Testimony before the
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Chairman Alexander, Ranking Member Murray, members of the committee, thank you for holding this hearing and for the opportunity to present testimony.

I direct health programs at The Pew Charitable Trusts, a nonprofit, nonpartisan research and policy organization. One of our focus areas is the challenge of rising drug spending.

Net spending on pharmaceuticals has increased 42 percent since 2006, with more than two-thirds of that growth occurring since 2013.[1] Indeed, prescription drug spending is now the fastest growing share of health spending, and projected to remain so.[2] Currently pharmaceuticals account for 16.7 percent of total expenditures.[3] This creates challenges for:

- Individual patients, who face high out-of-pocket costs. Surveys show that three-quarters of Americans think drug prices are unreasonable.[4]
- American taxpayers and businesses, which pay the bulk of the cost of drugs through taxes and insurance premiums.

[1] QuintilesIMS Institute, "Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021," May 2017, Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021

[2] The Centers for Medicare & Medicaid Services projects that prescription drug spending growth will continue to outpace overall health care cost increases over the next decade. Source: Centers for Medicare & Medicaid Services, "National Health Expenditure Projections 2016-2025," Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf

[3] Health and Human Services Assistant Secretary for Planning and Evaluation, "Observations on Trends in Prescription Drug Spending," March, 2016, Available at: https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf

[4] Kaiser Family Foundation, "Kaiser Health Tracking Poll: September 2016," September 2016, Available at: http://kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/

Rising drug spending is a challenge for policymakers, too, because while a competitive market is generally the best way to establish prices, the market for drugs is complex and deeply influenced by public policy, and effective competition is limited in a number of ways. These include:

- Monopoly pricing for new drugs,
- Lack of competition for some older drugs,
- Misaligned incentives and incomplete information for stakeholders, including payers, providers and patients at many points in the system, and
- A historical willingness to cover new therapies without ensuring that their clinical benefits justify the price.

In discussing potential policy options, it is important to understand the main drivers of increased drug spending. This trend is largely the result of the rising cost of new medicines, particularly high-cost specialty products (including biologics),[5] which are only used by a small share of the population, but account for more than 40% of drug spending.[6] Today, fewer than two percent of prescriptions account for over one-third of retail drug spending.[7] Some of these products are exciting therapeutic advances – true breakthroughs – but some are not. And they are reaching market at ever-higher launch prices. Net prices (i.e. prices after rebates) are also increasing. These products will typically not face generic competition for years. Increased volume of sales and year-on-year price increases for brand drugs that don't face competition are

[5] Examples include medicines for cancer, multiple sclerosis, and autoimmune conditions.
[6] QuintilesIMS Institute, "Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021," May 2017, Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021
[7] QuintilesIMS Institute, "Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021," May 2017, Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021

also a driver of spending. As more and more innovative medicines come to market, the growth in launch prices and the growing share of the population that could potentially rely on these products looks unsustainable.

While new brand drugs drive spending growth, generic drugs create significant savings. In 2016, about 90% of prescriptions dispensed were for generics, but total spending on these medications actually fell,[8] despite sharp increases in the prices of some individual products.

Net pharmaceutical manufacturer revenue from U.S. sales reached $323 billion in 2016.[9] This represents the large majority, but not the total of U.S. drug spending, because other entities, including pharmacy benefit managers, wholesalers and pharmacies, also each retain a portion of total spending on drugs.

Potential policy responses

Increased competition from generic and biosimilar products

Competition from generic drugs has long been the main tool used to manage drug spending in the United States.[10,] Currently, the FDA prioritizes the review of first generics, as

[8] QuintilesIMS Institute, "Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021," May 2017, Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021

[9] QuintilesIMS Institute, "Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021," May 2017, Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021

[10] Generics are now nearly 90 percent of all prescriptions filled, but less than 30 percent of drug spending. QuintilesIMS Institute, "Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021," May 2017, Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021

well as generic applications for drugs for which there is only one manufacturer;[11] however, other policy responses could facilitate generic entry, including:

- Policies to ensure that manufacturers of brand name drugs cannot block generic developers' access to sample products required for bioequivalence testing,[12] and
- Policies to limit so-called "reverse payment" settlements that can, in some cases, be anti-competitive by delaying generic market entry.[13]

However, the agency alone cannot address the challenge of escalating drug costs. In particular, it should be noted that biologic drugs are one of the most significant drivers of increased spending and they represent nine of the 10 highest expenditure products in Medicare Part B.[14] Any policy that hastens access to biosimilars and increases competition among these

[11] FDA Center for Drug Evaluation and Research, Manual of Policies and Procedures 5240.3. Rev 2. Prioritization of the Review of Original ANDAs, Amendments, and Supplements, 2016, http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf

[12] Barriers to generic entry exist when brand drug manufacturers prevent generic companies from obtaining their products in order to carry out the testing necessary to develop a generic version of a drug. In some cases, FDA orders a manufacturer to develop a program to ensure safe use of a high-risk product, such as a requirement that a drug can only be acquired through select providers, or the manufacturer may independently opt for a restricted distribution network. However, some generic manufacturers allege that these provisions are used to restrict generic company access. Litigation to obtain samples for comparative testing often takes years to conclude. Source: The Pew Charitable Trusts, "Policy Proposal: Improving Generic and Biosimilar Developer Access to Brand Pharmaceutical Samples, May 2017, Available at: http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2017/05/policy-proposal-improving-generic-and-biosimilar-developer-access-to-brand-pharmaceutical-samples

[13] Brand and generic companies frequently strike "reverse payment" or "pay-for-delay" settlements that involve a brand pharmaceutical manufacturer paying one or more potential generic competitors to resolve patent infringement lawsuits and agree upon a date by which the generic product can come to market. Both the brand and generic company benefit under such agreements, while the public pays higher prices than it would if the generic available sooner. In 2015, for example, the Federal Trade Commission (FTC) reached a $1.2 billion settlement with Cephalon, Inc. for illegally blocking generic competition to its blockbuster sleep-disorder drug Provigil, driving up costs for consumers, insurers, and pharmacies. FTC and the Congressional Budget Office have estimated that banning or otherwise limiting these agreements would generate significant savings for consumers and taxpayers. However, any policy should also consider that some such settlements may be pro-competitive.

[14] Medicare Payment Advisory Commission, "Report to the Congress, Medicare and the Health Care Delivery System," , June 2016, Available at: http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0

products would reduce spending.[15] This includes better aligning biologic and small-molecule exclusivity periods. Congress gave new biologics 12 years of monopoly, free of competition from biosimilars, which is more than double the five years of protection typically granted to new small molecule drugs.

In addition, an increasing share of drugs comes to market with the benefit of taxpayer subsidies and other benefits established through the Orphan Drug Act (ODA). While important to incentivize the development of products for rare diseases, in some circumstances, these products are used much more widely than the ODA intended.[16] Congress may wish to evaluate a number of policy options to ensure the appropriate balance, including:

- Limiting the 340B carve-out for products with an orphan designation, and
- Considering the potential to cap the value of public subsidies.

Increased competition among existing drugs

In cases where there are multiple competing, but non-identical brand drugs on the market, there are a range of tools that payers can use to manage spending while protecting patient access. These include formulary placement, prior authorization, and step therapy. While these approaches are well established in commercial insurance, they are absent or limited in parts of the Medicare program. For example, reimbursement policies in Medicare Part B, which pays for

[15] There is a substantial difference in the duration of market protection provided to makers of biological drugs, which are derived from living cells, and that given traditional pharmaceuticals. Reducing the period of guaranteed exclusivity for biologics from the current 12 years to seven years would bring them more in line with traditional drugs. Such a change could generate more than $4 billion in savings to Medicare and other federal health care programs over 10 years. Source: Kaiser Family Foundation, "Summary of Medicare Provisions in the President's Budget for Fiscal Year 2016," February 2015, Available at: http://kff.org/medicare/issue-brief/summary-of-medicare-provisions-in-the-presidents-budget-for-fiscal-year-2016/

[16] Daniel MG, Pawlik TM, Fader AN, *et al*. The Orphan Drug Act: Restoring the Mission to Rare Diseases. *Am J Clin Oncol*. 2016 Apr;39(2):210-3

the use of physician-administered drugs, creates a financial incentive for clinicians to choose high-priced drugs over lower cost alternatives of similar effectiveness.[17] In Medicare Part D, the private plans that administer the outpatient prescription drug benefit are required to cover all drugs on the market in six protected classes.[18] This mandate limits the ability of Part D plans to negotiate discounts for drugs in these classes. To increase competition among existing drugs in Medicare, consideration could be given to policies that would:

- Increase competition within the Medicare Part B program,[19]
- Increase competition within Medicare Part D,[20] and
- Shift some drugs from the medical to the pharmacy benefit.

An increased focus on value

Value-based or outcomes-based contracts (OBCs) between manufacturers and purchasers – contracts that tie the price of a drug to specified outcomes – may play an important role for some products, though their impact on health care costs has been limited to date. A recent survey of 45 health plans found that 24 percent of them have an outcomes-based contract in place today,

[17] Health and Human Services Assistant Secretary for Planning and Evaluation, "Medicare Part B Drugs: Pricing and Incentives," March 2016, Available at: https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf

[18] Current law requires Medicare drug plans to cover every medication within six broad classes, including antidepressants and antipsychotics. Giving greater flexibility to private Part D plans in how they design their drug benefits could improve their ability to negotiate lower drug prices on behalf of Medicare beneficiaries and the federal government. Source: Lee T, Gluck A, Curfman G, "The Politics Of Medicare And Drug-Price Negotiation (Updated)", *Health Affairs Blog*, September 19, 2016, Available at: http://healthaffairs.org/blog/2016/09/19/the-politics-of-medicare-and-drug-price-negotiation/

[19] The Medicare Part B program spends some $25 billion each year for drugs administered in clinics and physician offices. Policies to manage biosimilar drugs similar to the current approach for generics could create greater competition. Source: The Pew Charitable Trusts, "Can Biosimilar Drugs Lower Medicare Part B Drug Spending?" January 2017, Available at: http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-medicare-part-b-drug-spending

[20] Medicare price negotiation (which is currently prohibited by statute) would achieve savings only if combined with new authority for Medicare to design its own formulary or preferred drug list, similar to how private plans prioritize certain drugs among equally effective therapies. Source: Shih C, Schwartz J, Coukell A, "How Would Government Negotiation Of Medicare Part B Drug Prices Work?", *Health Affairs Blog*, February 1, 2016, http://healthaffairs.org/blog/2016/02/01/how-would-government-negotiation-of-medicare-part-d-drug-prices-work/

and an additional 30 percent are in negotiations to enter into one.[21] However, just one-third of plans with an OBC in place reported cost savings. There are numerous challenges in setting up these contracts, and their utility may be limited by their cost to negotiate and the need for sophisticated data systems to monitor success.[22] However, policymakers could examine to what extent federal law or regulations pose potential barriers for establishing OBCs. For example, the Centers for Medicare & Medicaid Services could consider whether Medicaid Best Price rules may impede these agreements and develop additional guidance, if warranted.

Nevertheless, policymakers should consider additional strategies to incorporate the value of a drug into coverage and payment decisions. Factoring value into coverage decisions – including the choice not to cover drugs whose cost isn't justified – would help reduce overpayment for marginal clinical gains. Alternatively, policies to limit the price of drugs based on assessments of their value when comparable alternative therapies exist are strategies that have the potential to lower spending on pharmaceuticals in public programs.

Opportunities to improve transparency in drug benefit contracting

Pharmacy benefits managers – the intermediaries that insurers and employers pay to both administer prescription drug benefits and negotiate discounts from drug companies – play a crucial role, using their large sales volumes and their ability to create formularies to spur drug manufacturers to offer price concessions. However, a share of the savings accrues to the pharmacy benefit managers themselves, and their contracts can be extremely complex, making it

[21] Avalere, "Health Plans Are Actively Exploring Outcomes-Based Contracts," Available at: http://avalere.com/expertise/life-sciences/insights/health-plans-are-actively-exploring-outcomes-based-contracts

[22] Garrison LP, Carlson JJ, Bajaj PS, et al. "Private Sector Risk-Sharing Agreements in the United States: Trends, Barriers, and Prospects." *American Journal of Managed* Care, September 2015, Available at: http://www.ajmc.com/journals/issue/2015/2015-vol21-n9/Private-Sector-Risk-Sharing-Agreements-in-the-United-States-Trends-Barriers-and-Prospects

difficult even for sophisticated benefits administrators to determine whether they've achieved optimal savings.

Congress could consider requiring greater transparency of contract terminology and definitions between payers and pharmacy benefit managers,[23] as well as mandating the ability for payers to audit these deals, and ensuring that entities that advise purchasers on PBM contracts do not also have financial relationships with the PBMs themselves.

Conclusion

As Congress seeks to manage the challenge of rising drug spending, it should look at the range of challenges and policy solutions to achieve a balance between access to innovative medicines and the equally important need to constrain cost-growth in health care. I thank you for holding this hearing, and welcome your questions.

[23] More than two dozen of the largest U.S. corporations, including American Express, Coca-Cola, IBM, Marriott, and Verizon, have proposed greater transparency in these contracts. Source: Silverman E, "The 'gouge factor': Big companies want transparency in drug price negotiations," *STAT News*, August 2, 2016. Available at: https://www.statnews.com/pharmalot/2016/08/02/drug-price-transparency-pharmacy-benefits-manager/