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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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July 9, 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Michael C. Burgess
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Walden and Chairman Burgess:

I am writing to request that the Energy and Commerce Committee hold a hearing examining the misuse of Risk Evaluation and Mitigation Strategies (REMS) by pharmaceutical manufacturers in an effort to block, impede, or delay competition. The hearing should also explore potential legislative solutions offered by H.R. 2212, the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES) of 2017, and H.R. 2051, the Fair Access for Safe and Timely (FAST) Generics Act of 2017.

As you know, the Committee has received primary referral on both bills. Such a hearing would allow the Committee to better understand how a regulatory program designed to ensure the safe use of certain approved drugs is being used in an anticompetitive manner, and to examine what steps Congress should take to end these abuses in order to facilitate timely approval of high-quality, low-cost prescription drugs.

This hearing is necessary at a time when many Americans simply cannot pay for the medicines they need. Over the years, the availability of generic drugs has helped to make treatments more affordable and accessible for those that need them. According to the Food and Drug Administration (FDA), generic drugs—which are bioequivalent to their brand-name counterparts—have saved our healthcare system almost $1.67 trillion over the past 10 years. This is a substantial cost savings for consumers. The initial availability of a generic drug—the first generic—helps reduce the cost of the more expensive brand-name version. The entry of additional generic versions to the marketplace often leads to further declines in price.

FDA Commissioner Gottlieb has been outspoken about how certain pharmaceutical manufacturers are "gaming" regulatory rules to delay generic competition. According to Commissioner Gottlieb, "in some cases, we know that branded companies are using our rules

that are intended to protect consumers, or meant to make the regulatory process more predictable, and taking advantage of these rules in order to deliberately forestall the entry of expected generic drug competition."[1] Much of FDA's attention related to the "gaming" of regulatory rules has focused on how certain pharmaceutical manufacturers are misusing REMS programs to block generic entry.

Recently, FDA took action to make public a list of companies that are potentially blocking access to samples of their products. This list identified more than 50 companies that have received requests for access to their samples from over 150 generic drug manufacturers. In some instances, generic drug manufacturers still have not received access even after having received a letter from FDA confirming that their safety protections are comparable to that of the reference drug manufacturer. FDA has also issued guidance intended to address some of the back-end abuses of the REMS program by clarifying requirements related to Shared Systems REMS and when waivers might be considered. While these actions are helpful, more must be done to prevent pharmaceutical manufacturers from abusing the REMS program once and for all.

Importantly, a broad coalition of stakeholders have come together to support policy that would help to deter abuses of the REMS and facilitate access to samples that will help with the development of generic alternatives. These organizations include AARP, the American Hospital Association, the Campaign for Sustainable Rx Pricing, America's Health Insurance Plans, Freedom Works, and Pharmaceutical Care Management Association, among others.

Furthermore, the Senate Judiciary Committee has taken action, passing a version of the CREATES Act by a vote of 15-6. This Committee, the lead committee with jurisdiction in the House, must now take action to fully examine these abuses and the potential policy solutions that could deter such abuse in the future.

I would urge you to a hold a hearing soon on the anti-competitive practices of pharmaceutical companies and the abuses of FDA's regulatory programs to delay generic competition. Ensuring robust competition in the pharmaceutical market is one tool to help address the increasing costs of prescription drugs, a concern that I believe all members of this Committee share. Thank you for your consideration of this request. I look forward to discussing this issue further.

Sincerely,

Frank Pallone, Jr.
Ranking Member

[1] Food and Drug Administration, Commissioner Scott Gottlieb, M.D., *Opening Remarks for Part 15 Public Meeting on Generic Drug Competition* (July 18, 2017) (https://www.fda.gov/NewsEvents/Speeches/ucm567323.htm).