



Statement before the House Committee on Ways and Means
On The Cost of Rising Prescription Drug Prices

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February 12, 2019

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Chairman Neal, Ranking Member Brady, and members of the committee, thank you for the opportunity to testify today on prescription drug prices. I am Joseph Antos, the Wilson H. Taylor Scholar in Health Care and Retirement Policy at the American Enterprise Institute. The views I offer today are mine alone.ⁱ

American consumers and policymakers are increasingly concerned about the high cost of prescription drugs. According to the Kaiser Family Foundation, one in four people taking prescription drugs report difficulty affording their medication.ⁱⁱ There is bipartisan support for policies that could help lower drug prices and their burden on consumers.ⁱⁱⁱ Legislation has been introduced and regulatory actions have been advanced to promote competition among drug manufacturers and slow the growth of prices.

Attention has focused on the cost patients pay out of pocket for their prescriptions. The Department of Health and Human Services recently proposed a regulation intended to lower list prices and reduce out-of-pocket spending for prescription drugs.^{iv} That is an important goal for policy, but other objectives also matter. We should be concerned about the total cost of health care, including payments made by patients and their health plans for drugs and other medical services. We should work to ensure that the money we spend for health care produces real value for patients.

Any single policy proposal can address some aspects of the overall problem of high drug costs. Not every issue can be resolved, and a solution for one problem may exacerbate others. A balanced policy agenda should be developed based on core principles that recognize the inherent trade-offs among objectives. Such an agenda would:

- Promote competition to lower prices while retaining appropriate incentives for the development of innovative new treatments,
- Ease the financial burden of rising drug prices on consumers while slowing the growth of total health spending,
- Promote greater efficiency in the delivery of health services, and
- Promote private sector solutions that can better adapt to changing conditions in the health market.

Public concern over prescription drug costs reflects the changing health needs of an aging population. We are living longer, and we are living longer with chronic disease. In many cases, pharmaceuticals are the major tool to manage chronic conditions. That growing demand has spurred drug development, which has led to the growing use of more expensive specialty medications. These massive demographic and clinical changes are most immediately apparent in the Medicare program, but their impact will be felt throughout the health system.

Balancing Innovation and Competition in the Pharmaceutical Industry

There is an ongoing tension between promoting pharmaceutical innovation and maintaining access to affordable, safe, and effective medical treatments. Pharmaceutical research is a high-cost, high-risk venture that can take years of work with no guarantee that the process will end with a product that a company can sell in the marketplace. Intellectual property protection through the patent system and other regulations is needed to foster that kind of research. But such protection also gives the innovator significant market power to set prices and slows the entry of competing products that can put downward pressure on prices. By granting what amounts to a temporary monopoly, federal rules allow the innovator to price its product at a higher level than otherwise.

Congress has adopted policies that temper that market power and promote competition in the pharmaceutical market. The Drug Price Competition and Patent Term Restoration Act of 1984— known as Hatch-Waxman, for its primary authors, Sen. Orrin Hatch (R-UT) and Rep. Henry Waxman (D-CA) — paved the way for competition from generic drugs. The Biologics Price Competition and Innovation Act of 2009, enacted as part of the Affordable Care Act (ACA), created an approval process for biosimilars (large molecule biologic products) that is roughly parallel to the process for generic drugs.^v

The shift in prescribing practices toward generics has been robust. IQVIA reports that generic drugs accounted for 90 percent of prescription medicines dispensed in 2017, up from 72 percent in 2008.^{vi} Between 2013 and 2017, patient out-of-pocket costs for generics fell from an average \$6.34 (per filled prescription) to \$5.76.

The introduction of new therapies to treat hepatitis C demonstrates the power of competition in lowering the cost of treating serious diseases. Sovaldi, the first drug to cure hepatitis C, was introduced to the market in 2014 at a list price of \$84,000 for a 12 week regimen.^{vii} The existing treatment at the time cost \$94,000 and was a less successful therapy. The subsequent introduction of competing products forced down prices in the market. Mavyret, introduced in 2017, has a list price of \$26,400.^{viii} Although not inexpensive, the price of a cure for a serious disease dropped by two thirds over a short period of time as a result of competition.

Hatch-Waxman and the Biologics Price Competition and Innovation Act created regulatory pathways to promote the introduction of competing pharmaceutical products to the market. There is no simple metric to determine whether the current mix of laws and regulations strike the right balance between promoting innovation and promoting innovation in the pharmaceutical market. Recent proposals to prevent pharmaceutical companies from refusing to sell their products to developers of generic competitors and limiting the distribution of drugs under the Risk Evaluation and Mitigation Strategy program represent a willingness in Congress to re-evaluate the effectiveness and appropriateness of the existing regulatory structure.^{ix}

Complicating this question is the role of pharmacy benefit managers (PBMs) and other intermediaries in the pharmaceutical supply chain and their interaction with third-party payers—including private insurance and public programs.

Insurance and Pharmaceutical Prices

Coverage for outpatient prescription drugs is a standard benefit in comprehensive health insurance plans, including private employer plans, non-group coverage that complies with the ACA's essential benefits requirement, the Veterans Health Administration, Medicaid, and Medicare. The price of the drug depends on a complex set of rules, rebates, discounts, and other cross-subsidies that vary depending on whether the consumer is paying fully out of pocket or is purchasing the prescription through a third party.

Employers and insurers hire PBMs to negotiate lower prices from drug manufacturers and retail pharmacy chains. PBM bargaining power comes from having large numbers of enrollees and the ability to tie the amount enrollees pay in cost-sharing to the drug's placement on the formulary. Multi-tier formularies are common, with generic drugs typically assigned to a lower tier with lower cost-sharing amounts. That incentive helps steer patients to preferred drugs, and greater sales volumes increase the

amount of rebates collected from the manufacturer.

Consumers benefit directly from rebates paid to PBMs. The Altarum Institute estimates that in 2016 PBMs earned \$11 billion in profits and passed on \$89 billion in rebates to employers and insurers.^x Health plans have strong incentives to pass on rebate revenue in the form of lower premiums and better coverage to attract new enrollees.

Reliance on rebates rather than upfront price discounts lowers the net price paid to the pharmaceutical manufacturer, but that reduction may not be reflected in what the consumer pays at the pharmacy. That amount depends on how their insurance benefit is structured, whether the prescribed drug is on a preferred tier of the formulary, and what price is used to determine the cost-sharing amount.

Consumers who have not met their annual deductible or are subject to coinsurance (rather than a fixed-dollar copayment) pay based on the list price rather than the net price after rebates. Consumers needing specialty drugs or non-preferred brands are likely to face substantial cost-sharing amounts. In some cases, the cash price is lower than the price negotiated by an insurance plan.

There is a decided lack of price transparency in the pharmaceutical market. The details of price negotiations are confidential, and there are a variety of pricing measures that can be used to characterize the market.^{xi} From the consumer's standpoint, what matters is what he or she must pay at the pharmacy counter. Out-of-pocket cost is a major factor in determining which drug is prescribed, and whether the patient picks it up from the pharmacy or leaves it behind.

Policy Options for Medicare

A vast range of federal policies affect pricing behavior in the pharmaceutical industry and its impact on consumers.^{xii} There are opportunities for reforms in the rules governing patent protection, business practices that impede the introduction of competing pharmaceutical products, the use of rebates in private plans and public programs, the management of drug benefits in Medicare and Medicaid, and many other areas. The following briefly discusses selected policy options for the Medicare program.

Medicare Part B. Drugs and biologics administered in physician offices and hospital outpatient departments are covered under Part B. These drugs generally require professional administration because they are injected or infused rather than consumed orally. Medicare reimburses physicians for Part B drugs that they purchase, known as buy-and-bill. Most Part B drugs are paid the average sales price (ASP) plus 6 percent.^{xiii}

Paying physicians on the basis of the ASP creates an incentive that increases program cost. Because providers keep the difference between the Part B payment and the price they actually pay, providers have a strong incentive to negotiate low prices for Part B drugs. The Medicare Payment Advisory Commission (MedPAC) analyzed invoice prices for 34 high-expenditure drugs purchased by providers under Part B.^{xiv} In most cases, the providers were paying a price that was below 102 percent of ASP, while Medicare was paying 106 percent of ASP for the products.

Further, because Medicare pays a 6 percent add-on to ASP, physicians and outpatient departments have an incentive to prescribe higher-priced products when lower-priced alternatives are available. A higher ASP creates a larger add-on payment from the Medicare program, giving suppliers more room to negotiate prices with purchasers.

Single-source drugs (for which there are no generics or biosimilars) are paid under their own unique billing code at ASP plus 6 percent. For multiple-source drugs, Medicare pays 106 percent of the weighted average ASP for both brand and generic versions.

Options that potentially could slow cost growth for Part B drugs include:

- Convert the Part B add-on payment to a fixed fee. This straight-forward change reduces the incentive to prescribe higher priced drugs.
- Assign the same billing code to the reference biologic and its biosimilars. Currently, each biosimilar is paid under its own billing code. The payment is 100 percent of its own ASP plus 6 percent of the originator biologic's ASP. This blended payment reduces the incentive to substitute a biosimilar rather than the higher priced product.
- Permit the flexibility to use tools to manage Part B drug costs. The Department of Health and Human Services (HHS) has proposed allowing Medicare Advantage plans to use step therapy for Part B drugs.^{xv}
- Replace the buy-and-bill system with a system of private vendors to negotiate prices. Variations on this proposal have been proposed earlier, including the Competitive Acquisition Program (CAP) under President George W. Bush, the Part B Drug Value Program proposed by MedPAC, and the latest CAP proposed by the Trump administration. Given the failure of the original CAP, there are questions about how to design and implement such a program.^{xvi}

Medicare Part D. Medicare's outpatient drug coverage is an optional benefit administered through stand-alone prescription drug plans (PDPs) and Medicare Advantage plans offering the drug benefit (MA-PDs). Under the 2019 standard benefit structure, enrollees are responsible for a \$415 deductible, 25 percent coinsurance for covered drug expenses up to \$3,820, and 5 percent of costs above a \$5,100 catastrophic limit.^{xvii} Part D plans often offer alternative benefits, such as lower deductibles or tiered copayments rather than coinsurance.

Part D operates solely through private plans, giving Medicare beneficiaries the opportunity to enroll in the plan that most closely meets their needs. In principle, the plans have strong incentives to negotiate low prices for the drugs on their formularies. However, flaws in Part D's design increase program spending and expose beneficiaries to the risk of high out-of-pocket costs.

Medicare provides a per-enrollee direct subsidy to Part D plans based on the national average of plan bids. This is a prospective subsidy, putting the plans at risk for managing costs below the catastrophic threshold. The program also subsidizes 80 percent of covered drug spending above the catastrophic threshold through individual reinsurance, with Part D plans paying 15 percent and enrollees paying the remaining 5 percent. This approach was adopted to avoid having Part D plans design their formularies and benefits to avoid enrolling individuals with exceptionally high expense, but it reduces the incentive for plans to manage costs above the threshold.

It has also led to a dramatic shift in federal payments toward reinsurance. Between 2007 and 2016, reinsurance payments increase from \$8 billion to \$35 billion while the direct subsidy dropped slightly from \$18 billion to \$16 billion.^{xviii} Because their liability for drug costs drops significantly once the enrollee has reached the catastrophic threshold, plans have strong incentives to negotiate larger rebates rather than lower up-front prices. Moreover, enrollees may be more likely to use brand name drugs rather than lower-cost generics because their liability also decreases above the threshold.

Reforming the individual reinsurance subsidy would help slow the growth of federal spending for Part D, and provide greater incentives for Part D plans to promote the use of lower-cost pharmaceuticals where appropriate. Additional policy changes advanced by MedPAC and the Administration would also contribute to a more sustainable program that is more affordable to enrollees.^{xi} They include:

- Reducing Medicare’s individual reinsurance subsidy below 80 percent. MedPAC suggests transitioning the payment to 20 percent of costs above the catastrophic threshold.
- Exclude manufacturers’ discounts in the coverage gap from enrollees’ true out-of-pocket spending. The ACA permits discounts offered for brand-name drugs to count toward the enrollee’s catastrophic spending threshold, even though those discounts do not constitute out-of-pocket spending by enrollees. That reduces the incentive to use lower-cost generics and increases the number of enrollees who exceed the threshold.
- Cap the amount that Part D enrollees spend out-of-pocket. Although their liability for drug costs is reduced to 5 percent once the threshold is reached, there is no limit on the total amount that could be paid by enrollees with exceptionally high drug needs.
- Allow Part D plans greater flexibility to manage protected drug classes. That could include removing certain drug classes from protected status, broader use of prior authorization and step therapy, or excluding specific drugs within protected classes.

Such policies have the potential of promoting more active price competition in the pharmaceutical market, but there may be unintended consequences. A recent HHS proposal to limit the use of rebates illustrates this point.^x Rebates on prescription drugs paid by manufacturers to PBMs, Part D plans and Medicaid managed care organizations would be excluded from safe harbor protection under the Anti-Kickback Statute. Instead, a new safe harbor would be created for discounts offered directly to patients. The intention is to lower the cost of prescription drugs to the patient. These rules would apply to Medicare Part D and Medicaid managed care organizations.

The net impact of this proposal on patients is uncertain. To the extent that current rebate levels are passed in whole to patients at the pharmacy counter, those who rely more heavily on prescription drugs will see some reduction in out-of-pocket cost. But health plan premiums are likely to rise, offsetting those savings. Moreover, it is far from certain that price negotiations under the new rules would yield the same or lower prices net of the rebate. Negotiated prices might rise, partly offsetting the benefit to patients.

The Medicare actuary estimates that households would save \$93 billion in lower out-of-pocket spending for prescription drugs over the next decade, but their insurance premiums would rise by \$50 billion.^{xi} On balance, persons with high drug costs would gain, but those with lower needs for medications would pay more for their health coverage. Moreover, the proposal would add fuel to medical cost inflation. Total drug spending would increase by \$137 billion and Medicare drug spending would increase by \$196 billion. While the intention of this proposal is to relieve the cost burden on patients, that would not be accomplished without imposing new costs on others.

Conclusion

The pricing of pharmaceutical products is a difficult subject for public officials because society has an interest in both medical progress and affordable access to beneficial treatments. There is growing concern that current policies do not strike the right balance between innovation and competition.

There are no simple fixes. As policymakers consider how to improve existing policies, they should keep the following considerations in mind.

Supply Competition. Manufacturers of pharmaceutical products have maximum leverage over pricing when they face little or no competition. Government regulation can affect how quickly a product will face competition from another effective therapy. Rapid generic competition is critical, of course, but so too is competition among patented, brand-name therapies to prevent full monopoly pricing power for a single manufacturer.

Rebates. The financial benefits of rebates come through lower premiums for insurance plans. Shifting the savings from rebates into lower prices paid at the point of sale would benefit patients with the highest drug costs through lower cost-sharing payments. However, lower cost-sharing might increase overall drug spending (as a result of higher utilization of prescription drugs) and increase plan premiums (to the extent that funds from drug rebates used to underwrite the cost of the plan are reduced). That could mean higher prescription drug consumption and higher total costs to taxpayers and consumers.

Discounting. Requiring drug manufacturers to guarantee substantial discounts to a few favored purchasers is likely to mean higher prices for those who are excluded from such discounts. The overall goal should be to lower prices for all consumers. This is likely to require a thorough rethinking of the current discount system.

The U.S. has a vibrant ecosystem of researchers, private-sector entrepreneurs, and capital investors that produces more new therapies than other countries. In this regard, current public policy has been incredibly successful.

There is no question, however, that conferring market exclusivity rights on important therapies will lead to high prices for purchasers or consumers in some circumstances. That's basic economics. The challenge for policymakers is to minimize the number of monopolistic pricing situations and to create the proper balance of financial burdens when supply competition is limited.

Today's ad hoc drug pricing arrangements are far from perfect. While there are no easy and politically safe answers, the system can be improved with sensible reforms.

Notes

- ⁱ This testimony is based on previous work with James C. Capretta of the American Enterprise Institute. See <http://www.aei.org/publication/prescription-drug-pricing-an-overview-of-the-legal-regulatory-and-market-environment/> and https://www.realclearpolicy.com/articles/2018/07/30/beware_of_simple_fixes_for_high_drug_prices_110735.html.
- ⁱⁱ https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/#item-annual-growth-in-rx-drug-spending-and-total-health-spending-per-capita_nhe-2017.
- ⁱⁱⁱ <https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2019/01/07/the-health-202-congress-and-trump-may-actually-take-action-in-2019-to-lower-drug-prices/5c2e6499b6514123d0ae8706/>.
- ^{iv} <https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf>.
- ^v <https://fas.org/sgp/crs/misc/R44620.pdf>.
- ^{vi} <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022>.
- ^{vii} <https://www.statnews.com/pharmalot/2016/08/03/gilead-fires-back-report-pricing/>.
- ^{viii} <https://www.managedcaremag.com/archives/2018/4/take-bow-pharma-hepatitis-c-drugs>.
- ^{ix} <https://www.washingtonpost.com/news/powerpost/paloma/the-health-202/2018/02/12/the-health-202-here-s-the-one-real-change-to-drug-pricing-being-ignored-by-congress/5a7de5f630fb041c3c7d7785/>.
- ^x <https://altarum.org/publications/impact-prescription-drug-rebates-health-plans-and-consumers>.
- ^{xi} <http://www.aei.org/publication/prescription-drug-pricing-an-overview-of-the-legal-regulatory-and-market-environment/>.
- ^{xii} <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.
- ^{xiii} http://medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_18_partb_final_sec.pdf.
- ^{xiv} http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf.
- ^{xv} <https://www.cms.gov/newsroom/fact-sheets/contract-year-cy-2020-medicare-advantage-and-part-d-drug-pricing-proposed-rule-cms-4180-p>.
- ^{xvi} <https://www.healthaffairs.org/doi/10.1377/hblog20181026.360332/full/>.
- ^{xvii} http://medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_18_partd_final_sec.pdf.
- ^{xviii} http://medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.
- ^{xix} <http://medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf>, <https://www.cms.gov/newsroom/fact-sheets/contract-year-cy-2020-medicare-advantage-and-part-d-drug-pricing-proposed-rule-cms-4180-p>.
- ^{xx} <https://www.hhs.gov/about/news/2019/01/31/trump-administration-proposes-to-lower-drug-costs-by-targeting-backdoor-rebates-and-encouraging-direct-discounts-to-patients.html>.
- ^{xxi} <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/RxSafeHarbor.html>.