"21-To-Buy" and a Pod Ban: FDA's Recent Actions on ESDs

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What is the FCAA, and what happened?

- The Further Consolidated Appropriations Act of 2020 is a budget bill signed into law on December 20, 2019 by the President.
  - Appropriations bills are massive undertakings, and due to the problems presented (shutdowns, etc) by operating *without* a federal budget, these bills are generally considered "must pass" legislation. This creates opportunities for add-ons…
- This year, the CAA contained the following provision:
  - **"The Federal Food, Drug, and Cosmetic Act is amended…by striking 18 years and inserting 21 years; and by adding at the end the following:**

    …It shall be unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age."

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Congress just made it illegal to sell tobacco/ESDs to anyone under 21…

So, what did FDA do?

When the President signed the FCAA legislation on December 20, 2019, many in the industry suspected that – as is customary – the FDA had 180 days to update its regulations with the change taking hold 90 days later.

However, on December 21, 2019 – just one day later – this showed up on the FDA's Website:

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. FDA will provide additional details on this issue as they become available.

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What does this mean for Maryland's "Tobacco 21" law?

- Conventional wisdom about federal vs. state law says that the action taken by Congress, signed into law by the President, and backed up by FDA's statement preempts Maryland's 2019 law, and replaces it entirely.
  - This invalidates the provision in Maryland's Tobacco 21 law exempting military personnel with ID from the "21 to buy" requirement.
- The Maryland General Assembly may have plans to correct this conflict during the 2020 Session now underway…
  - …BUT, even if the MGA doesn't act - federal law reigns supreme.
    - Tobacco/ESD retailers must comply or face enforcement actions by FDA and any other enforcement entity – including local health departments and the Comptroller's Field Enforcement Division.

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What *else* has the FDA been up to lately?

FDA website on January 2, 2020:

FDA NEWS RELEASE

FDA finalizes enforcement policy on unauthorized flavored cartridge-based e-cigarettes that appeal to children, including fruit and mint

Companies that do not cease manufacture, distribution and sale of unauthorized flavored cartridge-based e-cigarettes (other than tobacco or menthol) within 30 days risk FDA enforcement actions

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What *else* has the FDA been up to lately? (cont.)

- FDA's new enforcement policy "prioritize[s] enforcement against these illegally marketed ENDS products by focusing on the following groups of products:
  - Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
  - All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
  - Any ENDS product that is targeted to minors or likely to promote use of ENDS by minors."

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- **What led to this recent and aggressive action by FDA?**
  - Arguably, what preceded this action was years of inaction, as FDA's own press release notes:
    - "[FDA]…deferred enforcement of the premarket authorization requirements. To date, no ENDS products have been authorized by the FDA — meaning that all ENDS products currently on the market are considered illegally marketed and are subject to enforcement, at any time, in the FDA's discretion."
  - However, both the recent "EVALI" crisis and the President's multiple varied proposals about how to respond likely forced the FDA to take a stand, particularly against the products favored by and marketed towards children.

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What licensed Maryland businesses are affected?

- 46 ESD Retailers
- 87 Vape Shop Vendors
  - *44 MD vape shops are registered "manufacturers of e-liquids" with FDA
- Pod/Cartridge retail Points-of-sale:
  - 6082 – OTP Retailers**
  - 6285 – Cigarette Retailers**

*As of October 2019, Maryland law requires vape shops who create their own e-liquids to apply for an "ESD Manufacturer" license from the Comptroller's Office.

**Maryland law allows licensed Cigarette/OTP retailers to sell ESDs without acquiring an additional "ESD Retailer" or "Vape Shop Vendor" license.

Questions?

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