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Association for Accessible Medicines

2016 Annual Report

Formerly the Generic Pharmaceutical Association

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Chair's Letter

Dear Members:
Over the course of my 25 years in our dynamic industry, I have watched it grow, adapt to change, and tackle barriers that impede access to medicine. 2016 was no different. Our industry continued to evolve while facing tremendous challenges and opportunities over the past year — a time that reminds us there is far more to unite us than divide us.

Today our industry fills 89% of America's prescriptions and yet we are just 27% of the cost. However, despite our proven track record of saving the U.S. healthcare system billions of dollars every year and the overall deflationary generic market, our position as a solution to rising drug costs was lost in the nationwide drug pricing debate. And we were unfortunately painted as part of the cost problem. Simply put, generic medicines drive savings, not cost.

Our challenges aside, 2016 also will be remembered as a year in which this association set a new course in carrying out our mission. We bolstered the association by adding new talent, and took a more assertive, patient centric approach to our advocacy. We increased our budget and sharply focused our resources.

And most boldly, we took the step of reintroducing our association under a new name to better articulate what our industry uniquely owns — we are the industry that makes medicines more accessible to patients and families across the country. The launch of the Association for Accessible Medicine in 2017 is the start of a new chapter for our industry and the millions of Americans who rely on us to assure they have access to the medicines they need.

We now begin the year as stronger organization, with renewed vigor and a keener appreciation of the need to increase our share of voice in today's narrative. We need to tell our story until there is better understanding of the true costs and savings at the patient and payor levels. And we need to champion policies that create incentives for market-driven behaviors and ensure patients indeed experience our savings at the pharmacy counter.

It has been an honor to serve once again as chair of our board over the past year. I want to express my heartfelt appreciation to our professional team and to our president and CEO, Chip Davis, for his strong leadership. Thanks also to all of our member companies for their commitment to our cause. And a special thanks to my colleagues on the board of directors for their support. I look forward to continuing to tell our story of access and working with each of you in 2017 to carry our mission forward.

Best regards,

Heather Bresch, Board Chair, ~~AAM~~
and Chief Executive Officer, Mylan NV

From the President & CEO

To Our Members:
2016 marked the 15th anniversary of the founding of the Generic Pharmaceutical Association. Our achievements over the years and our contributions to the health system have been extraordinary. We have witnessed remarkable growth in the use of generic medicines, with nearly 3.9 billion generic prescriptions dispensed last year, up from just 1.3 billion prescriptions in 2001. The generic share of the prescription drug market has doubled over this period, increasing from approximately 44 percent in 2001 to 89 percent today. Our sector truly has become the backbone of the pharmaceutical industry.

The real story of our success is not the number of prescriptions, size of companies, or market share. Our success is the millions of Americans who have affordable access to the medicines they need to live healthier and more productive lives. Whether enabling those on fixed incomes to afford the medicines their doctors prescribe, or freeing up hundreds of billions of health dollars for use toward other critical needs, generics are the proven solution to sustainable healthcare.

To enhance our ability to communicate these values, the Generic Pharmaceutical Association is now the Association for Accessible Medicines. This relaunch of our association, with the new name and new logo, reflects substantive changes within our association. The new brand combined with our enhanced operational fundamentals are already boosting the effectiveness of our organization.

The success we have enjoyed over the years is a reflection of the commitment and dedication of the tens of thousands of people who work in the generic and biosimilars sectors to deliver high quality, affordable medicine to the public. We can all be proud of our achievements and together look forward to an even brighter future as we continue our long tradition of enhancing patient access to affordable medicines.

Best,

Chip Davis, President & Chief Executive Officer,
Association for Accessible Medicines

New Identity for a New Era

To advance the mission of our association and better represent the evolving generics and biosimilars industry, we have adopted a new name, logo, and messaging. The process of rebranding the association took months of work incorporating the thoughtful input of member companies, allies and other stakeholders.

The new name and its focus on patients fits the industry today, tomorrow, and 10 years from now. All that we do each day, from ensuring competition to enhancing FDA's approval processes, ultimately delivers on the promise of putting treatments within reach for patients. When patients can afford safe, quality medicines, not only do their health outcomes improve, but they also have the resources to enrich other parts of their lives.

This name also creates a dynamic where the association assumes a mantle of leadership to champion systemic changes in the supply chain to ensure patient access.

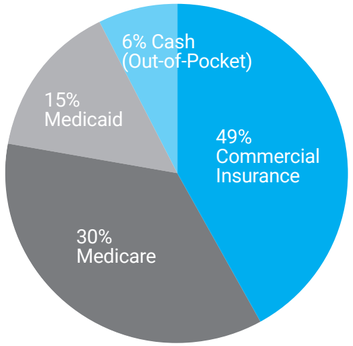
“I have a very good relationship with my pharmacist. He said, ‘Don’t waste your money on the brand names.’ I’m on a fixed income, and those savings really do add up.”

~ Michelle, 58, Stroudsburg, Pennsylvania

Our Story

Generics and biosimilars help more people in more places live healthier lives. And when a person has the foundation of health, they have a foundation for life. They're able to do more, be more and reach their potential; and our society, economy and country are stronger for it.

Generic Savings
by Payor Type



Key Findings

Generics are 89% of Prescriptions Dispensed but only 27% of Total Drug Costs

Total Savings in 2015

$227 Billion

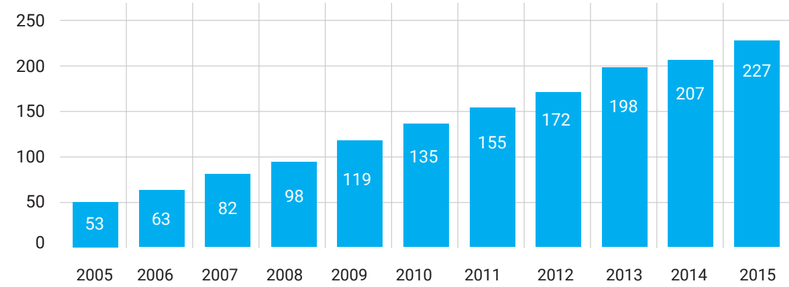
10-Year Savings

$1.46 Trillion

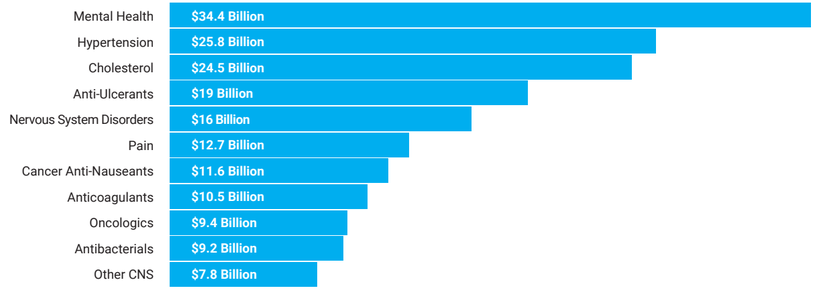
Medicare Savings: **$67.6 B** **$1,737** Per Enrollee

Medicaid Savings: **$32.7 B** **$450** Per Enrollee

Annual Generic Drug Savings ($ Billions)



Generic Savings by Therapy Area



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

~ Raeanne, 33, New York, NY

Rx Solutions

The great attention paid to drug prices has the potential to bear positive results. The one thing everyone — from policymakers to the Federal Government to insurers, PBMs, and even the brand pharmaceutical industry — agrees on is the solution to runaway brand drug prices is to enhance and increase competition.

Against the backdrop of public concern over rising drug prices, GPhA launched "Rx Solutions," a campaign promoting five policy prescriptions to speed generics and biosimilars to market, remove barriers to competition and increase utilization.

Visit **RxSolutions.us** to learn more.

Our Five-Point Plan

1. Promote timely access to quality, affordable generic drugs that meet high standards of a streamlined development and approval process

2. Create policies that recognize the different economic dynamics of the brand and generic markets

3. Ensure an intellectual property framework that balances the need for innovation and robust generic competition

4. Stop some brand drug companies from blocking or delaying generic drug development

5. Increase utilization of affordable generics across all patient populations

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

~ McKenzie, 24, Salt Lake City, Utah

The Biosimilars Council
A Division of AAM

Biosimilars: Accelerated Growth

The Biosimilars Council ensures a positive regulatory, reimbursement, political and policy environment for biosimilar products. The Council also is dedicated to educating patients, providers, and other stakeholders about the safety and effectiveness of biosimilars.

The Food and Drug Administration approved three biosimilars in 2016, providing further evidence that the regulatory approval pathway created by the 2009 Biologics Price Competition and Innovation Act (BPCIA) is showing progress. Coupled with the 2015 approval of Zarxio, a biosimilar to Neupogen, there now are four approved biosimilars in the United States. Gaining product approval is just one part of system-wide efforts to realize the promise of biosimilars. Regulators, policymakers and others must ensure that today's decisions on reimbursement, interchangeability, and other issues foster tomorrow's development of a robust biosimilars marketplace.

Biosimilar Approvals

Approval Date	Biosimilar Product	Non-Proprietary Name	Biosimilar Sponsor(s)	U.S. Launch	Reference Product	Originator
6-Mar-2015	Zarxio	filgrastim-sndz	Sandoz	3-Sep-2015	Neupogen	Amgen
6-Apr-2016	Inflectra	infliximab-dyyb	Celltrion/Pfizer	17-Oct-2016	Remicade	Janssen
30-Aug-2016	Erelzi	etanercept-szzs	Sandoz	pending	Enbrel	Amgen
23-Sep-2016	Amjevita	adalimumab-atto	Amgen	pending	Humira	Abbvie

The future is bright for biosimilars. Brand biologics with more than $80 billion in annual sales will lose patent protection by 2020, opening the door for approval of biosimilar versions of those medicines. Data from the FDA and European Medicines Agency show that late stage pipelines are swelling with more than 160 biosimilar products in different stages of development.

The Biosimilars Council's leadership was on display during a number of convenings it held over the course of the year bringing together leaders from government, industry, the patient community and media. The Council sponsored its inaugural Annual Conference in fall 2016. Over the two-day meeting, officials from the FDA and Federal Trade Commission, pharmaceutical executives, policymakers, and attorneys discussed an expansive range of issues dealing with biosimilar approvals, patent resolution, market uptake, and more.

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

~ Doug, 74, Pembroke Pines, Florida

Conferences

2017 AAM CMC Workshop
May 23 - 24, 2017
Bethesda North Marriott Hotel and Conference Center
North Bethesda, MD
This workshop will help you develop an in-depth understanding of FDA's current CMC expectations for ANDAs, the Office of Pharmaceutical Quality's (OPQ) current thinking regarding facility assessments, and up-to-date expectations on the FDA's quality standards as OPQ moves towards "One Quality Voice."

2017 AAM Policy Conference
June 21, 2017
Washington Court Hotel
Washington, DC
This first-ever Policy Conference is a one-day convening of member companies to discuss pricing and other pressing issues facing the industry. Representatives from Capitol Hill and the policy community will join us to provide a landscape analysis to inform our discussions.

Leading on Biosimilars: The 2017 AAM Biosimilars Council Conference
September 12 - 13, 2017
Washington Marriott Wardman Park
Washington, DC
Learn the most up-to-date information regarding not only regulatory and reimbursement, but also political and policy considerations surrounding biosimilar products. Additionally, sessions on educating the public, the patients, and healthcare professionals, about the safety and effectiveness of biosimilars, will be a focus.

2017 AAM Fall Technical Conference
November 6 - 8, 2017
Bethesda North Marriott Hotel and Conference Center
North Bethesda, MD
Hear presentations from experts from the FDA, industry and academia as they address key regulatory and technical issues that impact the generic industry.

ACCESS! AAM 2018 Annual Meeting
February 12 - 14, 2018
JW Marriott Orlando Grande Lakes
Orlando, FL
The preeminent generics industry meeting attracts leading speakers from around the globe who provide attendees with a comprehensive understanding of the opportunities and challenges for the generic pharmaceutical sector.

Year over year, generic prices go down.

Get Involved

Why should my company belong to AAM?
Your company can take an active role in helping shape the laws, regulations, and policies that govern the generic pharmaceutical industry and secure the continued growth of this vital market segment. AAM has working groups focusing on the key legislative, regulatory and legal issues affecting our business sector.

Who belongs to AAM?
Regular Members are corporations, partnerships, or other legal entities whose primary U.S. business derives the majority of its revenue from the manufacture or commercialization of finished-dose drugs approved by FDA via ANDAs and products sold as authorized generics. Associate Members are entities who are allied with the interests, needs, and policy positions of the generic pharmaceutical industry — including but not limited to API suppliers, contract research organizations, distributors, pharmacy benefit managers, consultants, laboratories, packagers, legal counsel groups, and pharmaceutical brokers.

Who belongs to the Biosimilars Council
The Biosimilars Council welcomes all companies (whether or not they are members of AAM) dedicated to bringing more affordable biosimilar treatments to patients in need. The Council provides education, regulatory, legislative, and advocacy services for companies investing in the emerging biosimilars marketplace.

Contact

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Your Generics and
Biosimilars Industry