The Price of Progress: Managing Prescription Drug Spending

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What is the price of progress? That question is central to debates over regulating the pharmaceutical industry and managing spending on drugs. In recent years, there has been incredible scientific progress, illustrated by the rapid development of highly effective COVID-19 vaccines. The COVID story demonstrates the critical role that government can play by investing in and negotiating prices for therapies that have large public health benefit. Purchase agreements reduced the financial risk for pharmaceutical manufacturers investing in these products and helped to ensure broad public access to COVID vaccines.

But in the United States, government's role in ensuring access to medications is often more circumscribed, and scientific progress is often accompanied by serious challenges. For instance, the advent of curative therapies has transformed treatment of hepatitis C, yet the lack of a coordinated national strategy for patient access has left many people untreated, despite the ability to cure this infectious disease in weeks (U.S. Senate Committee on Finance 2015). In myriad other cases, pharmaceutical companies have engaged in predatory pricing behavior, gamed the patent system to preserve brand-name market share and withhold lower-cost generic drugs from patients who need them, and adopted exorbitant list price increases that reduce access to medications for the uninsured and underinsured (Feldman 2019; Human Rights Watch 2022; I-MAK 2020; Kodjak 2018; Pierson 2017). Although insulin has been around for a century, rising prices have forced many people with diabetes in the United States to ration that essential medication (Fralick and Kesselheim 2019).

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Medicare enrollees often do not fill prescriptions for cancer and other specialty drugs because of the costs they face as a result of high prices and the limits of Medicare's drug coverage (Dusetzina et al. 2022). And out-of-pocket costs for medications in both public and private insurance contribute to the "financial toxicity" of cancer care that burdens many patients with costly bills and leads them to forgo treatments (Zafar 2016).

Simply put, the costs of and access to prescription drugs are a problem in the United States. There is both widespread public concern about drug prices and support for government action. In a recent poll, more than 80% of respondents agreed that the cost of prescription drugs was unreasonable and that the government should negotiate lower prices, limit price increases, speed access to generic drugs, and limit annual out-of-pocket costs for Medicare beneficiaries (Hamel et al. 2022). Because rising drug prices are a problem for insured Americans, the issue has broad (and potentially bipartisan) political resonance. Proposals to address drug prices have figured prominently in the presidential agendas of both Donald Trump and Joe Biden (Sachs 2021). States, grappling with the fiscal impacts of rising pharmaceutical costs in Medicaid, are pursuing a variety of legislative and administrative remedies (Mello, Riley, and Sachs 2021; Padula 2019).

The case for reform is compelling. The United States spends more on prescription drugs than any of our international peers, reflecting the absence of systemwide controls on prices. In 2018, drug prices in the United States were 256% of the prices in other Organization for Economic Cooperation and Development nations (Mulcahy et al. 2021). In 2019, the United States spent $1,376 per person on prescription drugs, compared to $935 per person in Germany, $864 in Canada, and $635 in France (Cicchielo and Gustaffson 2021). Higher spending does not translate to better access to drugs for many Americans, though, as one in four people report that paying for their drugs is difficult for them (Hamel et al. 2022). These affordability issues are largely the result of drug prices and coverage limits, including high and rising list prices for brand-name prescription drugs that are only bounded by "what the market will bear" and health insurance policies that ask beneficiaries to pay deductibles and substantial cost sharing when filling their medications. Many Americans are paying too much for drugs that they need while drug manufacturers, health plans, pharmacy benefits managers, hospitals, and other members of the convoluted supply chain make handsome profits from the sale of these products.

But if the case for action is compelling, the politics of reforming prescription drug pricing are daunting. For all the attention to rising prices and

medication access issues, and despite ostensible bipartisan concern, no major drug pricing reform legislation has passed Congress during the Clinton, George W. Bush, Obama, and Trump administrations (Diamond and Goldstein 2021; Weisman 2021). In part, that inaction was explained by the same barriers that more broadly limit the scope of health care reform in the United States. Partisan politics and differing ideas on the role of government, markets, regulation, and competition in pharmaceutical policy make legislative compromise difficult. Absent bipartisanship, narrow congressional majorities—Democrats currently hold extremely thin majorities in the House of Representatives and the Senate—mean that enacting legislation depends on (near) universal party unity.

Moreover, there are powerful economic interests, namely the pharmaceutical industry, that profit from the status quo, oppose reform, and have the incentives and resources to influence legislative deliberations and block, weaken, or overturn new regulations. Pharmaceutical companies have worked to ensure that the United States lacks a national system of drug price regulation (just as other health system stakeholders have helped to stymie price regulation of medical services). When Bill Clinton proposed federal regulation of drug prices as part of his 1993 universal health insurance plan, the drug industry joined the opposition to the plan, which failed to pass Congress (Diamond and Goldstein 2021). When Congress added outpatient prescription drug coverage to Medicare in 2003, the Medicare Modernization Act required that such coverage be delivered through private insurance plans and prohibited the federal government from negotiating drug prices (Oberlander 2007; Oliver, Lee, and Lipton 2004). Consequently, Medicare, which has more than 60 million enrollees and accounts for 20% of all health care spending in the United States, has not been able to leverage its purchasing power to constrain what it pays for prescription drugs. And when PhRMA, the pharmaceutical industry's chief lobbying group, negotiated a deal with Democrats to support the 2010 Affordable Care Act and pledged to produce savings that would help fund the law's insurance expansion, the Obama administration and congressional leaders promised to protect the drug industry from measures such as reimportation of drugs from Canada that would "further cut into [their] revenues" (Cohn 2010).

Over time, PhRMA's role in health policy debates has increased; and as the industry grows, so too does its economic and political pull on members of Congress whose districts and states have many constituents working in the pharmaceutical industry. In U.S. health care, the political rules of the

legislative road are clear: it is easier (though never easy) to enact reforms that expand insurance coverage and access to medical services than it is to adopt robust measures to limit spending.

The politics of health care cost control entails conflict since it requires curbing the flow of income to the health care industry. Health system stakeholders often portray cost control measures as threats to patients' timely access to high-quality medical care, invoking the specters of rationing and wait lists. But in the case of drug pricing reform, opponents argue that price regulation is a threat to medical progress. They warn that regulation will curb innovation and the development of new medications, ultimately harming Americans' health. As demonstrated by the case of Aduhelm, a controversial drug approved in the United States to treat Alzheimer's disease, it is difficult for federal regulators to resist pressures from the pharmaceutical industry as well as from some patients desperate for therapies, even when the evidence for their effectiveness and clinical impact is weak (Alexander et al. 2021). Indeed, the pharmaceutical industry not only influences the legislative process and regulatory (in)actions but also shapes the production and dissemination of medical knowledge about drugs through funding of research and clinical trials, payments to physicians, and other means (Mitchell et al. 2021; Sismondo 2008).

As drug pricing became an issue during 2019–21, the myriad barriers to enacting reform were again on display as legislation stalled in Congress—and in particular the Senate—even as its scope was curtailed in an effort to enhance the prospects of enactment (Diamond and Goldstein 2021; Sanger-Katz 2021; Weisman 2021). But in August 2022, that impasse was broken, and historic drug pricing reforms became law as part of the Inflation Reduction Act (IRA). Just as during the 1980s and 1990s, Medicare abandoned permissive payment policies for hospitals and doctors in favor of price regulation (Oberlander 2003), so price regulation also came to the pharmaceutical industry.

The 2022 IRA makes a number of important changes in drug pricing. It empowers Medicare, for the first time, to negotiate drug prices, starting with 10 high-cost retail medications (Part D) and expanding over time to encompass more drugs, including those administered by physicians (Part B). It requires drug companies to pay a rebate to the federal government if their prices increase at rates faster than inflation. The law also makes crucial improvements to Medicare's drug benefit, including establishing a new $2,000 cap on out-of-pocket costs in Part D for beneficiaries, eliminating the 5% coinsurance that Medicare enrollees with very high medication

costs now pay, instituting a $35 monthly cap for insulin copayments for Medicare beneficiaries, and making vaccines available under Part D with no cost sharing (Cubanski et al. 2022; Hwang, Kesselheim, and Rome 2022; Sachs 2022). The law's redesign of Medicare drug coverage will thus reduce the financial burdens that many beneficiaries have faced when obtaining medications. It also expands low-income subsidies to include individuals with incomes between 135% and 150% of the federal poverty level, substantially lowering out-of-pocket costs for these beneficiaries.

Taken together, these measures represent a transformative moment in US prescription drug policy. The IRA also represents a major political defeat for the pharmaceutical industry, which opposed these reforms. Still, the scope of the new law is limited. Opposition from Republicans and the constraints of the budget reconciliation process that Democrats used to pass the IRA mean the limits on insulin costs do not apply to private insurance. Those procedural constraints also mean the inflation rebates do not encompass price increases in the private market. The federal government is limited in how many drugs in Medicare it can negotiate, and such negotiated prices will only apply after a drug has been on the market for 9–13 years. Additionally, drug companies will not be required to offer those prices to private payers (Sachs 2022). In coming years, the drug industry will surely attempt to undermine the law's implementation, and we do not know how future presidential administrations will implement the law. In short, while the IRA represents progress, it will not solve the issues of high drug prices and medication affordability in the United States.

In the aftermath of the IRA's enactment, this special issue brings together scholars from an array of disciplines—economics, law, medicine, pharmaceutical policy, political science, public health, and more—to wrestle with the complex issues surrounding prescription drug costs and access. The issue explores a broad set of topics that encompass drug approval processes, patent reform, efforts to reduce or eliminate out-of-pocket costs for high-value drugs, state and federal efforts to improve access to and reduce spending on prescription drugs, regulation of industry payments to physicians, Medicaid and Medicare reform, challenges with achieving "pharmacoequity" amid systemic racism and injustice, and lessons from other countries' experiences in drug price regulation.

The challenges of prescription drug spending will continue to be a major issue in U.S. health care policy. We hope this special issue will illuminate the causes and consequences of such spending, the policy changes and trade-offs, and different paths to reform.

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