FEDERAL TOBACCO 21 AND THE FDA FLAVOR GUIDANCE
THE PUBLIC HEALTH LAW CENTER
LEGAL TECHNICAL ASSISTANCE

- Legal Research
- Policy Development, Implementation, Defense
- Publications
- Trainings
- Direct Representation
- Lobby
RESOURCES


Shortly before the end of 2019, the Senate voted to approve a $1.4 billion dollar spending package. The Control Act (“Tobacco Control Act”), which raises the minimum legal sales age for tobacco products from the Federal Tobacco Law, will begin enforcing these new regulations. The FDA also regulates to carry out its authority, and those regulations need to be taken into consideration. Congress needs to update the existing regulations to have a more effective response to the epidemic. The new regulations will be aimed at children and youth who are under the age of 21. This is true in states that have not yet raised the minimum age for service members. The minimum legal sales age is 21 for all people in all places. This holds true in all of these states.

Without an indication of the FDA’s new law, that is not a great sign for retailers who are in compliance with all applicable federal laws, meaning that a retailer could be found to be not in compliance by a local jurisdiction. With the new law, it has raised its own minimum sales age of 21.

Even with the new federal law, Tribal, state, and local governments should continue to move at a faster pace. Tribal Health Services Administration ("TANSA") under the Tribal Amendments will be the next to adopt a legal sales age of 21. The new law can be supported by the power of the law. It also makes enforcement easier for states and local authorities. Second, the law raises their minimum legal sales age of 21. Finally, Tribal, state, and local legislation could increase penalties and preventative measures, and other necessary behavioral measures that is particularly important for young people.

While the new federal law provides an opportunity for advocates and can act as a catalyst for change, incredibly important for public health professionals and advocates to remain vigilant and powerful players, and continue to support preemptive language, harmful, ineffective and distracting, other dangerous policies that threaten to erode public health gains.

Register for our January 22 webinar: Federal Tobacco 21 and the FDA Flavors Guidance

FEDERAL TOBACCO REGULATION

February 2019

Restrict Flavors

The FDA’s new law restricts e-cigarettes. The FDA had a guidance prohibiting all 10-day sell off period. This means that as of February 6, 2020, many flavored liquid products, including nicotine, is not a comprehensive response to the epidemic of youth use of flavored tobacco products, and other harmful flavored products. The failure to include menthol e-cigarettes and all flavored products, and the guidance to continue to ban tobacco-related health disparities.

Restriction of "cartridge-based ENDS products." In the guidance, this is defined as: cartridge or pod that holds liquid that is to be aerosolized through product use. For purposes of this notice, that is the only e-cigarettes made to look like other ordinary products to deceive teachers, or typically purchased in a vape shop (sometimes called "tank systems or mod systems") not disposable, non-carcinogen-based and caramlle-based menthol or tobacco products for now, the FDA may still remove some steps to reduce youth access to products, using marketing and sales strategies that are challenging for the FDA to continue to allow menthol products to remain on the market.

It originally proposed to prohibit flavored e-cigarettes as well, the agency has not followed through on that guidance as the FDA has not comprehensively addressed the epidemic of youth use and other significant public health issues on the removal of menthol from all tobacco products and specifically designed to end the public health. The choice to exempt menthol continues to perpetuate health disparities for these communities and put the FDA continues to allow menthol products to remain on the market.

If other newly deemed products like cigars, but neglects to do so. In the final guidance, the products in the absence of their "preferred" flavor. The FDA even discusses this evidence in the guidance. Menthol flavored e-cigarettes. Before this survey and the following year’s survey, just by far the most by far, menthol and tobacco flavors on the market. Not surprisingly, in 2019, high schoolers use of 7%. This is clear evidence that if any flavored products remain accessible to youth, youth will seek out those brands which will continue to be available in a wide variety of flavors, including fruit, candy, and mint. This is an approach that has historically contributed to the youth e-cigarette epidemic thus far. There is no evidence that these products can be addressed through this action.

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.
AGENDA

• Youth E-Cigarette Epidemic
• FDA Regulation of Tobacco
  – Premarket Review
  – Regulation of Flavors
• Federal Tobacco 21
• Q&A
YOUTH E-CIGARETTE EPIDEMIC


YOUTH E-CIGARETTE EPIDEMIC

YOUTH E-CIGARETTE EPIDEMIC

YOUTH E-CIGARETTE EPIDEMIC

YOUTH E-CIGARETTE EPIDEMIC


- Any Tobacco Product
- Cigarettes
- Cigars
- E-cigarettes

1/22/2020
YOUTH E-CIGARETTE EPIDEMIC

YOUTH E-CIGARETTE EPIDEMIC

YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions)
YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions)
YOUTH E-CIGARETTE EPIDEMIC

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Monthly E-Cigarette Sales (in Millions)
YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions) + Usage by Age Group (Population Estimates)
YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions) + Usage by Age Group (Population Estimates)

Monthly E-Cigarette Sales (in Millions) + Usage by Age Group (Population Estimates)
YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions) + Usage by Age Group (Population Estimates)
YOUTH E-CIGARETTE EPIDEMIC

E-Cigarette Users and Non-Users by Age Group

Users  Non-users

Youth and Young Adults

25+
YOUTH E-CIGARETTE EPIDEMIC

E-Cigarette Users and Non-Users by Age Group

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Users</th>
<th>Non-users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Youth and Young Adults</td>
<td>7.3%</td>
<td>2.6%</td>
</tr>
<tr>
<td>25+</td>
<td></td>
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</table>

Source: Public Health Law Center at Mitchell Hamline School of Law
YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions) + Usage by Age Group (Population Estimates)
YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions) + Usage by Age Group (Population Estimates)

- Market Total
- JUUL
- Youth and Young Adults
- 25+

1/22/2020
YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions)

- Pax Labs introduces Juul into U.S. Markets
- Deeming rule takes effect (FDA begins regulating JUUL)
- FDA announces new regulatory plan for tobacco products and delays premarket review deadlines
- FDA requests marketing documents from JUUL
- Juul vows to stop using models on social media
- FDA raids JUUL’s HQ
- FDA sends Juul a warning letter for unauthorized MRTP Claims
- First lung injuries reported
- Altria buys a 35% stake in JUUL
- Juul discontinues some flavors in convenience stores

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• Youth E-Cigarette Epidemic
• FDA Regulation of Tobacco
  – Premarket Review
  – Regulation of Flavors
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• Q&A
<table>
<thead>
<tr>
<th>FDA Regulation</th>
<th>Enforcement Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum sales age of 18 (age verification under 27)</td>
<td>August 8, 2016</td>
</tr>
<tr>
<td>Prohibition on vending machines in facilities where youth may enter</td>
<td>August 8, 2016</td>
</tr>
<tr>
<td>Prohibition on free samples</td>
<td>August 8, 2016</td>
</tr>
<tr>
<td>Manufacturer registration and submission of product lists</td>
<td>October 30, 2017</td>
</tr>
<tr>
<td>Submission of ingredient lists</td>
<td>May 8, 2018</td>
</tr>
<tr>
<td>Warning labels required on packages and advertisements</td>
<td>August 10, 2018</td>
</tr>
</tbody>
</table>
FDA REGULATION
FDA REGULATION

• No “new tobacco product” can be sold without marketing authorization from the FDA.
  – “new tobacco product” first sold after 2/15/07
  – “grandfathered product” available for sale on 2/15/07
• All currently marketed e-cigarettes are “new tobacco products.” (not sold on 2/15/07)
• All e-cigarettes require marketing authorization from the FDA in order to be sold.
In 2009, FDA was given authority to regulate cigarettes, smokeless tobacco, RYO & cigarette tobacco.

For all other tobacco products, FDA must “deem” them (with a rulemaking).

The FDA cannot accept marketing applications for e-cigarettes until they have been deemed.
FDA REGULATION

• Once the FDA has regulatory authority, all e-cigarettes require affirmative marketing authorization from the FDA before they can be sold.

• The FDA cannot accept marketing applications for e-cigarettes until they have regulatory authority.
FDA REGULATION

2016 Final Deeming Rule (Deadlines for E-cigarettes)

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

- 8/8/2016
- 8/8/2018
- 8/8/2019
- 8/8/2022

Today
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.
Ruling turns up pressure for FDA to strictly regulate e-cigarettes

By Jacqueline Howard and Michael Nedelman, CNN
Updated 2:43 PM ET, Thu May 16, 2019

FDA is proposing these new rules on vaping.

[CNN] — Some politicians and pediatricians have urged the US Food and Drug Administration to take strong, swift action on the growing use of e-cigarettes among America’s youth, but the latest move comes from a federal judge who ordered the agency to speed up its review of thousands of vaping products now on the market.
FDA REGULATION

2016 Final Deeming Rule (Deadlines for E-cigarettes)
- 8/8/2016
- 8/8/2018
- 8/8/2019
- 8/8/2022

2017 Regulatory Plan (Deadlines for E-cigarettes)
- 8/8/2016
- 8/8/2018
- 8/8/2019
- 8/8/2022

2019 Judicial Order from AAP v. FDA (Deadlines for E-cigarettes)
- 8/8/2016
- 5/12/2020
- 5/12/2021
- 8/8/2022

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

Today
AGENDA

• Youth E-Cigarette Epidemic
• FDA Regulation of Tobacco
  – Premarket Review
  – Regulation of Flavors
• Federal Tobacco 21
• Q&A
• Draft Guidance – 3/8/19
• Comment Period Ends – 4/30/19
• White House Announcement – 9/11/19
• Final Guidance to OMB – 10/25/19
• Final Guidance Clears OMB – 11/4/19
• White House Meeting – 11/22/19
• Final Guidance Published – 1/7/20
FDA REGULATION

Tobacco, Mint & Menthol
• Fewer Restrictions

Other Flavors
• More Restrictions
FDA REGULATION

Tobacco, Mint & Menthol
• Allowed to remain on the market

Other Flavors
• Removed from the market (temporarily)

Cartridge-based E-Cigarettes
FDA REGULATION

Tobacco, Mint & Menthol
• Allowed to remain on the market

Other Flavors
• Removed from the market (temporarily)

Cartridge-based E-Cigarettes

1/22/2020
High School E-Cigarette Flavor Preference

Cullen et al., E-Cigarette Use Among Youth in the United States, 2019, 322 JAMA 2095 (2019)
High School E-Cigarette Flavor Preference (NYTS)

Flavor Used Most Often by Grade Level (MTF)

Cullen et al., E-Cigarette Use Among Youth in the United States, 2019, 322 JAMA 2095 (2019)

Leventhal et al., Flavors of E-Cigarettes Used by Youths in the United States, 2019, 322 JAMA 2132 (2019)
YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions)

Retail & Juul's Website

- Classic Tobacco
- Mint
- Menthol
- Virginia Tobacco
- Crème
- Cucumber
- Fruit
- Mango

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at Mitchell Hamline School of Law

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YOUTH E-CIGARETTE EPIDEMIC

Monthly E-Cigarette Sales (in Millions)

Retail & Juul's Website

- Classic Tobacco
- Mint
- Menthol
- Virginia Tobacco

Juul's Website Only

- Crème
- Cucumber
- Fruit
- Mango

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1/22/2020
YOUTH E-CIGARETTE EPIDEMIC

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Retail & Juul’s Website
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NYTS & MTF

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Leventhal et al., Flavors of E-Cigarettes Used by Youths in the United States, 2019, 322 JAMA 2132 (2019)
Flavors Most Often Used (Youths Using Juul <20 Days)

- Classic Tobacco, Mint, Menthol & Virginia Tobacco
- Crème, Cucumber, Fruit, Mango

Flavors Most Often Used (Youths Using Juul ≥20 Days)

- Classic Tobacco, Mint, Menthol & Virginia Tobacco
- Crème, Cucumber, Fruit, Mango

Leventhal et al., Flavors of E-Cigarettes Used by Youths in the United States, 2019, 322 JAMA 2132 (2019)
Moreover, Juul's mint flavor is demonstrating - based on the new youth use data - that it's a candy flavor. That's why children have migrated to mint e-cigs. Any ban on e-cig flavors must include mint and menthol, and not carve out menthol only to see "mint" renamed "menthol".

Another key will be how it's enforced: Will a manufacturer seek to re-name a flavor to "menthol" or "tobacco" to evade the new restrictions and how will FDA enforce a flavor restriction on pods without final regulation that characterizes what a flavor is? That reg was pending...
Tobacco, Mint & Menthol
• Allowed to remain on the market

Other Flavors
• Removed from the market (temporarily)
Electronic nicotine delivery systems (or ENDS) include devices, components, and/or parts that deliver aerosolized e-liquid when inhaled. For example, FDA considers vapes or vape pens, personal vaporizers, e-cigarettes, cigalikes, e-pens, e-hookahs, e-cigars, and e-pipes to be ENDS.

- ENDS – “deliver aerosolized e-liquid when inhaled”
FDA REGULATION

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Cartridge-based ENDS products are a type of ENDS product that consists of, includes, or involves a cartridge or pod that holds liquid that is to be aerosolized through product use. For purposes of this definition, a cartridge or pod is any small, enclosed unit (sealed or unsealed) designed to fit within or operate as part of an electronic nicotine delivery system.20

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- Cartridge-based ENDS – “type of ENDS” “involves a cartridge or pod that holds liquid that is to be aerosolized”
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- Cartridge or pod – “designed to fit within or operate as part of an ENDS”
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FDA will prioritize enforcement of flavored, cartridge-based ENDS products (other than tobacco- and menthol-flavored products), which are produced primarily by large manufacturers. This policy should have minimal impact on small manufacturers (e.g., vape shops) that primarily sell non-cartridge-based ENDS products, unless they market to youth or fail to take adequate measures to prevent youth access. Specifically, FDA intends to prioritize enforcement regarding the lack of marketing authorization against:

- Exempt from Final Guidance:
  - Tank/Mod systems
FDA REGULATION

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\textsuperscript{20} An example of products that would not be captured by this definition include completely self-contained, disposable products.

- Exempt from Final Guidance:
  - Tank/Mod systems
  - Disposables
V. CHANGES TO COMPLIANCE POLICY REGARDING FLAVORED CIGARS
(OFFER THAN TOBACCO FLAVORED) THAT MEET THE DEFINITION OF
A NEW TOBACCO PRODUCT

In addition to reconsidering the compliance policy with respect to submission of premarket
applications for ENDS products, in its discretion, FDA has also reconsidered the compliance
policy with respect to other deemed tobacco products. At this time, in addition to modifying the
compliance policy for ENDS products, FDA is also modifying the August 2017 Compliance
Policy for flavored cigars. Beginning 30 days after issuance of a final guidance, FDA will
prioritize enforcement of actions with respect to flavored cigars (other than tobacco flavored)
that were on the market on August 8, 2016, and that meet the definition of a new tobacco
product.
V. CHANGES TO COMPLIANCE POLICY REGARDING FLAVORED CIGARS (OTHER THAN TOBACCO FLAVORED) THAT MEET THE DEFINITION OF A NEW TOBACCO PRODUCT

In addition to reconsidering the compliance policy with respect to submission of premarket applications for ENDS products, in its discretion, FDA has also reconsidered the compliance policy with respect to other deemed tobacco products. At this time, in addition to modifying the compliance policy for ENDS products, FDA is also modifying the August 2017 Compliance Policy for flavored cigars. Beginning 30 days after issuance of a final guidance, FDA will prioritize enforcement of actions with respect to flavored cigars (other than tobacco flavored) that were on the market on August 8, 2016, and that meet the definition of a new tobacco product.

V. PREMARKET REVIEW FOR OTHER DEEMED NEW TOBACCO PRODUCTS

FDA remains concerned with minors’ access to and use of all tobacco products, particularly flavored tobacco products, which appeal to minors and promote initiation.99 In addition to the tobacco products covered earlier in this guidance document, FDA has considered revising its enforcement priorities with respect to premarket authorization for other deemed new tobacco products. We note that several comments on the March 2019 Draft Guidance suggested that FDA begin immediately enforcing the premarket requirements for flavored deemed tobacco products such as cigars and other deemed tobacco products.

FDA received numerous comments relating to the proposed policy for flavored cigars in the March 2019 Draft Guidance. Some of the comments were supportive of that proposed policy, although some wanted the Agency to take even more aggressive action. Other comments opposed inclusion of flavored cigars as an enforcement priority and disagreed with the bases for the proposed policy. For example, some commenters argued that flavored cigars are used most commonly by adult users and that the inclusion of flavored cigars as an enforcement priority limits adults’ freedom to choose their preferred product. Other commenters argued that FDA did not have the data necessary to support the need for “a drastic and unprecedented change in enforcement priorities.” Some commenters also stated that the evidence cited by FDA discussing initiation of youth usage of flavored cigars was inconsistent and inconclusive. After consideration of the data regarding youth use of cigars generally and comments received on this issue, we have decided to not prioritize enforcement of flavored cigars before May 12, 2020. While there is no public health benefit associated with flavored cigars and FDA remains concerned with youth use of flavored cigars, current data indicate that youth are using flavored cigars at a lower rate than they are using flavored ENDS products.
YOUTH E-CIGARETTE EPIDEMIC


- Any Tobacco Product: 15.3%
- Cigarettes: 5.8%
- Cigars: 7.6%
- E-cigarettes:
AGENDA

• Youth E-Cigarette Epidemic
• FDA Regulation of Tobacco
  – Premarket Review
  – Regulation of Flavors
• Federal Tobacco 21
• Q&A
FEDERAL T21

- 12/20/19 – Bill Signed/Law Effective
- 6/17/20 – Final Rule Due
- 9/15/20 – Latest Possible Effective Date
FEDERAL T21

- 12/20/19 – Bill Signed/Law Effective
- 6/17/20 – Final Rule Due
- 9/15/20 – Latest Possible Effective Date
On Dec. 20, 2019, the President signed legislation amending the Federal Food, Drug, and Cosmetic Act, and raising the federal minimum age of sale of tobacco products from 18 to 21 years. It is now illegal for a retailer to sell any tobacco product—including cigarettes, cigars and e-cigarettes—to anyone under 21.

Effective immediately, retailers must not sell tobacco products to anyone under the age of 21. FDA recognizes that both the agency and some retailers will need to update current practices to implement this new law as FDA will need time to do outreach and education to retailers and update the Agency’s programmatic work to reflect this change in law. During this period of transition, the FDA expects retailers to follow the law and take measures to ensure an individual purchasing a tobacco product is 21 or older, including manually checking IDs when needed. However, during this ramp-up period, FDA will continue to only use minors under the age of 18 in its compliance check program.
Background: Federal MLSA = 21, State MLSA = 18

Scenario: Retailer sells tobacco product to a 22-year-old

Outcome:
- Federal Law = Not Violated
- State Law = Not Violated

Scenario: Retailer sells tobacco product to a 17-year-old

Outcome:
- Federal Law = Violated
- State Law = Violated
Scenario: Retailer sells tobacco product to a 20-year-old

Background: Federal MLSA = 21, State MLSA = 18
FEDERAL T21

Background: Federal MLSA = 21, State MLSA = 18

Scenario: Retailer sells tobacco product to a 20-year-old

Outcome:
- Federal Law = Violated
- State Law = Not Violated
Scenario: Retailer sells tobacco product to a 20-year-old

Outcome:

Federal Law = Violated
State Law = Not Violated

Background: Federal MLSA = 21, State MLSA = 18

Scenario: Retailer sells tobacco product to a 20-year-old with military ID

Outcome:

Federal Law = Violated
State Law = Not Violated

Background: Federal MLSA = 21, State MLSA = 21 with military exemption
Governments can raise the MLSA to 21

Easier for those trying to comply

Easier for those trying to enforce

No need to wait
• State preemption of T21 local ordinances
  – Careful evaluation
  – May open conversation to eliminating preemption
• Tribal Communities
FEDERAL T21

- Penalties
  - Same as before
  - Change in age for decoy buyer

- FDA’s current fee schedule available on website
FEDERAL T21

AGENDA

• Youth E-Cigarette Epidemic
• FDA Regulation of Tobacco
  – Premarket Review
  – Regulation of Flavors
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