Congress of the United States

Washington, D.C. 20515

July 16, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0991-ZA49
Health and Human Services (HHS) "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs"

Dear Secretary Azar:

We are writing to provide our comments regarding the Request for information (RFI) on the Health and Human Services (HHS) "Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs." We are committed to lowering overall health care costs and prescription spending is a large part of that as it is growing faster than any other part of the health care spending. Prescription drug spending accounts for nearly 20% of all health care costs.[1] One in four Americans reported that they pay more than they did the previous year for their prescription drug.[2] With rising costs it is no surprise that 1 in 7 Americans do not to fill a prescription or take it as directed to save money.[3] As members of Congress, we see the effects of high drug prices every day. Families across the country are struggling to afford the cost of the medications they need. No American should ever struggle to afford their prescriptions. It cannot be ignored and concrete steps must be taken provide Americans the relief they need.

That is why we appreciate the Administration focusing on lowering prescription drug costs. Proposals such as including the list price of prescription drugs in direct-to-consumer advertisements and updating Medicare's drug pricing dashboard are a good start, and we believe that those are important steps to bring more information to patients. However, by ignoring more effective approaches, the proposed policies contained in this RFI would do little to stop the fundamental problem of high list prices and pharmaceutical corporations' unchecked power to raise prices. There are critical cost-lowering approaches that are missing in the RFI, including negotiation. Instead, this RFI explicitly calls for raising the price of prescription drugs abroad, despite the lack of evidence that doing so will result in lower prices at home.

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[1] IMS Institute for Healthcare Informatics. (2012, February). Healthcare Spending Among Privately Insured Individuals Under Age 65.; MedPac. (2015, September). Medicare drug spending.
[2] Consumer Reports Survey: One in Four People Who Regularly Take Meds Hit with Sticker Shock at the Pharmacy. https://www.consumerreports.org/media-room/press-releases/2017/05/consumer_reports_survey_one_in_four_people_who_regularly_take_meds_hit_with_sticker_shock_at_the_pharmacy/, May 16, 2017.
[3] *Id.*

Policies Required to Lower Prescription Drug Costs

1. Negotiation

We support harnessing the purchasing power of the federal government by directly negotiating prescription drug prices under Medicare. As then-candidate Trump stated, "we're the largest buyer of drugs in the world, and yet we don't bid properly." We agree and believe that direct negotiation through Medicare is an effective solution to lower drug prices for seniors and people with disabilities in Medicare. Recent reports have found that older Americans continue to get price gouged by the pharmaceutical industry on widely-prescribed brand-name drugs. Prices increased for all the 20 top most-prescribed brand-name drugs for seniors in the last five years.[4] Those drug prices spiked on average 12% per year- approximately ten times higher than the average annual rate of inflation.

The pharmaceutical market does not operate according to traditional economic principles. Competition is not a silver bullet, and evidence demonstrates that having more drugs on the market does not necessarily bring down high prices. In fact, many times generics hitting the market have led to higher prices. For example, Novartis's cancer drug, Gleevec which treats a deadly form of leukemia, was listed at $26,000 when it first became available; the first generic was list priced around $140,000 annually. Today there are many effective drugs in the same family as Gleevec that cost on average $150,000 per year. That is an example of what economists call "sticky pricing," where each new drug costs more than its predecessors, and other drug corporations increase their prices to match the newcomer's. There is no incentive for pharmaceutical companies to compete against one another when each can profit. That is why direct negotiation is needed to drive down prices. Directly negotiating prescription drug prices under Medicare is not included in the RFI, but would save the federal government between $22 billion to $54 billion annually while also lowering prices for seniors and state and local governments.[5]

2. Transparency

Additionally, we believe that increased transparency of pharmaceutical corporations' drug pricing system would be effective in revealing the true cost of drug production. Currently, patients who buy prescriptions and taxpayers who fund federal research have no way of knowing how much money pharmaceutical corporations spend on research and development, direct-to-consumer advertising, or executive pay. Pharmaceutical corporations' price-setting process is opaque and lacks accountability. Americans watch their prescription drug costs rise year after year for the exact same medication with no explanation. Transparency is necessary to give

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[4] Manufactured Crisis: How Devastating Drug Price Increases Are Harming American's Seniors. https://www.hsgac.senate.gov/imo/media/doc/Manufactured%20Crisis%20-%20How%20Devastating%20Drug%20Price%20Increases%20Are%20Harming%20America's%20Seniors%20-%20Report.pdf, March 26, 2018.

[5] Reducing Waste with an Efficient Medicare Prescription Drug Benefit http://cepr.net/documents/publications/medicare-drug-2012-12.pdf, January 2013.

people answers not only about why some new breakthrough drugs are priced at hundreds of thousands of dollars, but why drugs like insulin that have been on the market for almost 100 years have seen a 240% price spike over the past decade. Transparency reporting requirements would provide basic information and accountability to patients and taxpayers.

3. Ending Patent Abuse

We also call for policies to end patent system abuses that pharmaceutical companies employ to extend market exclusivity and keep drug prices sky high. The longer a drug is patented, the longer pharmaceutical manufacturers have unfettered power to charge whatever they want for a drug. Anti-competitive practices like pay-for-delay deals, patent evergreening strategies that stockpile patents as a defensive strategy rather than genuine inventions that advance new medicines, and Risk Evaluation and Mitigation Strategies (REMS) abuse thwart competitors and keep competition out of the market. There are no proposals in the RFI that fully and comprehensively address those anti-competitive practices.

4. Safe Importation

We also support the safe importation of prescription drugs from other countries, as then-candidate Trump proposed stating, "[a]llowing consumers access to imported, safe and dependable drugs from overseas will bring more options to consumers."[6] We agree that allowing Americans to import safe drugs from other countries like Canada, where prescription drugs cost on average one third less than in the United States, would allow Americans access to lower-priced drugs while introducing more competition in the United States market, putting pressure on pharmaceutical corporations to lower prices at home.

5. Fair Trade Agreements

The RFI is correct that access to affordable medicines is affected not just by domestic but by trade policies. Unfortunately, the trade proposals would make affordable access less – not more – achievable.

The RFI's trade provision centers on "Foreign Freeloading" – the idea that forcing other countries to raise their prices will somehow result in pharmaceutical corporations lowering prices within the United States. The proposal is based on a completely unproven – and highly unlikely – belief that pharmaceutical companies have a set profit level that they want to achieve but will not exceed. In other words, the concept is that if a pharmaceutical company is allowed to raise prices and earn higher profits in Europe or Colombia, they will reduce prices and accept lower profit levels in the United States. There is no reason to believe that drug companies would voluntarily agree to a profit cap. After the enactment of H.R. 1, ten of the largest pharmaceutical

[6] Trump could mean new momentum for drug imports, http://thehill.com/policy/healthcare/medical-devices-and-prescription-drug-policy/314707-trump-could-mean-new-momentum, January 18, 2018.

corporations received a $80 billion tax windfall.[7] The Trump Administration's promise that the result would be lower prices to U.S. consumers has not occurred. Instead, those companies used $50 billion on new share buyback programs to boost their own stock prices, while actually increasing prices.[8] Even if the pharmaceutical industry would agree to a voluntary cap, with some companies earning as much as 42% profits, it is hard to imagine that they would set a reasonable level that would protect taxpayers (who fund R&D) and consumers.[9]

While we do not believe that the Trump Administration's reliance on the "Foreign Freeloading" is a sound idea, we do believe it would have extremely negative consequences. First, we know from experience that higher prices in other countries will prevent many individuals from receiving the essential medicines they need – presenting a global health threat that could affect the United States as well as those nations. Second, the Trump Administration's trade policies not only rely on the pharmaceutical industry to take voluntary action but have pushed our trading partners to accept provisions that would prevent government action if reliance on the industry proves to be unwise. Those trade proposals include 12-year exclusivity mandates for biologics, patent linkage, and other provisions that would tie the hands of Congress and the Administration itself.

Concerns with Policies in RFI

The Administration's blueprint extensively examines rebates, discounts, and the role of pharmacy benefit managers in the drug supply chain, but does nothing to address the primary actor responsible for high drug prices: pharmaceutical manufacturers. Without lowering list prices, any plan will simply fail to rein in costs.

The RFI includes provisions that do not lower drug prices, but would hurt consumers, like attacks on the 340B program which enables hospitals that serve low-income and rural patients to stretch scarce federal resources to reach more patients and provide more comprehensive services. Reports show that 340B hospitals use the discounts provided by pharmaceutical corporations to provide care for more low-income patients through uncompensated care and unreimbursed care than other hospitals.[10] Attacks on this program would do nothing to lower prescription drug prices, but would take away vital resources necessary for safety-net providers, drive health care costs up, and raise overall health care costs as 340B providers are forced to reduce services.

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[7] BAD MEDICINE: How GOP Tax Cuts Are Enriching Drug Companies, Leaving Workers & Patients Behind https://americansfortaxfairness.org/gop-tax-cuts-enriching-drug-companies-leaving-workers-patients-behind/
[8] Pharma's $50 billion tax windfall for investors, https://www.axios.com/pharma-share-buyback-tax-reform-40a30b93-6149-4c67-bd65-cd05ee814215.html, February 22, 2018.
[9] Big Pharma Profits and the Public Loses, Milbank Q, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4941970/, January 13, 2016.
[10] Analysis of 340B Disproportionate Share Hospital Services to Low Income Patients, https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf , March 18, 2018

Additionally, the RFI includes a plan that purports to give Medicare beneficiaries a prescription drug rebate instead of it going to insurance plans, but CMS has already determined this would hike soaring premiums and increase federal spending. Under this plan, CMS found that manufacturers would benefit up to $46 per Part D beneficiary per month and all Part D beneficiaries would see their premiums increased by as much as $44 per month, while taxpayers would spend up to $130 more a month for each Part D beneficiary. While it may lower the prices for some seniors and people with disabilities it raises premiums for everyone. This is because it does not get to the heart of the issue of lowering drug prices. This provision merely shifts the high costs around.

Again, we appreciate the attention to this important issue. But we believe that the proposals included in the RFI would do little to lower drug prices and do nothing to check the pharmaceutical industry's unlimited power to continue to raise drug prices as much as they want. We encourage you to consider the proposals we have outlined to bring meaningful relief for the millions of Americans facing high prescription drug costs and to ensure that we adopt effective solutions.

Sincerely,

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