PORTAL
Program on Regulation, Therapeutics, And Law

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Dear Ranking Member Jordan:

Thank you for your follow up questions regarding my testimony from the January 29, 2019 hearing entitled "Examining the Actions of Drug Companies in Raising Prescription Drug Prices." Your questions and my answers are listed below.

1) In 2018, FDA Commissioner Scott Gottlieb initiated the practice of publishing brand name drugs on the FDA website that have stymied the ability of competitor drug companies to develop affordable generic drugs. Is this public "name and shame" tactic effective in increasing the availability of generic drugs

No. I'm not aware of any cases in which companies responded to being on the list by making products available. Although it might have happened outside the public view, I would imagine that any manufacturer on the list would likely want to make its actions public. I am also not aware that the list has inspired any sustained public campaigns to encourage manufacturers on the list to stop their generic-delaying action.

2) What additional steps can the FDA take to ensure brand name drugs are not abusing the Risk Evaluation and Mitigation Strategies (REMS) program to block generic competition?

This is a good question. I think that legislation is needed to provide the greatest authority to the FDA (or other authorities) to ensure that REMS do not block generic competition. However, it is possible the FDA could take some additional steps. For example, the FDA could refrain from approving REMS that do not include a system for transferring samples requested by a generic manufacturer, could affirm publicly that conducting such transfers would not be violating the terms of a particular REMS, or facilitate the sample transfer to ensure it is safely done. The FDA could also work with Congressional staff to define what, if any, additional authorities it feels like it needs to reach this goal and whether the additional powers offered by legislation like the CREATES Act are sufficient. It would also be important to make sure that any patents covering REMS are not listed in the Orange Book—the FDA could try to filter those out via rulemaking, or Congress could enact a law to change the Orange Book listing procedure.

In May 2018, the FDA announced that it would try to increase the flexibility for generic manufacturers of drugs covered by REMS to set up their own independent, comparable systems rather than taking part in a single, shared REMS with the brand-name manufacturer. The need to take part in a single, shared REMS had been cited as a block to generic competition because brand-name manufacturers had refused to negotiate with generic manufacturers to develop such a shared system in a timely fashion. Whether this new orientation announced by the FDA last year has facilitated generic entry is something that the FDA should further study.

I was deeply honored by the opportunity to address the Committee in January and am glad to continue discussing these issues, or others, with you. If there is anything I can do to further help your important work in making prescription drug prices more rational for the benefit of patients and the health care system as a whole, please let me know.

Best regards,

Aaron Kesselheim, M.D., J.D., M.P.H.