

March ___, 2017

Honorable Thomas E. Price, M.D.
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Price:

I write today as a small business owner in the vapor products industry in strong opposition to the FDA's May 2016 Final "Deeming" Rule and ask that you utilize any available options you have to repeal, halt, or dramatically delay this rule. This rule, which has been hastily implemented, does nothing to address product standards or consumer safety issues, and is so overly burdensome that it is tantamount to a ban on these new and innovative vapor products.

Vapor products represent the first real game-changing technology in the ongoing campaign to reduce cigarette smoking and smoking-related disease. In fact, they represent a tremendous example of the free market working! Smokers have been voluntarily switching to these products by the millions, reducing their own health risks from smoking and modeling this better choice for future generations. These products, quite literally, could be the key to finally making combustible cigarette smoking in this country obsolete.

However, the FDA's current one-size-fits-all regulatory approach will remove nearly all vapor products from the market in short order by pulling these non-tobacco products into their regulatory jurisdiction as defined by the 2009 Tobacco Control Act ("Act"). The Act was written in response to the public health crisis generated by combustible cigarettes at a time when vapor products were virtually unknown. The Act actually proposed harm reduction through development of non-smoking alternatives. But, the FDA has taken that well-intentioned legislation and used it to punish a very low-risk, smoke-free product which is the first promising alternative for adult smokers by regulating them even more harshly than combustible cigarettes. However, the FDA issued regulations created for vapor products which do the opposite, actually punishes a very low-risk, smoke-free product and will quash the first promising alternative for adult smokers to come to market in history.

Moreover, FDA has required a retroactive "premarket" review of all products currently on the market. This review process is opaque, prohibitively expensive, and offers no pathway to success even for those who are able to attempt to navigate it. As a result, the deeming regulation not only will eliminate small and midsize vapor businesses from the market but also will protect the dominance of Big Tobacco. Most American manufacturers will begin the process of closing their businesses, rather than even try to gamble on this daunting and risky

Premarket Tobacco Application process. If there are no manufacturers left to make the products, American retailers also go out of business.

If the FDA does not immediately suspend or significantly extend each of the remaining compliance deadlines contained in the deeming regulation, we simply will not survive. Our small business cannot afford the millions of dollars we will be forced to spend in the coming months simply to keep our *existing* products on the market. This means thousands of vapor businesses like ours will be closing their doors, putting tens of thousands of Americans out of work. Furthermore, the millions of consumers who rely on vapor retailers for access to vapor products will be forced to seek out alternative sources. Rather than protecting consumers, the FDA regulations will create a new and vast black market that will operate outside of even common sense regulation.

The urgency of this issue cannot be overstated. With no certainty as to how our businesses might survive beyond any of the deeming regulation's deadlines, we will have no choice but to shut our doors in the coming months.

In order to save our industry and ensure that these life-changing products remain on the shelves, I urge you to take action now to suspend or indefinitely delay all of the remaining filing deadlines under the deeming regulation.

On behalf of America's small and midsize vapor businesses and all of our employees, I thank you for your consideration.

Sincerely,

INSERT:

Name:

Title:

Company name:

Address: