GENERIC PHARMACEUTICAL ASSOCIATION ANNUAL REPORT

GPhA
Generic Pharmaceutical Association

2014

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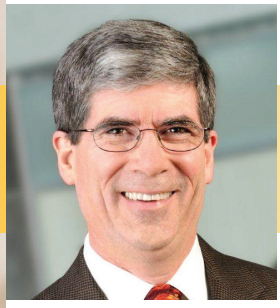


Letter from the Chair

Craig Wheeler
Chairman of the Board
Generic Pharmaceutical Association

For GPhA and our member companies, 2014 was a year of significant milestones and outstanding achievements. It marked the 30th Anniversary of the Hatch-Waxman Act and ushered in the start of our fourth decade as a productive and vibrant American industry. We saw generic utilization and the savings generated by generic use reach new highs. The first biosimilar applications were accepted by the Food and Drug Administration (FDA), triggering the official beginning of the U.S. biosimilars market. Last year, performance metrics under the generic drug user fee program became applicable to our submissions. We blocked dozens of anti-generic legislative initiatives in states across the country. Our working relationships at the FDA and with our international counterpart associations were never stronger. We worked with scores of strategic allies to amplify our industry's voice on issues from safety labeling to biosimilar naming. I am pleased to share that within our organization, we reported record annual revenues and levels of company engagement. As you read this report, I'm sure you will agree that we had a most remarkable year.

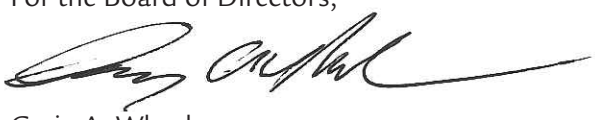
GPhA was founded for the unique purpose of representing the interests of manufacturers and distributors of generic pharmaceuticals and bulk chemicals used to make finished dosage form products. Our work is challenging, but we have become a proactive and strong advocate for our member companies and for millions of Americans who rely on the safe, effective and affordable generic medicines we produce. We have done this by "speaking with one voice" and engaging across all levels of public policy. On the regulatory front, the robust involvement of member companies in our committees, task forces and working groups has delivered substantial and measurable benefits for all generic companies. On the policy front, members have helped develop positioning on emerging reimbursement and cost issues. On the legislative front, member engagement has enabled us to increase our influence and advocacy power on Capitol Hill and at the state level. We raised our profile with both trade and mainstream media and issued a record number of research reports to increase our credibility with policymakers. With a renewed focus on international activities, we have worked diligently to ensure that trade agreements and harmonization actions do not become fertile ground for initiatives designed to disadvantage generic utilization in the U.S. and around the world.

As you know, our industry is changing rapidly and we face many challenges in the coming years. Acquisitions, emerging worldwide

markets, growth in specialty drugs, consolidated purchasing, and expanded health care have transformed us into an industry of global companies competing in both the generic and the brand market spaces. This evolution within the generic industry is expected to accelerate over the next five years as companies continue to build economies of scale, develop proprietary pipelines to boost revenues, and enhance technological expertise to compete in specialty and biosimilar markets. At GPhA, we have never been better positioned to meet the challenges that arise from these new dynamics and respond to the evolving needs of our member companies.

I want to thank the members of the GPhA Executive Committee and the Board of Directors for their dedication to our work in 2014, and their guidance in setting our priorities and defining our mission. I also want to thank the GPhA staff for their tireless work and their exceptional execution of our strategic plan throughout the year. I want to thank Ralph G. Neas, our President and CEO, for his leadership in advancing us toward our goal of being a strong and effective advocate for our member companies, our industry and all Americans who rely on the affordable medicines we provide. And finally, I want to thank each of our member companies for your support and advice. With your engagement and commitment of resources, we have achieved a higher level of success and excellence. I look forward to our continued journey together.

For the Board of Directors,



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

GPhA 2014 BOARD OF DIRECTORS

From the front row left: Thomas Moore (Hospira); Craig Wheeler (Momenta); Marcy Macdonald (Impax); John Ducker (Fresenius Kabi)
From the back row left: Paul McGarty (Lupin); Jeffery Glazer (Heritage); Doug Boothe (Perrigo); Joseph Renner (Zydus); Allan Oberman (Teva); Chirag Patel (Amneal); Peter Goldschmidt (Sandoz); Tony Mauro (Mylan); Jeffery Watson (Apotex); Chuck Caprariello (Ranbaxy)

From the President and CEO

Ralph G. Neas
President & CEO
Generic Pharmaceutical Association

It is my privilege to lead our Association as we soar to new heights in our mission to improve the lives of patients by advancing timely access to affordable generic medicines. Even as the pace of change in our industry and the health care landscape quickens, the value proposition of generic medicines remains a critical component of the sustainability of the U.S. health care system.

Recently, an FDA Advisory Committee unanimously recommended that the Agency approve what will be the first biosimilar medicine in the United States. This is an historic development for millions of patients awaiting access to safe, affordable versions of biologics, and an appropriate bookend to our 2014 Annual Meeting when we kicked off a year-long celebration of the 30th anniversary of the landmark Hatch-Waxman Act. With emerging opportunities from a global pharmaceutical marketplace, plus expanded health coverage here at home, our industry has never been stronger.

Last year, our Association made substantial progress toward achieving our strategic objectives. We continued to enhance our working relationship with FDA, including improvements to the generic drug user fee (GDUFA) implementation, through quarterly meetings between the Agency and our Board of Directors. Then in September, more than 20 member companies attended an FDA public hearing to call attention to areas in which implementation of GDUFA could be strengthened.

We also successfully highlighted patient safety and savings concerns around the FDA's proposed rule on generic drug labeling, amplifying our voice with the support of dozens of strategic allies and many members of Congress, and with survey data showing doctors and other healthcare providers strongly favor requiring FDA approval prior to any change in generic drug labeling. We championed legislation to end the abuse of REMS and restricted access programs, we continued robust support for e-labeling, and we fought to defend our interests in international trade negotiations.

At the state level, GPhA is supporting compromise legislative language that would allow interchangeable biologics to be automatically substituted at the pharmacy, reflecting our core principles of upholding current pharmacy practice, insisting on FDA determination of interchangeability, and treating all approved interchangeable biologics and their reference biologics equally. And we worked with PhRMA, BIO

and CHPA to address the legal, compliance, legislative, and educational aspects of drug disposal.

In a banner year for new research, GPhA published its sixth annual generic drug savings report, showing that the use of generic medicines in the U.S. saved our health care system more than $1.46 trillion over the past decade, $239 billion in 2013 alone. Yet misinformation about generic drug prices garnered significant media coverage. GPhA will continue to vigorously defend the value of generics as the solution to drug cost containment.

In 2015, we also will continue opposition to efforts to unnecessarily increase exclusivity for brand name products that would delay patient access to generics and increase costs to taxpayers. We will promote policies to increase generic utilization in order to encourage new drug innovation and competition.

This will be a pivotal year, but by harnessing the dedication of our GPhA team and the support of our member companies, we will reach ever greater heights of advancing generic access on behalf of patients, the industry and our nation's health care system.

Thank you for your continued support of our Association.

Warm regards,

Ralph G. Neas
President & CEO

6 Association Highlights

2014 was the year we celebrated three decades of phenomenal achievements made possible by the landmark Hatch-Waxman Act, the extraordinary legislation that since 1984 has provided millions of Americans access to safe, effective and affordable prescription drugs. To sustain this success, GPhA is dedicated to promoting and protecting the strategic interests of our member companies across multiple fronts. And while we made significant progress toward that goal in 2014, we know 2015 will hold many new and demanding challenges.

Much to Celebrate on Biosimilars

Five years after enactment of the Biologics Price Competition and Innovation Act, we were at last witnessing significant activity around biosimilars. The Food and Drug Administration (FDA) published the all new 'Purple Book,' listing biologic drug patents, exclusivities, and future interchangeable products; the first ever appellate court case involving a biosimilar application began; and just last month, FDA's Oncologic Drugs Advisory Committee met and voted unanimously to recommend approval of filgrastim, a Sandoz biosimilar, for each of the five indications of the counterpart brand biologic. Moreover, the FDA revealed in late summer that it had held dozens of meetings with biosimilar manufacturers to discuss the processes leading up to filing of at least 14 different brand biologic products and in 2014 the FDA accepted three biosimilar applications. The Congressional Affordable Medicines Caucus sponsored a briefing on biosimilars with a panel of experts comprised of key strategic allies and a GPhA member company. Add to these events the release of a new industry guidance on biosimilarity and another on exclusivity, and the picture is clear: the U.S. biosimilars market has taken flight. Yet, while we know the future for biosimilars is as bright as it was for small molecule drugs 30 years ago, there remain challenges to achieving the full potential of better health and increased savings.

- ***Biosimilars Naming:*** During 2014, the debate continued over how to assign international non-propriety names (INNs) to biosimilars. In July, the World Health Organization proposed adding a "Biological Qualifier," a random sequence of letters, to biosimilar names. GPhA's Biosimilar Working Group submitted a response to the proposal expressing our concern that such a designation would create confusion and lead to multiple labels for a single product when a company manufactures the same product at multiple sites. We also advocated that the naming system must be applicable to all biologic products, not just biosimilars. The Biosimilars Network also was actively engaged on this issue in 2014. On June 3, GPhA held a targeted luncheon briefing attended by 14 strategic partners from the pharmaceutical supply chain. By July, a total of 32 organizations had signed a letter calling on FDA to require biologics and biosimilars to have the same INN. The letter had strong representation from a variety of key stakeholders including patients, labor, providors and payors. GPhA and its member companies regularly visited Capitol Hill, the White House, the Department of Health and Human Services and the FDA advocating our position. Further, on September 15 and 16, more than a dozen Biosimilars Network members representing a diverse cross-section of health care stakeholders joined with our member companies and participated in approximately 20 bipartisan, bicameral Hill meetings. FDA has not yet responded to any of the citizen petitions concerning naming,

including one filed by GPhA. We will continue our advocacy efforts to influence this key issue in 2015.

- ***Substitution:*** In December, just in time for the 2015 state legislative sessions, an important compromise among parties on all sides of the issue was reached over the issue of notification requirements when substituting interchangeable biosimilars for their corresponding branded biologics. The "compromise automatic substitution legislation" will allow biosimilars designated by FDA as interchangeable to be automatically substituted by pharmacists without checking with or onerously notifying doctors before making the switch. The compromise reflects our core principles: upholding current pharmacy practice, insisting on the science-based FDA determination of interchangeability, and treating all interchangeables and their corresponding brand biologics the same.
- ***Reimbursement:*** In anticipation of the approval of biosimilars, and reflecting feedback from our members that this issue is a significant priority, GPhA organized a new Reimbursement Working Group. The Working Group promotes and protects GPhA policy objectives as reimbursement policies for generic and biosimilars medicines are developed and implemented. The full Working Group will discuss overarching reimbursement policy issues, while smaller task forces will address specific reimbursement issues, such as the 340B "Mega Rule."

GDUFA Engagement Takes Center Stage with FDA

Throughout 2014, GPhA continued to enhance its working relationship with FDA and the Office of Generic Drugs (OGD). One example of our significant progress is the quarterly meetings between the GPhA Board of Directors and the Agency to maintain open communications and transparency through the GDUFA implementation process. Year three of the five-year generic drug user fee program began October 1, meaning that GDUFA performance goals began applying to generic drug submissions and facility inspections. In September, more than 20 member companies attended an FDA public hearing to call attention to areas in which implementation of GDUFA could be strengthened. GPhA continues to work with its Congressional allies to improve the Agency's implementation. GPhA believes that the optimal way to ensure success of the GDUFA program is through continued collaboration and ongoing feedback from the generic industry on critical components of the program. Last year, generic companies paid over $300 million in fees to support the three core public health aims of GDUFA: safety, access and transparency. To that end,

GPhA advocated that FDA dedicate the added resources toward addressing the backlog of Abbreviated New Drug Applications (ANDA), which has grown from a median approval time of 31 months in FY2012 to an estimated 42 months in FY2014, and Prior Approval Supplement (PAS) submissions. It is our hope this will help orient FDA's new staff to the longstanding mission of OGD which is centered on Hatch-Waxman's purpose to stimulate competition by getting generics into the hands of patients on the earliest legally possible date. For GDUFA to be successful it must be implemented in a way that is mindful of the realities of the generic drug marketplace, and that continues to incentivize the development of generic medicines. We are encouraged by the FDA's recent plan outlined in December to carry out FDA's promise from early 2014 to increase communication for active ANDA's and to work to significantly increase the approvals of backlogged ANDAs.

GPhA also is working with the Agency and with companies in the brand sector on the FDA-EU mutual reliance initiative. And to address quality, GPhA formed the Quality Technical Group (QTG) to discuss overall quality metrics, culture and other quality-related topics. The QTG is a unified voice for quality in the generic drug industry. In September, QTG members met with Dr. Janet Woodcock, Director of the FDA Center for Drug Evaluation and Research, to share our mission and commitment.

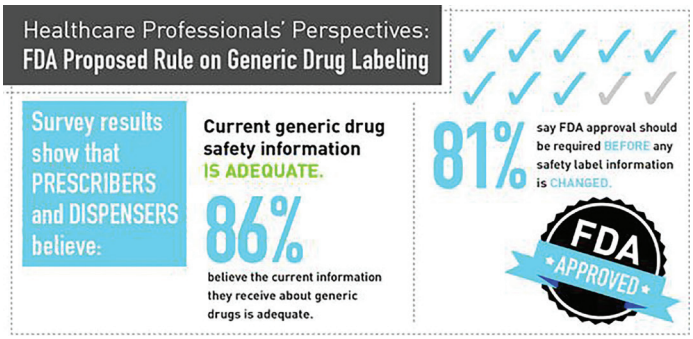
Encouraging a Labeling Alternative

Throughout 2014, GPhA continued our drumbeat around patient safety concerns posed by the FDA's proposed rule on generic labeling. We commissioned a study that found the rule would add $4 billion dollars annually to the nation's already high health care costs; $1.5 billion in new spending for Medicare and other government programs each year, and $2.5 billion per year for private insurers and patients. The study, by Matrix Global Advisors, was highlighted at a Congressional briefing in February and was referenced in many letters from Congress in opposition to the proposed rule. Dozens of strategic allies representing consumer, patient advocacy, minority, disability, and veterans groups, along with supply chain partners and several Members of Congress weighed in with the agency in support of our position.

GPhA also commissioned a survey of physicians, physician assistants and pharmacists, which showed that 81 percent of respondents believe FDA approval should be required prior to making generic drug safety label changes. And in April testimony before the House Energy and Commerce Subcommittee on Health we emphasized the Agency's role in approving all changes to safety labeling.

Proactively, GPhA developed the "Expedited Agency Review" (EAR) alternative to the rule. The EAR recognizes that FDA is the only recipient of all relevant data needed to make label changes; and therefore, is a science-based alternative to the Agency's plan of allowing generic manufacturers to independently change the safety information on the product labeling. GPhA presented this alternative to the Agency in May.

A key component of the EAR is electronic labeling, or e-labeling, which FDA says will help ensure that the most current drug safety information is publicly accessible. In December, GPhA applauded FDA's release of its long-awaited e-labeling proposed rule requiring that prescribing information be distributed to health care professionals in an electronic format. This streamlined 21st Century approach to label information sharing could mark a significant step forward for everyone who relies on updated prescribing information for patients. GPhA looks forward to working with FDA to finalize this rule, strengthen patient safety and improve public health through more effective information exchange. GPhA will be submitting formal comments on the e-labeling proposed rule early in 2015.



In November, FDA announced that it was delaying release of a final generic labeling rule until the fall of 2015. Notably, the year-end government funding bill passed by Congress in December calls for a listening meeting between the drug industry and the FDA to consider alternative solutions to the controversial rule, following earlier legislation that contained bi-partisan sponsored language raising safety concerns around the proposed rule. GPhA, however, has made it clear that should the rule be finalized as drafted, the Association will commence legal action.

Measurable Progress on REMS and Restricted Access Program Abuse

Amid continuing reports that FDA drug safety programs were being abused to prevent generic competition, GPhA made great strides in spotlighting this issue for policymakers and legislators. The misuse of Risk Evaluation and Mitigation Strategies (REMS) and other restricted access programs is costing the American health care system and patients $5.4 billion annually in unnecessary pharmaceutical spending, according to a Matrix Global Advisors analysis. The study also found that after biosimilars enter the market, such abuses would result in approximately $140 million in lost savings for every $1 billion in biologics sales. In September, months of GPhA and member company advocacy resulted in the introduction of the Fair Access for Safe and Timely (FAST) Generics

Act by Representatives Steve Stivers (R-OH) and Peter Welch (D-VT). If enacted, the law would effectively prohibit companies from adopting restricted access practices solely as a strategy to avoid generic competition. Although the FDA issued a draft guidance in December to remove hurdles encountered by generic companies seeking samples of brand name products to perform the bioequivalence studies needed for ANDA submissions and approvals, the Agency acknowledges that it lacks the authority to address the "increasingly aggressive use of" REMS to block generics and biosimilars from reaching the marketplace. For this reason, GPhA remains committed in 2015 to securing legislation to address the issue.

Blocking Anti-Generic Initiatives in State Legislature

GPhA's state government affairs team, working alongside our member companies and allies, tracked and were engaged in 298 bills in 40 state legislatures in 2014. Many of these initiatives, if they had been passed into law, would have had the effect of dampening generic substitution and restricting access to lower-cost generic and biosimilar products. Our activities included providing expert testimony, educating legislators and policymakers, direct advocacy before the Democratic and Republican Governors Associations, and submitting formal comments to state boards of pharmacy. We championed the message that increasing the use of safe and effective generic medicines can bend the cost curve in state-sponsored prescription drug benefit programs.

Pharmaceutical Waste Disposal Initiatives Remain Strong

In September, the 9th Circuit Court of Appeals affirmed an August decision from the U.S. District Court for the Northern District of California finding that a first-in-the-nation drug disposal ordinance passed by Alameda County (California) was not unconstitutional. GPhA, along with PhRMA and BIO, have petitioned the U.S. Supreme Court for review of the case. Similar litigation continues in King County, Washington. On the compliance front, the Pharmaceutical Product Stewardship Working Group, which includes many GPhA member companies, submitted to the county its plan to comply with the regulation, including new rules issued by the Drug Enforcement Administration (DEA) in September to regulate disposal of controlled substances. While there were 52 drug take-back bills introduced in 14 states in 2014, many more are expected in 2015. As the industry considers the potential alternative legislative approaches to the issue, GPhA has joined BIO, CHPA and PhRMA in undertaking a national consumer education initiative around drug disposal.

Opening Markets Through Balanced Trade Agreements

GPhA continued its engagement on the two global free trade agreements under negotiation in 2014: the 12-country Trans-Pacific Partnership (TPP) and the U.S.-EU Trans-Atlantic Trade and Investment Partnership (TTIP). Speaking at a press conference at the National Press Club in December, GPhA President and CEO Ralph G. Neas said industry has serious concerns that the TPP fails to strike the right balance between fostering innovation and ensuring expedited access to more affordable medicines. He cautioned against the danger of doing too much to extend already generous monopolies enjoyed by brand-name drugs and too little to ensure that safe, low-cost generic versions are available to patients as soon as legally possible. Moreover, the TPP would lock in policies covering biologic medicines that would contribute to putting these very expensive

drugs and vaccines beyond the reach of patients and governments. GPhA believes that the current TPP would close markets for generics and limits an avenue of vigorous growth for the U.S. economy. U.S. generic manufacturers have become major exporters, whose future growth rests on their ability to sell their products in other nations, business that can be facilitated by balanced free trade agreements.

With respect to the TTIP, negotiations remained in the early "pre-decisional" stage in 2014, which presented us with the optimal time to offer ideas to the negotiators. To follow up on presentations in Brussels in March and July, GPhA attended a stakeholder presentation and briefing in the TTIP seventh round in Washington in October. Going forward, GPhA will keep up the pressure on trade negotiators to ensure that international free trade agreements facilitate access to global markets.

Advocating in Support of Our Mission

There were myriad other issues in which we were engaged in 2014, including: advocating for increased generics utilization for the Medicare Part D Low Income Subsidy population, challenges to the structure of Hatch-Waxman, promoting the Affordable Medicines Caucus in Congress and assisting with their Hill briefings, and guarding against unreasonable track-and-trace policies. In dozens of speaking engagements, media interviews, Congressional visits and public presentations throughout the year, the GPhA team made the compelling case that generic drugs are the backbone of the U.S. pharmaceutical market and the solution to providing sustainability to the nation's health care system.

And as Congressional committees began exploring new ways to encourage the development of new cures for disease, GPhA continues advocacy efforts to ensure that policy makers understand the benefits of Hatch-Waxman and the importance of maintaining a balance between innovation and competition.

As we look ahead to the challenges of 2015, GPhA will build on the momentum of 2014 in service to our mission of maintaining a regulatory and legislative environment most conducive to optimizing the benefits of generic and biosimilar medicines.

Driving Access, Savings, & Innovation

The Hatch-Waxman Act of 1984, the landmark legislation that serves as the foundation of the modern-day generic drug industry, turned 30 years old on September 24, 2014. To celebrate the benefits of Hatch-Waxman for patients and consumers, as well as its positive impact on market competition and new drug innovation, GPhA conducted a month-long series of activities encouraging media, stakeholders, and industry to join in acknowledging the remarkable success of this extraordinary law.

White House Rose Garden, 1984. President Reagan signs the Hatch-Waxman Act of 1984.

Throughout September, the GPhA team created and circulated materials that leveraged the anniversary to raise awareness of the incredible contribution generic medicines have made to the sustainability of the U.S. health care system over the past 30 years. We also used this opportunity to highlight the bright future of generics and biosimilar medicines.

The centerpiece of this effort was our 30th Anniversary Report, "Hatch-Waxman: Driving Access, Savings, & Innovation," which we widely disseminated to Members of Congress and strategic allies.

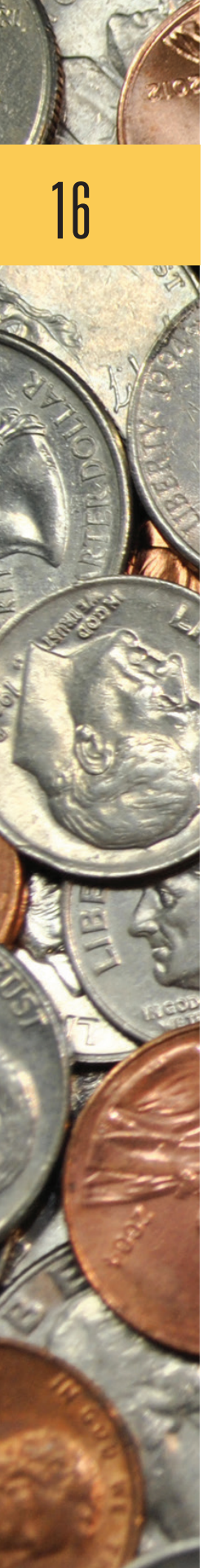
A press release on the day of the anniversary, plus an op-ed in Chain Drug Review, focused on the opportunities that lie ahead as we continue providing affordable generic drugs and move into the next frontier of medicines, lower-cost biosimilars. To complement the successful press coverage, our Media and Communications team sent daily tweets during September with facts and background about the law under the hashtag #HWturns30.

Independent press statements lauding the anniversary were released by Senator Orrin Hatch, NACDS, PCMA and other strategic partners.

Our celebration activities culminated on September 30 with a grand Hatch-Waxman 30th Anniversary reception at the GPhA offices in Washington, D.C., where supporters and friends gathered to commemorate the occasion of this significant event.

GPhA hosts roof-top reception to celebrate the 30th Anniversary of Hatch-Waxman.

Generics: Keeping Medicines Within Reach



GENERIC DRUGS: Keeping Medicines Within Reach for Patients

Generic medicines provide one of the clearest value propositions in health care today: they represent 86 percent of the drugs dispensed, but account for just 27 percent of U.S. pharmaceutical costs. And our industry's products continue to save the U.S. health care system hundreds of billions of dollars each year. The 2014 Generic Drug Savings in the United States report, compiled by the IMS Institute for Healthcare Informatics on behalf of GPhA, quantifies the savings generics deliver.

Generic Savings Continue to Increase

In the most recent decade, generics saved the U.S. health care system nearly $1.5 trillion. That is $239 billion in 2013 alone, up from $209 billion in 2012, representing a 14 percent increase in a single year.

To put the importance of these savings into context, health care spending comprises over 17 percent of the Gross Domestic Product (GDP) and remains a major investment by patients and taxpayers, federal and state governments, and payer organizations.

Generics Help Slow Health Spending Growth

In 2013, total spending on U.S. medicines increased 1.0 percent on a real per capita basis and the use of health care services overall rose for the first time in three years, according to separate findings from the IMS Institute for Healthcare Informatics.[1] Although drug spending levels continue to contribute to slower growth in overall healthcare spending, total dollars spent on medications in the United States reached $329.2 billion last year. Patent expiries in 2013 contributed $19 billion to the reduction in medicine spending, compared to $29 billion the previous year. Concurrently, 36 New Molecular Entities were launched in 2013, the largest number in a decade[2], demonstrating that competition spurs innovation. Taken together, these data show that the availability of generic medicines and policies that promote their utilization are vital to holding down health costs.

The report also highlights the important contribution that our member manufacturers, wholesalers and supply chain partners play in holding down health costs. Access to generics and the resulting savings from these more affordable medicines is critical.

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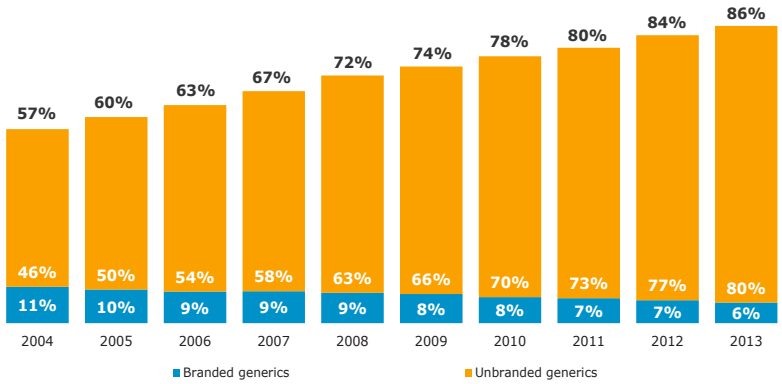
[1] *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013. IMS Institute for Healthcare Informatics, April 2014.*

[2] *Ibid.*

Generic Drug Savings in the U.S.

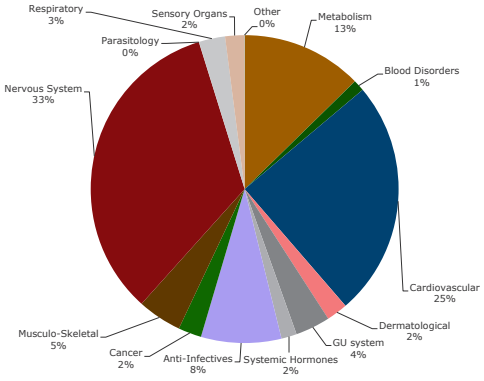
Generics share of prescriptions

Generics now account for 86% of all dispensed retail prescriptions

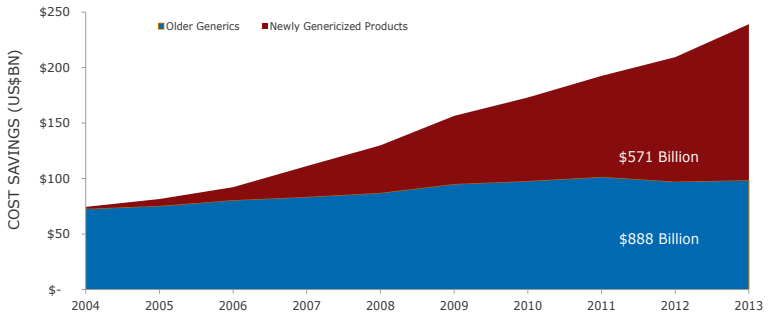


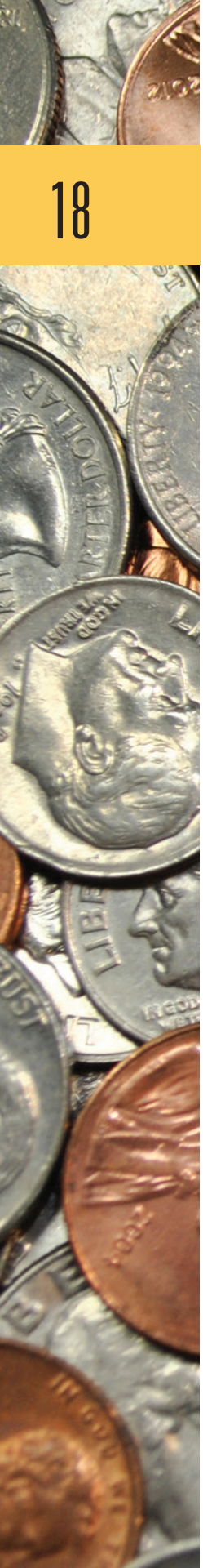
Generics Cost Savings by Year (2004-2013)

Generics Cost Savings by Therapeutic Areas (2004-2013)



Generics Savings over Time (2004-2013)

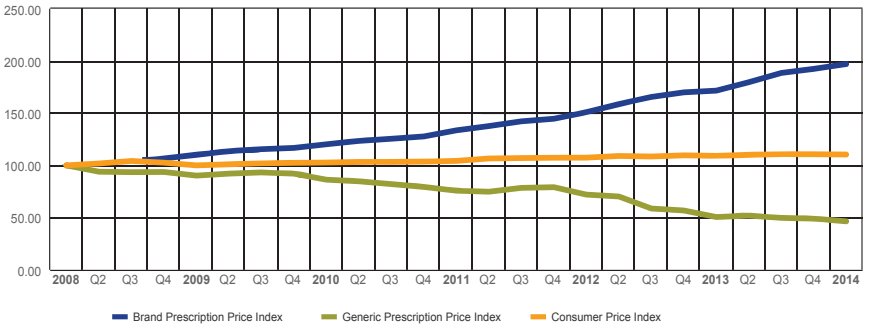




Generic Drug Costs in the U.S.

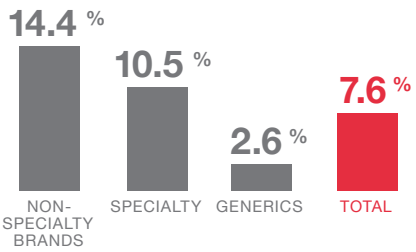
The Express Scripts Prescription Price Index

Prices for brand drugs grew but those for generic drugs dropped in 2013 compared to 2012.



The 2013 Drug Trend Report. The Express Scripts Lab.

2013 AWP TREND



Insights 2014: 7 Sure Things. CVS Health.

4.5% Increase in Utilization for Generic Drug Prescriptions

-0.5% Decline in Prices Paid for Generic Prescriptions

2013 Health Care Cost and Utilization Report. Health Care Cost Institute Inc.

Ingredient costs, 2013 vs. 2012	2013 net ingredient cost	Change from 2012
All traditional	$47.23	−1.0%
Brand-name	$161.15	10.0%
Generic	$19.84	1.7%
Specialty	$3,149.25	14.4%
Overall	**$58.99**	**2.2%**

"Despite higher ingredient costs for both brand-name and generic drugs, traditional drug costs actually decreased in aggregate (-1.0 percent). This is because of a continued shift toward generics and other less expensive traditional drugs."

2014 Report On Prescription Drug Costs. Prime Therapeutics.

Despite the incontrovertible evidence of savings and value, reported increases in the prices of some generic drugs generated significant media and Congressional attention last year. Many of the reports and rhetoric contained misinformation about generic drug prices or inaccurately conflated generics prices with those of high-cost specialty brand drugs. In October 2014, Senator Bernie Sanders (D-VT) and Representative Elijah Cummings (D-MD) sent letters to 14 companies seeking information around the rising prices of some generic drugs. Sen. Sanders, as Chair of the HELP Committee Subcommittee on Primary Health and Aging, held a hearing on November 20th on this issue, where Rep. Cummings appeared as the lead witness.

Correcting the Record

Working with member companies, GPhA developed and distributed aggressive, fact-based materials rebutting inaccurate data and explaining the industy point of view, blanketing the subcommittee members, media and stakeholders. These materials included a white paper providing an in-depth look at the role of various entities in the supply chain in providing inputs into generic drug prices, and a packet of third-party studies which validates the impact of generic drug savings on the health system.

In our messaging and advocacy, we noted that the most effective way to continue to keep prescription drugs affordable for patients is to increase competition in the marketplace. In order to do so, Congress should address factors causing delays to generic entry including the current backlog of roughly 3,500 abbreviated new drug applications (ANDAs) at FDA, and REMS abuses. We also emphasized the importance of understanding the role of market forces and FDA compliance actions in influencing prices. The hearing was attended by very few members and Ranking Member Senator Richard Burr (R-NC) successfully counteracted much of the misinformation raised at the hearing, using information provided by GPhA.

Misguided Legislation

Sen. Sanders and Rep. Cummings also introduced legislation which would require that if a manufacturer of a generic drug raises its price faster than inflation, the company must also provide an additional rebate to Medicaid as innovator drugs are required to do today in the Medicaid program. This is a proposal pulled from the President's FY15 budget which Sen. Sanders cites as scoring $500 million over 10 years.

GPhA issued a strong statement in opposition to the legislation, noting that it reflects a basic misunderstanding of the pharmaceutical marketplace, and attempts to impose brand pharmaceutical provisions on generic drugs. GPhA also proactively contacted key strategic allies from labor unions, consumer groups, public sector employee retirement systems and supply chain partners to educate them around the legislation, noting that this effort is misguided and will threaten patient access to affordable medicines. However, we may see similar legislation introduced in 2015.

GPhA staff will be working closely with the Board and member companies in the year ahead as this issue remains in the spotlight. Together, we will continue to vigorously defend the value of generics in helping to achieve drug cost containment.

20 The Industry

The Generic Industry in the United States: Delivering Savings, Improving Health & Driving the Economy

That the generic pharmaceutical industry delivers extraordinary savings, ensures access to affordable medicines, and provides sustainability of the U.S. health care system is well-understood. But in addition, the generic industry is a strong contributor to the U.S. economy. As manufacturers, research laboratories, suppliers of goods and services, and distributors of quality products, we employ thousands of workers in states across the country. A 2014 study by Tufts University's Center for the Study of Drug Development found that the 108 generic companies operating in the U.S. together employ more than 128,000 individuals in 30 states and Puerto Rico.

As a key partner in the health care supply chain, the effect on the U.S. economy of the generic industry goes far beyond the 9.5 million generic prescriptions dispensed every day and the nearly $4.6 billion saved every week.

But that is just the beginning of how the generic industry contributes to the economy. Generic manufacturers, and the products we sell, help mail order, retail and community pharmacies, pharmacy benefit managers, hospitals, wholesalers and distributors, and other businesses drive their profits.

For example, CVS Health, the nation's largest pharmacy chain, said last year profits grew measurably as its generic dispensing rate topped 80 percent. The company noted that growth has been boosted over the past years by the introduction of several new generics, including generic versions of the blockbusters Lipitor®, Plavix® and Lexapro®. It added that the influx of new generic drugs was a key driver of year-over-year profit growth.

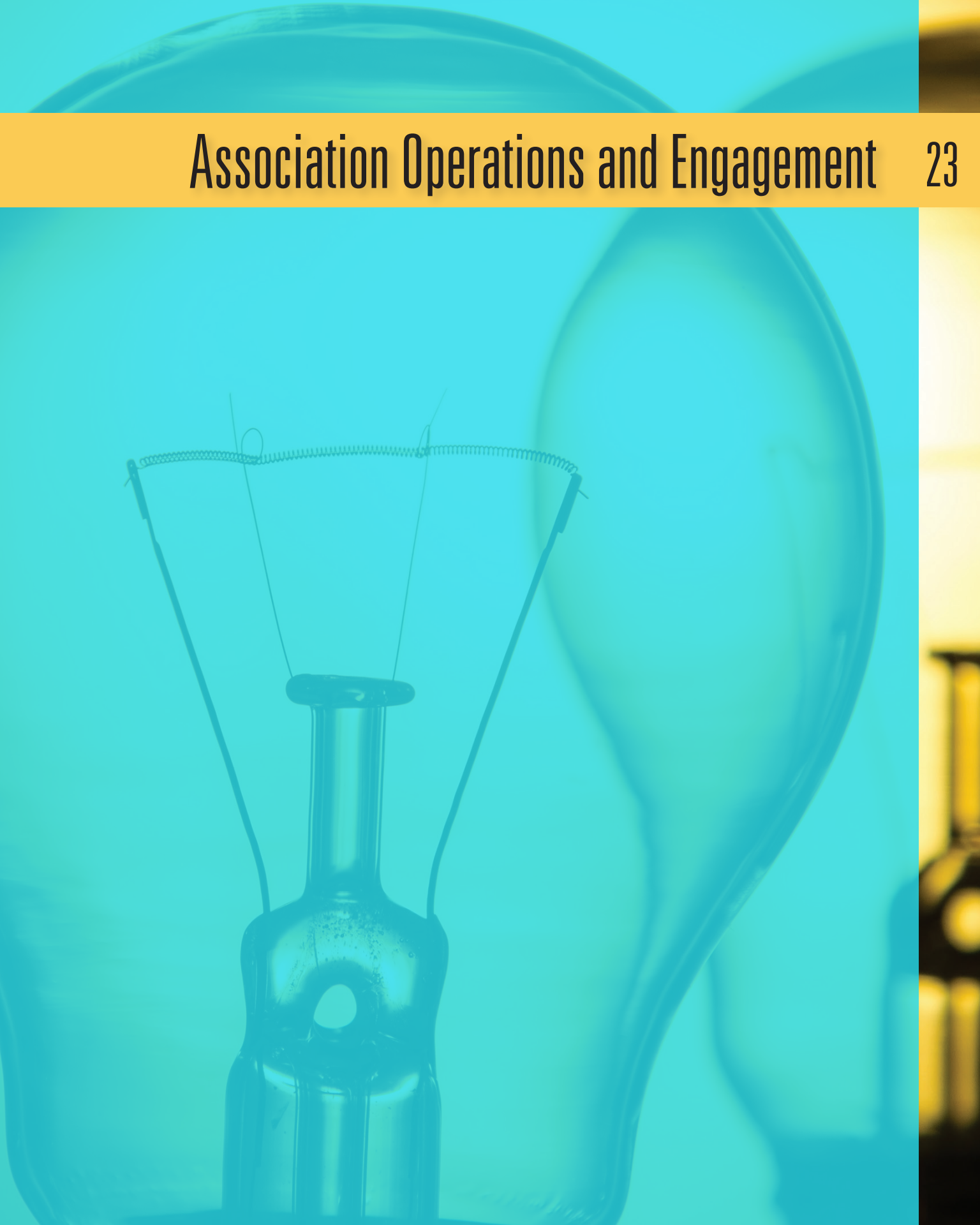
With respect to pharmacy benefit managers, the ability to maximize generic opportunities for clients by way of effective formulary use significantly expands margins. And in the wholesale business space, the story is similar. McKesson, Cardinal Health and AmerisourceBergen, companies that sell drugs to healthcare providers such as hospitals, pharmacies and clinics, also profit from generic distribution because it involves lower inventory costs and general operating expense. Because generics are sold in a highly commoditized market, they have a large reliance on wholesalers. Competition among generic manufacturers allows wholesalers to extract better terms from manufacturers, hence the much higher profit margins with generics than with branded drugs.

Corporations also benefit from generics as the cost per life in company-sponsored health plans is lowered as generic use increases. Data from Premera Blue Cross, for instance, show that companies pay about $211 for a 30-day prescription of Ambien® to treat insomnia, but only $33 for the 30-day prescription of the generic equivalent zolpidem. The brand version of the anti-seizure drug Lamictal® costs $451 a month, compared to $77 for the generic version. In total, commercial third-party payers, including corporations and insurance companies, saved $91 billion in 2012 and $583 billion over the decade 2003-2012 by using generic versions of higher priced brand name medicines.

The record is clear: the generic industry has a profound effect on both the economy and on the nation's public health system. As a key partner in the health care supply chain, the contribution and influence of the generic industry go far beyond the 9.5 million generic prescriptions supplied every day and the nearly $4.6 billion saved every week. In every sense, the generic industry is the back-

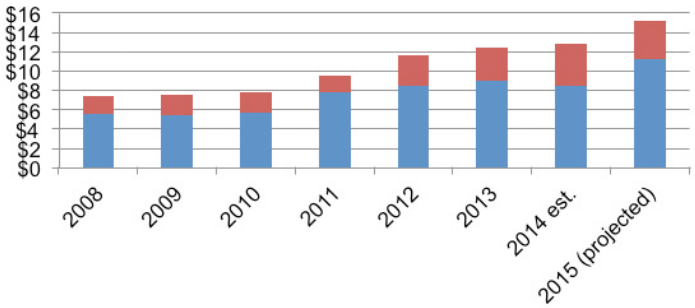
bone of pharmaceutical care, helping to improve the lives of millions while generating substantial to the health care system and contributing to the success of pharmacies, retailers, pharmacy benefit managers, wholesalers, insurers and corporations across America.

Association Operations and Engagement 23

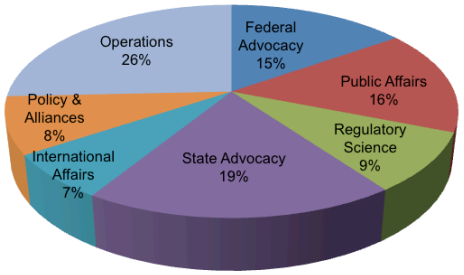


Operations

Total Revenue ($ In Millions)



2015 Expense Allocation By Cost Center



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Associate Manager, Meetings

Member Engagement Opportunities

Committees, Task Forces and Working Groups

Audit & Finance Committee
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.

Biosimilars Working Group
The Biosimilars Committee monitors the implementation of the approval pathway for biosimilars and engages with the FDA, Congress, and the Executive Branch.

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

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

Labeling Special Committee
The Labeling Special Committee updates member companies on all activities concerning the Proposed Rule on Labeling.

Legal Affairs Working Group
The Legal Affairs Committee evaluates all generic drug legal issues and makes recommendations to the Board with regards to potential action items and/or association positions.

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

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

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

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

State Affairs Committee
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.

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 benefit 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 part of GPhA, your company can take an active role in helping shape the laws, regulations, policies, etc. that govern the generic industry. This is accomplished through the member committee structure. GPhA has over 10 committees that our member companies initiate and drive, including Sciences and Regulatory Affairs, Biosimilars, Legal Affairs, Government Affairs, State Affairs, International Affairs, etc.

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 development, commercialization, manufacture, sales, and/or marketing 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 not limited to, API suppliers, contract research organizations, distributors, pharmacy benefit managers, consultants, laboratories, packagers, legal counsel groups and pharmaceutical brokers.

Engagement + Advocacy + Value = Satisfied Members

Contact us today about joining!

Call - 202.249.7100

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