Director's Forum

Drug Pricing Transparency: The New Retail Revolution

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As spending on medications in the United States increases with each passing year, the need for drug pricing transparency by manufacturers also increases. Drug spending, excluding rebates and discounts, was \$309.5 billion in 2015, up 8.5% from 2014. Drug pricing transparency has been a topic of debate across the health care system. This column reviews the issue of drug pricing and emphasizes the need for transparency in this area. We will discuss factors that influence drug pricing, policies and ways to reduce the rising costs of drugs, and the role of pharmacy leaders in managing this problem. A multitude of factors are driving the country to spend more and more on medications; pharmacy leaders can employ various strategies to counteract this escalation of drug prices. After reviewing this article, the pharmacy director will have an increased ability to address drug pricing issues with stakeholders as they develop patient-centered pharmacy services.

INTRODUCTION

As spending on medications in the United States increases with each passing year, the need for drug pricing transparency by manufacturers also increases. Drug spending, excluding rebates and discounts,

was \$309.5 billion in 2015, up 8.5% from 2014.¹ A breakdown of spending in the United States outside of retail locations (hospitals and clinics) is displayed in **Figure 1**. Advancements in health care are leading to the production of more complex medications

Figure 1. 2015: Spending in non-retail locations¹

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and clinical trials and thus to increased spending. The Tufts Center for the Study of Drug Development explains that the full product lifecycle cost per approved drug is \$2.9 billion (\$2.56 billion development cost in addition to \$312 million postapproval research and development cost) expressed in 2013 US dollars.² The total cost for one new medication has drastically increased when compared to Tuft's 2003 study. The cost for a new drug has increased by 145% between the 2 study periods, at a growth rate of 8.5% per year.²

A potential explanation for the increase includes higher failure rates for drugs tested in human subjects.² Increased out-of-pocket costs for individual drugs are a result of greater clinical trial complexity and larger clinical trial sizes. Research and development that targets chronic and degenerative diseases also drives up the costs. The rise in spending on medications in the United States and the rise in the manufacturer's cost per new medication are a reality. The goal is to promote medication accessibility in the US health care system while preserving the pharmaceutical companies' margins for developing new medications.

Drug pricing transparency has been a topic of debate throughout the health care system. Increased transparency on drug pricing, including rebates, would allow payers to optimize negotiation.³ This would give hospitals access to pricing information that they could use when communicating with manufacturers to establish rates. Similar to transparency of hospital prices and costs, drug pricing transparency would hold manufacturers accountable for the prices being charged for medications.³

The Centers for Medicare & Medicaid Services (CMS) publish average hospital-specific charges per patient and average Medicare payments for the most common diagnosis-related groups and procedures.⁴ The Affordable Care Act requires hospitals to report annually a list of hospital charges for items and services.⁴ Hospital pricing transparency has been a recent shift in trying to improve cost and care. In response to a TransUnion survey, 80% of respondents listed price transparency as an important factor to bedside manner when choosing a health care provider.⁵ The survey also reported that 79% of respondents said they would be more likely to pay their bills if they knew the cost before getting care.⁵ Similar to hospital price transparency, drug pricing transparency may improve the payers' autonomy and help them better understand the cost of medications.

However, there are some negative aspects of drug pricing transparency.³ Some argue that enforcing drug pricing transparency may result in an increase in drug prices, leading to an additional rise in costs and spending.³ In addition, if manufacturers are required to disclose drug pricing, the process of gathering and disseminating this information may become time intensive and potentially result in less profitability to the manufacturer, which may lead to less innovation. Currently, it is unclear how drug pricing transparency will alter the health care system, for better or worse.

This article reviews the issue of drug pricing and emphasizes the need for transparency in this area. Specifically, we will discuss factors that influence drug pricing, policies and ways to reduce the rising costs of drugs, and the role of pharmacy leaders in managing this problem. After reviewing this article, the pharmacy director will have a greater ability to address drug pricing issues with stakeholders as they develop patient-centered pharmacy services.

FACTORS INFLUENCING DRUG PRICES

A multitude of factors are driving the country to spend more on medications. Major influencers of increased spending include prices on brand medication, a lack of major patent expirations, increased prices of specific generic medication, and the expense of specialty medications. More than half of the total spending increase last year was on brand medications that have been available for less than 24 months.¹ In 2015, 73.3% of spending was on brand medications, while only 11.3% of total prescriptions were for brand medications.¹ Although brand medications make up the minority of prescriptions, they contribute the majority of costs. The average patient cost for a brand prescription filled through a commercial plan was \$44 per prescription in 2015, which was a 25% increase since 2010.¹

A lack of major patent expirations that would allow brand medications to be available as generics has indirectly contributed to increased medication spending. Although the average patient cost for generics has remained at about \$8 per prescription since 2010, certain generic medications have experienced noticeable price increases.¹ One example is doxycycline's reported increase from \$20 per bottle in October 2013 to \$1,849 per bottle in April 2014.⁶ Such unpredictable price increases on generic medications result in unanticipated excess spending by the health care system.

Another major contributor to increased drug spending in the United States is the expense of specialty medications. In 2015, specialty drug spending reached a net \$121 billion, up more than 15% from 2014.¹ **Table 1** includes the medications in order of most spending from 2015. Spending on specialty drugs has doubled over the last 5 years and has resulted in 70% of overall medication spending growth from 2010 to 2015.¹ Currently, more patients are receiving new treatments for hepatitis, autoimmune diseases, and oncology. Hepatitis C treatments were used in nearly 250,000 patients in 2015, up from 170,000 patients in 2014 and up even more than in earlier years.¹

Spending on oncology medication has increased 18% from 2014; the fastest growing classes are targeted therapies, including monoclonal antibodies and protein kinase inhibitors.¹ Certainly, prices on brand medication, a lack of major patent expirations, increased prices of specific generic medication, and the expense of specialty medications all contribute to the nation's increased health care spending.

Table 1. Top 20 drugs with greatest spending from 2015¹

Medication	Cost (nondiscounted, US billion dollars)
Harvoni	14.3
Humira	10.6
Enbrel	6.6
Crestor	6.3
Lantus Solostar	5.8
Remicade	5.0
Advair Diskus	4.7
Abilify	4.4
Copaxone	4.4
Januvia	4.2
Neulasta	4.1
Lyrica	3.8
Lantus	3.8
Rituxan	3.6
Nexium	3.5
Tecfidera	3.5
Spiriva Handihaler	3.4
Avastin	3.1
Sovaldi	3.0
Atripla	2.9

POLICIES TO CONTROL DRUG COSTS

The political landscape in the United States has helped shape current spending on medications. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments, continues to manage the generic drug approval process and was anticipated to save \$35 billion over 10 years.⁷ This act ensures that brand name drug manufacturers have patent protection and a period of marketing exclusivity to recoup their investments.⁷ Currently, there are no limits on the prices charged by the manufacturer for medications unless the payer is enrolled in a particular savings program. When the brand name patent expires, there is a reduction in spending because of the availability of lower priced generic versions. To speed up the process of bringing generic medications to market, section 505(j) established the abbreviated new drug application (ANDA) approval process.⁷ This allows generics to be approved without submitting a full new drug application (NDA) to the US Food and Drug Administration.⁷ However, if patent infringement is claimed, there is a 30-month stay on the approval of an ANDA.⁷ This can further delay competition and prolong spending on higher priced brand medication. Encouraging generic drug administration, the Orange Book provides pharmacists with information to substitute generic alternatives for brand medications to improve affordability for patients.⁷

Another policy that assists with controlling drug costs is the 340B Drug Pricing Program. This program allows certain hospitals and other covered entities to obtain discounted prices on covered outpatient medications from drug manufacturers.⁸ The Health Resources and Services Administration (HRSA) estimates that covered entities saved \$3.8 billion on outpatient drugs through the program in the 2013 fiscal year.⁸ HRSA calculates a ceiling price for the medication, which is the maximum price a manufacturer can charge.⁸ It was calculated that 340B hospitals receive a minimum discount of 22.5% of the average sales price to improve hospital and patient affordability.⁸

A recent policy shaping US spending on medications is the Biologics Price Competition and Innovation Act. This 2009 legislation allows for fast-track approval of biosimilar drugs to combat high-priced biologic medications.⁹ CMS explains that biosimilar products are an opportunity to achieve cost savings and greater patient access to expensive therapeutic treatments for chronic conditions.⁹ Considering the expense of these specialty medications, increasing biosimilar products will improve access and reduce spending.

WAYS TO REDUCE SPENDING

Different approaches for promoting cost savings can be helpful to counteract drug price escalation. Increased market competition through patent expiration leading to generic substitutions will largely result in cost savings. One notable generic anticipated to reduce spending is imatinib; *Gleevec* and *Glivec*, which was the fourth highest selling cancer treatment in 2015, became generic in February 2016.¹

Expansion of biosimilar products advancing through the developmental pipeline will result in additional cost savings to the health care system. Filgrastim biosimilars contributed savings of over \$72 million (*Zarxio* gained 5% of sales after 5 months on the market) as of December 2015.¹

Another way to reduce spending is to promote the use of health economics and outcomes research. Utilizing this research helps health care professionals determine whether a new medication's benefit is worth the price compared to other therapy options.

Drug cost should influence prescribing and administration decisions to further reduce spending for both hospital and patient. Formulary medications are the most cost-effective options; utilizing preferred drug lists at an institution can reduce excess spending. Negotiating rebates directly with manufacturers is another potential opportunity to promote drug cost savings. For patients, accessibility to insurance and drug coupons will offer added discounts.

The Affordable Care Act will continue to reduce medicine spending for patients due to expanded insurance coverage, improved coordination of care, and a shift to value-based payment.¹ Coupons for brand medication help to reduce patient cost exposure as well. Almost half of the patients taking diabetes medication, facing \$50 or more per prescription, were able to reduce their out-of-pocket cost to zero through commercial insurance in 2015.¹ There are a variety of approaches to help reduce medication spending for the health care system, and these options can result in visible savings.

ROLE OF PHARMACY LEADERS

Pharmacy leaders have a unique perspective on drug pricing and transparency. Pharmacists are responsible for promoting accurate medication administration while considering the cost to the patient and institution. Pharmacists are an advantageous resource for providers and patients alike. Due to their position in the health care network, pharmacists can direct patients who need assistance with payment (insurance,

coupons, etc) and suggest alternative medication substitutions for expensive therapies. Working with medications at all stages of care and through a variety of cost exchanges gives pharmacy leaders an appreciation for the complexity of medication spending.

Spending on medications and drug pricing will continue to rise in the coming years. US spending is anticipated to reach \$610 to \$640 billion (nondiscounted) in 2020.¹ Over the next 5 years, spending is expected to grow at a faster rate compared with the previous 5 years.¹ This steady growth will be driven by innovation and offset by loss of patent exclusivity (generics and biosimilar competition).¹ Innovation will contribute greatly to future increases in drug prices; 43 to 49 new active substances are expected to launch each year for the next 5 years, with oncology being the greatest research area.¹ Drug pricing transparency bills are beginning to be introduced and may impact future drug costs. At least 11 states have introduced legislation that would require manufacturers to validate drug prices by disclosing how much they spend on research, manufacturing, and marketing.¹⁰ Policymakers will play a large role in shaping drug cost transparency. Pharmacy leaders must remain connected to both lobbyists and policymakers to ensure that decisions are made in the best interests of the patients.

CONCLUSION

The issues of rising drug prices and pricing strategies are complex. The solution to the problem requires that all parties, including the pharmacy and manufacturers, be transparent about pricing and the reasons for higher prices. The US health care system must have a pricing scheme that balances medication accessibility with the cost to develop new medications. Pharmacy leaders can use a variety of strategies to combat negative views of drug pricing and work with policymakers and others to fix some of the current issues.

REFERENCES

1. Quintiles IMS. Medicines use and spending in the U.S. A review of 2015 and outlook to 2020. 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#form>. Accessed January 2017.
2. Tufts Center for the Study of Drug Development. Cost to develop and win marketing approval for a new drug is \$2.6 billion. November 2014. http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study. Accessed January 2017.
3. Coukell A, Shih C. What's driving increased pharmaceutical spending? *The PEW Charitable Trusts*. May 2016.

- <http://www.pewtrusts.org/en/research-and-analysis/analysis/2016/05/26/whats-driving-increased-pharmaceutical-spending>. Accessed January 2017.
4. American Hospital Association. Hospital price transparency. March 2014. <http://www.aha.org/content/14/14/pricetransparency.pdf>. Accessed January 2017.
 5. TransUnion. TransUnion survey: Healthcare cost transparency major factor in patients' choice of providers, health plans during open enrollment. November 2013. <http://newsroom.transunion.com/transunion-survey-healthcare-cost-transparency-major-factor-in-patients-choice-of-providers-health-plans-during-open-enrollment>. Accessed January 2017.
 6. Pollack A. Drug goes from \$13.50 a tablet to \$750, overnight. *The New York Times*. September 2015. http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0. Accessed January 2017.
 7. US Food and Drug Administration. Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). August 2013. <http://www.fda.gov/newsevents/testimony/ucm115033.htm>. Accessed January 2017.
 8. Medicare Payment Advisory Commission. Overview of the 340B Drug Pricing Program. May 2015. <http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0>. Accessed January 2017.
 9. Cauchi R. State laws and legislation related to biologic medications and substitution of biosimilars. National Conference of State Legislatures. June 2016. <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>. Last accessed January 2017.
 10. Ollove M. High drug prices prompt demands for transparency. *The PEW Charitable Trusts*. March 2016. <http://www.pewtrusts.org/en/research-and-analysis/blogs/state-line/2016/03/07/high-drug-prices-prompt-demands-for-transparency>. Accessed January 2017. ■