

# FDA'S COMPREHENSIVE PLAN FOR TOBACCO AND NICOTINE REGULATION

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CENTER FOR TOBACCO PRODUCTS

# AGENDA

- Background and Regulatory Authorities
- E-Cigarettes & the Public Health Standard
- FDA's Comprehensive Plan for Tobacco and Nicotine Regulation
  - Regulatory Policies on Addiction, Appeal & Cessation
  - Youth Tobacco Prevention Plan
  - Science-Based Review of Tobacco Products
- FDA's Adult Cessation Public Education Campaign
- Tracking Adverse Events from ENDS
- Questions

FDA

10 YEARS TOBACCO CONTROL ACT



# BACKGROUND AND REGULATORY AUTHORITIES

# THE TOBACCO CONTROL ACT BECAME LAW ON JUNE 22, 2009



- To protect the public and create a healthier future for all Americans – particularly youth – Congress passed the Tobacco Control Act (TCA)
- FDA's goal is to reduce the harm from all regulated tobacco products across the entire U.S. population:
  - Reducing the number of people who start using tobacco products
  - Encouraging more people to stop using these products
  - Reducing the adverse health impact for those who continue to use these products



# THE TOBACCO CONTROL ACT BECAME LAW ON JUNE 22, 2009



Since 2009, FDA had authority to regulate tobacco products intended for human consumption to reduce harm across the population

- Immediate authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own, and smokeless
- The law also permitted FDA to “deem” products meeting the statutory definition of tobacco product by issuing a regulation



- On August 8, 2016, a final rule went into effect 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





- Understand the regulated products
- Restrict 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
- Prevent youth initiation and encourage cessation via public education campaigns designed to create behavior change
- Expand the science base for regulatory action and evaluation
- Use authority to now regulate e-cigarettes, cigars, hookah, and other tobacco products, in addition to cigarettes and smokeless products



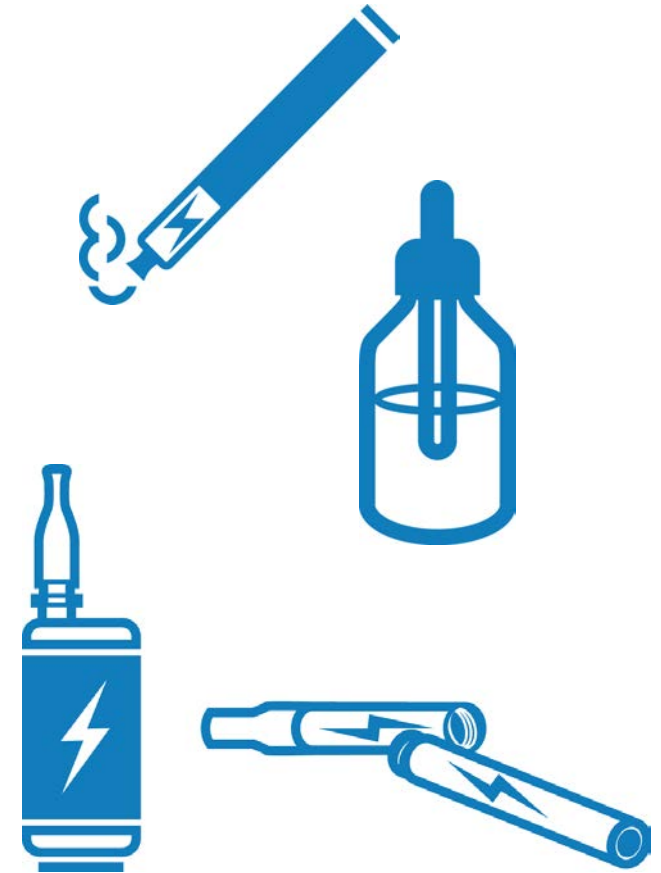


# E-CIGARETTES & THE PUBLIC HEALTH STANDARD

# WHAT ARE E-CIGARETTES?



- Electronic Nicotine Delivery Systems (ENDS) are a heterogeneous group of products that include e-cigarettes, vapes, e-cigars and e-hookah
- In general these products heat an “e-liquid” that usually contains nicotine into an aerosol inhaled by the user
  - Include varying compositions of flavorings, propylene glycol, vegetable glycerin and other ingredients
- First introduced to the US in ~ 2007
- Come in a variety of shapes and designs





- National Academies of Sciences, Engineering, and Medicine (NASEM) published *Public Health Consequences of E-Cigarettes* in January 2018
  - 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



- 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





# FDA'S COMPREHENSIVE REGULATORY PLAN



The efforts fall under several categories:

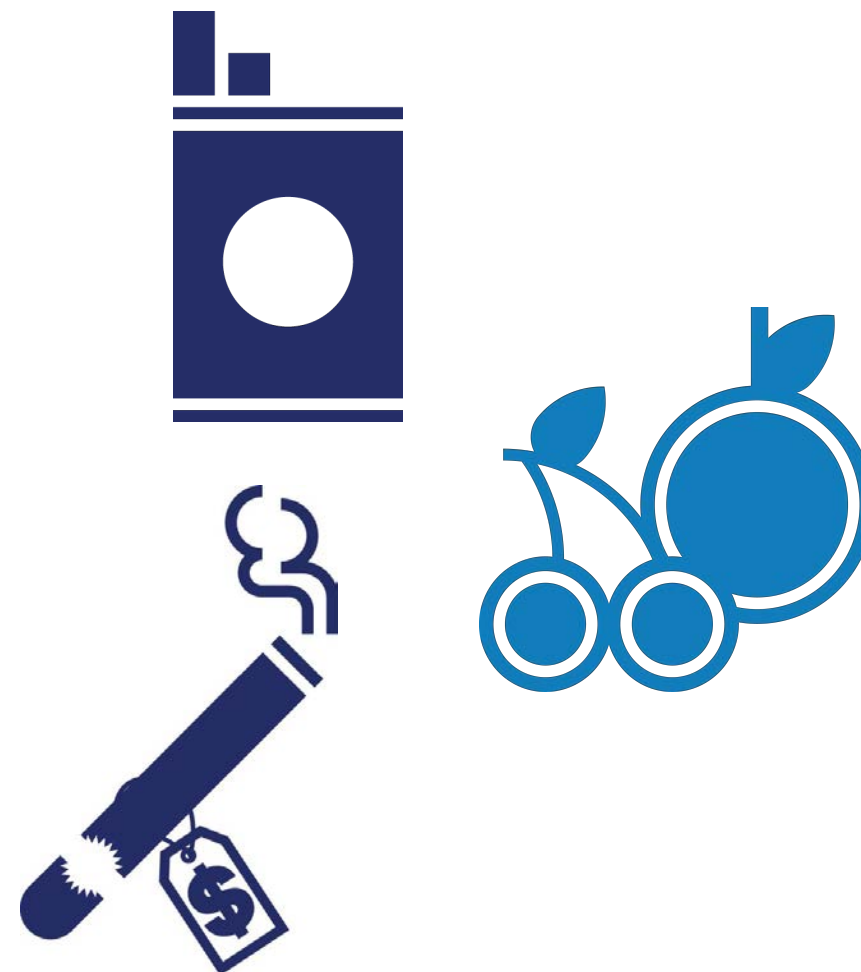
- 1) Regulatory Policies on Addiction, Appeal & Cessation
- 2) Youth Tobacco Prevention Plan
  - Access
  - Marketing
  - Education
- 3) Science-Based Review of Tobacco Products



# REGULATORY POLICIES ON ADDICTION, APPEAL & CESSATION

FDA issued three advance notices of proposed rulemaking in 2018 for public comment:

- **March 15:** *Tobacco Product Standard for Nicotine Level of Combusted Cigarettes*
- **March 20:** *Regulation of Flavors in Tobacco Products*
- **March 23:** *Regulation of Premium Cigars*

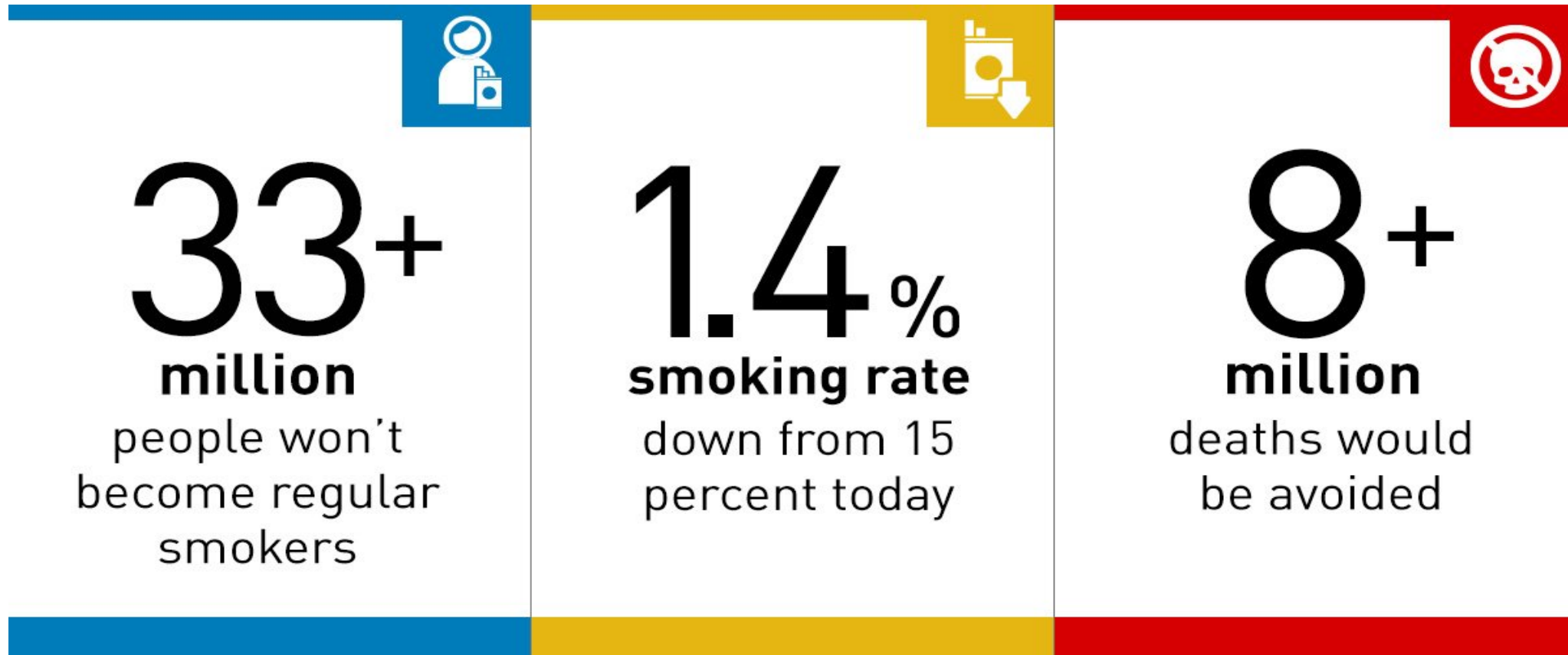




# ESTIMATES FROM ONE POSSIBLE NICOTINE PRODUCT STANDARD POLICY



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





- **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
  - Ensures alignment of FDA's centers; facilitates consensus and development of unified positions on cross-cutting issues
- **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”
- Recently announced public scientific workshop entitled “Youth Tobacco Cessation: Science and Treatment Strategies”
  - Purpose is to discuss the challenges and latest science on youth tobacco use, addiction and cessation treatment strategies
  - Will be held at the FDA White Oak Campus on May 15, 2019
  - Submit electronic or written comments by May 31, 2019





# 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



- In Spring 2018, 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

- In May 2018, 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

### E-liquid or food product?



FDA, FTC warn companies to stop misleading kids

CENTER FOR TOBACCO PRODUCTS







- In September 2018, 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

# YOUTH TOBACCO PREVENTION PLAN ACTIONS



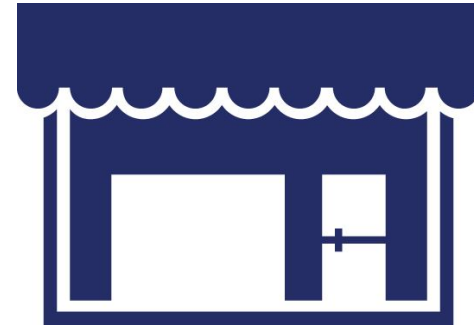
- On October 11, 2018, issued warning letter to HelloCig Electronic Technology Co. Ltd for various violations, including selling two e-liquids that contain prescription drugs, leading the FDA to determine that the products are unapproved new drugs
- On October 12, 2018, sent letters to 21 companies as 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 ACTIONS



- In February 2019, initiated enforcement action against certain retail locations of Walgreen Co. and Circle K Stores Inc. for repeated violations of restrictions on the sale and distribution of tobacco products, including cigars and menthol cigarettes, to minors
  - Filed complaints seeking No-Tobacco-Sale Orders (NTSO), which seek to bar the retail locations from selling tobacco products for 30 days
  - Walgreens is currently the top violator among pharmacies that sell tobacco products, with 22 percent of the stores inspected having illegally sold tobacco products to minors
- In April 2019, issued letters to Walmart, 7-Eleven, and 10 other convenience store chains, whose rates of violations for selling tobacco products to minors exceed 15 percent of their total inspected stores since FDA's retailer compliance check inspection program in 2010
  - Letters request that each company submit within 30 days plans describing how they will address and mitigate illegal sales to minors



# YOUTH TOBACCO PREVENTION PLAN ACTIONS



- In April 2019, 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



A close-up, artistic photograph of a compass rose. The compass is centered on a circular dial with fine, concentric scale markings. The needle and its shadow are cast across the dial. The image is overlaid with a semi-transparent blue horizontal band that contains the title text.

# POLICY ACTION TO ADDRESS YOUTH ACCESS AND MARKETING TO YOUTH

# 2018 NATIONAL YOUTH TOBACCO SURVEY RESULTS RELEASED



- 2018 National Youth Tobacco Survey data show an alarming surge in youth e-cigarette use with more than **3.6 million teens currently vaping**
- From 2017 to 2018:
  - Current e-cigarette use **increased 78 percent** among high school students
  - Current e-cigarette use **increased 48 percent** among middle school students
- From 2017 to 2018, among high school students who currently used e-cigarettes
  - Frequent use (on 20 or more days) **increased from 20 percent to 28 percent**
  - Use of flavored tobacco products **increased from 61 percent to 68 percent**



# 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 will take effect 30 days after it is finalized
  - Comments submitted by April 30 will help inform FDA’s work on the final guidance





- 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, are now subject to enforcement beginning 30 days after guidance is finalized
- Enforcement of this policy change 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 CIGAR



- 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 meet the definition of a new tobacco product, are now 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



- Public education campaigns are a proven strategy in preventing and reducing population-level tobacco use
- FDA has multiple efforts targeting discrete, youth at-risk audiences:
  - ✓ *The Real Cost*: General market teens at risk of smoking (February 2014)
  - ✓ *Fresh Empire*: Multicultural teens at risk of smoking (October 2015)
  - ✓ *The Real Cost Smokeless*: Rural male teens at risk of using smokeless (April 2016)
  - ✓ *This Free Life*: Lesbian, Gay, Bisexual, Transgender (LGBT) young adults at risk of becoming regular smokers (May 2016)
  - ✓ *The Real Cost ENDS*: General market teens at risk of using e-cigarettes (September 2018)
- In addition, FDA has a retailer education campaign, *This is Our Watch*, a voluntary program that educates retailers, clerks and the public on how to comply with federal tobacco laws by providing free materials (November 2017)



- “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

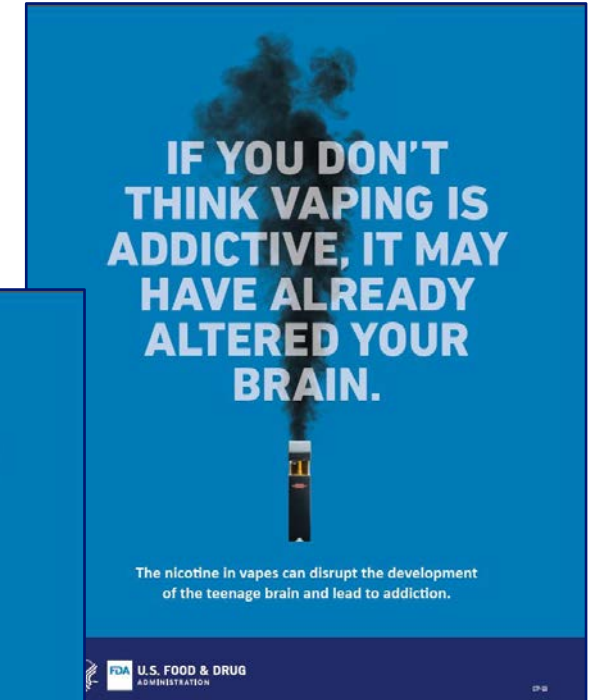


# YOUTH E-CIGARETTE PREVENTION POSTERS



- “The Real Cost” developed posters for use by doctors, youth groups, state and local public health agencies, and others who may find these resources helpful in educating youth on the dangers of e-cigarette use
- The posters, which also address the potential health consequences of e-cigarette use, are available for download or for print via the CTP Exchange Lab:

<https://digitalmedia.hhs.gov/tobacco/>



A photograph of four scientists in a laboratory setting. They are wearing white lab coats and blue gloves. One scientist in the foreground is wearing safety goggles. They are gathered around a computer workstation, looking at the monitor and keyboard. The background shows laboratory equipment like a pipette and a flask.

# SCIENCE-BASED REVIEW OF TOBACCO PRODUCTS

# REVIEWING PRODUCTS IN EVOLVING TOBACCO MARKETPLACE: MODIFIED RISK 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 tobacco 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 tobacco 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 tobacco products
  - TPSAC meeting held Feb. 6-7, 2019, comment period closes May 13, 2019





# FDA'S ADULT CESSATION PUBLIC EDUCATION CAMPAIGN

# ADULT CESSATION PUBLIC EDUCATION CAMPAIGN: *EVERY TRY COUNTS*



- FDA is using public education campaigns to help adult smokers quit
- “Every Try Counts” is aimed at encouraging cigarette smokers, ages 25-54 who have attempted to quit smoking in the last year but were unsuccessful, to quit through messages of support that underscore the health benefits of quitting
- The goals of the campaign are to:
  - Change attitudes and beliefs about what it means to quit smoking
  - Increase motivation to try quitting again
  - Encourage smokers to ‘practice the quit,’ as each attempt makes them more likely to succeed



- “Every Try Counts” is currently present in **over 2,000 convenience stores in 35 counties**
- Messages are displayed in and around the retail locations where tobacco products are sold



\*Campaign materials, including posters, tip cards, and more, are available to order on the CTP Exchange Lab:  
<https://digitalmedia.hhs.gov/tobacco/>



# TRACKING ADVERSE EVENTS FROM ENDS

- FDA has become aware that some **people who use e-cigarettes have experienced seizures**. Seizures or convulsions are known **potential side effects of nicotine toxicity** and have been reported in the scientific literature in relation to intentional or accidental swallowing of e-liquid.
- A recent uptick in voluntary reports of adverse experiences with tobacco products that mentioned seizures occurring with e-cigarettes use **signal a potential emerging safety issue**.
- We don't yet know if there's a direct relationship between the use of e-cigarettes (and other ENDS) and a risk of seizure; sharing this information to communicate potential safety concerns associated with the products we regulate. This will **encourage the public to voluntarily report** additional adverse events that can better inform our work.
- FDA continues to monitor all adverse experiences reported to the agency about the use of ENDS and encourages the public to report cases of individuals who use ENDS and have had a seizure or any other adverse events via CTP's Safety Reporting Portal: [www.safetyreporting.hhs.gov](http://www.safetyreporting.hhs.gov)

QUESTIONS?



THANK YOU

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