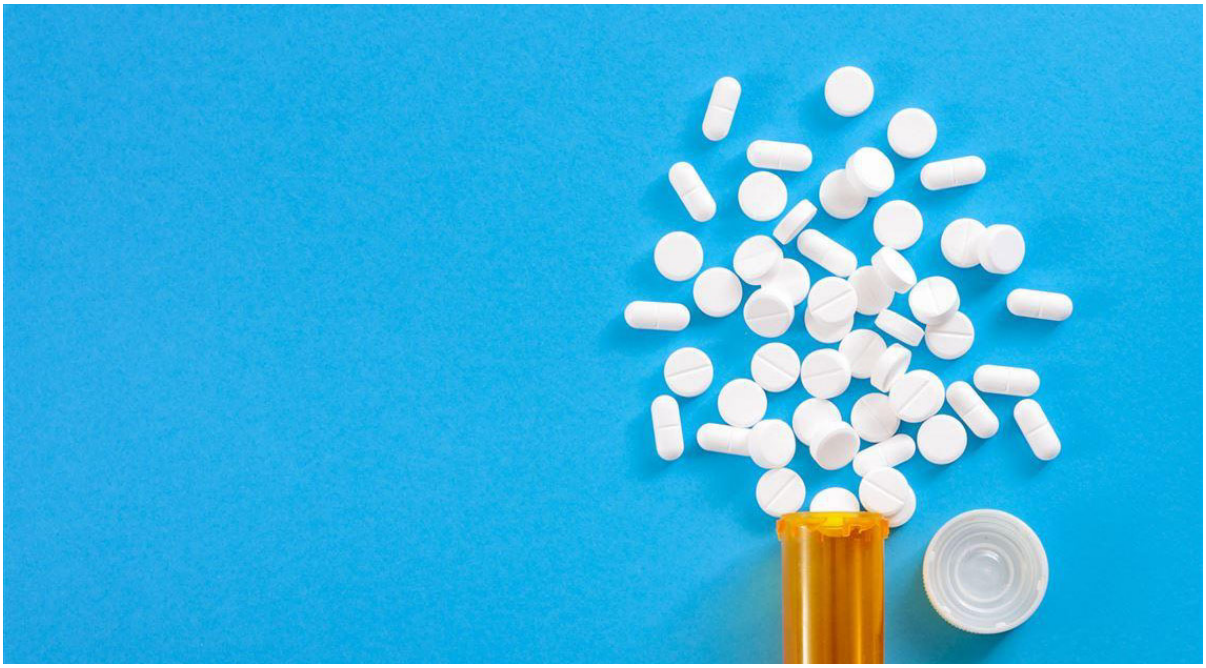

Other Voices: Congress should lower drug costs, but look beyond numbers

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In Congress, policy negotiations often center on a couple questions: how much does the bill cost and how much does the bill save? But the intense focus on these matter-of-fact numbers can have the effect of distancing congressional members from the real-world impact policies will have on Americans.

Congressional caucuses, like the Rare Disease Congressional Caucus which Joe co-founded in 2009, provide members opportunities to hear from people who confront life-altering decisions on a daily basis. Hearing directly from people affected by rare diseases changes the way members consider legislation. It also allows members to lower their political hackles for a moment and get to know each other on a human level.

As our former colleagues begin to consider H.R. 3, the Lower Drug Costs Now Act, we hope they will look beyond the numbers and endeavor to understand the real-world impact of potentially reducing access to

breakthrough drugs or undermining the development of drugs for rare diseases like muscular dystrophy, Lou Gehrig's disease, and other debilitating conditions.

Our friends have the best of intentions. Millions of Americans struggle to afford steep out-of-pocket drug costs, and something must be done to help them.

One provision in H.R. 3 would index U.S. drug reimbursements to the considerably lower prices paid in six other high-income countries. We think it's worth digging deeper into how those countries establish the prices they pay for medicines and be clear-eyed in viewing the negative aspects of those systems.

In the six reference countries — Australia, Canada, France, Germany, Japan, and the United Kingdom — government officials use opaque "health technology assessments (HTAs)" to make drug reimbursement decisions. In some cases, these assessments render certain lifesaving medicines inaccessible to patients.

Pegging our reimbursements to the arbitrary prices generated by those HTAs could saddle Americans with the same access barriers that patients in these other countries currently face, while simultaneously discouraging lifesaving research projects nationwide.

All six of the reference countries have health care systems controlled mostly or exclusively by the government. The governments — not doctors and their patients — decide which medicines should be used to treat patients.

Government agencies conduct health technology assessments to determine which medicines should be covered, and at what prices. The HTA process in several countries is often likened to a "black box" by interested parties — a medicine goes in one end and a decision comes out the other. But no one really knows the exact methodologies used to make those decisions.

Take Australia for example. The Australian system focuses on "value for money." That is, the agencies won't recommend a new drug that's "too expensive" in relation to the clinical benefits it provides.

Value for money is an inherently subjective metric. How much is a human life worth? If a new $10,000 a month cancer drug extends some patients' lives by only a few months, but sends a minority of patients into remission for years, is it worth trying?

There's no one objective answer. But in the United States, doctors and patients get to make those decisions for themselves. In the reference countries, government officials make that call. And they often decide that new drugs aren't worth the cost.

Consider Germany. The country's Federal Joint Committee (G-BA) deems 54% of new medicines to be no more clinically effective than those already on the market. From 2013 to 2017, half the new cancer drugs the Germans judged to be no more effective than those on the market were considered breakthroughs by the FDA.

Such decisions help explain why Germans had access to just 64% of all new treatments launched globally from 2011 to the end of 2020, while Americans had access to 86% of those medicines. From a numbers perspective, a 22-percentage-point difference might not feel all too big, but it's huge from a human perspective.

Germany isn't an anomaly. The British have access to just 60% of those medicines, the Japanese 52%, the French 48%, and the Canadians 47%. Australians have access to a paltry 38%.

Proponents of H.R. 3 must ask themselves if it's worth indirectly importing these access restrictions to America. Because that's exactly what would happen. Pegging reimbursements to the arbitrary prices in those reference countries could discourage some drug firms from launching their medicines in the United States.

And in the long run, it would dissuade firms from investing in new research projects.

These private sector firms fund a majority of biopharmaceutical R&D in the United States, more than $100 billion annually, to be exact. The NIH, by comparison, put just under $3 billion toward pharmaceutical clinical trials in 2018.

The scientists at American biopharmaceutical firms undoubtedly enjoy bringing new lifesaving medicines to patients. But these companies won't pour billions of dollars into challenging R&D projects if the resulting medicines stand no chance of earning a return. R&D spending could plummet if H.R. 3's main components become law.

Lowering patients' pharmacy bills is an urgent and necessary goal — but cutting off Americans' access to lifesaving drugs and undermining the

development of future treatments isn't the right solution.

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