



aam

Association for Accessible Medicines

Securing Our Access & Savings

2020 Generic Drug & Biosimilars
Access & Savings in the U.S. Report





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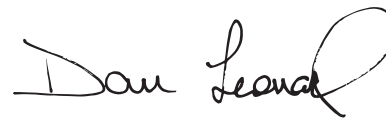
Letter from the President and CEO

Generic medicines fill 9 out of every 10 U.S. prescriptions, and the quality, safety, effectiveness and tremendous affordability of these medicines help patients and their families maintain and improve health.

In 2019, according to data provided by IQVIA, U.S. savings from generic drugs added up to \$313 billion — including \$96 billion and \$48.5 billion in Medicare and Medicaid savings, respectively. The last decade has seen close to \$2.2 trillion in savings. Those health care system savings could be even greater by increasing Americans' access to low-cost generics.

The report also presents data on the class of biologic medicines known as biosimilars. Despite obstacles, U.S. biosimilars savings are growing steadily, totaling \$2.2 billion in 2019 and \$4.5 billion over the past 10 years. Constructive policies, like ending Medicare policies that reward the use of higher-cost brand drugs, could enhance that growth as specialty medicines account for an increased share of pharmaceutical costs.

The COVID-19 public health emergency in 2020 has shown America that the generics and biosimilars industry is fundamentally strong and essential to saving lives. Our medicines, from the injectables that are critical to placing a patient on a ventilator, to the steroid drugs that have reduced the risk of death in COVID patients by one-third, have proven themselves to truly be the bridge to a vaccine.



Dan Leonard
CEO, Association for Accessible Medicines



Letter from the Chairman

Patient Access Throughout the Pandemic and Beyond

The pharmaceutical supply chain has been stressed by the COVID-19 pandemic, but the generics and biosimilars industry has responded to unprecedented demand with strategies that ensured uninterrupted access to essential medicines for millions of patients. Based on ongoing drug shortage reports, at the time of publication there have been no national shortages of generic medicines used in the care of COVID-19 patients.

To secure continued access through the pandemic and beyond for all America's patients who rely on our medicines, the generics and biosimilars industry supports a global diversified pharmaceutical supply chain and policies that enhance our already significant manufacturing presence in the United States.



Alok Sonig

CEO, US Generics, and Head, Global R&D and Biosimilars of Lupin Ltd.
Chairman, Board of Directors, Association for Accessible Medicines





The Generics Industry Responds to COVID-19

We extend our sympathy to all of those who have suffered or are grieving because of the pandemic. During this time of unprecedented health insecurity, the generics industry in the United States has risen to meet the moment:

- Generic medicines – from intravenous drugs for patients being placed on ventilators, to steroids responsible for reducing deaths by a third* – saved the lives of millions of those fighting the virus.
- Generic manufacturers donated tens of millions of doses of medicine to the federal Strategic National Stockpile.
- The generic manufacturing supply chain proved resilient.
- The Food and Drug Administration's in-person inspections of facilities were suspended, yet no exceptional quality issues arose.
- Prices remained stable during a period of great uncertainty and added logistical and shipping costs.

*Source: <https://www.who.int/news-room/detail/16-06-2020-who-welcomes-preliminary-results-about-dexamethasone-use-in-treating-critically-ill-covid-19-patients>.
World Health Organization. June 16, 2020





Medication costs for COVID-19 patients hospitalized in the United States have dropped sharply since May, reflecting advances in treatment, shorter stays and use of cheaper generic drugs.



The New York Times
August 19, 2020





About AAM

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. The Association for Accessible Medicines (AAM) works to make more generic and biosimilar medicines more accessible to more people who need them. AAM improves access to safe, quality and effective medicines.
- Generic pharmaceutical companies manufacture 9 out of every 10 prescriptions dispensed in the United States. Our members form an integral and powerful part of the health care system.
- The Biosimilars Council, a division of AAM, works to ensure a positive regulatory and policy environment for biosimilar products, and educates the public, providers and patients about the safety and effectiveness of biosimilars medicine.

Generics: Made in the U.S.A.

Generic and brand-name drugs are made all over the world, including here in the United States. The sources of ingredients are global, too. A strong domestic presence, along with a diversified manufacturing and supply chain, has ensured patient access to quality, safe and effective medicines for decades.

Generic drugmakers already produce tens of billions of doses of safe, effective and affordable medicines here in America, and the industry's recommendations to increase that production capacity, "A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain," is available at accessiblemeds.org/blueprint.





**More than 52,000
workers across
the country.**



**More than 50% of
FDA-regulated API*
facilities are in the
U.S. and Europe.**

“*The quality of our drug supply is better than ever before. There is no difference in the quality of drugs based only on where they are made. We use the same tools to assure quality whether a drug is manufactured in the United States or abroad. We apply the same quality standards and conduct the same inspections of manufacturing facilities regardless of where they are located – and we inspect all over the globe.*”

Michael Kopcha, PhD, RPh

Director, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

PATIENT CASE STUDY

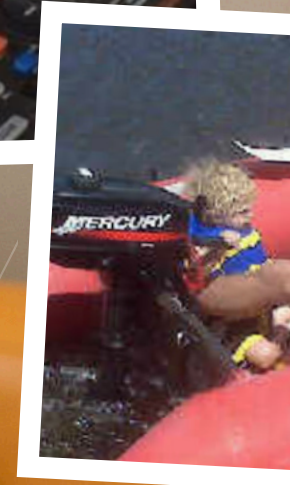
Rich

High Blood Pressure

Laurel, MD

Formerly an educator and home lending professional, Rich Lichty, 72, is now a part-time DJ for parties. His greatest passion — besides his wife, three children and four grandchildren — is boating on the Chesapeake Bay.

Rich takes candesartan for his moderate high blood pressure. “My insurance doesn’t pay for it,” he says. “I don’t have a copay. I have a ‘me-pay,’ so without access to generic medicines, I don’t know what I’d do.”





Key Findings

U.S. Generic Drug Savings: **\$313 Billion**



Generic Rx Filled



Generics are **90%** of Prescriptions Filled Yet Account for Only **20%** of Prescription Drug Spending

92% of Generic Prescriptions Are Filled for **\$20** or Less



Source: IQVIA 2020.

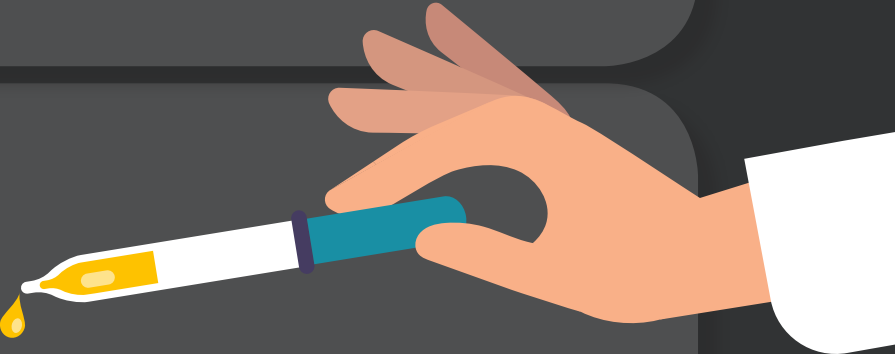
Key Findings

Average Generic Copay: \$6.97
Average Brand-Name Copay: \$56.32

Medicaid Savings: \$48.5 Billion
Medicare Savings: \$96 Billion



2019 Biosimilars Savings: \$2.2 Billion



Source: IQVIA 2020.

Key Findings

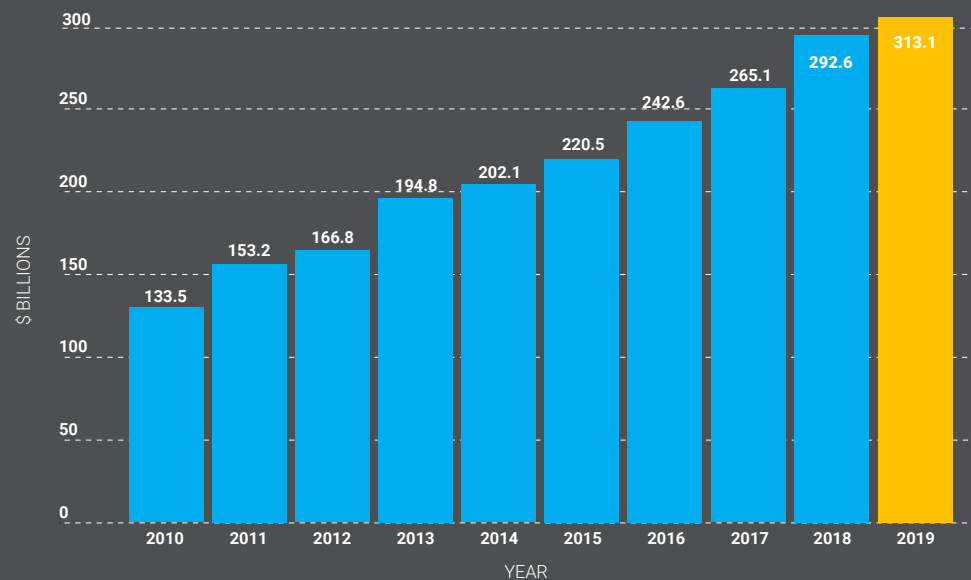
Generic 10-Year Savings: Nearly \$2.2 Trillion

Biosimilars 10-Year Savings: \$4.5 Billion

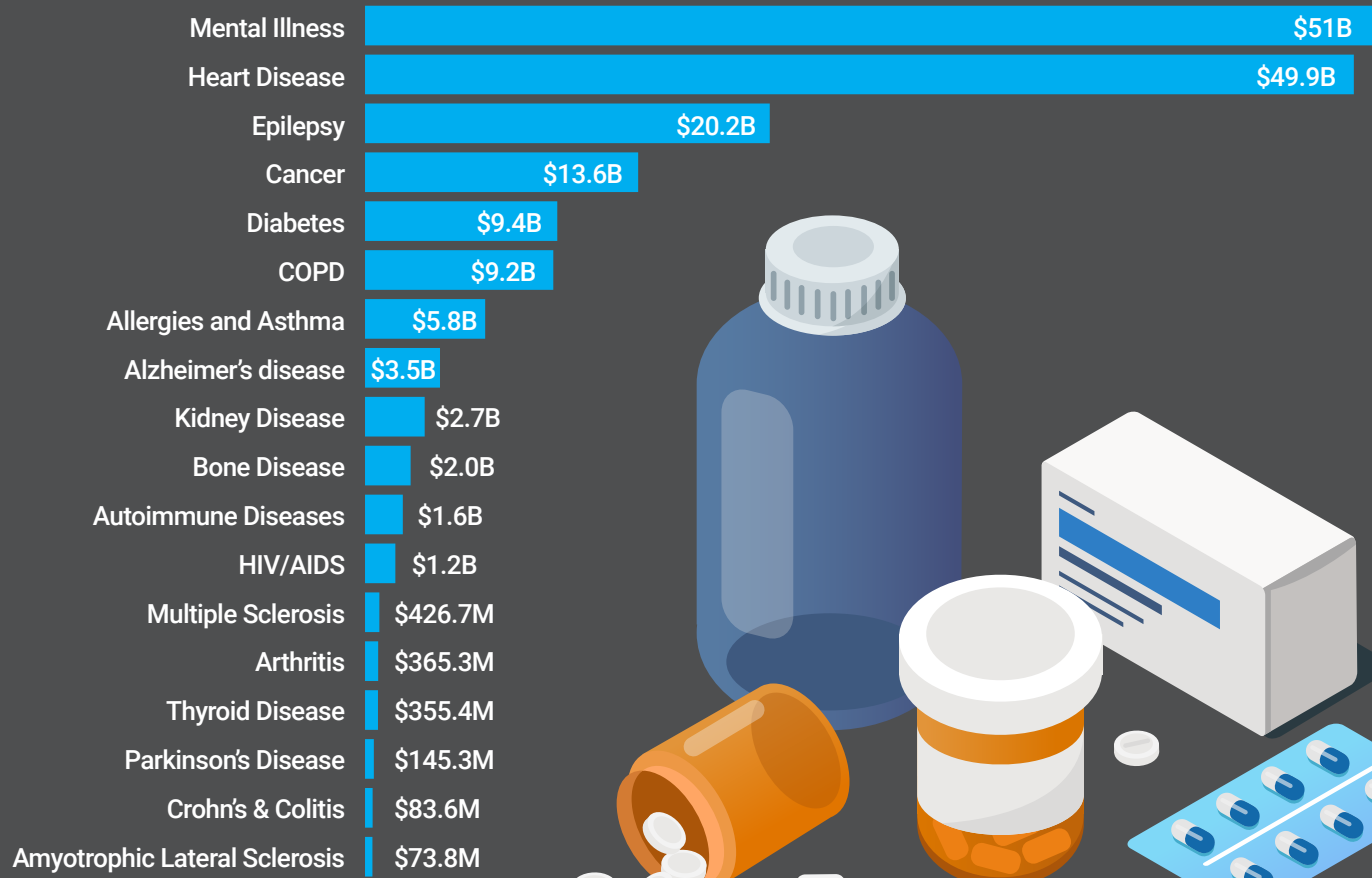


Source: IQVIA 2020.

Annual Savings from Generics 2010 to 2019

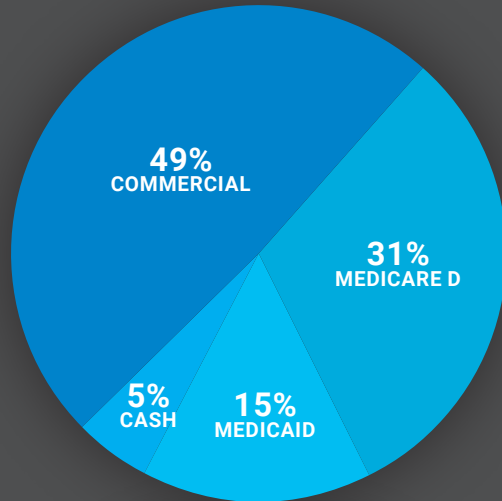


Savings by Primary Patient Condition



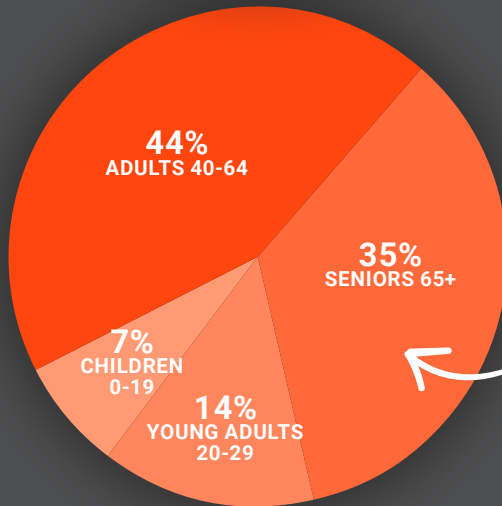
Source: Condition-level savings calculated using IQVIA savings data.

Key Findings



2019 Savings by Payer Type

Nationally, the Medicare program saved \$96.1 billion in 2019, or \$1,053 per participant, by using generics. Medicaid programs saved \$48.5 billion, or \$770 per participant.



2019 Savings by Age Group

A report from Avalere Health shows that patients are needlessly spending too much out of pocket for affordable generics. Since 2015, America's seniors have paid nearly \$22 billion in out-of-pocket costs for their prescription drugs in Medicare.



Source: IQVIA 2020.

2019 Top 10 Generic Drugs Ranked By Savings

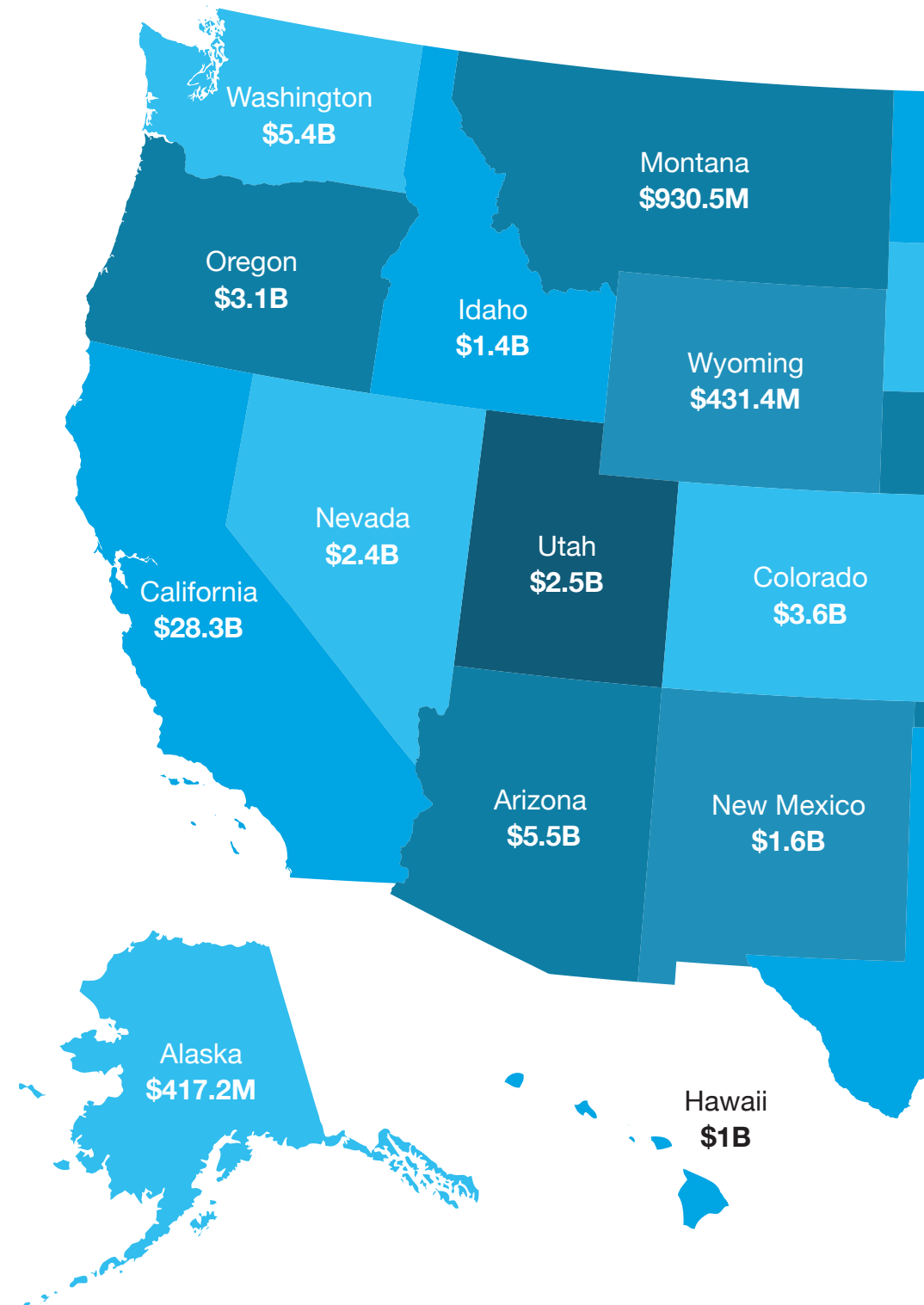
Brand Products (Generic Equivalent)	Brand Pre-Expiry Price (per unit)	Price of Generic Equivalent 2019 (per unit)	2019 Savings (\$B)	Percent Savings	2019 Dispensed Rx's (Mn)
Lipitor® (atorvastatin)	\$3.29	\$0.08	\$17.7	98%	118.0
Zofran® (ondansetron)	\$21.67	\$0.16	\$14.4	99%	26.9
Prilosec® (omeprazole)	\$3.31	\$0.06	\$11.1	98%	64.1
Crestor® (rosuvastatin)	\$5.78	\$0.08	\$8.4	99%	29.9
Abilify® (aripiprazole)	\$21.68	\$0.40	\$7.8	98%	11.6
Neurontin® (gabapentin)	\$1.02	\$0.07	\$7.2	93%	68.7
Norvasc® (amlodipine)	\$1.54	\$0.02	\$6.8	99%	88.7
Singulair® (montelukast)	\$3.74	\$0.09	\$6.3	98%	40.9
Cymbalta® (duloxetine)	\$4.61	\$0.21	\$6.0	95%	27.3
Zocor® (simvastatin)	\$2.62	\$0.03	\$5.9	99%	39.7

Source: IQVIA 2020.

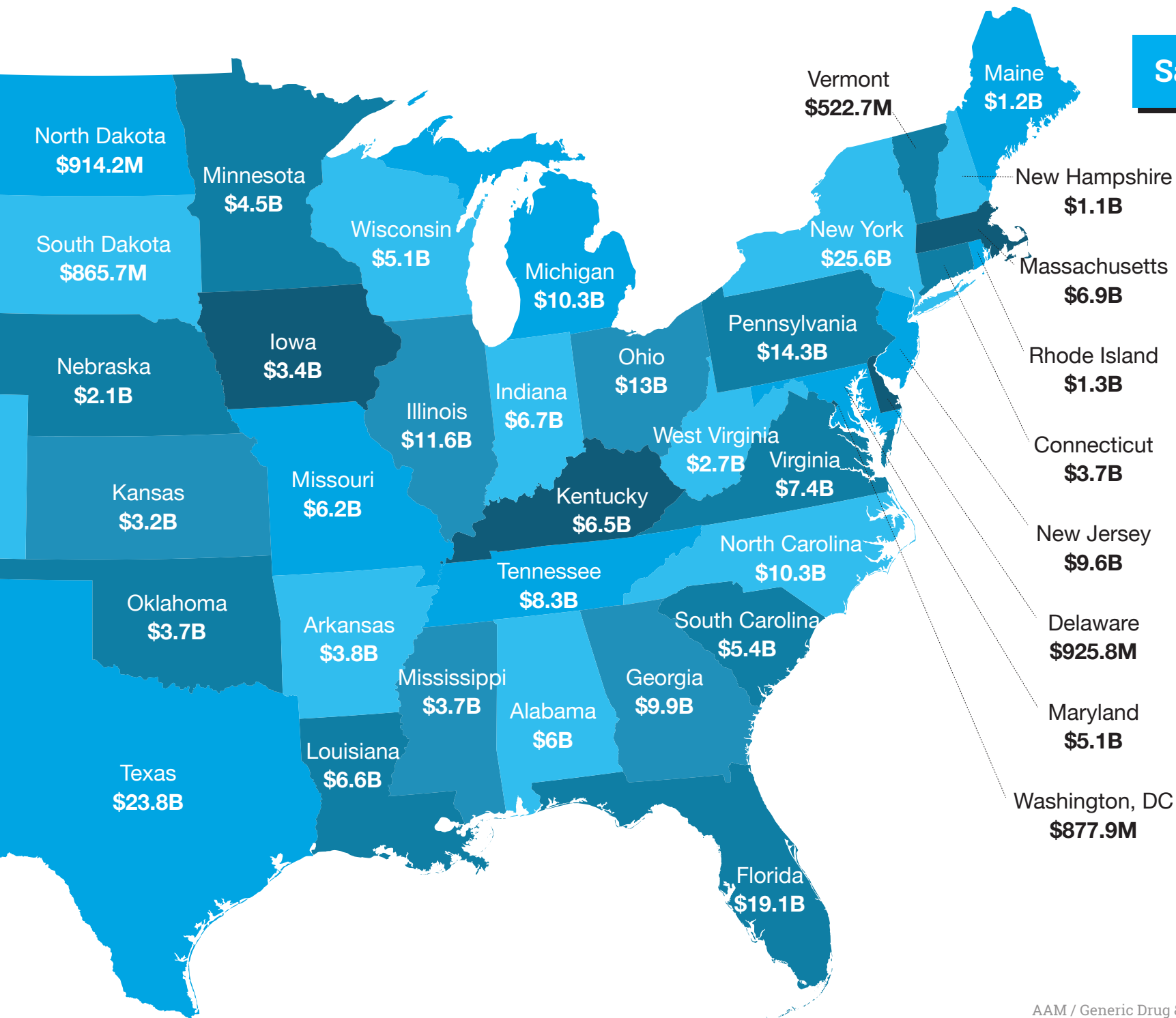
Savings by State

Highlights

- Patients in California saved \$8.9 billion in Medicare drug spending and \$6 billion in Medicaid spending.
- In New York, the use of generics resulted in \$8.6 billion in Medicare savings and \$5.4 billion in Medicaid spending.
- In Florida, nearly 7 million Medicare beneficiaries generated \$6.9 billion in savings through use of generics.
- The state of Texas saved nearly \$2 billion in Medicaid across 3.5 million Medicaid enrollees.



Savings by State 2019



Biosimilars

Securing the Promise

Biologic medicines represent one of the medical breakthroughs of our time, treating cancer, rheumatoid arthritis, Crohn's and more, but not all of them are accessible to patients. Fortunately, more and more lower-cost biosimilars, medicines that are prescribed for these conditions and are just as safe and effective as brand biologics, are being approved by the FDA.

Biosimilars are projected to save America tens of billions of dollars over the next decade, but only if patients can access them. Since 2010, the FDA has approved 28 biosimilars but only 17 currently are available to patients. Greater use of these medicines, however, could generate even more savings. AAM's Biosimilars Council series Failure to Launch found that delayed launch of biosimilars due to patent thickets has cost the U.S. health care system an astounding \$9.8 billion in lost savings since 2015.



biosimilarscouncil.org

“ *The promise of biosimilars means expanding treatment options for people in need. We must keep the momentum high and continue pushing our members of Congress to fight for increased access to biosimilars to save health care dollars.* ”

John O'Brien
Former Senior Advisor, U.S. Department of Health and Human Services and Deputy Assistant Secretary for Health Policy
August 2020



“ Biosimilars have so much to offer for America’s patients, but the potential savings that they can bring is being squashed by burdensome patent thickets in the name of profits. Patent thicketing, and Humira is the poster child for this, builds a patent fortress around their product to protect their ability to continue their monopoly pricing. ”

Christine Simmon
Executive Director, Biosimilars Council
Quoted in The Washington Post, January 2020

PATIENT CASE STUDY

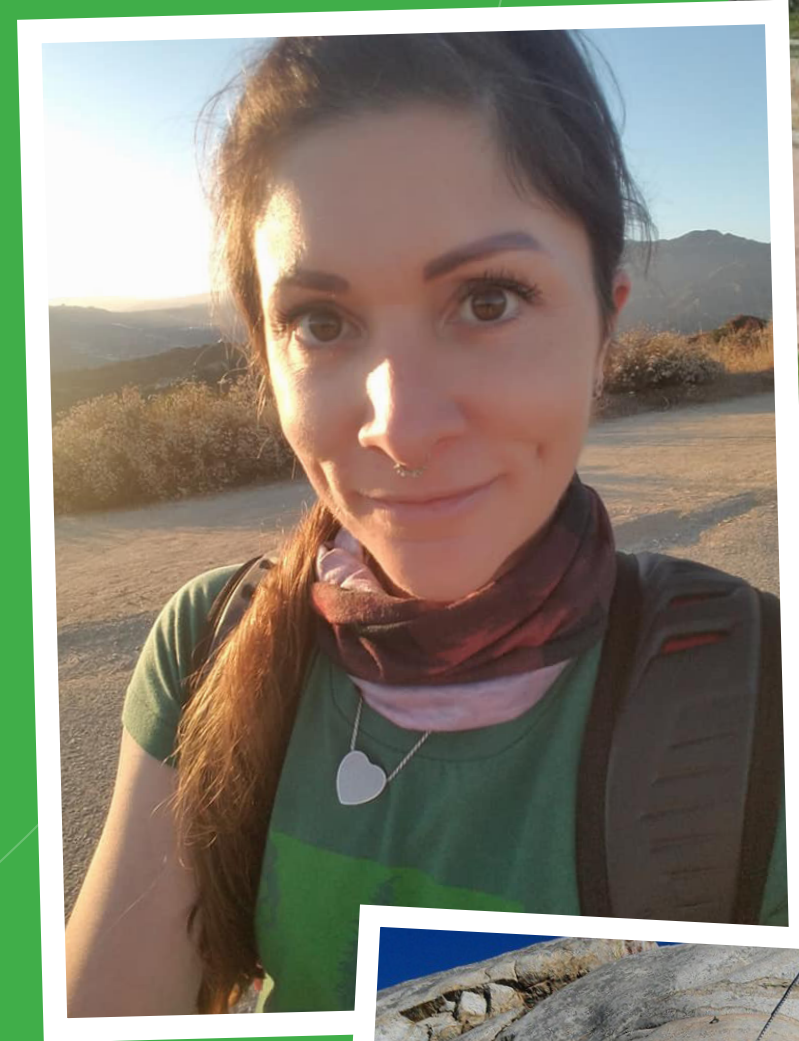
Jeni

Pancolitis

Newhall, CA

Jeni Doerr, 35, has recently gone back to school to become a medical coder, and when she is not online learning she is outside enjoying everything California has to offer through hiking, rock climbing and mountain biking with her dog Sally.

Jeni takes the biosimilar Inflectra for her pancolitis. She had previously taken a brand biologic, but it didn't do anything for her symptoms. "I have gained my life back through Inflectra, and I don't have to worry about any expenses because it was covered. Had I known about biosimilars and Inflectra from the beginning I would have never tried anything else."







Securing Access & Savings

Securing Access & Savings

Without addressing the undervaluation of generic and biosimilar medicines in the U.S. to ensure a sustainable market for these medicines, security of the domestic pharmaceutical supply will remain at risk.

ENHANCE THE RESILIENCE OF THE U.S. PHARMACEUTICAL SUPPLY CHAIN.

With strategic support from the U.S. government, the economic footprint of the generic drug industry in the U.S. can expand even more, leading to reduced dependence on any one country for key pharmaceuticals or their components and increasing the number of U.S. manufacturing jobs.

UNLEASH MARKET COMPETITION.

FDA-approved generic and biosimilar medicines are just as safe and effective as their brand counterparts. We need policies that take full advantage of their savings potential. This means adopting measures necessary for restoring the competitive balance between high-priced monopoly brand drugs and generic competition.

- Update Medicare Part D to encourage use of generics and biosimilars, including through a dedicated tier for specialty generic and biosimilar medicines.
- End the use of brand drug rebates that exclude lower-priced generics and biosimilars from formulary coverage.
- Ensure that state-regulated health plans prioritize coverage of lower-cost generics.



Securing Access & Savings

IMPROVE SENIORS' ACCESS TO LOW-COST MEDICINES IN PART D.

Medicare policies often reward use of higher-cost brand drugs and biologics. Policymakers should update the Medicare program to encourage use of generics and biosimilars through payment policy and lower patient cost-sharing.

STOP PATENT ABUSE THAT BLOCKS ACCESS TO BIOSIMILARS FOR AMERICA'S PATIENTS.

Widely available in the European Union and around the globe, biosimilars are an integral component of efforts to reduce the high cost of brand-name biologics and enhance patient access to lower-cost treatments. Unfortunately, many are not available to patients even after they have successfully navigated the stringent regulatory process to obtain FDA approval. Policymakers should take steps to ensure the viability of this market to improve access to biosimilars for America's patients.

EMBRACE TRADE STRATEGIES THAT ENHANCE COMPETITION.

America's trade policy should reflect U.S. law and promote a balance between supporting the development of innovative medicines and promoting competition through greater access to generic and biosimilar medicines. Unfortunately, this policy objective, included in the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, is often absent in U.S. trade policy.

Core Beliefs

We believe

- better access to affordable, high-quality medicine is critical to everybody because after all, we're all patients at some point.
- people shouldn't have to make decisions between paying their rent or paying for their medicine, which is why we are committed to driving down the costs of existing drugs.
- patients and payers should have choices in the marketplace, and competition from generic and biosimilar medicines gives them that choice.
- a secure, diversified supply chain with a strong U.S. manufacturing presence is necessary to ensure uninterrupted access to generic and biosimilar medicines for U.S. patients.
- safe, effective and more-affordable medicines positively affect not only the health of individuals and families, but also our entire economy and our nation as a whole.





Methodology

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 815 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 815 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 2018, focusing on the 10-year savings for the period 2009 to 2018. Savings from generics launched in the 1993 to 2018 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 IQVIA.

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 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 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.

Patient Condition Savings Estimates: The base savings were calculated by IQVIA. We 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. Product condition assignments were conducted by a Doctor of Pharmacy. Importantly, many products treat multiple conditions. For purposes of this analysis, we ensured that the most common used of the product was the condition into which it was assigned.

In previous editions of this study, the IQVIA 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 \$1.26 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 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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Biosimilars Council

A division of the Association for Accessible Medicines
biosimilarscouncil.org

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