UPDATES FROM FDA'S CENTER FOR TOBACCO PRODUCTS

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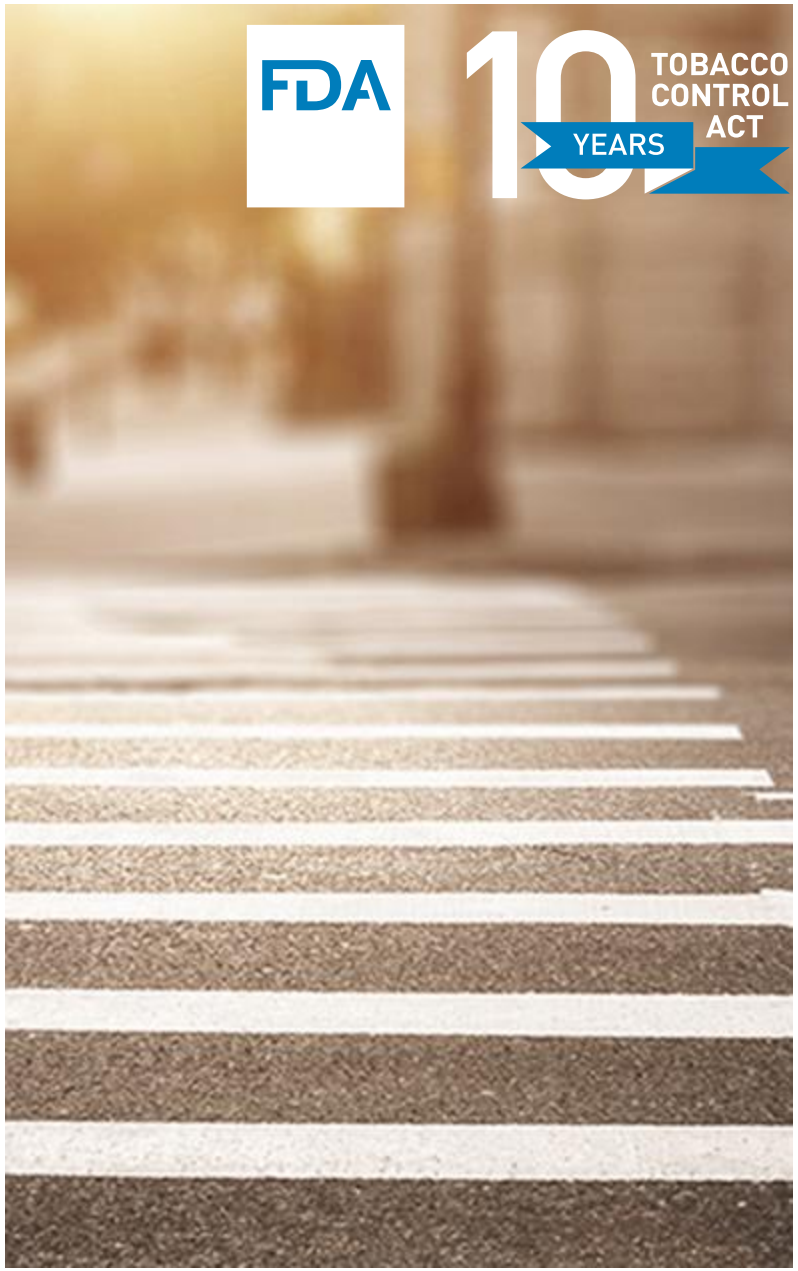
AGENDA

- Update on Regulations and Guidances
- Update on Product Review
- Update on Compliance and Enforcement
- Update on Public Education
- Update on Vaping-related Illnesses



UPDATE ON REGULATIONS AND GUIDANCES

RULES ISSUED OVER THE LAST YEAR

Proposed Rules:

- Content and Format of Substantial Equivalence Reports; Food and Drug Administration Actions on Substantial Equivalence Reports – *April 2019*
- Required Warnings for Cigarette Packages and Advertisements – *Aug. 2019*
- Premarket Tobacco Product Applications and Recordkeeping Requirements – *Sept. 2019*

SUBSTANTIAL EQUIVALENCE PROPOSED RULE

- On April 2, 2019, FDA issued a proposed rule to establish requirements for the content and format of reports intended to establish the substantial equivalence of a tobacco product 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
- Comment period has closed; the comments are currently under review and analysis

CIGARETTE HEALTH WARNINGS

June 2011

FDA published a final rule requiring color graphics depicting the negative health consequences of smoking

Aug. 2012

Final rule was vacated after the U.S. Court of Appeals for the District of Columbia held that the rule violated the First Amendment

March 2013

The government announced its decision not to seek further review of the court's ruling

2013 onward

FDA has been conducting comprehensive research and development activities in support of a new cigarette health warning rule to satisfy the requirements of the TCA based on – and within the limits of – both science and the law

Oct. 2016

Lawsuit filed by several public health groups challenging the time it was taking FDA to issue a new rule; order issued March 2019

Aug. 2019

FDA announced a proposed rule to require new health warnings on cigarette packages and in advertisements. When finalized, this rule would fulfil the agency's statutory mandate under the TCA.

March 2020

FDA plans to publish final rule

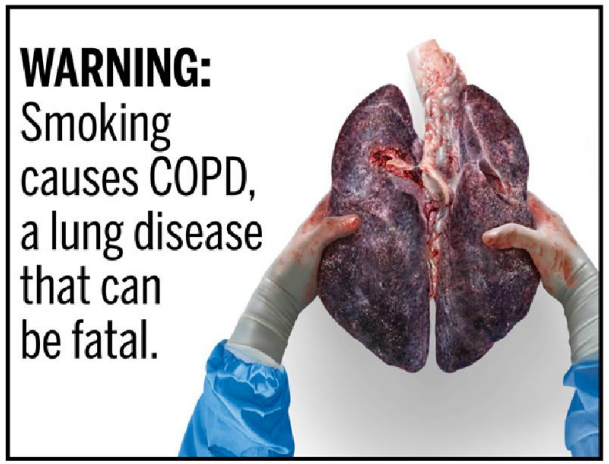
CIGARETTE HEALTH WARNING RULE – 2019 PROPOSED RULE

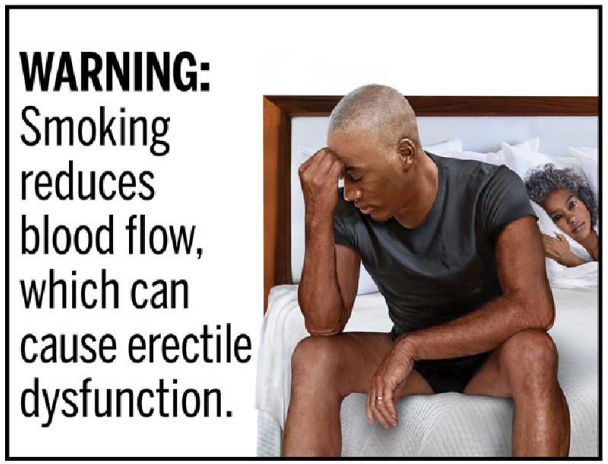
- The proposed rule includes **13 cigarette health warnings** accompanied by photo-realistic images
- The warnings would be required to appear on packages and in advertisements **15 months after a final rule is issued**
- The warnings would appear prominently on cigarette packages and in advertisements, as shown in the below examples:

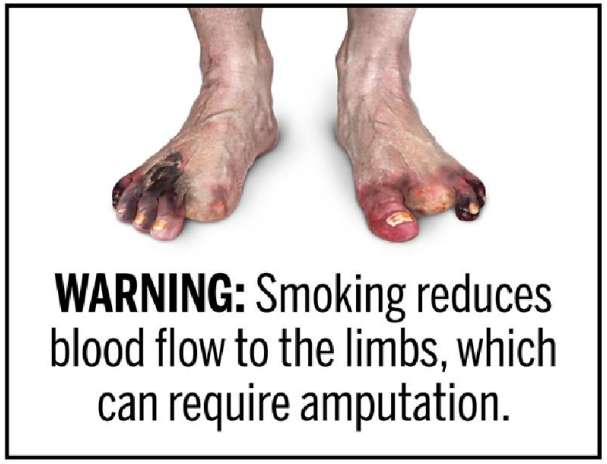
Occupying the top 50 percent of the area of the front and rear panels of cigarette packages

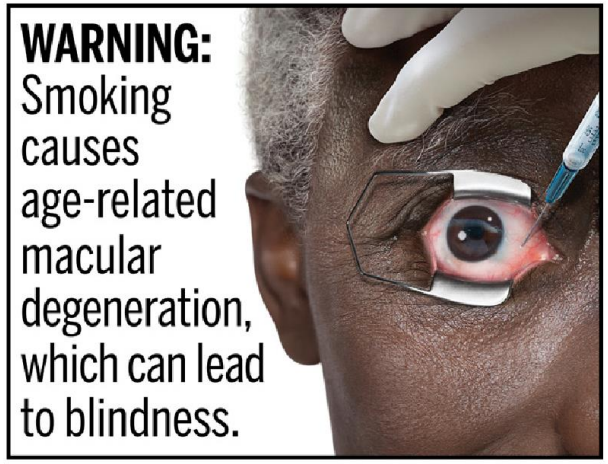
Occupying at least 20 percent of the area at the top of cigarette advertisements

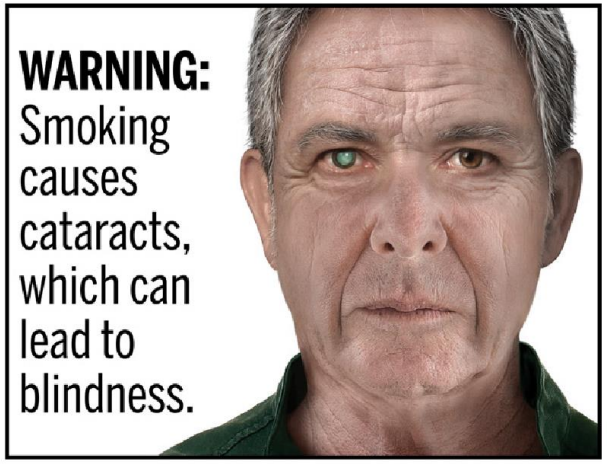
EXAMPLES OF CIGARETTE HEALTH WARNINGS INCLUDED IN THE 2019 PROPOSED RULE

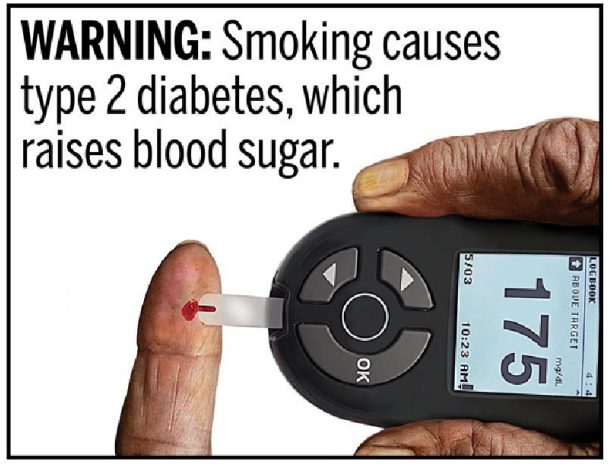












PMTA PROPOSED RULE

- On Sept. 25, 2019, FDA issued a proposed rule to set forth requirements related to the content, format, and FDA's review and communications procedures for premarket tobacco product applications

- When finalized, the proposed rule would:
  - Help to ensure that PMTAs contain sufficient information for evaluation (e.g. details on physical aspects of a tobacco product, information on potential public health benefits and harms)
  - Codify the procedures by which the agency would review PMTAs
  - Establish the requirements for manufacturers to maintain records related to the legal marketing status of their tobacco products

- The proposed rule will be available for public comment through Nov. 25

GUIDANCES ISSUED OVER THE LAST YEAR

Final Guidances:

- Interpretation of and Compliance Policy for Certain Label Requirements; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops – *March 2019*
- Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS) – *June 2019*

Draft Guidances:

- Enforcement Policy for Certain Marketed Tobacco Products – *Feb. 2019*
- Modifications to Compliance Policy for Certain Deemed Tobacco Products – *March 2019*

Revised Guidances:

- Listing of Ingredients in Tobacco Products – *Nov. 2018*
- Use of Investigational Tobacco Products – *Feb. 2019*
- Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule – *March 2019*
- FDA Deems Certain Tobacco Products Subject to FDA Authority, Sales and Distribution Restrictions, and Health Warning Requirements for Packages and Advertisements – *March 2019*

PMTA ENDS GUIDANCE

- On June 11, 2019, FDA finalized the guidance, “Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS),” which further clarifies the premarket tobacco product application (PMTA) process for manufacturers of e-cigarettes and related tobacco products

- The guidance explains, among other things:
  - Products to which this guidance applies
  - When a PMTA is required under the statute and regulations
  - General procedures for review of an ENDS PMTA
  - What information the FD&C Act requires you to submit in a PMTA

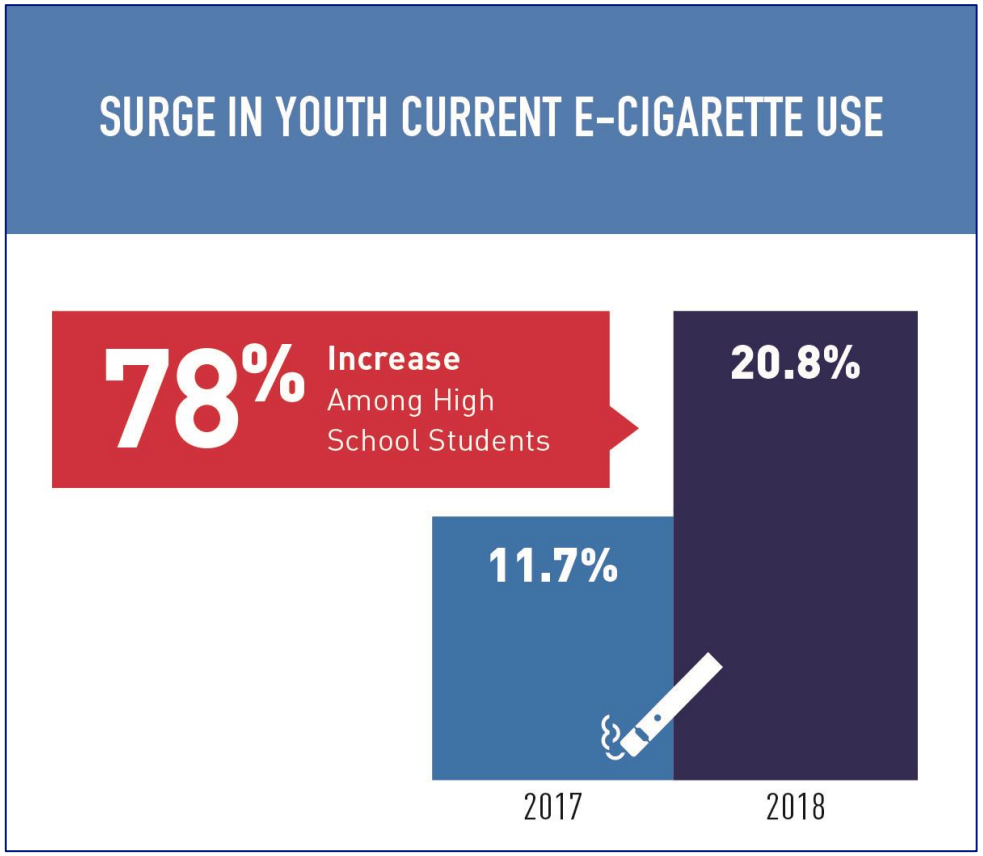
PREMARKET REVIEW OF DEEMED TOBACCO PRODUCTS

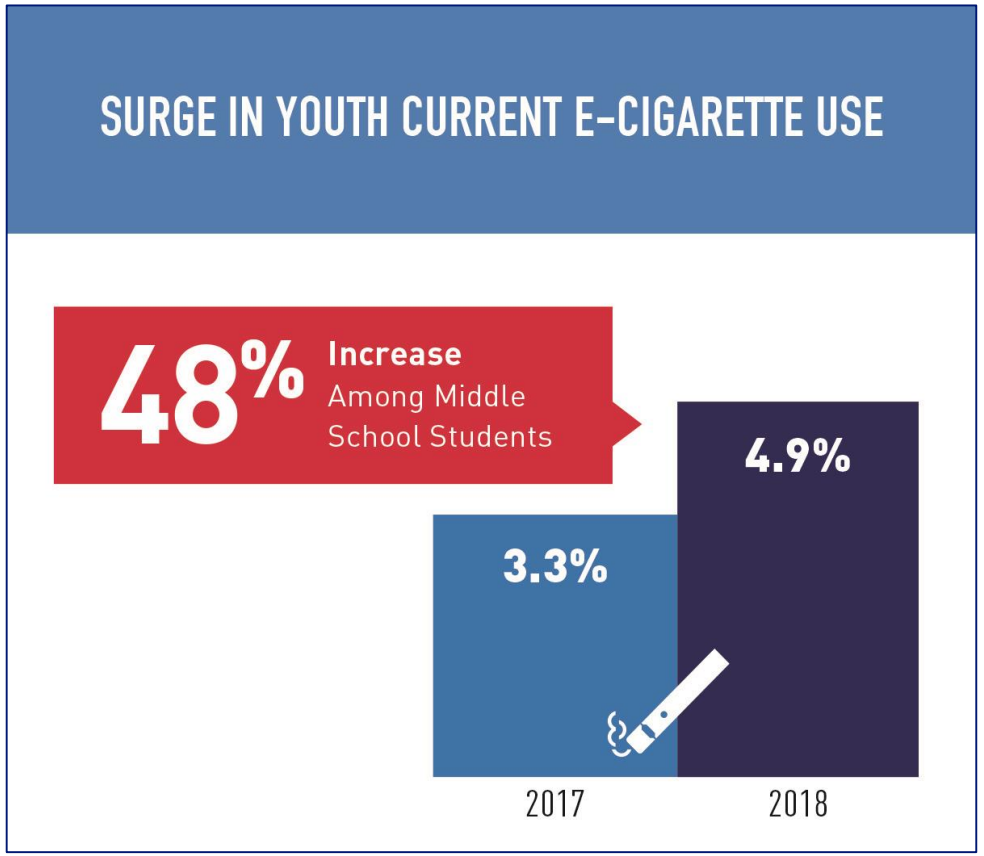
- By law, tobacco products on the market in the U.S. as of Feb. 15, 2007 are considered "grandfathered" and do not require prior authorization to be marketed
- As part of the deeming rule, FDA issued a compliance policy to provide additional time for manufacturers of deemed products on the market as of Aug. 8, 2016 to obtain marketing authorization
- In 2017, as part of the agency's comprehensive plan, FDA stated that it would further defer enforcement of the premarket authorization requirements for these deemed products [this policy is now vacated]

Type	Example	Date per Aug. 2017 Guidance [now vacated]
Combustibles	Cigars, Pipe Tobacco, Hookah Tobacco	Aug. 8, 2021
Noncombustibles	E-cigarettes and other ENDS, gels and certain dissolvables	Aug. 8, 2022

2018 NATIONAL YOUTH TOBACCO SURVEY RESULTS

From 2017 to 2018, there was an alarming increase in current e-cigarette use among middle and high school students





LITIGATION OVER 2017 COMPLIANCE POLICY

- As a result of litigation over the 2017 Compliance Policy, a court ordered that applications for marketing orders for deemed tobacco products on the market as of Aug. 8, 2016 must be filed within 10 months of the order (no later than May 12, 2020)
  - Products for which applications have not been filed within this period shall be subject to FDA enforcement action
  - Products for which applications have been timely filed may remain on the market for up to a year (no later than May 12, 2021) while FDA reviews the application
  - If FDA has not made a final decision within a year, those products must come off the market or be subject to enforcement
- The order does not restrict FDA's authority to enforce premarket review requirements before the close of either the 10-month application submission period or the FDA application review period

RESPONSE TO THE SURGE IN YOUTH E-CIGARETTE USE

- In March 2019, FDA issued draft guidance, “Modifications to Compliance Policy for Certain Deemed Tobacco Products,” that outlined proposed policy changes (to the now-vacated Aug. 2017 Compliance Policy) and prioritization of enforcement resources

- Preliminary NYTS 2019 data show:
  - **More than a quarter (27.5%) of high school students** were current e-cigarette users
  - Majority of high school e-cigarette users cited **the use of fruit and menthol/mint flavors**

- In Sept. 2019, the Trump Administration announced that FDA intends to finalize a compliance policy that would prioritize the agency’s enforcement of the premarket authorization requirements for flavored e-cigarettes
  - More details on the plan and implementation will be released soon

LOOKING AHEAD

- FDA is also working to advance rulemaking on a number of other foundational rules, including:
  - Modified Risk Tobacco Product Application (MRTP) rule
  - Tobacco Product Manufacturing Practice (TPMP) rule

- FDA continues to assist manufacturers through online information, meetings, and webinars
  - Upcoming Public Meeting: ***Deemed Tobacco Product Applications, Oct. 28-29***

UPDATE ON PRODUCT REVIEW

SUBSTANTIAL EQUIVALENCE AND EXEMPTION FROM SUBSTANTIAL EQUIVALENCE

- In total, CTP has received submissions of:
  - **Over 3,000** regular SE Reports
  - **Over 3,600** provisional SE Reports
  - **Over 500** EX Requests

- Of those, CTP has closed:
  - **96%** of all regular SE Reports
  - **83%** of all provisional SE Reports
  - **85%** of all EX Requests

- In Fiscal Year 2018, CTP met the goal for all established SE and EX performance measures

As of Sept. 30, 2019

PRE-MARKET REVIEW OF NEW TOBACCO PRODUCT – RECENT PMTA DECISION

- In April 2019, FDA 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 Act
  - **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 the 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

FIRST MODIFIED RISK ORDER ISSUED

- This week, FDA authorized the marketing of products through the MRTP pathway
  - **Authorized products include**: Eight Swedish Match USA, Inc. snus smokeless tobacco products sold under the "General" brand name
  - **Authorized to market these products with the modified risk claim:**
    - "Using General Snus instead of cigarettes puts you at a lower risk of mouth cancer, heart disease, lung cancer, stroke, emphysema, and chronic bronchitis"

- FDA's review determined that:
  - The claim proposed by the company in its application is supported by scientific evidence
  - Consumers understand the claim and appropriately perceive the relative risk of these products as compared to cigarettes
  - The modified risk products, as actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole

MODIFIED RISK TOBACCO PRODUCT APPLICATIONS UNDER REVIEW

Product	Company	TPSAC Meeting	Comment Period
VLN™ King VLN™ Menthol King	22nd Century Group, Inc.	TBD	Open
Copenhagen Snuff Fine Cut	U.S. Smokeless Tobacco Company	Feb. 6-7, 2019	Open
IQOS system with Marlboro Heatsticks	Philip Morris Products S.A	Jan. 24-25, 2018	Closed Feb. 11, 2019
Camel Snus	R.J. Reynolds Tobacco Company	Sept. 13-14, 2018	Closed May 13, 2019

UPDATES ON COMPLIANCE AND ENFORCEMENT

YOUTH TOBACCO PREVENTION PLAN: ACCESS & MARKETING

- Sent letters to about 90 companies seeking information on over 110 brands, including ENDS products, to determine if those products are being illegally marketed

- Issued warning letters to four companies for manufacturing, selling, and/or distributing a combined 44 flavored e-liquid and hookah tobacco products without the required marketing authorization

- Issued joint warning letters (with the Federal Trade Commission) to four e-liquid manufacturers for violations related to online posts by social media influencers on each company's behalf, including failure to include the required nicotine warning statement

WARNING LETTER TO JUUL

- On Sept. 9, 2019 FDA issued warning letters to JUUL Labs, Inc. for marketing unauthorized modified risk tobacco products

- Examples of claims made by JUUL representatives speaking to students:
  - JUUL "was much safer than cigarettes," and "FDA would approve it any day"
  - JUUL was "totally safe"
  - A student "…should mention JUUL to his [nicotine-addicted] friend…because that's a safer alternative than smoking cigarettes, and it would be better for the kid to use"
  - "FDA was about to come out and say it [JUUL] was 99% safer than cigarettes…and that…would happen very soon…."

LETTER REQUESTING INFORMATION

- The agency also sent a letter to the company expressing concern, and requesting more documents and information, about several issues raised in a July Congressional hearing on JUUL
- Including statements and representations made as part of JUUL's "Make the Switch" campaign and JUUL's "Switching Program" presentation to the Cheyenne River Sioux Tribe
  - "'[JUUL is] a smart, really well thought-out alternative to smoking.' Make the switch"
  - "I think [JUUL is] an amazing invention…I don't know how we lived without that. The alternative for adult smokers"
  - "Elimination of combustible cigarettes is crucial to reduce risk of harm"
- The agency is concerned these statements/representations may convey that switching to JUUL is a safer alternative to cigarettes, i.e. that using JUUL products poses less risk or is less harmful than using cigarettes

ENFORCEMENT ACTIONS

Since the enforcement program began in 2010, FDA has completed ***over 1.1 million inspections*** of tobacco retailers resulting in the following enforcement actions:

- Over 93,000 Warning Letters *(ENDS: over 10,000)*
- Over 23,000 Civil Money Penalties *(ENDS: over 1,500)*
- 167 No-Tobacco-Sale Order Complaints

Just Released - "Compliance and Enforcement Report - Accomplishments and Activities of FDA's Center for Tobacco Products' Office of Compliance and Enforcement"

- Report highlights past and ongoing efforts designed to ensure regulated industry understands and complies with the Tobacco Control Act and related regulations to protect public health

As of Sept. 30, 2019

UPDATE ON PUBLIC EDUCATION

FDA'S PUBLIC EDUCATION CAMPAIGNS

- Public education campaigns are a proven strategy in preventing and reducing population-level tobacco use

- FDA has efforts targeting specific audiences:
  - ✓ *The Real Cost:* General market teens at risk of smoking (Feb. 2014)
  - ✓ *Fresh Empire:* Multicultural teens at risk of smoking (Oct. 2015)
  - ✓ *The Real Cost Smokeless:* Rural male teens at risk of using smokeless tobacco (April 2016)
  - ✓ *This Free Life*: Lesbian, Gay, Bisexual, and Transgender (LGBT) young adults at risk of becoming regular smokers (May 2016)
  - ✓ *Every Try Counts*: Smokers who have tried to quit in the last year but were unsuccessful (Dec. 2017)
  - ✓ *The Real Cost Youth E-Cigarette Prevention*: General market teens on the dangers of e-cigarette use (Digital Ads launched Sept. 2018; TV Ads launched July 2019)

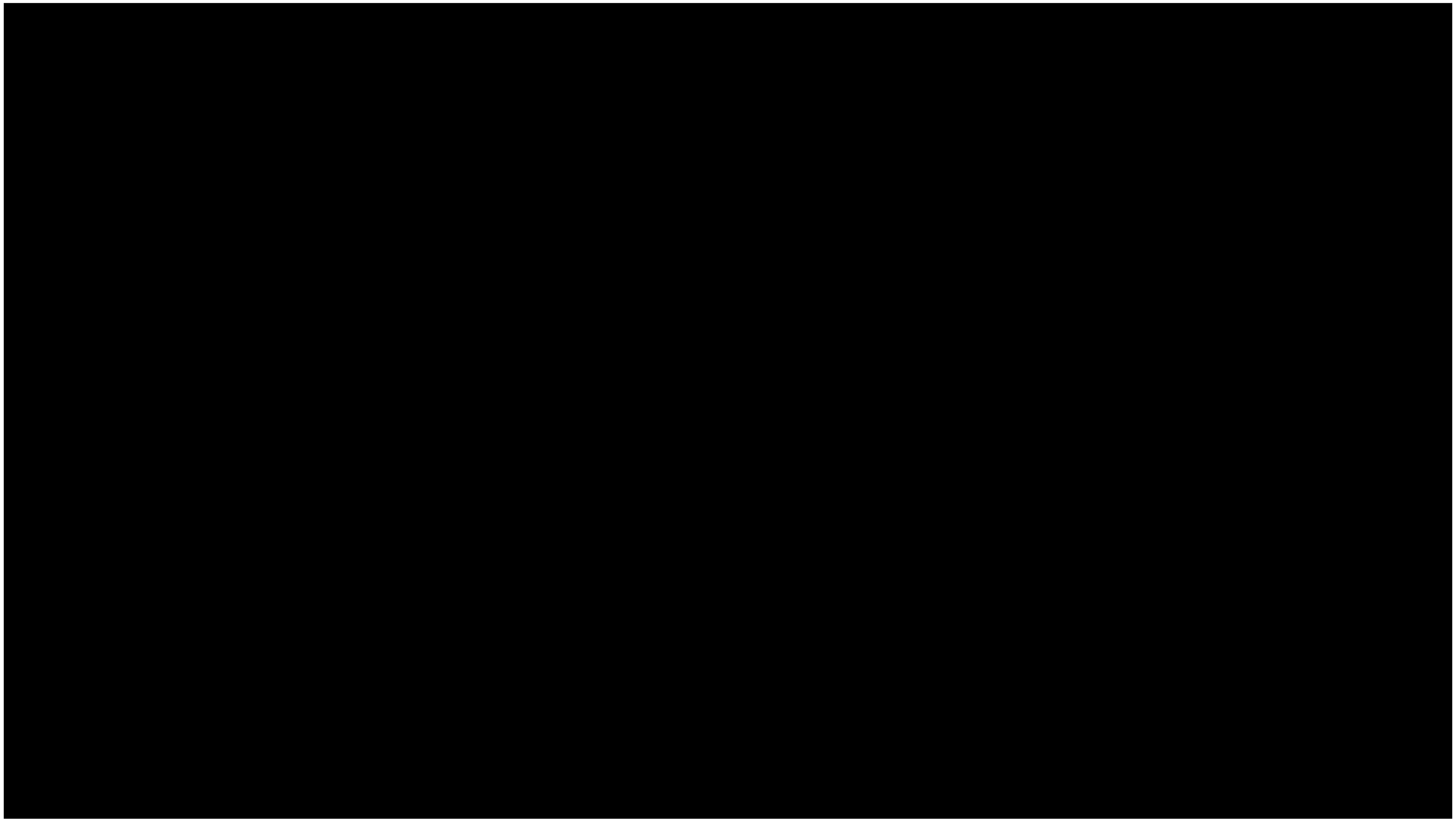
- FDA also has a voluntary retailer education campaign, *This is Our Watch,* which educates retailers, clerks, and the public on how to comply with federal tobacco laws (Nov. 2017)

IMPACT OF "THE REAL COST"

“THE REAL COST” YOUTH E-CIGARETTE USE PREVENTION CAMPAIGN

- “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 Sept. 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 on television and online; include location-targeted advertising around high schools nationwide, as well as posters in school bathrooms

NEW TV AD “MAGIC”



YOUTH E-CIGARETTE PREVENTION IN SCHOOLS

- “The Real Cost” reaches 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 distributed to all public and private high schools in the United States
- Snarky tone will catch their attention, but the facts will deliver a strong prevention message

YOUTH E-CIGARETTE PREVENTION IN SCHOOLS

- Collaboration with Scholastic to bring lesson plans, infographics, and scientific facts to more than 700,000 teachers and administrators nationally
- New outreach slated for all high schools and middle schools in 2019 and 2020

www.scholastic.com/youthvapingrisks

YOUTH E-CIGARETTE PREVENTION RESOURCES

The CTP Exchange Lab has a comprehensive suite of free e-cigarette prevention resources in both English and Spanish for order or download at: **https://digitalmedia.hhs.gov/tobacco/**

ADULT CESSATION PUBLIC EDUCATION CAMPAIGN: *EVERY TRY COUNTS*

- FDA is also 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

UPDATE ON VAPING-RELATED ILLNESSES

TRACKING VAPING-RELATED LUNG ILLNESS

- FDA and CDC are working closely with state and local health officials to investigate cases of respiratory illness to determine whether illnesses may be linked to specific devices, ingredients, contaminants, or substances associated with e-cigarette use or vaping

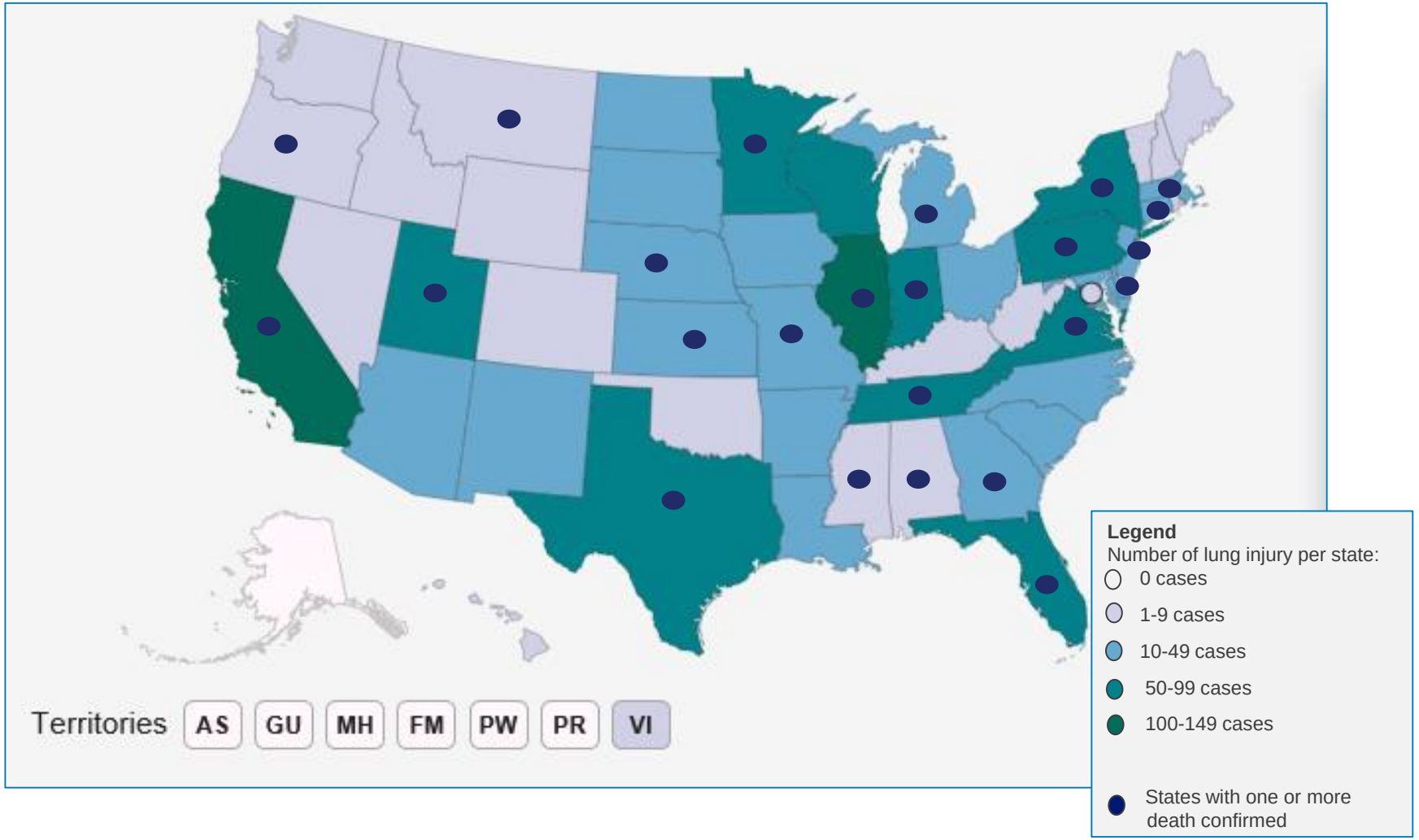
- FDA continues to seek more information and test e-cigarette samples to better understand the relationship between e-cigarette use or vaping and the adverse experiences
  - Although cases appear similar, it is not clear if these cases have a common cause or if they are different diseases with similar presentations
  - According to recent findings, most of the patients impacted by these illnesses reported using THC-containing products, a psychoactive component of the marijuana plant

- FDA has developed a new webpage "Lung Illnesses Associated with Use of Vaping Products" to provide the latest information and resources on this issue

TRACKING VAPING-RELATED LUNG ILLNESS

As of Oct. 15, 2019, 1,479 lung injury cases associated with the use of e-cigarette or vaping products have been reported from 49 states, the District of Columbia, and 1 U.S. territory

33 deaths have been confirmed in 24 states



REPORTING TOBACCO-RELATED ADVERSE EXPERIENCES

FDA continues to monitor all adverse experiences reported to the agency about the use of e-cigarettes and encourages the public to report any problems with any tobacco products via CTP's Safety Reporting Portal:

www.safetyreporting.hhs.gov

QUESTIONS?

THANK YOU

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