

An Independent Health Pharmacy Rx Report – September 2015

The Alarming Side Effects of Unchecked Generic Drug Pricing

Higher generic drug prices further burden the health care industry and consumers



Introduction

As the U.S. health care system continues to struggle to address and contain the unsustainable, high costs of health care, the rapidly increasing price of generic drugs – traditionally vital cost-savers for consumers, health plans and taxpayers – now threatens to stretch already strained budgets even further.

The Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS) recently projected health spending in the U.S. will have reached \$3.1 trillion, or \$9,695 per person, in 2014. This marks an increase of 5.5 percent over the previous year.¹ This surge results from a number of factors, including prescription drug spending, which jumped nearly 13 percent in 2014 to \$374 billion, the largest increase in more than a decade.²

When pharmaceutical companies invent a new drug, the company receives a patent, granting them exclusive production rights for that new product for a set amount of time (usually 20 years). This protection incentivizes

innovation and allows time for companies to recoup production costs. When that patent expires, other drug companies can gain approval from the Food and Drug Administration (FDA) to manufacture and sell generic versions of the product. These equally effective pharmaceuticals have traditionally been priced much lower than the branded version, due in part to competitive pressures.

As a result of their efficacy and low costs, generic drugs account for about 80 percent of all prescriptions nationally³ and 85 percent at Independent Health. Therefore, generics play a pivotal role in controlling health care costs both nationally and locally. During the 10-year period between 2004 and 2013, generic drug products saved the U.S. health care system nearly \$1.5 trillion.⁴

However, for various reasons, including lack of competition, generic drug prices have soared over the past couple years, including a 10.2 percent spike in the third quarter of 2014 alone.⁵

As overall prescription drug spending has reached its largest annual increase since 2001,⁶ it's imperative the health care system turn its attention to stemming the rapid growth of pharmaceutical costs, including generic drugs.

Cost Impact

Consumers and health plans paid an average of \$13.14 per prescription for the 50 most popular generic drugs in 2010. In 2014, they paid \$62.10, representing a 373 percent increase.⁷

Locally, the average cost of generic medications to Independent Health has jumped from \$21 to \$32 over the last 18 months.

More than a third of available generics cost health plans and consumers more than \$100 per prescription.⁸

A *Modern Healthcare* article on the subject cited a study by Pembroke Consulting, which compared CMS data for average generic drug acquisition costs between July 2013 and July 2014, and found half of the generic drugs listed rose in cost, with a median increase of nearly 12 percent.⁹

Examples include some of the most common prescriptions. The price-per-capsule for tetracycline, an antibiotic prescribed to treat bacterial infections, increased from \$0.05 cents to \$8.59 per capsule, a more than 17,000-percent increase.¹⁰

Tetracycline's sudden spike in cost demonstrates the arbitrary pricing set by drug companies. It's interesting to note, though the drug's capsule form rose in cost, tetracycline is still available as a tablet from a different manufacturer for the original low price. Clinically, the forms of the drug do not differ.

Some of the oldest products on the market are not immune to exorbitant price hikes. Digoxin, a heart medicine mentioned in medical literature dating back to 1785, once cost pennies per pill. Now, a month's supply of digoxin runs about \$50 per month.¹¹ Millions of Americans use digoxin every day, so the impact of the price hike on the health care system adds up quickly.

In 2007, EpiPen, the most prescribed epinephrine injector in the U.S. for treatment of anaphylaxis, cost \$56.64 per pen. In 2014 it cost \$184.35 to equip people with the potential to suffer life-threatening allergic reactions with EpiPen – a 222 percent increase.¹²

An egregious example of pharmaceutical companies taking advantage of the market involves H.P. Acthar Gel, a drug developed in the 1950s. Its most important use has been to treat infantile spasms caused by West syndrome, a rare seizure disorder affecting infants. The anti-inflammatory has also been used to treat conditions like arthritis and gout.

Questcor bought the rights to manufacture the drug in 2001 for \$100,000. In 2007, the company raised Acthar's price from \$1,650 per vial to \$23,000 per vial, citing the drug's small market.¹³ In 2014, the drug cost \$32,000 per vial.¹⁴

Questcor now markets the drug for other rheumatologic conditions, multiple sclerosis and nephrotic syndrome – representing much larger markets, though markets with cheaper and arguably equally effective alternatives. As of 2012, treatment of infantile spasms accounted for only 10 percent of the drug's sales. During the five years after Questcor raised the price of Acthar, the company's shares rose from about 60 cents to about \$50, one of the best performances of any stock in any industry.¹⁵

Every stakeholder in the health industry endures the consequences of arbitrary price hikes. Dennis C. Galluzzo, R.Ph., executive director of the Pharmacists Association of Western New York (PAWNY), says patient access to certain medications may become an issue, as pharmacies are forced to pay thousands of dollars more per month to carry certain medicines.

“Pharmacists have been outraged at the recent spikes in the cost of generics that have been on the market for a long time at very reasonable prices,” says Galluzzo. “Independent Health is one of the few insurance companies that recognize the detrimental impact these price hikes have on pharmacies as well as consumers.”

Edward Stehlik, M.D., MACP, of Northtowns Medical Group, P.C., in Tonawanda, agrees the problem is widespread and says the rash of unconscionable generic drug price increases should spark outrage among consumers and physicians in the U.S., where generic medications cost much more than in other countries.

“We are now frequently seeing new drugs that cost thousands, and sometimes tens of thousands, of dollars a month and generic drugs that have increased in price one thousand-fold faster than inflation without any increase in the cost of making the medication,” says Stehlik. “However, most of these costs remain obscure or hidden to the people who actually use them except when they pay their insurance premium, which turns out to be much higher than it should be due to the drug companies’ huge markups on these medications.”

Reasons

The capricious pricing behavior of drug manufacturers demands an explanation, though answers are not apparent.

Industry consolidation represents one key reason. To maintain profitability, generic drug makers have consolidated over the past several years, resulting in decreased competition. Around 2009, facing saturated generic drug markets, many companies turned to mergers and acquisitions. As a result, when patent protection expires on a brand-name drug, fewer companies produce generic versions. The lag in competition has added up to fewer options and higher prices.¹⁶

Quality and manufacturing issues can also cause drug shortages, and in turn drive up prices as demand exceeds supply. Increased regulations from the FDA and strict monitoring can halt or delay production and force manufacturers to invest more in quality systems to comply with higher standards.¹⁷

These factors, however, cannot solely account for the staggering increase in generic drug prices. For example, no shortage and no new formulation explains the increase in the cost of digoxin, a mainstay prescription relied upon in the cardiology field.¹⁸

Remedies

To counteract this alarming trend toward higher cost generics, Independent Health and other health plans, including national pharmacy benefit managers, like CVS Health Corp. and Express Scripts Holding Co.,¹⁹ have been forced to adjust the drug formularies that determine which prescriptions are covered, and under which copays.

Specially designed formularies encourage the use of effective, low-cost drugs and help contain premium costs by requiring the highest copays for high-cost, low-value prescriptions and the lowest patient copays for low-cost, high-value medications.

Independent Health operates several tiered prescription drug formularies for its various lines of business (i.e.; large groups, small groups, individuals and Medicare). A Pharmacy and Therapeutics (P&T) Committee, composed of 15 practicing community physicians and four practicing community pharmacists, analyzes and reviews all pharmaceuticals on Independent Health’s formulary and bases its placement decisions on efficacy and safety first, then cost, relative to other products in the same class or used for similar purposes.

The recent and sudden price hikes for certain generic medications has necessitated formulary changes. Formulary changes (moving certain high-cost drugs to higher tiers or removing them altogether when another higher value drug in the same classification is available) can help reduce demand for high-cost, low-value medications and over time force drug manufacturers to lower costs.

For example, with clinical effectiveness at the forefront of deliberations, the P&T Committee decided to remove the capsule form of tetracycline and another antibiotic, doxycycline, from the formulary, while keeping the equally effective and low-cost tablets available to members on a low tier (requiring a low copay). Should other health plans do the same, demand for the capsule version of the drugs would be reduced and the manufacturer would be pressured to lower its price.

While formularies and other tools can help shift the market to balance demand for high-cost generic prescriptions, requiring increased transparency in how drug manufacturers price their products would help unveil the mystery of seemingly arbitrary price hikes. Price-transparency standards would also place much-needed pressure on the pharmaceutical companies to maintain fair prices by disclosing development costs and profits from each drug.

Legislative Attention

The spike in generic drug prices has drawn the ire of members of Congress, particularly Sen. Barry Sanders, I-Vt. of the Senate Committee on Health, Education, Labor and Pensions' Subcommittee on Primary Health and Aging, which held hearing on the matter late last year.

Advocates for the pharmaceutical industry testified. Scott Gottlieb, M.D., asserted the rise in generic prices is tied to market challenges, and industry policies and FDA oversight, which boost regulatory costs. He also pointed to decreased competition and material shortages.²⁰

Sen. Elizabeth Warren, D-Mass., questioned how a 40-percent increase in the price pharmacies paid for generic drugs in the third quarter of 2014 could be blamed on enhanced FDA scrutiny. She pointed out while there was a significant increase in FDA warning letters issued between 2011 and 2013, the FDA sent very few of those to generic drug manufacturers. The FDA only addressed 11 of the 7,000 warning letters issued in 2013 to generic drug companies, down from 20 in 2011.²¹

All three executives from generic drug companies the committee invited to testify declined, including the chief executive at Lannett, the company that raised the price of centuries-old digoxin by nearly 1,000 percent.²²

During the hearing, Sen. Sanders announced he would propose legislation titled, "The Medicaid Generic Drug Price Fairness Act," which would require generic drug makers to pay state Medicaid programs rebates if generic drug prices rise faster than the rate of inflation. Such a rule already stands in effect for brand-name drug makers. As of May 2015, the bill had been referred to the Senate Committee on Finance.²³

New York State legislators have also begun to seek legislative solutions. A bill, "New York's Pharmaceutical Cost Transparency Act of 2015," was introduced in the New York State Senate on May 13 and is pending in the Senate Health Committee.

If made law, the legislation would require pharmaceutical manufacturers to submit a report to the state disclosing total costs of the production of certain expensive drugs

(specifically drugs with a wholesale acquisition cost of \$10,000 or more annually or per course of treatment). The information in these reports would be published on a public website.²⁴

Conclusion

First steps toward legislation represent a step in the right direction, and as health plans and consumers push back against the pricing schemes of the drug manufacturers by seeking lower-cost, but effective, drug alternatives, perhaps this damaging market trend will subside.

More can and should be done on the legislative end to compel drug manufacturers to release information on their research and development costs and other pricing factors. Transparency in the industry will go a long way in preventing random spikes in traditionally affordable generic medications as well as unfairly priced new drugs.

“New drug pricing and generic drug price increases are unsustainable and threaten the affordability of health care in America, the only place where the most extreme prices are being charged,” implores Dr. Stehlik. “Select drug manufacturers are taking advantage of lax regulation and charging whatever they want, however unreasonable and excessive. Until our federal legislators act, we will continue to be targeted for more monopolistic price gouging.”

While legislative action can play a vital role in helping to remedy the situation, Independent Health also believes education and awareness among consumers and all stakeholders are tantamount to understanding the pressures weighing on our heavily burdened health care system. Collaborative efforts to seek sustainable solutions in all areas of health care, including pharmacy, must continue to ensure affordable and quality care.

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