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E-Cigarettes: The Congressional Noise Before the Regulatory Storm

House and Senate Democrats have unleashed a barrage of attacks on e-cigarettes over the past several weeks, highlighting an increase in emergency room visits linked to children swallowing cartridge liquid and urging FDA to strongly regulate the products.

And yesterday the House Energy and Commerce Committee held its first tobacco hearing since 2010. Democrats used much of their time to slam e-cigarettes and confirm with a Government Accountability Office (GAO) witness that FDA has the necessary authority to regulate the products much the same as cigarettes, including banning flavors that might appeal to children. The answer was yes, and we continue to believe that FDA will take that route.

For their part, Republicans used the hearing to criticize FDA's slow pace on reviewing industry substantial equivalence (SE) applications. The GAO has urged the agency to address this backlog, as well, finding in a 2013 report that the agency has completed only 30 of the roughly 4,500 applications that have been submitted so far.

On paper, the hearing was intended to discuss legislation to establish FDA tobacco user fee performance benchmarks. But we think it was likely geared more toward giving members an opportunity to speak their piece before FDA's proposed deeming regulations pertaining to e-cigarettes and other products are released. It is notable that all this attention comes as Congress is about to depart for its two week Easter recess, which could mean members have received some indication that the regulations could be released during that time.

Commissioner Hamburg has only publicly told the Hill that e-cigarette regulations will be released "very soon," but we wouldn't be surprised to see the deeming regulations by the end of this month. In the meantime, Congress has little influence at this point on how FDA will propose handling "deemed" products like e-cigarettes - the regulation has been pending with the White House's OMB since October. While the OMB can be lobbied, we see members' recent comments about e-cigarettes as mostly noise.

For more resources on e-cigarettes, please see our earlier coverage [here](#). Also, please join us for our weekly Thursday spotlight call tomorrow at 11am ET, where we will cover the regulatory risk for the consumer staples space, including tobacco. The call dial-in is 877-641-3135 / code 19981318.

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