Hearing: Aggressive E-Cigarette Marketing and Potential Consequences for Youth
Date of Hearing: June 18, 2014

Written Questions for the Record from Senator John Thune for
Mr. Scott Ballin

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*Question 1.* Mr. Ballin, as we consider possible regulation of e-cigarettes, how do we ensure that the smaller players in this market can compete with the larger, more established tobacco companies, so as to encourage innovation that might lead to continued improvement and safety of the products?

**Answer:** First and foremost, there needs to be regulatory oversight of this rapidly growing industry. Second, protection of the public health must be given the highest of priorities but without stifling innovation and competition within the market place. Smaller companies that are true innovators, accept the importance of regulation, and have public health considerations as part of their business plans need to be given additional incentives and possibly allowed a longer period for adjusting to the market place regulations. This is something that is not unique to tobacco and nicotine products and has been applied by the FDA in areas such as food. The Center for Tobacco Products already recognizes the distinctions between small and large tobacco product manufacturers and the Tobacco Products Scientific Advisory Committee (TPSAC) has non-voting slots for both large and small manufacturers. While these slots reflect more traditional products and manufacturers it might be possible to add slots for novel alternative products - both large and small. That said, merely because a company is a smaller player should not be a justification for the development or marketing of an inferior product. It will be critical that as FDA moves forward with its deeming regulations and sets product standards that all players have ample opportunity to participate in the process.

*Question 2.* Mr. Ballin, in your testimony, you mentioned your work with the Institute for Environmental Negotiation at the University of Virginia on holding a series of safe haven dialogues to discuss tobacco and nicotine issues. At the hearing, Senator Blumenthal spoke about his work on the Big Tobacco lawsuits and settlement and asked Mr. Healy (blu eCigs) and Mr. Weiss (NJOY) about their willingness to "come together to sit down, to commit to reaching a settlement, an agreement, a protocol that stops any possible ads and pictures that appeal to children and teenagers." While I think it may be a bit early to produce another master settlement agreement like that which was entered into between the four tobacco companies and the state attorneys general in 1998, do you have any further thoughts on how the industry and other stakeholders can get together to develop voluntary best practices for the industry?

**Answer:** My experience over the years, both as an active participant in dialogues (as part of the American Heart Association, the Coalition on Smoking OR Health, and the Campaign for Tobacco Free Kids) , and now in working with the University of Virginia, is that 'safe-haven' engagement with stakeholders and other experts does work. I appreciate Senator Blumenthal's raising the issue of 'sitting down' but I don't think it should be for the purposes of 'negotiating a settlement.' The e-cigarette industry is not 'Big Tobacco' and is very diverse and as I said, the tobacco and nicotine environment is one that is rapidly changing with many challenges but more

importantly many **opportunities**. Also critical is that unlike the days of the Master Settlement Agreement (MSA) we now have a fully funded regulatory agency in place where the bulk of the work can be done. As one who was actively involved in the 'wars' with and against 'Big Tobacco,' I think we need to realize that, as I and others have said, including FDA/CTP Director Zeller, we are in a 'New Era.' We have a very unique opportunity to shape policy that both protects children and youth from the aggressive advertising and marketing of all tobacco and nicotine products (as well as access and use) and at the same time allows the 40 million smokers in this country the opportunity to switch to science-based lower risk products such as e-cigarettes. As to how we can move forward, there are a number of avenues to take. One is for the Food and Drug Administration to play a more active leadership role in convening workshops and generally engaging with a broad spectrum of stakeholders and interests in a transparent manner. Two is for interested stakeholders and interested parties to take an active role in the rule making process. Three is for there to be more private sector discussions in forums like those at the University of Virginia as well as in other venues, such as at the Food and Drug Law Institute, scientific conferences and other tobacco and nicotine conferences. Out of such meetings, forums etc there could possibly come a set of guiding principles developed specifically aimed at the e-cigarette industry that could be used as a tool to govern industry behaviors and practices as we await FDA regulations. During the hearing Chairman Rockefeller seemed to take the view that 'sitting down' and actively engaging in discussions in a 'safe-haven' venue was an act of futility. My own experiences and what I have seen accomplished at the FDA and in other forums respectfully, suggests otherwise.