United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

July 15, 2016

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:

I write to reiterate my request for information about the U.S. Food and Drug Administration's (FDA) regulation over e-cigarettes and its potential consequences. I first wrote to you on May 17, 2016 requesting information and data regarding the consequences that this new regulation may have on small businesses and the public's health.[1] After I did not receive a response, I wrote a follow-up letter on June 6, 2016 that reiterated my initial questions and requested documents and materials based on FDA communications relating to the regulation.[2] The FDA provided partial responses on June 16, 2016 and July 8, 2016.[3] The FDA's answers to my questions, however, provided only limited new information, and the FDA did not provide a complete document production.[4] While I appreciate the FDA's offer of a briefing, the Committee must first possess the full universe of requested documents and materials to fully understand FDA's decision-making process. Therefore, I write to again reiterate my requests.

In my initial letter, I asked the FDA for data on the number of e-cigarette businesses that will be affected by the rule.[5] The FDA gave an inadequate response that lacked the requisite details. Further, the FDA noted that it did not possess some important information about the economic effect of the rule, writing that "[t]he baseline number of manufacturers and importers of [e-cigarette] products is uncertain."[6] The FDA's acknowledgement that it has, at best, incomplete information raises questions about the adequacy of the FDA's justification for the rule. Further, many job creators in the e-cigarette industry fear that they will be forced to shut down if the rule is implemented. Without a concrete understanding of the rule's effect on a

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[1] Letter from Senator Ron Johnson, Chairman, Comm. on Homeland Sec. & Governmental Affairs, to Robert M. Califf, M.D., Commissioner, U.S. Food and Drug Admin. (FDA) (May 17, 2016).

[2] Letter from Ron Johnson, Chairman, Comm. On Homeland Sec. & Governmental Affairs, to Robert M. Califf, M.D., Commissioner, FDA., (June 6, 2016).

[3] Letter from Dayle Cristinzio, Associate Legislation Commissioner, FDA, to Senator Ron Johnson, Chairman, Comm. on Homeland Sec. & Governmental Affairs, (June 16, 2016 and July 8, 2016).

[4] *Id.*

[5] Letter from Senator Ron Johnson to Robert M. Califf, M.D., (May 17, 2016).

[6] Letter from Dayle Cristinzio to Senator Ron Johnson, (June 16, 2016).

growing industry, the FDA's decision to implement this regulation could lead to the elimination of thousands of jobs and businesses.

Additionally, I asked whether the FDA would issue a revised rule if sufficient data demonstrates that e-cigarettes are a safer alternative to traditional cigarettes.[7] The FDA did not answer this question. Instead, the FDA gave an ambiguous answer, reasoning that the FDA must regulate in order to obtain more information about e-cigarettes. The FDA stated:

> The rule is the *beginning* of the process of the regulation of e-cigarettes, and the other products covered in the final rule. That regulatory framework will evolve over time as we learn more about the products. Now that FDA will finally have regulatory authority over these previously unregulated products, the Agency can expand its knowledge base regarding these products.[8]

The FDA's statement is concerning. Rather than conduct research to better understand the effects of the product prior to regulating, the FDA chose to issue a rule without a proper understanding of the product itself. Because federal regulatory agencies seldom shrink their own jurisdiction, the FDA's action could result in a far-reaching regulation that fails to consider the regulatory impact on small businesses selling e-cigarettes, product innovation, and the public's health.

I also 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.[9] The FDA responded by citing to a scientific paper that concluded that the decline in adolescent smoking rates slowed in states that enacted restrictions on access to e-cigarette products.[10] However, the FDA also cited "several limitations" with the study.[11] The FDA states that it "acknowledges this paper as a first attempt to study the potential impacts of youth [e-cigarette] access restrictions, but more research will be necessary to explore the potential effects of this rule on product switching or dual usage."[12]

In addition to asking the FDA to respond to several questions, I also requested documents and communications referring or relating to the FDA's regulation of the e-cigarette industry. On July 8, 2016 the FDA provided the Committee with an initial document production that consisted of materials that were already publicly available.[13] Based on conversations between my staff and

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[7] Letter from Senator Ron Johnson to Robert M. Califf, M.D., (May 17, 2016).

[8] Letter from Dayle Cristinzio to Senator Ron Johnson, (June 16, 2016).

[9] Letter from Senator Ron Johnson to Robert M. Califf, M.D., (May 17, 2016).

[10] Letter from Dayle Cristinzio to Senator Ron Johnson, (June 16, 2016).

[11] *Id.*

[12] *Id.*

[13] Letter from Dayle Cristinzio, Associate Legislation Commissioner, FDA, to Senator Ron Johnson, Chairman, Comm. on Homeland Sec. & Governmental Affairs, (July 8, 2016); U.S. Food and Drug Administration, A Public Workshop – Electronic Cigarettes and the Public Health, (Dec. 10- 11, 2014), http://www.fda.gov/tobaccoproducts/newsevents/ucm414814.htm; U.S. Food and Drug Administration, June: A

the FDA, I am willing to accommodate the FDA's request to prioritize the production of certain material. As discussed between our staffs, I ask that the FDA initially prioritize its production of documents and communications referring or relating to the FDA's interactions with industry, advocacy groups, government entities, and other stakeholders as the FDA developed its regulation.

The American public deserves complete answers from the FDA about its rulemaking. The information and material that I requested from the FDA will help to inform the Committee's oversight responsibilities and address the public's concerns about the e-cigarette regulation. Therefore, I request that you please provide complete responses to my prior letters as soon as possible but no later than 5:00 p.m. on July 29, 2016. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
Chairman

cc: The Honorable Thomas R. Carper
Ranking Member

Public Workshop – Electronic Cigarettes and the Public Health, (Jun. 1- 2, 2015), http://www.fda.gov/tobaccoproducts/newsevents/ucm439029.htm; U.S. Food and Drug Administration, March: A Public Workshop – Electronic Cigarettes and the Public Health, (Mar. 9- 10, 2015), http://www.fda.gov/tobaccoproducts/newsevents/ucm428317.htm.