

Four Things for Tobacco Investors to Watch This Fall

- We see four main Washington issues that tobacco investors will need to watch this fall: tobacco language in the pending Trans-Pacific Trade Partnership, FDA's comment period on menthol cigarettes, and likely FDA proposals to regulate e-cigarettes and flavored cigars.
- This note provides our quick thoughts on timing and outcome for these topics, as well as links to our past coverage.
- We continue to see close to zero real effort by the Obama Administration or public health groups to push the proposed tobacco excise tax increase included in the White House's FY14 budget so do not discuss it here.

Menthol

In July, FDA issued an Advanced Notice of Proposed Rulemaking (ANPR) soliciting stakeholder input on whether and how the agency should regulate menthol cigarettes. The agency provided 60 days for public comments, which will likely be extended another 30, pushing the comment close date to October.

Although the comment period closing is not necessarily an actionable event for investors, it's a tick of the clock for FDA's very deliberate decision making process regarding menthol. ANPR's are an optional step in the regulatory process and are seldom used, so the agency is clearly going out of its way to show it is being very thorough.

FDA is likely to receive hundreds of comments that will take months to review, and we do not anticipate it will choose a course of action until at least the second or third quarter of 2014. And from there any potential regulation will face several months of review by the White House's Office of Management and Budget (OMB), the last step in the regulatory process, so it may be late 2014 at the earliest before a proposed rule (assuming there is one) is released.

Please see our extensive coverage of FDA's menthol consideration [here](#).

Trans-Pacific Trade Partnership (TPP)

The US and 11 other countries bordering the Pacific Ocean are negotiating a trade pact regarding agricultural and other products that Senate leadership has eyed for floor consideration this fall. For tobacco, last year the Obama Administration sought to include provisions in the pact to prevent tobacco companies from using trade agreements to challenge countries' anti-smoking laws. However, after an outcry from the tobacco industry, business groups and tobacco state congressmen, the

administration backed off and moved to watered down language that only requires pact countries to consult each other before waging a trade dispute.

At issue is whether negotiators might revert to the more stringent tobacco provisions or whether tobacco products may be specifically prevented from taking advantage of trade terms in the pact, as anti-smoking groups are advocating. So far, tobacco companies have supported Ukraine, Honduras and Dominican Republic trade challenges against Australia laws that require cigarettes to be sold in generic packages. And Indonesia filed and won in 2012 a World Trade Organization complaint against the US's ban on flavored cigarettes that lead US trade negotiators to initially seek the stronger tobacco language in the TPP.

We give 25% odds that more stringent tobacco language or a carve out will be included in the final version of the pact. Tobacco is a side issue in the broader trade agreement, and we doubt the White House would want to risk a tough vote in the Senate over it. However, negotiators have opted to delay a final decision on tobacco after Malaysia offered a proposal to protect countries' tobacco laws, and the outcome of the TPP will likely determine how tobacco will be handled in future trade agreements, so it bears watching.

E-Cigarettes

FDA continues to say it will issue proposed regulations this October to regulate or "deem" several products that were not included in the Tobacco Control Act of 2009, which we are confident will include e-cigarettes. Recall that the law only covers cigarettes but provides the FDA authority to extend regulations to other products if it chooses to do so. Although FDA has missed several other self-imposed schedules on deeming regulations, we believe the menthol ANPR shows that it is working through its agenda with a greater sense of urgency than in the past.

Assuming FDA deems e-cigarettes tobacco products, we would expect the agency to propose restricting sales to individuals 18 and over, limiting points of sale, and application of FDA manufacturing standards, at least for vapor cartridges. The good news for manufacturers is that deeming regulations would follow the standard proposed rule-comment period-final rule regulatory process that can easily take months, if not years, and allows for industry opportunity to influence the process.

Although no industry welcomes additional product regulation, we think deeming could be a positive for large tobacco players like LO, MO and RAI that have recently moved into the e-cigarette space. We believe all have the experience and infrastructure necessary to comply with possible new e-cigarette regulations fairly easily. This is unlikely to be the case for the small e-cigarette only companies that have dominated the market in the past, which could potentially reduce competition and create takeover opportunities for traditional cigarette manufacturers, as we discuss [here](#).

Flavored Cigars

A recent Center for Disease Control report showing that flavored cigars have eclipsed cigarettes as young/underaged smokers' preferred product have spurred public health groups and several of their allies in Congress to pressure FDA into banning the products. Sources indicate that FDA is likely to seek to ban flavored cigars under its

deeming authority, again possibly in October, but the agency has struggled with how to ensure that such a ban would not impact traditional large cigar manufacturers.

We think FDA will eventually proceed with a ban, and the CDC report and increased Congressional attention could help ensure it is proposed by the end of the year. However, like e-cigarettes, deeming regulations for flavored cigars would have to be completed via the lengthy agency rulemaking process.

While flavored cigar companies are not publicly traded, a successful ban on the products would be a notch in the belt for FDA tobacco center head Mitch Zeller that could inspire him to take a harder, faster line on other issues, like menthol, than we'd otherwise expect. On the flip side, flavored cigar manufacturers are likely to file a legal challenge against any regulation that bans the products, which could strain agency resources and slow the clock on other topics.

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