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Height Commentary

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Tobacco

Despite All the Previewing, FDA's Announcement Had Some Surprises

THE TAKEAWAY

FDA Commissioner Scott Gottlieb formally announced today plans to ban menthol cigarettes and regulate other flavored e-cigarettes. We now think the FDA can finalize a menthol cigarette ban as soon as November / December 2020, which is roughly a year sooner than our prior projections. We are still skeptical that the FDA can actually implement a ban at this time due to likely litigation brought by the manufacturers. On e-cigarettes, we were surprised the FDA did not go further in its proposed e-cigarette regulations and instead created a regulatory framework that's bound to be easier for larger manufacturers to comply with than their smaller competitors.

FDA Commissioner Scott Gottlieb issued his formal announcement today on new menthol cigarette and broader flavor e-cigarette regulations. Here are our top takeaways:

Menthol Ban Is Now Possible As Soon As Late-2020

- **FDA intends to ban menthol cigarettes as quickly as possible, and it chose a pathway that again proves Commissioner Gottlieb will take creative and aggressive approaches to regulating tobacco products**.
- **We now think the agency can finalize a menthol ban as soon as late-2020, which is a year sooner than we previously projected.**

In our November 12 report, we outlined three different pathways we thought the FDA could take to advance a menthol cigarette ban:

1. Pathway 1: advancing a 2013 menthol cigarette rulemaking;
2. Pathway 2: advancing a broader 2018 tobacco product flavors rulemaking; or
3. Pathway 3: launching a new menthol tobacco product rulemaking.

FDA chose a combination of Pathways 2 and 3. Gottlieb announced that the agency would issue a notice of proposed rulemaking (NPRM) on menthol cigarettes specifically, but the FDA would use the broader tobacco product flavors regulation from early 2018 as the starting point. It appears Gottlieb will significantly narrow the scope of the original advance notice of proposed rulemaking (ANPRM) in this new NPRM to focus only on

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menthol in cigarettes, and the agency will not address the role of flavors in other tobacco products. This process is important because it effectively mitigates the drawbacks we initially saw in Pathway 2: the enormous amount of corresponding work that other tobacco product flavor regulations will require and how that would likely distract the FDA and slow their work on menthol. Stripping out those other regulations eliminates those immediate distractions for the FDA. Additionally, we think the FDA faces little legal risk by taking this approach; agencies have the authority to narrow the scope of a rule as they move it through the regulatory process.

The remaining drawback is one that we previously highlighted for Pathway 3: a final menthol ban will likely face serious litigation risk that makes gaming out an implementation timeline difficult. A new NPRM on menthol in cigarettes could come as soon as this week. Whenever it comes, we think it starts a roughly two-year clock before we see a final regulation in place. We have not seen the FDA advance regulations more quickly than two years between NPRM and final rule stages. Our sample size is very small, however, since there has only been one high-profile regulation to move from NPRM to final rule: the deeming regulations. Using this precedent to make a prediction, we estimate the FDA can complete a final menthol rule in November or December 2020. This timing is now roughly one year earlier than our prior projections, which put completion more likely in the 2022 timeframe. Litigation risk still remains major factor, which we highlighted previously, since lawsuits filed against the FDA will by tobacco manufacturers would have a reasonable chance of success in delaying or even ultimately derailing FDA's work on menthol. Therefore, we do not have high conviction that by the end of 2020 the FDA will have formalized a menthol regulation that the federal government can quickly implement and enforce. For manufacturers with exposure to U.S. menthol sales (**BTI**, **MO**, **IMBBY**), this means we are not confident that - even if our timing predictions are correct and FDA issues a final menthol ban in late-2020 - these manufacturers will actually need to remove their menthol cigarettes from the market at that time.

E-Cigarette Regulations Are Not Nearly As Tough As We Projected

- **FDA was compelled to enact formal, e-cigarette public policy rather than allow companies to self-police as JUUL, Altria, Imperial and other companies announced in recent days and weeks**.
- **However, FDA did not come out as tough as we expected; the agency does not intend to ban any category of e-cigarette flavors from the market completely.**
- **FDA did come out tougher than expected in other ways; FDA did not delineate between closed or so-called "pod-like" systems and open systems: FDA will treat all flavors equally.**
- **Mint is officially safe.**

On e-cigarettes, the FDA's actions do not go as far as self-policing by JUUL Labs, Altria, or Imperial. JUUL Labs will continue to sell its tobacco, mint, and menthol products via all distribution channels, but the company will restrict its other flavors (mango, fruit, creme, and menthol) to online sales. Altria will continue to sell its tobacco, mint, and menthol flavors of pod-like e-cigarette products but pulled its other flavors from the market entirely. Imperial will restrict website sales of all its Blu products to customers 21 years old or older (up from 18).

FDA intends to limit the sale of most e-cigarettes in brick-and-mortar retailers to "age-restricted" areas of the shop. This policy will impact both open and closed systems (it will not specifically target "pod-like" systems). As expected, it will not apply to tobacco, menthol, or mint flavors. Whether mint would formally be captured in this policy announcement was a big unknown, so the FDA's measure should be welcome news to e-cigarette manufacturers.

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Gottlieb continues to cite the premarket tobacco application (PMTA) pathway as his tool to implement these changes. We remain skeptical that FDA has the authority to use PMTA approvals to achieve distribution restrictions. This is reinforced by the fact that Gottlieb is asking companies to take actions like JUUL, stating that he and others at the FDA "hope that within the next 90 days, manufacturers will choose to remove flavored [e-cigarettes] from stores where kids can access them and from online sites that do not have sufficiently robust age-verification procedures." He is also encouraging all e-cigarette manufacturers to submit PMTAs quickly themselves, which we think companies like JUUL Labs must do to show a good faith effort in trying to comply with the FDA's regulatory efforts.

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COMPANIES MENTIONED IN THIS REPORT

Altria Group Inc (MO), Imperial Brands PLC (IMBBY), British American Tobacco PLC (BTI), JUUL Labs Inc. (JUUL)

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