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Chairman Burgess, Ranking Member Green, members of the sub-committee, thank you for holding this hearing and for the opportunity to present testimony.

Pew is a nonprofit, nonpartisan research and policy organization with programs that touch on many areas of American life. I have been asked to focus today on the challenge of rising pharmaceutical costs, within and beyond the user-fee context.

Drug spending in the United States rose nearly 9 percent in 2015, to more than $300 billion per year[1] and surveys show that three-quarters of Americans think prices are unreasonable.[2]

This would not be an issue if health budgets could rise indefinitely. But drug spending is rising faster than the rest of healthcare spending.[3] This hits consumers in the pocketbook, and helps drive up insurance premiums and the cost of Medicare and other taxpayer funded programs. All the evidence suggests this is not a short-term fluctuation, but a long-term trend.

[1] IMS Institute for Healthcare Informatics, "Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020," April 2016, Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020
[2] 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/
[3] The Centers for Medicare & Medicaid Services projects that prescription drug spending growth will continue to outpace overall healthcare 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

It is largely the result of the rising cost of new medicines – especially high-cost specialty drugs,[4] which are only used by one to two percent of the population, but account for more than one-third of drug spending.[5]

Some of these products are exciting therapeutic advances – true breakthroughs – but some are not. And they are reaching market at ever-higher launch prices. Year-on-year increases in the prices of brand-name on-patent drugs are also a major contributor to rising spending.[6,7]

A number of generic drugs have also undergone steep price hikes. But in general, generic prices, as a category, remain flat or falling.[8]

What can be done in response?

FDA's approval processes outlined in the generic and other user-free agreements may offer some potential to address drug spending, but many key opportunities lie elsewhere. Competition – in the form of generic drugs – has long been the main tool used to manage drug prices in the United

[4] Examples include medicines for cancer, hepatitis C, multiple sclerosis, rheumatoid arthritis and other autoimmune conditions.
[5] Express Scripts, "2015 Drug Trend Report," 2016.
[6] Pharmaceutical list prices can often increase by more than 10 percent annually, though payers have negotiated larger rebates with manufacturers to partially offset these price increases. Nevertheless, annual net prices are a major driving factor. Source: IMS Institute for Healthcare Informatics, "Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020," April 2016, Available at: http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020
[7] For example, older therapies for multiple sclerosis introduced in the 1990s, entered the market with list prices of $8,000 to $11,000 annually, but now these same products have list prices of more than $60,000 per year. Source: Daniel M Hartung, et al., "The cost of multiple sclerosis drugs in the US and the pharmaceutical industry," *Neurology*, 84.21 (2015): 2185.
[8] Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Understanding Recent Trends in Generic Drug Prices," January 2016, Available at: https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices

States.[9] The first generic user fee agreement has helped reduce the backlog of pending ANDA applications,[10] but more can be done to reduce barriers to generic entry, such as:

- policies to ensure that generic companies have access to brand-name products for bioequivalence testing,[11] and
- policies to limit so-called "pay-for-delay" settlements that can, in some cases, be anti-competitive by delaying generic market entry.[12]

Reducing review time for generic drugs at FDA would also be beneficial. The Lower Drug Costs through Competition Act (H.R. 749) would award a generic priority review voucher to any manufacturer that brings a generic drug to market in cases of limited competition or a drug shortage. It would also establish a six-month timeline for FDA review of priority applications, compared to the eight-month review goal in the draft GDUFA II agreement for priority ANDA applications. However, it is important to note that FDA already prioritizes

[9] Generics are now nearly 90 percent of all prescriptions filled, but less than 30 percent of drug spending.

[10] There was a backlog of 2,866 generic applications awaiting FDA review as of October 1, 2012, when GDUFA passed. The Agency has met its GDUFA commitment to take first action on over 90% of these applications. As of December 31, 2016, the FDA had approved or tentatively approved 842 of the 2012 backlog applications. Since the start of GDUFA implementation, the agency has met its hiring goals, but received more applications (nearly 1500 in FY14) than the 750 that were anticipated. Sources: https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM542929.pdf; https://www.fda.gov/NewsEvents/Testimony/ucm484304.htm

[11] 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.

[12] Brand and generic companies frequently strike "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 were the generic available. 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 estimates that a ban on pay-for-delay agreements would save consumers and taxpayers $3.5 billion annually. However, any policy should also consider that some such settlements may be pro-competitive.

generic applications when there is only one competing product on the market (brand or "sole-source" generic). The net benefits and practical feasibility of a six-month review are unclear as is, consequently, the market value of a priority review voucher for generic applications.

Perhaps more important than shortening the duration of review is reducing the number of review cycles.[13] We applaud the shared commitment of FDA and the industry in the GDUFA II agreement to improving success rates for first cycle review.

When focusing on measures to increase competition, it must be noted that the biologic drugs that are a significant driver of increased spending will be unaffected by changes to the generic review process, because there is a different FDA pathway for approval of biosimilars. Anything that hastens biosimilar development – including better aligning biologic and small-molecule exclusivity periods – would reduce spending.[14]

Potential to increase competition among existing drugs

There is a set of tools that can be used to provide leverage on prices while protecting access – such as formulary placement and prior authorization that are well established in commercial insurance, but are absent or limited in parts of the Medicare program. Consideration could be given to policies that would:

[13] Woodcock J. Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA). Testimony before the Senate HELP Committee. Jan 28, 2016.

[14] 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, which typically receive five years of exclusivity. Such a change could generate more than $4 billion in savings to Medicare 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/

- increase competition within the Medicare Part B program,[15]
- increase competition within Medicare Part D,[16,17] and
- shift some drugs from the medical to the pharmacy benefit.

An increased focus on value

Both within public programs and in the commercial market, formal value-based or outcomes-based agreements between manufacturers and purchasers – contracts that tie the price of the drug to specified outcomes – may play an important role for some products, but the utility of such arrangements may be limited by their cost to negotiate and the need for sophisticated data systems to monitor success. More broadly, factoring value into coverage decisions – including the choice not to cover drugs whose cost isn't justified – will help reduce overpayment for marginal clinical gains.

Opportunities to improve transparency in drug benefit contracting

[15] 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

[16] 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/

[17] Independent of government price negotiation, current law requires Medicare drug plans to cover every medication within six different broad classes, such as antidepressants and antipsychotics. This policy limits the ability of privately-run Medicare prescription drug plans to negotiate lower prices. 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, http://healthaffairs.org/blog/2016/09/19/the-politics-of-medicare-and-drug-price-negotiation/

Pharmacy benefits managers – the middlemen 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 force drug companies to offer deep price concessions. However, a share of the savings accrues to the pharmacy benefit managers themselves, and their contracts can be extremely complex, making it difficult even for sophisticated benefits administrators to determine whether they've achieved optimal savings.

Congress could consider requiring greater transparency of contract terms and definitions between payers and pharmacy benefit managers,[18] as well as mandating the ability 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

The FDA user fee agreements have done much to speed the approval of brand and generic drugs. As Congress seeks to manage the challenge of rising drug spending, it should look both within and beyond these agreements to achieve a balance between access to innovative medicines and the equally important need to constrain cost-growth in healthcare. I thank you for holding this hearing, and welcome your questions.

[18] 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/