



OnPoint: Health Policy Brief

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Rx Reality Check: 2016 Update

Pharmaceutical Industry Driving US Health Care Costs

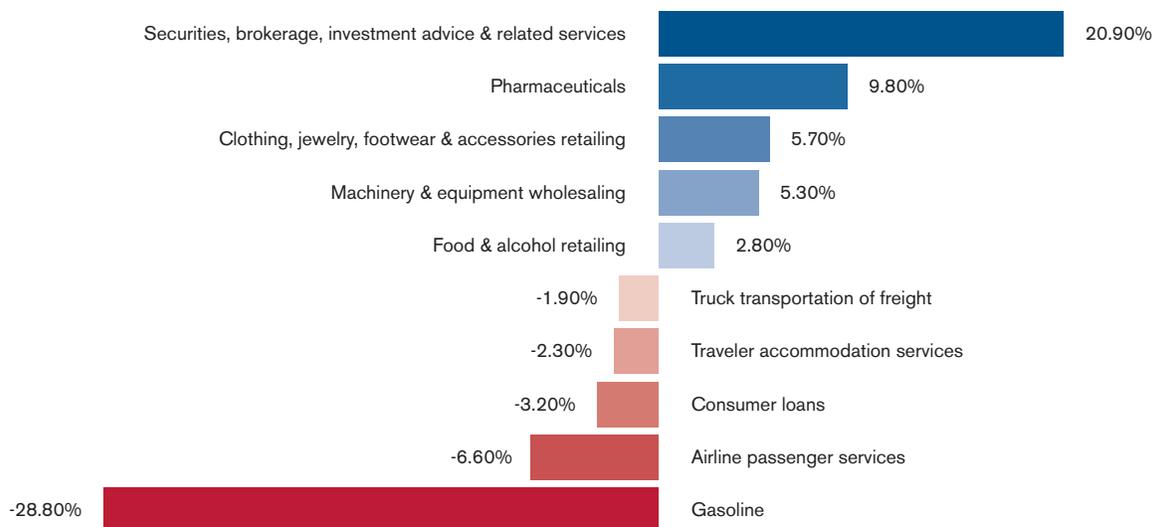
While breakthrough medications may offer tremendous clinical benefits for patients, prescription drug prices continue to rise across the country and in the Commonwealth. Nationally, double-digit price increases for prescription drugs have taken place over the past several years, including average increases of 12.6 percent in 2014¹ and 10 percent in 2015.² In its 2015 *Performance of the Massachusetts Health Care System* annual report, the Center for Health Information and Analysis found that pharmacy spending grew by roughly 13 percent in 2014. In 2015, the Center noted that prescription drug costs continued to play a significant role in health care spending, increasing by 10.1 percent and accounting for one-third of the overall growth in total health care expenditures. MAHP's latest *On Point* examines current pharmacy trends in the marketplace, efforts at the state and federal levels to contain costs, and outlines a series of steps policymakers should consider for greater transparency of prescription drug prices.

Pricing Increases – More Than Just A Few “Bad Apples”

While the high cost of specialty drugs has garnered significant attention, prices have increased across all segments of the pharmaceutical industry – specialty, brand-name and generics. Despite the suggestion that the drastic price increases for drugs that have been on the market for decades represent the actions of a few bad apples, price hikes are pervasive.

According to the *Wall Street Journal*, over the past year, prices received by drug manufacturers rose second-most among the 20 largest components in the Producer Price Index.³ Based on data from the Bureau of Labor Statistics, the chart below shows the largest price increases and decreases for products and services from May 2015 to May 2016, noting that pharmaceutical prices have increased 9.8 percent during that period.

Select Price Increases* – Producer Price Index



*source: Wall Street Journal, June 14, 2016 based on data from the Bureau of Labor Statistics

The following chart provides an overview of the substantial increases over the past five years in the prices charged for a variety of prescription drugs. Some will argue that these prices do not reflect discounts that health plans and pharmacy benefit managers negotiate and that pharmaceutical companies offer discounts off these prices. However, these prices are usually the starting point, and net prices in many cases continue to rise despite these discounts.³ As the Massachusetts Attorney General's examination on specialty drugs noted, "Even after accounting for all discounts and rebates, growth in the health plans' spending on prescription drugs has significantly outpaced overall health care spending growth."⁴

Top Selling U.S. Drug Prices Over Five Years

DRUG (COMPANY)	PRICE*		PRICE GROWTH
	Dec. 31, 2010	Present	
Humira (AbbVie) 40 mg/0.8 ml pre-filled syringes	\$1,676.98	\$3,797.10	126%
Enbrel (Amgen) 50 mg/ml subcutaneous sol.	\$427.24	\$932.16	118%
Copaxone (Teva) 20 mg/ml subcutaneous sol.	\$3,025.04	\$6,593.00	118%
Crestor (AstraZeneca) 10 mg tablets	\$350.17	\$745.41	112%
Abilify (Otsuka) 10 mg tablets	\$454.07	\$891.97	96%
Lantus Solostar (Sanofi SA) 100 units/ml subcutaneous sol.	\$191.96	\$372.76	94%
Advair Diskus (GlaxoSmithKline) 250/50 inhalation discs	\$199.90	\$334.63	67%
Remicade (Johnson & Johnson) 100 mg IV powder for solution	\$657.87	\$1,071.48	63%
Neulasta (Amgen) 6 mg/0.6 subcutaneous sol.	\$3,320.00	\$5,155.65	55%
Nexium (AstraZeneca) 10 mg oral packets	\$162.55	\$250.94	54%

* Reflects wholesale acquisition prices before volume-related rebates and other discounts. Prices are based on most commonly prescribed dose. Source: Truven Health Analytics

04/04/2016 REUTERS

Increases in Specialty Drug Prices

Nationally, specialty drugs account for less than one (1) percent of all private insurance prescriptions, but more than 30 percent of prescription drug spending.⁴ The financial impact of these medications is projected to reach 50 percent of drug spending by 2018⁵ and will only increase as more specialty pharmaceuticals gain approval from the Food and Drug Administration (FDA). For example, according to the Pharmaceutical Research and Manufacturers of America, 771 new drugs and vaccines are in development by US companies, including: 98 being developed for lung cancer; 87 for leukemia; 78 for lymphoma; 73 for breast cancer; 56 for skin cancer; and 48 for ovarian cancer. Despite the promise these new drugs present, how pharmaceutical manufacturers establish the prices for these and other drugs remains a mystery.

Increases in Brand-Name Drug Prices

The increase in prescription drug costs has not been restricted to specialty drugs. In 2015, the average price of brand-name drugs increased 16.2 percent and by more than 98 percent since 2011. Further, one-third of branded products experienced price increases greater than 20 percent in 2015, including for drugs that have been on the market for decades.

- EpiPen. A lifesaving treatment for millions whose allergies can send them into severe shock, including many schoolchildren who are advised to keep an injector handy at all times, Mylan has raised the cost of this allergy treatment by 548 percent since it began selling the drug in late 2007.
- Gleevec. When this breakthrough cancer medicine was first launched in 2001, the list price was \$26,400 a year. Since then, similar drugs have come on the market, but the U.S. wholesale list price for a year's supply of Gleevec has soared to more than \$120,000, a 350 percent increase.

- Evzio. At the time that the FDA announced that it had approved the drug in April 2014, Kaléo Pharma charged \$690 per kit for this handheld auto-injector that is used for administering naloxone. In November 2015, the wholesale price rose to \$900 and rose again in February 2016 to \$4,500.
- Humulin R U-500. The cost of this insulin injector jumped from \$12.01 to \$54.48 per milliliter between 2007 and 2014, a price increase of more than 350 percent.

Increases in Generic Drug Prices

Significant price increases have also been occurring with generic drugs. Much of this is driven by the consolidation among generic manufacturers, which has produced a much less competitive market. For example, a 30-gram tube of generic topical ointment used to treat eczema and psoriasis cost roughly \$8.00 in 2013. Today, the same 30-gram tube costs \$180, a 2200 percent increase in just 3 years. According to testimony submitted to the Health Policy Commission as part of its annual Health Care Cost Trends hearings, one health plan noted that a common generic drug to treat congestive heart failure increased by nearly 820 percent, from \$0.12 a tablet in 2013 to \$0.98 a tablet. While these prices may seem modest, especially when compared with new specialty medications, it is important to remember that generics account for a significant portion of prescription drug utilization.

The Myth That High Prices Are Needed To Fund Research & Development

Although high prices are often justified to support the cost of drug development, there is no evidence of an association between research and development costs and prices. In fact, recent research indicates that important innovation that leads to new drug products is often performed in academic institutions and supported by investment from public sources such as the National Institutes of Health.⁶ For example, in examining the most transformative drugs of the past 25 years, researchers found that “more than half of the 26 products or product classes identified had their origins in publicly funded research in such nonprofit centers.”⁷ In instances in which new drugs are not funded through federal grants, biotech startups, funded by venture capital, “frequently take early-stage drug development research that may have its origins in academic laboratories and continue it until the product and the company can be acquired by a large manufacturer.”⁶ This was the case of Sovaldi, a drug that treats hepatitis C. Sovaldi was acquired by Gilead after the original research occurred in academic labs.

Impact To The Commonwealth

Public programs have not been insulated from higher-than-expected drug costs. Between 2014, when Sovaldi came on the market, and January 2016, the state's Medicaid program, MassHealth, spent \$318 million on hepatitis C drugs for its members. This unanticipated cost threatened to put public health plans at severe financial risk. In response, the Attorney General's office threatened possible legal action for unethical pharmaceutical pricing using the state's consumer protection laws, driving Gilead and Bristol-Myers Squibb to negotiate supplemental rebate agreements with the state to provide hepatitis C drugs to MassHealth enrollees at a significantly lower cost.⁸

Public Perceptions On Prescription Drug Prices

Large majorities of Americans favor a wide range of policy changes to curb prescription drug costs, including transparency. A September 2016 survey⁹ by the Kaiser Family Foundation of 1,204 Americans found that more than three quarters (77 percent) of respondents perceive drug costs as unreasonable, compared to 72 percent in August 2015, while one in five (21 percent) say they are reasonable. Among policy ideas to address prescription drug costs, 86 percent of respondents support requiring drug companies to explain how they set drug prices. Further, 78 percent support limiting the amount drug companies can charge for high-cost drugs for illnesses like hepatitis or cancer.

Greater Transparency Is Needed

The current state of prescription drug pricing and the projections of continued increases in drug spending in the years ahead have prompted a variety of proposals from both federal and state lawmakers. In 2016 alone, 13 state legislatures considered bills addressing the rising costs of prescription medications. The aim of many of these efforts focused on greater transparency into the manner by which drug companies set their prices. Likewise, recent efforts at the federal level have sought to require basic transparency for proposed increases in pharmaceutical drug prices.

Making health care more affordable requires holding the entire system accountable. Health plans and providers have been accountable to meeting the state's cost benchmark, but increases in prescription drug prices will threaten the ability for the state to meet the cost benchmark, and similar transparency is needed for pharmaceutical manufacturers. Among the approaches for greater transparency of prescription drug prices that policymakers in Massachusetts should consider:

- 1. Transparency of Prescription Drug Price Increases.** Given the annual double-digit growth in the price of prescription drugs, transparency around the reasons for these increases would benefit the public. The Health Policy Commission, in collaboration with the Center for Health Information and Analysis, should identify a list of prescription drugs for which the state spends significant health care dollars and the prices that have increased significantly over the past 12 months. Those manufacturers should be required to provide an explanation for the increase, including disclosing the research, development, marketing and manufacturing costs, as well as the profits, attributable to those drugs. Likewise, pharmaceutical companies that propose to raise their prices by 10 percent or more should be required to provide notice to the Health Policy Commission 30 days before the new price is to take effect, explaining the rationale for the increase, so that consumers, employers, providers, health plans and the state have notice before the increase takes effect.
- 2. Participation in the Commonwealth's Annual Cost Trends Hearings.** As part of its annual health care cost trends hearings, pharmaceutical and biotech companies should be required to submit data to the Health Policy Commission and to be called as witnesses to present testimony under oath. Requiring drug manufacturers to be part of the annual hearings would be an important step to understanding the impact pharmaceutical pricing plays on the statewide cost benchmark, whether the costs associated with these therapies offer value in comparison to other therapies and treatments, and if they are improving patient care.
- 3. Promotion of Comparative Effectiveness in Examining Treatments & Technologies.** Consumers have a right to know which treatments and drug regimens work and which are less effective. Understanding the medical efficacy and cost of new treatments, including prescription drugs, is essential so that patients can make the most informed decisions about their care. In the absence of a national process for measuring both the cost and clinical effectiveness of new procedures and drugs, states can fill that void. The Health Policy Commission or a collective of interested organizations should bring together stakeholders – clinicians, patients, health plans, academics, pharmaceutical and device manufacturers – to evaluate the safety, effectiveness and cost of new therapies to determine whether the added benefits of more expensive drug treatments are sufficient to warrant the additional costs, as well as to determine appropriate standards of care so that best practices are followed in deciding when to use different therapies.
- 4. Early Dissemination of New Drugs to Market.** Currently, the FDA prohibits pharmaceutical manufacturers from sharing information about drugs in development until they are approved. However, this restriction leaves little time for health plans, employers and government payers to understand the potential cost of new medications or develop appropriate clinical criteria, as was the case with Sovaldi. To provide more notice and give payers an opportunity to prepare in advance of new therapies being brought to the marketplace, the FDA should permit pharmaceutical manufacturers to share clinical and pricing information with health plans and other purchasers prior to a drug's approval.

Footnotes

1. ***Rising Cost of Drugs: Where Do We Go From Here?*** Ifrad Islam (August 31, 2015), *Health Affairs Blog* <http://healthaffairs.org/blog/2015/08/31/rising-cost-of-drugs-where-do-we-go-from-here/>
2. ***Prescription drug prices jumped more than 10 percent in 2015, analysis finds***, Brady Dennis (January 11, 2016), *Washington Post* <https://www.washingtonpost.com/news/to-your-health/wp/2016/01/11/prescription-drug-prices-jumped-more-than-10-percent-in-2015/>
3. ***Drugmakers' Pricing Power Remains Strong***, Joseph Walker (June 14, 2016), *Wall Street Journal* <http://www.wsj.com/articles/drugmakers-pricing-power-remains-strong-1468488601>
4. ***Examination of Health Care Cost Trends and Cost Drivers***, Massachusetts Office of the Attorney General (October 7, 2016).
5. ***Express Scripts 2015 Drug Trend Report***. <https://lab.express-scripts.com/lab/drug-trend-report>
6. Kesselheim AS, Avorn J, Sarpatwari A. ***The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform***. *JAMA*. 2016;316(8):858-871.
7. Kesselheim AS, Tan YT, Avorn J. ***The roles of academia, rare diseases, and repurposing in the development of the most transformative drugs***. *Health Aff (Millwood)*. 2015;34(2):286-293.
8. ***MassHealth to pay for hepatitis C drugs for all infected members***, Felice J. Freyer (June 30, 2016), *Boston Globe*.
9. ***Poll Finds Majority of Americans Want Restraints on Drug Prices***, *Kaiser Health News* (September 29, 2016). <http://khn.org/news/poll-finds-majority-of-americans-want-restraints-on-drug-prices/>