

FDA UPDATES

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Presentation Outline

Federal vs. State vs. Municipal

FDA compliance checks in MA

E-cigarettes

JUUL

Menthol

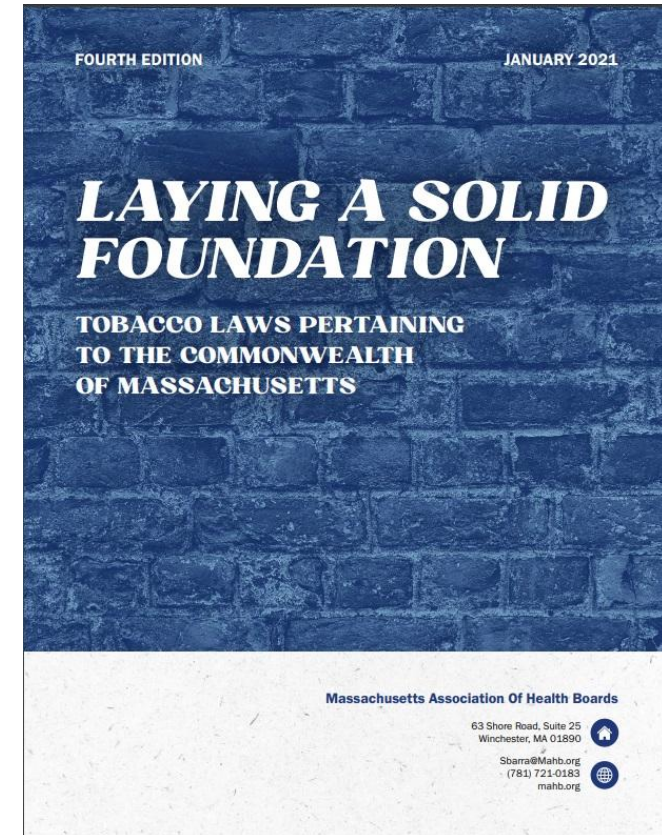
Synthetic Nicotine

Nicotine Reduction



Federal vs. State vs. Municipal

- The FDA did not have the authority to regulate tobacco until 2009. Before then, Congress did not intend such oversight because tobacco was too deadly for the FDA to regulate.
- 2009 Family Smoking Prevention and Tobacco Control Act.
- No preemption. The FDA learned tobacco control from Massachusetts and a few other states.
- <https://www.fda.gov/tobacco-products>



<https://www.mhoa.com/aws/MHOA/pt/sp/tobacco-control-program>

FDA Compliance Checks in MA

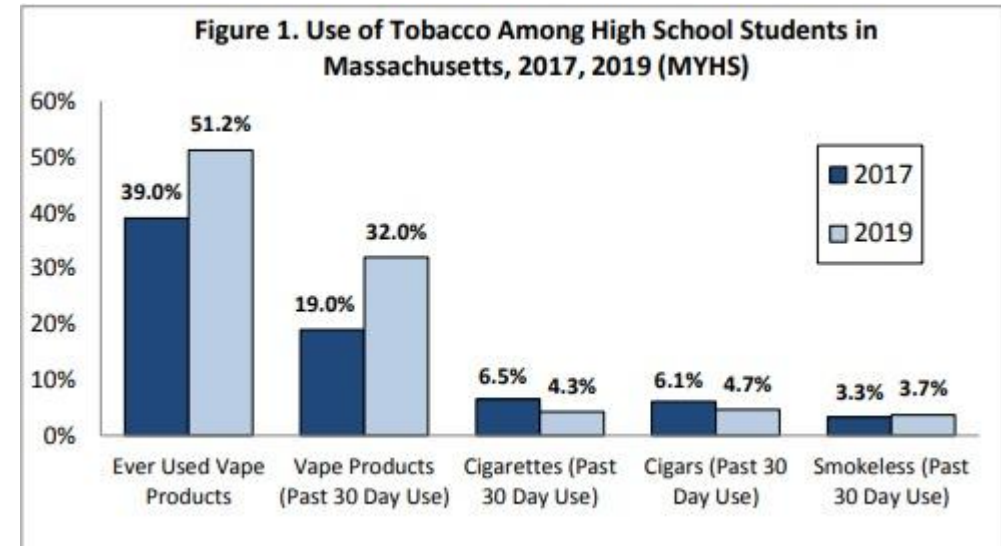
- The FDA does compliance checks only for its law..
- Massachusetts and municipal regulations are more comprehensive and more effective than FDA retailer regulation. FDA inspections do not (and cannot) replace MA BOH inspections

https://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm

The screenshot shows the FDA website's search interface for tobacco product retailer inspections. The page title is "Compliance Check Inspections of Tobacco Product Retailers (through 08/31/2022)". A prominent note states: "Note: On December 20, 2019, the President signed legislation to amend the Federal Food, Drug, and Cosmetic Act, and raise 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." Below the note is a search form titled "Search Inspection Decisions" with fields for Retailer Name, City, State (set to Connecticut), Zip, Inspection Result (set to All), Product Type Purchased by Minor, Decision Date (mm/dd/yyyy), and Minor Involved. A "Search" button is at the bottom of the form. To the right of the form is a map of the Northeast United States, showing major cities like Boston, Worcester, Springfield, and Hartford. The map includes navigation controls like "Map", "Satellite", and a person icon.

E-Cigarettes

- FDA took a tougher stance (and regulations) against e-cigarettes in May 2016.
- FDA has authority to regulate e-cigarettes because any products not on the market as of 2009 are required to apply for market approval.
- The deadline for c-cigarette companies to apply was May 14, 2022.
- One million e-cigarette products submitted by more than 200 manufacturers.
- Many applications were denied but many unauthorized products remain on the market.



JUUL

- MA Attorney General's Office started investigating JUUL in July 2018, and filed suit against JUUL in February 2020.
- JUUL made approximately \$3.3 billion in U.S. retail sales between September 2018 and August 2019 and controlled approximately three quarters of the e-cigarette market. Altria paid the \$12.8 billion in 2018 to acquire a 35% stake in JUUL.
- E-cigarette use exploded in popularity among high school age youth in MA.
- JUUL stopped selling its flavored products in 2018 after pressure from the FDA but continued online until 2019. Menthol JUUL is still being sold, except in MA.
- FDA ordered all JUUL products removed from the market in June 2022, and one month later, said is needed to review its order and allowed JUUL back on the market.

MENTHOL

- Proposed regulations prohibiting the sale of menthol cigarettes and cigars published by the FDA in May 2022. Public comment closed in August 2022.
- The tobacco industry targeted menthol promotion in black communities.
- Menthol can facilitate addiction and make quitting more difficult.
- The proposed rules does not apply to e-cigarettes or cigars. The proposal would also prohibit all flavored cigars.
- Federal rules are typically effective 30 days after being published, but the FDA has said the effective date for banning menthol could be up to 1 year after the final rule is published.
- MA is the only state in the US with a comprehensive ban on menthol tobacco products.

SYNTHETIC NICOTINE

- E-cigarette makers like, Puff Bar, used synthetic nicotine to try to circumvent FDA regulations.
- In March 2022, Congress authorized the FDA to regulate synthetic nicotine.
- The FDA has issued warning letters, but has not taken enforcement actions.



- None of these flavored products are allowed in IA because of your local regulations and state law!

NICOTINE REDUCTION

- In June 2022, the FDA stated it plans to propose a rule to reduce nicotine levels in cigarettes and other combustible tobacco.
- Nicotine is highly addictive and is primarily responsible for the maintenance of cigarette smoking.
- The plan is combusted tobacco would become less addictive. Experimentation would lead to fewer addicted users, and previously addicted smokers could quit more easily.

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