*Celebrating* *Years*

# VALUE & QUALITY

## Our Mission

To execute a WINNING advocacy strategy that optimizes the benefits of generic and biosimilar medicines; to CREATE and maintain a regulatory and legislative environment that facilitates the ROBUST GROWTH of our member companies; to champion the message that generic drugs are a fundamental SOLUTION to the sustainability of affordable health care.

# CONTENTS

# FROMtheChairman

**Tony Mauro**
GPhA 2013 Chairman of the Board

In 2013, GPhA played an important role in furthering the generic pharmaceutical industry's collective goal to improve the lives of consumers by providing timely access to high quality, affordable medicine. Together, as an association strengthened by an engaged and committed membership, we continue to drive quality and value for patients.

This year was full of milestone achievements for GPhA and for our industry. Generic utilization rates in the U.S. hit an all-time high with approximately 84 percent of all prescriptions dispensed being filled with a generic medicine when an equivalent generic alternative is available. More than ever, patients and our pharmacy partners trust in the true value and reliability of the products and health care solutions we provide.

Additionally in 2013, Congress passed the Drug Quality and Security Act to establish a nationwide, reliable system for tracking prescription medicine that further safeguards our nation's prescription drug supply and protects patients. The law also enhances the ability of regulators to limit risks posed by counterfeit or adulterated products and reassures patients that the generic medicines they receive are secure from the manufacturer all the way to the pharmacy.

We should all be proud of – and never underestimate – our role in improving the lives of patients in the U.S. I applaud the work of our member organizations, the GPhA board of directors, the entire GPhA staff and GPhA's president and chief executive officer, Ralph G. Neas, for their hard work and leadership in helping us to achieve these, and many more, great milestones in 2013.

It is amazing to me that it's been nearly 30 years since the creation of the Hatch Waxman Act in 1984, which exponentially accelerated the development of our industry. Since then, we've generated trillions of dollars in savings for the U.S. health care system. Yet, as we shift our sights toward 2014, significant opportunities remain to further drive quality and value for patients across the nation.

To that end, we've made progress implementing, in partnership with the Food and Drug Administration (FDA), the Generic Drug User Fee Act (GDUFA), a landmark piece of legislation that will help to ensure a safe, effective and transparent drug supply in the U.S. market. In 2014, we must continue to study and fulfill our commitments under the law and plan for the upcoming performance metrics phase. GDUFA's success depends on industry and FDA working together, and I am confident in our ability to continue improving the lives of patients by bringing new generic medicines to the U.S. marketplace in a more timely and efficient manner..

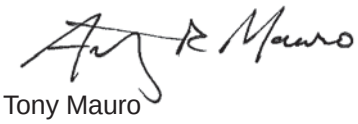
We also must never forget about the importance of continuing our work to build transparent federal and state regulatory frameworks that increase access to generic drugs, including ensuring patient access to interchangeable biosimilars.

In addition, we must work together with FDA to continue educating patients, prescribers, dispensers and payors on the safety and efficacy of high quality, more affordable generic medicines and continue our efforts to ensure labeling clarity and sameness between generic and brand drugs as mandated by law, all while providing passionate leadership as a member-focused association comprised of companies dedicated to advancing policies that strengthen each of these efforts and fighting barriers that seek to limit access to generics.

Ensuring the ongoing development of a successful generic drug system in the U.S. depends on all of us. By further growing and diversifying our membership, and with a focus on long-term sustainability, we will better position GPhA to champion our most meaningful goal: working together to drive quality and value for patients across the country.

I thank you again for your ongoing dedication and commitment to GPhA in 2013 and look forward to seeing what exciting developments 2014 will bring.

Sincerely,



Tony Mauro
President, Mylan North America
Chairman, GPhA Board of Directors

## GPhA 2013 Board of Directors

From the front row left: Craig Wheeler (Momenta); Carole Ben-Maimon (Impax); Charlie Mayr (Actavis); Joseph Renner (Zydus); Debra Barrett (Teva); Chuck Caprariello (Ranbaxy); Jeff Glazer (Heritage).

From the back row left: Tony Mauro (Mylan); Jeff Watson (Apotex); George Stevenson (Kremers Urban); Chirag Patel (Amneal); Don DeGolyer (Sandoz); Thomas Moore (Hospira); Doug Boothe (Perrigo).

# FROM the President & CEO

**Ralph G. Neas**
President and CEO

It is an honor for me to lead GPhA at this extraordinary time for our trade association and the member companies we serve. Our industry is changing at a faster pace today than at any time in recent history. And the growing demand for effective, affordable medicine has put us in the center of the struggle to keep health care costs in check while providing consumers and patients around the world with the value and quality that generic medicines bring.

Along with this changing environment has come several unique and difficult challenges with respect to generic labeling, bioequivalency standards for certain therapeutic categories, physical characteristics of generic tablets and capsules, and biosimilar naming and substitution, to name a few. But we know that success is not the absence of challenges; rather, it is the ability to face challenges head on and keep on advancing.

In 2013, we made excellent progress together in meeting challenges and achieving our strategic goals. We worked to support the Drug Quality and Security Act to establish a nationwide, reliable system for tracking prescription medicine that further safeguards our nation's prescription drug supply and protects patients. The law also enhances the ability of regulators to limit risks posed by counterfeit or adulterated products and reassures patients that the generic medicines they receive are secure from the manufacturer all the way to the pharmacy.

In the states, we challenged legislation that would hinder access to biosimilars and interchangeable biosimilars. Bills were introduced in 19 states in 2013, blocked in 11, enacted with significant amendments in three states, and enacted with Amgen and Genentech-backed provisions intact in only one state (North Dakota).

Also in 2013, the Supreme Court reaffirmed the constitutionality of patent settlements with consideration and preserved the unprecedented success of the current path for getting generics quickly to patients and consumers.

Our Regulatory Sciences team enhanced their working relationship with the FDA to its highest level ever as we collaborated with regulators on issues related to biosimilar approvals, Quality by Design, and GDUFA implementation. And we continued to protect our interests during negotiations of the Trans-Pacific Partnership, the Transatlantic Trade and Investment Partnership, and other free trade agreements.

GPhA's influence on Capitol Hill, in state capitals and at the FDA continued to grow. Our activities were chronicled in numerous articles in the national media, including *The New York Times, Los Angeles Times, The Washington Post, The Wall Street Journal, Forbes, USA Today* and many others. We published our fifth annual generic savings report showing that the use of generic drugs saved the U.S. health care system more than $1.2 trillion over the past decade, $217 billion in 2012 alone. Our annual Fall Technical Conference, co-sponsored with the FDA, and the 2013 Annual Meeting had record levels of attendance.

These accomplishments were possible because of the dedication of our GPhA team and the support and engagement of our member companies as they establish a strong platform for GPhA's 2014 priorities.

As we move forward together, let us commit ourselves to turning our challenges into opportunities for growth. Together, we hold the key to opening the door for millions who without us have no access to medicines.

Warm regards,

Ralph G. Neas
President & CEO

# THE ASSOCIATION

Coming together is a beginning; keeping together is progress; working together is success.

HENRY FORD

# ASSOCIATION Highlights

2013 was a year of significant achievements for GPhA and the industry on the member-designated priority issues at the state, federal and international levels. In addition, we posted record annual operating revenues of $12.6 million, record attendance of 677 at our Annual Meeting in Orlando, and a record attendance of 578 at our GPhA/FDA Fall Technical Conference. We also hired a total of six new colleagues across the Communications, Government Affairs and Science & Regulatory Affairs departments. And we moved into new office space that gives us more room to grow.

In January, state legislatures kicked off their sessions and biosimilars implementation bills were slated for consideration in many. A front-page *New York Times* story detailed efforts by biotech Goliaths Amgen and Genentech to erect barriers to competition from interchangeable biosimilars. Ultimately in 2013, biosimilar implementation legislation efforts took place in 19 states and GPhA claimed a dozen victories. In more than 10 states, legislators rejected measures that would hinder access to interchangeable biosimilars. Three states passed bills with significant amendments and only one state, North Dakota, passed the legislation as introduced. Florida enacted a law that promotes access to biosimilars without burdensome physician notification requirements.


A record crowd of 677 attended GPhA's Annual Meeting in Orlando in February.

In California, GPhA led an extensive advocacy and strategic allies outreach campaign to oppose SB 598 that resulted in a dramatic last-minute veto by Governor Jerry Brown and had a clear impact on other states where similar measures were introduced.

In February, we enjoyed a successful Annual Meeting that included the keynote by FDA Commissioner Margaret Hamburg (her fourth consecutive Annual Meeting appearance) and the popular "CEOs Unplugged" session.

Spring saw execution on one of the key GPhA 2013 priorities: ensuring that Quarterly Meetings occurred between the GPhA Board and the FDA's Center for Drug Evaluation and Research (CDER) and Office of Generic Drugs (OGD). In late March, CDER Director Dr. Janet Woodcock led a meeting on the Generic Drug User Fee Act (GDUFA) implementation update and the reorganization of OGD. Soon afterward, Dr. Woodcock followed up with GPhA to introduce her Quality Metric Initiative, a new system whereby pharmaceutical manufacturers measure the quality of their facilities and systems through a set of metrics. GPhA continues its collaboration with FDA on this effort and continues its regular meetings with CDER and OGD, now with new Acting Director Dr. Kathleen Uhl.

Also in the Spring, two congressional committees released draft legislation to provide a federal pre-emption to state laws on drug supply chain security. GPhA testified before the House Energy and Commerce Subcommittee on Health on April 25, 2013 and continued its intensive education and advocacy efforts for legislation that contained a Federal pre-emption and realistic requirements to protect the nation's drug supply chain. These efforts came to fruition later in 2013 when the Drug Quality and Security Act was enacted into law. GPhA and its member companies also strengthened the compounding provisions in that legislation.

As Federal Budget sequestration took effect, generic drug user fees were impacted and no longer fully available to the FDA to implement GDUFA. GPhA worked with congressional FDA appropriations subcommittees, along with PhRMA and BIO to restore the fees.

Prior to that, the association sent letters to Congress offering a "prescription for sequestration pain," in the form of ways to lower government spending through a simple and proven means: by increasing the use of life-saving and affordable generic medicines. These included: encouraging generic drug use for the Medicare Low Income Subsidy (LIS) population; closing the loopholes in the current "REMS" policy; passing policy prohibitions against state carve-outs that block generic access; and integrating incentives for generic utilization/adherence in chronic management reforms, among others.

By early Summer, the U.S. Supreme Court issued its ruling on the issue of patent settlements in *Federal Trade Commission v. Actavis*. The Court rejected the FTC's position that patent settlements were presumptively illegal and held that settlements should be judged by a rule of reason, with each settlement carefully reviewed. To help block legislation on the issue, GPhA commissioned legal and policy white papers, and economic studies. The Association coordinated a robust multi-faceted media campaign which included numerous op-eds, press briefings and paid advertisements. (See, "The Industry," p. 15). In addition, Jonathan Orszag testified on behalf of GPhA at a hearing of the Senate Judiciary Committee Anti-Trust Subcommittee.

Days later, the Court ruled in *Mutual Pharmaceutical Co. v. Bartlett* that state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law. This led directly to the FDA's November release of a Proposed Rule mandating that generic drug firms update their labels for drugs under approved ANDAs by submission of a Changes Being Effected Supplement – 0 days (CBE-0). GPhA is strongly opposed to the Rule as drafted because it would open the floodgates for multiple versions of labels for the same medicines to be on the market, not only seriously jeopardizing patient safety, but also burdening consumers, taxpayers, large and small businesses, and state and federal governments with billions of dollars in increased costs for generic medicines. (See, "The Industry," p. 16).

In the Fall, GPhA submitted a citizens petition to request that the FDA implement its International Nonproprietary Name (INN) policy equally to all biologics. Adoption of unique non-proprietary names for each biosimilar could jeopardize patient safety, inhibit market competition and disrupt the current global naming system. Six senior senators wrote to the FDA raising their concerns about changing the current biosimilars naming policy.

In addition, last year, GPhA continued its fight against ongoing abuse of REMS programs to delay generic competition. GPhA convened the REMS working group and met with the FTC. GPhA will continue to look for opportunities to insert REMS legislative language into appropriate vehicles, call for greater congressional pressure and continue to implement a coordinated media strategy.

The GPhA Fall Technical Conference in Bethesda, Maryland, attracted regulatory and science experts from around the globe.

Also in 2013, the Association continued to build international and domestic partnerships to strengthen the Trans-Pacific Partnership (TPP) and ensure an acceptable Transatlantic Trade and Investment Partnership (TTIP). GPhA had multiple meetings with Ambassador Michael Froman and other key USTR officials, White House and Commerce Department staff, members of the Senate and the House of Representatives, as well as members of the European Parliament. In partnership with the International Generic Pharmaceutical Alliance (IGPA) and our members, GPhA has made great strides advocating at the global level.

Dr. Kathleen Uhl presented the Office of Generic Drug's Director's Update at the 2014 GPhA Fall Technical Conference.

And, as stewards of patient and environmental safety, GPhA bolstered its support of patient and prescriber education on the proper usage of prescription medicines and showed strong support of e-labeling through meetings with OMB and the FDA. Working with the Pharmaceutical Research and Manufacturers of America, the Biotechnology Industry Organization and the Consumer Healthcare Products Association, GPhA continues to oppose state, county, and municipal government efforts to require manufacturer-funded take-back programs, including joining in suits against measures by Alameda (CA) and King (Washington) counties.

State activities last year also included successful opposition to dozens of carve-out bills beyond biosimilars, and to legislation that would allow only tamper-resistant opioids to be prescribed.

This snapshot of 2013 captures just the highlights of the work GPhA and its member companies did throughout the year to ensure the industry can continue to deliver quality and value to patients and the health care system.

# GENERIC DRUG:
# Keeping Medicines Within Reach

This year was another historic success for generic drugs! The 2013 Generic Drug Savings in the United States report, compiled by the IMS Institute for Healthcare Informatics on behalf of GPhA, quantifies the savings generated by more affordable generic medicines, and, for the first time, spotlights retail savings from generics.

In the most recent decade, generics saved the U.S. health care system $1.2 trillion. That is $217 billion in 2012 alone, up from $188 billion in 2011. To put this in context, health spending continues to make up nearly 18 percent of the Gross Domestic Product (GDP) and remains a major investment by patients and taxpayers, federal and state governments, and payer organizations.

The Affordable Care Act, particularly the introduction of the new health exchanges, highlights affordability and access for uninsured and under-insured Americans. Generics will play a key role in this important endeavor, expanding treatment options for millions of people. In 2012, total spending on U.S. medicines fell 3.5 percent on a real per capita basis and the use of health care services overall declined for the second consecutive year, according to separate findings from the IMS Institute for Healthcare Informatics.[1] Total


lars spent on medications in U.S. reached $325.8 billion st year, or real per capita ending of $898, down $33 om 2011. Indeed, patent xpiries in 2012 contributed $28.9 billion to the reduction in medicine spending, their largest impact to date.[2] These data conclusively demonstrate that the availability of generic medicines and policies that promote their utilization are vital to holding down health costs.

This year, a special section of the report is dedicated to retail pharmacy savings. Notably, generics have saved the retail market $931 billion over the last 10 years. And, over the recent decade, the federal government accounted for 31 percent of retail savings.

Savings to Medicare Part D plans reached approximately $180 billion since the Part D program began in 2006, while Medicaid savings totaled more than $96 billion. During this same period, generics have saved out-of-pocket cash payers $78 billion, making a critical difference to these typically uninsured and poorer customers.

On the private payer side, generics in the last decade have saved commercial third-party payers $552 billion. Future savings are expected to accumulate at an increasing rate.

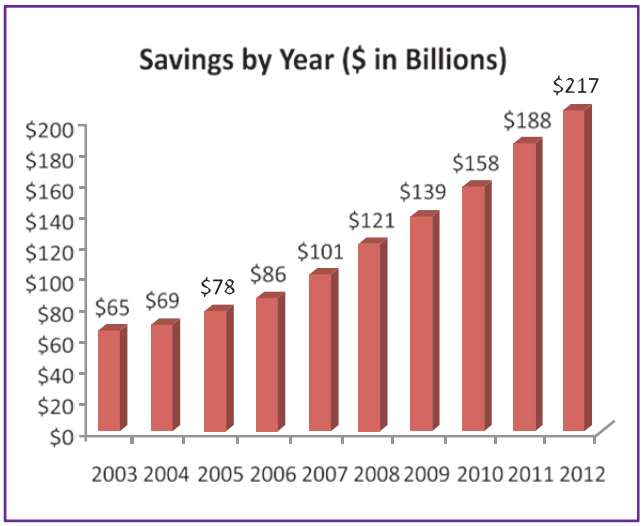
The report highlights the important contribution that our member manufacturers, wholesalers and supply chain partners play in holding down health costs. Access to generics and the resulting savings from these more affordable medicines is critical.

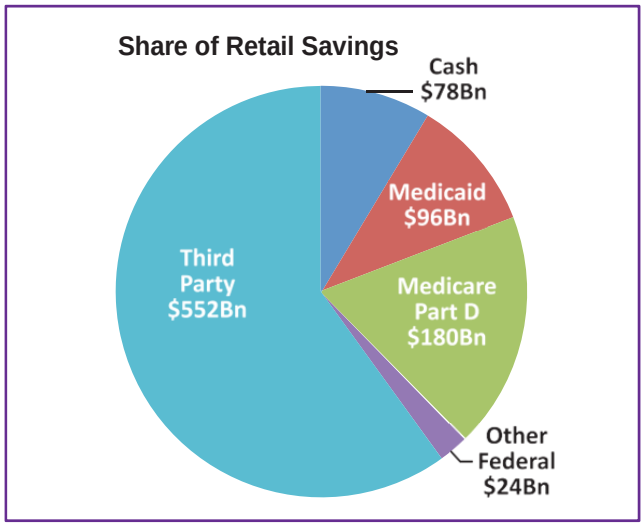
Our population is aging and health costs continue to rise despite short term fluctuations. The continued success of our members translates directly to health savings for patients, taxpayers, state and local government, large and small businesses, payors and others.

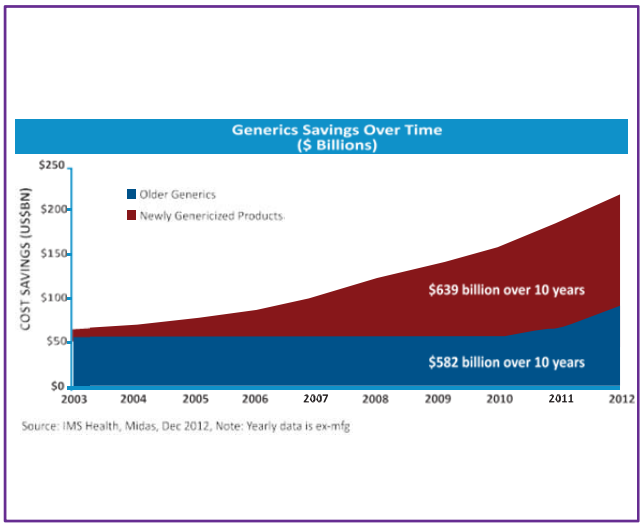
It is important to recognize the success of 2013 with an eye toward the future. Despite a roller coaster of systemic change to the health care system, generic drugs remain one of the few areas experiencing unquestionable success—generating billions in savings and keeping treatment within reach for patients that rely on access to more affordable medicine.

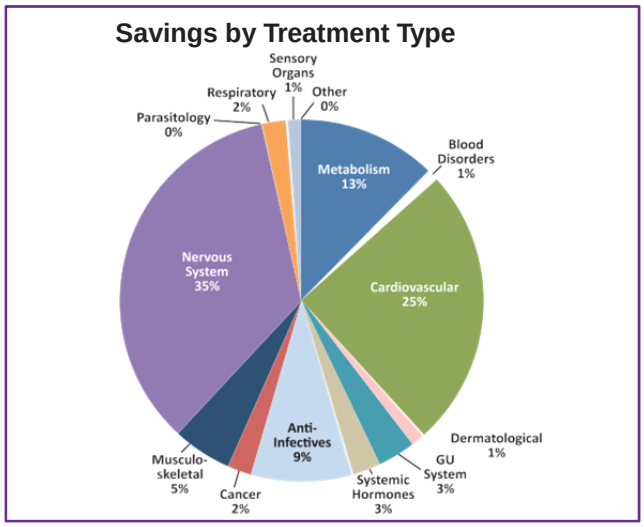
[1] Declining Medicine Use and Costs: For Better or Worse? IMS Institute for Healthcare Informatics, May 2013.
[2] Ibid.

# GENERIC DRUG Savings in the U.S.



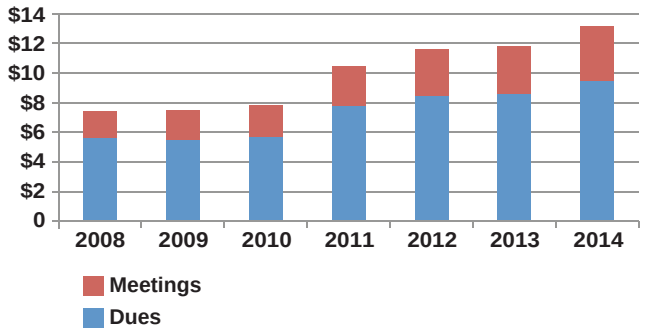



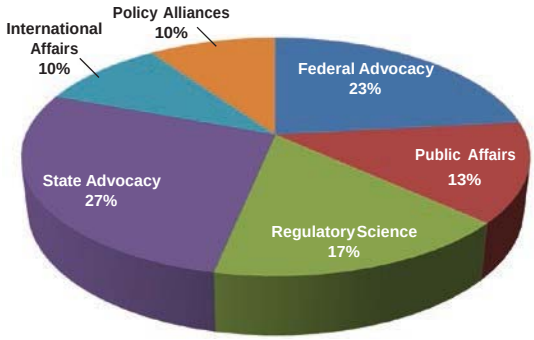



# Operations

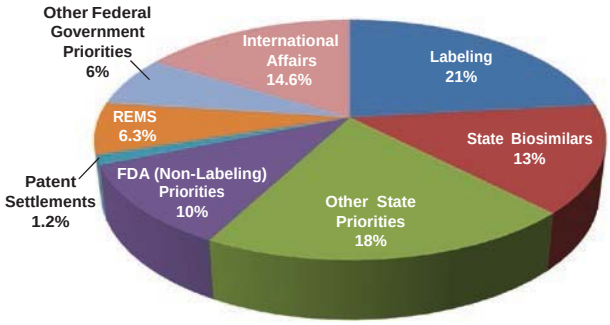
**TOTAL REVENUE ($ IN MILLIONS)**




**PROGRAM ALLOCATION BY COST CENTER (2014)**




**ALLOCATION OF PROGRAM MONEY BY PRIORITY ISSUE (2014)**




**OFFICE OF THE PRESIDENT & CEO**
Ralph G. Neas
President & Chief Executive Officer

Kathy Altman
Executive Assistant to the President & CEO

Kendra Janevski
Senior Director, Human Resources & Admin.

**GOVERNMENT AFFAIRS**
Melissa Schulman
Senior Vice President, Government Affairs

Jason Money
Associate Vice President,
Federal Government Affairs

Brynna Clark
Senior Director, State Affairs

Chris Davis
Director, Federal Government Affairs

Heidi Wilson
Director, Federal Government Affairs

John Zoshak
Manager, Government Affairs

**REGULATORY SCIENCE**
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Senior Vice President, Sciences & Regulatory Affairs

Gordon Johnston
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Mark Hendrickson
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Ashlee Koonce
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**OPERATIONS**
Rachelle Kosky
Senior Director, Finance & Operations

Jennifer Nguyen
Director, Meetings & Marketing

Cookie Cottrell
Senior Manager, Administration

Aquera Agee
Associate Manager, Meetings

# MEMBER ENGAGEMENT OPPORTUNITIES

## Committees, Task Forces and Working Groups

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

**Biosimilars Working Group**
The Biosimilars Working Group works with FDA on implementation of the approval pathway for biosimilars and the biosimilar user fee program.

**Drug Shortages Working Group**
The Drug Shortages Group works with FDA to mitigate shortages of critical medicines and assure that facts surrounding drug shortages are accurately presented.

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

**Foreign Inspections/Import Safety**
The Task Force advocates for fair balance between domestic and foreign inspections and works to block excessive import drug user fees.

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

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

**Media Task Force**
The Media Task Force strategizes on a consensus approach to our most pressing public affairs issues. The group is made of GPhA member and staff communication leaders.

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

**REMS Working Group**
The REMS Working Group works to develop regulatory and legislative approaches free of impediments that impose onerous conditions and other barriers that block generic competition.

**Science and Regulatory Advisory Board (SRAB)**
The Advisory Board drives strategies for science and regulatory policies and proposes actions to the Board to address science and regulatory issues.

**State Affairs Committee**
The 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.

**Supply Chain Task Force**
The Task Force advocates on the federal level for nationally uniform track-and-trace legislation; on the state level the task force works to prevent burdensome track-and-trace laws.

# THE INDUSTRY

Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives.

WILLIAM A. FOSTER

# INDUSTRY Moments

Legal, regulatory and state and federal legislative activity in 2013 proved once again that there is never a dull moment for the generic drug industry. We highlight below some of the most significant moments in 2013 that will shape our industry for years to come.

## SUPREME COURT RULES ON PATENT SETTLEMENTS

On June 17, 2013, the Supreme Court ruled on the issue of patent settlements in *Federal Trade Commission v. Actavis.* The Court unanimously rejected the Federal Trade Commission's position that settlements with consideration are per se anti-competitive. Rather, a majority of the Court found that settlements should be judged by a rule of reason, with each settlement carefully reviewed. GPhA was pleased that the Supreme Court confirmed our long standing position that settlements with consideration are not automatically anti-competitive.

GPhA released two important studies in response to the Supreme Court decision. An IMS savings study was released on July 11, 2013 and found that generic pharmaceuticals launched prior to patent expiry as a result of the 33 settlements analyzed have resulted in a reduction of $25.5 billion in drug costs from 2005 through December 2012. Almost one third of the estimated savings accrues to the Federal Government or $8.3 billion over the past eight years.

On July 23, 2013, the study, "Reverse Payment Patent Settlements and New Survey Evidence on Factors Affecting Generic Drug Investment," was released in conjunction with a hearing by the Senate Judiciary Committee Anti-Trust Subcommittee. The study concluded that: (1) generic companies lose approximately two-thirds of the cases that they litigated to judgment, suggesting that branded patents can be relatively strong; and (2) the ability to settle patent litigation is a factor considered by generic companies in deciding whether and how much to invest in drug development. As a result, competition policy should put substantial weight on dynamic (long-run) not just static (short-run) competitive effects. Limiting the right to settle patent litigation could result in fewer patent challenges and fewer generic competitors, leading to higher prices for consumers and mitigating the success of the Hatch-Waxman law.

## HIGH COURT AFFIRMS LABELING SAMENESS LAW

On June 24, 2013, the Supreme Court ruled in *Mutual Pharmaceutical Co. v. Bartlett* that state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law as under *Pliva v. Mensing*. The Court confirmed both existing statute and long standing FDA guidance and regulation that the sameness of the label between the brand and the generic is essential to ensuring patient safety and confidence in generic medicines.

## GENERIC DRUG USER FEE ACT (GDUFA) YEAR ONE DRAWS TO A CLOSE

In October, FDA celebrated the end of GDUFA year 1 by announcing the agency and industry met all year 1 metrics. Industry contributed $300 million in user fees and registered more than 2,000 facilities throughout the world. FDA announced the hiring of 234 employees to the Generic Drug User Fee Amendments Human Capital Team. The goal was to hire 231 as part of a three-year push with hopes to hire 921 new staff, including 461 during fiscal year 2014.

## FDA RELEASES PROPOSED RULE ON LABELING

On November 13, FDA released a proposed rule on labeling changes for ANDA holders titled *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products.* The proposed rule mandates that generic drug firms update their labels for drugs under approved ANDAs by submission of a Changes Being Effected Supplement – 0 days (CBE-0) to add warnings, precautions, adverse reactions, contraindications and certain other information, even if the innovator has not implemented the same labeling change. According to the agency, these proposed revisions would create parity between NDA holders and ANDA holders with respect to submission of CBE labeling supplements.

Commenting on the Proposed Rule, GPhA President and CEO Ralph G. Neas said, "Patient safety is the foremost concern for manufacturers of generic medicines, which is why generic companies comply with federal law and strict FDA labeling rules and regulations. Generic drug companies proactively participate with the FDA in ensuring the timeliness, accuracy, and completeness of drug safety labeling in accordance with current regulatory requirements, to ensure doctors and all health care professionals and patients have access to the most up-to-date information.

Flooding the marketplace with multiple versions of labels for the same medicines would not only seriously jeopardize patient safety, but also would burden consumers, taxpayers, large and small businesses, and state and federal governments with billions of dollars in increased costs for generic medicines."

GPhA is energetically opposing this rule with the support of many in Congress.

## PRESIDENT OBAMA SIGNS TRACK AND TRACE/ COMPOUNDING BILL

In a landmark accomplishment, and after many years of advocacy, bi-partisan legislation was enacted that would, for the first time, provide a single, uniform national standard for prescription drug tracking, thus preempting California law scheduled to go into effect in 2015. The final legislation also addresses GPhA's major concerns with proposals to provide the FDA with additional authority to monitor compounding facilities, including restricting the drug shortages exemption for "outsourcing facilities" (known as "compounding manufacturers" in previous versions of the bill) to the official FDA drug shortages list, rather than regional or private lists, and prohibiting the compounding and distribution of marketed drugs by "outsourcing facilities" once the product is no longer in shortage. The Drug Quality and Security Act was signed into law by President Obama on November 27, 2013 and represents a major accomplishment and victory for GPhA and the generic industry.

## FDA ESTABLISHES OFFICE OF GENERIC DRUGS AS A "SUPER OFFICE"

In December, HHS officially approved the overhaul of the FDA's Office of Generic Drugs (OGD) into a super office. Janet Woodcock, the director of the FDA's Center for Drug Evaluation and Research, said the reorganization would strengthen the OGD's operations and allow it to "meet the evolving needs of generic drug review." The new structure of the OGD will include an Office of Research and Standards, an Office of Bioequivalence, an Office of Generic Drug Policy and an Office of Regulatory Operations, each of which will have multiple divisions under it.

## STATES TAKE UP CARVE-OUTS, TAKE-BACKS, AND BIOSIMILARS

The state activity in 2013 was especially strong. From carve-out legislation, to take back programs; GPhA successfully defended the industry across the 50 states. Over 34 bills that contained anti-generic utilization provisions were introduced in the states. Not one state approved any carve out legislation. Additionally, 29 pharmaceutical take back bills were introduced, but did not move forward due to GPhA's advocacy efforts.


FDA reorganization elevates stature of the Office of Generic Drugs.

A series of bills was introduced across the country in an attempt to stymie competition before any biosimilar therapies are approved in the United States. Legislation that would erect obstacles to interchangeable biologic substitution was introduced in 19 states in 2013, blocked in 11, enacted with significant amendments in three states, and enacted as proposed in only one state (North Dakota). Florida enacted a law that promotes access to biosimilars without burdensome physician notification.

GPhA worked with our members and strategic allies from throughout the healthcare distribution system on these issues.

# GENERIC INDUSTRY
# By The Numbers

## Sales of leading corps in Unbranded Generics

| Sales of unbranded generics by leading corporations | MAT Nov 2013 US$mn | % Market Share | % Growth |
|---|---|---|---|
| US Industry | 56,507 | 17.1 | 6.9 |
| 1 Teva | 6,895 | 12.2 | -4.7 |
| 2 Mylan Labs, Inc. | 6,669 | 11.8 | 8.6 |
| 3 Actavis US | 6,316 | 11.2 | -1.8 |
| 4 Sandoz (Novartis) | 4,282 | 7.6 | -2.0 |
| 5 Par Pharma | 2,385 | 4.2 | 7.5 |
| 6 Sun Pharma | 2,079 | 3.7 | 35.2 |
| 7 Lupin Pharma | 1,418 | 2.5 | 55.5 |
| 8 Dr Reddy Inc | 1,394 | 2.5 | 42.8 |
| 9 Greenstone (Pfizer) | 1,326 | 2.3 | 12.7 |
| 10 Apotex Corp | 1,249 | 2.2 | 35.4 |
| Top 10 | 34,013 | 60.2 | 6.5 |

Source: IMS Health, National Sales Perspectives, Nov 2013

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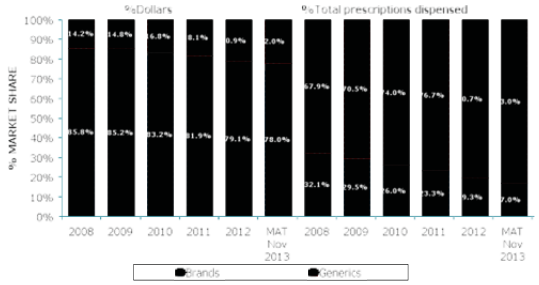
Branded Generics Disaggregated

## Generic's Share Dollars and Prescriptions




Source: IMS Health, National Sales Perspectives, Nov 2013, National Prescription Audit, Nov 2013, Branded generics disaggregated

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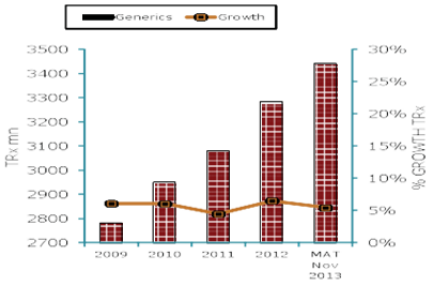
Branded Generics Disaggregated

## Generics TRx and Growth




Source: IMS Health, National Sales Perspectives, Branded generics disaggregated, Nov 2013

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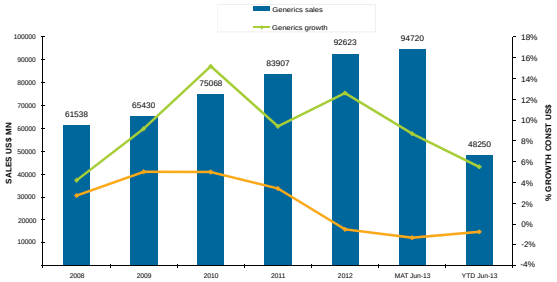
## Generic Sales and Growth – 8 Key Markets




Source: IMS Health, MIDAS, Market Segmentation, MAT Jun 2013, Rx only. *Market Segmentation universe

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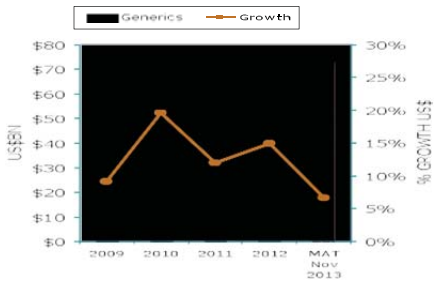
# GENERIC INDUSTRY
# By The Numbers

**Branded Generics Disaggregated**

Generics Dollar Sales and Growth




Source: IMS Health, National Sales Perspectives, Branded generics disaggregated, Nov 2013

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Top Molecules- 12 months ending Nov. 2013

TRx

| Rank | Molecule | TRx (000) | Share | Growth |
|---|---|---|---|---|
| 1 | ACETAMINOPHEN/ HYDROCODONE | 128,221 | 3.1% | -5.6% |
| 2 | LEVOTHYROXINE | 110,075 | 2.7% | 2.5% |
| 3 | LISINOPRIL | 93,510 | 2.3% | 3.3% |
| 4 | METOPROLOL | 79,624 | 1.9% | 2.1% |
| 5 | SIMVASTATIN | 76,989 | 1.9% | -11.6% |
| 6 | AMLODIPINE | 70,405 | 1.7% | 7.2% |
| 7 | OMEPRAZOLE | 69,310 | 1.7% | 6.1% |
| 8 | ATORVASTATIN | 66,425 | 1.6% | 23.0% |
| 9 | METFORMIN | 66,159 | 1.6% | 7.7% |
| 10 | ALBUTEROL | 63,857 | 1.5% | 5.0% |

Source: IMS Health, National Prescription Audit, Nov 2013

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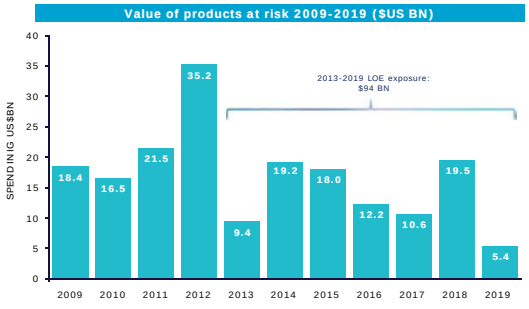
$94 BN exposed to generic competition by 2019

Excluding biologics




Source: IMS National Sales Perspectives, Nov 2013; sales in year prior to expiry for 2009-12; MAT Nov 2013 sales shown for 2013-19

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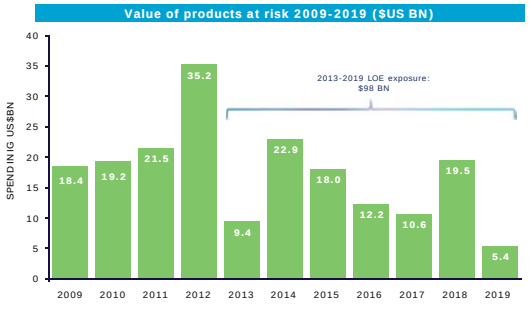
$98 BN exposed to generic competition by 2019

Including biologics




Source: IMS National Sales Perspectives, Nov 2013; sales in year prior to expiry for 2009-12; MAT Nov 2013 sales shown for 2013-19

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# MOVING FORWARD

Price is what you pay. Value is what you get.

WARREN BUFFET

# GPhA: A Bright and Shining Future

Our business is undergoing unprecedented change. Companies are expanding into emerging markets. Customers are consolidating into global purchasing giants. And patients around the world are increasing the demand for effective, affordable medicines. The confluence of mergers, acquisitions, vertical integration, proprietary pipelines and enhanced technological expertise is transforming the generic industry of yesterday into the world's leading supplier of prescription drugs. In fact, 84 percent of today's prescriptions are generic, according to the 2013 Generic Drug Savings in the U.S. report. And, as we move deeper into specialty and biosimilar markets, the role we play in providing access to safe, effective, quality medicine grows even larger.

Our 2014 strategic plan prepares to overcome difficult challenges and maximize the new opportunities that arise as we move forward. It is not the triumphs of our past, but how we face the challenges and seize the opportunities of our future that will be the true measure of our industry's success.

## LABELING AND PATIENT SAFETY

Our top priority is to protect patient safety and access to affordable medicines. One way GPhA will continue the industry's legacy of success is working with stakeholders to ensure that the FDA's proposed rule on prescription drug labeling reflects sound policy and science.

GPhA continues to oppose as drafted the FDA proposed rule that would engender prescriber, pharmacist and patient confusion as they try to reconcile multiple labels for the same medicines. A multi-stakeholder collaboration led by GPhA is the only way to make sure that the unintended consequences of this rule do not burden generic manufacturers, put patients at risk or raise costs for millions of people who rely on generics.

## BIOSIMILARS

The development of a market in the U.S. for biosimilars and generic biologic medicines is a significant bright spot in our future. In 2014, we will move forward in our collaboration with our member companies and the biosimilar team at the FDA to assure a regulatory process that facilitates the approval of lower cost biologic medicines. Thousands of patients are in need of lifesaving treatments but prohibitive costs keep them out of reach. Yet, many of these products are no longer covered by patents that protect them from competition. By creating a competitive biosimilar marketplace, free of barriers such as differentiated naming, patients will gain affordable access to medicine they need.

We will advocate in the states for legislation that opens the door to substitution of interchangeable biosimilars, free of unwarranted mandates that could restrict their use. We will educate policy makers, health care providers, payers, consumers and patients about the efficacy, safety and savings available through the use of biosimilars.

## NEW GENERICS

Although many had predicted that the post 2011-2012 'patent cliff' would bring a slowdown in generic growth, that did not materialize. Indeed, generics continue to be a growth market in terms of sales with the increasing use of many newer generics. From 2014 to 2016, patents will expire for drugs with approximately $51 billion in annual brand name sales, opening those markets to generic competition. And there still are ample growth opportunities in drugs that recently have lost patent protection as evidenced by the increasing number of generic applications submitted to the FDA. In December 2013 alone, the Agency received a one-month record of 225 applications, beating the previous one-month record of 210 set in December 2011 during the midst of the patent cliff.

FDA's decision last year to elevate the Office of Generic (OGD) drugs to "super office" status within the Agency was a positive both for our industry and for consumers. By putting OGD on the same organizational level as the Office of New Drugs, the Agency will be better able to meet generic approval goals built into the generic drug user fee program.

Informed by science, quality is a cornerstone of the generic industry. Consistent and diligent enforcement of FDA manufacturing standards, process and protocol for development and distribution is the mindset for all GPhA members. The association stands firmly in support of regulatory goals outlined in the Generic Drug User Fee Act (GDUFA). User fees continue to be instrumental in the shared effort by the FDA and our industry to help patients gain timely access to more affordable medicine. These fees, give FDA the needed resources for timely review and feedback for companies developing generic and biosimilar products, helping to speed treatments to market and give consumers a more affordable alternative to brand medicines.

We continue to support the use of generic industry money and adequate federal appropriations to expedite site inspections, enhance the drug application and review process and work together with FDA to make sure that patients, government, businesses and others have timely access to more affordable generics.

## AFFORDABLE CARE ACT

The Centers for Medicare and Medicaid Services (CMS) projects that enactment of the Affordable Care Act (ACA), which will provide health care to millions of previously uninsured individuals, will increase spending on prescription drugs by 5.2 percent in 2014, compared with 0.6 percent growth in 2013. As more Americans gain access to the medicines they need, the use of generics will grow.

ACA also will close the Medicare coverage gap (the "doughnut hole"), which is expected to increase the number of prescriptions bought by senior citizens. This is especially meaningful since the number of people on Medicare is climbing. By 2020, seniors will make up 22 percent of the population, up from 19 percent today. The medical needs of our rapidly aging population are unprecedented. Generic utilization will continue to rise as these seniors, many on fixed incomes, rely on lower cost generic drugs to meet their medicine needs.

## EXPANDING GROWTH OPPORTUNITIES

Generic companies increasingly are finding alternative sources of growth. Brand and specialty drug capabilities, over-the-counter opportunities and biosimilar development provide opportunities for robust expansion. Adding to this diversified growth platform are the emerging global markets. With double-digit growth in pharmaceutical spending projected for countries such as Brazil, China, South Korea and Turkey, these emerging markets offer the promise of significant business expansion for our industry. In all of these growth areas, we will work with regulators at the FDA and with colleagues in the International Generic Pharmaceutical Alliance to build a climate that is most conducive to the continued success of our industry.

International expansion continues to be a GPhA priority as the Obama Administration, U.S. Trade Representative and participants from all levels of the health supply chain work together on agreements such as the Trans-Pacific Partnership (TPP). GPhA also will build on last year's work with Congress, the U.S. Trade Representative and others involved with international trade negotiations. These agreements will be integral in efforts to open access to global markets and preserve the balance between promoting innovation and competition. The association will continue to ensure that barriers to entry for generic products in TPP countries are limited, including mandates of patent term extensions, patent linkage and exclusivity.

## 2014 STRATEGIC PLAN

To achieve the overall legislative and regulatory goals set by the membership and the Board for the Association in 2014, we developed Comprehensive Action Plans (CAPs) for GPhA's top cross-functional priorities. These are:

- Ensure that any changes to prescription drug labeling policies protect patient safety and access to affordable medicines by collaborating with stakeholders throughout the health care sector.
- Strengthen relationships with CDER/OGD to facilitate collaboration on all policy and regulatory sciences issues.
- Promote policies that facilitate the development and maturity of a market in the United States for biosimilars and interchangeable biosimilars, including full implementation of approval regulations with no differentiated naming.
- Protect the rights of parties to settle drug patent litigation out of court.
- Assure access to bioequivalence samples for brand products and prevent the misuse of REMS.
- Mitigate current drug shortages and prevent future shortages through implementation of the Accelerated Recovery Initiative.
- Defeat state anti-generic initiatives, such as burdensome biosimilars legislation, carve-outs, generic bidding, and pharmaceutical take-back programs and promote pro-generic use programs.

We believe our 2014 strategic plan and accompanying operating budget offer a significant value proposition for all member companies.

## TOGETHER, DRIVING QUALITY AND VALUE!

Safe and effective generic medicines remain a major component of any solution to affordable and sustainable health care. Generic pharmaceuticals represent one of the best ways to meet growing demand for expanded access to high quality, affordable treatment options. As we look to the months and years ahead, taking steps to preserve and promote the tremendous quality and value that generic pharmaceuticals offer is the only way forward. Together, we will achieve our mission of maximizing the advantages of generic and biosimilar medicines.

In 2014 and beyond, GPhA will champion those programs and policies that make savings possible and provide the headroom for innovation in the pharmaceutical sector. Generic manufacturers can proudly point to a legacy of savings and access that will continue to bring expensive treatments within reach for millions of people.


# 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 15 committees that our member companies initiate and drive, including Sciences and Regulatory Affairs, Biosimilars, Legal 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 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 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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