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### Tobacco: SFATA Conference -- Key Takeaways

Tobacco

- **E-Cigarette/Nicotine Debate Needs to be Re-Focused on Opportunity to Reduce Net Population-Level Harm Caused by Smoking** – We attended the Smoke-Free Alternatives Trade Association (SFATA) Conference outside of Chicago, “headlined” by Mitch Zeller, Director of the FDA's Center for Tobacco Products. Encouragingly, Director Zeller underscored the importance of “opening up the dialogue” across various stakeholders in the nicotine space, suggesting to us that he and the agency remain committed to using science and data to shape regulation while recognizing the nicotine continuum of risk which is consistent with his previous comments. **Director Zeller even remarked that conference participants were “preaching to the choir” with regards to the need for the debate to change.** Other takeaways from Director Zeller: **(1)** The societal debate around e-cigs needs to be re-focused on “issues that really matter” – namely what role e-cigs or other potentially less harmful, non-combustible nicotine delivery systems could play in net population-level harm reduction, potentially reversing the trend of 500K Americans dying annually from tobacco-related harm; **(2)** The issues driving the e-cig/nicotine debate center around youth access, flavors, and marketing, which are undoubtedly very important but have diverted attention from the bigger-picture issues as described in #1; **(3)** The FDA has “taken seriously” the comments, considerations and concerns of small manufacturers who don't have the financial and human resources of Big Tobacco; and **(4)** The FDA is engaged with other FDA “centers” – particularly the Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH) to explore the role of “therapeutic nicotine.” **Bottom line - we remain cautiously optimistic that the FDA “gets it” with regards to a nicotine risk continuum that will ultimately be reflected in regulation. We remain bullish on vapor long-term, but near-term we're more cautious given increased uncertainty.**
- **Rare, Sizeable Opportunity to Reduce Smoking Harm and Generate Profits – Ups the Ante for Industry to “Get it Right”** – A consistent theme throughout the day was the need for alternatives for smokers who can't or won't quit, within a “continuum of risk” framework. To achieve this, there were calls to put the “tobacco wars and mentality that goes with it” behind us, take “emotion and rhetoric” out of public debate, and accept the vaping industry must be regulated within a relative risk framework. Further, encouraging examples were cited from public health domains/industries that have embraced harm reduction such as methadone clinics for drug abusers or the auto industry developing safer vehicles. **Bottom line – the vapor industry needs to “rise up” and “take the spotlight” away from the anti-e-cig camp which is taking the spotlight right now, promulgating negative public perception.**
- **Deeming Regulations – Industry Encouraged to Think About Regulatory World and Stay Active/Engaged with Regulators** – Once the deeming rule is final, it will go to the OMB (Office of Management and Budget) for review (it'll be publically known that the rule is at OMB but not what it says). The OMB's cost/benefit analysis typically will likely take 3-6 months. Regardless of what the final rule entails, conference speakers encouraged the industry to start preparing (compiling ingredients lists, implementing manufacturing standards, etc.), even though implementation and enforcement of the regs will likely take years in our view. Further, the final rule could be more of a “guideline” in nature with guidance being issued over time to govern the specifics as one speaker suggested the FDA has historically regulated by “guidance” which triggers certain specific requirements as the industry evolves.

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