



GENERIC DRUG SAVINGS IN THE U.S.



SEVENTH ANNUAL EDITION: 2015



2015 Annual Report



2015
GPhA
Annual Report

Table of Contents

From Our Chairman	2
From the President & CEO	3
2015 in Review	4
The Biosimilars Council	6
A Look Ahead	8
U.S. Generic Market Data	10
New Member Spotlight	12
Generic Value Proposition	14
Financial Highlights	17
GPhA Team	18
About GPhA	19

From Our Chairman

Craig Wheeler
Chairman of the Board
Generic Pharmaceutical Association



To our members:

It has been a profound honor to serve as your Chairman of the Board for the past two years. Reflecting on what I have enjoyed most, it has been our collective commitment to a common purpose and the satisfaction we can share in knowing our work helps people around the world get the affordable medicine they need to treat disease and live healthier lives.

Our business is changing at an incredible pace. Unprecedented acquisition activity is altering the face of the traditional generic industry; consolidation among purchasers is entrenching a global supply chain and distribution network; specialty drugs and biosimilars are accounting for increasing shares of pharmaceutical sales; and the expansion of healthcare in developing regions of the world is creating new and exciting marketplaces.

It is a testament to your dedication that in this shifting landscape our Association has made remarkable progress. Consider that we launched the Biosimilars Council, the nation's first organization dedicated to educating patients, providers and policymakers about the safety and benefits of biosimilar medicines. We successfully delayed finalization of the onerous drug labeling rule. We blocked several harmful exclusivity provisions from being added to the 21st Century Cures legislation; secured favorable changes in the Trans-Pacific Partnership trade agreement; accelerated improvements in the generic drug user fee program; and produced record levels of savings for the U.S. healthcare system; among other accomplishments.

We have demonstrated that together much can be achieved, and that the power of speaking with one voice across all levels of public policy and scientific regulation can produce substantial results. And I am confident that with your persistent engagement we will continue our winning track record as we move into the exciting days ahead.

My heartfelt appreciation goes out to the GPhA Board of Directors and the Executive Committee for lending their expertise and leadership during my tenure as Chairman. I also thank the GPhA team for their extraordinary work and steadfastness to our mission, and President and CEO Chip Davis for his exemplary leadership. Above all, I thank you, our members, for your faithful support and active participation in our Association. I look forward to working alongside you in the years ahead as we continue our endeavors.

Respectfully yours,

A handwritten signature in black ink, appearing to read 'Craig Wheeler', with a long, sweeping underline that extends to the right.

Craig Wheeler
Chairman of the Board
President and CEO, Momenta Pharmaceuticals

From the President & CEO

Dear Colleagues:

Since the Board of Directors afforded me the privilege to join GPhA as President and Chief Executive Officer last Fall, I have been most fortunate to meet so many outstanding people who work in this incredible industry. These interactions have not only helped tremendously with my assimilation into the Association and with our membership, but equally—if not more importantly—they have reinforced the abiding commitment this industry has to delivering high-quality, effective and affordable medicines to patients in the United States and throughout the world.

No other industry can claim such a level of success. Today, 88 percent of the prescriptions dispensed in the U.S. are generic, yet they account for just 28 percent of total drug costs. These statistics almost defy belief. Has any industry, in any major economy, been able to deliver almost 90 percent of market demand, at less than one-third of the total cost? Truly amazing indeed.

While collectively we all know firsthand the value proposition that generic medicines provide—to patients, providers, payers, governments and the overall healthcare system—the unfortunate political reality is that our industry is under a significant amount of pressure and scrutiny related to ongoing concerns about prescription drug costs. An increasing number of industry critics, including some policymakers and journalists, have sought to link the entire generic drug sector to a small handful of outlier cases, in an effort to drive a narrative that would place profits over patients. Further compounding this off-balanced and misguided attack is that many of the off-mentioned examples are not even generic drugs, but rather older, off-patented medicines that have had little to no market competition.

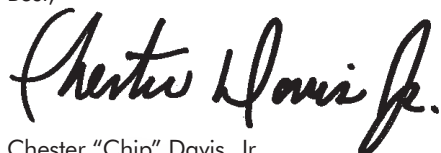
To ensure the continued success of generics, and now biosimilars, we need to recognize that the landscape is shifting, and as such we must do the same. No longer should anyone presume that the billions of dollars in savings we generate will inoculate us from policies and legislation that are harmful to our companies and the patients they serve.

Now more than ever before we need to tell our story and define our own narrative, more in-depth and across a broader base of engaged stakeholders than in the past. Why? Because when election-year rhetoric stops, and the next phase of health policy making begins in earnest, we need to ensure that our members are positioned on the right side of the ledger; seen accurately for what they have been, are today, and must continue to be, and that is an engine for delivering lifesaving and life-enhancing affordable medicines that also drive future scientific advancements and innovation for generations to come.

A promising future is ours to claim. As we move forward into 2016 and beyond, let us renew our commitment, increase our engagement, and advance with confidence knowing that together we can write our own story of continued success in delivering on the generic and biosimilar value proposition.

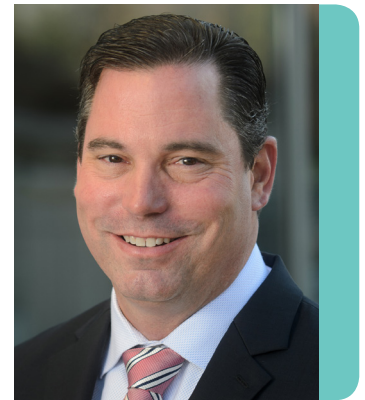
I am extremely grateful for the opportunity to work with all of you.

Best,



Chester "Chip" Davis, Jr.
President & CEO

Chester "Chip" Davis, Jr.
President & CEO
Generic Pharmaceutical Association



2015 in Review

GPPhA and its BIOSIMILARS COUNCIL: Highlights of 2015

2015 was an eventful year for the generic pharmaceutical sector. We saw an extraordinary number of healthcare and drug-related bills introduced in Congress and state legislatures, a high level of merger and acquisition activity, and unprecedented focus on drug prices. We also saw several generic records eclipsed, including the number of prescriptions dispensed and the healthcare savings achieved through generic drug use. Here are some of the highlights of 2015.

January GPPhA congratulates Dr. Kathleen “Cook” Uhl on her appointment as the permanent director of the Office of Generic Drugs

GPPhA organizes stakeholders to attend and send letters of support to the FDA Oncologic Drugs Advisory Committee as it considers the application for the first U.S. biosimilar

February The 2015 GPPhA Annual Meeting attracts more than 700 attendees, making it the world’s largest gathering of generic industry leaders

GPPhA praises FDA Commissioner Hamburg for her service to the nation



March GPPhA commends FDA on approval of the first biosimilar application

April PhRMA and GPPhA urge FDA to adopt the Expedited Agency Review (EAR) plan as an alternative to the Agency’s controversial generic drug labeling rule, and GPPhA submits comments to the agency stating that any final rule must assure patient and practitioner access to consistent, science-based information to best inform treatment decisions

and noting that the proposed rule’s intent to address liability is the sole purview of Congress and exceeds the agency’s authority

More than 40 minority provider groups, pharmaceutical supply chain partners, and other stakeholders send letters to FDA supporting the EAR

GPPhA launches the Biosimilars Council, a new division of the Association dedicated to ensuring a positive regulatory, reimbursement, political, and policy environment for these new medicines and educating about their safety and effectiveness

May The Biosimilars Council recognizes legislatures in Colorado, Georgia, Tennessee, Utah and Washington state for passing biosimilars substitution legislation that reflects principles embraced by the Council and a coalition of brand companies

June A group of healthcare stakeholders representing the pharmaceutical supply chain, union retiree beneficiaries, pharmacists and others joined GPPhA in a letter to Congressional leaders pledging vigorous support for the Fair Access for Safe and Timely (FAST) Generics Act to stem the abuse of restricted access programs and speed generic approvals

The Biosimilars Council and its strategic partners send a letter to FDA supporting maintaining the same nonproprietary names for biosimilars, noting that different INNs for biologics and biosimilars could lead to patient and prescriber confusion, increase the possibility of medication errors, and effectively separate the biosimilar from existing safety information about the underlying molecule while limiting the utilization of these new medicines and impeding access and savings for patients

FDA holds GDUFA meeting at which GPPhA says the Agency is falling short of meeting its performance goals and pledges support to improve results

GPPhA conducts a 2-day CMC workshop with record-setting attendance covering FDA’s CMC expectations for Abbreviated New Drug Applications

July GPPhA selects Chester “Chip” Davis, Jr. as its new President and CEO

The Biosimilars Council announces that Dr. Bertrand C. Liang, Chief Executive Officer of Pfenex Inc., will be the Council's first Chairman of the Board

GPhA sends a letter to Congressional leaders opposing any amendments to patent reform legislation that would carve out pharmaceutical patents from the Inter Partes Review (IPR) process

GPhA and its Biosimilars Council send a letter to President Barack Obama, reproduced in full-page newspaper ads, warning that the current text of the Trans-Pacific Partnership prevents market entry for lower-cost pharmaceuticals in a number of ways, including patent linkage, patent extensions and increased exclusivity periods and threatens the availability of biosimilars

August The Biosimilars Council says FDA's naming proposals warrant serious scrutiny for potential barriers to patient access to lower-cost biologic treatments

The Biosimilars Council urges CMS to wait for FDA to provide clarity on interchangeable biosimilars before finalizing Part B reimbursement rules

September GPhA supports the 10th Annual DEA National Prescription Drug Take-Back Day



GPhA President and CEO Chip Davis congratulates Dr. Robert Califf on his nomination for Commissioner of the Food and Drug Administration

GPhA and the Biosimilars Council laud the launch of the first U.S. biosimilar

October GPhA speaks out against CMS biosimilars reimbursement rule

GPhA condemns budget deal over provision implementing an inflation-based Medicaid rebate penalty for generic drugs

The Biosimilars Council applauds California for enacting a workable biosimilars substitution law

The Biosimilars Council voices optimism that the Trans-Pacific Partnership will achieve the goal by embracing competition from biosimilar therapies

November GPhA President and CEO Chip Davis testifies at the HHS Pharmaceutical Forum

The Biosimilars Council praises New Jersey biosimilars substitution law

New IMS report shows generic drugs delivered a record \$254 billion in healthcare savings in 2014, and a record \$1.6 trillion in savings over the most recent decade

GPhA launches D.C.-based advertising campaign across digital media and radio to promote Generic Drug Savings in the U.S. report and counter criticism levied at generics in the context of the drug price debate

GPhA holds the annual Fall Technical Conference in Bethesda, MD; this year the Conference was expanded by a full-day, which attracted a record-setting audience from industry, academia and the FDA

December The Biosimilars Council presents at FDA's first BsUFA Reauthorization meeting

GPhA commends Senate Aging Committee for recognizing that competition from generics can hold down health costs

GPhA applauds FDA for delaying the generic drug labeling rule while the Agency considers alternate proposals

A group of healthcare stakeholders representing the pharmaceutical supply chain, union retiree beneficiaries, pharmacists and others joined GPhA in a letter to Congressional leaders supporting the Fair Access for Safe and Timely (FAST) Generics Act

The Biosimilars Council

BIOSIMILARS COUNCIL: GPhA Establishes New Division to Support Education & Advocacy in Growing Sector

GPhA launched the Biosimilars Council on April 16, the first organization established to support the broad components of the biosimilar industry, thereby enabling patients increased access to safe, effective and affordable biosimilar medicines. The Biosimilars Council works to ensure a positive environment for patient access to biosimilar medicines. It is a leading source for information about the safety and efficacy of these more affordable alternatives to costly brand biologic medicines. Areas of focus include public and health expert education, strategic partnerships, government affairs, legal affairs and regulatory policy.



GPhA is well positioned to represent this growing business area given its long track record of success supporting the generics industry, and the broad participation in the biosimilars marketplace by several of its current members. Biosimilars are one of the most important opportunities to bring more affordable medicines to the United States market and the patients that need them. “The Biosimilars Council is the culmination of GPhA’s longstanding and unwavering commitment to patient access to safe, affordable and lifesaving biosimilar medicines,” said GPhA Board Chairman Craig Wheeler.

Among the first offerings of the Biosimilars Council was a new educational handbook, *The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products*. The handbook explains the benefits and science behind biosimilar medicines and outlines the legal and regulatory framework for biosimilar approvals.

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 FDA and EMA show that late stage pipelines are swelling with more than 160 biosimilar products in different stages of development. Express Scripts projects savings of \$250 billion in 10 years should only the 11 likeliest biosimilars enter the market. The EMA has approved biosimilars for somatropin, epoetin, filgrastim, follitropin, insulin glargine and infliximab—21 different products in all. Biosimilars for etanercept, adalimumab, rituximab and pegfilgrastim are under review in the U.S. and EU. Approvals of more biosimilars for anti-TNF biologics and oncology products are anticipated for 2016.

As this sector continues to blossom, the Biosimilars Council welcomes all companies dedicated to bringing more affordable biosimilar treatments to patients in need. More information about the Biosimilars Council, the biosimilars educational handbook, and future events is available at www.biosimilarscouncil.org.

Coming This Fall!

LEADING ON BIOSIMILARS: The 2016 GPhA Biosimilars Council Conference will be held September 7-8, 2016, at the Bethesda North Marriott Hotel and Conference Center, North Bethesda, MD.

Sessions will include presentations from industry leaders, FDA officials, academia and subject matter experts. Topics will include biosimilars education, access, the regulatory environment, reimbursement and legal affairs. Registration is now open at www.biosimilarscouncil.org.



Biosimilars Council Member Companies 2015

Accord Healthcare · Amneal Biosciences
Apobiologix · Biocon · Dr. Reddy’s · Momenta
Mylan · Pfenex · Sandoz · Sun · Teva · TPI · Zydus

BIOSIMILARS: A year of progress; a future of opportunity

It took more than five years after enactment of the Biologics Price Competition and Innovation Act (BPCIA), but the September launch of Sandoz' Zarxio™, a biosimilar for Amgen's oncology drug Neupogen® (filgrastim), officially opened the U.S. biosimilars market. "The launch of Zarxio is a victory for all champions of improving access and affordability in healthcare," the Biosimilars Council said. Sandoz is a founding member of the Biosimilars Council. Patients using Zarxio™ in place of Neupogen® immediately began enjoying savings—approximately \$500 per chemotherapy cycle. Although Zarxio™ was approved by the FDA on March 6, legal wrangling held up the product's launch until September 3. It is estimated that the U.S. lost more than \$270 million in savings during the six-month delay from approval to market entry. Other significant events in the biosimilars sector in 2015 include:

FDA Guidances In August, FDA released a proposed rule and draft guidance suggesting that reference products and biosimilars be assigned nonproprietary names that share the core substance name and include an FDA-designated suffix. The Biosimilars Council is advocating that biologics and biosimilars share the same nonproprietary name with no added suffix. The EU has approved 21 biosimilars to date and all of them have been issued under the same nonproprietary name as the reference product. Among outstanding guidances expected from FDA is one that will govern obtaining biosimilar interchangeability status. A biosimilar can obtain such a rating by showing that it can be expected to have the same clinical result as the reference product and that switching between the reference and biosimilar does not increase safety risks or diminish efficacy.



It is critical that FDA proceed with this and other key guidances such as labeling and statistical considerations for

demonstrating analytical similarity. Additionally, FDA should prepare a guidance to address life-cycle management or post-approval requirements, as well as supporting manufacturing changes such as the need to establish similarity to originator or comparability to the approved biosimilar.

Reimbursement In October, the Center for Medicare and Medicaid Services issued a rule assigning a single billing code and payment calculation to all non-interchangeable biosimilars referencing the same brand biologic. The Biosimilars Council has objected to the payment plan, arguing it will discourage innovation and erect barriers to developing biosimilars. "There is no scientific evidence that suggests it would be appropriate to blend all biosimilar products into a single payment calculation, independent of the reference product," said Biosimilars Council chairman Bert Liang.

Legal Also in October, the Federal Circuit Court of Appeals let stand a July decision that the information-sharing provision (the so-called "patent dance") in the BPCIA is optional, not mandatory. The Court also let stand a previous ruling that the six-month advance notice of first commercial marketing can be given only *after* FDA has approved the biosimilar, not upon FDA's acceptance of the biosimilar application.

Biosimilar User Fees In December, FDA held its first biosimilar user fee (BsUFA) reauthorization meeting. The current 5-year BsUFA program, which ends in 2017, must be reauthorized to allow FDA to continue collecting biosimilar user fees. The Biosimilars Council made a presentation at the meeting telling FDA it is critical that BsUFA policies promote competition and create opportunities to speed patient access to biosimilars. In 2016, biosimilar manufacturers will pay \$237,420 for each biosimilar development program, \$2.37 million with each application submission, and \$585,200 in establishment fees per facility.

State Action By the close of 2015, 19 states and Puerto Rico had enacted legislation allowing for substitution of interchangeable biologics. The Biosimilars Council continues to work with coalition partners to ensure favorable legislation progresses in the remaining states.

GPhA and its members historically have been the industry pioneers on biosimilars.

The Biosimilars Council is the next evolution in this leadership.

2016: A Year of Promise and Challenges for Generic Medicines

2016 promises to be a game-changing year on many fronts—one with plenty of opportunities, but also laced with challenges and uncertainties. As a nation, we will elect a new president and a new Congress, and possibly install a new U.S. Supreme Court Justice. These changes have implications both for the healthcare sector generally, and for our industry specifically.

It took less than a week into the new year for the Republican-controlled House of Representatives to pass a bill to repeal Obamacare. Although the President immediately vetoed the bill, uncertainties remain as the legislation potentially lays the groundwork for undoing the Affordable Care Act. And while the U.S. Supreme Court in 2015 upheld the federal subsidies within the ACA Exchanges, the political debate over Obamacare continues.

There also is an overall increasing push for greater generic drug use as millions of Americans have gained health insurance under the Affordable Care Act. Roughly 17 million more Americans have health insurance coverage since the launch of the ACA's Exchanges and Medicaid expansion two years ago. While pharmaceuticals represent just 10 percent of healthcare spending, higher numbers of insured patients provide a tailwind for drug manufacturers.



to lawmakers eager to address the issue. For example, our advocacy for legislation to stop the abuse of Risk Evaluation and Mitigation Strategies (REMS) and REMS-like programs has been strengthened by the admission by a certain brand company that it sought to block generic competition for its costly product.

Additionally, there is a stronger spotlight now on the backlog of ANDAs at the FDA. We will continue to work with FDA toward improved implementation of GDUFA I, while also negotiating an agreement for GDUFA II that will address the shortcomings of the first round.

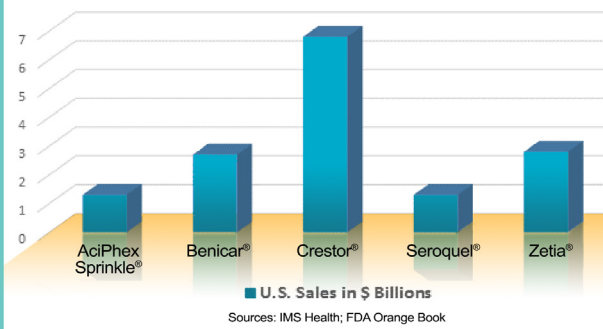
Also uncertain is whether or not FDA will alter in any way its controversial generic drug labeling rule. The proposal has faced fierce opposition since its introduction more than two years ago and has missed two targeted final rule dates. FDA said late in 2015 that the final rule will be issued in July 2016. While blocking the implementation of the generic drug labeling rule is GPhA's top priority, we have worked with relevant stakeholders to develop the Expedited Agency Review alternative proposal and continue to work to encourage the FDA to adopt it.

2016 will also see new biosimilars under FDA review, bringing opportunities in this emerging market, and to further our successes at the state level. However, there may be challenges for biosimilars growth in expected regulatory guidance on key issues such as extrapolation and interchangeability.

Beyond the policy and political arena, industry business opportunities include a list of several highly profitable brand drugs that are slated to go off-patent in 2016, including Crestor[®], with \$6.4 billion in annual sales, Benicar[®] and Zetia[®], each with \$2.6 billion in annual sales, and Seroquel XR[®] and AcipHex Sprinkle[®], each exceeding a billion dollars in sales. With the cost of capital remaining relatively low, and the appetite for deals in the biopharmaceutical market continuing, industry analysts see 2016 as another interesting year of consolidation and strategic positioning. With approximately a quarter of a trillion dollars in acquisition activity, 2015 was the biggest year on record for pharmaceutical M&A.

While each new year brings new possibilities for our industry and issues, election years are an especially ripe time to increase our engagement with policymakers and the media in furtherance of our priorities. Working with our members, GPhA will continue to leverage the current environment to maximize the generic industry's share of voice.

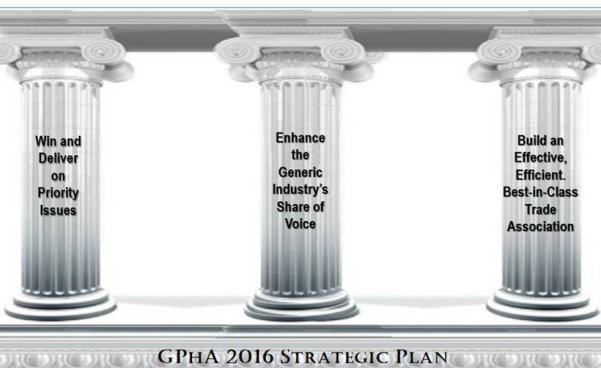
Blockbuster Drugs Losing Patents in 2016



Increasing political rhetoric on drug pricing, especially as the presidential campaigns pick up full steam early in the year, will challenge GPhA's message that generics are an essential part of the solution to sustaining healthcare. The industry experienced this challenge in the form of legislation agreed to behind closed doors that imposes a new costly Medicaid rebate penalty for generic drugs. A state form of this federal law has now also been raised in New York. The debate over the cost of prescription drugs in the health system also provides a greater opportunity to showcase our policy solutions

CHARTING THE COURSE: GPhA Unveils 2016 Strategic Plan

The 2016 GPhA Strategic Plan is built upon three inter-related Strategic Pillars that serve both as our navigation plan and the driver of our work moving forward. “The mission of our Association is to conduct effective advocacy for public policies that encourage the development, manufacturing, sales and marketing of generic drugs and biosimilars. Underlying this mission is a commitment—a commitment to ensuring that patients and consumers have access to safe, effective and affordable medicines. Our Strategic Plan will guide us to achieving this mission,” GPhA President and CEO Chip Davis told the Board of Directors at the October CEO Leadership Summit in Washington, DC.



1st Pillar: Win and Deliver on the Priority Issues

2nd Pillar: Enhance the Generic Industry’s Share of Voice

3rd Pillar: Build an Effective, Efficient, Best-in-Class Trade Association

Executing a winning strategy means delivering on the legislative and regulatory priorities of the industry, which is the foremost priority for GPhA. These priorities include:

Biosimilars Advocate on a wide variety of issues relevant to the development of a robust biosimilars market, including naming, reimbursement, public education, and others.

Costs/Market Access Continue to lead on issues directly related to generic costs and patient access, including continued engagement on inquiries into generic drug pricing.

Generic Drug User Fee Act (I & II) Work with FDA towards continued implementation of GDUFA I, while also negotiating an agreement for GDUFA II that will improve upon the shortcomings of the first round.

Labeling Actively oppose the finalization of the FDA’s proposed rule on labeling changes, and prepare for litigation should FDA move forward as proposed.

Risk Evaluation & Mitigation Strategies

Increase awareness of brand industry practices that deny generic manufacturer access to samples, and advocate for legislation to stop abuse of REMS and REMS-like programs.

Exclusivity Oppose all attempts to extend patent protection and lengthen brand drug exclusivity periods.

An important component of the plan is to heighten the visibility of GPhA and member-company executives across key constituencies to assure that generic industry expertise is “at the table” and is influential in shaping and driving health policies in Washington, the states and internationally. Executive visibility is not simply publicity. It is a means of achieving a larger goal, which is to highlight thought leadership and bolster the reputation of the generic drug industry among stakeholders, policymakers, providers and the public.

This will require an aggressive outreach program to healthcare professionals and patient advocates. We will introduce our executive teams to allies across various sectors to strengthen our relationships among core constituencies who are able to provide critical support in advancing our policy priorities. Successfully executing this part of the strategic plan will elevate the reputation, influence and value of the trade Association and empower us to better serve the generic drug and biosimilars industries.

Finally, we will instill a commitment to political engagement among our member companies. Total engagement of our membership in the political process reveals to lawmakers that our industry is invested in and concerned about the policies they debate and act upon. Political engagement, both at the state and federal level, is the best way to assure that our industry does not get counted as part of the problem, but instead remains part of the solution for a sustainable healthcare system. To deliver on this strategic plan will require an increased level of engagement—by our association, and by our industry. Together, we will continue accomplishing our mission of providing all Americans access to the medicine they need.

“To deliver on this strategic plan will require an increased level of engagement—by our association, and by our industry.”

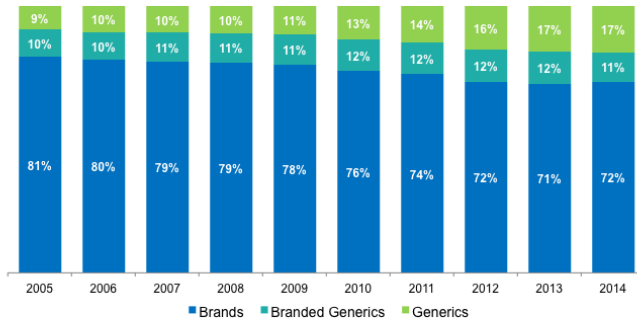
*GPhA President & CEO
Chip Davis*

U.S. Generic Market Data

Generics account for 28% of total medicines spending

Spending on generics totaled \$106Bn in 2014

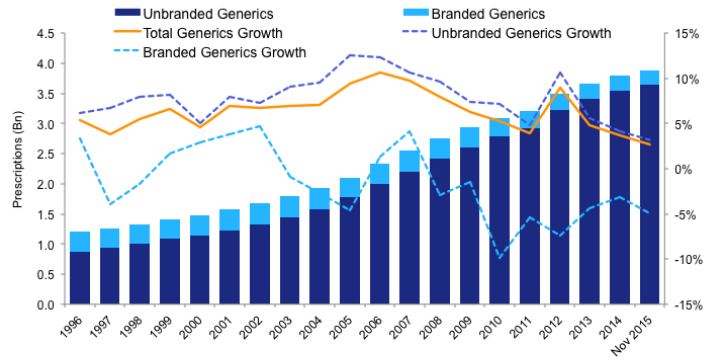
Brands and Generics Share of Total Medicines Spending (%)



Source: IMS Health, National Sales Perspectives, Mar 2014

Americans filled 3.87Bn generic scripts in the last 12 months

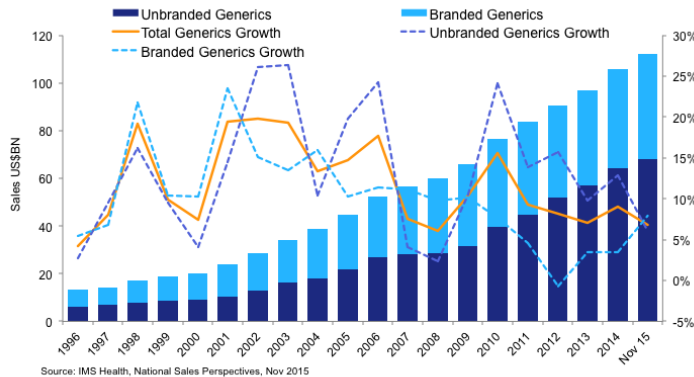
Demand for generics has tripled in the last twenty years



Source: IMS Health, National Prescription Audit, Nov 2015

The market for generic medicines increased 6.8% to \$112Bn

Generic sales increased \$7.2Bn in the last twelve months



Source: IMS Health, National Sales Perspectives, Nov 2015

The 10 most commonly dispensed medicines

MAT Nov 2015

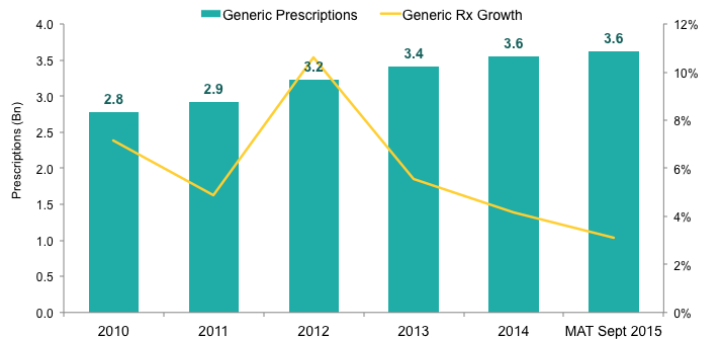
Rank	MAT Nov 2015	TRx	Share (%)	Growth (%)
Total U.S. Market		4,374	100.0	1.6
1	levothyroxine	121	2.8	0.9
2	lisinopril	106	2.4	2.1
3	acetaminophen-hydrocodone	98	2.2	-19.4
4	atorvastatin	92	2.1	16.0
5	metoprolol	86	2.0	1.4
6	amlodipine	81	1.9	4.4
7	metformin	80	1.8	4.8
8	omeprazole	77	1.7	2.6
9	albuterol	70	1.6	5.6
10	simvastatin	66	1.5	-9.4
Top 10		877	20.0	-0.1

Source: IMS Health, National Prescription Audit, Nov 2015

Branded Generics Disaggregated

Americans filled 3.6Bn generic prescriptions in 2015

Demand for generics increased 2.6% last year

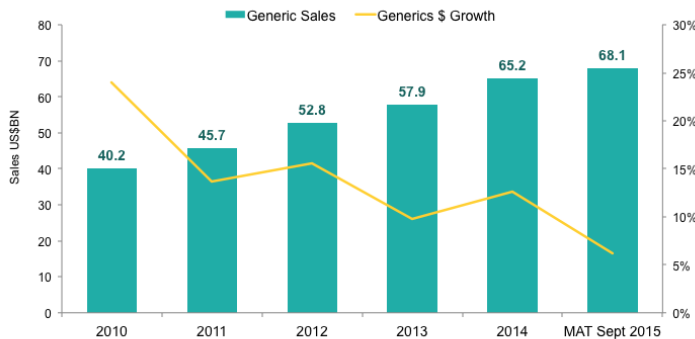


Source: IMS Health, National Prescription Audit, Sept 2015

Branded Generics Disaggregated

Generic sales increased 6.2% to \$68Bn in MAT Sept 2015

Sales of generics increased \$3.9Bn in the last twelve months



Source: IMS Health, National Sales Perspectives, Sept 2015



New Member Spotlight



GPhA is pleased to welcome our newest Associate Member, the **Dispensary of Hope**. The Dispensary of Hope is a charitable, wholesale pharmaceutical distributor that links the pharmaceutical industry with a national network of safety net clinics and charitable pharmacies to improve the health of the most vulnerable people in the United States—those with no health insurance, and low income—by distributing the medications they need to regain and maintain their health.

The Dispensary of Hope has nurtured this vision of connecting abundance with need for the last 12 years. Founded in 2003 and based in Nashville, TN, the Dispensary of Hope is approved to distribute pharmaceuticals in 41 states, and the District of Columbia. Today they serve 93 distribution points in 22 states and have aggressive plans to obtain approval and distribution points in all 50 states.

Since 2013, generic industry members have generously partnered with the Dispensary of Hope to provide monthly product offers and donations of lifesaving medications for use throughout the safety net. These quality products are made available at no charge to the patients that receive them.

In 2015, the Dispensary of Hope was offered more than \$3.56 billion Average Wholesale Price (AWP) and \$1.3 billion Wholesale Acquisition Cost (WAC) in medication, and distributed \$13,989,069 WAC, resulting in 123,588 patient encounters in 76 sites across America. That is an astounding 359,878 30-day fills.

A collaborative of generic manufacturers offered this medication each month, saved millions of dollars in reduced storage and destruction costs, and heroically served the needs of the nation's most vulnerable patients.

ABUNDANCE—HOPE—NEED

The Dispensary of Hope collects surplus medication that would otherwise have been destroyed and securely delivers it to outpatient pharmacies, charitable pharmacies and free clinics so that they may improve the health of their most vulnerable patients: the poor and uninsured.



As a wholesale distributor, the Dispensary of Hope is fully compliant with all federal and local regulations, including the Prescription Drug Marketing Act (PDMA), Drug Quality and Security Act (DQSA) and United States Pharmacopeia (USP 1079-Good Shipping and Storage Practices).

The future looks exceptionally bright for all the partners in this collaborative effort. By 2020, the Dispensary of Hope will almost quadruple its medications delivered per year to almost \$50 million WAC, assemble a formulary of 400 essential medicines; and increase the number of people served by 400%. Please visit www.dispensaryofhope.org to join this collaborative effort.

THE BENEFITS OF PARTICIPATING

- ♥ Demonstrates corporate good will.
- 👤 Increases employee engagement.
- 📦 IRS Section 170E3 "Enhanced Inventory Tax Benefit" of double the cost of production not to exceed fair market value.*
- ✓ Verifiably fulfills corporate social responsibility effort goals.
- 🗣️ Creates a strong industry-wide message supporting access.
- 📦 Reduces the cost of inventory and destruction.
- 🌟 Transforms the lives of our low income uninsured friends, family, and neighbors.



WITH YOUR HELP WE CAN GIVE HOPE WHERE THERE WAS NONE

Generic Value Proposition

Generics Drive Savings, Not Costs

Solutions for Policymakers Who Want to Reduce Pharmaceutical Costs for Patients

For months America has been witness to an abundance of media attention and public focus on increasing health-care costs, and in particular prescription drug prices.

That focus has been wide and varied. In some instances it has focused on the high costs associated with new specialty medicines and biologics, and in other situations it has been centered on older, branded, off-patented medicines where there is little to no market place competition and for which there have been significant price increases. This was the case with the Turing Pharmaceuticals product Daraprim. GPhA has spent a significant amount of time educating policymakers and journalists that Daraprim is not a generic drug and that it was never approved by the FDA through an ANDA.

There has been a lot of concerning rhetoric being espoused by some asserting that generic drugs, and generic drug prices, are driving overall healthcare costs. And if rhetoric translates into policy implementation, there is a real risk of implementing “solutions” in search of problems, as

opposed to considering options that can actually address some of the very real challenges that currently exist.

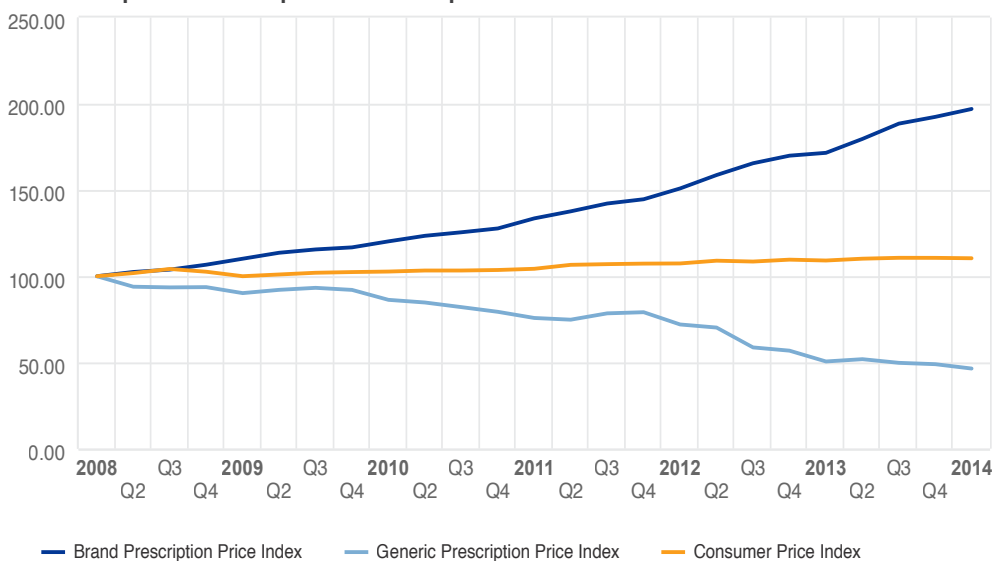
Fundamentally, generics drive savings - not costs for our healthcare system. As the January 2016 Department of Health and Human Services (HHS) ASPE issue brief, *Understanding Recent Trends in Generic Drug Prices*, says, “Our review of evidence strongly supports the conclusion that generic drug prices are not an important part of the drug cost problem facing the nation.” This is reflected in the fact that 88 percent of dispensed prescriptions are for generic drugs, yet they account for only 28 percent of total drug spending. Generics saved the U.S. health system \$254 billion in 2014, according to the *Generic Drug Savings in the U.S.* report compiled by IMS Health.

Over the last few years we have seen significant decreases in prices of drugs facing competition, and even now only a small percentage of the 14,000 generics approved by FDA have seen significant increases. In fact, the 2014 Express Scripts Drug Trend Report showed that since 2008, the over-

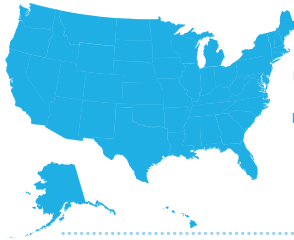
all price of generic drugs has been cut roughly in half. Meanwhile, the price of innovator drugs has nearly doubled in the same time frame.

Competition among generic manufacturers, not price regulations or the ill-considered Medicaid rebate penalty on generics implemented by Congress in October, will allow the most cost-effective and reliable generic pharmaceutical marketplace in

The Express Scripts Prescription Price Index



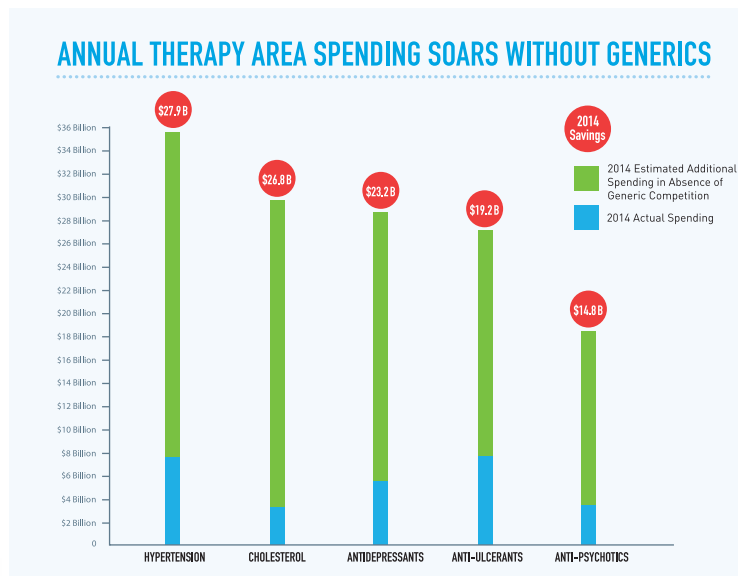
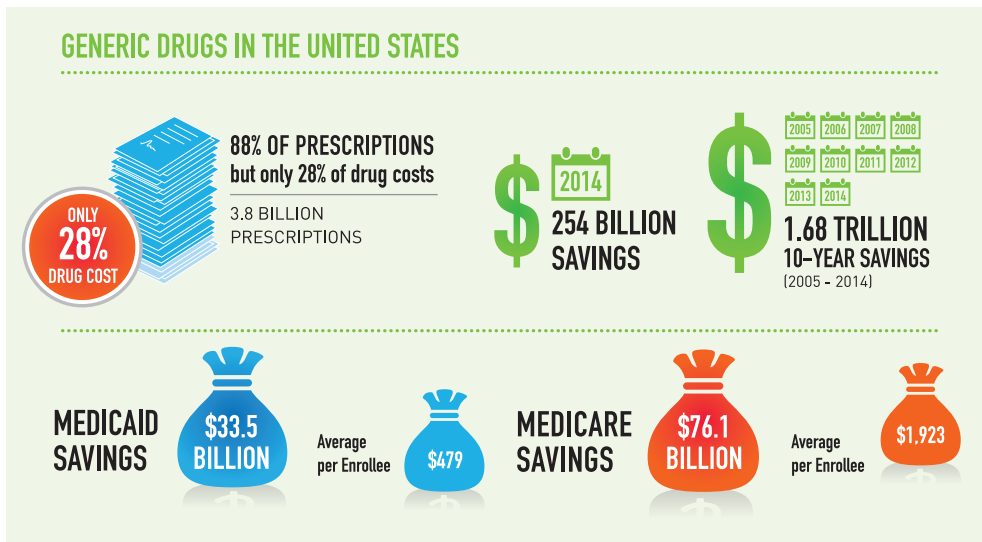
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GENERIC DRUG SAVINGS IN THE UNITED STATES

Generic drugs are an essential part of controlling health care spending. Generic drugs saved the U.S. \$254 billion in 2014, according to new data from the 2015 Generic Drug Savings in the U.S. report compiled by the IMS Institute for Healthcare Informatics on behalf of the Generic Pharmaceutical Association (GPhA).

GPhA welcomes the opportunity to work with policymakers, the FDA and stakeholders from all corners of the supply chain to ensure patient and health system savings. Together, more can be done to encourage pharmaceutical competition and expand access to safe, effective and more affordable generic medicines.



GPhA
 Generic Pharmaceutical Association
 For more information visit www.gphaonline.org

Generic Value Proposition

the world to thrive. Policymakers instead have the opportunity to support numerous solutions that would boost generic competition to bring about even more savings, including:

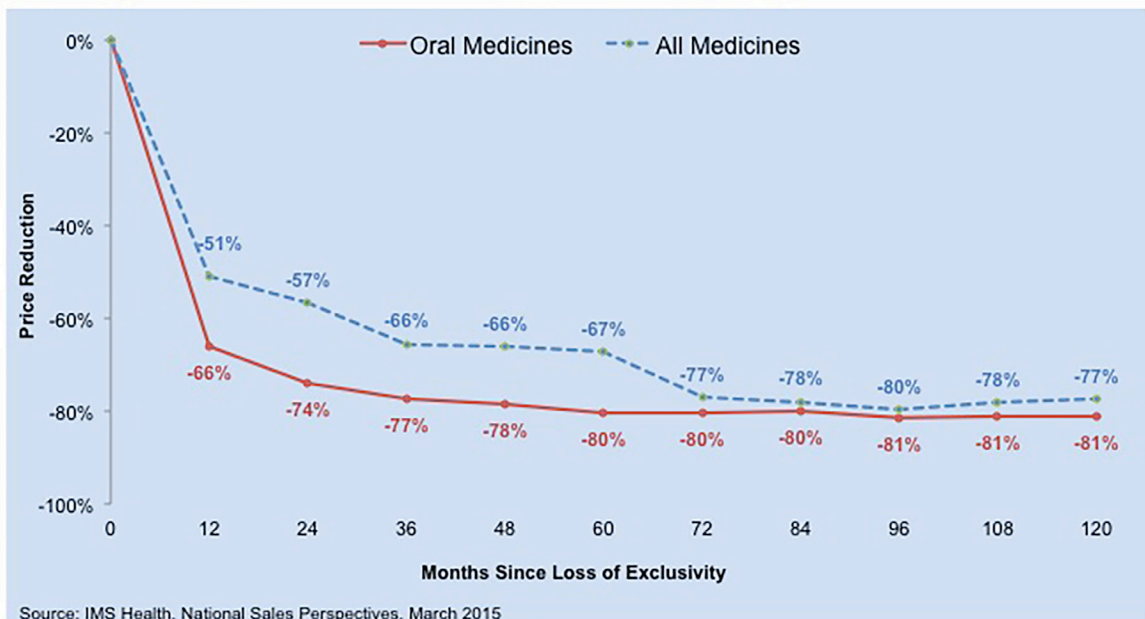
- Ensure a fully-resourced FDA can address the backlog of more than 3,800 generic drug applications stalled while waiting for approval and shorten FDA median generic drug approval timelines, which, at the industry's best estimate, currently stand at 48 months.
- Increase generic utilization among the low-income Medicare population, which could save up to \$17.7 billion over 10 years.
- Pass the bipartisan FAST Generics Act to curb some brand drug company abuses of FDA safety programs such as Risk Evaluation and Mitigation Strategies (REMS) used to keep generics off the market, an estimated savings of \$2.4 billion over 10 years.

- Work closely with industry and regulatory partners to ensure that the framework for biosimilars, safe and effective alternatives to costly brand biologic drugs, expands and expedites patient access. Estimated savings biosimilars savings range from \$44 billion to \$250 billion.
- Repeal Sec. 602 of the Bipartisan Budget Act of 2015. The Medicaid rebate increase for generic drugs in the budget deal is bad for Medicaid and its beneficiaries, bad for taxpayers, and it should be immediately repealed.

GPhA will continue to highlight the undeniable role of generics in lowering health costs. Together with Congress, the Administration, regulators, stakeholders and others we can do more to ensure the generic pharmaceutical industry continues to enhance patient access and drive patient savings for years to come.

Generic drugs enter the market at lower prices than the brands they replace, and their prices continue to decline

Monthly Price Reductions after Loss of Exclusivity

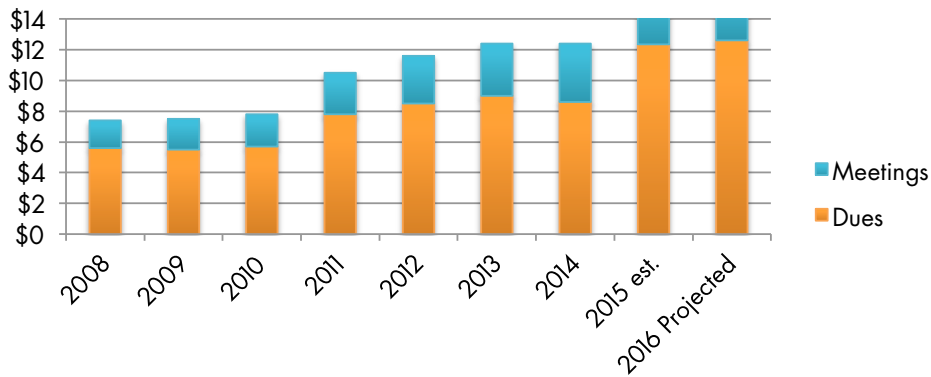


Price Declines after Branded Medicines Lose Exclusivity in the U.S.

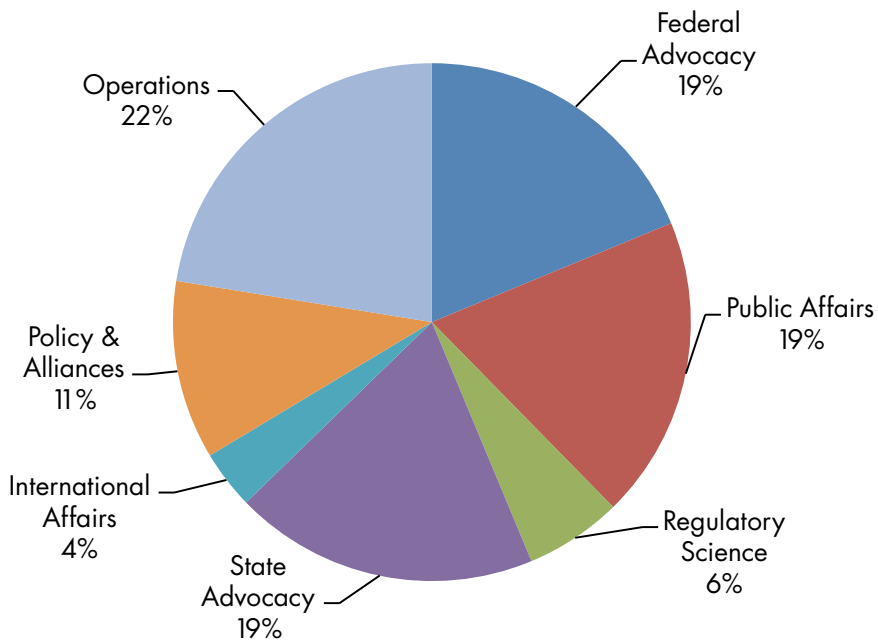
IMS INSTITUTE
HEALTHCARE INFORMATICS

Financial Highlights

TOTAL REVENUE (\$ IN MILLIONS)



2016 PROGRAM EXPENSE ALLOCATION BY COST CENTER



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President & Chief Executive Officer

Kathy Altman
Executive Assistant to the President & CEO

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Jennifer Nguyen
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Cookie Cottrell, CAE
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Culley Stine
Senior Manager, Administrations & Operations

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Ashlee Koonce
Associate Manager, Sciences & Regulatory Affairs

Member Engagement Opportunities GPhA

The **Audit & Finance Committee** assists the Board of Directors in oversight of GPhA's audit and financial reporting process and oversees the integrity of GPhA's financial accounting process.

The **Governance Committee** reviews Association policies with respect to significant issues of responsibility and accountability. The Committee, in conjunction with the Board, reviews and oversees the Association's liability and risk mitigation plans and activities. The Committee reviews and assesses the adequacy of good nonprofit governance principles applicable to the Association.

The **Government Affairs Committee** advises the Board of Directors on the development, coordination and implementation of strategies surrounding federal legislation.

The **International Affairs Working Group** evaluates and comments on international issues of concern to the generic pharmaceutical industry, particularly free trade agreement provisions.

The **Legal Affairs Committee** evaluates all generic drug legal issues and makes recommendations to the Board of Directors with respect to potential action items and/or Association positions.

The **Media Working Group** strategizes on a consensus approach to our most pressing public affairs issues. GPhA member and staff communication leaders participate on this committee.

The **Membership Advisory Committee** is tasked with reviewing all submitted new membership applications to determine if the applicant meets all eligible membership criteria.

The **Reimbursement Working Group** promotes and protects GPhA policy objectives as reimbursement policies for generic medicines are developed and implemented.

The **Science and Regulatory Advisory Committee** drives strategies for science and regulatory agencies and proposes actions to the Board of Directors to address science and regulatory issues.

The **Small and Midsized Company Committee** provides an opportunity for our member companies of this size range to provide a collective voice on matters that are specific to their strategies. Once positions are developed they will be presented to the GPhA Board for consideration.

The **State Affairs Committee** works with coalition partners and allies in state legislatures and regulatory agencies to initiate and promote legislation and policies that advance generic drug utilization.

Member Engagement Opportunities Biosimilars Council

The **Education/Strategic Partnerships Committee** develops education materials for policymakers, providers, patients and others, and leads engagement of these groups for both education and advocacy.

The **Government Affairs Committee** informs member companies of state and federal legislative issues and develops legislative policy positions and strategies. The committee coordinates member company activity, working to secure public policy and legislation favorable to the biosimilars industry at the local, state and federal level. The committee leads relationship building for political strategy and priorities in the federal and state legislative government branches.

The **Legal/IP Committee** tracks key biosimilars legal and intellectual property issues, identifies opportunities to submit amicus briefs, and makes recommendations to the Board around potential action items and/or positions.

The **Regulatory Committee** develops strategies, tactics and metrics regarding all science and regulatory matters and issues. Once approved by the Council Board, these will be implemented by the GPhA staff with coordination and collaboration of Committee members. This Committee will have direct interface responsibility with all U.S. Agencies for science and regulatory matters.

The **Reimbursement Committee** ensures that reimbursement policies for biosimilars are developed and implemented in a manner that supports Council policy objectives.

The Who, Why and What of GPhA Membership

Who is GPhA? GPhA is a trade association for the generic pharmaceutical industry. Our membership includes manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA represents its member companies on matters pending before Congress, the Administration, regulatory agencies and the courts.

Who belongs to GPhA? Our membership includes the world's largest generic finished dose manufacturers and active pharmaceutical ingredient suppliers. GPhA member companies supply nearly 90 percent of the generic prescription drugs dispensed in the U.S. each year. Distributors, pharmacy benefits managers, contract research organizations, packagers and legal counsel groups also benefit from the value of belonging to GPhA.

Why Should My Company Join GPhA? By becoming a part of GPhA, your company can take an active role in helping shape the laws, regulations, and policies that govern the

generic pharmaceutical industry and help secure the future of this vital pharmaceutical market segment. This is accomplished through the member committee structure. GPhA has over 10 committees that our member companies initiate and drive, including Science and Regulatory Advisory, Legal Affairs, Government Affairs and International Affairs.

What Kinds of Memberships are Offered? GPhA extends two types of membership. Regular Members are corporations, partnerships or other legal entities whose primary U.S. business derives the majority of its revenues from sales of (1) finished dose drugs approved via ANDAs; (2) products sold as authorized generic drugs; (3) biosimilar products; or (4) DESI products. Associate Members are entities, other than Regular Members, who are allied with the interests, needs and policy positions of the generic pharmaceutical industry; including, but is not limited to: API suppliers, contract research organizations, distributors, pharmacy benefit managers, consultants, laboratories, packagers, legal counsel groups and pharmaceutical brokers.

The Who, Why and What of Biosimilar Council Membership

Who is the Biosimilar Council? GPhA's new Biosimilars Council provides education, regulatory, legislative, and advocacy services for companies investing in the emerging biosimilars marketplace. GPhA is well positioned to represent this growing business area given its long track record of success supporting the generics industry and the broad participation in the biosimilars marketplace by several of its current members.

Who belongs to the Biosimilars Council? All companies working to develop biosimilar products with the intent to compete in the U.S. market are welcome as full members. These companies may already be members of GPhA, or they may be new to the organization. The goal is to have a "big tent" to bring as much of the industry under one roof to maximize our access and influence as the forces shaping our industry flow through the political and regulatory channels.

Why Should My Company Join the Biosimilars Council? Biosimilars are one of the most important opportunities to bring more affordable medicines to the United

States market and the patients that need them. The global biologics market will reach more than \$250 billion in value by 2020. Without lower cost alternatives to these important therapies, these medicines will remain out-of-reach for many Americans who need them. FDA's March 6, 2015 approval of Zarxio™ (filgrastim-sndz), the first biosimilar medicine in the United States, heralds a new era for cancer patients and the American health care system, one where access to safe, affordable versions of lifesaving biologics will finally be a reality. Consumers, employers, private insurers, taxpayers, state governments and federal programs all will benefit from the advent of biosimilars, as intended by the Biologics Price Competition and Innovation Act (BPCIA) that was enacted as part of the Affordable Care Act.

What Kinds of Memberships are Offered? The Biosimilars Council currently offers a single category of membership to any organization working to develop biosimilar products with the intent to compete in the U.S. market.



Today's Generic Drug Savings Help Fund Tomorrow's Health Innovation

Generic drugs drive savings to the U.S. health care system, not costs. Generics make up 88% of U.S. prescriptions dispensed at only 28% of drug costs. Savings from generics make spending on innovation possible, providing the headroom for investments in cancer research and other areas. We can continue to grow generic savings and increase patient access **if** Congress prioritizes pharmaceutical competition.

Learn more at gphaonline.org

BROUGHT TO YOU BY

GPhA
Generic Pharmaceutical Association



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