Congress of the United States
Washington, DC 20510

June 10, 2020

The Honorable Gene L. Dodaro
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Dodaro:

We write to ask the Government Accountability Office (GAO) to conduct an assessment of the prevalence of rebate traps in pharmaceutical markets and their effects on pharmaceutical pricing, competition, and innovation.

Over the last several years, we have been hearing increasing concerns about the effects of certain rebating practices in U.S. drug markets. While manufacturer rebates can help to lower drug prices, they can also be used in harmful ways to strategically exclude competing products. So-called "rebate traps" (or "rebate walls") may stifle pharmaceutical competition and product development, potentially limiting patients' access to lower-cost generic drugs and biosimilars, as well as new innovative drugs. Due to the lack of transparency in the pharmaceutical supply chain and the complexity of drug pricing and development, taking action against these harmful rebating practices can be extremely challenging. Accordingly, we request that the GAO conduct a study on the prevalence of rebate traps in drug markets and their effects on pharmaceutical pricing, competition, and innovation.

A pharmaceutical manufacturer can set up a rebate trap when it controls access to an established "must have" product – or portfolio of products. Such a manufacturer can use its negotiating leverage to withhold valuable volume-based rebates from buyers unless the buyers grant preferential placement for the seller's products on the buyer's drug formulary. In some cases, the pharmaceutical company will demand that the buyer exclude rival drugs from their formularies altogether or risk forfeiting all rebates on the seller's drugs. Such exclusionary terms can cripple an upstart drug's ability to gain a competitive foothold against the established product.

Rebate traps represent one of the latest in a long line of strategies used by sellers of established branded drugs to entrench the dominance of their products for as long as possible by limiting the ability of alternative drugs to compete. They can be used to undermine the market prospects of new, low-cost generic drugs and biosimilars,[1] as well as new, more-effective branded drugs, limiting patient access to these medications. Although drug buyers may end up paying less in the short-term by submitting to the rebate trap, there is a risk that manufacturers systematically

[1] *See* Eric Palmer, "Could adoption of biosimilars be slowed by 'rebate trap'? Yale experts think so," FIERCEPHARMA (May 5, 2017), https://www.fiercepharma.com/pharma/could-adoption-biosimilars-be-slowed-by-rebate-trap-yale-experts-think-so; Eric Mehr, "Is There an Escape From the Rebate Trap?" BIOSIMILARS REVIEW & REPORT (Jan. 9, 2018), https://biosimilarsrr.com/2018/01/09/escape-rebate-trap/.

suppressing the prospects of lower-cost drugs by manipulating rebates could increase overall drug spending in the long-term. More troublingly, if new drugs cannot effectively enter the market because of rebate traps, biotechnology companies will be less likely to spend the resources required to develop new medicines, which would be detrimental to drug competition, drug pricing, and patient welfare.

There have been some attempts to take action against rebate traps, but these efforts do not appear to have had a significant effect. The Federal Trade Commission (FTC) is reportedly conducting an investigation of Johnson & Johnson's rebating practices in connection with the sale of its biologic drug Remicade.[2] The FTC's investigation of AbbVie's proposed acquisition of Allergan also appears to have involved some consideration of the likely effects of the merger on the combined company's potential rebating, but no action seems to have been taken on that basis.[3]

Given the numerous concerns raised regarding rebate traps and the lack of reliable objective information regarding these practices, we request that the GAO conduct a study on the following issues:

- The current trends regarding the prevalence of rebate traps in U.S. pharmaceutical markets;

- The types and function of rebate traps employed in U.S. pharmaceutical markets;

- The impact of rebate traps on pharmaceutical pricing and overall rates of drug spending; government health care spending; patient health care spending; patient access to prescription drugs; drug competition; physician drug prescribing practices; market entry of new generic drugs, biosimilars, and innovative branded drugs; and incentives to invest in the development of new therapies;

- The impact of pharmaceutical mergers and acquisitions on a combined firm's incentives and ability to impose rebate traps; and

- Policy recommendations to address the harms caused by rebate traps.

In conducting the study described above, we urge you to consult with appropriate personnel at the Centers for Medicare and Medicaid Services, the Food and Drug Administration, and the Federal Trade Commission.

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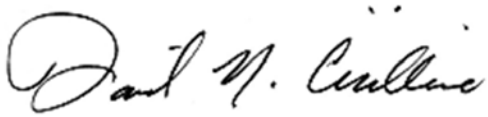
[2] *See* Diane Bartz, "J&J says FTC probing efforts to protect arthritis drug Remicade," REUTERS (July 29, 2019) https://www.reuters.com/article/us-johnson-johnson-ftc-antitrust/jj-says-ftc-probing-efforts-to-protect-arthritis-drug-remicade-idUSKCN1UO27Q.

[3] *See* Statement of Chairman Joseph J. Simons, Commissioner Noah Joshua Phillips, and Commissioner Christine S. Wilson Concerning the Proposed Acquisition of Allergan plc by AbbVie Inc., at 5, 10 (May 5, 2020), at https://www.ftc.gov/system/files/documents/public_statements/1574619/abbvie-allergan_majority_statement_5-5-20.pdf.

The coronavirus pandemic puts into sharp focus the urgent imperative to ensure that critical medications are actually available to patients in need. Thank you for your prompt attention to this request.

Sincerely,

Amy Klobuchar
United States Senator



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Copy to: Joseph J. Simons, Chairman, Federal Trade Commission
Stephen M. Hahn, M.D., Commissioner of Food and Drugs
Seema Verma, Administrator of the Centers for Medicare & Medicaid Services