United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

May 17, 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 Committee on Homeland Security and Governmental Affairs is examining the regulatory burdens that federal agencies place on small businesses. On May 5, 2016, the U.S. Food and Drug Administration (FDA) finalized a new regulation that expanded its authority over electronic cigarettes, commonly known as "e-cigarettes."[1] I write to request your assistance in understanding the consequences that this new regulation may have on small businesses and the public's health.

According to the FDA, the final rule extends "the Agency's 'tobacco product' authorities in the [Federal Food, Drug, and Cosmetic Act]," as amended by the Family Smoking Prevention and Tobacco Control Act, to include other products such as e-cigarettes.[2] The new rule prohibits the sale of e-cigarettes to people under the age of 18.[3]

The regulations also require e-cigarette manufactures to submit premarket applications to the FDA in order to obtain federal approval for their products.[4] According to recent reports, the new requirements would force e-cigarette companies to complete a burdensome and costly

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[1] Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, As Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, & 1143); Press Release, Food & Drug Admin., FDA Takes Significant Steps to Protect Americans from Dangers of Tobacco Through New Regulation (May 5, 2016), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm499234.htm.

[2] *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act*, FOOD & DRUG ADMIN., http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm (last visited May 9, 2016).

[3] *Id.*

[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; Jayne O'Donnell and Laura Ungar, *Feds Announce Much Tougher E-cigarette, Cigar Rule*, USA TODAY (May 5, 2016), http://www.usatoday.com/story/news/politics/2016/05/05/feds-expected-announce-final-e-cigarette-rule-could-nearly-ban-them/83951786/; Lydia Wheeler, *Feds Limit Cigar, E-cigarette Sales*, THE HILL (May 5, 2016), http://thehill.com/regulation/healthcare/278824-feds-limit-cigars-e-cigarettes-sales.

application process.[5] Some manufacturers could spend more than 5,000 hours to complete an application, with a minimum cost of $330,000 per e-cigarette product, according to some estimates.[6] As a result of these expensive and time-consuming applications, many e-cigarette manufacturers—most of which are reportedly small businesses—could close down.[7]

According to Christian Berkey, the Chief Executive Officer of Johnson Creek Vapor Company located in Hartland, Wisconsin, the FDA e-cigarette regulations would "extinguish a multi-billion dollar industry and put tens of thousands of people out of business."[8] Mr. Berkey also stated that the new FDA rule would have more than just a burdensome impact on the e-cigarette industry, the effect of the rule would be "catastrophic."[9] In its regulatory analysis, the FDA itself acknowledged that the cost of the rule "would be high enough to expect additional product exit, consolidation, and reduction in variety compared with the baseline."[10]

Unfortunately, the FDA's attempt to improve the public's health by scrutinizing the e-cigarette industry could ultimately result in negative unintended health consequences. The costly impact the rule will have on e-cigarette manufacturers will stifle innovation and make it harder for e-cigarette companies to continue to offer products that serve as an alternative to smoking.[11] It is possible that without a cost-effective alternative, some consumers will resort to traditional cigarettes.

In order to assist the Committee in better understanding the FDA's decision to expand its authority on e-cigarettes, I ask that you please provide the following information and materials:

1. The final rule notes that the FDA does "not currently have sufficient data about e-cigarettes and similar products to fully determine what effects they have on the public health."[12] Further, the final rule states that "comments were divided on the safety and toxicity of e-liquids, e-cigarettes, and the exhaled aerosol."[13]

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[5] Michael Siegel, *The FDA's Vaporous Thinking about E-Cigs*, WALL STREET JOURNAL (May 5, 2016), http://www.wsj.com/articles/the-fdas-vaporous-thinking-about-e-cigs-1462487690.
[6] Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, As Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, & 1143); Michael Siegel, *The FDA's Vaporous Thinking about E-Cigs*, WALL STREET JOURNAL (May 5, 2016), http://www.wsj.com/articles/the-fdas-vaporous-thinking-about-e-cigs-1462487690.
[7] *Id.*
[8] 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).
[9] *Id.*
[10] FOOD & DRUG ADMIN., FDA-2014-N-0189, DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT: PRELIMINARY REGULATORY IMPACT ANALYSIS 35 (2014), *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM394933.pdf.
[11] Michael Siegel, *The FDA's Vaporous Thinking about E-Cigs*, WALL STREET JOURNAL (May 5, 2016), http://www.wsj.com/articles/the-fdas-vaporous-thinking-about-e-cigs-1462487690.
[12] Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, As Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,974 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, & 1143).
[13] *Id.*

a. Will the FDA issue a revised rule if there is sufficient data that finds that e-cigarettes are a safer alternative to traditional cigarettes? Please explain.
b. How is the FDA's regulation of e-cigarettes not a premature restriction on an industry given the FDA's admission that it does not have "sufficient data" about e-cigarettes to determine the effects on the public's health?

2. Some stakeholders claim that the FDA's rule on e-cigarettes will stifle innovation and result in the closure of many small businesses that create and sell e-cigarette products.[14]
   a. Did the FDA determine how many e-cigarette businesses will be affected by the rule? If not, why?
   b. If so, please provide that data.
   c. Of the e-cigarette businesses that will be affected by the rule, how many of those businesses does the FDA predict will exit the market as a result of the new requirements?

3. Has the FDA considered the unintended consequences if decreased access to e-cigarettes leads to increased consumption of traditional cigarette and tobacco products? Please explain.

Please provide this material as soon as possible but no later than 5:00 p.m. on May 31, 2016. When delivering production sets, please produce to Majority staff in room 340 of the Dirksen Senate Office Building and to Minority staff in room 613 of the Hart Senate Office Building.

The Committee on Homeland Security and Governmental Affairs is authorized by Rule XXV of the Standing Rules of the Senate to investigate "the efficiency and economy of operations of all branches of the Government."[15] Additionally, S. Res. 73 (114th Congress) authorize the Committee to examine "the efficiency and economy of all branches and functions of Government with particular references to the operations and management of Federal regulatory policies and programs."[16] For purposes of responding to this request, please refer to the definitions and instructions in the enclosure.

[14] Press Release, Vapor Technology Assoc., Vapor Technology Association on Proposed FDA Regulations (April 14, 2016), *available at* https://www.nicopure.com/wp-content/uploads/2016/04/FINAL-VTA-FDA-Release_4-14-16-002.pdf.
[15] S. Rule XXV(k); *see also* S. Res. 445, 108th Cong. (2004).
[16] S. Res. 73 § 12, 114th Cong. (2015).

If you have any questions about this request, please contact Scott Wittmann or Josh McLeod of the Committee staff at (202) 224-4751. Thank you for your prompt attention to this matter.

Sincerely,

Ron Johnson
Chairman

cc: The Honorable Thomas R. Carper
Ranking Member

Enclosure