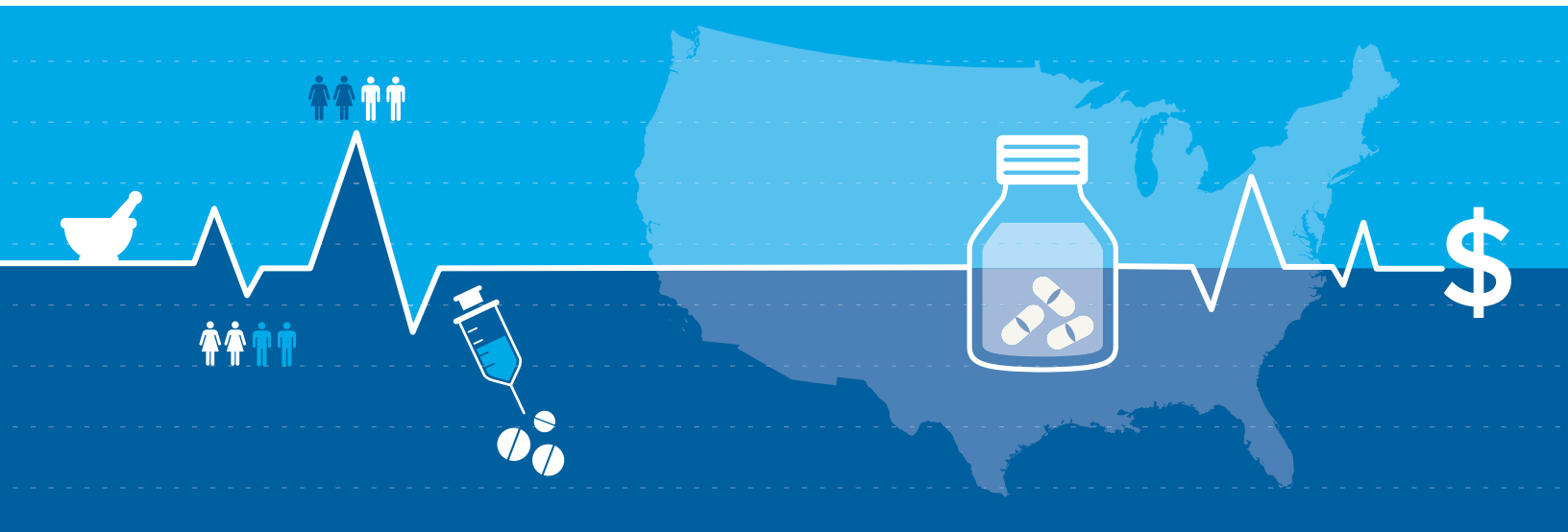


September 2017

Understanding the Drivers of Drug Expenditure in the U.S.



Introduction

The increasing list prices of specific medicines has been widely reported in a series of media events over the past two years, drawing the attention of the public, healthcare stakeholders, and politicians. Much of the coverage has focused on list prices without the more complex context of the prices actually received by manufacturers or paid by intermediaries or patients, or the context of volume usage of the drugs in question, or of the longer term context of the changes in a drug's price over time. The lifecycle of pharmaceuticals includes a period of patent protection where prices may rise but after which generic competition significantly reduces costs of the medicines, overall.

This issue brief provides analysis around a key aspect of medicine spending growth trends: manufacturer net revenues. It draws on previously published analysis from our reports *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021 (Apr 2017)* and *Outlook for Global Medicines Through 2021: Balancing Cost and Value (Dec 2017)*. In particular, the brief highlights the dynamics between prices and volume and introduces a novel way of combining market segments to consider the impact of patent expiry alongside other price related elements to more clearly reflect trends that affect the costs of medicines in the market.

The brief also demonstrates that the trend of manufacturer revenues is just one of the elements influencing patient costs and suggests that patient exposure to cost trends are not uniformly distributed across all patients.

This issue brief is based on research and analysis undertaken by the QuintilesIMS Institute with support from Merck Sharpe & Dohme Corp., a subsidiary of Merck & Co. Inc. The contributions of Paul Duke, Deanna Nass and Alana Simorellis are gratefully acknowledged.

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Definitions

When analyzing or describing drug spending or pricing, different sources and methodologies are often used for the same or similar terms. In this report, metrics are defined as follows:

List price: Most often the wholesaler acquisition cost (WAC) is reported as the list price of a medicine. Typically, this price influences the final price paid at pharmacy but is often not the exact price. Intermediary markups and a patient's insurance plan design can influence the price paid by patients and/or their insurers.

Manufacturer net revenue/price: The net revenues or price of a medicine represent an estimate, after all discounts, rebates and other concessions or statutory payments have been made by the manufacturer. These can include discounts provided to wholesalers, for volume of purchases, prompt payment and other payment terms; rebates paid to insurers and pharmacy benefit managers; discounts under the 340B program; government insurance program discounts and rebates in accordance with their rules; payments to the pharmacy for the value of coupons provided to patients; payments to the federal government for fees or taxes associated with the Affordable Care Act, or the Medicaid program. For more details on the methodology used for estimating net revenues, please see the Methodology section at the end of this report.

Payer net spending/price: The net amounts spent by payers on medicines include the contributions of patients and their health insurance, and are impacted by the markups and margins that intermediaries make relative to list prices and the discounts and rebates they are able to negotiate (or which are mandated for some government payers). While "payer net spending" and "manufacturer net revenues" both include some of the same cost reductions for both statutory and voluntarily negotiated discounts and rebates, they do differ in other important ways. Payer spending includes intermediary profits and fees, whereas manufacturer net revenues do not.

Publicly reported statistics on drug spending: The Centers for Medicare and Medicaid Services (CMS) report prescription drug spending as part of their publication of National Health Expenditures. Drug spending in these reports represents spending by retail and mail-order pharmacies only (excluding hospitals, doctor's offices, clinics, long-term care facilities, etc.). The spending reflected by CMS includes their estimates of the net amounts spent by all payers (including patients).

Intermediaries: Parties participating in the distribution or reimbursement of medicines and operating between the manufacturer and the ultimate consumer. Depending on a patient's type of insurance, or the medicine involved, the exact nature of intermediaries may vary but generally include wholesalers, pharmacies, pharmacy benefit managers (PBMs) and health plans.

Loss of Exclusivity (LOE): A branded product which loses patent protection and faces market competition is said to have lost exclusivity.

Executive summary

Drug Pricing Media Coverage

Reports of increasing drug list prices and overall spend on medicines have been escalating over the past few years. This reporting has been accompanied by pushback from policy makers, challenging long-held assumptions around pricing and pain-points for patients, as well as questions around overall trends on medicine spending in the healthcare system (see Published Articles on Pricing in the appendix).

Patient out-of-pocket costs for prescription medicines are determined by three main insurance cost-sharing mechanisms in combination with other market dynamics, including but not limited to the product's list price (see Mechanisms Influencing Patient Out-of-Pocket Costs in the appendix).

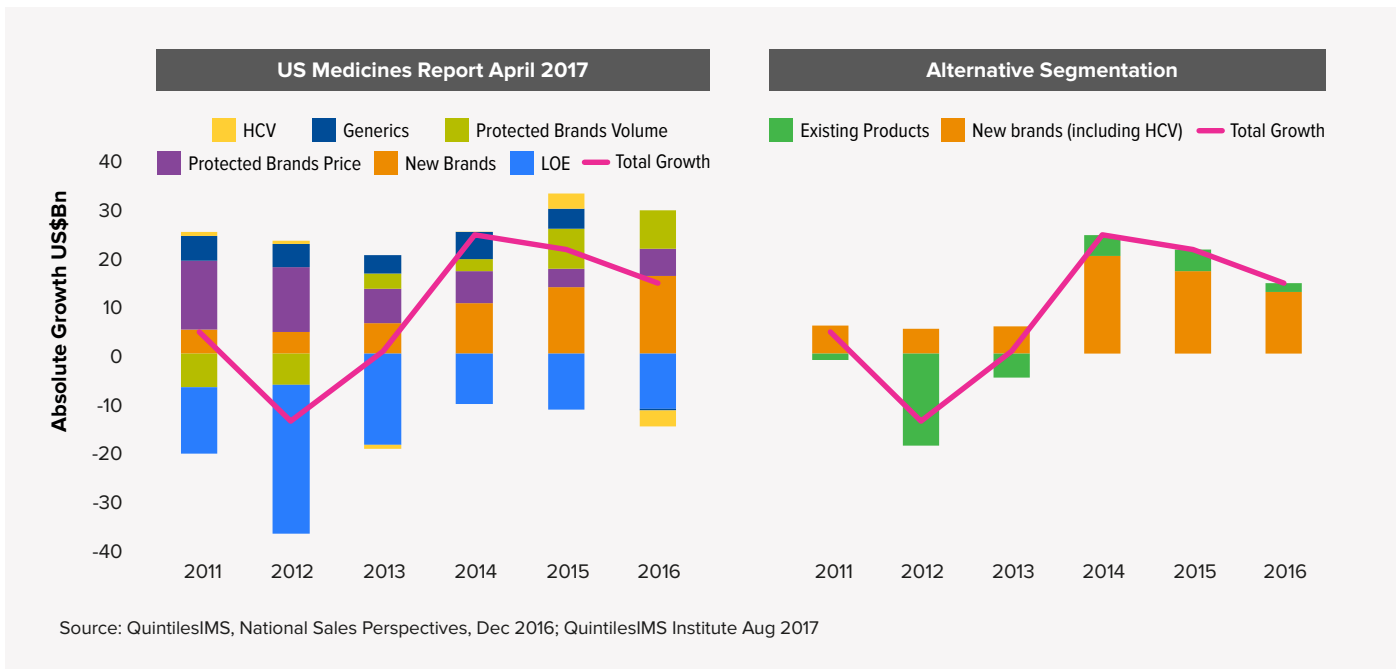
Pricing trends at a macro level, often referring to list prices and taken out of context, continue to be reported widely, however, in-depth analysis of the trends behind the data suggest a far more complex situation than one of prices set by manufacturers simply being too high or growing too fast.

Analysis of Manufacturer Net Revenues

- Net manufacturer revenues increased at a rate of 3.9% per year on average from 2010 to 2016, driven by new product launches (+3.8%) and volume increases on existing products (+2.6%), and partially offset by negative net price changes (-2.5%).
- Net price levels of existing products have declined at a CAGR of -2.5% over the last 6 years, driven by significant patent expiries (-5.8%) and offset by price changes for brands and generics (+3.3%).
- CMS reports that spending on retail prescriptions has been growing 4.8% from 2006–2015, and 4.4% from 2010–2015, which are both at lower rates or on par with other components of healthcare spending.
- Manufacturer net revenues averaged \$895 per person per year in 2016 when adjusted for economic growth (GDP deflator), up 1.1% per year since 2006.
- Traditional medicine costs are declining due to patent expiries, creating “headroom” for new specialty medicines, which now represent \$384 per person per year, or 43% of net spending, but represent less than 2% of overall volume.
- The market impact of LOE for both biologics and small molecules totaled \$93.6 billion in the past five years and is expected to be 50% higher in the next five years through 2021 (\$140.4 billion).
- In the five years to 2021, the combined impact on net price growth of branded, generic, and LOE medicines will decline between 1 and 4% through a combination of low net price increases of brands and generics and the increased impact of losses of exclusivity.
- Net revenue growth for prescription medicines is projected to average 2–5% through 2021; growth will be driven by new products and the wider use of existing medicines, and offset by lower costs of existing medicines as patent expiries offset price changes for other existing brands.

Net revenue growth for medicines has been driven by new medicines, which peaked in 2014 but have declined since then; existing products have more complex dynamics

Chart 1: Net Revenue Growth by Product Type, Segmentation Comparison US\$Bn



- In prior publications, growth drivers have been reported separately, highlighting the complex interplay between new products, existing products’ pricing and volume dynamics, patent expiries and generics uptake.
- In this brief, a more simple view of growth drivers is shown to help explain overall dynamics of medicine revenue growth.
- In the graphic from April 2017, shown above left, hepatitis C products have been reported separately

from new products, while in the alternative view, above right, they are combined.

- Existing products includes products not within 24 months of their launch, comprising patent protected brands that are more than two years old, off-patent brands and generics.
- Products within each of these sub-segments of existing products have historically gained or lost volume, changed prices up or down and in aggregate have driven the growth trend.

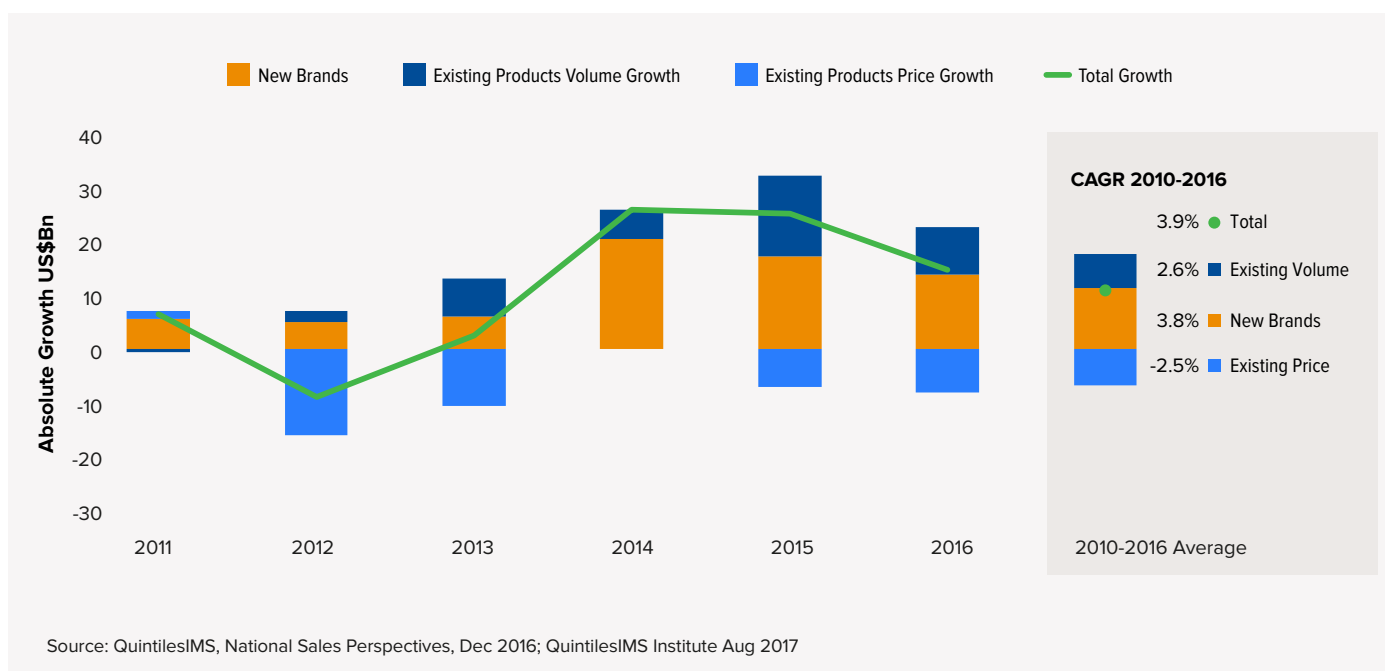
Chart notes:

Both charts represent absolute net manufacturer revenue growth in billions of US\$. The left chart was previously published and includes six distinct segments driving growth. In that version, hepatitis C drugs were separated from product types and reported in aggregate. The right chart represents a novel way of aggregating growth drivers, simplifying to new products compared to existing products. Hepatitis C products have not been reported separately.

New brands are protected branded products on the market less than 24 months during the year reported. Protected brands are products which are no longer “new” and have yet to reach patent expiry. Loss of Exclusivity (LOE) are brands which were once protected and have since lost patent protection. Generics include both unbranded and branded generics. In the left chart, all segments exclude hepatitis C treatments. Hepatitis C revenue growth is reported separately from the other segments in the chart as, unusually, there are declines in revenue in both the new and protected segments for these drugs.

Revenue growth has been driven by new products and volume growth from existing products; price has been a net negative driver

Chart 2: Net Revenue Growth by Product Type US\$Bn



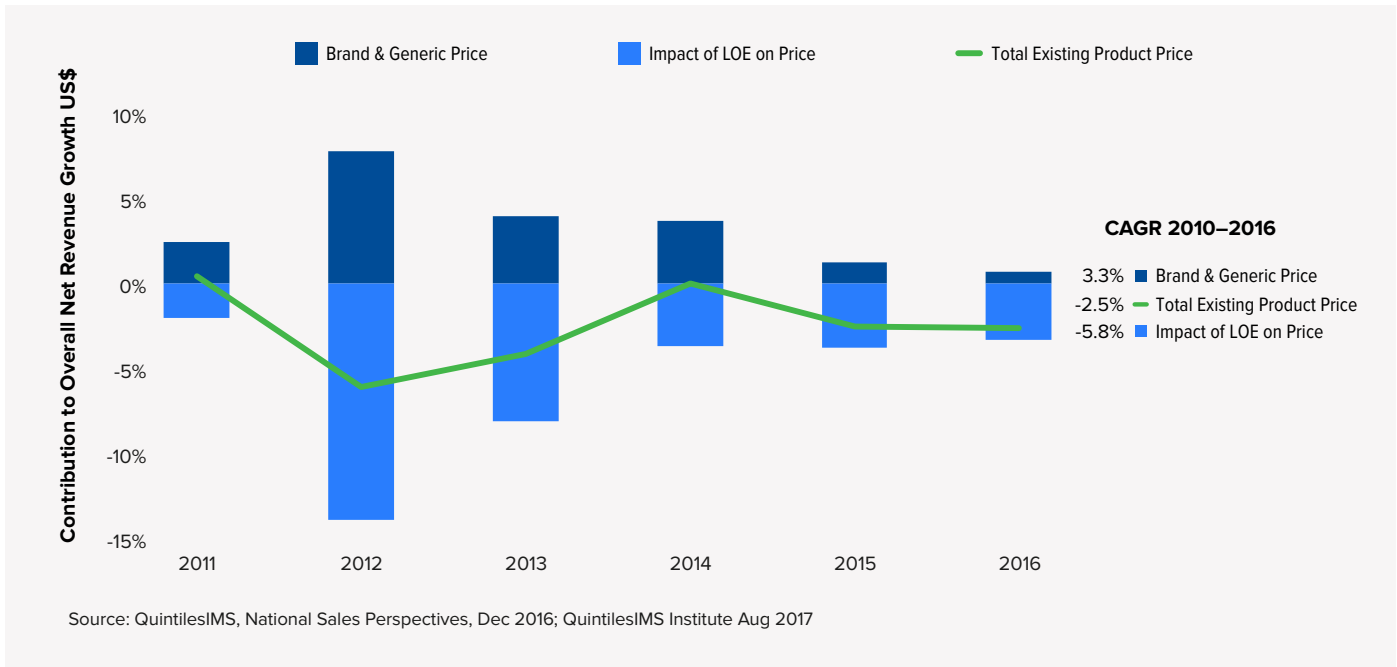
- Net manufacturer revenues increased at a rate of 3.9% per year on average from 2010 to 2016, driven by new product launches (+3.8%) and volume increases on existing products (+2.6%) which were partially offset by negative net price changes (-2.5%).
- New products included cures for hepatitis C, revolutionary cancer drugs that significantly prolong life and a significant number of specialty and orphan medicines, among others.
- Growth of existing products (including brands & generics) has been flat (+0.1% on average), consisting of volume increases (+2.6%) partially offset by negative price growth (-2.5%).
- For existing products, growth due to price has been a negative driver of medicines costs in all but one year from 2010 to 2016, including price changes for protected brands, offset by changes in off-invoice discounts and rebates, as well as price changes for generics and overall lost revenues for off-patent brands.
- Volume growth includes dynamics around changing usage of protected branded products and generics which can increase or decrease as a result of competitive dynamics, demand dynamics (population growth, aging and/or the reduction of the uninsured), or as a result of a patent expiry, where reduced payer formulary restrictions for generics and lower generic copayments may encourage greater use of a medicine overall.

Chart notes:

New brands are protected branded products on the market less than 24 months during the year reported. All other products including brands and generics are analyzed based on changes in price or volume growth measured at prior year prices. See methodology appendix for chart data. Analyses derived from QuintilesIMS Institute report Medicines Use and Spending in the U.S., April 2017.

Price growth of existing products has been declining as protected brands price increases have slowed and been offset by the impact of losses of exclusivity

Chart 3: Net Price Growth % Contribution to Overall Revenue Growth, Existing Products US\$



- Overall price effects of existing products on net manufacturer revenues are the result of price changes for existing products as well as the impact of losses of exclusivity.
- While these trends vary across products, by assessing price effects in this way, the composite effects of all growth drivers that affect the cost of medicines are included in a single segment.
- The significant reduction in the price of a medicine after LOE and introduction of competition, illustrates the need to consider lower cost due to expiry as a “price” event.
- The impact on aggregate manufacturer net revenues of patent expiries has outweighed the impact of manufacturer price increases over the past six years.

Chart notes:

The chart shows the price growth for existing products including brands and generics and segments them by the impact of losses of exclusivity compared to the other price effects.

Distinct from earlier publications, the view of price growth in this report considers patent expiries to be an “event” which impacts the prices of a medicine, and includes them often offsetting other positive price drivers in the market. See methodology appendix for chart data.

Analyses derived from QuintilesIMS Institute report Medicines Use and Spending in the U.S., April 2017.

CMS reports that spending on retail prescriptions has been growing at lower rates or is on par with other components of healthcare spending

Chart 4: Year over Year Spending Growth

Segments of National Health Expenditure	Year over Year Growth in Spending										CAGR	
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2006-2015	2010-2015
National Health Expenditures	6.5%	6.5%	4.5%	4.0%	4.1%	3.5%	4.0%	2.9%	5.3%	5.8%	4.7%	4.3%
Retail Prescription Drugs	9.2	5.2	2.5	4.7	0.1	2.3	0.2	2.1	12.4	9.0	4.8	4.4
Hospital Care	7.0	6.3	4.9	7.4	5.5	3.6	5.9	3.9	4.6	5.6	5.5	4.9
Professional Services	5.2	5.8	5.5	2.9	3.0	4.1	3.8	2.1	4.5	6.0	4.3	3.9
Net Cost of Health Insurance	11.6	4.6	-2.6	-1.3	11.3	3.8	3.9	5.0	12.4	7.6	5.6	7.3

Source: CMS National Health Expenditure Accounts, Jan 2017

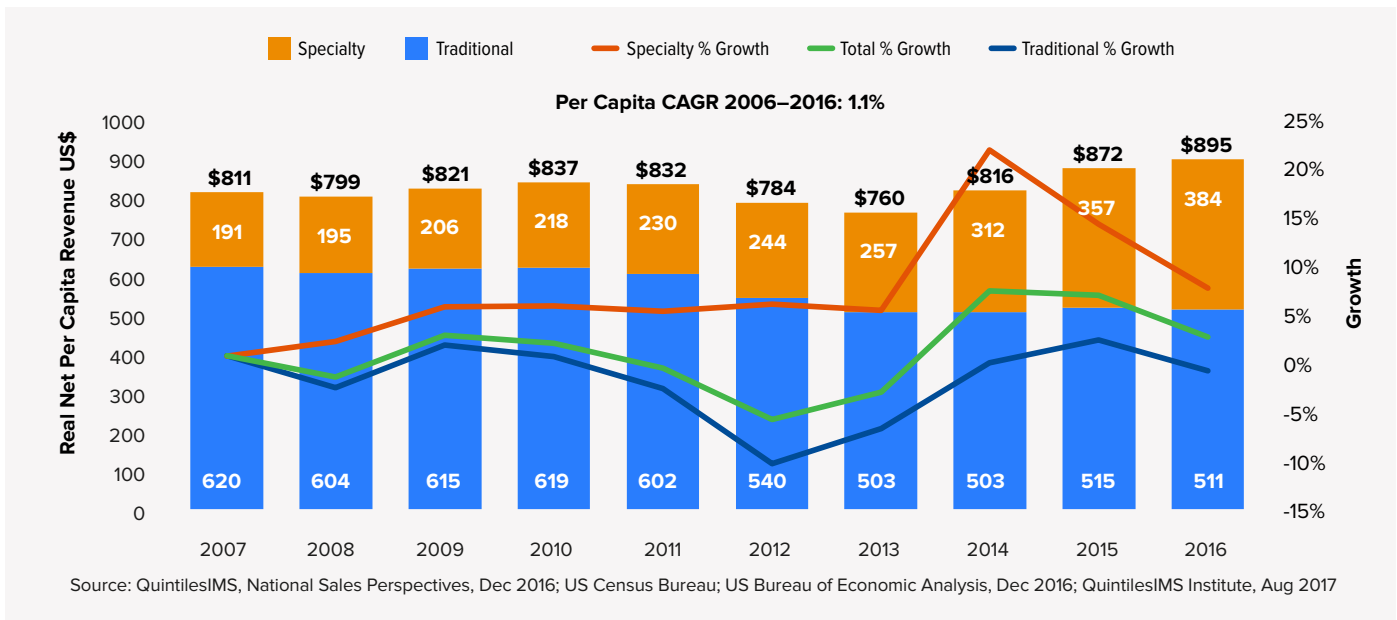
- Healthcare spending averaged 4.7% growth in the past 10 years based on National Health Expenditures (NHE) from the Centers for Medicare and Medicaid Services (CMS).
- Hospital Care (~32% of total NHE) has been growing 5.5% per year and accounts for 1.7% of the total 4.7% NHE increase.
- Professional Services (~27% of NHE) grew more slowly than overall health spending at 4.3% per year and accounted for 1.1% of the total 4.7% growth.
- Annual spending changes for hospital care and professional services is less variable than prescription medicines because they are driven primarily by labor cost increases each year .
- Variability in prescription medicines is primarily due to timing of patent expiries and the launch of new medicines. Averaging the growth over time eliminates the fluctuations caused by timing and normalizes the comparison to the other sectors.
- Retail prescription medicines spending accounts for about 10% of total NHE and grew 4.8% per year, contributing only 0.7% of the total 4.7% increase, but excludes non-retail drugs.
- Differences in prescription drug growth rates since 2010 between QuintilesIMS estimates (average 3.9%) and CMS (average 4.4%) are attributed to differences in the statistic being measured (see chart note below and Methodology section of the brief).

Chart notes:

Prescription medicine spending in CMS reporting includes estimates of pharmacy spending by all payers, public and private, and patients, and includes estimates of off-invoice discounts and rebates. CMS estimates do not include estimates of inpatient or outpatient drug expenditures where a medicine is administered to a patient by a healthcare provider. QuintilesIMS reporting reflects manufacturer net revenues for medicines including pharmacy as well as inpatient and outpatient medicines.

Traditional medicine costs are declining due to patent expiries, creating “headroom” for new specialty medicines while overall adjusted per patient costs grew at 1.1%

Chart 5: Real Net Per Capita Medicine Manufacturer Revenue and Growth by Type, US\$



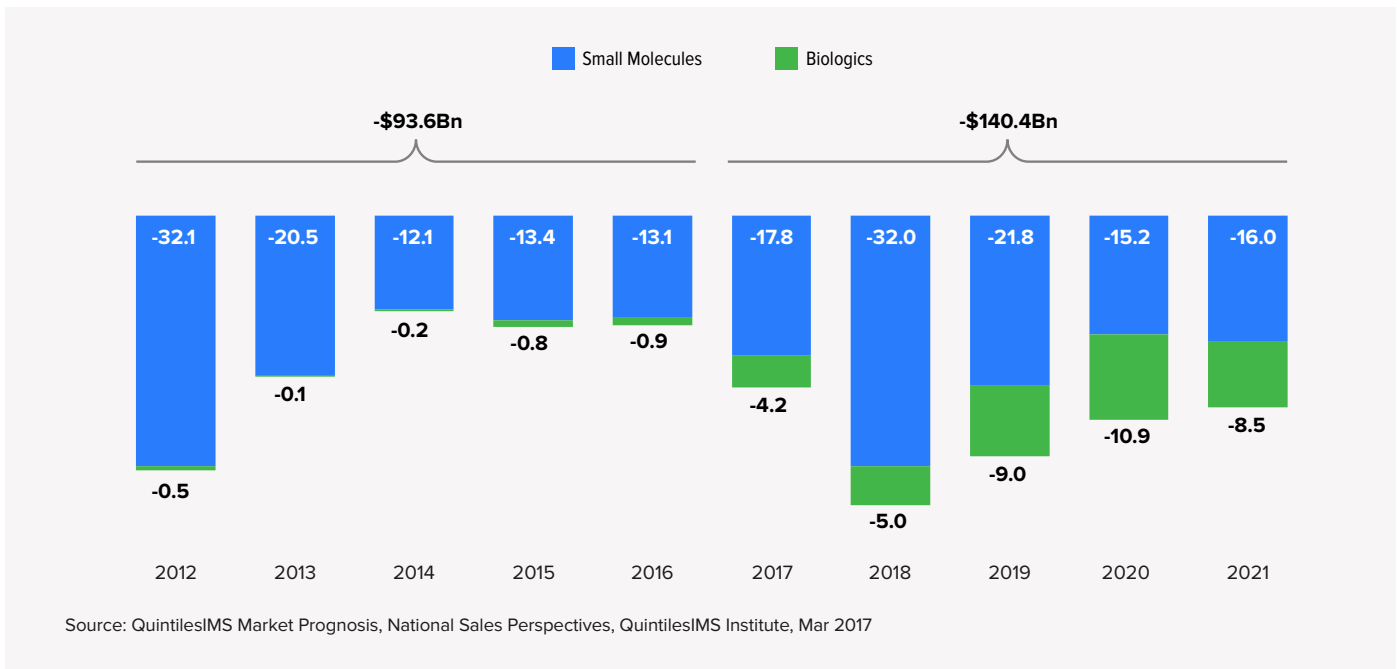
- When adjusting for economic growth, in 2016 each person in the United States on average resulted in \$895 per year in net manufacturer revenue for medicines dispensed through pharmacies as well as those administered to patients in doctors’ offices, clinics and hospitals.
- Normalized in this way, revenues have been increasing at approximately 1.1% per year since 2006, while revenue for specialty medicines has been largely offset by reduced revenue for traditional drugs.
- While specialty medicines often cost more per patient, far fewer patients are treated with them compared to more traditional drugs and specialty medicines have consistently accounted for less than 2% of overall medicines volumes.
- Despite higher costs, recent research suggests that specialty medicines may offer value for money comparable to that of traditional drugs.¹
- The authors further suggested that although specialty drugs often have higher costs than traditional drugs, they also tend to confer greater benefits and hence may still offer reasonable value for money.
- Specialty drugs are also often on a separate insurance tier with higher coinsurance rates for patients, in both retail and non-retail settings, which suggests that while the overall growth trend is very low, patient exposure to costs may vary significantly.

Chart notes:

Chart shows QuintilesIMS audited medicine revenues adjusted for off-invoice discounts and rebates, and for population and economic growth. Adjustment for economic growth, using gross domestic product deflators to 2009 US\$ instead of a consumer price inflation adjustment. ¹Chambers JD, Thorat T, Pyo J, Chenoweth M, Neumann PJ. Despite High Costs, Specialty Drugs May Offer Value For Money Comparable To That Of Traditional Drugs. Health Aff (Millwood). 2014 Oct;33(10):1751-60.

The market impact of loss of exclusivity for both biologics and small molecules has offset spending growth and is expected to have a larger impact through 2021

Chart 6: Lower Brand Spending Due to Loss of Exclusivity US\$Bn



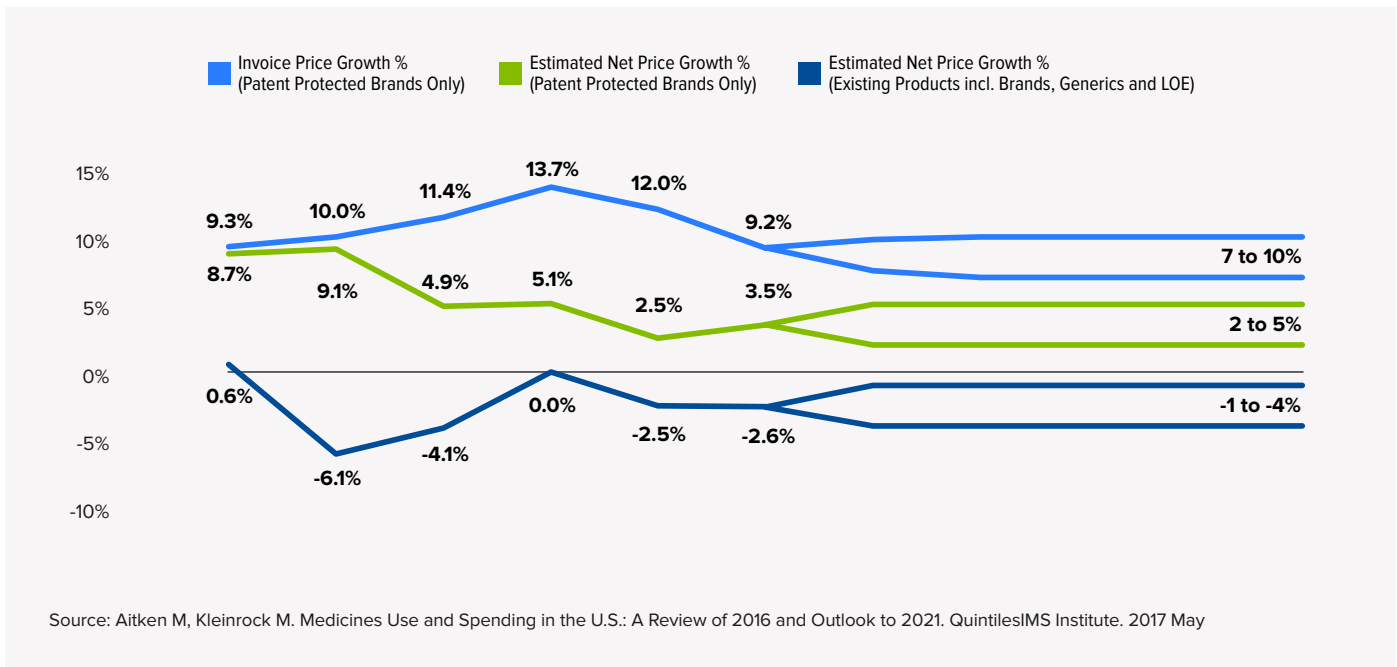
- The impact of patent expiries has been relatively unchanged for the past three years but is expected to increase sharply in 2017 and again in 2018.
- In the past five years, 21 products lost exclusivity and had revenues reduced by more than \$1Bn, with aggregate impact of \$67.2Bn, including blockbuster drugs Lipitor, Plavix, Abilify, Singulair, Cymbalta, Seroquel, Nexium, Lexapro, Zyprexa, Actos, Celebrex, Crestor, Diovan, Diovan HCT, Tricor, Namenda, Geodon, Provigil, Eloxatin, Gleevec, and Copaxone 20mg.
- The total impact of patent expiries is expected to be 50% higher in the next five years than in the last five, however, excluding biosimilars the impact is expected to be \$102.9Bn compared to \$91.1Bn in the prior five years.
- Biosimilar impact is expected to be highly variable and each molecule will present different challenges and opportunities to payers, providers, patients, originators and biosimilar manufacturers.
- Biosimilars of insulin glargine (Lantus) and infliximab (Remicade) were introduced in 2016, with impact expected to increase through 2017 and 2018.
- The largest selling branded medicine, adalimumab (Humira) is expected to face biosimilar competition in late 2018, while other biosimilars expected in 2018 or 2019 include cetuximab (Erbix), trastuzumab (Herceptin), and bevacizumab (Avastin).

Chart notes:

Lower brand spending based on invoice prices. Historic impacts from QuintilesIMS National Sales Perspectives, forecast impacts are modeled by projecting individual products sales growth to the point of patent expiry and then modeling expected impact based on historical analogues and actual data for in-progress events.

The combined net price impact on growth of branded, generic and LOE medicines is projected to decline between 1 and 4% through 2021

Chart 7: Net Medicine Price Growth



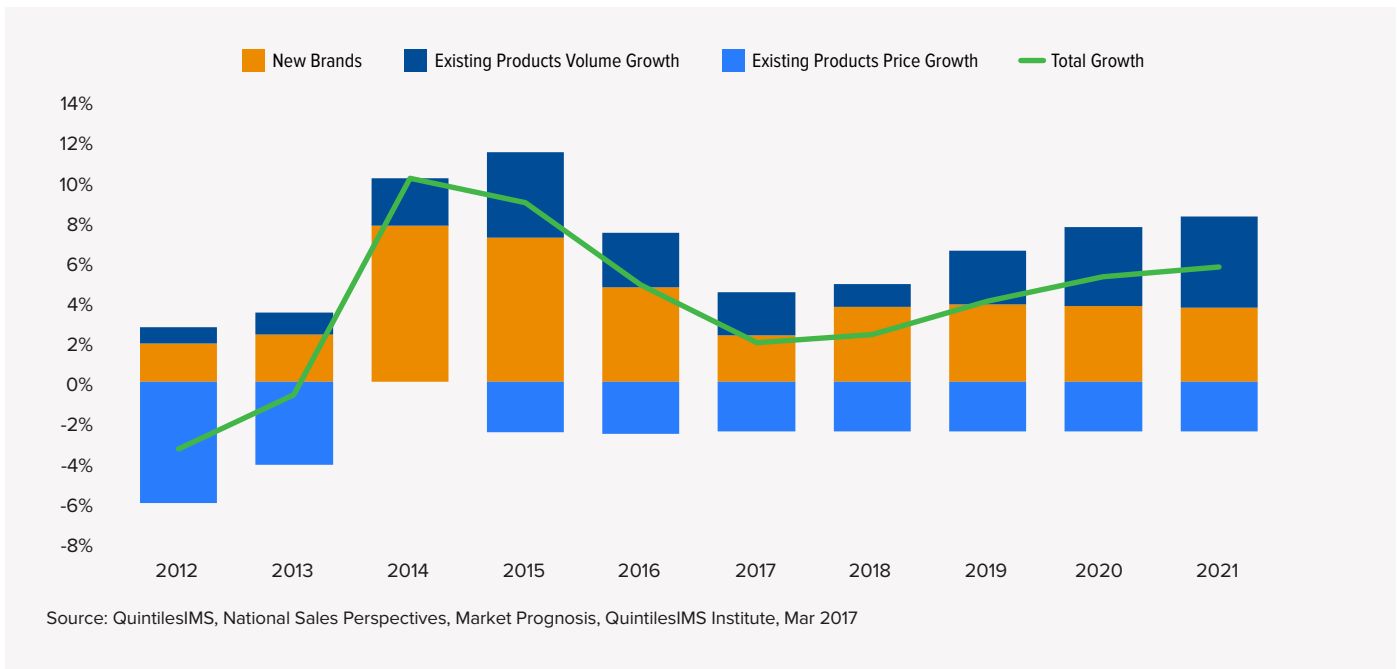
- Invoice price growth of branded products reached a peak of 13.7% in 2014 and has slowed through 2016.
- Net price growth for protected brands has slowed to 2–5% per year for the last four years and is projected to remain in this range through 2021.
- These estimates are in line with recent price transparency initiatives from Janssen Pharmaceuticals, Merck & Co and Eli Lilly & Co; however, they do not take into consideration the price reductions that occur post patent expiry.
- When factoring in the pricing dynamics for all products including generics and those cost reductions both pre and post patent expiry, net price growth has been negative almost every year since 2010 (-2.5% per year on average) and is projected to continue to be negative into the foreseeable future.
- The level of expected impact from brand LOE from 2017–2021 vs. prior years is expected to be more than 50% greater than in the last 5 years and will continue to offset brand price increases and new brand revenue.

Chart notes:

Protected brands are those which are still patent protected and are not within their first two years of marketing. Invoice price growth reflects changes in prices in aggregate for brands as reflected on data collected by QuintilesIMS. Invoices are between wholesalers and their customers and do not reflect off-invoice discounts and rebates paid to other market participants like insurers or statutory rebates paid to government. Net prices represent manufacturer net revenues divided by total volumes. Estimates of net price growth for all existing products include both protected brands, off-patent brands and generic products, but do not include new brands.

Net revenue growth for prescription medicines will average 2–5% through 2021; growth will be driven by new and existing products and offset by patent expiries

Chart 8: Net Medicines Revenue Growth and Contribution by Type



- QuintilesIMS projects that net revenue on all types of prescription medicines will grow at 2–5% over the next five years, driven by new products and the wider use of existing medicines, and offset by lower costs of existing medicines as patent expiries offset price changes for other existing brands.
- Price trends including average protected brand net price increases of 2–5%, and 50% larger impact of patent expiries in the next five years will combine to drive average price growth for existing products at -1 to -4% through 2021.
- QuintilesIMS projects that LOE will create an additional approximately \$140Bn in savings from 2017–2021 including the impact of biosimilars.
- Existing product volume growth is expected to be more highly variable in the forecast, ranging from 1.1% contribution in 2018 but rising to 4.5% in 2021 as previously new launch drugs continue to grow, and generic uptake from patent expiries lift volume.
- There are expected to be 40–45 new innovative product launches per year through 2021 contributing 3.5–4.5% to growth per year from 2018 onwards.

Chart notes:

Analyses derived from QuintilesIMS Institute report Medicines Use and Spending in the U.S., April 2017.

Existing product price growth is estimated as -1 to -4% over the five year forecast and the chart illustrates the midpoint of the range while year to year variations are to be expected.

Notes on Sources

This report is based on the QuintilesIMS services detailed in the panel below.

IMS National Sales Perspectives (NSP)[™] measures revenue within the U.S. pharmaceutical market by pharmacies, clinics, hospitals and other healthcare providers. NSP reports 100% coverage of the retail and non-retail channels for national pharmaceutical sales at actual transaction prices. The prices do not reflect off-invoice price concessions that reduce the net amount received by manufacturers.

IMS National Prescription Audit (NPA)[™] is a suite of services that provides the industry standard source of national prescription activity for all products and markets.

Market Prognosis is a comprehensive, strategic market forecasting publication that provides insight to decision makers about the economic and political issues that can affect spending on healthcare globally. It uses econometric modeling from the Economist Intelligence Unit to deliver in-depth analysis at a global, regional and country level about therapy class dynamics, distribution channel changes and brand vs. generic product spending.

QuintilesIMS Formulary Impact Analyzer (FIA) provides insight into what impact utilization-control measures enforced by managed care organizations have had on prescription volumes including the dynamics that affect patient behavior in filling and/or refilling prescriptions. Formulary measures include tiered copay benefit designs, prior authorization restrictions, and often result in non-preferred prescriptions being rejected or switched at the pharmacy. FIA offers visibility to claims rejected for other reasons such as contraindications as well as those attempted to be refilled too soon. FIA sources include national and regional chains, independent pharmacies and a claims coordination switch company providing a comprehensive view of retailers and across geographies.

Appendix

Published Articles on Pricing

High profile events for drug price hikes:

- McCarthy M. Drug's 5000% price rise puts spotlight on soaring US drug costs. *BMJ*. 2015 Sep 24;351
- Bloomberg. Koons C, Keller M, Langreth R. How EpiPen's Price Rose. 2016 Sep 1. Available from <http://www.bloomberg.com/graphics/2016-epipen-pricing/>
- ProPublica. Ornstein C, Thomas K. A Drug Quintupled in Price. Now, Drug Industry Players Are Feuding Over the Windfall. 2017 May 31. Available from: <https://www.propublica.org/article/drug-quintupled-in-price-now-drug-industry-players-feuding-over-windfall>

Pushback from policy makers:

- Obama B. United States Health Care Reform: Progress to Date and Next Steps. *JAMA*. 2016 Aug 2;316(5):525-32.
- Health Affairs Blog. Sachs R. At Drug Hearing, Senators Discuss Meanings Of Price And Value—And Debate Health Reform. 2017 Jun 20. Available from: <http://healthaffairs.org/blog/2017/06/20/at-drug-hearing-senators-discuss-meanings-of-price-and-value-and-debate-health-reform/>
- The New York Times. Thomas K. Trump Vows to Ease Rules for Drug Makers, but Again Zeros In on Prices. 2017 Jan 31. Available from: https://www.nytimes.com/2017/01/31/health/trump-vows-to-ease-rules-for-drug-makers-but-prices-remain-a-focus.html?_r=1
- Politico. Karlin-Smith S. Trump says drug industry 'getting away with murder'. 2017 Jan 11. Available from: <http://www.politico.com/story/2017/01/trump-press-conference-drug-industry-233475>
- Politico. Karlin-Smith S. Trump's drug price 'remedy' expected to be industry friendly. 2017 June 16. Available from: <http://www.politico.com/story/2017/06/16/trump-drug-prices-industry-239659>
- The New York Times. Thomas K. A Look at Major Drug-Pricing Proposals. 2017 May 29. Available from: <https://www.nytimes.com/2017/05/29/health/a-look-at-major-drug-pricing-proposals.html>

Are prices really going up?

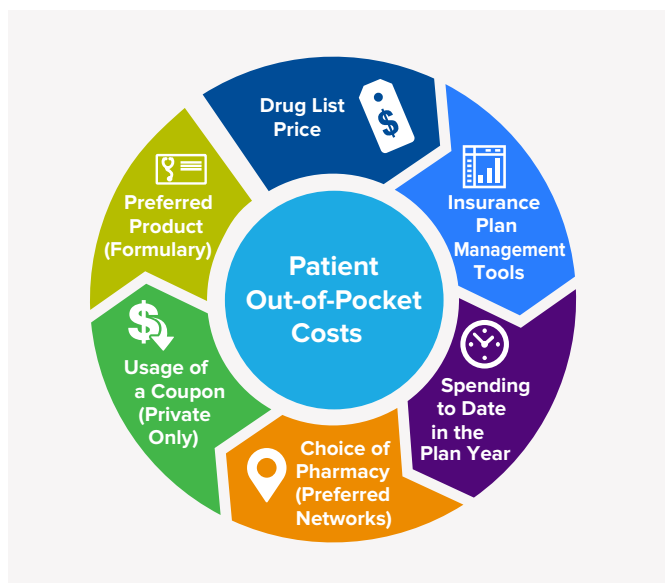
- Express-Scripts. Express Scripts 2016 Drug Trend Report. 2017. Available from: <http://lab.express-scripts.com/lab/drug-trend-report>
- Keehan SP, Stone DA, Poisal JA, Cuckler GA, Sisko AM, Smith SD, et al. National Health Expenditure Projections, 2016-25: Price Increases, Aging Push Sector To 20 Percent Of Economy. *Health Aff (Millwood)*. 2017 Mar 1;36(3):553-563.

Are prices really going up? *continued*

- ProPublica. Ornstein C, Thomas, K. Generic Drug Prices Are Declining, But Many Consumers Aren't Benefiting. Updated 2017 Aug 8. Available from: <https://www.propublica.org/article/generic-drug-prices-are-declining-but-many-consumers-arent-benefiting>
- CVS Health. Press release. CVS Health PBM Clients Achieved Lowest Prescription Drug Trend in Four Years, Despite Rising Drug Prices. 2017 Mar. Available from: <http://www.prnewswire.com/news-releases/cvs-health-pbm-clients-achieved-lowest-prescription-drug-trend-in-four-years-despite-rising-drug-prices-300423726.html>
- PhRMA. The Catalyst. Zirkelbach, R. Why won't the insurance industry tell the truth about medicine costs? 2017 May 10. Available from: <http://catalyst.phrma.org/why-wont-the-insurance-industry-tell-the-truth-about-medicine-costs>
- Prasad V, Wang R, Afifi SH, Mailankody S. The Rising Price of Cancer Drugs-A New Old Problem? JAMA Oncol. 2016 Oct 6.
- Health Affairs Blog. Purvis L, Kuntz C. Is High Prescription Drug Spending Becoming Our New Normal? 2017 May 17. Available from: <http://healthaffairs.org/blog/2016/05/17/is-high-prescription-drug-spending-becoming-our-new-normal/>

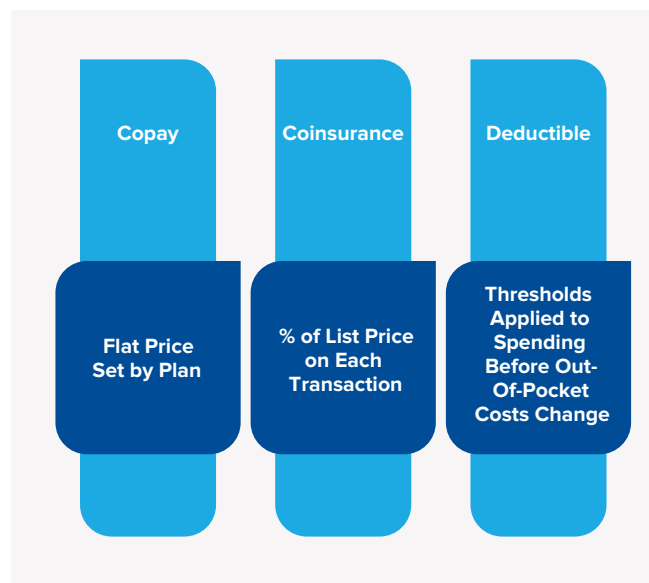
Mechanisms Influencing Patient Out-of-Pocket Costs

Factors Affecting Out-of-Pocket Costs



- The price of a drug is determined as either a fixed amount copay, or with variable costs through coinsurance or deductible mechanisms, which in combination with a complex interplay of multiple variables determine a patient’s costs.
- While fixed copays have been relatively stable in plan designs, more patients have drug benefit deductibles and more plans have added separate cost tiers which use coinsurance for specialty or otherwise high cost products, meaning more patients have greater exposure to the list prices of medicines.
- Rates of coinsurance for drugs have been relatively stable, averaging 30% in separate tiers in employer plans, but as more new specialty products become available, more patients will use them and face their higher list prices as part of their cost-sharing.
- Deductibles have been a common feature of medical insurance, but have become much more common in drug benefits, and the thresholds have

Out-of-Pocket Cost Calculation Types



- been rising, particularly in private plans, and are typically followed by a coinsurance level up to an out-of-pocket maximum.
- Patients may pay list price rather than a lower copay or coinsurance if they fail to comply with insurance plan cost management tools such as plan rules for prior authorizations, step therapy or product formulary exclusions.
- Medicare Part B uses a fixed 20% coinsurance model for the coverage for administered medicines and services, while Part D uses the cost-sharing model which operates with a coinsurance concept that varies during the year based on a patient’s spending.
- A majority of private health insurance plans have out-of-pocket maximums during a year, whereas Medicare Part B and D have no maximums, and in Part D catastrophic coverage lowers patient coinsurance to 5%, which remains a significant cost for some medicines.

Methodology

Publicly Available Data Sources

- CMS Office of the Actuary Annual Report of National Health Expenditures
- QuintilesIMS Institute Annual Summary of Medicine Use and Spending in the US using its proprietary data along with other publicly available datasets such as SEC filings (e.g., 10k reports, annual reports, etc.)
 - Breaks down the components of pharmaceutical spending into categories including but not limited to 1) price (both list and net); 2) volume; 3) and markups from middlemen including wholesalers, pharmacies and insurers.
 - Includes additional detail for patent protected brands, generics, new products, and products that are in the process of losing their patent exclusivity (LOE products).

Pushback from policy makers:

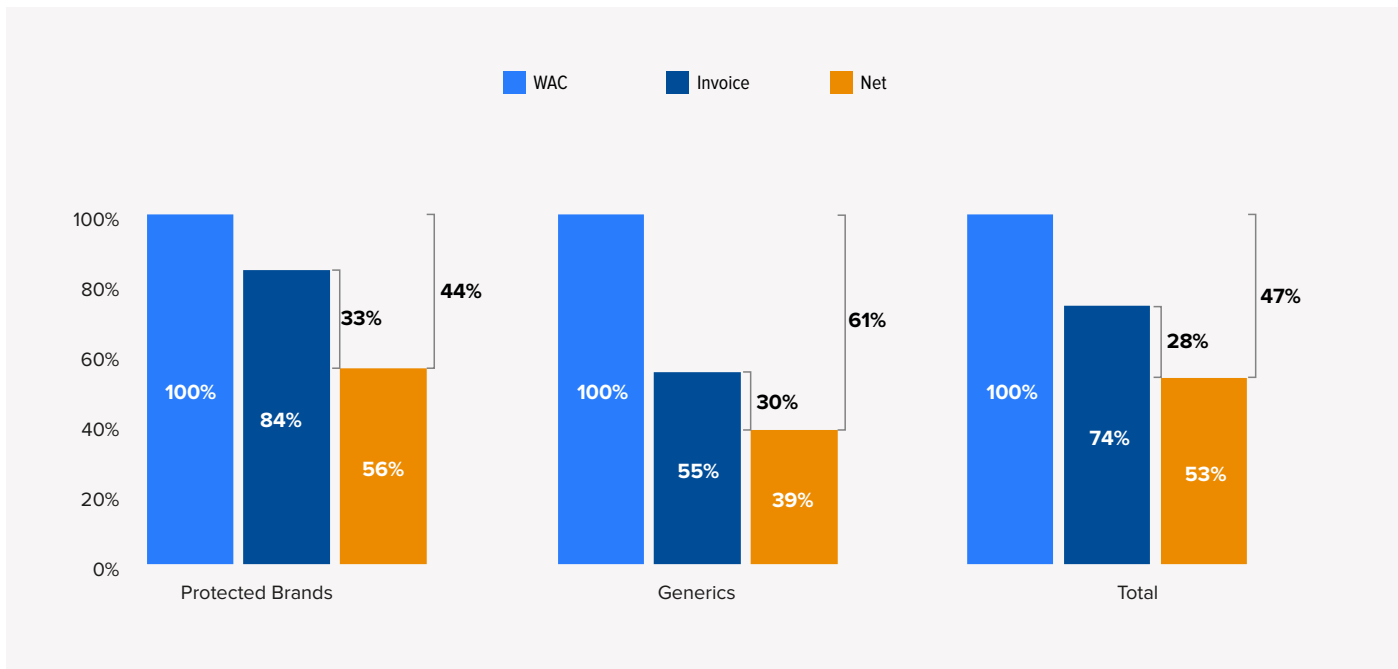
- The QuintilesIMS Institute methodology represents the revenues that manufacturer's earn, whereas CMS reports what the "system" spends.
 - Manufacturer concessions that CMS does not exclude, patient out-of-pocket costs and intermediary profits (i.e., "Middlemen" markups) are the largest contributors to the difference between the QuintilesIMS revenue estimates and CMS spending estimates.
 - CMS does not deduct mandated ACA pharmaceutical fees, donut-hole subsidies from their estimates. Furthermore, while CMS would presume that a patient using a coupon would be reflected in their out-of-pocket cost estimates, in practice this is unlikely to be robust due to only periodic updates of out-of-pocket and rebate assumptions.
 - CMS updates various assumptions in the NHE projections on a periodic five year basis, resulting in some editions of the reports where events have evolved but the projections are based on assumptions that are five years old. Rebates are understood to have increased substantially over the past five years as have the use of patient copay coupons; as a result, it is possible that CMS is understating rebates and coupons and overstating spend.

Estimates of Net Revenues

There is a difference between “spending” on pharmaceutical and the “revenues” manufacturer’s earn. Net spending reported by CMS and private insurers include patient out-of-pocket costs and intermediary profits which are often funded partly from markups and insurance premiums. Manufacturer’s net revenues are reduced by both statutory payments they make (ACA pharmaceutical fee, Part D donut hole subsidies) as well as statutory rebates (Medicaid), and patient copay assistance coupons. These items reduce manufacturer net revenues but do not correspondingly reduce all aspects of payer reported net spending.

WAC-based pricing is derived from list-prices of products as reported to QuintilesIMS. Invoice-based pricing is derived from QuintilesIMS proprietary information gathered from wholesalers and company direct sales. While QuintilesIMS invoice prices reflect supply-chain price concessions such as prompt-payment and volume discounts, they do not reflect the off-invoice discounts and rebates separately paid to insurers, or other price concessions paid to patients or other health system participants.

2016 Average Net Sales Adjustment By Product Type

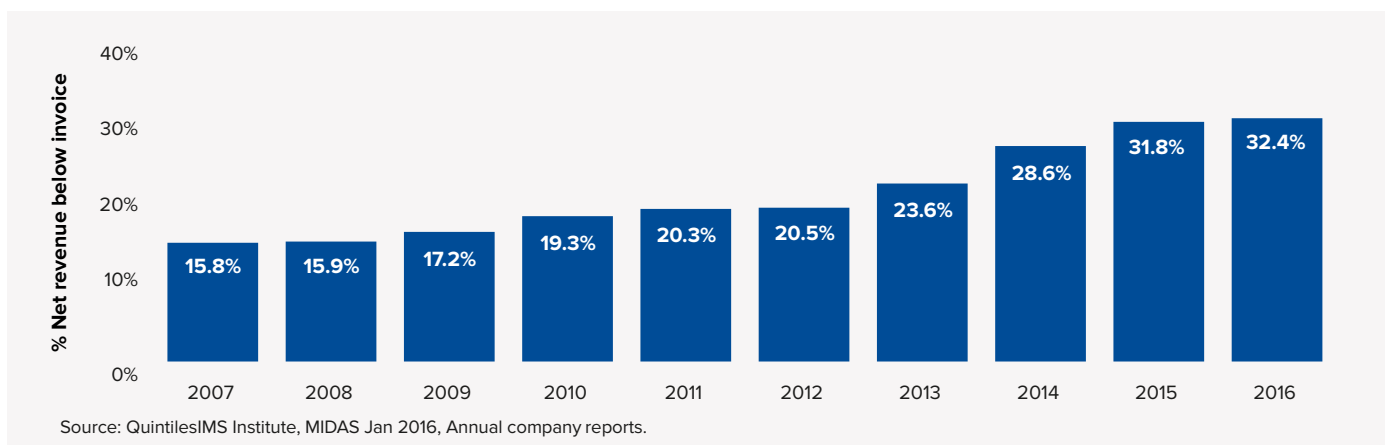


Estimated net price growth in this report are projected from a sample of large and mid-sized companies analyzed from 2011–2016. The sample includes between 225 to 299 product franchises, which represent between 79 to 93% of protected branded product sales in each of the years shown. Branded Products are included in the sample if their net sales amount is disclosed in financial filings with the Securities and Exchange Commission and if the volume of sales captured in QuintilesIMS audits is consistent with information provided directly by manufacturers in support of QuintilesIMS proprietary datasets. For generic companies, a sample of five large generic companies’ generic portfolios were analyzed in aggregate consistent with their SEC filings, as specific generic product analyses are not possible.

METHODOLOGY

Net prices are calculated by dividing publicly reported net sales values by volumes for the same products reported to QuintilesIMS. Estimated brand net price growth for the total market is projected from the analysis sample to the total market. Net prices represent an estimate of the average manufacturer realized price, reflecting any reductions in net sales due to off-invoice discounts, rebates, co-pay assistance or other price concessions, and do not necessarily reflect the net costs paid by insurers, the federal government or patients, which all vary significantly and independently. The percent net revenue is below invoice price revenue reflecting the aggregate impact of all the reductions to manufacturers revenue that take place in the market due to statutory requirements, insurer negotiations or coupons. The last ten years have seen these rates more than double for protected brands, partly driven by competitive market negotiations and partly by the interaction of “price increase protection” contract terms that automatically offset list price increases for payers.

% Net Revenues Below Invoice Revenues, Protected Brands 2007–2016



Data for Charts 2 & 3, Net growth of New and Existing Products, 2010–2016

Components of Growth	Net Manufacturer Revenues and Growth US\$Bn							% Change vs. Prior Year							6-Year CAGR
	2010	2011	2012	2013	2014	2015	2016	2010	2011	2012	2013	2014	2016	2016	2010-2016
Net Revenues for All Products	\$256.8	\$263.4	\$254.5	\$2571	\$2831	\$308.3	\$323.1	3.5%	2.5%	(3.4%)	1.0%	10.1%	8.9%	4.8%	3.9%
Growth from New Products	\$3.9	\$5.7	\$5.0	\$6.1	\$20.6	\$17.3	\$13.9	1.6%	2.2%	1.9%	2.4%	8.0%	6.1%	4.5%	3.8%
Growth from Existing Products	\$4.7	\$0.8	(\$13.9)	(\$3.5)	\$5.4	\$7.9	\$0.9	1.9%	0.3%	(5.3%)	(1.4%)	2.1%	2.8%	0.3%	0.1%
Growth Due to Price*	(\$6.2)	\$1.4	(\$16.0)	(\$10.5)	\$0.0	(\$7.1)	(\$8.0)	(2.5%)	0.6%	(6.1%)	(4.1%)	0.0%	(2.5%)	(2.6%)	(2.5%)
Growth Due to Volume	\$10.9	(\$0.6)	\$2.1	\$7.0	\$5.4	\$15.0	\$8.9	4.4%	(0.2%)	0.8%	2.7%	2.1%	5.3%	2.9%	2.6%

Source: QuintilesIMS Institute, May 2017

Table notes:

Table Notes: Revenue and growth are based on estimated manufacturer net revenues after deducting all off-invoice discounts and rebates, (statutory or negotiated) and other deductions made by manufacturers as they report their net revenues in.

* Growth Due to Price includes price changes on patent protected brands and generics as well as brands/molecules that have lost their patent protection. Negative growth values shown in parentheses and in red text. Analyses derived from QuintilesIMS Institute report Medicines Use and Spending in the U.S., April 2017.

Authors



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Executive Director, QuintilesIMS Institute

Murray Aitken is Executive Director, QuintilesIMS Institute, which provides policy setters and decision makers in the global health sector with objective insights into healthcare dynamics. He assumed this role in January 2011. Murray previously held other roles within QuintilesIMS Health, which he joined in 2001. Prior to IMS Health, Murray had a 14-year career with McKinsey & Company, where he was a leader in the Pharmaceutical and Medical Products practice from 1997 to 2001. Murray holds a Master of Commerce degree from the University of Auckland in New Zealand, and received an M.B.A. degree with distinction from Harvard University.



Michael Kleinrock
Research Director, QuintilesIMS Institute

Michael serves as Research Director for the QuintilesIMS Institute, setting the research agenda for the Institute, leading the development of reports and projects focused on the current and future role of biopharmaceuticals in healthcare in the U.S. and globally. He joined IMS Health in 1999 and has held roles in consulting, service and marketing and assumed his current role in 2011. Michael holds a B.A. in History and Political Science from the University of Essex, Colchester, U.K. and an M.A. in Journalism and Radio Production from Goldsmiths College, University of London, U.K.

About the QuintilesIMS Institute

The QuintilesIMS Institute leverages collaborative relationships in the public and private sectors to strengthen the vital role of information in advancing healthcare globally. Its mission is to provide key policy setters and decision-makers in the global health sector with unique and transformational insights into healthcare dynamics derived from granular analysis of information.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision-making and improved patient care. With access to QuintilesIMS's extensive global data assets and analytics, the Institute works in tandem with a broad set of healthcare stakeholders, including government agencies, academic institutions, the life sciences industry and payers, to drive a research agenda dedicated to addressing today's healthcare challenges.

By collaborating on research of common interest, it builds on a long-standing and extensive tradition of using QuintilesIMS information and expertise to support the advancement of evidence-based healthcare around the world.

Research Agenda

The research agenda for the Institute centers on five areas considered vital to the advancement of healthcare globally:

The effective use of information by healthcare stakeholders globally to improve health outcomes, reduce costs and increase access to available treatments.

Optimizing the performance of medical care through better understanding of disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.

Understanding the future global role for biopharmaceuticals, the dynamics that shape the market and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.

Researching the role of innovation in health system products, processes and delivery systems, and the business and policy systems that drive innovation.

Informing and advancing the healthcare agendas in developing nations through information and analysis.

Guiding Principles

The Institute operates from a set of Guiding Principles:

The advancement of healthcare globally is a vital, continuous process.

Timely, high-quality and relevant information is critical to sound healthcare decision-making.

Insights gained from information and analysis should be made widely available to healthcare stakeholders.

Effective use of information is often complex, requiring unique knowledge and expertise.

The ongoing innovation and reform in all aspects of healthcare require a dynamic approach to understanding the entire healthcare system.

Personal health information is confidential and patient privacy must be protected.

The private sector has a valuable role to play in collaborating with the public sector related to the use of healthcare data.

QuintilesIMS – INSTITUTE –

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