United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

June 6, 2016

The Honorable Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

The Senate Committee on Homeland Security and Governmental Affairs is continuing to examine the U.S. Food and Drug Administration's (FDA) recent regulation that expands its authority over e-cigarettes. On May 17, 2016, I wrote to request your assistance in understanding the consequences that this new regulation may have on small businesses and the public's health.[1] To date, you have not responded to my letter. Therefore, I write again to reiterate my request for information about FDA's regulation and its potential consequences.

I requested that the FDA provide data on the number of e-cigarette businesses that will be affected by the rule.[2] I also asked the FDA whether it would issue a revised rule if sufficient data demonstrate that e-cigarettes are a safer alternative to traditional cigarettes.[3] Further, I questioned the FDA about the potential unintended consequences of its rule that may result in decreased access to e-cigarettes and increased consumption of traditional cigarettes.[4]

Since I sent my initial letter to you, I have heard from many small-business owners who manufacture or sell e-cigarette products. These job creators have contacted my office expressing their grave concerns about the FDA's regulatory overreach. They fear that the FDA's e-cigarette rule will force them out of business by requiring them to complete costly and time-consuming premarket applications for each e-cigarette product. In addition, a large number of individuals have contacted my office to tell their stories about how they use or have used e-cigarettes to quit smoking. They do not want the FDA to make access to e-cigarettes more difficult for them—or others like them—as they fight to kick an addiction to smoking.

As chairman of the primary oversight Committee of the United States Senate, I urge the FDA to be transparent and accountable in its regulatory actions. I ask that you please respond to my requests for information so that the Committee and the American public may fully understand the FDA's rulemaking and its consequences for small businesses and the public's health. With this in mind, please respond to each of the questions in the letter I sent on May 17,

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[1] Letter from Ron Johnson to Robert M. Califf, M.D. (May 17, 2016).
[2] *Id.*
[3] *Id.*
[4] *Id.*

2016. In addition, because of the significant public interest in this matter, I ask that you please provide all documents and communications referring or relating to the FDA's regulation of the e-cigarette industry.

Please provide this information and material as soon as possible but no later than 5:00 p.m. on June 20, 2016. If the FDA does not provide an adequate response to these inquiries, the Committee may be forced to resort to other means to compel the production of this information. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
Chairman

cc: The Honorable Thomas R. Carper
Ranking Member