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The Foundation *for* Research *on* Equal Opportunity

April 5, 2019

Ms. Laura Rush
Deputy Chief Clerk
House Committee on Oversight and Reform
2157 Rayburn House Office Building
Washington, DC 20515-6143

Dear Ms. Rush,

As requested, below please find my answers to the Questions for the Record that were submitted to me with regards to the January 29, 2019 House Oversight and Reform hearing on "Examining the Actions of Drug Companies in Raising Prescription Drug Prices."

QUESTIONS FROM RANKING MEMBER JIM JORDAN

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?*
   —"Name and shame" could be effective in a few instances where companies believe that by responding to this tactic, they avoid more direct statutory or regulatory reform of their practices. But once they perceive that the danger of reform has subsided, they are likely to return to the old tactics. The CREATES Act could help in this regard. So could more vigorous enforcement of anticompetitive practices by the Federal Trade Commission.

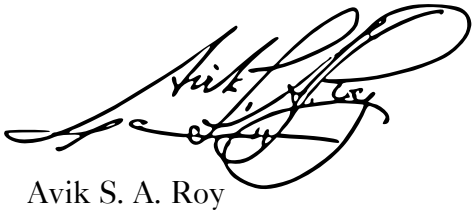
2. *What additional steps can the FDA take to ensure brand name drugs are not abusing the Risk Evaluation and Mitigation Strategies (REMS) program to block generic competition?*
   —As noted above, the CREATES Act is designed to address the problem of companies abusing the REMS program to stymie generic competition. However, it is important to note that abuse of the REMS program is a narrow and discrete problem principally affecting the practices of one company, Celgene. I would encourage Congress to consider a broader effort to tackle anticompetitive practices by branded drug companies when it comes to styming the development of generic alternatives.

QUESTIONS FROM REP. CAROL MILLER

1. *Can you discuss some of the shortfalls of the Affordable Care Act on the cost of prescription drugs?*
   —The authors of the Affordable Care Act were keen to get the pharmaceutical industry's support for their bill. As a result, the bill does many things to drive up the cost of prescription drugs. I discussed a number of them in my written testimony, including: changes to the structure of the Medicare Part D deductible and catastrophic cap, which has resulted in exploding Part D spending; the enactment of the Biologics Price Competition and Innovation Act (Title VII of the ACA), which has stymied competition for biologic medicines; and coverage mandates within ACA plans for branded drugs, handcuffing the negotiating power of insurers against high drug costs.
2. *What steps can Congress take to address the taxes imposed by the Affordable Care Act on prescription drugs?*
   —Congress should repeal the tax on over the counter drugs purchased using an FSA.
3. *Could you elaborate further on the Administration's proposal to create a fiduciary duty for PBMs? Would this be the most effective path?*
   —PBM rebates distort the market by incentivizing overutilization of costly drugs, leading to higher insurance premiums and higher prescription drug prices over time. I fully support the Trump Administration's proposed rule eliminating the safe harbor for PBM rebates, and am encouraged by a supplemental demonstration project, introduced today, that would narrow the risk corridor for Part D plans in 2020 so as to smooth the transition into this new system. For more of my thoughts on the Administration's PBM rule, please refer to my *Forbes* article from February 2, 2019, entitled "Trump's New Pharmacy Benefit Manager Rebate Rule Will Reshape Prescription Drug Prices."
   https://www.forbes.com/sites/theapothecary/2019/02/02/trumps-new-pharmacy-benefit-manager-rebate-rule-will-reshape-prescription-drug-prices/#30d190c440e3

Thank you for the opportunity to testify before the Committee, and I look forward to working with you in the future.

Sincerely,



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