

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

CHRISTOPHER R. HIXON, STAFF DIRECTOR
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May 17, 2017

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

Dear Dr. Gottlieb:

Congratulations on your confirmation as Commissioner of the U.S. Food and Drug Administration (FDA). I look forward to working with you as Congress and the Administration strive to repair overregulation that has expanded the size, scope, and cost of government.

Since May 2016, I have been conducting oversight of the FDA's burdensome regulation over e-cigarettes.¹ The rule threatens an emerging industry as well as former smokers who have switched to vaping. The regulation requires e-cigarette manufacturers to complete costly and time-consuming applications to get federal approval to sell e-cigarette products.² Based on some estimates, these applications could cost manufactures, many of which are small businesses, more than \$1 million to complete.³ That is a cost that these small businesses cannot afford.⁴

In December 2016 and February 2017, I wrote to Vice President-elect Pence and Secretary Price, respectively, urging the administration to consider repealing or suspending the FDA's e-cigarette rule. I am pleased that the FDA recently announced that it would delay enforcement of the regulation.⁵ Although that is a positive first step, more must be done to permanently rein in this burdensome rule. As you begin your tenure as Commissioner of the FDA, I respectfully urge you to review the FDA's e-cigarette regulation so that the industry can continue to innovate and offer vapors an alternative to smoking.

¹ See, e.g., Letter from Ron Johnson to Robert M. Califf, M.D. (May 17, 2016), www.hsgac.senate.gov/download/chairman-johnson-letter-to-fda-on-e-cigarette-regulation.

² Michael Siegel, *The FDA's Vaporous Thinking About E-Cigs*, WALL ST. J. (May 5, 2016), <http://www.wsj.com/articles/the-fdas-vaporous-thinking-about-e-cigs-1462487690>.

³ Sabrina Tavernise, *F.D.A. Imposes Rules for E-Cigarettes in a Landmark Move*, NY TIMES (May 5, 2016), http://www.nytimes.com/2016/05/06/science/fda-rules-electronic-cigarettes.html?_r=0.

⁴ Michael Siegel, *The FDA's Vaporous Thinking About E-Cigs*, WALL ST. J. (May 5, 2016), <http://www.wsj.com/articles/the-fdas-vaporous-thinking-about-e-cigs-1462487690>.

⁵ Juliet Eilperin, *FDA delays enforcement of stricter standards for e-cigarette, cigar industry*, WASH. POST (May 2, 2017), https://www.washingtonpost.com/politics/fda-suspends-enforcement-of-stricter-standards-for-e-cigarette-cigar-industry/2017/05/02/be7e557a-2ed6-11e7-9534-00e4656c22aa_story.html?utm_term=.e53f67fe895d.

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Thank you for your attention to this important matter.

Sincerely,

A handwritten signature in blue ink that reads "Ron Johnson". The signature is fluid and cursive, with a large initial "R" and a long horizontal stroke at the end.

Ron Johnson
Chairman

cc: The Honorable Claire McCaskill
Ranking Member