3 MAY 2018

Height Commentary

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Tobacco

Policy Conferences Abound to Address Regulatory Uncertainty

THE TAKEAWAY

The Food and Drug Administration (FDA) continues to send signals that reinforce our view that the agency intends to pursue a number of regulatory actions in specific order over the months and years ahead that will partially mitigate for major tobacco manufacturers the most burdensome of regulatory headwinds (e.g., rules that require cigarettes contain minimally or non-addictive levels of nicotine) via a series of regulatory actions that create tailwinds for these companies (e.g., approvals to sell new next generation tobacco products in the U.S., approvals to market those products as relatively less harmful than cigarettes, etc.). Today's report highlights our takeaways from a tobacco regulatory policy conference in Washington earlier this week, and previews a second conference slated to begin later today.

The FDA views tobacco control holistically, requiring the agency overcome a series of regulatory hurdles before it will be ready to regulate nicotine levels in cigarettes. As we have written previously, for months now we have seen signs that the FDA is creating a longer-term pathway that will ultimately place all tobacco products on a continuum of risk with nicotine replacement therapies (such as nicotine gums) on one end and combustible cigarettes on the other end and all other nicotine delivery products in between, ranked in order of potential harm (see **Figure 1** below for a visualization of what this could look like).

While we do not think it is realistic for the relative harm of *all* tobacco products to be defined any time soon (we view this as a 10+ year endeavor based on the amount of work required by companies and the FDA), comments by the FDA's Center for Tobacco Products (CTP) Director Mitch Zeller at the E-Cigarette Summit earlier this week reinforced to us that *before* the FDA can advance more burdensome regulations that will require companies to reduce the amount of nicotine in combustible cigarettes to yet-to-be-defined "minimally or non-addictive levels," the FDA intends to begin to place at least some products along the so-called harm continuum. The strategy here is that the agency hopes to make cigarettes less attractive while simultaneously providing less-harmful alternatives for smokers who are unwilling or unable to quit.

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This will be positive for **PM** / **MO**, which has its IQOS product before the FDA for approval to sell in the U.S. and for approval to market as relatively less harmful than combustible cigarettes.

- We think the first approval - the Premarket Tobacco Approval (PMTA) to sell IQOS in the U.S. - will come within the next few months. While there is no real deadline for the FDA to act, we think it is reasonable to expect the FDA Commissioner Scott Gottlieb would be interested in having this as a "win" on the board in time for the one-year anniversary of his July 28, 2017 announcement of the agency's comprehensive approach to nicotine regulations.
- We think the second approval to market IQOS as relatively less harmful than combustible cigarettes - known as the Modified Risk Tobacco Product (MRTP) request - is unlikely to come until 4Q2018 at the earliest in our view, and more likely at some point during 2019. It is clear there is more work to be done by the FDA and **PM** around the application after the negative feedback handed down by the FDA's tobacco advisory committee in late January. We note that at the E-Cigarette Summit earlier this week, CTP Director Zeller went out of his way to remind the audience that the advisory committee votes are non-binding and will not force the FDA to act in one way or another, further reinforcing why we are bullish on prospects that IQOS ultimately receives the MRTP designation.

This overall trend we continue to witness at FDA is also positive for **BATS:LN**, which has submitted a number of MRTP applications for a suite of snus products under its Camel brand, and also plans to submit two more applications for its glo heat-not-burn product (one PMTA and one MRTP).

We think the FDA's Center for Tobacco Products - under Commissioner Gottlieb and Director Zeller's leadership - is highly incentivized to approve all of these applications in order to continue to bring to the U.S. market new and relatively less-harmful tobacco products that are messaged to the public as such. We think this means the FDA will approve as soon as it can the modified risk tobacco product (MRTP) applications for IQOS, Camel snus products, and likely glo should an MRTP be submitted for the product. We think a reasonable timeframe for all of these applications to clear FDA approval is end of 2019. This view is based on the amount of work required by the companies and the FDA, combined with the historical sluggish pace we've seen at the FDA. See **Figure 1** at the end of this report for a visual representation of our thinking.

There is no silver bullet scientific study that will appear - and it is clear that at no point in the near-future will public health advocates and the FDA have sufficient evidence to conclusively support any one approach to tobacco regulation. Whether it is the ongoing uncertainty around youth initiation vs. adult cessation, the outstanding questions around the degree of harm posed by toxins that exist in next generation products, the uncertainty around whether certain flavors create health risks or health gains - these are all questions that remain and that the FDA will not receive conclusive answers to. In fact, at the E-Cigarette Summit earlier this week, one of the individuals who served on the National Academies panel that produced a report in January 2018 to the FDA on the various risks and potential benefits of e-cigarettes revealed that there was real disagreement among report committee members themselves about the threat of e-cigarettes as a gateway to combustible cigarette use. Some individuals on the committee, including the presenter at the E-Cigarette Summit Dr. Nancy Rigotti, were comfortable saying that they found no conclusive evidence that e-cigarette use causes future combustible cigarette use. Others on the committee have apparently communicated the opposite to members of the tobacco control community - that the panel found that e-cigarette use does in fact lead to combustible cigarette use. Someone in the audience at the E-Cigarette conference this week verbally

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acknowledged that this and other studies have become essentially Rorschach tests for the individuals conducting and interpreting them.

JUUL illustrates the divide within the public health community around the youth initiation vs. adult cessation issue. About one-third of the conference centered on JUUL specifically. Panelists ranged from voicing concern with the "epidemic" of youth use, to applauding JUUL for being the first company to enter the tobacco space and quickly disrupt the combustible cigarette market. Neither side, we note, has conclusive evidence supporting their claims. Further, there was no consensus among public health officials around whether JUUL poses a threat or an opportunity, and that ambiguity is clearly coloring the FDA's approach. According to Director Zeller, the FDA is essentially in fact-finding mode per the 904(b) request sent to JUUL last week for more information. We think for now, this information gathering is most likely to continue and be the extent of what the FDA does regarding JUUL.

We question, however, the extent to which JUUL specifically and e-cigarettes more broadly are cannibalizing combustible cigarette sales in the United States. A large amount of the conference was devoted to discussing the misunderstanding within the general public of the risks of various tobacco products and around the perceived dangers of nicotine. There continues to be evidence that a majority of adults believe that nicotine causes cancer, which may indicate that all nicotine delivery systems may be viewed as equally harmful by many in the United States. Separately, many public health officials at the conference discussed how the use of JUUL by adolescents is particularly alarming in light of recent and dramatic decreases in youth consumption of combustible cigarettes. Taken together, these cast uncertainty around recent claims that more dramatic declines in cigarette sales are being *caused* by an uptick in JUUL sales. We think at the very least a few more quarters of consumption data will be required to understand if there is any correlation (let alone causation) of increased JUUL sales and decreased combustible cigarette sales.

Another conference today and tomorrow

The Food and Drug Law Institute (FDLI) annual conference today (May 3) and tomorrow (May 4) will continue to inform our thinking around these and other issues. Panels we think will be particularly helpful:

- Keynote address by FDA Commissioner Scott Gottlieb (May 3 at 9:30 a.m.)
- A panel on PMTA and MRTP regulatory approvals, featuring remarks by **MO** among others (May 3 at 11:30 a.m.)
- A panel featuring remarks and updates by Mitch Zeller (May 3 at 2:10 p.m.)
- A debate between **PM** and Matt Myers, President of the Campaign for Tobacco Free Kids (May 4 at 10:30 a.m.)
- A panel to discuss policy mechanisms that can promote or limit sales of reduced risk tobacco products, including the role of taxation (May 4 at 1:35 p.m.)

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A final topic we are hoping to learn more about at the FDLI conference - the FDA's actions last month to quietly remove some work from its plate

We think it is important to highlight the FDA's April 5 action to clear 1,500 products from its provisional Substantial Equivalence (SE) backlog - giving the agency more time to focus on other regulatory approvals. The FDA announced that it would remove approximately 1,500 products out of 2,500 total from review under a transitional SE program from the early days of tobacco regulatory control. Essentially what this announcement means is that the FDA has removed a lot of work it had cut out for itself, while simultaneously allowing a number of tobacco products to indirectly receive the agency's approval to be sold in the United States. The SE regulatory pathway is important in that it is intended to provide tobacco companies with a less burdensome approval pathway relative to the Premarket Tobacco Application (PMTA) pathway for new products. Companies may submit SE applications when they introduce products that are highly similar to existing tobacco products on the market. Removal of these 1,500 products from the so-called "provisional" SE review allows them to stay on the market without needing any additional blessings from the FDA.

Why investors should care: glo, the BATS:LN heat-not-burn product, will require SE regulatory review and approval before it can be sold in the U.S. Clearing the backlog of SE reviews facing the FDA should be incrementally positive to British American Tobacco, which intends to submit an SE application for its glo product. There is some information around how long new SE application reviews take - the FDA self-reports that in FY 2017 it completed these reviews for 73% of applicants within 90 days of submission for cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco products. The FDA does not disclose the length of time for review for the other 27% of applicants in FY 2017. We would expect BATS to categorize glo as a cigarette in its SE application (as **PM** did with IQOS in its PMTA application - the reason for this is that the e-cigarette / alternative products category regulatory approval pathway is in its nascent stages). But it would still be the first heat-not-burn product to move through the SE pathway (just as IQOS is the first heat-not-burn product to move through the PMTA review process), so that's likely to make the review more complicated relative to other SE applications. We expect to learn more about the FDA's thinking around a possible glo SE and MRTP request at FDLI later today and tomorrow.

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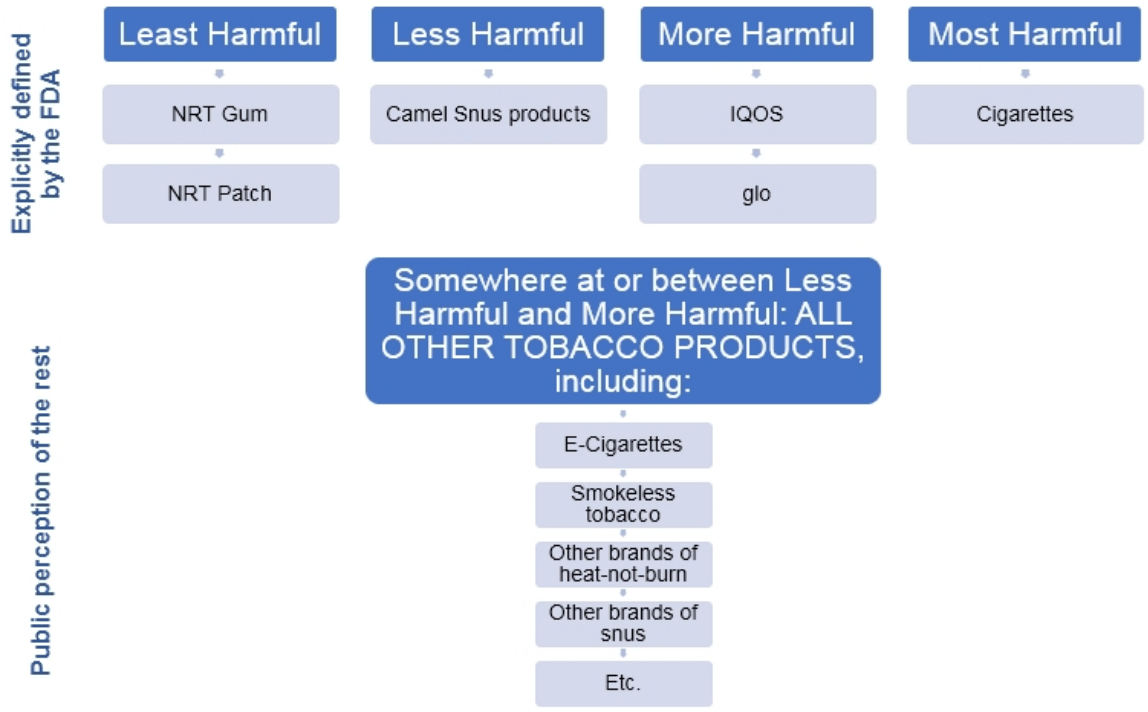
Figure 1: Height projection of the tobacco products harm continuum - Expected state of play by YE 2019



Source: Height analysis and projections

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COMPANIES MENTIONED IN THIS REPORT

British American Tobacco PLC (BTI), Imperial Brands PLC (IMBBY), Imperial Tobacco Group PLC (IMT.L), Altria Group Inc (MO), Philip Morris International Inc (PM)

RISKS

The legislative and regulatory agendas are subject to change at the discretion of leadership. Unprecedented economic conditions could instigate unanticipated and/or sweeping shifts in policy. Predicting the future is a hazardous endeavor and economic / market forecasting is an imprecise science. Actual outcomes may differ substantially from our forecasts. The predictions and opinions expressed herein are subject to change at any time.

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I, Stefanie Miller, certify with respect to each security or issuer covered in this research report that (i) the views expressed in this research report accurately reflect my personal views about those subject securities or issuers and (ii) no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed by me in this research report.

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