

The logo for the U.S. Food & Drug Administration, consisting of the letters 'FDA' in white on a blue square background.

U.S. FOOD & DRUG
ADMINISTRATION

UPDATE ON FDA'S COMPREHENSIVE PLAN FOR TOBACCO AND NICOTINE REGULATION

Mitch Zeller, J.D.
Director, FDA Center for Tobacco Products

December 4, 2018

CENTER FOR TOBACCO PRODUCTS

- Background and Regulatory Authorities
- Comprehensive Plan for Tobacco & Nicotine Regulation
 - Regulatory Policies
 - Youth Tobacco Prevention Plan
 - Product Review
- Collaboration with NCI
- Questions



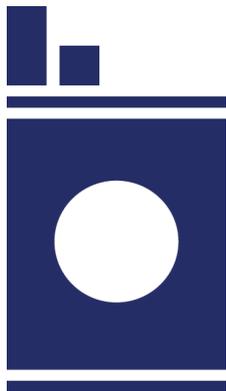
BACKGROUND AND REGULATORY AUTHORITIES

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



FINAL DEEMING 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



- 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



The Tobacco Control Act amended the Food, Drug, and Cosmetic Act to provide FDA authority for:

- Premarket review of new and modified risk tobacco products
- Post-market surveillance
- Product standards
- Testing and reporting of ingredients
- Reporting of harmful and potentially harmful constituents
- Adverse event reporting
- New warning labels
- Advertising and promotion restrictions
- User fees – entirely funded through industry-paid user fees based on market share (not applications)

HOW FDA IS USING ITS TOBACCO AUTHORITIES



- Understand the regulated products
- Review new products before they can be marketed
- Review proposed modified risk products that state/imply reduced exposure or risk before they can be marketed
- 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
- Expand the science base for regulatory action and evaluation

HOW FDA IS USING ITS TOBACCO AUTHORITIES



- Understand the regulated products
- Review new products before they can be marketed
- Review proposed modified risk products that state/imply reduced exposure or risk before they can be marketed
- 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
- **Expand the science base for regulatory action and evaluation**

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)

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

COMPREHENSIVE PLAN FOR TOBACCO AND NICOTINE REGULATION

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 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

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 Potential Modified Risk Tobacco Products

REGULATORY POLICIES ON ADDICTION, APPEAL & CESSATION

FDA issued three advance notices of proposed rulemaking 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



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



33+

million

people won't
become regular
smokers



1.4%
smoking rate

down from 15
percent today



8+

million

deaths would
be avoided

YOUTH TOBACCO PREVENTION PLAN

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

“But as we work to keep kids from making the deadly progression from experimentation to regular cigarette use, it’s imperative that we also make sure children and teenagers aren’t getting hooked on more novel nicotine-delivery products.”

– Commissioner Gottlieb, April 24, 2018

- 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

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

MAY 2018: YOUTH TOBACCO PREVENTION PLAN

- 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





SEPTEMBER 2018: NEW STEPS

- 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
 - Later met with all five companies to discuss 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 also announced it would be reconsidering all policy options with respect to deemed products



OCTOBER: ADDITIONAL ACTIONS

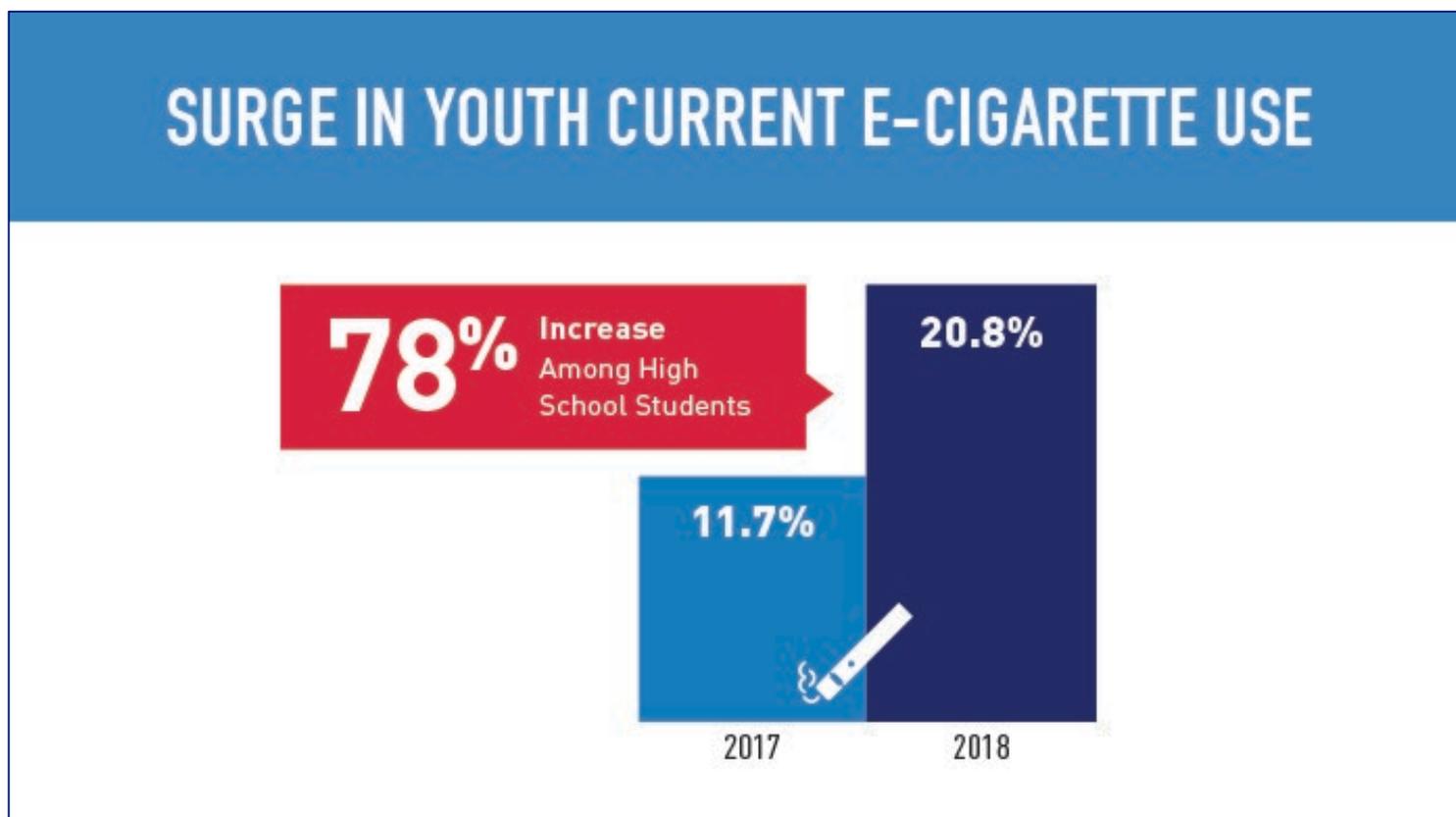
- On October 11, issued warning letter to HelloCig Electronic Technology Co. Ltd for various violations, including selling two e-liquids that contain prescription drugs, leading the FDA to determine that the products are unapproved new drugs
- On October 12, sent letters to 21 companies as part of investigation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



NOVEMBER: 2018 NATIONAL YOUTH TOBACCO SURVEY RESULTS RELEASED



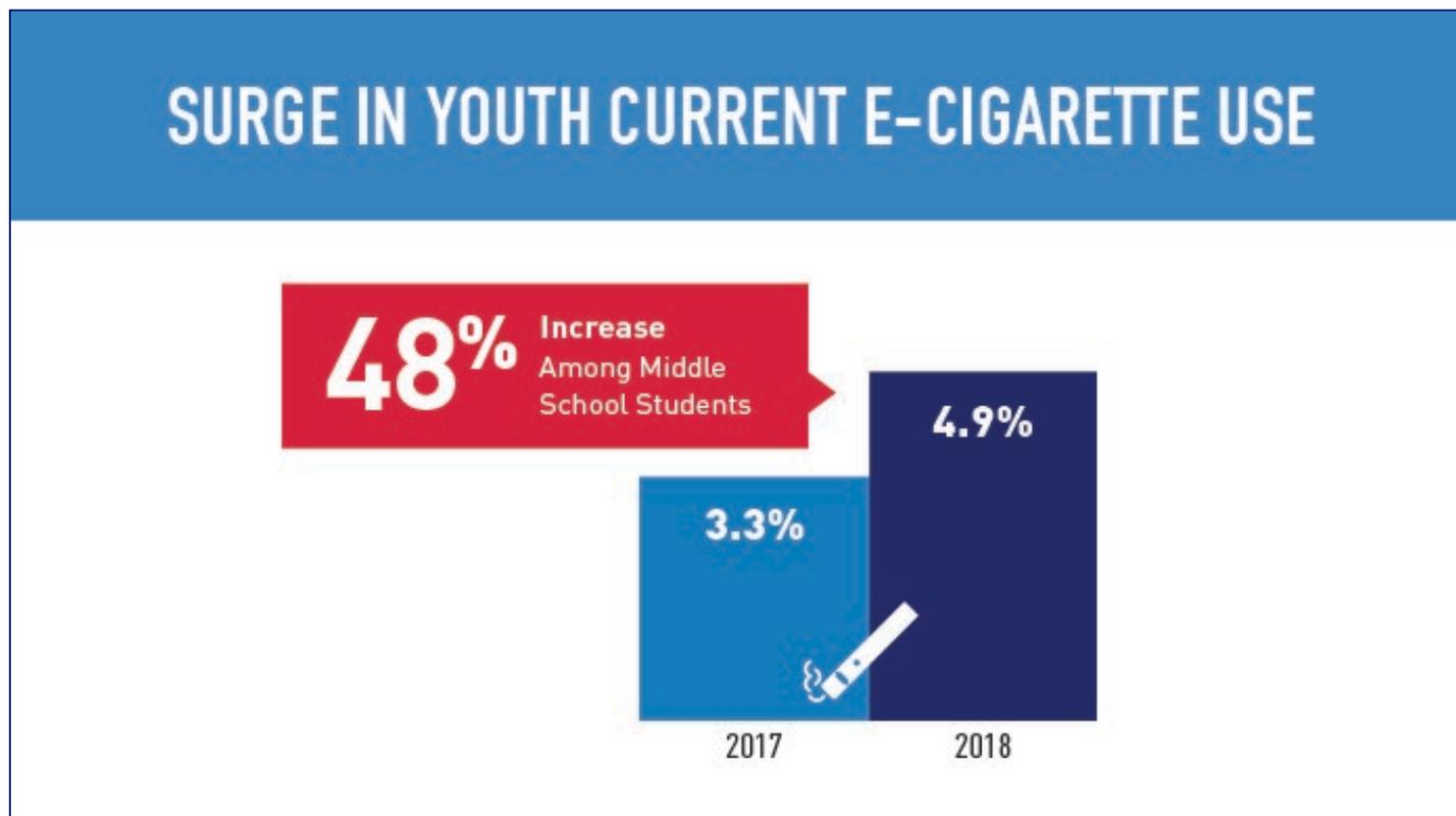
*From 2017 to 2018, there was a **78 percent increase** in current e-cigarette use among high school students*



NOVEMBER: 2018 NATIONAL YOUTH TOBACCO SURVEY RESULTS RELEASED

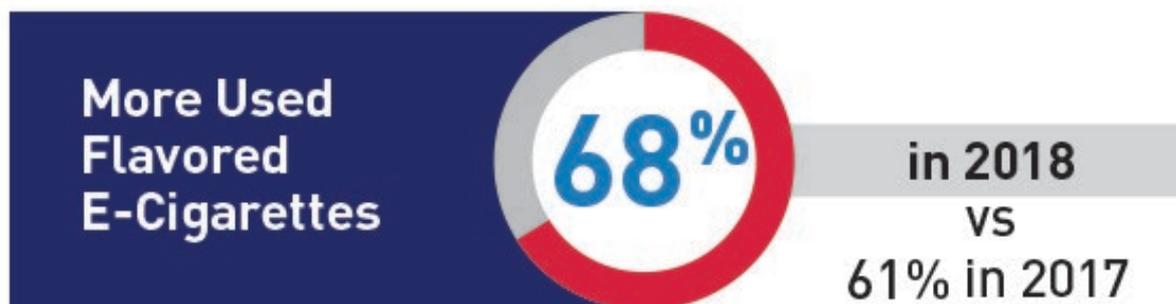


*From 2017 to 2018, there was a **48 percent increase** in current e-cigarette use among middle school students*



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

AMONG HIGH SCHOOL CURRENT E-CIGARETTE USERS —
Rise in Use of Flavors



- Because of these increases, Commissioner Gottlieb announced changes to our policy framework that focuses on flavored tobacco products
- FDA will be taking steps on the following product categories:
 - Flavored ENDS products (other than tobacco, mint, and menthol flavors or non-flavored products) that are *not sold in an age-restricted, in-person location*;
 - Flavored ENDS products (other than tobacco, mint, and menthol flavors or non-flavored products) that are *sold online without heightened age verification processes*;
 - Flavored cigars;
 - ENDS products that are marketed to kids; and
 - Menthol in combustible products, including cigarettes and cigars
- FDA intends to provide additional details soon, including timing

NOVEMBER: ELECTRIC LOTUS WARNING LETTER

- Issued a warning letter to Electric Lotus LLC for selling e-liquids with labeling and/or advertising that cause them to resemble kid-friendly food products such as cereal, candy and peanut butter and jelly
 - Company was also cited for illegally selling products to a minor, for failing to list its products with FDA and for selling e-liquids without the required FDA premarket authorization



CENTER FOR TOBACCO PRODUCTS



- “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
- 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



“EPIDEMIC”



YOUTH E-CIGARETTE PREVENTION IN SCHOOL

- “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 are currently being 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 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

COLLABORATION WITH NCI

CTP AND NCI COLLABORATION



CTP and NCI collaborate in several areas, including:

- **Tobacco Regulatory Science Program (TRSP)**
 - This partnership is critical to making sure FDA has the best available science to inform its regulatory policies and action
 - More than 250 grants funded (FY10-FY18)
 - 97 with NCI
- **Public education/cessation efforts (“Every Try Counts”)**
 - NCI’s support of the website helps get cessation resources and content to smokers ages 25-54 who have attempted to quit smoking in the last year but were unsuccessful





TRY A TEXT PROGRAM TO QUIT

Try a text message program that fits where you are in your quit journey. You'll receive texts with tips and encouragement to keep you on track.

You haven't failed if you keep trying.

HOW DO YOU FEEL ABOUT QUITTING TODAY?

CHOOSE **1** OF OUR TEXT MESSAGE PROGRAMS TO HELP YOU QUIT

I WANT TO TRY A SMALL STEP

Help me build skills to try quitting

I WANT TO PRACTICE QUITTING

Try it for a few days

I'M READY TO QUIT FOR GOOD

Set a quit date



NCI-ADMINISTERED TCORS 2.0



QUESTIONS?

FDA

THANK YOU

FOLLOW US ON TWITTER: [@FDATOBACCO](https://twitter.com/FDATOBACCO)