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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

November 21, 2016

CHRISTOPHER R. HIXON, STAFF DIRECTOR
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The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

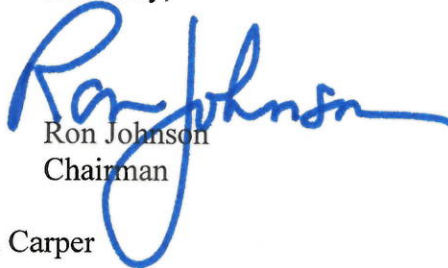
Dear Dr. Califf:

On November 8, the American people voiced their disapproval of the type of government that ignores the input of small business owners, consumers, and job creators. The incoming Administration and the 115th Congress will likely re-examine and unwind burdensome regulations imposed by the Obama Administration. The U.S. Food and Drug Administration's (FDA) deeming regulation of e-cigarettes is a primary example of a rule that could eliminate an entire nascent industry. Accordingly, given the substantial likelihood that this burdensome rule will be undone, I urge the FDA to cease implementation of its deeming regulation to spare the growing e-cigarette industry unnecessary and avoidable compliance costs that it currently faces.

Many stakeholders have raised concerns about the costs this regulation will have on the emerging e-cigarette industry. Christian Berkey, the Chief Executive Officer of an e-liquid company located in Hartland, Wisconsin, has said that the effect of this rule on the e-cigarette industry would be "catastrophic."¹ In light of the significant economic costs on the e-cigarette industry and the substantial likelihood that the incoming Administration and the 115th Congress will unwind this burdensome regulation, I call on the FDA to cease its implementation of the current regulation over e-cigarettes. I hope the FDA will acknowledge the reality of the situation and ensure that small businesses and consumers do not continue to incur avoidable financial costs due to this regulation.

Thank you for your prompt attention to this important matter.

Sincerely,



Ron Johnson
Chairman

cc: The Honorable Thomas R. Carper
Ranking Member

¹ Telephone Call by Chairman Johnson's Staff, S. Comm. on Homeland Sec. & Governmental Affairs, with Christian Berkey, CEO, Johnson Creek Vapor Co. (May 16, 2016).