

Electronic Vaping Coalition of America

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July 17, 2017

Food and Drug Administration – United States Government
Scott Gottlieb, M.D., Commissioner
10903 New Hampshire Avenue
Silver Spring, MD 20993-002

Dear Commissioner Gottlieb:

The Electronic Vaping Coalition of America congratulates you on being confirmed and on the manner in which you straightforwardly presented your expectations in your opening remarks to your Department. It is encouraging to know that you are looking to quality science and information as the base for regulation of electronic vaping.

Our Coalition has worked tirelessly to demonstrate that the Deeming Regulations now in place are harmful to a sound policy of protecting public health, safety and welfare which is the principal mission of your Department. We have submitted written and verbal comments to meetings and hearings all over the country, urging the same restraint requested in a letter of June 14, 2017 penned by Iowa Attorney General Thomas Miller. Writing for an amazingly broad, celebrated team of scientists and policy makers, General Miller wrote: “It is clear beyond reasonable doubt that vapor products present lower risks to nicotine users than smoking.” Yet, as he points out, the Regulations place more restrictions on the safer products than are placed on the dangerous traditional cigarettes.

We agree with the premise in General Miller’s letter that there must be some appropriate regulations to guide the use of the vaping devices and liquids. Such regulations will flow from the legislation which Representative Duncan Hunter of California has introduced in the House of Representatives. His legislation aims to repeal the current regulations and replace them with regulations appropriate to the accurate relative characteristics of the products being reviewed.

His legislation recognizes that the regulations in place do nothing toward moving the veteran smoker from lighting up a combustible cigarette to use of a vaping device that is safer for him and gives off no harmful second hand smoke. The Deeming Regulations now in place are far too restrictive for products shown conclusively to be lower risks than traditional combustible cigarettes. They condemn far less harmful products to more severe restrictions than those applied to traditional combustible cigarettes. In fact, as General Miller pointed out “the more risky cigarette products have been ‘grandfathered’ and thousands of cigarette brands are on widespread sale without ever having faced an approval process.”

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We suggest you consult with your accountant or legal advisor.

While the more dangerous cigarettes are on sale, the manufacturers of the safer electronic products face enormous costs for testing without benefit of clearly stated standards by which the tests will be administered and judged. The estimates made by your Department before your appointment are that application costs of up to \$2.5 million PER PRODUCT can be anticipated. It tests the credulity of our executive-legislative system that such amounts can even be mentioned in serious discussion. They are so monumentally prohibitive as to virtually guarantee that the vaping industry will go out of business. General Miller said his talented group of experts “are concerned that the impact of the deeming rule will eliminate almost all of the vapor products that form the market.”

Some people have taken the position that it would be a hard carry for us to file a lawsuit based on failure to coordinate as required by federal statute, and based on deprivation of due process of law and equal protection of law. But several attorneys and constitutional specialists see it differently. They see a case in which a merchant is subjected to an exorbitant fee for submitting his product for approval without knowing what standards and criteria he must meet and satisfy for approval. They see it as a case in which the merchant is subjected to that uncertainty at great expense without the benefit of having any kind of hearing---even of the most informal known to man---. To subject a person to that uncertainty, and the enormity of the sacrifice with no pre-cost hearing, even informal in nature, would cause our Founders to blanch.

The breadth of support shown by those who signed General Miller’s letter is astounding and should go a long way in persuading you to act in the best interests of the community. Just a few months ago, one would not have predicted that a letter like that of the general would be signed by experts from the Yale School of Public Health, University of Minnesota, Dean for Global Public Health, New York University College of Global Public Health, University of Chicago, Director for Global Tobacco Control, Harvard T.H. Chan School of Public Health, Yale University School of Medicine, University of Ottawa, Centre for Health Law, and Director Smoking Cessation Leadership Center University of California, San Francisco.

The expertise represented in that group deserves your serious attention. And so, we believe, do the Trustees of Hartland Wisconsin whose findings and conclusions make out the same case as that of General Miller for either abandonment of the Deeming Regulations or again delay their implementation to get either resolution of a coordination case or Hunter’s legislation pass.

Sincerely,



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