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United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

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January 17, 2019

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

Dear Commissioner Gottlieb:

I appreciate your willingness to discuss and share information with the Committee about the Food and Drug Administration's (FDA) recent actions regarding e-cigarettes. When you announced that the FDA will limit the sale of certain e-cigarette flavors, you cited data from the 2018 National Youth Tobacco Survey.¹ This survey found an increase in current e-cigarette use among high school and middle school students.² We both agree that e-cigarettes and traditional tobacco products should be kept out of the hands of minors. This data will help us understand the basis for the FDA's actions.

I understand that the FDA has done a fair amount of research to inform its actions. I would appreciate the FDA providing the Committee with any other data, studies, and economic effect analyses it may have used to inform its decision to restrict the sale of flavored e-cigarettes, including any projection of how its recent actions will affect future sales of cartridge-based products and non-cartridge based products.

Also, if the FDA has information about direct sales of e-cigarette products to (1) minors and (2) adults, I respectfully ask that the FDA provide that data to the Committee. It would be particularly helpful to understand how many products are purchased online, in stores with age-restrictions, and in stores without age-restrictions in place.

Finally, I respectfully ask that the FDA explain why it plans to issue guidance rather than a rulemaking to remove certain e-cigarette products from retail stores.

¹ Specifically, brick-and-mortar stores that do not have age-restricted areas or entries, like convenience stores, will only be able to sell tobacco, mint, and menthol e-cigarette flavors. Vape and tobacco shops that do have age-restrictions in place can continue to sell e-cigarette flavors for cartridge-based systems and other open-tank systems. The FDA also announced that it will permit the sale of flavors online for sites that have "heightened measures for age verification." See Press Release, U.S. Food & Drug Admin., Statement From FDA Commissioner Scott Gottlieb, M.D., On Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes (Nov. 15, 2018), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm>.

² According to the FDA, the survey found that, "from 2017 to 2018, there was a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among middle school students. The total number of middle and high school students currently using e-cigarettes rose to 3.6 million . . ." See *Id.*

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Again, I appreciate your willingness to share information with the Committee and look forward to continuing to work with you on this important issue. If you have any questions, please ask your staff to contact Josh McLeod or Scott Wittmann of the Committee staff at (202) 224-4751.

Respectfully,

A handwritten signature in blue ink that reads "Ron Johnson". The signature is fluid and cursive, with the first name "Ron" being particularly prominent.

Ron Johnson
Chairman

cc: The Honorable Gary C. Peters
Ranking Member