



# SRNT

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March 22, 2017

The Honorable Greg Walden, Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

Re: H.R. 1136, the FDA Deeming Authority Clarification Act of 2017

Dear Representative Walden:

This letter is to convey strong opposition from the Society for Research on Nicotine and Tobacco (SRNT) to H.R. 1136, the FDA Deeming Authority Clarification Act of 2017.

H.R. 1136 would exempt e-cigarettes, cigars, and other tobacco products from an important product review designed to protect public health. Under the Family Smoking Prevention and Tobacco Control Act (TCA), which Congress enacted with bipartisan support in 2009, any tobacco product introduced to the market or modified after February 15, 2007 must be reviewed by the FDA. This scientific review enables the FDA to assess a new tobacco product's health harms and addictiveness. It ensures that the decision to market a potentially addictive and harmful product is not left to manufacturers alone and is based instead on an independent assessment of the product's effect on public health. H.R. 1136 would fundamentally change the TCA by exempting from this FDA review e-cigarettes, cigars, and certain other tobacco products that entered the market between February 15, 2007 and August 8, 2016.

FDA's authority to review new tobacco products correctly places the responsibility on manufacturers to provide information that will enable the FDA to assess the risks of these products to consumers and the broader public. Manufacturers should inform the FDA about what these products contain, how they are made, and what their health risks are. Without this authority, FDA would be left in the dark about important aspects of these products and its ability to protect public health would be significantly weakened.

The FDA has issued a draft of guidance for the industry to apply for Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems. Careful reading of this document shows that the FDA is mindful of the complexities involved in the application process and is willing to work flexibly with applicants to ensure successful outcomes when warranted. (<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM499352.pdf>)

SRNT is acknowledged in the TCA as an expert source for providing guidance to the FDA in how best to regulate, promote, and encourage the development of innovative products and treatments, including nicotine-based and non-nicotine-based products and treatments. Our focus is on ensuring that state of the art science is used to develop public health policy. We believe H.R. 1136 would significantly impair the ability of science to inform tobacco/nicotine policy.

We urge you to oppose this legislation.

Sincerely,

Judith J. Prochaska, PhD, MPH  
President, Society for Research on Nicotine & Tobacco  
Associate Professor of Medicine, Stanford University