

February 25, 2016

The Honorable William Lindsay
Chair/ Planning Committee Chair
Colorado Commission on Affordable Health Care

Re: Follow up to PhRMA's "The Cost of Prescription Drugs in Context" Presentation

Dear Bill,

In November, Tara Ryan presented the "The Cost of Prescription Drugs in Context" to the Colorado Commission on Affordable Health Care (CCAHC). Following the presentation, additional questions were raised about specific information on certain slides. We appreciate the opportunity to respond to those questions.

The biopharmaceutical industry is committed to working with Colorado's lawmakers, patients, doctors, and other health care stakeholders to pursue policies that promote innovation and help ensure consumers know which doctors, hospitals, and medications are covered by their health plan and the out-of-pocket costs required to access these benefits.

Prescription Drug Spending:

The presentation highlighted that retail prescription medicines have consistently accounted for just **10% of U.S. health care spending**.¹ The most recent national health spending projections show that it is expected to grow at rates in line with overall health care spending through 2024.² For Medicaid, it was even less: spending on retail pharmaceuticals was 5.1 percent of TOTAL spending on Medicaid services and benefits in Colorado.

Spending on prescription medicines has remained constant due to several factors, including the high rate of generic utilization and competition among brand-name medicines. When brand name medicines lose their patent protection generic drugs become available. **Nearly 90 percent of all prescriptions are generics** and cost pennies on the dollar compared to the initial price of the drug. The cost of a **generic medicine is typically 80% less than that of the brand medicine**.³ Consequently, medicines are the *only* part of the healthcare system where cost goes down over time. When brand name medicines lose their patent protection, generic drugs become available. Nearly 90% of all medicines prescribed today are generic, and cost pennies on the dollar, making access to these medicines easier for patients.

A new IMS Institute health care brief found that net price increases in 2014 for branded medicines was the "lowest in the past five years" after accounting for discounts, rebates, coupons and other concessions to payers. The brief complements research the IMS Institute previously published that

¹ PhRMA analysis of CMS data. National health expenditures by type of service and source of funds, CY 1960-2014 Baltimore, Md.: CMS; 2015. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2014.pdf>

² <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>

³ <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/ucm167991.htm>

found brand drug invoice prices increased 13.5% in 2014. However, this price growth did not reflect the substantial, and typical, discounts negotiated by insurers and pharmacy benefit managers. According to the brief, after accounting for all of the concessions, prices increased by just 5.5% percent last year, which was in line with overall health care spending growth. According to IMS, “payers appear to be limiting overall branded product price growth through the negotiation of discounts and rebates.”⁴ What is more, this slight increase is a result of over 40 new drugs receiving Food and Drug Administration (FDA) approval, including cures for Hepatitis C, very few patents expiring, and over 10 million new Medicaid enrollees.

There are a variety of stakeholders involved in determining what is paid for a medicine including insurers, pharmacy benefit managers, and wholesalers. Currently, four major pharmacy benefit programs negotiate steep discounts on prescription drugs for more than 80 percent of all prescriptions filled in the United States—Express Scripts alone covers 90 million Americans.

For hepatitis C medicines, payers are receiving discounts of up to 40% for commercial members and 55%–65% for Medicaid/VA members. In a September 2, 2015 editorial, *The New York Times* Editorial Board concluded that “competitive market forces and hard-nosed bargaining” make “tremendously effective” new hepatitis C medicines not just more accessible to ailing patients – but also offer good value to the U.S. health care system. Additionally, a recent actuarial analysis of pharmacy benefit manager drug trend reports show that trends for “specialty” medicines are frequently misleading, and often use inconsistent definitions and methods which can inflate and bias reported trends.

It is important to note that health insurance and plan *administration costs* are rising at more than twice the rate of drug spending. Over the past five years, spending growth on prescription drugs averaged 2.2% while growth in health plan administrative costs averaged 4.6%. In 2013, Americans spent more than \$200 billion to support administrative costs of insurance including sales commissions, dividends, and other health plan costs.⁵

Hospital spending would be even higher than it is if not for the beneficial impact of prescription medicines. For example, from 2000 to 2012, research conducted by the Altarum Institute showed total inpatient hospitalizations for cancer treatment declined by 15%, in favor of shifting cancer care to lower cost free-standing or outpatient hospital cancer care clinics. On a per capita basis, that decline was 25% over that same time period. More effective prescription cancer medicines helped to enable that shift in the site of care to occur, which resulted in an overall reduction in health care costs. Even as new retail oral oncologic agents have come on to the market in recent years, and prescription drug coverage has expanded due to Medicare Part D and the Affordable Care Act (ACA), prescription drug spending has remained fairly stable.

Innovative medicines developed by biopharmaceutical companies have been transforming patient care for over a century – helping patients live longer, healthier lives and reducing overall health care costs. Prescription medicines are often the most cost-effective means of preventing and treating disease. A 2013 study by IMS Institute for Healthcare Informatics estimated that the U.S. health care system could save \$213 billion annually if medicines were used properly. An article in *Health Affairs* echoed this sentiment and found that an extra \$1 spent on medicines for adherent patients with congestive heart

⁴ http://www.imshealth.com/files/web/IMSH%20Institute/Healthcare%20Briefs/IIHI_Branded_Medicine_Price_Increases_Healthcare_Brief.pdf

⁵ PhRMA analysis of CMS data, available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Tables.zip>

failure, high blood pressure, diabetes and high cholesterol can generate \$3 to \$10 in savings on emergency room visits and inpatient hospitalizations.⁶

A recent article in the Health Affairs journal, "Increased Use of Prescription Drugs Reduces Medical Costs In Medicaid Populations," cites the positive impact of prescription drugs on reducing other medical costs in the Medicaid program. The article found that when prescription drugs are taken appropriately as prescribed by a physician, there is a reduction in other medical costs for certain Medicaid populations. The authors looked at data on more than 1.5 million Medicaid enrollees to examine the impact of changes in prescription drug use on medical costs. The researchers found a 1% increase in overall prescription drug use was associated with decreases in non-prescription drug medical costs for three distinct groups of Medicaid beneficiaries. Among blind or disabled adults, a 1% increase in drug usage was associated with a 0.108% decrease in total non-drug costs; for other adults there was a 0.167% decrease; and for children, there was a 0.041% decrease.⁷

Medicines are an important part of the solution to the cost challenges facing the nation's health care system, not the cause. Without new medicines to treat Alzheimer's disease, Parkinson's, cancer and other conditions, the cost to treat these diseases could bankrupt our health care system. Medicines have helped raise average U.S. life expectancy from 47 years in 1900 to 78 years today. Since its peak in 1991, the cancer death rate in the U.S. has fallen 22% and 2 out of 3 patients diagnosed with cancer are now living at least 5 years following diagnosis. And new hepatitis C therapies have cure rates above 90% and dramatically decrease the burden of the disease on the U.S. health care system and the economy into the future.

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Cost of Innovation:

As one of the most research-intensive and science-driven industries in the U.S., the biopharmaceutical industry is committed to the research and development (R&D) of new treatments and cures for patients, including those who have serious unmet medical needs. There are more than 7,000 innovative drugs in development worldwide by biopharmaceutical companies and over \$500 billion invested in R&D since 2000.

The rapid pace of scientific advances is enabling a greater understanding of diseases at the molecular level. In turn, scientific, technical, and regulatory challenges related to drug development create complexities as companies often focus their R&D where the science is difficult and the risk of failure is higher. As a result, the process for researching and developing new medicines is growing in difficulty and length. On average, it takes at least ten years for a new medicine to complete the journey from initial discovery to the marketplace, with clinical trials alone taking six to seven years on average. The average cost to research and develop each successful drug is estimated to be \$2.6 billion. This number incorporates the cost of failures – of the thousands and sometimes millions of compounds that may be screened and assessed early in the R&D process, only a few of which will ultimately receive approval.

⁶ <http://content.healthaffairs.org/content/30/1/91.abstract>

⁷ <http://www.pharmacytimes.com/association-news/health-affairs-issue-features-nacdsphrma-research-on-impact-of-prescription-utilization-on-medicare-costs>

The overall probability of clinical success (the likelihood that a drug entering clinical testing will eventually be approved) is estimated to be less than 12%

As an example, a report, “Researching Cancer Medicines: Setbacks and Stepping Stones,” highlights the number of investigational drugs/medicines/treatments for cancer medicines that did not succeed in clinical trials and how these so-called “failures” are a critical part of the drug development process.⁸

- 96 potential treatments for melanoma did not make it through clinical trials, but paved the way for 7 approved medicines, a nearly 14:1 ratio of “failures” to “successes.”
- Ten medicines have been approved to treat lung cancer, whereas 167 other potential treatments did not make it through clinical trials.
- Only 3 new medicines have been approved to treat brain cancer, while another 75 investigational medicines were unsuccessful in the development process.

Despite the high rate of failure, researchers in the biopharmaceutical industry are dedicated to discovering and developing new medicines to help many patients whose needs are not yet met.

Patient Out-of-Pocket Costs:

Recent studies have shown that insurers are increasingly requiring patients to pay exorbitant out-of-pocket costs to access the medicines they need. Today, a patient pays about 5% for out-of-pocket hospital costs but 20% or more for their medicine. A recent IMS Health report reveals that commercial health plans are also increasingly applying deductibles to prescription drug benefits, something that has never happened before.⁹

According to the report, the share of commercial health plans requiring a deductible for prescription medicines doubled from 23% in 2012 to 46% in 2015. When patients enroll in a plan where drugs are subject to a deductible, their prescription drugs are not covered until the deductible is met, at which point they likely still have to pay a copay or coinsurance.¹⁰

Not surprisingly, these out-of-pocket costs can be a huge burden on patients. The study found that patients with a prescription drug deductible have higher abandonment of prescribed drug therapies and lower adherence to other prescription medicines than patients in plans that do not subject drugs to a deductible.

Health plans with higher deductibles and greater cost sharing—including for services like prescription medicines—are creating barriers for consumers in accessing needed care. A new Kaiser Family Foundation/*New York Times* survey highlights the challenges American households are having with medical bills even if they have insurance coverage.¹¹ The survey that found among adults with private

⁸ <http://www.phrma.org/sites/default/files/pdf/2014-cancer-failures-setbacks.pdf>

⁹ https://www.imshealth.com/files/web/IMSH%20Institute/Reports/Medicines_Use_and_Spending_Shifts/Medicine-Spending-and-Growth_1995-2014.pdf

¹⁰ https://www.imshealth.com/files/web/IMSH%20Institute/Reports/Medicines_Use_and_Spending_Shifts/Medicine-Spending-and-Growth_1995-2014.pdf

¹¹ <http://kff.org/health-costs/report/the-burden-of-medical-debt-results-from-the-kaiser-family-foundationnew-york-times-medical-bills-survey/>

insurance, those with deductibles higher than \$1,500 for an individual or \$3,000 for a family were even more likely to report having medical bill problems than those with lower deductibles. And among adults with insurance, 75% say the out-of-pocket costs (copays, coinsurance, or deductibles) were more than they could afford.

Medicaid is limited in what it can charge an enrollee for a prescription. In Colorado, if your prescription is for a generic medication, your copay will only be \$1.00. If your prescription is for a brand name medication, your copay will only be \$3.00. Clients 18 years of age and younger, clients in a nursing home and clients in a maternity cycle or 60 days postpartum do not have a copayment.¹²

Exchange Plans Out-Of-Pocket Costs:

Recent research finds that coverage offered through the Exchanges threatens to have a negative impact on patients' health due to limits on prescription drug coverage and increased out-of-pocket costs through higher deductibles and co-pays.

Exchange Plans are More Likely to Require Patients to Meet Deductible Before Drug Coverage Begins

Many exchange plans require patients to pay thousands of dollars out of pocket before receiving any coverage for medicines or non-preventive services. Recent Milliman analysis found that Silver plans are nearly four times more likely to have a combined deductible for medical and pharmacy benefits (46 percent of the time) than typical employer-sponsored plans (12 percent of the time).¹³ In the Colorado exchange, 58% of Silver plans had combined deductibles. Silver plans were the most popular within the Exchanges for the enrollment period that ended March 31, 2014 (65 percent of total enrollment as of April 19, 2014).¹⁴

Under combined deductible plans, prescription medicines are not covered until patients meet the deductible. This is particularly relevant for patients who rely on prescription medicines to treat chronic illnesses. Silver plans with combined deductibles impose 130% higher member cost sharing for pharmacy benefits than a typical employer-sponsored plan, compared to about a 20% increase for other types of services.¹⁵ The average silver plan deductible is \$2,000 in plans which have a single deductible for all medical spending.¹⁶ In the lower-cost Bronze plans, almost all plans require patients to reach a deductible before medicines are covered – and those deductibles average nearly \$5,000.¹⁷

Even after a Deductible is Met, Patients Often Have High Cost-Sharing for Prescription Medicines

High cost-sharing for prescription drugs in the Exchanges reduces patients' access to life-saving medicines and drives up health care costs. Cost-sharing for prescription medicines often remains higher

¹² <https://www.colorado.gov/hcpf/member-faqs#prescriptions1>

¹³ Milliman, Inc. "Impact of the Health Insurance Marketplace on Participant Cost Sharing for Pharmacy Benefits." Prepared for PhRMA, May 2014. Found at: <http://www.phrma.org/sites/default/files/pdf/milliman-impact-of-hix-on-pharmacy-benefits-report.pdf>

¹⁴ U.S. Department of Health and Human Services. "Enrollment in Health Insurance Marketplaces Totals Over 8 Million People." Found at: <http://www.hhs.gov/news/press/2014pres/05/20140501a.html>.

¹⁵ U.S. Department of Health and Human Services. "Enrollment in Health Insurance Marketplaces Totals Over 8 Million People." Found at: <http://www.hhs.gov/news/press/2014pres/05/20140501a.html>.

¹⁶ Breakaway Health. "The New ACA Health Insurance Exchanges." Prepared for PhRMA, January 2014. Found at: <http://www.phrma.org/sites/default/files/pdf/aca-exchanges-breakaway-report.pdf>.

¹⁷ Breakaway Health. "The New ACA Health Insurance Exchanges." Prepared for PhRMA, January 2014. Found at: <http://www.phrma.org/sites/default/files/pdf/aca-exchanges-breakaway-report.pdf>.

in Silver plans compared to employer plans. Silver plans are more likely than employer plans to use coinsurance, which requires patients to pay for a percentage of the cost of a medicine instead of a fixed dollar copayment. 85% of Silver plans in the Colorado exchange use coinsurance. For specialty tier medicines, 52% of plans require on average 29% coinsurance. Out-of-pocket costs from coinsurance are harder for patients to predict and can potentially be very high for innovative specialty products.

This is why our companies offer prescription assistance programs. Since 2005, the Prescription Assistance Program (PPARx) has helped link over 71,000 Colorado residents to patient assistance programs that help them get their medications for free or nearly no cost at all.

The facts are that prescription drugs are not a main driver of health care costs and growth in prescription drug spending over the past five years has been at a historically low level. The biopharmaceutical industry is committed to continue innovating in the State of Colorado. We also want to work with all stakeholders to help patients have the best access to the health care they need.

PhRMA appreciates the opportunity to submit additional comments. Should you need additional information, please let us know.

Sincerely,



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