored cigars (other than tobacco-flavored) on the market as of Aug. 2016 – and that meet the definition of a new tobacco product – would be subject to enforcement beginning 30 days after guidance is finalized
- Products would have to receive premarket authorization to be re-introduced to the market
- FDA also plans to move forward with a proposed rule to ban all characterizing flavors in cigars

PUBLIC EDUCATION CAMPAIGN

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 September 2018
- Campaign messages focus on educating youth that using e-cigarettes, just like cigarettes, puts them at risk for addiction and other health consequences
- Ads are running online and include location-targeted advertising around high schools nationwide, as well as posters in school bathrooms
- This summer, FDA plans to extend the campaign to include television ads

“THE REAL COST” YOUTH E-CIGARETTE PREVENTION CAMPAIGN: EPIDEMIC

YOUTH E-CIGARETTE PREVENTION POSTERS

- "The Real Cost" will reach students with an e-cigarette prevention message in the exact moment and location that they are faced with the decision to use e-cigarettes

- Posters were distributed to more than 10,000 high schools to place in bathrooms

- Snarky tone will catch their attention, but the facts will deliver a strong prevention message

SCIENCE-BASED REVIEW OF TOBACCO PRODUCTS

APRIL 2019: PMTA DECISIONS

- FDA recently authorized the marketing of new tobacco products for Phillip Morris Products S.A's IQOS "Tobacco Heating System"
  - Electronic device that heats tobacco-filled sticks wrapped in paper to generate a nicotine-containing aerosol. Referred to as "heat-not-burn" or "heated" tobacco products but meet the definition of a cigarette in the FD&C.
  - Authorized products include the IQOS device, Marlboro Heatsticks, Marlboro Smooth Menthol Heatsticks and Marlboro Fresh Menthol Heatsticks
- The authorization of these products is appropriate for the protection of public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes
  - Stringent marketing restrictions on the products to prevent youth access, use and exposure
  - Postmarket requirements include monitoring market dynamics such as potential youth uptake

MODIFIED RISK TOBACCO PRODUCT (MRTP) APPLICATIONS

- *IQOS*: In May 2017, FDA filed for scientific review three applications from Philip Morris Products S.A. for its *IQOS* system and three Marlboro *HeatStick* products
  - TPSAC meeting held Jan. 24-25, 2018, comment period closed Feb. 11, 2019
- *Camel Snus*: In Dec. 2017, FDA filed for scientific review applications from R.J. Reynolds Tobacco Company for six smokeless products
  - TPSAC meeting held Sept. 13-14, 2018, comment period closes May 13, 2019
- *Copenhagen Snuff Fine Cut*: In Sept. 2018, FDA filed for scientific review an application from U.S. Smokeless Tobacco Company for one moist snuff product
  - TPSAC meeting held Feb. 6-7, 2019, comment period remains open
- *General Snus*: In Dec. 2016, FDA denied one request and deferred on two other requests in Swedish Match North America's MRTP applications for eight smokeless products
  - TPSAC meeting held Feb. 6-7, 2019, comment period closes May 13, 2019


FDA
10
YEARS
TOBACCO
CONTROL
ACT
CLARIFYING RULES OF THE ROAD

SUBSTANTIAL EQUIVALENCE PROPOSED RULE

- On April 2, 2019, FDA published a proposed rule to establish requirements for the content and format of reports intended to establish the substantial equivalence of a tobacco products and provide information as to how the agency intends to evaluate these submissions

- The proposed rule is intended to provide more clarity to applicants and support efficient and predictable reviews of SE Reports

- The comment period is open through June 17, 2019

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 (PMTA, MRTP)
  - Guidance for industry (PMTA for ENDS Final Guidance)
  - Tobacco Product Manufacturing Practices (TPMP)

- Rolling out updates to make the review process more efficient, predictable and transparent while upholding our public health mission

INVESTMENT IN REGULATORY SCIENCE

INVESTMENT IN REGULATORY SCIENCE

To expand the scientific foundation for FDA tobacco product regulation:

- Fund research that is then administered by the National Institutes of Health Tobacco Regulatory Science Program
  - Investigator initiated awards
  - Supplements to existing grants or cooperative agreements
  - Tobacco Centers of Regulatory Science (TCORS) in areas of importance to FDA (awarded in September 2013; TCORS 2.0 awarded September 2018)
  - Population Assessment of Tobacco and Health (PATH) Study (tobacco longitudinal cohort study)
- Support for national surveys (e.g. NYTS)
- Laboratory analyses (FDA, CDC, NCTR)

CLOSING THOUGHTS

- FDA is committed to pursuing our Comprehensive Plan, and these policies reflect that careful balance:
  - For adults: Proposal does not include tobacco-, mint-, and menthol-flavored ENDS products because recent evidence indicates adults prefer them more than minors and may be using them with the goal of quitting
  - For youth: Concerns about teens and nicotine in any form remain, and we cannot let a new generation of kids initiate tobacco use

- Our responsibility is to assess the "net" impact on the population
  - 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
  - This is only possible in a regulated marketplace where public health considerations and the relevant science serve as the foundation for science-based oversight of the marketplace

QUESTIONS?

THANK YOU

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