

# The Case for Competition

2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report

### Ariel

Fought and beat cancer with the help of generic drugs



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The American public is clamoring for systemic changes to address skyrocketing drug prices. Specialty drugs — a fast-growing category that includes biologics and other complex medicines — are of particular concern. These medicines account for only 2% of prescriptions but already represent almost half of all drug spending.

The Association for Accessible Medicines along with our member manufacturers of generic and biosimilar medicines have an important role to play in this dialogue. We are pleased to present the 11th annual edition of our Access and Savings Report. Subtitled "The Case for Competition," this publication details how America's patients and our health care system continue to save through generic drug competition and how future savings are possible through biosimilar alternatives to brand-name biologic medicines.

### Some topline data from the report, which we publish based on findings by the data firm IQVIA:

• Traditional generic savings totaled \$293 billion in 2018; 10-year savings amount to nearly \$2 trillion.

- Across the United States, more than 4 billion generic prescriptions were filled in 2018. That's 90% of dispensed prescriptions – an increase from 75% in 2009. But generics account for only 22% of total drug spending. As a result, the future affordability of medicines for patients is inextricably linked to the success of the generic and biosimilar industry.
- At \$5.63, the average copay for a generic prescription is almost one-seventh of the average copay for a brand-name prescription. That means more money in the pockets of U.S. patients.
- Together, generic usage by Medicare and Medicaid saved taxpayers more than \$137 billion last year, with \$2,254 in average savings per Medicare beneficiary and \$817 in savings per Medicaid enrollee.
- Generic medicines taken by adults age 40-64 accounted for \$127 billion in savings, while generics taken by seniors (over age 65) accounted for \$102 billion in savings.
- Average savings per state exceeded \$5.7 billion in 2018.



#### In one word, the reason for these savings is competition.

When this report went to print, the developers of generic medicines had sustained price decreases for 36 out of 38 months. This deflation is due, in part, to the generic industry being the most competitive sector in health care.

The picture painted by the Access and Savings Report, however, is far from perfect. We see numerous policy opportunities to save patients and taxpayers even more money. Some areas for improvement include patent abuses, market imbalances and formulary design.

Trust is another critical element driving savings. In order for patients and our health care system to benefit from more affordable medicines, we must all have confidence in the U.S. Food and Drug Administration (FDA) to help ensure drug safety. The FDA unequivocally states, "The U.S. drug supply chain remains one of the safest in the world." Thanks to the standardized, transparent and dynamic system our nation maintains for ensuring quality in the drug supply chain, patients from all walks of life place their trust in the medications that their doctors prescribe. On behalf of AAM's member companies, I am honored by this trust, and I assure everyone who reads this report that our commitment to quality is the foundation upon which we build this case for competition.

Sincerely,

Cherter Down of

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

#### **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 medicine.

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 the 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.

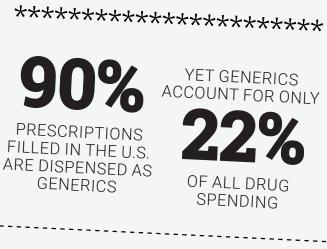
#### FOUR CORE BELIEFS OF OUR INDUSTRY

- We believe that better access to affordable, high-quality medicine is critical to everybody because after all, we're all patients at some point.
- We believe that 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.
- We believe that patients and payers should have choices in the marketplace, and competition from generic and biosimilar medicines gives them that choice.
- We believe that 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.

AAM / Generic Drug & Biosimilars Access & Savings Report **7** 

### **Key Findings**

**4 Billion** Generic Prescriptions Filled in 2018



95% OF GENERIC PRESCRIPTIONS ARE FILLED AT \$20 OR LESS

\*\*\*\*

AVERAGE BRAND-

NAME COPAY

0.65

AVERAGE

GENERIC COPAY

Source: IQVIA 2019.

5.63

50

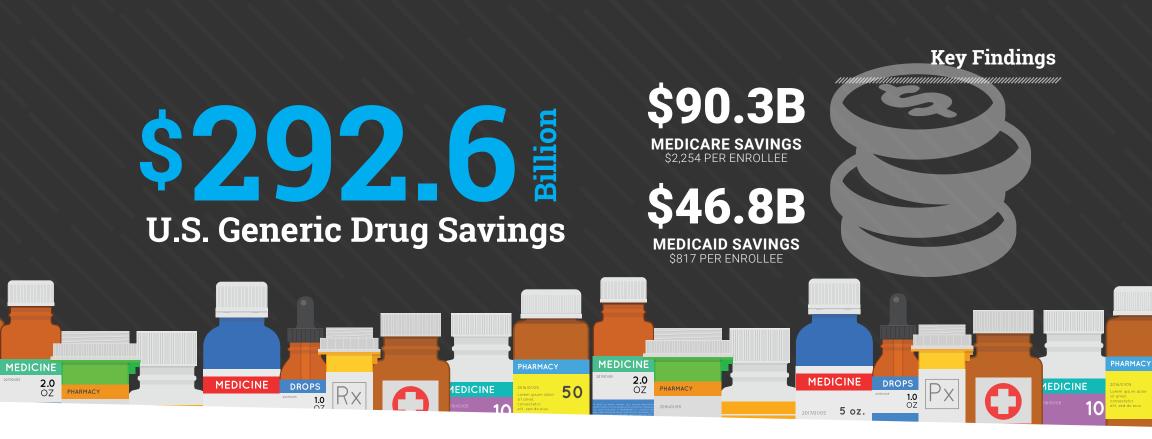
MEDICINE

2.0

## A vital component of the U.S. health care system

More than 4 billion generic prescriptions were filled across the United States in 2018. That's 90% of dispensed prescriptions, up from 75% in 2009. When generics are available, they are dispensed 97% of the time. At first glance, it may seem the industry has maxed out, but we see

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opportunities for even greater savings on the horizon, especially when it comes to biosimilars and specialty generic drugs – more complex molecules that are often administered in other ways than pill form. At \$5.63, the average copay for a generic prescription is one-seventh of the average copay for a brand-name prescription.

#### That means more money in the pockets of U.S. patients.

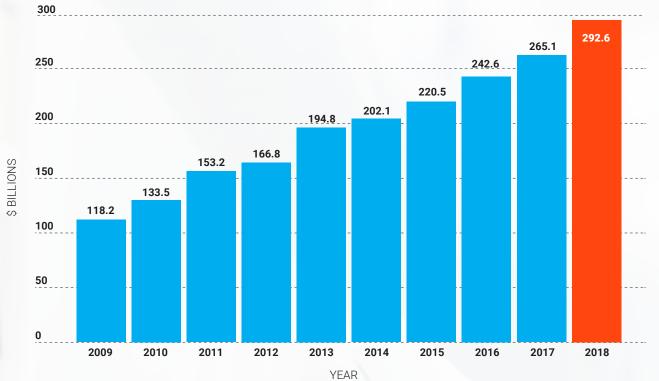
### Savings for all

Generic prescription drugs make a difference across the U.S. health care system, with nearly half of the savings going to patients with private health insurance. Government programs are also a big slice of the pie. Together, generic usage by Medicare and Medicaid saved taxpayers more than \$137 billion last year, with \$2,254 in savings for each Medicare beneficiary and \$817 in savings per Medicaid beneficiary. ley Findings

### \*\*\*\*\*

Over the past 10 years, generic drugs have saved the U.S. health care system nearly two trillion dollars, with greater savings every year.

### **Annual Savings From Generics 2009 to 2018**



Source: IQVIA 2019.

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### **Key Findings**

### Savings from generics and biosimilars are tremendous but America's seniors are still paying more than they should.

Over the past four years, seniors have been forced to spend almost \$22 billion in unnecessary out-of-pocket costs because Medicare Part D plans are increasingly placing lower-cost generics on brand drug formulary tiers with higher copayments. It is important that policymakers ensure generic drugs are automatically placed on formulary tiers with lower cost-sharing immediately upon launch so seniors reap the full benefit of these less expensive options.

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#### PATIENT SAVINGS CASE STUDY

### **Jonnie Heart Disease Patient** Skiatook, OK

Jonnie of Skiatook, OK, manages her heart condition with metoprolol ER, the generic form of the brand-name drug Toprol XL.

Each year, more than 12 million Americans use extended-release metoprolol to treat high blood pressure and prevent angina (chest pain).

In 2018, the brand price for Toprol XL (by unit) was \$1.06, while the generic price (by unit) was only \$0.09.

With more than 130 million prescriptions dispensed in 2017, metoprolol was the most commonly used betablocker by doctors and the eighth most-prescribed medicine overall in the United States.





When you pay for a name brand, it's super expensive. Do you know what it's like to have to take a drug that equals your car payment each month? And I'm not rich. If it weren't for these generic medications, I don't know where my life would be.



### Patients are leaving the pharmacy without their prescriptions

In 2017, patients (both commercially-insured and seniors with Medicare Part D) 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."

Consumers abandon hundreds of thousands of prescriptions each year at the pharmacy, often because of high prices, jeopardizing their health and often leading to higher costs down the road, studies show.

**KAISER HEALTH NEWS, 2019** 

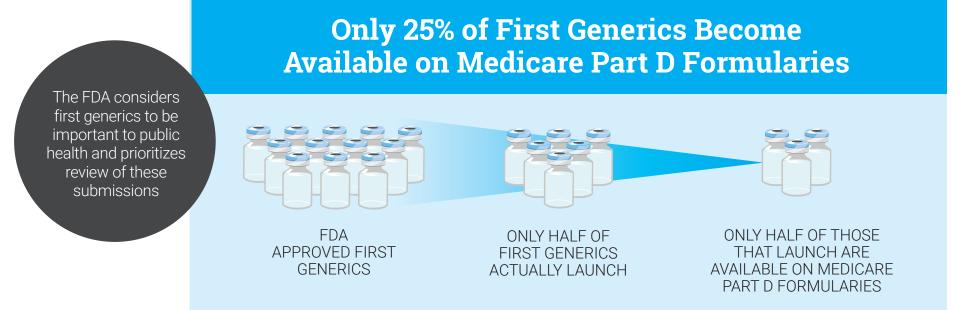


### **Market Obstacles**

### Three threats to patient access

**PATENT ABUSE.** Brand manufacturer patent abuse perpetuated by schemes consistently delay biosimilar competition, extending high prices for brand products. **2 MARKET ACCESS.** Medicines that do not enter the market cannot help patients. AAM has investigated this issue and found that while FDA has approved 166 first-time generic drugs since 2016, fewer than half are commercially available.

**FORMULARY ISSUES.** Insurance company decisions affect whether patients can obtain and save through use of generic medicines. Too often, health plans do not cover generic competitors or place generic medicines on brand cost-sharing tiers resulting in higher out-of-pocket costs for patients.



#### **Biosimilars**

### Biosimilar savings are growing, but not as promised

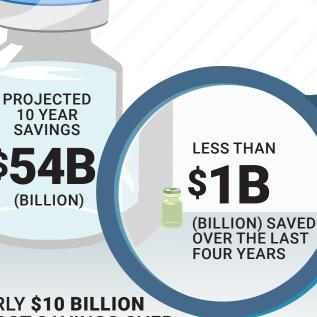
Fewer than 2% of all prescriptions are biologics, yet they account for 36% of total drug spending, comprising \$125.5 billion in 2018, a 9.5% increase over 2017.

Biosimilars are competitive versions of biologic brand medicines used to treat debilitating and life-threatening diseases, such as Crohn's disease, ulcerative colitis, cancer and psoriatic arthritis. They promise hope of new access to medicine to more than 1.2 million patients who are projected to gain access to treatment through lower-priced biosimilars.

Unfortunately, many biosimilar medicines are not available to patients even after they have successfully navigated the stringent regulatory process to obtain FDA approval. In fact, although 24 (August, 2019) biosimilars have been approved by the FDA, only nine are currently commercially available.

There are different obstacles that affect poor launch rates; perhaps one of the most egregious factors is patent abuse perpetrated by brand manufacturers. Patent abuse consistently blocks biosimilar entry, bolstering higher prices for brand products. In fact, a recent Biosimilars Council white paper found that the U.S. health care system has lost \$7.6 billion in savings since 2015 as a result of brand biologic manufacturer patent barriers, and the Medicare program has been unable to realize \$1.5 billion from available biosimilars since 2015.

### Falling Short of the Promise of Biosimilars



#### NEARLY **\$10 BILLION** OF LOST SAVINGS OVER THE LAST FOUR YEARS

Source: IQVIA 2019.

**Biosimilars** 

The good news is that cheaper biotech drugs are coming. Known as biosimilars, these complex copycat drugs have been allowed in Europe since 2004 and in America since 2010. At first, owing to policy roadblocks and anti-competitive tactics by incumbents, only a few came to market. But the firms that make them, which range from biotech giants to scrappy upstarts, are turning the trickle into a torrent.

**THE ECONOMIST, 2018** 



#### **Biosimilars**

Former FDA Commissioner Scott Gottlieb noted that patent thickets the subterfuge some brand-name drug companies use to pile on patent after patent to wall-off their medicines from competitors — "are purely designed to deter the entry of approved biosimilars [and] are spoiling this sort of competition."

These thickets and other nefarious patent schemes are being employed by some brand-name pharmaceutical companies to maintain their lucrative product pricing monopolies beyond the period Congress deemed reasonable. A brand company's win is an access and costsavings loss for patients and taxpayers. The United States health care system is bearing an untenable burden from delayed access to biosimilars.

The drug industry has plenty of tools to fend off the new, cheaper competitors called biosimilars — from lawsuits that prevent them from launching to deals that limit their profits after they launch.

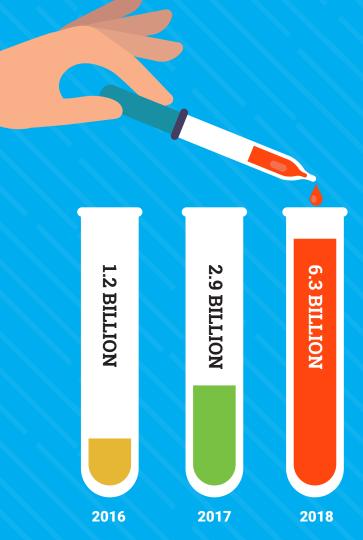
**AXIOS, JUNE 2019** 



Since not all biosimilars are available to patients after being approved, we lose their great savings potential.

### Estimated Lost Savings on Biosimilars

BY YEAR



Source: IQVIA 2019.

### "How cheaper drugs are kept off the market" AXIOS

"Secret 'Rebate Trap' Strategy Blocks Patients From Buying Generic Drugs" The Daily Beast

### Challenges to adoption

When a generic or biosimilar finally manages to enter the market, manufacturers of brand products, which have been enjoying years of exclusivity, have been known to threaten to cancel rebates to payers unless the generic or biosimilar is effectively excluded from formulary. Sometimes the threat encompasses a bundle or portfolio of unrelated products that the brand manufacturers produce.



#### **Top Drugs by Savings**

These top 10 products represent 29.4% of the overall savings in 2018. The number one drug, Atorvastatin, targets high cholesterol and triglyceride levels. This drug may reduce the risk of angina, stroke, heart attack, and heart and blood vessel problems. The drug with the next greatest savings, Ondansetron, prevents nausea and vomiting caused by cancer drug treatment and radiation therapy. Omeprazole, the generic drug with the third highest level of savings, treats certain stomach and esophagus problems (such as acid reflux, ulcers). It also helps heal acid damage to the stomach and esophagus, helps prevent ulcers and may help prevent cancer of the esophagus.

In the appendix you will find a list of the top 100 generic drugs sold in the U.S. (by volume) with their unit price in 2018 and the unit price of their brand-name equivalent.

### 2018 Top 10 Generic Drugs Ranked By Savings

| Brand Products (Generic Equivalent) | Brand Pre-<br>Expiry Price<br>(per unit) | Price of Generic<br>Equivalent 2018<br>(per unit) | 2018<br>Savings (\$B) | Percent<br>Savings | 2018<br>Dispensed Rxs<br>(Mn) |
|-------------------------------------|--|---|-----------------------|--------------------|-------------------------------|
| Lipitor® (atorvastatin)             | \$3.29                                   | \$0.11  | \$17.1                | 97%                | 114.1                         |
| Zofran <sup>®</sup> (ondansetron)   | \$21.67                                  | \$0.17  | \$13.4                | 99%                | 24.8                          |
| Prilosec® (omeprazole)              | \$3.31                                   | \$0.08  | \$12.1                | 98%                | 66.7                          |
| Crestor® (rosuvastatin)             | \$5.78                                   | \$0.11  | \$7.2                 | 98%                | 25.8                          |
| Neurontin® (gabapentin)             | \$1.02                                   | \$0.07  | \$6.9                 | 93%                | 67.3                          |
| Abilify® (aripiprazole)             | \$21.68                                  | \$1.07  | \$6.8                 | 95%                | 10.7                          |
| Norvasc® (amlodipine)               | \$1.54                                   | \$0.02  | \$6.2                 | 99%                | 87.2                          |
| Zocor® (simvastatin)                | \$2.62                                   | \$0.03  | \$6.0                 | 99%                | 45.7                          |
| Singulair® (montelukast)            | \$3.74                                   | \$0.11  | \$5.7                 | 97%                | 39.7                          |
| Seroquel® (quetiapine)              | \$6.00                                   | \$0.42  | \$5.3                 | 93%                | 20.9                          |

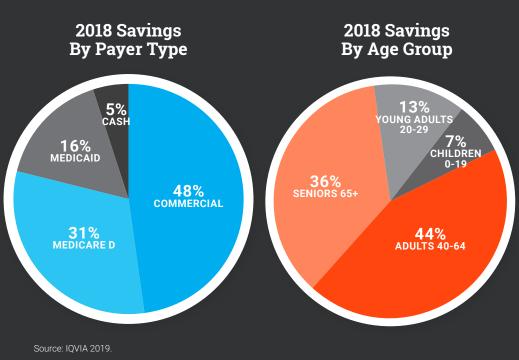
Source: IQVIA 2019.

### Top Drugs by Savings

### **2018 Savings By Class**

| Mental Health                    | \$46,277,894,729  |
|----------------------------------|-------------------|
| Lipid Regulators                 | \$37,861,381,919  |
| Antihypertensives, Plain & Combo | \$32,429,111,697  |
| Anti-Ulcerants                   | \$24,881,192,460  |
| Nervous System Disorders         | \$18,492,456,119  |
| Pain                             | \$16,252,478,951  |
| Cancer Detox Ag, Anti-Nauseants  | \$ 13,900,882,253 |
| Oncologics                       | \$11,673,938,123  |
| Antibacterials                   | \$9,640,254,773   |
| Osteoporosis                     | \$1,900,712,183   |
| Parkinson's Disease              | \$1,710,286,026   |

Source: IQVIA 2019.



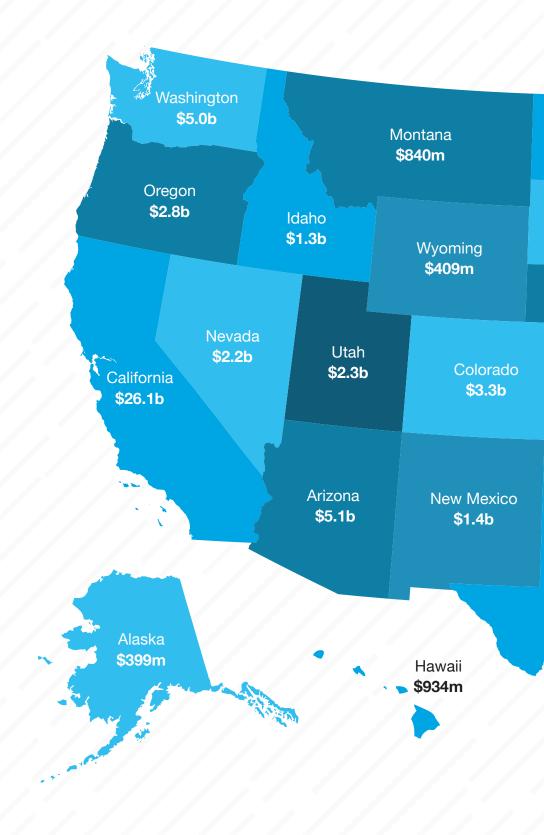
Medicines taken by older adults and seniors account for the majority (80%) of the \$293 billion in savings generated by generics in 2018. Generic medicines taken by older adults aged 40-64 accounted for \$127 billion in savings, while generics taken by seniors over age 65 accounted for \$102

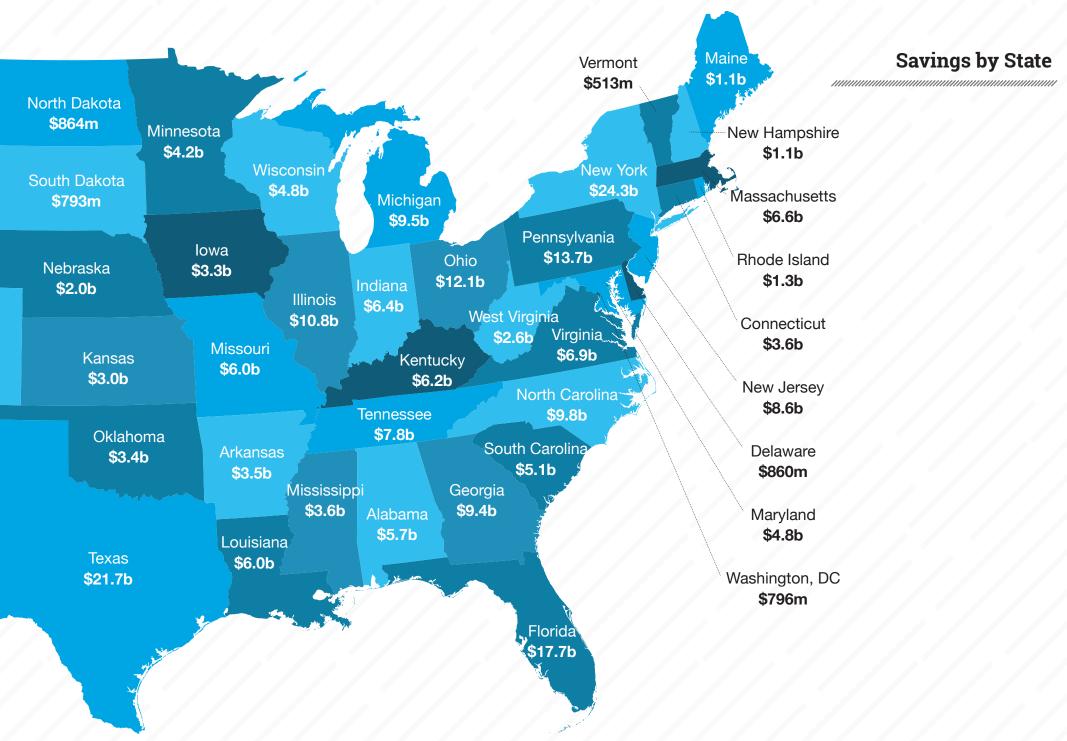
billion in savings, over one-third of the pie.

### **Savings by State**

The average state saved \$5.7 billion from the use of generics in 2018. California led the way at \$26 billion. Average Medicare Generic Savings Per State: \$1.7Bn Average Medicaid Generic Savings Per State: \$917Mr







There's no question in my mind that generics work. The doctor explained it was a generic I would be taking, it was no different than the brand and it would be much cheaper. 77

PATIENT SAVINGS CASE STUDY **Rich Thyroid Condition** Trumbull, CT

Levothyroxine, the generic version of Synthroid<sup>®</sup>, has been a safe and effective treatment for hypothyroidism for nearly 20 years. In 2018, more than 218 million levothyroxine prescriptions were dispensed in the U.S., making it the fourth most-prescribed medicine in America.

Fortunately for the 20 million patients needing treatment, generic levothyroxine is available at a fraction of the brand-name Synthroid's cost.

Access to the lower-cost generic is saving patients, insurers and the health system between \$4 billion and \$6 billion each year.



**Advancing the Case** 

### How AAM advances the case for competition

### Patients win when market-based competition from FDA-approved generics and biosimilars deliver savings at the pharmacy counter.

More FDA-approved generic and biosimilar medicines are available now than ever before. Today, America's patients are benefiting from significant savings at the pharmacy counter and in lower out-of-pocket costs. But those savings are increasingly at risk due to anti-competitive abuses and misguided policies that block access to lower-cost medicines.

That's why the Association for Accessible Medicines is calling on lawmakers from Capitol Hill to the statehouses around the nation to take meaningful action to lower prescription drug costs. Here are some key opportunities.

#### I. INTELLECTUAL PROPERTY & PATENT REFORM

The patent system exists to protect the intellectual property of innovators. AAM and our members support innovation. Yet far too often, some brand-name drug companies attempt to patent features of drugs that do not represent true innovation. Some brand-name drug companies attempt to delay competition from generic and biosimilar drugs for decades by finding ways to repackage existing inventions in later, secondary patents. These patent thickets chill competition by discouraging competitors from entering a market because of the exorbitant cost of litigating meritless patents.

AAM opposes abuses of the patent system by brand-name drug companies, and we advocate for patent reform that leads to faster access to safe, effective and more affordable medicines for patients in the United States.

### Congress and the president can take steps to address abuses of the patent system that threaten generic and biosimilars competition.

• **Protect and Preserve the IPR System.** Inter partes review (IPR) is an important tool that Congress enacted as a bipartisan solution to allow the United States Patent and Trademark Office (PTO) to eliminate bad patents efficiently. Patent examiners face heavy caseloads, spending an average of just 19 hours on each patent. There are many advantages to allowing the PTO to police its own patent-granting decisions: PTO reexamination of granted patents is cheaper, faster and benefits from the greater technical expertise PTO holds to review patents than generalist judges. When IPR eliminates an invalid patent, it cancels a government-granted monopoly and allows free market competition to lower prices.

Improve the Biosimilars Process.

Congress could take steps to provide a date certain for more affordable biosimilar competition upon expiration of the 12-year market exclusivity (monopoly) under the Biologics Price Competition and Innovation Act. For example, Congress could ensure that patents do not create a bar to biosimilar competition upon expiration of the 12-year monopoly already guaranteed to brand-name manufacturers of biologics.

• Stop Gaming the Patent Litigation Process. Another issue generics and biosimilars developers face is that some brand-name drug companies hold patents in reserve to delay the completion of litigation that provides a date certain for generic or biosimilar access. This tactic enables brand-name drug companies to threaten generic and biosimilar companies with years of litigation, carrying the possibility of massive damages liability later in the process. Congress could enact legislation that forces brand drug companies to assert all relevant patents promptly so that generic drug and biosimilar drug developers can cut through pharmaceutical patent thickets faster.

AAM / Generic Drug & Biosimilars Access & Savings Report

#### **Advancing the Case**

#### II. TRADE

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

U.S. trade has too often put the interests of pharmaceutical monopoly owners over the needs of the larger U.S. health care sector and, specifically, America's generic and biosimilar manufacturers. As the U.S. government works to lower barriers for U.S. exports, the impact of trade policies on the U.S. economy must be considered. Restrictions and provisions included in trade agreements affect what laws and amendments Congress can and cannot pass. Therefore, it is critical that trade agreements, as they enter into force, have a holistic view of their benefits and costs.

#### U.S. trade policy should:

- Lower market access barriers for U.S. generic and biosimilar manufacturers
- Promote policies that do not prop up high U.S. drug prices
- Encourage patent and exclusivity policies that meet the needs of each trading partner and do not impede access to generic and biosimilar drugs
- Incentivize generic and biosimilar market access in the United States and in foreign markets

On October 1, 2018, the U.S. Trade Representative announced a proposed agreement with Canada and Mexico to revise the North American Free Trade Agreement. The trade agreement — now called the U.S.-Mexico-Canada Agreement (USMCA) — will decrease competition from more affordable generic and biosimilar medicines and keep patients paying high drug prices for longer.

Without changes to the agreement, USMCA will slow the development of biosimilars in the U.S., increase brand-name drug exclusivity (monopolies) for biologics in Canada and Mexico, restrict the enactment of policies aimed at lower the cost of biologic medicines and expand protections for brand-name drugs beyond current U.S. law.

Competition from generic and biosimilar medicines is a centerpiece of the president's Blueprint to Lower Drug Prices and is a proven solution to bring down the cost of prescription drugs in the U.S. When patients are able to access more affordable generics and biosimilars, significant cost savings are realized at the pharmacy counter. However, the USMCA undermines the blueprint by decreasing prescription drug competition.

#### **III. STATE LEGISLATION**

The availability of safe, effective and affordable generics means savings for a state's residents and taxpayers. 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.



Unfortunately, many of the solutions proposed at the state level have focused only on "price transparency" or pricing limitations 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 isolated price spikes in terms of percentage increase, while neglecting to mention the overall deflationary pricing trend – price decreases – for the vast majority of generic medicines.

Our state policy team educates legislators in every state on the value that generic prescription drugs represent — and how to protect those savings.

• **Drug Price Transparency.** Some state bills rely on percentage price increases alone, which place disproportionate burdens on the generics industry and could ultimately chill competition among manufactures. Decreased competition and increased regulatory burdens could reduce the savings seen by patients and the health care system overall.

- State Drug Take Backs and Mandates. These mandates place significant financial burden on generic drug manufacturers. They create additional costs on generic manufacturers exclusively related to the normal course of business and undermine the ability of generic manufacturers to remain in low-volume markets.
- **Price Controls.** These laws may work for public utilities, but not for prescription medicines. There is only one proven way to bring down drug prices: market-based competition.

#### 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 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 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 2009-2018. Savings from generics launched in the 1993-2018 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 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<sup>®</sup>. These figures represent the portion of the national savings generated by each age group, not the sum of the patients' personal savings.

#### Methodology

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 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 were divided evenly based on the number of prescriptions filled by patients of each pay type.

#### Notes on changed methodology from prior editions of the study

In the four recent 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 preexpiry brand prices. Offsetting these reduced savings modestly were the inclusion of some medicines where brands ceased marketing between 1992 and 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.

#### Appendix

Generic costs have been going down for years, but many patients are paying more for these medicines.

#### That doesn't add up.

This contradiction reflects middleman markups all along the supply chain and legal gamesmanship by brand-name drug companies that subvert the savings power of generic medicines. It runs counter to the intent of Congress when it established the modern generics industry 35 years ago. At a time when some players in the pharmaceutical ecosystem are fighting to keep price data hidden from view, the generic and biosimilar industry wants patients and policymakers to know the costs of its medicines at the point when these products leave the manufacturer and begin their journey to the consumer.

| Rank | Generic Medicine               | Brand-Name Equivalent Medicine | Generic Units | 2018 Brand price<br>(per unit) | Price of Generic Equivalent<br>2018 (per unit) |
|------|--------------------------------|--------------------------------|---------------|--------------------------------|--|
| 1    | POLYETHYLENE GLYCOL            | Miralax                        | 8,413,045,204 | N/A                            | \$0.02   |
| 2    | METFORMIN                      | Glucophage                     | 7,748,310,699 | \$1.06                         | \$0.09   |
| 3    | GABAPENTIN                     | Neurontin                      | 7,315,935,047 | \$4.52                         | \$0.08   |
| 4    | METOPROLOL                     | Toprol-XI                      | 5,380,789,877 | \$1.06                         | \$0.09   |
| 5    | ATORVASTATIN                   | Lipitor                        | 5,359,675,510 | \$7.39                         | \$0.09   |
| 6    | LISINOPRIL                     | Zestril                        | 4,596,638,021 | \$4.41                         | \$0.02   |
| 7    | ACETAMINOPHEN/HYDROCODONE      | Acetaminophen Hydrocodone      | 4,498,874,364 | N/A                            | \$0.10   |
| 8    | AMLODIPINE                     | Norvasc                        | 4,042,122,461 | \$5.90                         | \$0.02   |
| 9    | OMEPRAZOLE                     | Prilosec                       | 3,781,311,812 | \$9.08                         | \$0.11   |
| 10   | LACTULOSE                      | Chronulac                      | 3,748,478,706 | N/A                            | \$0.02   |
| 11   | AMOXICILLIN                    | Amoxil                         | 3,738,683,793 | N/A                            | \$0.03   |
| 12   | CARVEDILOL                     | Coreg                          | 2,759,475,105 | \$6.91                         | \$0.05   |
| 13   | LOSARTAN                       | Cozaar                         | 2,701,121,595 | \$3.76                         | \$0.04   |
| 14   | FUROSEMIDE                     | Lasix                          | 2,527,797,656 | \$0.78                         | \$0.05   |
| 15   | TRAMADOL                       | Ultram                         | 2,337,837,671 | \$3.00                         | \$0.04   |
| 16   | SIMVASTATIN                    | Zocor                          | 2,321,882,965 | \$6.99                         | \$0.03   |
| 17   | ALPRAZOLAM                     | Xanax                          | 2,295,495,300 | \$5.75                         | \$0.03   |
| 18   | RANITIDINE                     | Zantac                         | 2,239,466,001 | \$5.90                         | \$0.09   |
| 19   | HYDROCHLOROTHIAZIDE            | Hydrodiuril                    | 2,182,669,400 | N/A                            | \$0.01   |
| 20   | SERTRALINE                     | Zoloft                         | 2,165,988,683 | \$9.57                         | \$0.05   |
| 21   | IBUPROFEN                      | Motrin                         | 2,105,115,037 | \$0.14                         | \$0.04   |
| 22   | NAPROXEN                       | Ec-Naprosyn                    | 2,039,640,864 | \$5.95                         | \$0.12   |
| 23   | DIPHENHYDRAMINE                | Benadryl                       | 1,835,799,375 | N/A                            | \$0.03   |
| 24   | PANTOPRAZOLE                   | Protonix                       | 1,799,535,702 | \$6.97                         | \$0.07   |
| 25   | ACETAMINOPHEN/OXYCODONE        | Percocet                       | 1,782,700,612 | \$18.16                        | \$0.17   |
| 26   | BUPROPION                      | Wellbutrin                     | 1,745,047,718 | \$30.19                        | \$0.32   |
| 27   | TRAZODONE                      | Oleptro                        | 1,744,913,560 | N/A                            | \$0.07   |
| 28   | TRIAMCINOLONE ACETONIDE        | Aristocort                     | 1,703,746,386 | N/A                            | \$0.08   |
| 29   | CETIRIZINE                     | Zyrtec                         | 1,673,339,889 | N/A                            | \$0.06   |
| 30   | LEVETIRACETAM                  | Keppra                         | 1,586,047,939 | \$5.59                         | \$0.11   |
| 31   | MONTELUKAST                    | Singulair                      | 1,576,975,922 | \$7.02                         | \$0.11   |
| 32   | FLUOXETINE                     | Sarafem                        | 1,543,998,182 | \$18.03                        | \$0.14   |
| 33   | ESCITALOPRAM                   | Lexapro                        | 1,487,616,605 | \$10.14                        | \$0.07   |
| 34   | CLONAZEPAM                     | Klonopin                       | 1,430,486,138 | \$2.62                         | \$0.04   |
| 35   | TAMSULOSIN                     | Flomax                         | 1,409,621,798 | \$2.21                         | \$0.08   |
| 36   | ALBUTEROL/IPRATROPIUM          | Combivent                      | 1,392,209,913 | \$86.09                        | \$0.09   |
| 37   | METRONIDAZOLE                  | Flagyl                         | 1,340,477,415 | \$3.27                         | \$0.04   |
| 38   | GLIPIZIDE                      | Glucotrol                      | 1,314,954,615 | \$0.98                         | \$0.07   |
| 39   | ROSUVASTATIN                   | Crestor                        | 1,271,296,720 | \$7.57                         | \$0.09   |
| 40   | PRAVASTATIN                    | Pravachol                      | 1,263,233,970 | \$4.50                         | \$0.11   |
| 41   | DULOXETINE                     | Cymbalta                       | 1,220,169,504 | \$7.58                         | \$0.26   |
| 42   | LORAZEPAM                      | Ativan                         | 1,217,102,594 | \$19.03                        | \$0.05   |
| 43   | HYDROXYZINE                    | Vistaril                       | 1,189,536,343 | \$2.61                         | \$0.06   |
| 44   | MELOXICAM                      | Mobic                          | 1,167,452,741 | \$7.09                         | \$0.02   |
| 45   |                                | Keflex                         | 1,139,620,478 | \$8.55                         | \$0.08   |
| 46   | HYDROCHLOROTHIAZIDE/LISINOPRIL | Prinzide                       | 1,132,505,060 | \$5.53                         | \$0.03   |
| 47   | ATENOLOL                       | Tenormin                       | 1,128,502,550 | \$9.28                         | \$0.05   |
| 48   | CYCLOBENZAPRINE                | Flexeril                       | 1,120,810,704 | \$0.98                         | \$0.08   |
| 49   | VENLAFAXINE                    | Effexor                        | 1,112,644,954 | \$11.89                        | \$0.29   |
| 50   | CITALOPRAM                     | Celexa                         | 1,098,712,619 | \$8.27                         | \$0.03   |

#### Top 100 Generic Drugs by Sales Volume 2018

### Appendix

#### Top 100 Generic Drugs by Sales Volume 2018, cont.

| Rank     | Generic Medicine                | Brand-Name Equivalent Medicine | Generic Units | 2018 Brand price<br>(per unit) | Price of Generic Equivalent 2018 (per unit) |
|----------|---------------------------------|--------------------------------|---------------|--------------------------------|---|
| 51       | BUSPIRONE                       | Buspar                         | 1,067,375,120 | N/A                            | \$0.08                                      |
| 52       | AMOXICILLIN/CLAVULANIC ACID     | Augmentin                      | 1,051,490,989 | \$4.98                         | \$0.19                                      |
| 53       | ALLOPURINOL                     | Zyloprim                       | 1,041,133,310 | \$1.82                         | \$0.11                                      |
| 54       | CLOPIDOGREL                     | Plavix                         | 1,022,689,230 | \$6.21                         | \$0.11                                      |
| 55       | LAMOTRIGINE                     | Lamictal                       | 1,018,855,146 | \$15.80                        | \$0.20                                      |
| 56       | TOPIRAMATE                      | Topamax                        | 1,018,389,350 | \$11.32                        | \$0.62                                      |
| 57       | ETHINYLESTRADIOL/NORGESTIMATE   | Ortho-Tricyclen                | 1,015,477,764 | \$0.89                         | \$0.42                                      |
| 58       | FOLIC ACID                      | Folic Acid                     | 975,203,416   | N/A                            | \$0.04                                      |
| 59       | ZOLPIDEM                        | Ambien                         | 973,322,171   | \$16.09                        | \$0.07                                      |
| 60       | CLONIDINE                       | Catapres                       | 966,776,630   | \$25.70                        | \$0.10                                      |
| 61       | HYDROCHLOROTHIAZIDE/LOSARTAN    | Hyzaar                         | 919,832,980   | \$4.76                         | \$0.06                                      |
| 62       | CIPROFLOXACIN                   | Cipro                          | 917,062,679   | \$1.38                         | \$0.06                                      |
| 63       | QUETIAPINE                      | Seroquel                       | 911,679,505   | \$13.20                        | \$0.16                                      |
| 64       | HYDROCORTISONE                  | Solu-Cortef                    | 910,645,197   | N/A                            | \$0.14                                      |
| 65       | HYDRALAZINE                     | Apresoline                     | 903,102,030   | N/A                            | \$0.05                                      |
| 66       | TIZANIDINE                      | Zanaflex                       | 899,978,494   | \$2.55                         | \$0.12                                      |
| 67       | WARFARIN                        | Coumadin                       | 886,810,730   | \$1.40                         | \$0.10                                      |
| 68       | SPIRONOLACTONE                  | Aldactone                      | 886,152,312   | \$2.90                         | \$0.12                                      |
| 69       | DIVALPROEX                      | Depakote                       | 872,610,489   | \$3.27                         | \$0.28                                      |
| 70       | DILTIAZEM                       | Dilacor                        | 854,386,946   | \$6.64                         | \$0.36                                      |
| 71       | FAMOTIDINE                      | Pepcid                         | 848,638,894   | \$12.94                        | \$0.11                                      |
| 72       | GUAIFENESIN                     | Mucinex                        | 835,780,909   | N/A                            | \$0.10                                      |
| 73       | BACLOFEN                        | Lioresal                       | 822,204,105   | N/A                            | \$0.12                                      |
| 74       | AMMONIUM                        | Lac-hydrin                     | 810,003,456   | N/A<br>N/A                     | \$0.05                                      |
| 75       | NYSTATIN                        | Mycostatin                     | 808,819,358   | N/A<br>N/A                     | \$0.03                                      |
| 76       | PROPRANOLOL                     | Inderal                        |               | \$44.13                        | \$0.23                                      |
| 70       |                                 |                                | 801,700,450   | \$1.37                         | \$0.23                                      |
| 78       |                                 | Sinemet                        | 801,292,583   | \$2.83                         |   |
| 78<br>79 | GLIMEPIRIDE<br>FLUTICASONE      | Amaryl                         | 793,902,600   | \$13.01                        | \$0.06                                      |
|          |                                 | Flonase                        | 769,858,216   |                                | \$0.33                                      |
| 80       | DEXTROMETHORPHAN/PROMETHAZINE   | Phenergan DM                   | 735,957,667   | N/A                            | \$0.01                                      |
| 81       | ONDANSETRON                     | Zofran                         | 730,042,488   | \$26.91                        | \$0.19                                      |
| 82       | KETOCONAZOLE                    | Nizoral Shampoo                | 717,125,152   | \$0.30                         | \$0.21                                      |
| 83       | LOPERAMIDE                      | Imodium                        | 688,655,748   | N/A                            | \$0.08                                      |
| 84       | AMITRIPTYLINE                   | Elavil                         | 679,775,475   | N/A                            | \$0.14                                      |
| 85       | SULFAMETHOXAZOLE/TRIMETHOPRIM   | Bactrim                        | 677,019,648   | \$2.35                         | \$0.09                                      |
| 86       | CLINDAMYCIN                     | Cleocin T                      | 674,797,478   | \$0.39                         | \$0.15                                      |
| 87       | PROPOFOL                        | Diprivan                       | 664,194,940   | N/A                            | \$0.16                                      |
| 88       | DOXYCYCLINE                     | Vibramycin                     | 625,070,949   | \$1.14                         | \$0.51                                      |
| 89       | FENOFIBRATE                     | Tricor                         | 591,753,020   | \$0.27                         | \$0.53                                      |
| 90       | DICLOFENAC                      | Zorvolex                       | 589,771,441   | \$0.52                         | \$0.21                                      |
| 91       | ETHINYLESTRADIOL/LEVONORGESTREL | Ortho-Tricyclen                | 571,253,207   | N/A                            | \$0.36                                      |
| 92       | PAROXETINE                      | Paxil                          | 562,953,450   | \$3.29                         | \$0.20                                      |
| 93       | ESOMEPRAZOLE                    | Nexium                         | 550,140,812   | \$7.61                         | \$0.38                                      |
| 94       | MORPHINE                        | Morphine                       | 548,851,654   | N/A                            | \$0.46                                      |
| 95       | HEPARIN                         | Heparin                        | 546,105,787   | N/A                            | \$0.34                                      |
| 96       | FINASTERIDE                     | Propecia                       | 529,122,920   | \$3.37                         | \$0.09                                      |
| 97       | PROMETHAZINE                    | Phenergan                      | 527,870,442   | N/A                            | \$0.06                                      |
| 98       | CODEINE/PROMETHAZINE            | Phenergan Codeine              | 507,125,461   | N/A                            | \$0.02                                      |
| 99       | HYDROCHLOROTHIAZIDE#TRIAMTERENE | Dyazide                        | 503,094,140   | \$1.99                         | \$0.08                                      |
| 100      | DICYCLOMINE                     | Bentyl                         | 497,353,719   | \$0.51                         | \$0.11                                      |

The prices in this chart reflect the list price from a manufacturer to a wholesaler or a direct purchaser without any discounts or rebates a/k/a Wholesale Acquisition Costs (WAC).

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