



2017

Association for
Accessible Medicines

Generic Drug Access & Savings in the U.S.

aam
Association for Accessible Medicines

Editor's Note

Perhaps not since the passage of 1984's Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Amendments, has there been an opportunity such as there is now for Congress and the Administration to improve the competitive framework of our nation's pharmaceutical system. From the President to policymakers to patients, there is a consensus in this country supporting the need for meaningful change.

Crafting effective and sustainable policies that achieve the aspirations of the American people with regard to drug pricing and accessibility demands timely and relevant data. It also requires an understanding of the industries and markets involved.

We encourage you to read through this report and use its findings to inform your own conversations about prescription drug pricing and access to patients. With all of the emotions and misperceptions informing the debate around drug pricing, there could not be a better time to hear the facts about generic and biosimilar medicines — one of our healthcare system's true success stories in terms of patient health and our country's economic well-being.

Generic Drug Access & Savings in the U.S.

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CEO's Note

A Healthier America

On behalf of the Association for Accessible Medicines, I am pleased to share with you the 2017 Generic Drug Access and Savings Report. This ninth annual edition of the report finds that generic medicines generated \$253 billion in savings for patients and taxpayers in 2016. In the last decade, the U.S. healthcare system has saved \$1.67 trillion due to the availability of low-cost generics.

Savings for the two largest government healthcare programs, Medicare and Medicaid, totaled \$77 billion and \$37.9 billion, respectively in 2016. That means every Medicare enrollee saved an average \$1,883, while every Medicaid enrollee saved an average \$512.

Compiled by the QuintilesIMS Institute on behalf of the Association for Accessible Medicines, the report details the savings generics provide across multiple segments, including by therapy area, payer type, patient demographic, and state.

Last year when this report came out, our association was still named the Generic Pharmaceutical Association. Today, we have a new name to reflect this evolving industry and to advance our patient access mission more powerfully.

Access is a value we uphold at every opportunity. All of our work, from promoting marketplace competition to advocating strategic enhancement of the Food and Drug Administration's (FDA) generic drug and biosimilar approval process, comes down to the promise of putting treatments within the reach of patients. Affordable medicines are inherently more accessible. Every dollar saved at the pharmacy counter is a dollar that can be spent on life's essentials and other pursuits — or put away for future use.

We must never take healthcare access and savings for granted. AAM looks forward to working with all stakeholders to ensure and expand access to generics and biosimilars — the proven, reliable way to drive down the cost of medicine, which helps patients, strengthens our economy, and benefits our society.

Sincerely,



Chester "Chip" Davis, Jr.
President and Chief Executive Officer

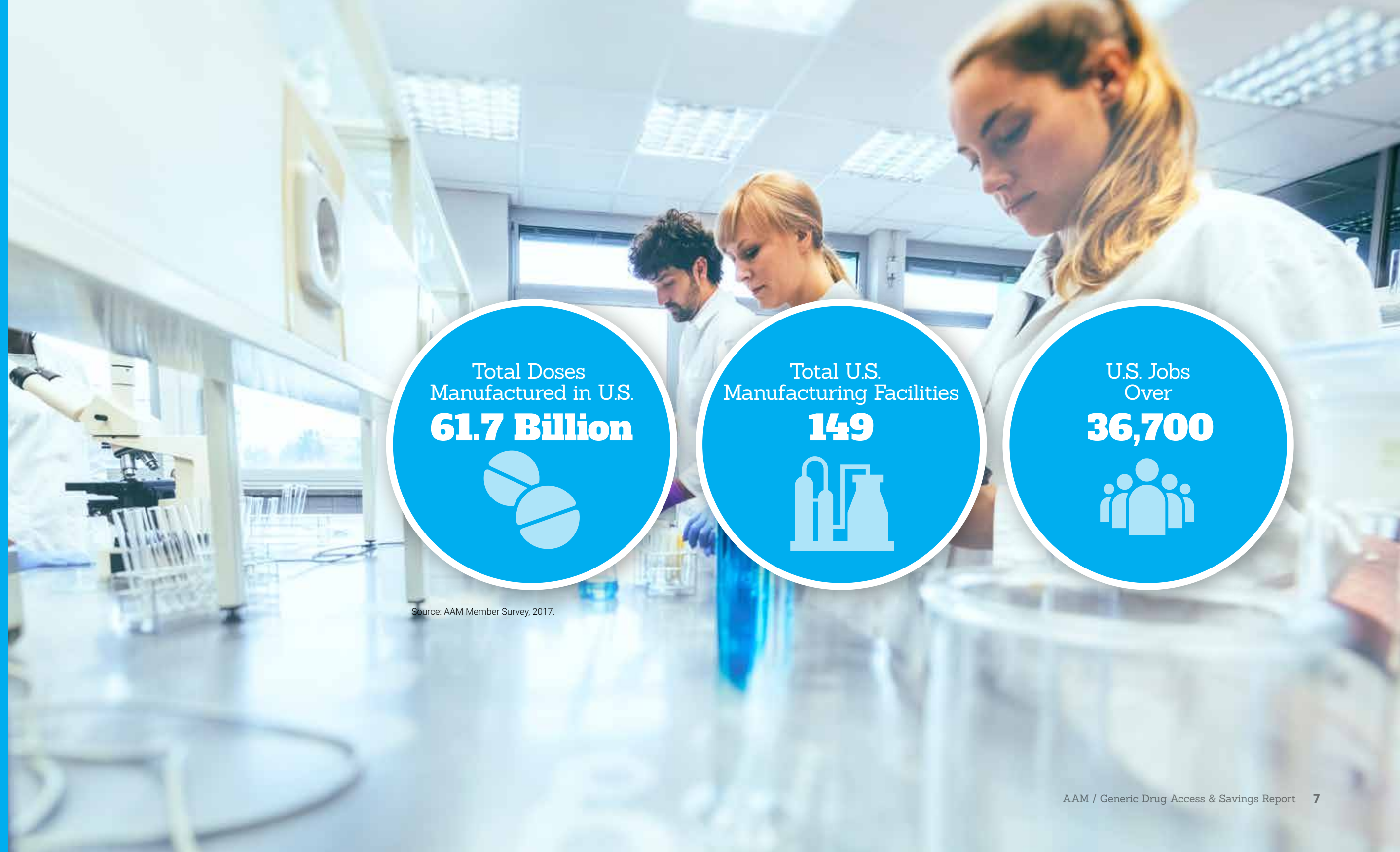
Solutions

Generics & Biosimilars Drive Solutions

Your Generics and Biosimilars Industry

The Association for Accessible Medicines, formerly the Generic Pharmaceutical Association, improves access to safe, quality, effective medicine. Better access to medicine is relevant to everybody because, after all, we're all patients at some point. Health is the foundation for everything in life. Healthy people are better able to reach their full potential. Generics and biosimilars help more people in more places live healthier and longer.

- Driving down the costs of existing drugs and developing new ones means people can afford the medicines they need.
- Increasing competition means payers and patients have a choice in the marketplace.
- Working to get safe, effective, and more affordable medicines out of the lab and into the hands of the people who need them is a goal that touches not just individuals and families, but the overall economy, and the entire nation



Total Doses
Manufactured in U.S.
61.7 Billion



Total U.S.
Manufacturing Facilities

149



U.S. Jobs
Over

36,700



Source: AAM Member Survey, 2017.

Solutions

Healthcare continues to dominate national headlines. And no wonder, with health expenditures climbing 5.8% to \$3.2 trillion in 2015 (the most recent figure available according to the government's Centers for Medicare and Medicaid Services), or \$9,990 per person, and accounting for 17.8% of Gross Domestic Product.

In today's ever-changing healthcare economy, it is important to distinguish between the factors contributing to cost increases and those that drive savings. Take, for example, specialty drugs, a class of prescription drugs generally used to treat complex diseases. Biologics, which are drugs derived from living cells, are often classified in this way. Today, branded specialty drugs comprise 1% of prescription drugs prescribed but remain responsible for more than 32% of total drug spending, according to separate QuintilesIMS data.

This report should enhance your understanding of the place generics hold in the pharmaceutical ecosystem. Its data provides a quantitative foundation for the argument so many parties make that generic and biosimilar medicines are the key to containing our nation's runaway prescription drug costs.

“The savings created by generic copies free up resources to invest in new treatments - creating headroom for innovation - and resulting in significant progress against some of the most costly and challenging diseases.”

Pharmaceutical Research and Manufacturers of America (PhRMA)

Total U.S. Healthcare Spending



Source: Centers for Medicare and Medicaid Services.

Solutions

As illustrated in the next chart, general deflation of the generic market continues to help millions of patients and taxpayers increasingly strained by soaring brand and specialty drug costs. It is a near universally acknowledged fact that the generic drug industry is responsible for making medicines more affordable and accessible for Americans.

We urge policymakers to recognize the very different dynamics that exist between branded and generic drug business models and marketplaces, and adopt policies to enhance the competitive prescription drug market that is essential to ensuring both patient access and system savings.

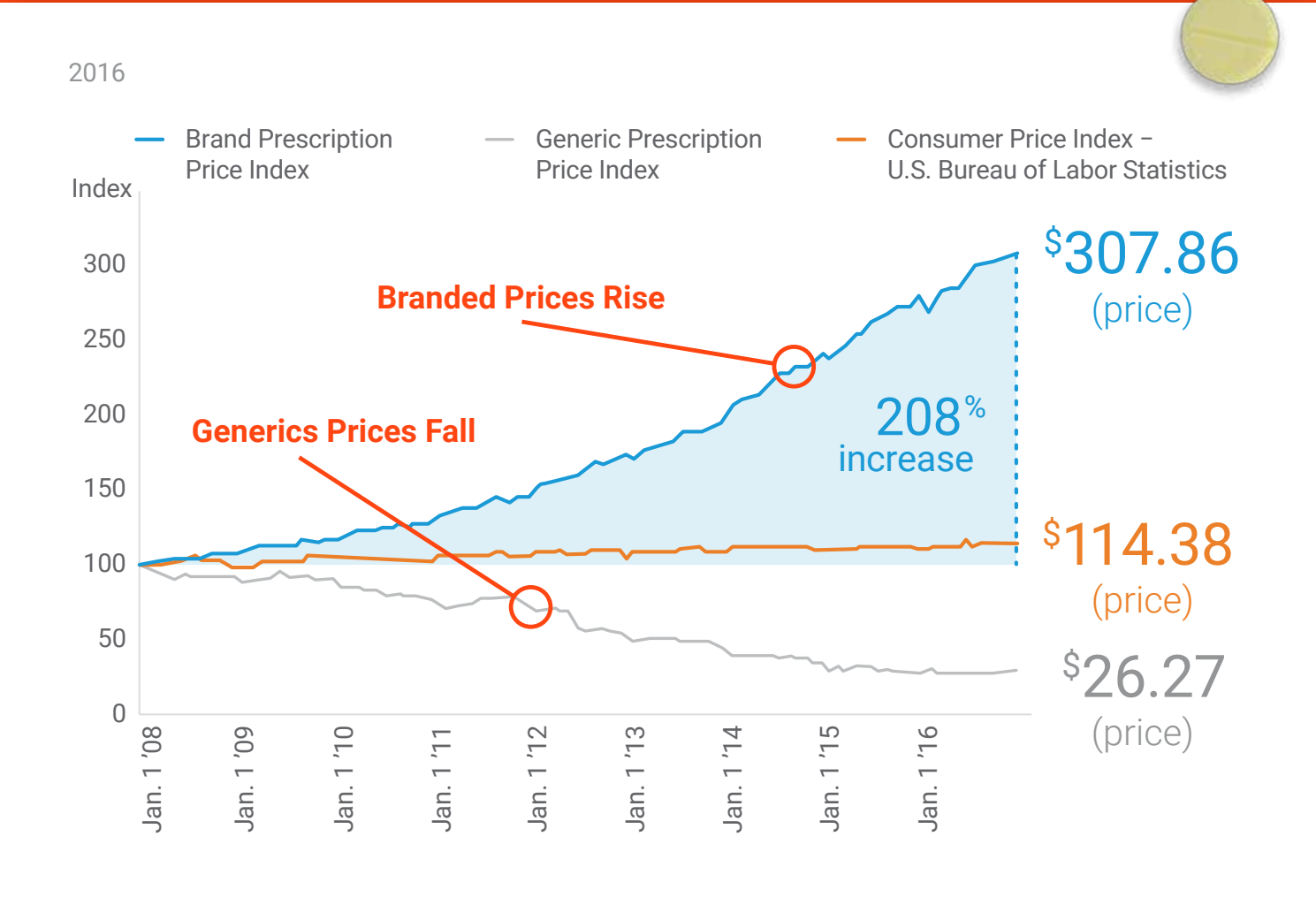
AAM will continue working with Congress, regulators, industry and patient groups to create a framework to bring greater savings and affordable medicines to our country. The foundation of that framework is greater competition. As policymakers evaluate their options, it is important to ensure that policy proposals enhance and not chill pharmaceutical competition.

“One factor that will help drive down costs for patients is ensuring there is a market for generic competitors.”

Senator Susan Collins (R-ME)
September 2, 2016



Express Scripts Prescription Price Index





“Generic drugs have for several decades offered relief from rising prescription drug costs. This occurs because there is robust competition among multiple interchangeable products that drive prices for generic drugs to be a fraction of that of the corresponding brand name drug. The result is that decreases in generic drug prices have partially offset large increases in prices for brand drugs.

Reports of spikes in the prices of some generic drugs have raised concerns that generic drugs are contributing to increases in overall prescription drug spending. This has led policy makers to ask whether markets for generic drugs are operating efficiently...**Our review of evidence strongly supports the conclusion that generic drug prices are not an important part of the drug cost problem facing the nation.**”

Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, “Understanding Recent Trends in Generic Drug Prices,” January 2016



Solutions

Patient Access & Savings May be Impeded by Some Branded Pharmaceutical Companies

Some branded companies use practices that have the effect of blocking affordable generic competition. One older, off-patient branded drug, Daraprim® was brought to the nation's attention when its manufacturer raised the price of the drug by 5000% in 2015. The pain of this increase was acutely felt by patients who had no access to a generic alternative.

Other brand pharma companies are gaming and abusing patient safety programs and the patent system to keep affordable and life-saving generic and biosimilar competitor medicines off of the market and out of the hands of patients.

The Association for Accessible Medicines is committed to increasing patient access through advocating for policies that curb these anti-patient and anti-competitive practices.

“In the case of Daraprim®, the retention of a new specialty pharmacy distributor to carry on a closed distribution system was considered an integral part of the company's desire to block a generic entrant for at least three years.”

Howard Dorfman, Former General Counsel, Turing Pharmaceuticals, Hearing of the United States Senate Special Committee on Aging, March 16, 2016



Key Findings

Nearly 3.9 Billion Generic Prescriptions
were Dispensed in 2016



Generics account for 89% of prescriptions dispensed but only
26% of total drug costs in the US.

Source for Key Findings: QuintilesIMS.

90%
of Generic
Copays
are Under
\$20

as compared to 39% of branded
copays for patients in the
commercial and Part D markets

“ I take generic medications for asthma. I don't have a lot of time or money to spare, so I tell the doctors to give me the generic because they work the same, and it's way less than half the cost of the brand name. I've been able to use the savings to go back to school. ”

Raeanne, 33, New York, NY

Key Findings

Consider the data on the opposite page while reflecting on your own experience at the pharmacy counter. If you or a family member take a generic version of a popular brand drug, you know the feeling when you switch to a more affordable medicine. The relief is palpable and the positive effect on your purse or wallet is undeniable. Generics and biosimilars don't just put your medicines within reach, they put the rest of your life within reach as well.

The patients featured throughout this report, like Raeanne, a single mother of three in New York City, rely on generics to maintain their families' health and use savings to afford everyday needs like filling the tank, paying for rent and putting food on the table. Without generics, so many Americans — our family, friends and neighbors — would face incredibly difficult and heartbreaking choices between their health and life's other essentials.

Top 10 Generic Drugs Ranked by Savings

| Brand Products | Generic Entry Year | Brand Pre-expiry price (per unit) | Price of Generic Equivalent 2016 (per unit) | 2016 Savings (\$B) | Percent Savings | 2016 Dispensed Rx's (Mn) |
|----------------|--------------------|-----------------------------------|---|--------------------|-----------------|--------------------------|
| Lipitor® | 2011 | \$3.29 | \$0.11 | \$14.4 | 97% | 106.3 |
| Prilosec® | 2002 | \$3.31 | \$0.08 | \$11.1 | 98% | 76.3 |
| Zofran® | 2006 | \$21.67 | \$0.20 | \$10.0 | 99% | 23.2 |
| Cymbalta® | 2013 | \$4.61 | \$0.45 | \$8.2 | 90% | 49.0 |
| Zocor® | 2005 | \$2.62 | \$0.03 | \$6.9 | 99% | 60.4 |
| Neurontin® | 2004 | \$1.02 | \$0.09 | \$5.8 | 92% | 64.2 |
| Norvasc® | 2007 | \$1.54 | \$0.02 | \$5.6 | 99% | 87.4 |
| Singulair® | 2012 | \$3.74 | \$0.17 | \$4.7 | 95% | 39.0 |
| Abilify® | 2015 | \$21.68 | \$3.62 | \$4.6 | 83% | 9.8 |
| Seroquel® | 2012 | \$6.00 | \$0.29 | \$4.5 | 95% | 20.6 |

Key Findings

2016 Savings

\$253

Billion

Generic medicines generated \$253 billion in savings in 2016. One-quarter of a trillion dollars.

10-Year Savings

\$1.67

Trillion

The U.S. healthcare system has saved \$1.67 trillion in the last decade due to the availability of low-cost generics.

2016 Medicare Savings

\$77

Billion

Nationally, generics saved Medicare **\$1,883** per enrollee.

2016 Medicaid Savings

\$37.9

Billion

Nationally, generics saved Medicaid **\$512** per enrollee.

AAM's Five-Point Plan

1. Promote timely access to quality, affordable generic medicines that meet high standards of a streamlined development and approval process
2. Create policies that recognize the different economic dynamics of the brand and generic markets
3. Ensure an intellectual property framework that balances the need for innovation and robust generic competition
4. Stop some brand drug companies from blocking or delaying generic drug development
5. Increase use of affordable generics across all patient populations



“Too many patients are priced out of the medicines they need. While FDA does not play a direct role in drug pricing, we can take steps to facilitate entry of lower-cost alternatives to the market and increased competition. This is especially true when it comes to safe and effective generic medicines.”

Dr. Scott Gottlieb, Commissioner, Food and Drug Administration, Appropriations Subcommittee Hearing, U.S. House of Representatives, May 25, 2017

Generics & Biosimilars Drive Access

The pills may look different, but medically, generic medicines work the same as costlier brand-name drugs. They have the same active ingredients, and the manufacturing and packaging must pass the same quality standards. And the research confirms that generics work just as well as brand name drugs.

The U.S. Food and Drug Administration (FDA) requires generic drugs to have the same quality and performance as brand name drugs. The FDA states: “Generics have the same quality as brand name drugs. When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity, and potency.”

The significant difference between generic and brand name prescription drugs is cost. Generic manufacturers can sell their products for lower prices because they don't repeat the clinical trials of new drugs. Whereas brands pay huge sums for advertising, marketing, and lobbying — for example, according to Kantar Media, AbbVie spent \$259 million in 2015 on direct-to-consumer advertising for Humira® — generics don't incur that tremendous expense and are able to pass savings on to the patient.

“...when a drug is very expensive, like the biologics used to treat rheumatoid arthritis that cost \$4,000 a month, patients are less likely to take them... which renders them less effective.”

Dr. William Shrank, Chief Medical Officer, University of Pittsburgh Health Plan, April 2017

Generics Drive Better Health

It is a public health and patient safety imperative that patients take medicines as prescribed and adhere to the instructions of their doctor, pharmacist or healthcare provider.

Prescription medication cannot help the patient who doesn't take it. That's why health experts are actively investigating the phenomenon of "abandonment" — the term given for instances when the patient brings or calls in his or her prescription to the pharmacy but does not collect the medicine. After visiting their physician, filling a prescription is the first step on a patient's journey to maintaining their health, followed by taking their medicine as prescribed — or "adherence."

Not taking medicines as prescribed has significant repercussions on people's health and our country's economic well-being. According to the latest available research, in the United States lack of adherence is responsible for approximately 125,000 deaths, at least 10% of hospitalizations, and a substantial increase in morbidity and mortality. The economic impact of nonadherence translates to system costs of between \$100 billion and \$289 billion annually.

Overall, new patient abandonment rates for generics abandonment are

3X Lower

than **branded** abandonment.

Source: QuintilesIMS.

Branded products make up 20% of approved claims but account for

40%

of all abandoned claims for new patients.

Branded abandonment is

20.5%

compared to 7.7% for generics for new patients.

Access

Why wouldn't patients fill the prescriptions they need? Sticker shock is believed to be a primary reason for abandonment. There is a direct correlation between price and abandonment, and studies show that patient cost sensitivity is similar for branded and generic products, but across copays, the distribution of claims significantly favors generics.

To reiterate, these are medications prescribed by the doctor, approved by the insurer, and desired by the patient enough for him or her to place the order — but 14 days later, that bottle of pills hasn't left the pharmacy.

Brand-name products make up about 20% of approved claims but account for about 40 percent of all abandoned claims

Overall, new patient abandonment rates for generics are about two-thirds lower than branded abandonment. Specifically, 20.5% of brand-name prescriptions are abandoned, compared to 7.7% of generics.

It stands to reason that the affordability of generics is a key reason for increased patient compliance. About 90% of generic copays are under \$20. Fewer than 4 in 10 of brand-name copays are under \$20. Generics are more likely to start a patient on their journey to good health.



13%
of brand abandonments lead to generic switching within 30 days of initial approval.

87%
of patients save money when switching to a generic alternative.

More than half of all patients switching from a brand to a generic medication realize more than a

\$50
cost reduction.

Source: QuintilesIMS.

Access

Biosimilars are safe and effective alternatives to brand biologic medicines used in the treatment of cancer, rheumatoid arthritis and other conditions. Common biologics are drugs like Enbrel® and Humira®. These are medications you may see advertised on television in commercials many times a day. They are often infused or injected. They are also typically very expensive.

Biosimilars enable patients, payers, physicians and others to benefit from greater choice when it comes to treatment options. Unfortunately, the U.S. is about 10-15 years behind Europe in terms of market-access to biosimilars. We have five FDA-approved biosimilars in the U.S. today, while there are nearly 30 approved biosimilars in the EU.

A significant barrier to patient access are the “patent estates” that brand manufacturers have built to protect their monopolies. These brand drug companies are using a strategy – to create a litigation backlog to maintain their monopoly and prevent competition from biosimilars – similar to what they have done to interrupt generic entry into the pharmaceutical marketplace. Mountains of non-innovative patents keep generic manufacturers in court for years before being able to enter these markets, long after exclusivity for the product would have otherwise expired. In addition to impeding further innovation, these tactics impact patient’s lives – and their wallets – delaying access to safe, more affordable life-saving biosimilar medicines.


Biosimilars promise tens of billions of dollars in patient, insurer and health system savings – projections range up to \$250 billion (Express Scripts) over 10 years. We believe that manufacturers, government and regulatory groups must work together to create policies that create competition and prioritize patient access.

“ Let’s create more competition to lower the cost of prescription drugs by increasing the flow of generics and biosimilars to the market...bringing more competition to the market needs to be a top priority, as well as promoting policies that do not delay generic and biosimilar entry. ”

Tom Moriarty, Chief Health Strategy Officer and General Counsel for CVS Health, December 19, 2016

Biosimilar Approvals

| Approval Date | Biosimilar Product | Non-Proprietary Name | Biosimilar Sponsor(s) | U.S. Launch | Reference Product | Originator |
|---------------|--------------------|----------------------|-----------------------|-------------|-------------------|------------|
| 3/6/15 | Zarxio® | filgrastim-sndz | Sandoz | 9/3/15 | Neupogen® | Amgen |
| 4/6/16 | Inflectra | infliximab-dyyb | Celltrion/Pfizer | 10/17/16 | Remicade® | Janssen |
| 8/30/16 | Erelzi | etanercept-szsz | Sandoz | Pending | Enbrel® | Amgen |
| 9/23/16 | Amjevita | adalimumab-atto | Amgen | Pending | Humira® | Abbvie |
| 4/24/17 | RenFlexis | Infliximababda | Samsung/Bioepis | Pending | Remicade® | Janssen |



“The general acceptance of generic substitution has increased the efficiency of the prescription drug market. Use of generic drugs leads to higher levels of adherence and has decreased healthcare costs while improving outcomes. Critical to the growth of the generic drug market was the idea of therapeutic equivalence and hence substitution of generic for branded drugs.”

Michael E. Johansen, MD, MS; Caroline Richardson, MD,
“Estimation of Potential Savings Through Therapeutic Substitution,” *Journal of the American Medical Association*, June 2016

Savings

Generics Drive Savings

In 2016, generic drug savings reached \$253 billion.

Ever since the 1984 signing of the Hatch-Waxman Amendments, generics have been controlling costs for American patients. Savings have grown since then and are expected to continue to grow as generic drug manufacturers deliver on the promise of timely access to safe, effective and more affordable medicines for millions of people. When signing Hatch-Waxman into law, President Ronald Reagan predicted generics might save patients one billion dollars in 10 years time. Last year **generics saved Americans almost \$5 billion every week.**

Generic drug use has increased while the share of pharmaceutical spending attributed to generics has gone down. Nearly 3.9 billion prescriptions dispensed in the United States are for generics.

Generics make up 89% of prescriptions dispensed but only 26% of total medicine spending. Put another way, brand drugs are only 11% of prescriptions but are responsible for 74% of drug spending. Vital generic products help millions of patients. Today's generic drug savings provide the health system with the ability to make investments in tomorrow's new medicines.



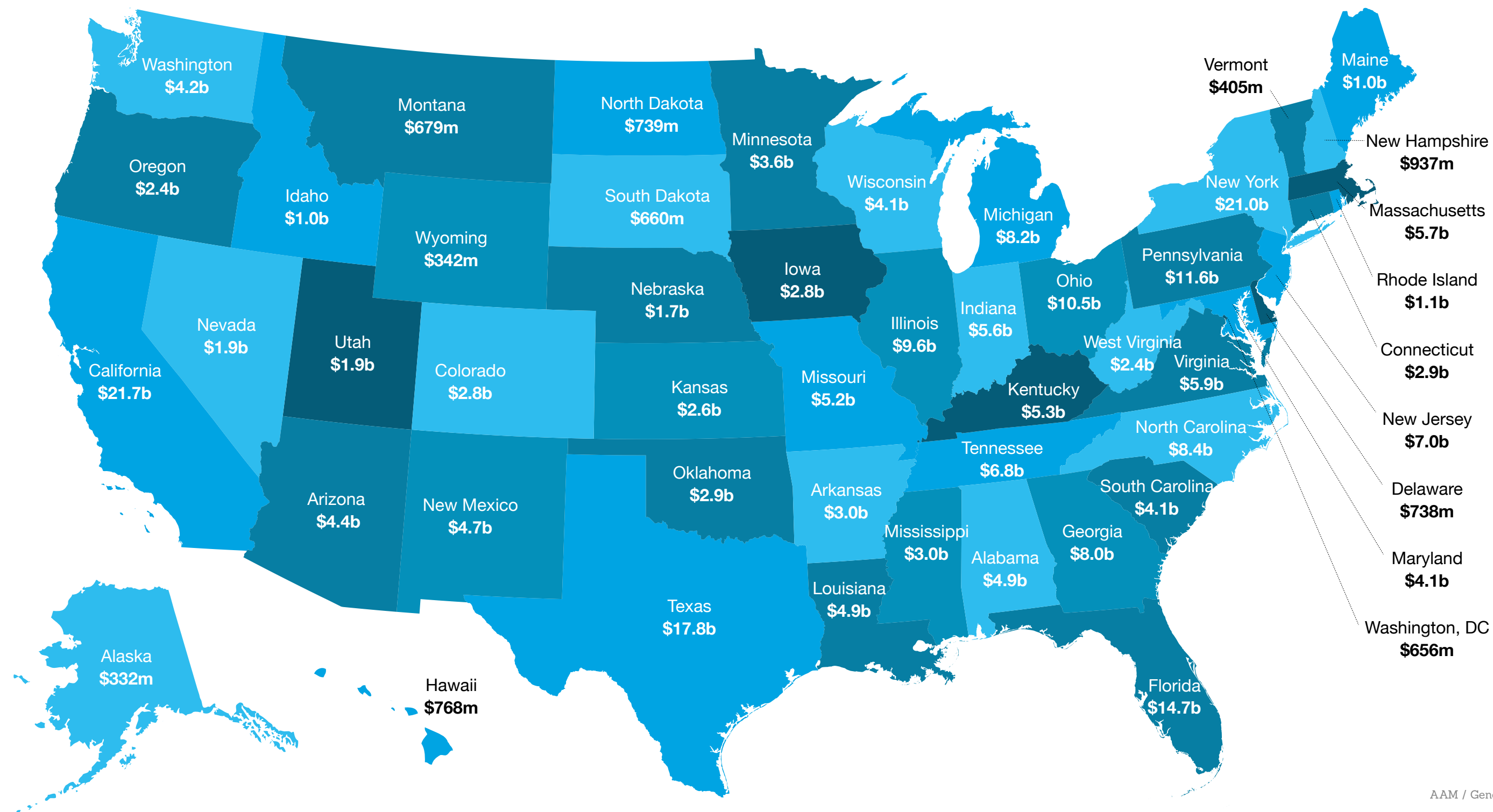
“I have a very good relationship with my pharmacist. He said, ‘Don’t waste your money on the brand names.’ I’m on a fixed income, and those savings really do add up.”

Michelle, 58, Stroudsburg, Pennsylvania

Savings

Savings by State

On average, in 2016 the use of generic medicines saved each state \$4.9 billion compared to the price of relevant branded medicines. This means that state Medicaid savings averaged \$744 million and state Medicare savings averaged \$1.5 billion per state.



Savings

Sustainable Competition Drives Savings, Not Costs

Rising drug prices aren't just a problem for patients. The entire healthcare system falters if consumers can't afford the products they need.

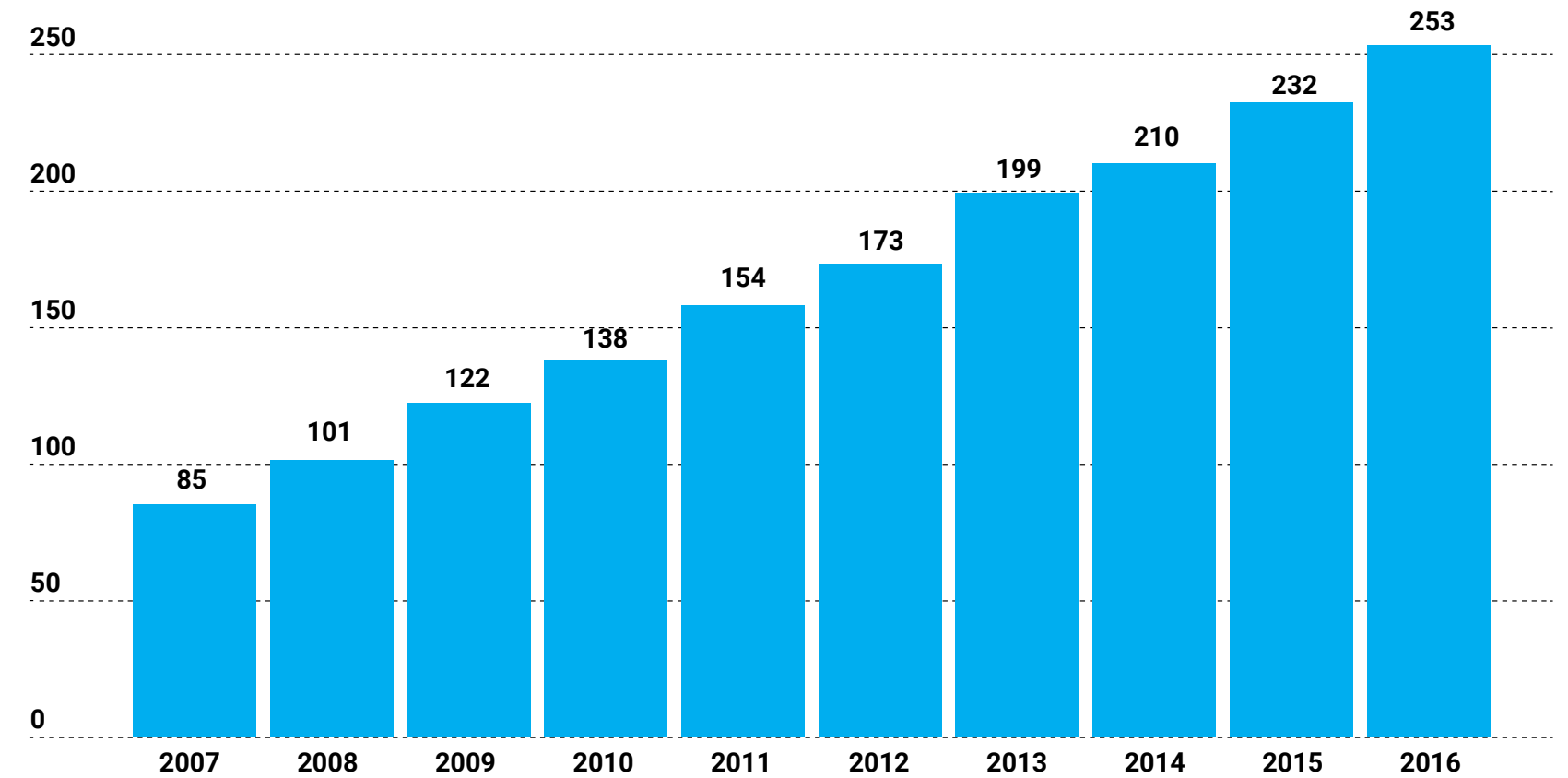
Experts agree that what's needed is a market where growth and innovation are balanced with factors that hold prices down — on a sustainable basis. Without the element of competition that generics bring to the market, drug prices could become even more erratic, harming patients and families who rely on medication.

Unfortunately, year-over-year savings realized from use of generic medicines (reflected in the chart opposite) are increasingly at risk. Due to a number of factors, including consolidation in the payer market; brand company patent abuses and other anti-competitive actions; and the preponderance of ill-advised federal and state policy recommendations, barriers to generic market entry are increasing.

With patient access as a north star, policymakers need to understand the holistic and long term effects of efforts to burden a well-functioning market. Energies are best spent on initiatives that enhance and sustain competition which provides patients with greater choice of affordable medicines.



Savings from Generics Totaled \$253 Billion in 2016



Source: QuintilesIMS.

Savings

Savings by Treatment Area

The highest levels of savings in 2016 were found in drugs for mental health, hypertension, cholesterol and ulcers. These four treatment areas represent \$123 billion in savings.

While the potential of innovator drugs often capture the attention of organizations representing different diseases and therapeutic areas, the maintenance of chronic illness and disease through generics provide tremendous savings and relief for millions of patients nationwide. With the introduction of more biosimilars, the representation and savings for an even greater number of therapeutic areas will grow.

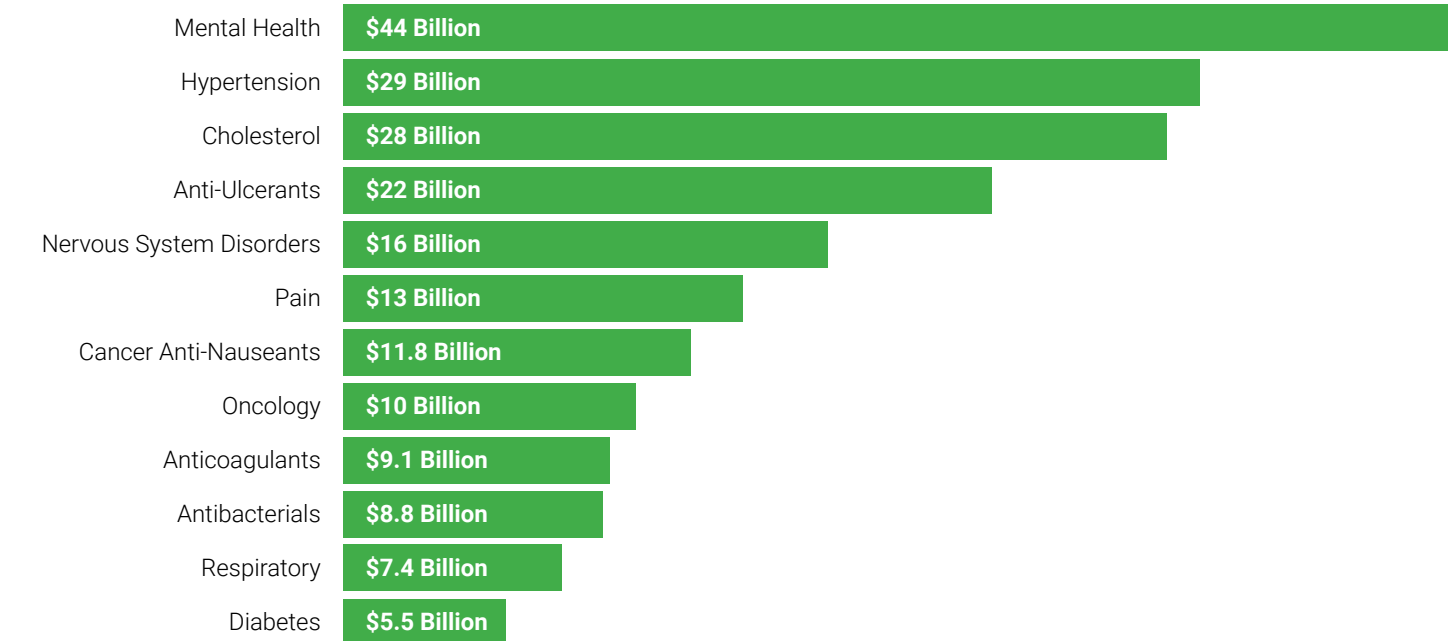
“ My medications are very essential. I’m pretty much living paycheck to paycheck, and without generic medicine, I probably wouldn’t even be able to put gas in my tank. ”

McKenzie, 24, Salt Lake City, Utah

Generic Mental Health, Hypertension, Cholesterol, and Ulcer Medications Account for Half of the Savings in Last Ten Years

Generics saved the U.S. healthcare system \$1.67 trillion since 2007

2016 Savings from Generics in Billions



Source: QuintilesIMS.

Savings

Savings by Payer Type

The federal government is the nation's largest purchaser of generic drugs. In fact, without generics Medicaid and Medicare spending on prescription medicines would nearly double.

A 2016 GAO report found that prices for generic drugs in Medicare Part D declined 59% from the first quarter of 2010 to the second quarter of 2015.

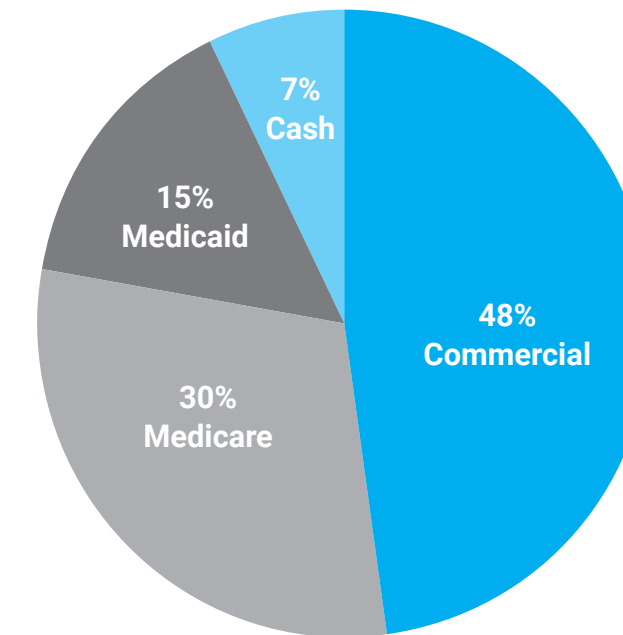
Medicare savings from generics totaled \$77 billion in 2016 with savings of \$1,883 per enrollee. Medicaid program savings from generics reached \$37.9 billion, which translates to savings of \$512 per enrollee.

“The best way to reduce prescription drug costs is to expedite approval of brand and generic drug competitors.”

Mark Merritt, PCMA President and CEO

Nearly Half of Generic Savings Goes Directly to Consumers

2016 National Generic Savings by Method of Payment (%)



Source: QuintilesIMS.

Sample State Results

- In New York, the use of generics resulted in \$4.6B in Medicaid savings, or approximately \$729 per enrollee.
- In New York, the use of generics resulted in \$7B in Medicare savings, or approximately \$2,664 per enrollee.
- Using generics saved California \$4.1B in Medicaid drug spending in 2016.
- Using generics saved California \$6.9B in Medicare drug spending in 2016.
- Medicaid saved \$1.6B in Texas, a state with 4.7 million Medicaid enrollees.
- Medicare saved \$5.2B in Florida, a state with over 3 million enrollees.

Savings

Savings by Payer Type

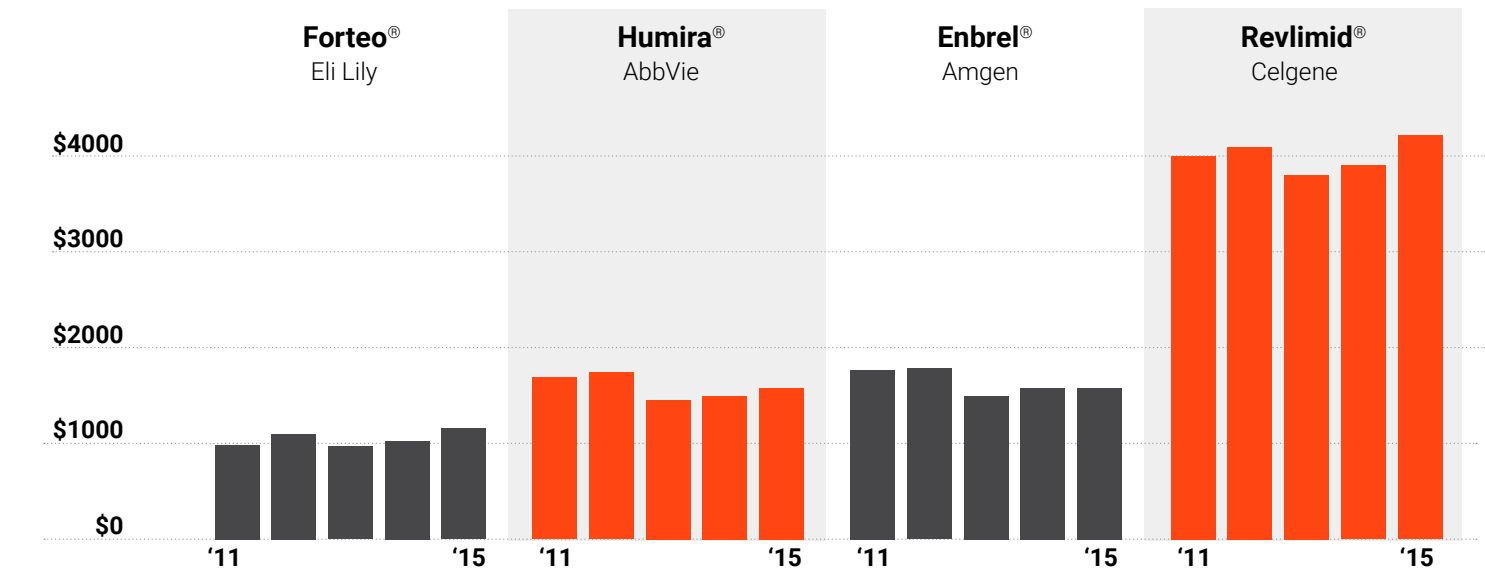
An analysis of government data by The Wall Street Journal found expensive patent-protected brand medicines are increasingly denting the pocketbooks of seniors and other beneficiaries in Medicare's prescription-drug program, known as Part D. The median out-of-pocket cost for a drug purchased through Part D was \$117 in 2015, up nearly half from \$79 in 2011. Some 220 Part D drugs had annual out-of-pocket costs of \$1,000 or more in 2015, up 86% from 118 drugs in 2011. Factors driving the trend include sharply rising drug prices for patent protected brand products, which grew by an average 14% a year from 2011 to 2015, and the introduction of new medicines with prices that commonly exceed \$50,000 annually.

“Medicare beneficiaries aren't always fortunate. The median out-of-pocket cost for a Medicare beneficiary taking Revlimid is \$11,500 per year. It is the most expensive Medicare drug. It's clear to me that Celgene is gaming our system. It is using the bogus pretext of Risk Evaluation and Mitigation to unlawfully deny samples to generic manufacturers in order to prevent them from developing a cheaper alternative.”

David E. Mitchell, Founder, Patients For Affordable Drugs, Hearing of the U.S. House of Representatives Committee on Oversight and Government Reform Subcommittee on Health Care, Benefits, and Administrative Rules, March 22, 2017

Burden on Patients

The median out-of-pocket cost in 2015 for the top 100 drugs by total spending in Medicare Part D was up 32% to \$376 from 2011. Here is what patients spent for four expensive medicines.



| | | | | |
|-------------------------------------|---------|---------|---------|---------|
| Medicare Spending 2015 | \$0.43B | \$1.66B | \$1.39B | \$2.08B |
| Unit Price Change, 2011-2015 | +79.6% | +70.2% | +70.9% | +26.7% |

Note: Out-of-pocket costs exclude patients who receive low-income subsidies. All spending figures are adjusted for inflation, 2015 dollars. Unit prices reflect retail costs, prior to discounts and rebates. Source: Centers for Medicare and Medicaid Services. Reprinted with permission from Dow Jones.

Savings

Savings by Patient Age

Medicines typically prescribed to adults (40-64) accrued \$100 billion in savings, while those typically prescribed to seniors (65+) account for \$75 billion in savings. Medicines taken by these two population segments represent patients most likely to benefit from 79% of generic drug savings.

Medicines for young adults (20-39) saved \$30.4 billion while medicines predominantly treating children (0-19) made up \$16 billion in savings.

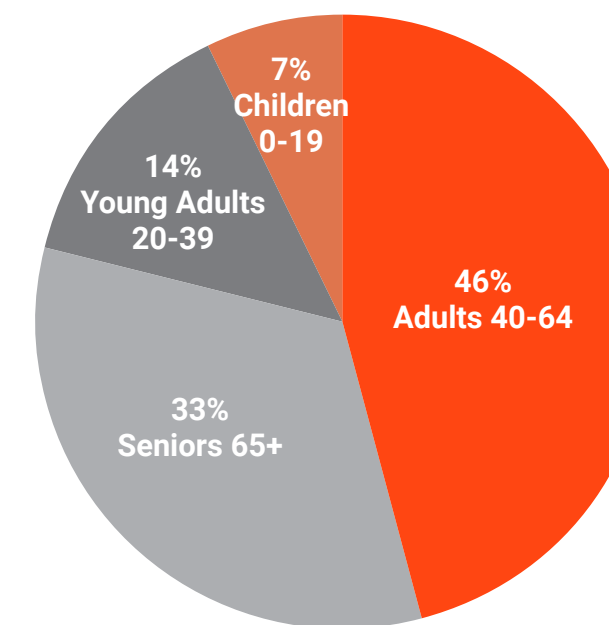
Patients often have multiple chronic diseases, and their costs add up quickly. Out-of-pocket costs can vary between traditional commercial insurance plans with set copayments, high-deductible health plans or Medicare Part D.

“ I'd been on the brand-name cholesterol drug for quite a while, but then the insurance company discontinued coverage of it. My doctor recommended the generic, and it's done everything that the brand-name drug did, plus it's much cheaper. Those generic savings have really come in handy, because I've been able to help my grandchildren with their college savings. ”

Doug, 74, Pembroke Pines, Florida

Generic Medicines Used by Seniors Account for 1/3 of Savings

2016 Generic Savings by Patient Age (%)



Source: QuintilesIMS.

- Medicines taken by older adults and seniors account for the majority (79%) of the \$253B in savings generated by generics in 2016.
- Generic medicines taken by older adults aged 40-64 accounted for \$115B in savings in 2016.
- Generic drugs taken by seniors over age 65 accounted for \$84B in savings

Methodology

Data compiled by QuintilesIMS Institute. Generic industry data on doses, facilities and employees are results from a survey of the membership of the Association for Accessible Medicines (AAM). Additional metrics curated by AAM from publicly available sources or with permission from the owners.

2007-16 Update

- Used SMART database 2007-16 sales and volume data
- Savings calculations include 814 generic molecules
- Value of Generics = Generic Units x Pre-Expiry Brand Prices
- Generic Savings = Value of Generics – Actual Generic Sales
- Pre-Expiry brand price determined using sales and unit volumes in the year prior to the first appearance of a generic within a molecule
- Pre-Expiry brand price generated back to sales in 1992

How was the data collected?

The value of generics currently on the market was estimated using the pre-expiry prices of the brands they replaced. The current dataset includes pre-expiry brand prices for 814 generic molecules. The value of each generic molecule was determined by multiplying its pre-expiry brand price by the generic volume sold in each of the last ten years. This value represents what would have been spent on brand name medicines in the absence of generic competition.

The savings attributed to each of the 814 generic molecules was determined by subtracting historic generic spending from the estimated brand spending in the absence of generic competition. This analysis was refreshed with annual sales and volume data for all medicines sold in the United States between 1992 and 2016, focusing on the 10-year savings for the period 2007 to 2016. Savings from generics launched in the 1993 to 2016 study period are based on the most current knowledge of their pre-expiry prices. Savings from generics launched prior to 1993 were calculated using brand prices from 1992 which is the oldest archived data period retained by IMS Health.

Generic savings were calculated at the molecule-class level using a single average price for each molecule across all formulations (oral solid, liquid). Molecules that are available in multiple formulations are assumed to have the same pre- and post-expiry utilization patterns. Molecules with injectable formulations were calculated related to specific formulations to appropriately measure the cost differences between brands and equivalent generic forms.

State level generic savings was estimated by apportioning total savings for each molecule by each state's share of the national retail prescription volume. This method embeds two assumptions; first, that prices are uniform across the country, and second, that retail prescription activity mirrors prescription activity in other channels, notably mail order.

Savings generated by children, young adults, older adults, and seniors were estimated based on national prescription trends captured in the IMS New to Brand Audit™. These figures represent the portion of the national savings generated by each age group, not the sum of the patients' personal savings.

Savings by pay type was estimated using the share of each molecule dispensed via retail pharmacies to patients paying with cash and those covered by Medicare, Medicaid, and commercial insurance. After calculating savings at the molecule, state, and payer level, results were summed to the state-payer level. This method does not analyze the cost to the patient who may have a co-pay or discount card; rather it divides generic savings equally amongst patients based on prescription use, regardless of insurance plan.

Patients with Medicaid, Medicare, and commercial insurance pay different prices for their medications based on their insurance benefit design. This analysis did not attempt to estimate savings to individual patients based on their method of payment. Instead, total generic savings for each molecule was divided evenly based on the number of prescriptions filled by patients of each pay type.

In the two recent editions of this study, the IMS Institute has employed not previously available historic archives. The prior versions of this study were based on archives and live data covering periods 2003-present. The current edition of the study includes archives extending a further 11 years to 1992. The calculation of generic savings depends upon the brand's pre-expiry price, or the oldest available brand price if the pre-expiry price is not available. Older generics, particularly those first launched 1992-2003, and even those first launched before 1992, now have improved accuracy in the study. Brand prices change post-expiry, and therefore the more complete and accurate prices have improved the accuracy of the savings estimated in the study.

In the study released in 2015, the 10-year savings 2005-2014 were \$1.68 Trillion. Using the method from the new study, the 2005-2014 savings would have been \$1.31 Trillion, with the majority of the difference from older generics, due to more complete and accurate availability of pre-expiry brand prices. Offsetting these reduced savings modestly were the inclusion of some medicines where brands ceased marketing between 1992-2003, leaving only generics available for those medicines. These medicines were excluded previously due to the absence of a brand price for calculations of savings, but can now be included.

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