



2018

Generic Drug Access & Savings in the U.S.

Access in
Jeopardy

aam
Association for Accessible Medicines

TM

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CEO's Note

GENERIC AND BIOSIMILAR SAVINGS IN THE U.S.

A recent survey conducted by Harvard's School of Public Health found that Americans considered action to lower prescription drug prices more important than any issue, including immigration reform. Generic drugs play a key role in this effort, saving patients and the public hundreds of billions of dollars annually, and almost two trillion dollars over the last decade. And new biosimilar medicines represent additional savings and access on the horizon.

Thanks to the generic and biosimilar medicines made by member companies of the Association for Accessible Medicines, lifesaving drugs are within reach for hundreds of millions of people.

Today, a number of factors are combining to jeopardize patient access to critical, lifesaving medicine:

- **Market changes**, which have created an unsustainable climate for generic and biosimilar manufacturers.
- **Anti-competitive tactics** designed to artificially extend government-provided monopolies on high-priced brand drugs.
- **Misguided government policies** that fail to account for the differences in the business models for generic, biosimilar and brand-name drugs.

As in previous years, the tenth edition of this annual report presents the independent findings of IQVIA regarding the savings that our companies bring about. In 2017, generics generated a total of \$265 billion in savings. Savings for Medicare and Medicaid amounted to \$82.7 billion and \$40.6 billion, respectively, which translates to an average \$1,952 for every Medicare enrollee and \$568 for every Medicaid enrollee.

Anybody who cares about the U.S. health care system, and all the patients who depend on it, should recognize the role that generic and biosimilar medicines play in keeping people healthy and productive. I believe that this report will inform the conversation, in Washington D.C. and in state capitals, about how to rein in prescription drug prices. To accomplish our shared national goal we need to keep medicines accessible, preserving and, indeed, expanding generic savings must remain a priority.

Sincerely,



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



About AAM

AAM Works to Ensure More Generic and Biosimilar Medicines Are More Accessible to More People Who Need Them

The Association for Accessible Medicines (AAM), the trade association representing generic manufacturers, works to improve access to FDA-approved safe, effective and high-quality generic and biosimilar medicines. Better access to medicine matters to everyone because we're all patients.

Generics and biosimilars help people live healthier lives by:

- Driving down the costs of existing drugs so people can afford the medicines they need.
- Increasing competition so patients and payers have a choice in the marketplace.
- Enhancing access to safe, effective drugs so more consumers take their prescriptions.

As manufacturers of 9 out of every 10 prescriptions dispensed in the U.S., members of AAM form an integral and powerful part of the health care system.





Key Findings

93% of Generic Prescriptions Are Filled at **\$20** or Less



Prices for generic medicines have been falling year-over-year at a rate of almost 7 percent (Raymond James & Associates). Meanwhile, brand drug prices continue to rise at a pace greater than 100 times inflation according to AARP.

Average Primary Copay*

Generics	Brands
\$6.06	\$40.30

*The amount set by the insurance plans.

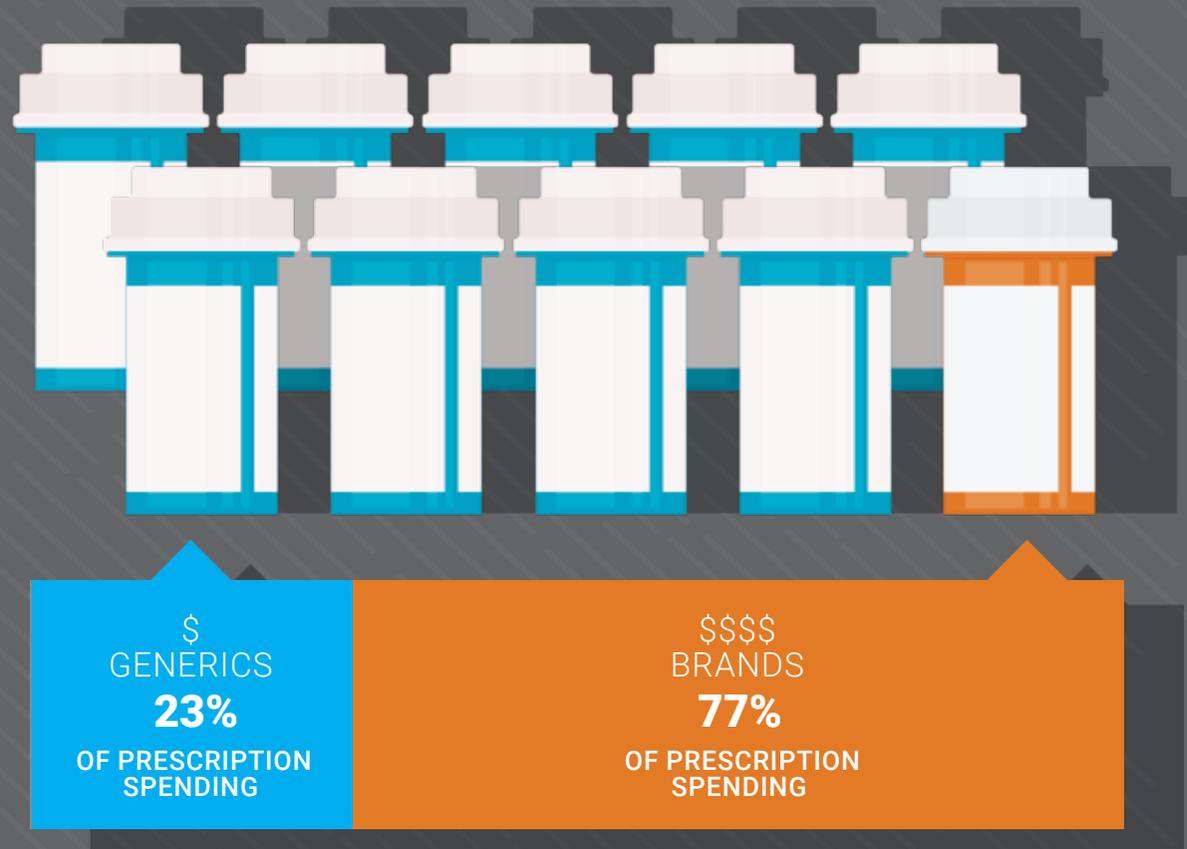
What's At Stake

OVERALL SAVINGS 2017

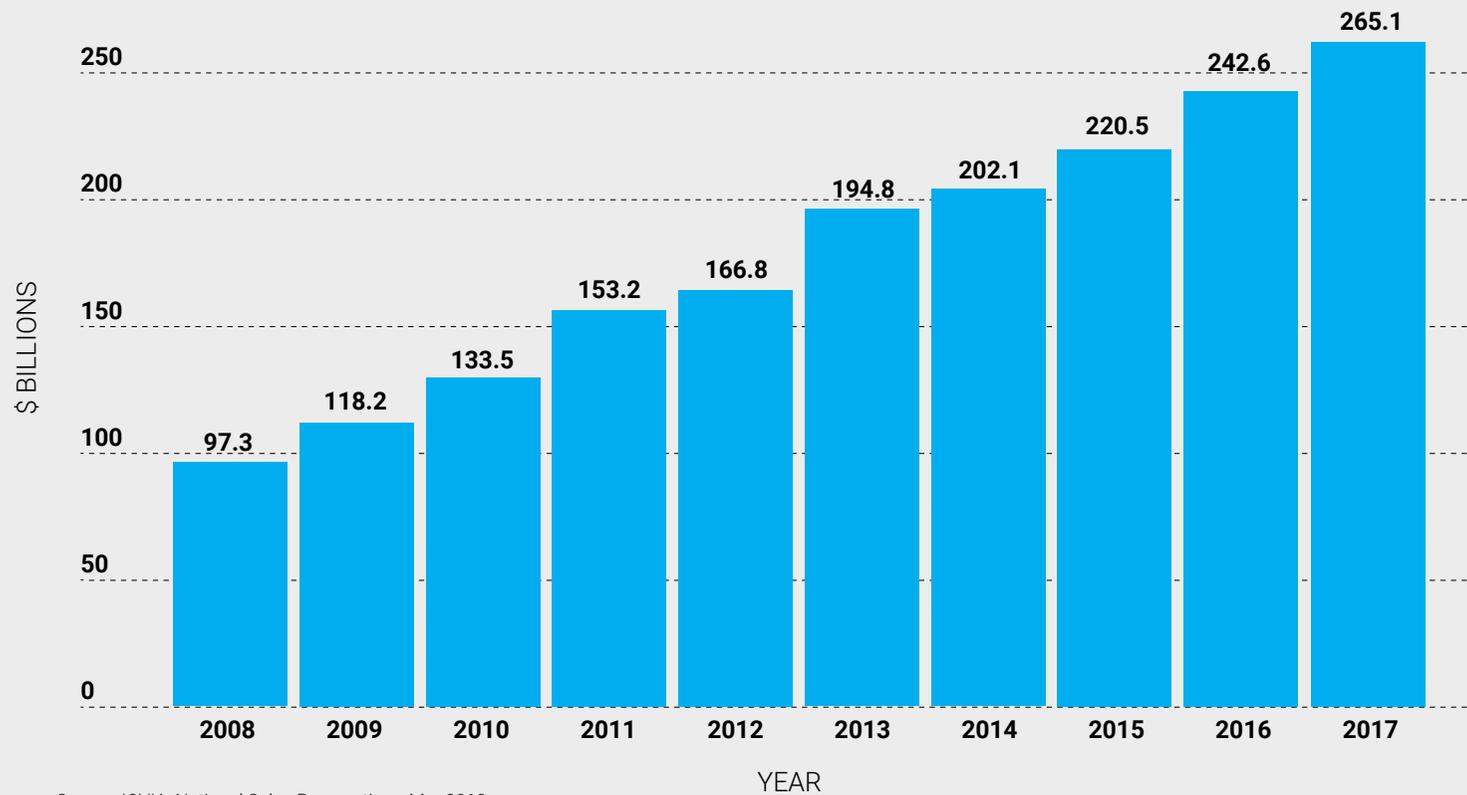
Brand-Name Drugs Represent Only 10 Percent of Prescriptions but 77 Percent of Drug Spending

In 2017, nine out of every 10 prescriptions in the U.S. were dispensed using generic drugs. When both brand and generic versions of the prescribed medication were available, the generic was chosen 97 percent of the time, resulting in significant patient savings. By any definition, generics represent a health care success story.

GENERICS ACCOUNT FOR 9 OUT OF 10 PRESCRIPTIONS FILLED IN THE U.S.



Savings from Generics in U.S. Totaled \$265.1 Billion in 2017

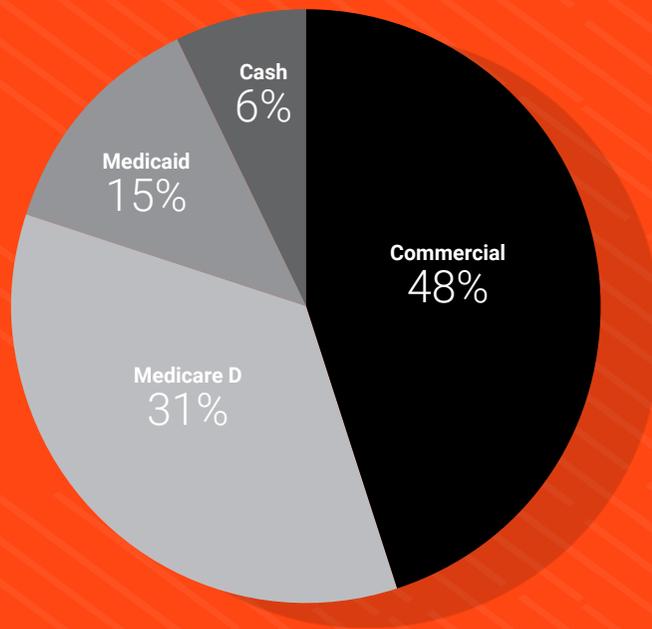


What's At Stake

SAVINGS BY PAYER TYPE AND AGE

All Payers Benefit from Generic Savings

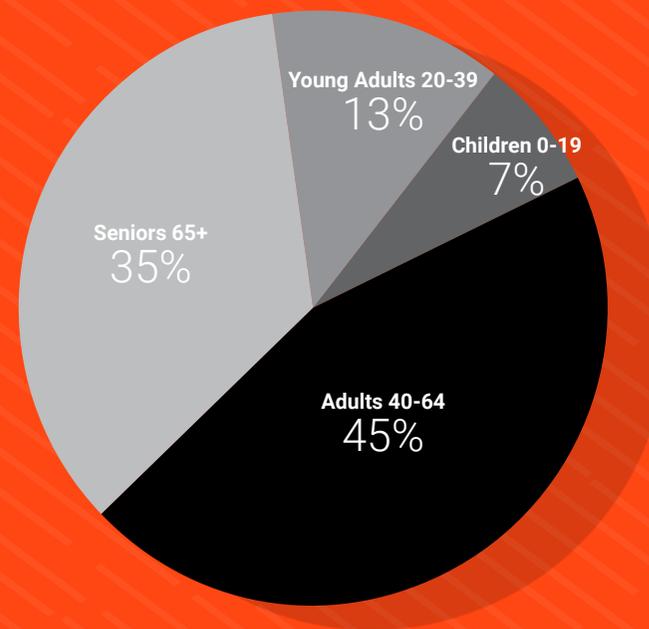
2017 Generic Savings by Method of Payment



IQVIA's analysis apportions the \$265 billion in savings from generics by method of payment, leading to this estimate of savings breakdown by payer. (This estimate assumes the same price for each prescription, regardless of pay type.)

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

2017 Generic Savings by Patient Age



Generic medicines used by seniors account for one-third of savings. Taken together, medicines taken by older adults (40-64 years old) and seniors account for 80 percent of the \$265 billion in savings generated by generics in 2017.

Sources: IQVIA, National Sales Perspectives, Mar 2018; PayerTrak, Mar 2018; CMS National Expenditures Feb 2018.

What's At Stake

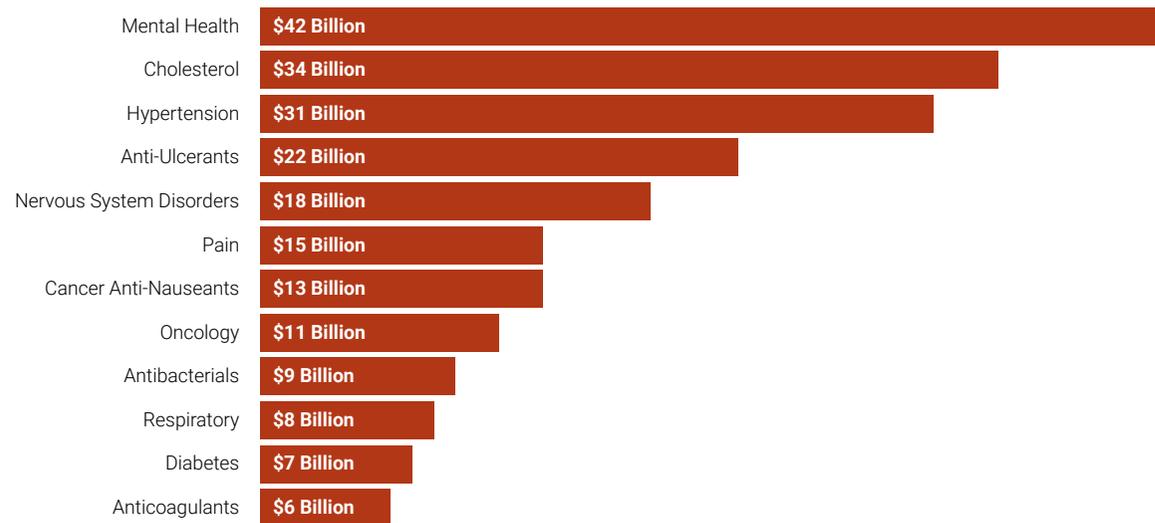
SAVINGS BY TREATMENT AREAS

Generic drugs for mental health, hypertension, cholesterol and ulcer generated the majority of savings in 2017. Without generic medications, spending on anti-ulcerants would have reached \$24.6 billion in 2017, rather than the \$3 billion that was actually spent.

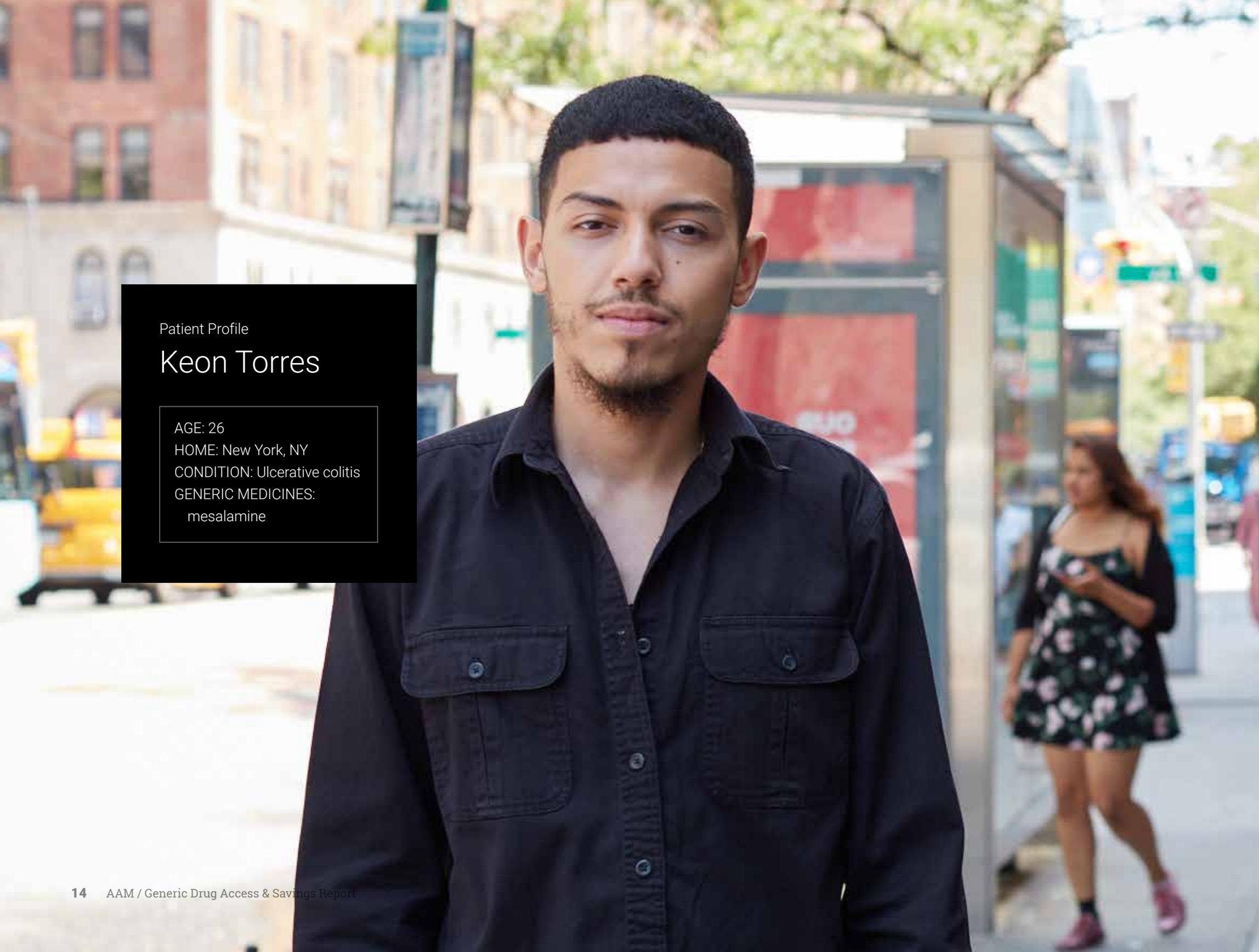
Savings by Drug Class

Generics saved the U.S. health care system \$265b in 2017

2017 Savings from Generics in Billions



Source: IQVIA, National Sales Perspectives, Mar 2018.



Patient Profile

Keon Torres

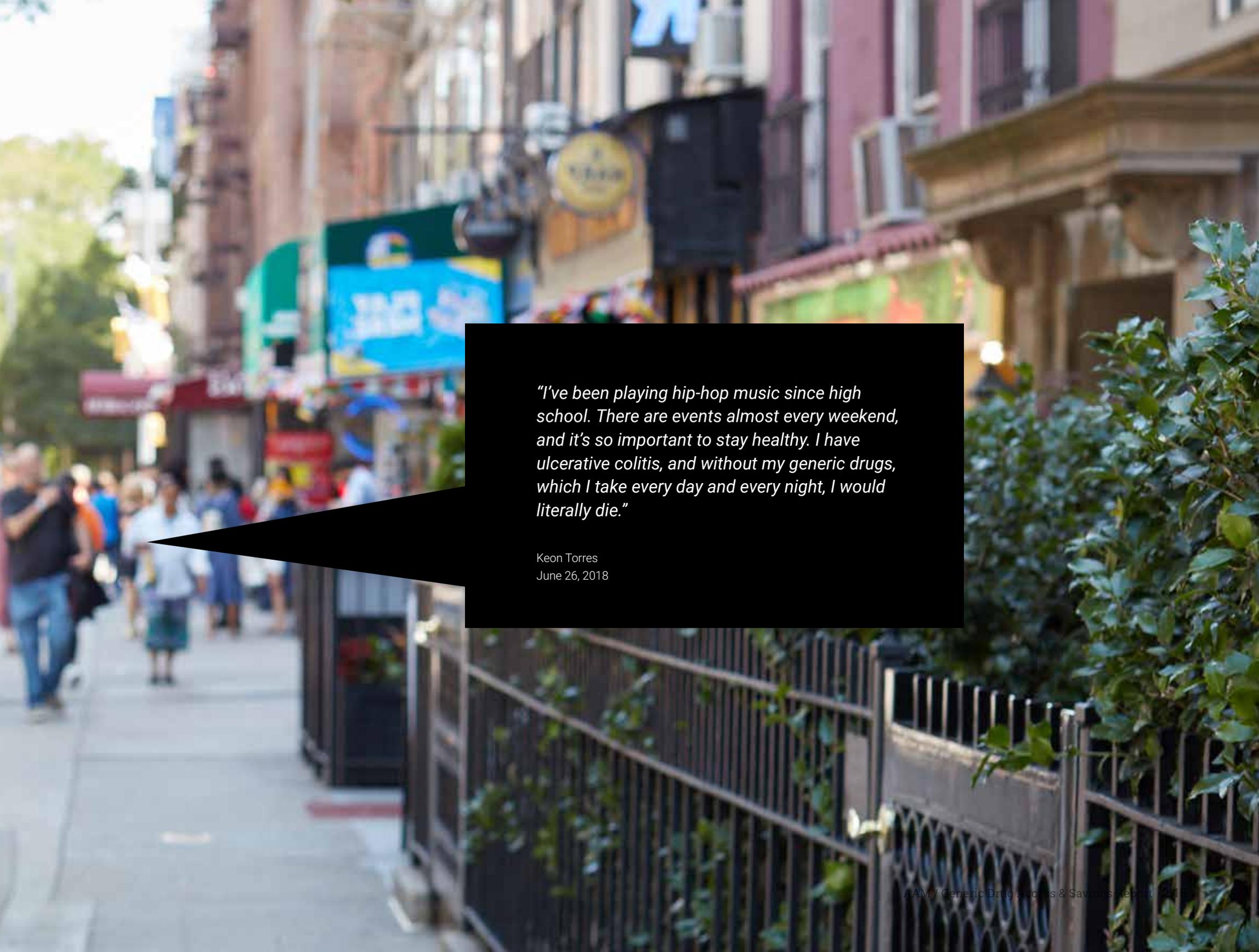
AGE: 26

HOME: New York, NY

CONDITION: Ulcerative colitis

GENERIC MEDICINES:

mesalamine



"I've been playing hip-hop music since high school. There are events almost every weekend, and it's so important to stay healthy. I have ulcerative colitis, and without my generic drugs, which I take every day and every night, I would literally die."

Keon Torres
June 26, 2018

What's At Stake

ABANDONMENT

In 2017, all patients who were prescribed more expensive brand-name drugs were 2-3 times more likely to abandon their prescriptions, never getting the treatment they need.

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 the physician, filling a prescription is the first step on a patient's journey to maintaining his or her health, followed by taking medicine as prescribed – or "adherence."



What's At Stake

ABANDONMENT



GENERICS

Overall
Abandonment

8.1%



BRANDS

Overall
Abandonment

21.3%

What's At Stake

PATIENT SAVINGS

Atorvastatin: A Generic Success Story

Atorvastatin, the generic version of Lipitor®, improves cholesterol levels and decreases risk for a heart attack and stroke. It entered the market in 2011. Last year, 114.2 million atorvastatin prescriptions were dispensed.

From 2010 to 2016, **Lipitor's price went up 17.4 percent**, while the price of generic atorvastatin went down **36.8 percent**.

Consider the savings to the government. Medicare Part D paid for either Lipitor or atorvastatin for nearly 9.5 million beneficiaries in 2016, at a total cost of \$822.4 million. If only the brand had been available that year, the additional cost to Medicare for this one drug would have been \$20.2 billion.

Source: CMS/Office of Enterprise Data & Analytics (OEDA),
November 2017

2017 Top 10 Generic Drugs Ranked by Savings

Brand Products (Generic Equivalent)	Brand Pre-Expiry Price (per unit)	Price of Generic Equivalent 2017 (per unit)	2017 Savings (\$B)	Percent Savings	2017 Dispensed Rxs (Mn)
Lipitor® (atorvastatin)	\$3.29	\$0.11	\$16.3	97%	114.2
Zofran® (ondansetron)	\$21.67	\$0.17	\$12.8	99%	25.2
Prilosec® (omeprazole)	\$3.31	\$0.08	\$11.3	98%	73.4
Neurontin® (gabapentin)	\$1.02	\$0.07	\$6.7	93%	68.4
Zocor® (simvastatin)	\$2.62	\$0.03	\$6.4	99%	54.2
Crestor® (rosuvastatin)	\$5.78	\$0.11	\$5.9	98%	23.2
Norvasc® (amlodipine)	\$1.54	\$0.02	\$5.7	99%	89.2
Abilify® (aripiprazole)	\$21.68	\$1.07	\$5.7	95%	10.2
Singulair® (montelukast)	\$3.74	\$0.11	\$5.3	97%	40.9
Seroquel® (quetiapine)	\$6.00	\$0.42	\$4.8	93%	21.3

Source: IQVIA.

What's At Stake

PATIENT SAVINGS

Savings by Patient Condition

Arthritis	\$154,573,232
Autoimmune Diseases	\$1,027,061,436
Cancer	\$10,093,397,494
Diabetes	\$7,757,796,210
Epilepsy	\$17,290,107,706
Heart Disease	\$47,617,946,027
Kidney Disease	\$2,287,158,164
Mental Illness	\$48,440,025,255
Multiple Sclerosis	\$28,384,966
Osteoporosis	\$1,900,712,183
Parkinson's Disease	\$1,710,286,026

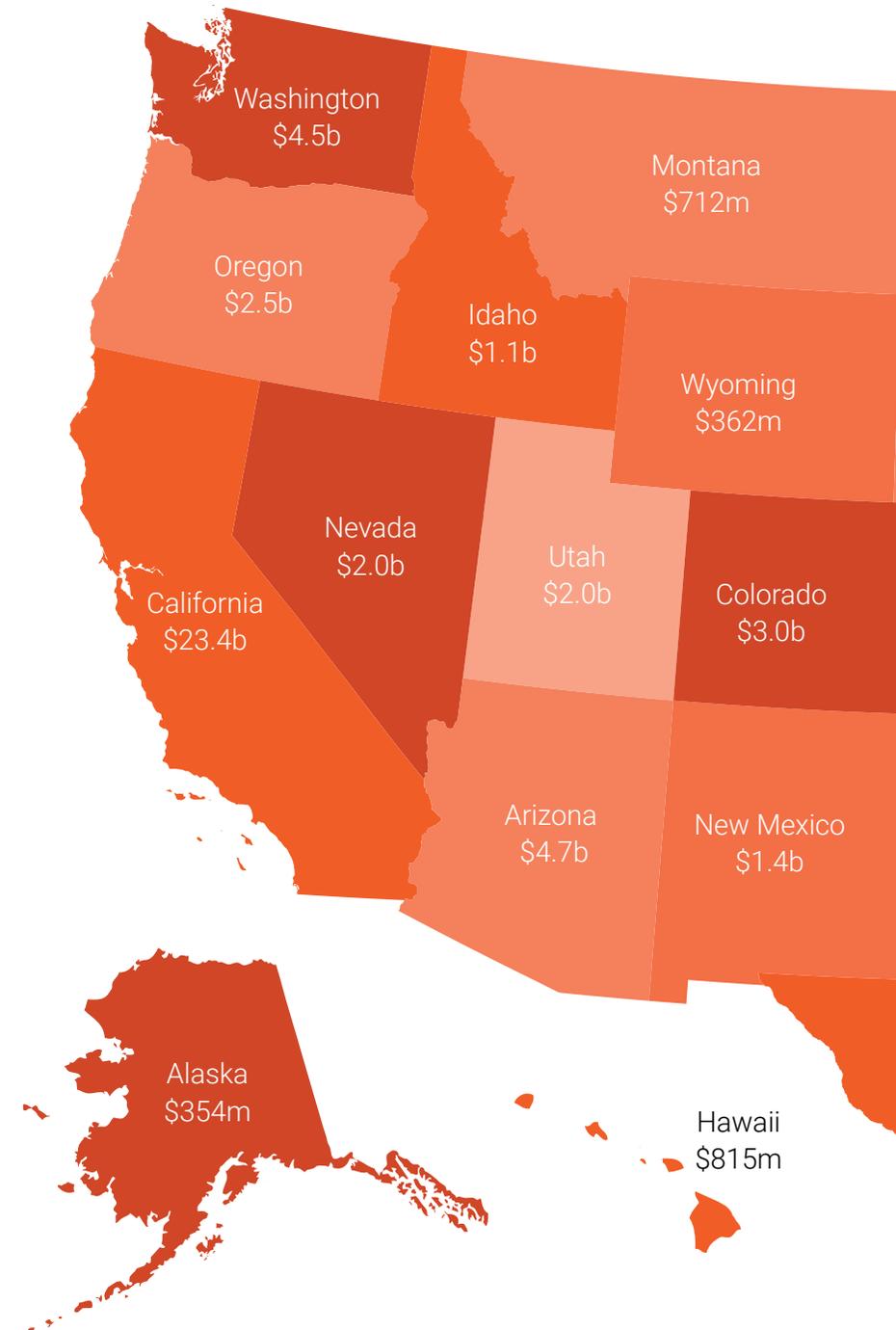
Source: IQVIA.



What's At Stake

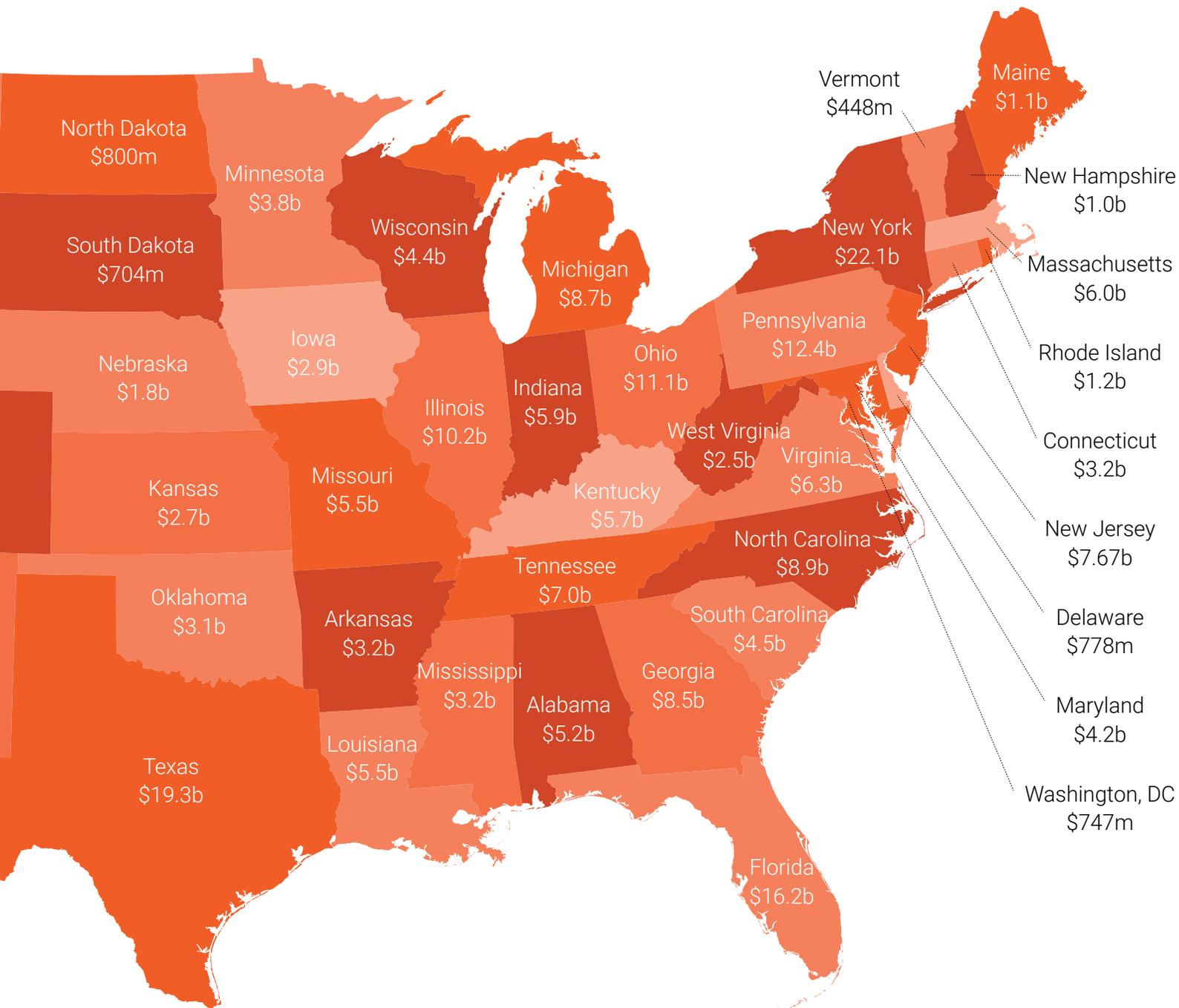
STATE-BY-STATE SAVINGS

In 2017, the average state saved \$5.2 billion through use of generic prescription drugs. The statewide annual amount saved ranged from \$354 million in Alaska to a high of \$23.4 billion in California.



What's At Stake

STATE-BY-STATE SAVINGS



Patient Profile

Ariel Leaty

AGE: 29

HOME: Bloomfield, NJ

CONDITION: Cancer

GENERIC MEDICINES:

methotrexate

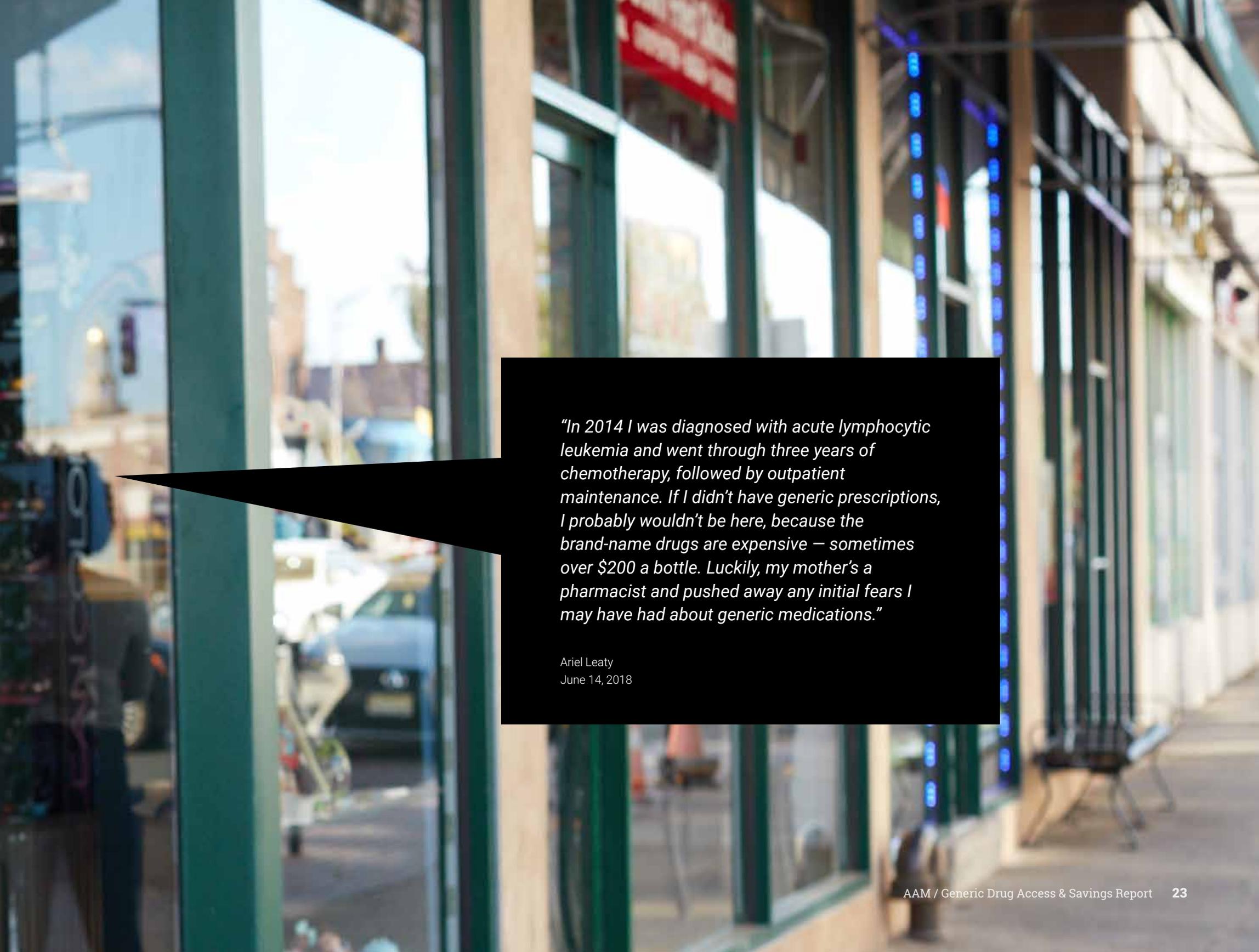
fluconazole

acyclovir

ciprofloxacin

mercaptopurine





"In 2014 I was diagnosed with acute lymphocytic leukemia and went through three years of chemotherapy, followed by outpatient maintenance. If I didn't have generic prescriptions, I probably wouldn't be here, because the brand-name drugs are expensive – sometimes over \$200 a bottle. Luckily, my mother's a pharmacist and pushed away any initial fears I may have had about generic medications."

Ariel Leaty
June 14, 2018

What's At Stake

BIOSIMILARS

The Great Promise of Biosimilars

Biologic medicines are often the only treatments available for serious illnesses, like cancer or genetic disorders, but they come at steep expense to patients, taxpayers and insurers. Biosimilars are safe, effective alternative versions of existing biologic medicines.

Biosimilars have the potential to improve the quality of life for American patients while at the same time saving the health system billions of dollars each year — provided that the right policies are in place to nurture a robust marketplace.

Data from Europe, where biosimilars have been available since 2006, show that the use of lifesaving biologic treatments has grown significantly as lower-cost biosimilars have become available and given patients an affordable option to expensive brand products.

Biosimilar Approvals in the U.S. and Europe



In the first 8 years since the passage of the BPCIA, the FDA has approved 11 biosimilars with 60+ more in development^{1,2}



In Europe, more than 40 biosimilars approved in at least 8 therapeutic classes³

References

1. FDA-Approved Biosimilar Products. Available at: <https://bit.ly/2BQwQig>. Accessed June 18, 2018.
2. FDA Commissioner Gottlieb Speech: "Capturing the Benefits of Competition for Patients," March 7, 2018. Available at: <https://bit.ly/2FuFjN>. Accessed June 18, 2018.
3. Biosimilars Approved in Europe. Available at: <http://bit.ly/2vY8hvt>. Accessed: June 18, 2018.

What's At Stake

BIOSIMILARS

Biosimilar Approvals

(As of June 25, 2018)

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	Inflextra®	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
4/21/17	Renflexis®	infliximab-abda	Samsung Bioepis/Merck	7/24/17	Remicade®	Janssen
8/25/17	Cyltezo®	adalimumab-adbm	Boehringer Ingelheim	Pending	Humira®	Abbvie
9/14/17	Mvasi®	bevacizumab-awwb	Amgen	est. 2019	Avastin®	Genentech
12/1/17	Ogivri™	trastuzumab-dkst	Mylan/Biocon	Pending	Herceptin®	Genentech
12/13/17	Ixifi™	infliximab-qbtx	Pfizer	none planned	Remicade®	Janssen
5/15/18	Retacrit®	epoetin alfa-epbx	Pfizer	est. 2018	Epogen®	Amgen
6/4/18	Fulphila™	pegfilgrastim-jmbd	Mylan/Biocon	est. 2018	Neulasta®	Amgen

What's At Stake

BIOSIMILARS

Biologic Monopolies

The 2010 Biologics Price Competition and Innovation Act (BPCIA), which gave FDA authority to establish a regulatory process for approving lower-cost biosimilar versions of pricey brand biologic medicines, gives new drug innovators 12 years of market exclusivity in which to recoup their research and development costs. This is a longer monopoly period than is available in any other country around the world. Despite this generous period of exclusivity, some brand-name drug companies game the U.S. patent and legal systems to block competing biosimilars from coming to market and further extend their monopolies. This puts profits ahead of patients by denying access to affordable, needed medicines.

Just one example is the brand biologic drug Humira®, the world's biggest-selling drug, used to treat rheumatoid arthritis and Crohn's disease. An annual treatment with Humira comes with a list price of \$38,000. The primary patent for Humira has expired, and there currently are two FDA-approved biosimilar versions of Humira that could offer relief from staggering costs. However, Humira's manufacturer has delayed competition through abuse of the patent process, compelling the biosimilars to navigate what the brand drug maker has called its "patent estate." With no competition, the list price of Humira continues to rise, increasing 122 percent over the past five years.



What's At Stake

BIOSIMILARS

"The cost of prescription drugs is an ongoing concern; however, a growing market for potentially lower-cost biological products called biosimilars can offer more competition and options for patients. Biosimilars can potentially reduce costs for consumers by creating price competition for products that previously faced few market competitors."

Scott Gottlieb, M.D., Commissioner
Leah Christl, Ph.D., Associate Director for Therapeutic Biologics
Food and Drug Administration
October 23, 2017

Savings In Jeopardy

Risks to the Generic and Biosimilars Industry

Despite the proven value of generics and biosimilars to patients and the health system, sustainability of the industry is in jeopardy. Eroding prices, shrinking profits and weakening investor interest in the sector have resulted in plant closings, reductions of workforce and fewer product launches.

The risks include:

- **Market imbalance.** The list of generic drug purchasers has consolidated into three large buying consortia controlling 90 percent of the market and exerting outsized pricing power over generic manufacturers.
- **Anti-competitive abuses.** Some brand manufacturers are gaming regulations to attain unwarranted extensions of their market monopolies by keeping generic and biosimilar competitors from developing and introducing lower-cost medicines.
- **Policy miscues.** Too many lawmakers in Washington and in state legislatures do not understand the differences between the generic and brand business models and fail to appreciate the disparity between a brand monopoly market and a generic multi-competitor commodity market. Consequently, “one-size-fits-all” laws and regulations have been enacted with unintended and harmful outcomes.



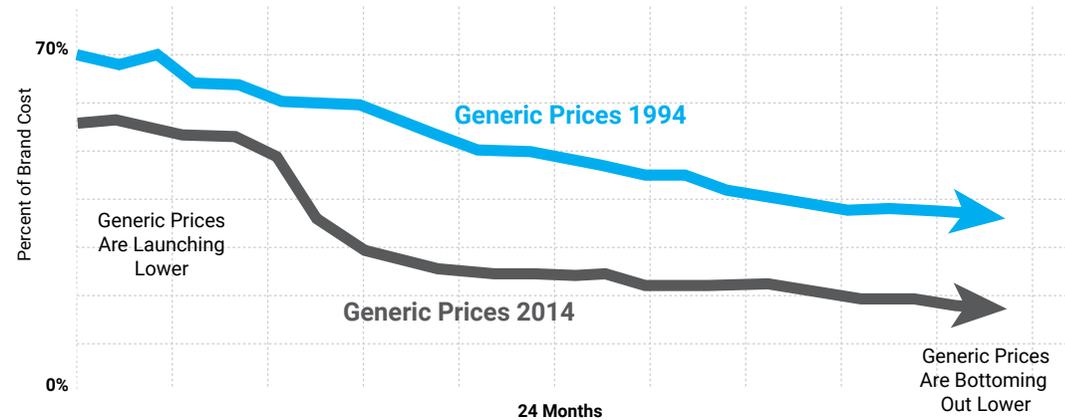


Savings In Jeopardy

MARKET IMBALANCE

Prices Fall Too Far Too Fast

Percent of Generics Price Vs. Brand Pre-Expiry Price Across Patent Expiry Year



Source: QuintilesIMS, SMART US Launch Edition, Jun 2017.

Unsustainable Deflation

Just a decade ago there were multiple wholesalers and pharmacies that contracted with generic manufacturers for the purchase of prescription drugs. Over the past few years, rapid consolidation has whittled down the number of buyers so that today three large buying consortia control 90 percent of all generic drug purchases for the retail market.

As this consolidation on the buyers' side has occurred, the number of manufacturers supplying generics has increased, with each company getting a slimmer share of the market.

Too Few Buyers Hold Too Much Power



Three Large Buying Consortia Control **90 Percent** of the Market

Source: Fein, Adam J. Fein. The 2016-2017 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors, September 2016.

This market imbalance has resulted in more than two years of price deflation in the generic market and has driven companies to execute portfolio optimization strategies for the products they sell. In many cases today, generic companies are deciding not to launch new approvals and even opting to exit markets where drugs are priced as

commodities with razor-thin margins. Not only does this threaten sustainability of the industry, it lowers the number of competitors in the market, which could lead to drug shortages and increased prices.

Savings In Jeopardy

ANTI-COMPETITIVE ABUSES

Brand Monopolies Inflate Pricing

Competition from generic drugs brings down drug prices. Yet every year we see increasing anti-competitive activity by brand drug companies to obstruct generic competition and thereby extend marketing monopoly for their high-priced brand drugs. Manipulating FDA safety programs to block generic drug development, renting sovereign immunity to circumvent patent laws, filing sham citizen petitions to derail generic approvals are among the schemes used to gain unwarranted market protection.

Unless these practices are stopped, consumers and patients will never see any meaningful relief at the pharmacy counter. Everybody wins when our prescription drug system operates as designed, with the brand and generic industries working in tandem:

- Brand companies get patents that provide a period of market exclusivity during which they recoup their development expense and earn profits for future investment in new drugs.
- And when those patents expire, generic companies introduce lower-priced competing versions that drive down costs.

When this equilibrium is skewed by anti-competitive behavior, patients suffer by losing access to the affordable medicine they need to live healthier lives.

“Generic drug approvals save American consumers billions of dollars each year. The FDA will continue to work to ensure that safe and effective generic drugs are approved expeditiously and not hamstrung by unfair practices that brand-name drug manufacturers sometimes use to thwart competition.”

Secretary Alex M. Azar II, Health and Human Services
Commissioner Scott Gottlieb, M.D., Food and Drug Administration
Seema Verma, Administrator Centers for Medicare and Medicaid Services

Savings In Jeopardy

ANTI-COMPETITIVE ABUSES

Brand-Name Drug
Companies Have Filed
to **Extend** More Than

100

Patents for
More Than

30

Years

Almost

80%

of the Roughly

100

Best-Selling Drugs
Extended Their
Monopoly Protection
at Least Once

The results [of the study "May Your Drug Price Be Ever Green"] show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals.

Key results include:

1. Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones.
2. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs.
3. Once a company starts down this road, there is a tendency to keep returning to the well.
4. The problem is growing across time.

Source: Feldman, Robin, May Your Drug Price Be Ever Green (October 29, 2017). UC Hastings Research Paper No. 256.



Savings In Jeopardy

POLICY MISCUES

Policy Miscues

According to a survey conducted by the Kaiser Family Foundation¹, 80 percent of Americans say the cost of prescription drugs is unreasonable. While this sentiment can be attributed to the high starting price and constant increases in the cost of brand-name medicines, campaigns of distortion and deflection have stymied attempts to address this fundamental problem.

AAM believes that any policy, federal or state, intended to tackle the high cost of prescription drugs must increase competition rather than simply shift costs among health care stakeholders, leaving us no better off than we were before.

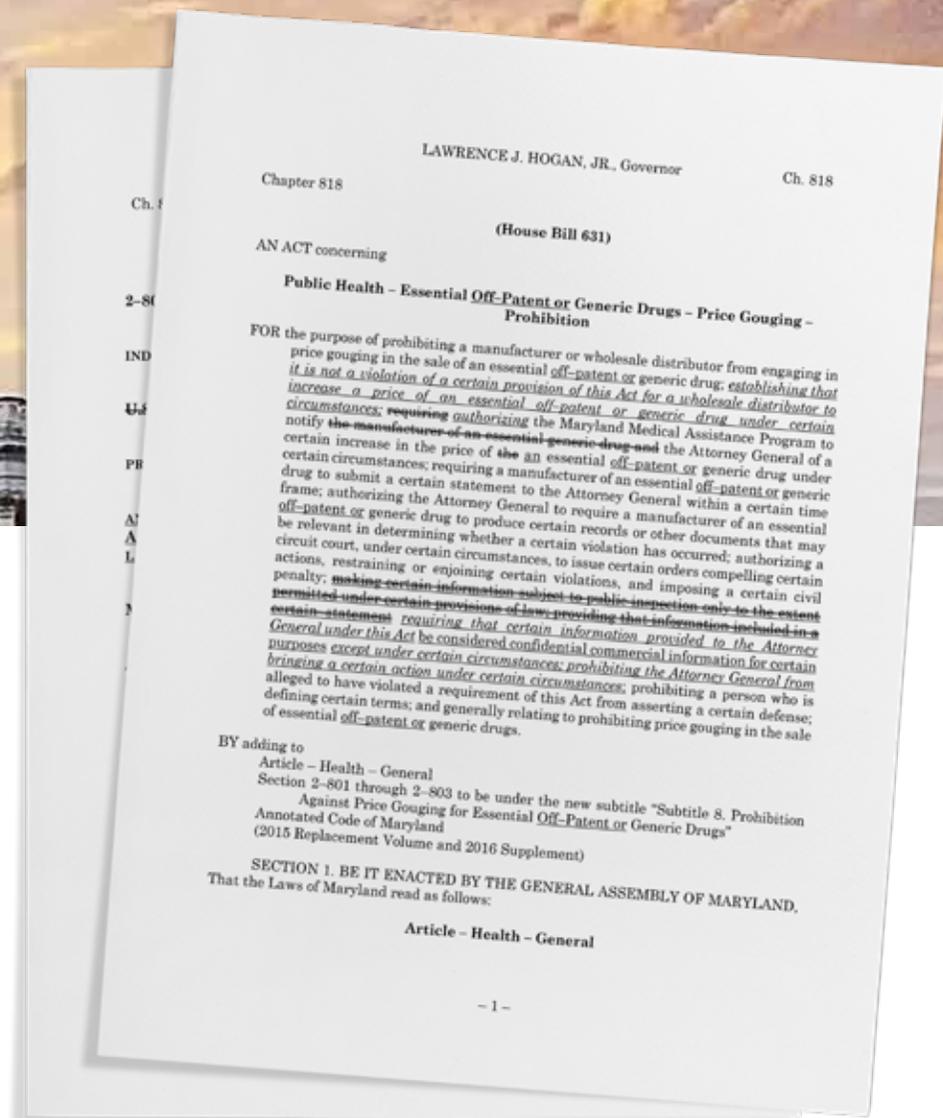
Sadly, many of the solutions proposed at the state level have focused only on “price transparency” or “price gouging,” with no recognition of the differences between the brand industry that drives higher prices and the generic industry that drives savings. In addition, some policymakers emphasize price spikes in terms of percentage increase, while neglecting to mention the overall small dollar changes in the price of the majority of generic drugs.

1. Kaiser Health Tracking Poll – March 2018: Views on Prescription Drug Pricing and Medicare-for-all Proposals



Maryland Overreaches

Maryland's 2017 price-gouging law, for example, targeted the generic industry (as well as off-patent drugs), which saved the state \$4.2 billion last year, while ignoring the brand industry whose drug prices have increased faster than the rate of inflation for the past several years. Fortunately, the U.S. Court of Appeals for the Fourth Circuit found the law to be unconstitutional in violation of the Commerce Clause. Had the misguided law remained in force, it would have reduced generic competition, decreased patient access to affordable medicines and caused higher prescription prices.



Methodology

This report estimates savings from generic drugs for the 10-year period between 2008 and 2017, as well as a single year estimate for 2017.

Base savings estimates: The base savings were calculated by IQVIA. Avalere generated condition-level savings by assigning drugs to a list of common conditions, as well as a list of conditions provided by AAM and aggregating savings for all drug that are used to treat these conditions.

Comorbidity estimates: Avalere used published epidemiological data to determine the three most common comorbidities for each of the index conditions provided by AAM. Avalere calculated the base savings for the primary condition in the same manner as described above, and then assigned a weighted savings to each of the three selected comorbid conditions based on published prevalence data. Because the IQVIA data provided units rather than patients, we used units as a proxy for the number of patients treated and adjusted the units, and thus savings, in proportion to the published prevalence of each comorbid condition.

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 812 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 10 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 812 generic molecules were 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 2017, focusing on the 10-year savings for the period 2008 to 2017. Savings from generics launched in the 1993 to 2017 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 were 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 IQVIA 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 were 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 copay or discount card; rather it divides generic savings equally among 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 were divided evenly based on the number of prescriptions filled by patients of each pay type.

In the three recent editions of this study, the IQVIA Institute for Human Data Science has employed historic archives not previously available. 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 \$1.26 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. 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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