

# Height Commentary

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## Tobacco

### Gottlieb's Move to Halt E-Cigarette Sales Should Not Be a Surprise

#### THE TAKEAWAY

We have been writing since mid-July that we saw signs that Food and Drug Administration (FDA) Commissioner Scott Gottlieb was poised to take some sort of action against JUUL and potentially other e-cigarette manufacturers as the issues of youth use shifted from a back-burner concern to something of high-priority for the agency. Gottlieb is officially [labeling](#) the e-cigarette youth use an "epidemic" and continues to believe in a causal relationship between certain flavors of e-cigarettes and their attractiveness to minors. Despite the lack of sufficient evidence to support this assertion, Gottlieb is positioning the FDA to take action sooner rather than later against "youth appealing" flavors. At risk are the [manufacturers](#) of JUUL (JUUL Labs), Vuse (BTI), Blu (IMBBY), MarkTenXL (MO), and Logic (JAPAY), which all have 60 days to submit a plan to the FDA on what each company will do to "address the widespread youth access and use of their products." We think there is a 65% chance that regulators will force the removal of a material number of these companies' e-cigarette products from the U.S. market before the end of CY 2018, pending additional regulatory approvals that will likely take years to complete. How many products remains unclear at this time, but these are certainly substantial headwinds forming against these companies' e-cigarette products. For additional background, see our [August 3](#), [July 20](#), [July 19](#), [July 10](#), and [May 3](#) reports.

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Within the FDA's deeming regulations - the rules [finalized](#) in August 2016 that deemed e-cigarettes to be tobacco products and therefore under the FDA's regulatory control - the agency created a series of approval pathways for manufacturers to follow before their products could be sold in the United States. The pathway that nearly all e-cigarette manufacturers are required to follow is the premarket tobacco application (PMTA) pathway, which is expected to take companies months (if not years) and hundreds of millions of dollars to complete. In order not to decimate the e-cigarette industry, despite codifying these rules in August 2016, the FDA essentially said that it would not enforce these premarket approval requirements for many years to allow for companies to prepare adequately for them. For the PMTA pathway, companies were initially granted three years (until August 2019) of non-enforcement by the FDA, and Gottlieb actually [extended](#) this timeline last year until August 2022.

What Gottlieb [said](#) today is that he is now considering rescinding that non-enforcement window for certain products that he believes are major contributors to what he labels a youth use epidemic. The FDA [sent](#) letters to five e-cigarette manufacturers (JUUL Labs, BTI, MO, JAPAY, and IMBBY) asking them to submit plans to the agency within 60 days that describe what they will do to "address the [issue of] widespread youth access and use of their products." At the end of the 60 days, the FDA will determine whether some or all of these manufacturers' products should be removed from the market unless and until they complete the burdensome PMTA approval process. As we noted, we think that process will take years for companies and the agency to complete, which is why we think Gottlieb extended these enforcement actions until August 2022.

This puts all flavors of aforementioned e-cigarette products at risk, in our view, even those with clear evidence of compliance with existing rules. The point of today's announcement is that FDA is saying it's considering adjusting its enforcement decisions around existing regulations, which we believe is well within the FDA's authority.

The FDA is also saying that it continues to increase its enforcement efforts against illegal sales of e-cigarettes to minors, which is predominantly a retailer issue and not one for which we see exposure for JUUL or any of the other aforementioned manufacturers.

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## COMPANIES MENTIONED IN THIS REPORT

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

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