Government Price Setting Threatens Access to Medicines

So-called government "negotiation" proposals have different names and mechanisms, but they all could open the door to the government deciding which medicines patients can access and which medicines they cannot. That's because many of these proposals undermine important patient protections, rely on deeply flawed and often discriminatory decision standards used in other countries, and impose one-size-fits-all judgments about value. These government price-setting proposals empower bureaucrats to interfere with decisions about which treatments are best for patients and, ultimately, could restrict access to medicines. Independent public polling demonstrates that support for government "negotiation" evaporates once people learn about the trade-offs. According to the Kaiser Family Foundation, for example, 65% of Americans oppose negotiation if it could lead to less research and development of new medicines or if it limits people's access to medicines once they come to market.[i] We need patient-centered policies that will ensure Americans have access to the best treatments, address high out-of-pocket costs, and protect the ability of doctors and patients to make informed decisions about which treatments are right for each individual patient. Government price setting proposals do the opposite.

Government "negotiation" approaches have a history of restricting access to medicines.

Some government "negotiation" proposals would allow the government to set prices based on those paid by foreign governments (also known as "foreign reference pricing") that determine which medicines are worth providing access to and which are not based on the decisions of those foreign governments—regardless of what patients and their doctors think.

Other proposals would implement "domestic reference pricing" which typically would allow the government to develop their own decision standards to determine the clinical benefit or value of a medicine to set the price. These approaches often rely on deeply flawed standards, such as the quality adjusted life year, or "QALY," that discriminate against seniors, the chronically ill and individuals with disabilities. They also often require the government to make a judgement based on what works for the "average patient," which ignores the specific needs, characteristics and preferences of individual patients.

Patients in other countries that use both these approaches to set prices have access to fewer new medicines and wait longer to get the medicines they need. In fact, the United States has access to nearly 90% of all medicines launched between 2011 and 2020, while just 64% are available in Germany, 50% in the U.K., 47% in Canada and 38% in Australia.[ii] Patients also wait longer to access new treatments when these approaches are used. For example, the first transformative CAR-T cancer therapy was available in the United States 7 months before any other country, with patients in countries like Canada and Japan waiting nearly 2 years for it to be available. We cannot accept policies that will result in the creation of a system in which a life-saving cure exists, but American patients might not be able to access it.

Some government "negotiation" proposals would even eliminate critical patient protections in Medicare.

Proponents of many of these proposals also aim to make changes to Medicare to allow the government to set prices under the guise of "negotiation." However, achieving these stated goals would require eliminating critical patient protections and undermine the broad choices and access to medicines that seniors and individuals with disabilities rely on today. Today, the average Medicare beneficiary can choose among 30 stand-alone drug plans or 27 Medicare Advantage drug plans.[iii] Patients are empowered to choose the plan and coverage that works best for them depending on the medicines they need. Broad choice of plans and robust coverage of medicines in Medicare is possible, in part, because of the non-interference provision in the Medicare statute that prohibits the government from interfering in private negotiations that occur in Part D between manufacturers, pharmacy benefit managers (PBMs) and health plans. That same provision prevents the government from creating a single formulary or setting prices in Part D. Many government price-setting policy approaches target repealing this part of the Medicare statute to enable the government to "negotiate" medicine prices directly with manufacturers in Part D.

Unfortunately, these proposals threaten to unravel the patient protections that are relied on by seniors and individuals with disabilities in Medicare. In fact, the Congressional Budget Office (CBO) has repeatedly said that government "negotiation" proposals will only produce further savings for Medicare (beyond those already achieved by private and commercial negotiations) if they are accompanied by a source of pressure on manufacturers to secure additional price concessions, such as removing patient protections or establishing a national formulary that excludes certain medicines from coverage, or if prices are set by the government.[iv] In other words, to achieve savings, these proposals would need to require that the government make decisions that influence which medicines people on Medicare can get and which they cannot.

Government price-setting would stifle research and development of treatments and cures.

Price setting policies would significantly reduce incentives for biopharmaceutical research and development in the United States and disproportionately impact new treatments in areas of serious unmet need—including rare diseases, oncology, and neurology.[v] America leads the world in biopharmaceutical innovation because our unique innovation ecosystem is supported by a policy framework that includes strong intellectual property protections, a well-functioning science-based regulatory system, and coverage and payment policies that reward innovation. But government price-setting policies threaten our innovative ecosystem and would discourage continued investment in R&D. In fact, the CBO's own analysis of the impact of certain price-setting policies, employing conservative assumptions, found at least at least 60 new treatments and cures will be sacrificed over the next 30 years if these policies become a reality.[vi] Another analysis found an even larger impact, with 61 fewer medicines over the next 10 years alone.[vii] These analyses are the latest proof that patients with devastating diseases could be denied access to medicines today and in the future. History also shows what happens when government price setting and other anti-innovation policies discourage R&D investment. In the 1980s and early 1990s, Europe led the world in biopharmaceutical innovation. However, major countries in Europe began implementing stringent price setting and other anti-innovation policies at this time. And by the late 1990s to early 2000s, industry growth in Europe stalled as it accelerated in the United States, making the U.S. the global leader in biopharmaceutical innovation.[viii]

Government price-setting proposals disregard what works well in Medicare today.

Brand medicines in Medicare currently face significant competition in the marketplace from generic drugs, biosimilars and other brand medicines. That is because existing market-driven designs in Medicare Parts D and B balance access to medicines while leveraging this competition to contain costs. For example, in Part D current private negotiations between manufacturers, PBMs and health plans produce sizable discounts and rebates, at levels that continue to grow over time and exceed discounts in commercial insurance.[ix] Part D plans and PBMs negotiated an estimated $44 billion in manufacturer rebates for brand medicines in 2019 alone and about $212 billion from 2011-2019.[x] In addition, the market-based methodology used in Part B to reimburse providers for medicines they administer is heavily influenced by negotiations in the commercial market between payers and manufacturers and has successfully managed costs while ensuring robust and timely access to these medicines for beneficiaries. A recent analysis found that the reimbursement model used in Part B saved the government and seniors a total of $132 billion from 2005 to 2017 in Part B medicine spending.[xi] There is no harmless way for the government to "negotiate" prices for medicines covered by Medicare—whether in Part D or in Part B. Even if targeted approaches to government "negotiation" sound reasonable, they all inevitably lead to the government disrupting the successful private negotiation and payment mechanisms that already exist in Medicare. Instead, policymakers should focus on ways to make sure savings already negotiated in Medicare make their way to patients by lowering out-of-pocket costs.

There are better ways.

There are better solutions than government price-setting that would reduce rising out-of-pocket costs for patients and modernize the Medicare program without upending the health care system or jeopardizing American innovation. These include capping annual out-of-pocket costs for medicines in Part D, lowering Part D cost-sharing, making costs more predictable throughout the year, and ensuring that discounts biopharmaceutical manufacturers already negotiate with health plans and PBMs get directly passed along to patients at the pharmacy counter. Policymakers could also institute a market-based adjustment in Part B to achieve greater savings for the government and beneficiaries while protecting access to medicines and provider reimbursement. Our goal should be lowering out-of-pocket costs and improving patient access through commonsense solutions – not government "negotiation."

i A. Kirzinger et al., **KFF Health Tracking Poll - May 2021: Prescription Drug Prices Top Public's Health Care Priorities**, June 2021.
ii PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration, European Medicines Agency, Japan Pharmaceuticals and Medical Devices Administration, Health Canada and Australia Therapeutic Goods Administration data. Note: Sample includes new active substances launched globally from January 1, 2011 to December 31, 2020. Updated April 2021.
iii J Cubanski, **Medicare Part D: A First Look at Medicare Prescription Drug Plans in 2021**, KFF, October 2020.
iv CBO Letter to the Hon. Ron Wyden, April 10, 2007, CBO Letter to Hon. Max Baucus, CBO Letter to the Hon. Chuck Grassley, May 17, 2019
v Vital Transformation. **H.R. 3 and Reference Pricing. Total Market Impact**. 2021.
vi CP Adams, **CBO's Simulation Model of New Drug Development**, CBO, August 2021.
vii Vital Transformation. **H.R. 3 and Reference Pricing. Total Market Impact**. 2021.
viii ND Pham, M Donovan, **Will US Leadership in Biopharmaceutical R&D Continue?**, NDP Analytics, November 2020.
ix Medicare Trustees Report 2021, **Table IV.B8**
x Avalere analysis for PhRMA of 2015 and 2019 Part D Drug Dashboards, 2020 Medicare Trustees Report, and 2018 Part D Proposed Rule
xi The Moran Company. **Average Sales Price Reimbursement: Significant Savings from Prior Benchmark**, December 2018.