FDA’S CENTER FOR TOBACCO PRODUCTS: AN UPDATE ON FDA’S COMPREHENSIVE PLAN ON TOBACCO AND NICOTINE REGULATION

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Disclaimer: This information is not a formal dissemination of information by FDA/CTP and does not represent Agency position or policy.
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
- Updates from CTP’s Office of Science
- Updates on FDA’s Public Education Campaigns
- Questions
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

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.

FDA continues to review the comments and consider a product standard.
ESTIMATES FROM ONE POSSIBLE NICOTINE PRODUCT STANDARD POLICY

Includes 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
• On March 20, 2018, 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

• FDA has expedited review and analysis of these comments, and intends to proceed with developing proposed regulation
• **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
  – 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
  – Additional guidance coming on new potential clinically relevant outcomes for cessation products
Public Hearing on *Eliminating Youth Electronic Cigarette and Other Tobacco Product Use: The Role for Drug Therapies* held on January 18, 2019

Convened to hear public perspectives on:
- Available scientific evidence related to drug therapies for e-cigarette cessation as it relates to youth users
- Issues impacting the development of such therapies
- How the FDA may support further research in this area

Links to the recorded webcast available on the FDA website
YOUTH TOBACCO PREVENTION PLAN
• The last year has 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 over several years now
While latest #s from National Youth Tobacco Survey are encouraging, it's critical we ensure downward trend continues fda.gov/NewsEvents/New ...
“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
Protecting future generations from tobacco-related disease/death will always be our #1 priority. As FDA moves forward w/ our comprehensive plan on nicotine; we’re committed to efforts/policies that will best protect kids from all nicotine-containing products, incl. e-cigarettes

1:09 PM - 24 Jan 2018
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.

I hope these actions send a clear message to all tobacco product manufacturers/ retailers that the #FDA is taking on this issue w/ urgency, and if kids are flocking to your product or you’re illegally selling these products to kids, you’re on FDA’s radar: go.usa.gov/xQZze
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
SPRING 2018: 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
• 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
Scott Gottlieb, M.D.
@SGottliebFDA

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
Scott Gottlieb, M.D. ☑
@SGottliebFDA

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
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.
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 also announced it would be reconsidering all policy options with respect to deemed products
Opinions

We cannot let e-cigarettes become an on-ramp for teenage addiction

By Alex M. Azar and Scott Gottlieb
October 11 at 8:05 AM

Alex M. Azar is the secretary of health and human services. Scott Gottlieb is the commissioner of the Food and Drug Administration.

The efforts at HHS to combat tobacco's lethality focus on two key goals: First, reducing the nicotine levels in combustible cigarettes to render them minimally or nonaddictive. Second, harnessing new forms of nicotine delivery, including medicinal products and e-cigarettes, to give adult smokers less harmful substitutes for cigarettes.
OCTOBER 2018: 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.
From 2017 to 2018, there was a 78 percent increase in current e-cigarette use among high school students.
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, frequent use of e-cigarettes increased.
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

More Used Flavored E-Cigarettes

68% in 2018 vs 61% in 2017
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 2018: 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
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 sales of 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.

The two retail outlets that are the subject of these NTSO actions are:
- Walgreens store in Miami, Florida
- Circle K store in Charleston, South Carolina

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

FDA has multiple efforts targeting discrete, 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)
- **Every Try Counts**: Smokers who have tried to quit in the last year but were unsuccessful (December 2017)
- **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**, which educates retailers, clerks and the public on how to comply with federal tobacco laws by providing free materials (November 2017).
SCIENCE-BASED REVIEW OF POTENTIAL MODIFIED RISK TOBACCO PRODUCTS
• **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.

• **Camel Snus**: In Dec. 2017, FDA filed for scientific review applications from R.J. Reynolds Tobacco Company for six smokeless tobacco products.

• **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.

• **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.
• 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

• In October 2018, FDA held Tobacco Product Application Review public meeting to solicit practical feedback and suggestions to improve our processes
From the Office of Science

• Latest on regulatory science research and some findings
• Status of the four modified risk tobacco product applications that have been filed for review
• Narrowing research gaps to help reverse the surge in youth e-cigarette use

From the Public Education Campaigns

• How FDA is leveraging the findings from “The Real Cost” campaign to address youth e-cigarette use
• Latest findings and next steps for the “Every Try Counts” adult cessation campaign
THANK YOU!