THE FDA TOOLS TO TACKLE THE JUUL EPIDEMIC
LEGAL TECHNICAL ASSISTANCE

- Legal Research
- Policy Development, Implementation, Defense
- Publications
- Trainings

- Direct Representation
- Lobby
Social Determinants of Health

based on work for First Nations Health Authority at Gathering Wisdom VI

Drawing Change

Photo credit: Sam Bradd https://drawingchange.com/gathering-wisdom-visuals-for-a-healthy-future/
OVERVIEW

1. E-Cigarette Epidemic
   - No End in Sight
   - How Did We Get Here?
   - 2017 Regulatory Plan

2. Premarket Review and Enforcement Discretion

3. JUUL

4. FDA Action

5. State and Local Regulation
E-CIGARETTE EPIDEMIC

FDA TAKES NEW STEPS TO ADDRESS EPIDEMIC OF YOUTH E-CIGARETTE USE

“Today FDA took a series of critical actions to address the epidemic of youth e-cigarette use. We also intend to take new, significant steps to stem this challenge, including re-examining our compliance policy regarding flavored e-cigarettes.”

- Scott Gottlieb M.D., FDA Commissioner
E-CIGARETTE EPIDEMIC
NO END IN SIGHT

Monthly E-Cigarette Sales (in Millions)

Nielsen All-Channel Data

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E-CIGARETTE EPIDEMIC
NO END IN SIGHT

Monthly E-Cigarette Sales (in Millions)

Market Total  JUUL

NYTS Survey Periods

Nielsen All-Channel Data

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E-CIGARETTE EPIDEMIC
NO END IN SIGHT

Monthly E-Cigarette Sales (in Millions)

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Market Total  JUUL

NYTS Survey Periods

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E-CIGARETTE EPIDEMIC
CDC’S CURRENT TOBACCO USE AMONG HIGH SCHOOL STUDENTS

FIGURE 2. Estimated percentage of high school students who currently use any tobacco product,* any combustible tobacco product,† ≥2 tobacco product types,§ and selected tobacco products — National Youth Tobacco Survey, 2011–2018§,**,††
E-CIGARETTE EPIDEMIC

CDC’S CURRENT TOBACCO USE AMONG HIGH SCHOOL STUDENTS

FIGURE 2. Estimated percentage of high school students who currently use any tobacco product,* any combustible tobacco product,† ≥2 tobacco product types,§ and selected tobacco products – National Youth Tobacco Survey, 2011–2018,*,**,††

- Any tobacco product
- Any combustible
- ≥2 Types
- E-cigarettes
- Cigarettes
- Cigars
- Smokeless tobacco
- Hookahs
- Pipe tobacco

2018: 20.8%
FIGURE 2. Estimated percentage of high school students who currently use any tobacco product,* any combustible tobacco product,† ≥2 tobacco product types,§ and selected tobacco products — National Youth Tobacco Survey, 2011–2018.**††
AUTHORITY AND THE DEEMING RULE
HOW DID WE GET HERE?
AUTHORITY AND THE DEEMING RULE
HOW DID WE GET HERE?

Monthly E-Cigarette Sales (in millions)

Deeming Rule Effective Date

Nielsen All-Channel Data

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DEEMING RULE
WHAT IS ENFORCEMENT DISCRETION?

STAY UP PAST BEDTIME?

SURE, THAT WON'T CAUSE ANY PROBLEMS.
DEEMING RULE
HOW DID WE GET HERE?

2016 Final Deeming Rule (Deadlines for E-cigarettes)


“Freeze Date”  Today

Continued marketing without application
Continued marketing with application
Marketing with affirmative order

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FDA TOBACCO & NICOTINE REGULATORY PLAN

FDA ANNOUNCES COMPREHENSIVE REGULATORY PLAN

“Addressing the addictive levels of nicotine in combustible cigarettes must be part of the FDA’s strategy for addressing the devastating addiction crisis that is threatening American families.”

FDA COMMISSIONER Scott Gottlieb, M.D.
FDA TOBACCO & NICOTINE REGULATORY PLAN

2016 Final Deeming Rule (Deadlines for E-cigarettes)

- 8/8/2016 to 8/8/2018: Continued marketing without application
- 8/8/2018 to 8/8/2019: Continued marketing with application
- 8/8/2019 to 8/8/2022: Marketing with affirmative order

2017 Regulatory Plan (Deadlines for E-cigarettes)

- 8/8/2016 to 8/8/2018: Continued marketing without application
- 8/8/2018 to 8/8/2019: Continued marketing with application
- 8/8/2019 to 8/8/2022: Marketing with affirmative order

“Freeze Date”

“Freeze Date” refers to the point in time when the regulatory timeline is set and no new applications for marketing approval are considered. 

Today

Today marks the current date on the timeline, indicating the status of ongoing and future regulatory actions.
2017 Regulatory Plan (Deadlines for E-cigarettes)

“Freeze Date”

- Continued marketing without application
- Continued marketing with application
- Marketing with affirmative order
JUUL enters the market

“Freeze Date”

Continued marketing without application

Continued marketing with application

Marketing with affirmative order

2017 Regulatory Plan (Deadlines for E-cigarettes)

JUUL enters the market

2017 Regulatory Plan (Deadlines for E-cigarettes)

6/1/2015
JUUL enters the market

8/8/2016

“Freeze Date”

2/2018 ITG releases myBlu

11/2018 Reynolds releases Vuse Alto

8/8/2018

8/8/2019

8/8/2022

Continued marketing without application

Continued marketing with application

Marketing with affirmative order

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# FDA RESPONSE

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<td>Announcement of FDA’s Intentions</td>
<td><strong>November 15, 2015</strong></td>
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Oh, you actually thought letting me stay up way past my usual bedtime would make me sleep later in the morning? Welcome to 5:48 am...
ENFORCEMENT DISCRETION

- Flavored products
- Adult-only facilities
- Internet sales
- Nicotine salts
- Limit nicotine content to the user

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Guest opinion: Tobacco 21 is the right thing for Utah

Duluth clamps down on flavored tobacco sales

E-cigarette maker Juul boosts lobbying spend by 452% amid regulatory crackdown

San Francisco Voters Uphold Ban on Flavored Vaping Products

The measure is considered the strictest in the nation. Voters backed it despite an expensive advertising campaign funded by a major tobacco company.

Angelica LaVito
CNBC
October 23, 2018

CNBC
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EXTENSIONS & AN EPIDEMIC
The FDA’s Gatekeeping Authority for E-Cigarettes

The premarket review process for commercial tobacco products determines whether or not a particular tobacco product can be legally sold in the U.S. The manner in which the process is implemented has a major impact on public health in communities across the country.

Premarket review is one of the U.S. Food and Drug Administration’s most powerful regulatory tools, as it makes the agency the gatekeeper of the tobacco product marketplace.
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