Principles to Inform Drug Pricing, Access and Innovation Policy

Policymakers have made generational progress in advancing policies to lower prescription drug prices, especially through the passage into law of price negotiations, inflation rebates, and a $2,000 out-of-pocket cap for patients on Medicare. Yet critical work remains to provide relief for both people with Medicare and without, through lower prices for more patients and more medicines, and on a quicker timeline. Three in ten adults in the United States report not taking their medicine as prescribed due to cost, with even higher rates of rationing among younger adults, Hispanic adults and lower income households.[i] New gene and cell therapies may provide life-changing benefits for patients but prescription drug companies are launching them at prices reaching millions of dollars, placing an unprecedented burden on patients and health systems.[ii] A large majority of Americans across party lines say that the government needs to do more to limit the prices of prescription drugs.[iii]

The following principles articulate shared goals and a north star to build on the important progress policymakers have made and chart a course for further reform. As undersigned, we will advocate for policy changes that move us closer as a nation toward these shared goals.

1. Overall

1.1. Everyone should be able to access the medications they need, at prices they can afford, in order to live healthy and productive lives.

2. Pricing and affordability:

2.1. High list prices charged by manufacturers drive pharmaceutical costs throughout the healthcare system and are the root cause leading to the unaffordability of medicines in the United States.

2.2. Patients and health programs in the United States should not pay prices far higher than their counterparts in other high-income countries.

2.3. The federal government should enact policies to ensure that prices are fair and affordable for newly launched treatments, including cell and gene therapies as well as products currently on the market.

2.4. Meaningful cost control will require simultaneously reforming perverse incentives and putting an end to anticompetitive practices in the supply chain, including those of wholesale distributors, pharmacy benefit managers, insurers, and pharmacies.

3. Protecting and building on policies to lower drug prices and out-of-pocket costs:

3.1. Medicare drug price negotiations, inflation rebates, and annual out-of-pocket cost limits passed into law as part of the Inflation Reduction Act (IRA) provide a foundation for further reforms to be built upon. Congress and future administrations should reject any attempt to weaken IRA provisions.

3.2. Policymakers should build on the IRA to bring down the prices of more drugs, for more patients, sooner. We recommend as top policy priorities:

3.2.1. People not enrolled in Medicare and other payers should have access to negotiated prices.

3.2.2. All branded drugs purchased by Medicare should be eligible for negotiations, including by removing negotiation delay periods, and requiring negotiation for an increased number of drugs each year.

3.2.3. The prices of drugs negotiated by Medicare should not exceed an upper limit based on the average of prices for the same drugs in other high-income countries.

3.2.4. Savings from lower drug prices should accrue to patients in the form of lower premiums and out-of-pocket costs, and improved coverage.

3.3. All savings to the government from lower drug prices achieved through improvements to the IRA should be reinvested to meet health needs.

3.4. Appropriators must ensure that agencies whose work impacts prescription drug pricing, access, innovation, and safety and efficacy, including HHS, CMS, FDA, NIH, HRSA, FTC and PTO have sufficient resources to fulfill their missions.

4. Innovation and Competition

4.1. Public policy—including incentives for and funding of research and development (R&D)—should prioritize the promotion of drug innovation that achieves the greatest possible gains in health and well-being and health equity.

4.2. Policy changes should include reforms to anticompetitive monopoly abuses that keep prices higher, such as expansive patent thickets, pay-for-delay patent settlements, and filing spurious citizen petitions.

4.3. Policymakers must ensure the public receives a fair return on investments in medicines developed with public support. These policies should require that companies marketing medicines developed with public support sell them at accessible and affordable prices, reflecting public investment.

5. Transparency

5.1. Greater transparency should be required throughout the prescription drug market, including transparent information about expenses, prices, rebates and discounts, profits, PBM negotiations and business practices, and related information about costs and revenues.

5.2. The costs of R&D should be made fully transparent, including the extent to which public dollars or science contributed to a drug's discovery, development, and manufacturing.

5.3. The results of clinical trials and other drug studies should also be made fully transparent, through measures such as strengthened reporting requirements and strong enforcement actions. This transparency should enable insights into a drug's implications or efficacy for different patient populations.

[i] https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/
[ii] https://www.ajmc.com/view/high-cost-gene-therapies-present-reimbursement-access-challenges
[iii] https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices/