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Ensuring Access, Innovation, and Affordability of Prescription Drugs in Our Delivery System

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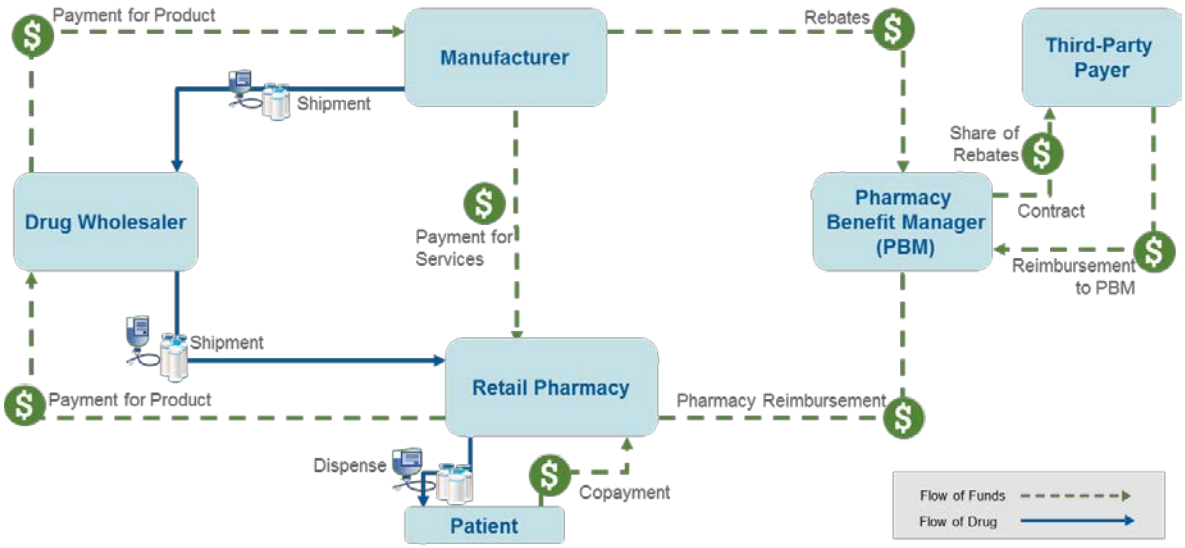
Introduction

The prices that consumers pay for drugs are determined jointly by health system design, pharmaceutical company pricing, and decisions by health plans, pharmacy benefit management (PBM) practices, and other transactions involving distributors and pharmacies along the supply chain. As the healthcare system moves from volume- to value-based payments, the incentives underlying many of these market-based pricing decisions are also changing rapidly. The purpose of this testimony is to elucidate how these factors ultimately determine the prices paid by the consumer for drugs.

How Net Prices to the Consumer Are Determined

The pharmaceutical supply chain is the means through which prescription medicines are delivered to patients (Figure 1).[1] Drugs typically originate in manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail-order, and other types of pharmacies; subject to price negotiations and processed through quality and utilization management screens by PBMs; dispensed by pharmacies; and ultimately delivered to and taken by patients. There are many variations on this basic structure, as the players in the supply chain are constantly evolving, and commercial relationships vary considerably by geography, type of medication, and other factors. The pharmaceutical supply system is complex and results in price variability across different payers and consumers.

Figure 1. Retail, Pharmacy Benefit Product and Reimbursement Flow



1 Avalere Health (formerly The Health Strategies Consultancy), "Follow the Pill: Understanding the US Commercial Pharmaceutical Supply Chain," Kaiser Family Foundation, March 2005.

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Drug Spending Trends

Drugs dispensed in the pharmacy and medical benefit account for approximately 13% of total US healthcare costs.[2] This frequently-cited figure uses total national health expenditures as a basis for calculating the percentage. Other experts sometimes use a subset of national health expenditures or total medical claims as the denominator, which accounts for the range of percentages often cited in this context. In recent years, new innovations have increased spending on specialty medications, which now account for $384 of the $895 per person per year spent on drugs.[3] These trends particularly impact the Medicare program, in which the Medicare Trustees project that Part D spending will grow at an average annual rate of 9.2% from 2016-2025.[4]

Over the past five years, list prices for protected pharmacy benefit drugs have increased 11.5%, while net prices have increased 6.1% (Figure 2).[5] The difference is the result of rebates and other discounts from manufacturers to public and private payers. These considerable differences between list and net pricing trends show the power that competition and payer negotiation have on drug prices. As multiple products for a given indication come to market, plans and PBMs may negotiate rebates and other price concessions from manufacturers in exchange for preferred formulary placement and improved access. Typically, payers use these price concessions to reduce overall premiums, but the rebates are not shared directly with patients at the point of sale. As a result, most patients who fill a prescription are paying cost-sharing based on a price that is generally not reflective of rebates negotiated by a health plan or PBM.

2 Centers for Medicare & Medicaid Services, National Health Expenditure Data. NHE Tables. December 2016. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html; Altarum Institute Center for Sustainable Health Spending, "A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail," May 2017 (Addendum II).

3 Quintiles IMS Institute. "Medicines Use and Spending in the US," May 2017. http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021#form.

4 Medicare Trustees. "2016 Annual Report," June 2016. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/tr2016.pdf.

5 Quintiles IMS Institute. "Medicines Use and Spending in the US," April 2016, 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.

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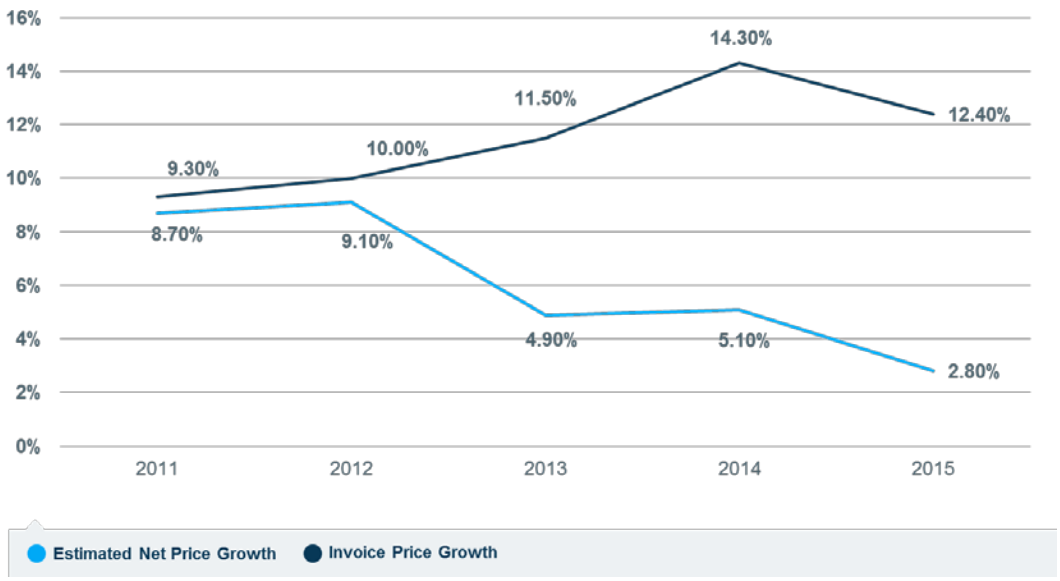
Figure 2. List vs. Net Price Growth, Protected Pharmacy Benefit Drugs, 2011-2015



Benefit Design

Insurance benefit designs increasingly expose consumers to the full cost of their medicines through percentage co-payments for drugs. Further, consumer exposure to out-of-pocket costs has increased as deductibles have grown across benefit programs.

In recent years, payers have been under increasing pressure to meet consumer demand for constrained premium growth through changes to benefit design. In particular, the financial crisis accelerated adoption of high deductible health plans (HDHPs) among employers.[6] In addition, the patient protections put in place under the Affordable Care Act (ACA) required payers to focus on benefit design as a way to offer competitive premiums in an environment where price-sensitive consumers focus on monthly costs. Consumers are therefore paying more out-of-pocket for prescription drugs as deductibles increase and use of coinsurance for drugs becomes more common. Of course, other factors unrelated to the delivery system effects that are the focus of this hearing are also responsible for increased payment by consumers – such as the cost of newly launched products and the increases in list prices over time referenced in cost sharing.

Health plan deductibles have grown steadily over time. Among individuals with employer coverage, average deductibles increased 49% over the last five years, rising to $1,478 in

6 Bureau of Labor Statistics. "Consumer-Driven Health Care: What Is It, and What Does It Mean for Employees and Employers?" October 2010. https://www.bls.gov/opub/mlr/cwc/consumer-driven-health-care-what-is-it-and-what-does-it-mean-for-employees-and-employers.pdf.

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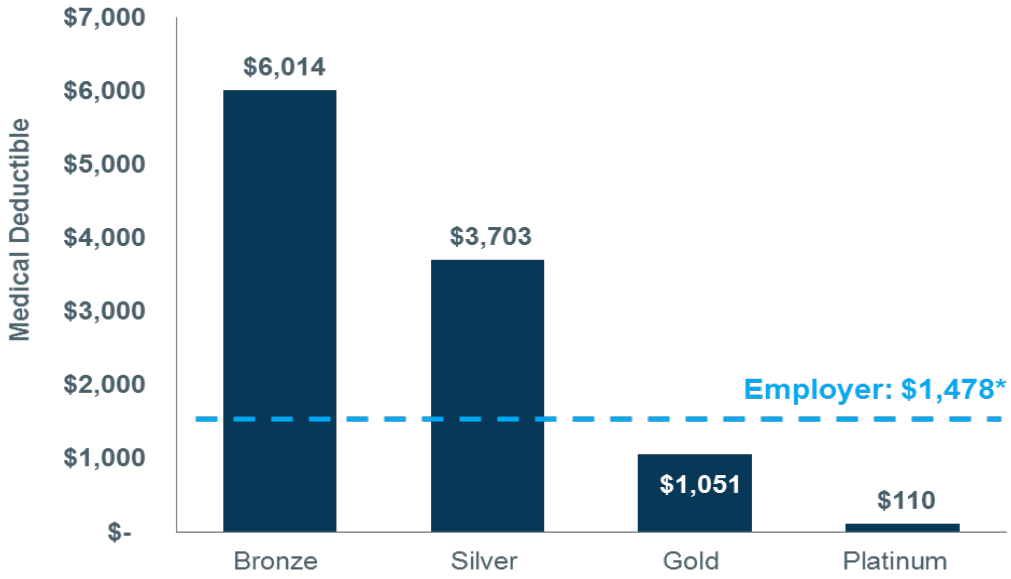
2016.[7] For individuals enrolled in coverage through exchanges, 2017 unsubsidized silver plans had average deductibles of $3,703—a 20% increase from 2016 and a 49% increase from 2014 levels.[8] Importantly, 56% of exchange consumers receive cost sharing reduction subsidies (CSRs), which lower deductibles to between $243 and $3,070 on average based on consumer income. The American Health Care Act (AHCA) would repeal the CSRs.[9]

Figure 3. Average Combined Deductibles for Exchange Plans by Metal Level in 2017 Compared to Employer Plans in 2016[10]



For drugs dispensed in the deductible, consumers pay the full cost of the drug based on the price negotiated by the pharmacy or provider. This price generally does not reflect rebates or other post point-of-sale price concessions offered by the manufacturer to the health plan or PBM. As a result, patients who choose plans with significant deductibles and also use specialty and high-cost medications can face large bills for these drugs early in the calendar year, which may cause them to forego care or prevent them from complying with prescribed drug regimens. Research shows that high out-of-pocket costs

7 Kaiser-HRET. "2016 Employer Health Benefits Survey," September 2016. http://www.kff.org/health-costs/press-release/average-annual-workplace-family-health-premiums-rise-modest-3-to-18142-in-2016-more-workers-enroll-in-high-deductible-plans-with-savings-option-over-past-two-years/.

8 Avalere Health, "Consumer Costs Continue to Increase in 2017 Exchanges," January 18, 2017, http://avalere.com/expertise/life-sciences/insights/consumer-costs-continue-to-increase-in-2017-exchanges..

9 Avalere Health, "AHCA Will Remove Low-Cost Sharing Guarantees for Low-Income Individuals," May 16, 2017. http://avalere.com/expertise/managed-care/insights/ahca-will-remove-low-cost-sharing-guarantees-for-low-income-individuals.

10 Avalere PlanScape®, a proprietary analysis of exchange plan features, December 2016 and Kaiser-HRET, "2016 Employer Health Benefits Survey." Avalere analyzed data from the FFE Individual Landscape File released October 2016 and the California and New York state exchange websites.

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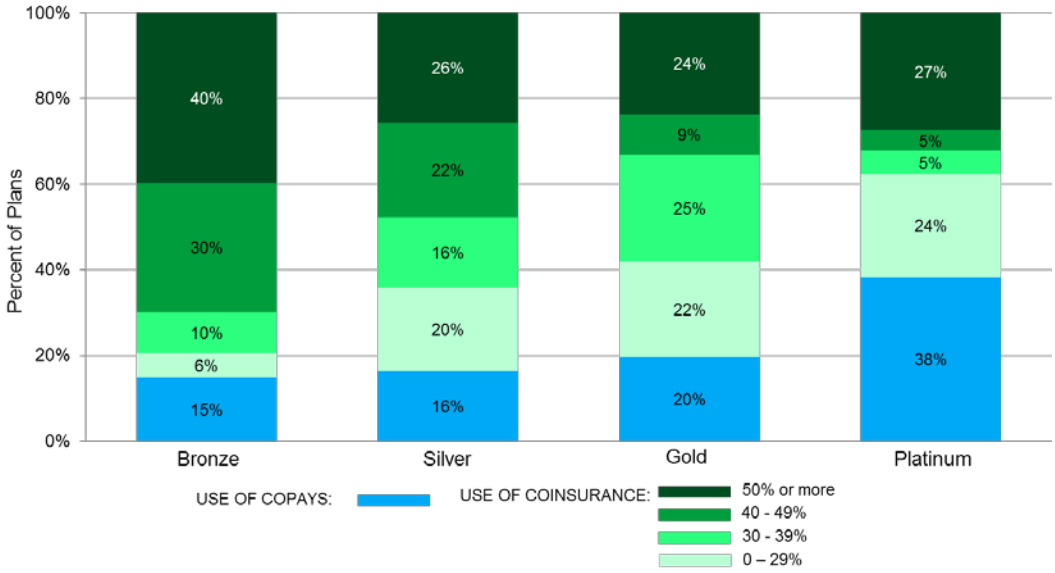
reduce medication adherence and use.[11] Indeed, only 9% of patients without a deductible abandon prescriptions, while patients with a deductible abandon medications at a rate of 23% and 27% for brand and specialty drugs respectively.[12]

Once consumers spend through the deductible, they continue to pay cost-sharing as they access products and services. Increasingly for prescription drugs, this cost sharing takes the form of coinsurance, in which individuals pay a percentage of the cost of the drug rather than a fixed dollar copayment. Coinsurance is calculated based on a price that is not reflective of most discounts or rebates negotiated by the health plan or PBM.

As the number of specialty medications on the market has increased, so too has the use of specialty drug tiers. In 2016, 43% of employer plans had separate tiers for these products. Among those plans, 46% charge coinsurance averaging 26%.[13] This trend is more pronounced in the exchange markets where 84% of all 2017 silver plans charge coinsurance for specialty drugs with average coinsurance amounts of 37% of the drug cost (Figure 4).[14]

Figure 4. Prescription Drug Cost Sharing on Specialty Tier in Exchange Plans



Notably, the ACA implemented a maximum out-of-pocket limit that caps consumer costs across all healthcare services. This limit offers important protection for chronically ill

11 Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *Jama.* 2007;298(1):61-69. Kirkman MS, Rowan-Martin MT, Levin R, et al. Determinants of adherence to diabetes medications: findings from a large pharmacy claims database. *Diabetes care.* 2015;38(4):604-609. Li P, Schwartz JS, Doshi JA. Impact of Cost Sharing on Therapeutic Substitution: The Story of Statins in 2006. *Journal of the American Heart Association.* 2016;5(11).

12 Quintiles IMS Institute. "Medicines Use and Spending in the US," May 2017. http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021#form.

13 Kaiser-HRET. "2016 Employer Health Benefits Survey," September 2016. http://www.kff.org/health-costs/report/2016-employer-health-benefits-survey/.

14 Avalere PlanScape®, a proprietary analysis of exchange plan features, December 2016. Avalere analyzed data from the FFE Individual Landscape File released October 2016 and the California and New York state exchange websites.

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individuals against catastrophic healthcare costs, but does not extend to Medicare beneficiaries. In addition, as benefits expose consumers to increasing costs, use of copay assistance has also risen. IMS reports that 19% of commercial brand drug claims in 2016 included the use of a copay coupon to reduce out-of-pocket costs, with significant variation across therapeutic classes.[15]

Across all forms of insurance, consumer out-of-pocket burden is not evenly distributed among covered benefits. Outpatient prescription drugs are covered at lower percentage rates than some other services. One study, using data from 2014, showed that for all drugs covered by insurance in the US, consumers paid 13% of every dollar compared to 3% for hospital stays, 7% for emergency care, and 14% for physician office visits.[16] These data demonstrate the role of benefit design in shaping consumer perception of cost.

Market Competition

Consumer experience with drug costs is importantly determined by the competitiveness of drug classes. Increased competition in a class–whether through the introduction of a generic or a competitive branded product–typically results in substantial net price reductions, particularly for legacy products.

Health plans and PBMs play an important role in negotiating drug rebates and discounts on behalf of employees, individual market consumers, and government programs. This role is exemplified when a second-to-market brand medication enters the market. While underlying data is proprietary, recent experience associated with the Hepatitis C market suggests competition among brands led to significant reductions in net prices for innovative medicines.[17] In addition, managed care entities incent use of lower-cost alternatives, including generics. Health plans and self-insured employers expect that their PBMs will effectively manage cost–and often compensate on that basis.

In addition to managed care stakeholders, drug approval and exclusivity processes introduce competition into the marketplace. For traditional, small-molecule drugs, the generic approval system created under the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the Hatch-Waxman Act) has been effective at maintaining commercial incentives for drug development through market exclusivity, while creating strong pricing pressure through generic competition later in the product lifecycle. Despite concerns during the passage of Hatch-Waxman, the number of approved New Drug Applications (NDAs) has remained relatively constant in over three decades since its enactment, and generic drugs now comprise 89% of all drugs

15 Quintiles IMS Institute. “Medicines Use and Spending in the US,” May 2017. http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021#form.

16 Avalere analysis of Medical Expenditure Panel Survey, 2014, from the US Department of Health and Human Services, Agency for Healthcare Research and Quality. https://meps.ahrq.gov/mepsweb/. Accessed February 2017. Analysis includes all individuals with any source of health care coverage, including public and private.

17 Humer, Caroline, “HCV price war will save an estimated $4 billion,” Reuters, January 2015. http://www.reuters.com/article/us-express-scr-hepatitisc-idUSKBN0KV26X20150122.

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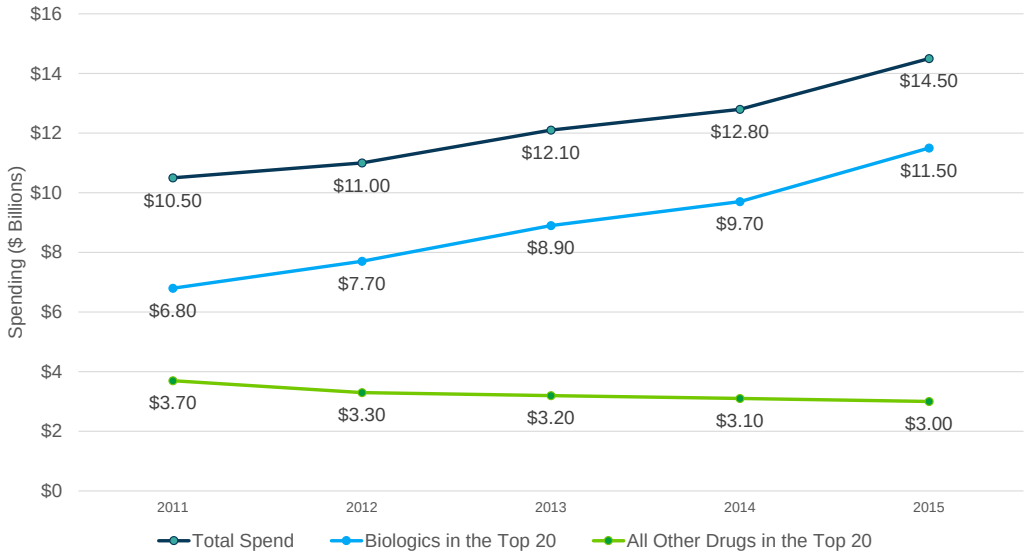
dispensed in the US.[18] On average, drug prices decrease by 51% within 12 months of generic competition and decrease by nearly 80% within 6 years. In the past 10 years, cost savings from generics are estimated at $1.68T.[19]

There are a few exceptions where competition does not produce dramatic cost savings for patients in today's environment. First, is the case of generics with limited or no competition, in which the traditional competitive pricing pressures do not always apply.[20] FDA Commissioner Scott Gottlieb has already indicated his support of initiatives to focus on speeding entry of second-to-market generics.[21] For products that have not yet reached the end of their exclusivity, the FDA may also be able to accelerate approval of the second product to market to encourage more rapid competition and price concessions from branded drugs.

Biologics are another area of focus for improved competition. Biologics have grown to represent 79% ($11.5B) of Medicare Part B (Figure 5) and 21% ($8.7B) of Medicare Part D spending for the top 20 drugs in each program.[22]

Figure 5: Medicare Top 20 Part B Spending Trends



18 FDA. "Summary of NDA Approvals & Receipts, 1938 to the present." 2011. https://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm. Last accessed 2 May 2017.

19 Ostroff, Stephen. "Building a Modern Generic Review Process." Food and Drug Administration. FDA, 4 Feb 2016. Web. 28 April. 2017. https://blogs.fda.gov/fdavoice/index.php/2016/02/building-a-modern-generic-drug-review-process/.

20 Government Accountability Office. "Generic Drugs under Medicare," August 2016. http://www.gao.gov/assets/680/679022.pdf.

21 Edney, Anna, "Drug Prices Become Target for FDA as Chief Expands Purview," Bloomberg, June 2017. https://www.bloomberg.com/news/articles/2017-06-05/drug-prices-become-target-for-fda-as-chief-expands-agency-s-view.

22 Avalere Health, "Five Obstacles to Competition in the United States Biologics Market," http://avalere.com/expertise/life-sciences/insights/five-obstacles-to-competition-in-the-united-states-biologics-market.

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In 2010, a biosimilar approval pathway was created with an expectation that a multi-source competitive market could offer potential savings for the US health system.[23] However, obstacles remain that may limit the pricing benefits of a truly competitive biologics market—including both innovator and biosimilar products:

1. Complexity of Development: While generics typically experience a 3-5 year development timeline and a cost of $1-5M dollars, biosimilar development requires 8-10 years and potentially costs $200M or more due to the complexity of the molecules involved.[24] As a result, it is unlikely that biosimilars pricing will ever match the level of savings in the generic pharmaceutical market.

2. Prescribing Patterns: Patient and provider reticence to switch from a reference biologic to a biosimilar may also hamper market competition, though this manifests itself differently in different therapeutic areas.

3. Interchangability: As of yet, the FDA has not issued final guidance on how products would be designated as interchangeable, which limits the potential for automatic substitution and associated cost savings.

4. Physician Reimbursement Model: Within Medicare Fee-For-Service, the Average Sales Price (ASP) payment methodology may limit competition by paying physicians the same plus 6% add-on payment for either the innovator or the biosimilar product, which does not encourage providers to prescribe the biosimilar.

5. Consumer Out-of-Pocket Costs: Within Medicare Part D, the current benefit structure results in beneficiaries paying substantially more out-of-pocket for biosimilars relative to the innovator product.[25]

Market-Driven Interventions

As payers strive to link payment to value, healthcare stakeholders must agree on how to define and measure the value of any given product or service. In 2015, a series of new public-facing value frameworks emerged to address this question—attempting to balance clinical benefits of a given product against the system-wide costs. Many of these frameworks failed to adequately consider patient preferences in their assessments.

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23 The biosimilar pathway was created by the Biologics Price Competition and Innovation Act (BPCIA) as Title VII of the Patient Protection and Affordable Care Act in 2010. Available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM216146.pdf.

24 DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen. "Innovation in the pharmaceutical industry: new estimates of R&D costs." Journal of Health Economics 47 (2016): 20-33. Federal Trade Commission. Emerging health care issues: follow-on biologic drug competition. June 2009 Report. Available at: http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

25 Avalere Health. “Patient Out-of-Pocket Costs for Biosimilars in Medicare Part D”. Avalere Health, April 2016. Web. 19 May 2017. Available at: http://go.avalere.com/acton/attachment/12909/f-02c0/1/-/-/-/-/20160412_Patient%20OOP%20for%20Biosimilars%20in%20Part%20D.pdf.

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In 2017, Avalere and *FasterCures* launched the Patient-Perspective Value Framework that assesses the benefits and costs of different healthcare options in the context of patients' personal goals and preferences, including things like symptom relief, complexity of regimen, and cost to the patient's family. This sort of holistic assessment of value that is broader than clinical outcomes and customized to reflect individual patient perspectives will be crucial for continuing to evolve our drug payment and delivery system to reward value.

Importantly, assessments of value should consider not only cost of the medication but total cost of care, including pharmacy and medical spending. Unfortunately, in many instances, public program structures, contractual relationships, and data limitations prevent effective assessments of value based on total cost of care. For instance, the Medicare Part D program is inherently structured to encourage lower, more competitive premiums for drugs by reducing pharmacy benefit spending—even if higher spending on medications could reduce costs in Medicare Parts A and B.

Outcomes-based contracts also represent a significant opportunity to shift away from prescription drug list prices toward value-based reimbursement models. A recent survey conducted by Avalere found that 70% of health plans have favorable attitudes toward outcomes-based contracts, and one-half of health plans indicate they have outcomes-based contracts already in place or are actively negotiating them.[26] Unfortunately, existing regulatory barriers, including standards related to government price reporting and the Anti-Kickback Statute, presently hamper further development of this trend.[27]

Effective outcomes-based contracts require next-generation data analysis and interventions that enable payers and manufacturers to identify patients eligible for treatment, target outreach to ensure appropriate adherence and quality improvement, and measure product performance against pre-agreed-upon outcomes on an ongoing basis. Consumer benefit can be substantially enhanced through data-based engagement around pharmaceuticals, including:

1. Data Aggregation and Management: Facilitating data sharing between a health plan and manufacturer to enable real-time contract management and ongoing evaluation of results.

2. Patient Identification: Designing algorithms to proactively identify patients most likely to benefit from a given therapy based on their demographics, geography, treatment type, and insurance coverage. Conducting statistical modeling to predict patient outcomes and potential benefit from the product.

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26 Avalere Health, "Health Plans are Actively Exploring Outcomes-Based Contracts," May 30, 2017, http://avalere.com/expertise/life-sciences/insights/health-plans-are-actively-exploring-outcomes-based-contracts.

27 Eli Lilly and Company and Anthem, "Promoting Value-Based Contracting Arrangements," January 2016, https://lillypad.lilly.com/WP/wp-content/uploads/LillyAnthemWP2.pdf.

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3. Patient and Provider Engagement: Conduct targeted outreach to providers and directly to patients with interventions intended to improve adherence and achieve desired outcomes.

As more manufacturers and health plans embark on these data-driven partnerships, the market will evolve away from historical pricing models and toward new, innovative ways to reward outcomes.

Conclusion

The focus of this testimony is how the healthcare delivery system affects the pharmaceutical prices faced by consumers. Consumer exposure to drug costs is determined by benefit design, the competitiveness of drug classes, and approaches to provider payment. As benefit design evolves, deductibles and cost sharing for medications have increased across government and commercial payers, increasing out-of-pocket spending. Of course, consumer costs are also importantly determined by the pricing decisions made by pharmaceutical companies prior to entry of product into the supply chain, and the level and type of rebates and discounts granted.

Active management of the pharmaceutical benefit is vital to establishing a competitive pricing dynamic and achieving optimal patient outcomes. However, it is critical to ensure that benefit designs are achieving their promise, and not effectively serving as barriers to good medical and cost management. The value of pharmaceuticals should always be assessed in the context of total medical costs, and unfortunately, many government programs and employer benefit strategies fail to integrate the pharmaceutical expense line into the context of overall medical management.

Increased competition in the pharmaceutical markets holds promise for substantially reducing costs. Speeding the approval of the second- and third-branded drugs in a therapeutic class would expedite competition and lead to more rapid price concessions. Ensuring a continued robust market for generic pharmaceutics is vital for effective cost management and improvement of population health outcomes. Finally, there is strong potential for consumers in growing biosimilar competition.

Health system change is increasingly assigning value to improvements in population outcomes for common medical conditions, and many of these outcomes can be effectively achieved through better use of medication. A patient-oriented perspective on value is key to ensuring that the American healthcare system continues to evolve toward the consumer. Further alignment of stakeholder interests around the use of pharmaceuticals holds promise to benefit consumers as payment systems evolve towards value-based design.