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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

KOLAN L. DAVIS, *Chief Counsel and Staff Director*
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September 20, 2018

VIA ELECTRONIC TRANSMISSION

The Honorable Dr. Scott Gottlieb
Commissioner
Food and Drug Administration

Dear Commissioner Gottlieb:

I read with interest your September 12, 2018, statement regarding the Food and Drug Administration's (FDA) enforcement efforts related to the sale and marketing of e-cigarette products to minors.¹ You rightly describe e-cigarette use as an epidemic among our nation's youth that must be stopped. The measures that you are taking to penalize retailers that sell these products to minors and to require manufacturers that are marketing products in violation of federal laws to submit plans on how they will combat use by minors are steps in the right direction.

Your statement and the accompanying press release also raise important questions about the FDA's investigative and enforcement efforts. According to the FDA's September 12, 2018, press release, the agency "issued more than 1,300 warning letters and civil monetary complaints (fines)..."² Although the names of businesses that were warned or fined have been made public on your website, information concerning the amounts of the fines imposed have not.

In addition, the FDA has stated that it is currently "[i]nvestigating whether manufacturers of certain e-cigarette products may be marketing new products that were not on the market as of Aug. 8, 2016, thus falling outside of the FDA's compliance policy, and have not gone through premarket review."³ It is important for the Committee to better understand the FDA's plans to investigate potential violations of premarket review requirements and the history and efficacy of past enforcement efforts.

¹ United States Food and Drug Administration, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use* [FDA Statement] (September 12, 2018). Retrieved from <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>

² United States Food and Drug Administration, *FDA Takes New Steps to Address Epidemic of Youth E-cigarette Use, Including a Historic Action Against More than 1,300 Retailers and 5 Major Manufacturers for their Roles Perpetuating Youth Access* [News Release] (September 12, 2018). Retrieved from <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620184.htm>

³ *Id.*

Please answer the following no later than October 4, 2018:

1. With respect to the 1,300 civil monetary penalty cases, please provide a list of all companies that received an order to pay a fine and the amount. In addition, please note whether the company has paid the fine, and, if not, what steps you have taken, or plan to take, to ensure the fine is paid.
2. What efforts were undertaken prior to September 12, 2018, to identify and penalize manufacturers marketing e-cigarette products in violation of the FDA's premarket review requirements? If efforts were not undertaken, please explain why not.
3. For companies that have marketed and sold e-cigarette products that were not on the market as of August 8, 2016, and have not gone through premarket review, please explain in detail what type of enforcement efforts the FDA has engaged in to bring the companies back into compliance, to include any fines.
4. Will you make responses to your warning letters public and produce them to the Committee? If not, why not?
5. Will you make plans for combatting the youth e-cigarette use epidemic submitted by e-cigarette manufacturers public and produce them to the Committee? If not, why not?

Thank you in advance for your prompt attention to these matters. Should you have any questions, please contact Josh Flynn-Brown of my staff at (202) 224-5225.

Sincerely,



Charles E. Grassley
Chairman
Committee on the Judiciary