GENERIC PHARMACEUTICAL ASSOCIATION 2012 ANNUAL REPORT

About the Cover

We chose "Vision" as the theme of our 2012 annual report to communicate our conviction that the first step toward building a successful future is developing the ability to envision it. But vision without action is only a dream; transforming vision into action produces achievement.

The pages that follow highlight what GPhA and its members accomplished in 2012, the most successful year yet in our history. And while there still is much to do, our vision of being an influential and effective advocate for the interests of our member companies remains the blueprint for our future. We enter 2013 knowing we are limited not by our abilities but by our vision.

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.

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FROM THE CHAIRMAN

Tony Mauro
GPhA 2012 Board of Directors

In 2012, GPhA transformed its vision into action to improve health care outcomes for millions of patients across the U.S., and together we made unprecedented progress on our goal to expand access to high quality, more affordable medicines.

Truly, it's an exciting time to be part of the generic pharmaceuticals industry. This year, we learned that the products and services that our member organizations provide helped to save the American health care system more than $1 trillion over the past decade—a record figure that averages out to more than $1 billion every other day due to the expanded use of generic prescription drugs.

And while these savings speak volumes about the robust growth opportunities available to our industry in a market that continues to discover and understand the true value and reliability of our products, they also highlight the importance of continuing to improve how health care is delivered in our country by helping to further reduce costs, while expanding access.

In July, we took a giant leap forward when President Obama signed into law the Food and Drug Administration Safety and Innovation Act (FDASIA). This legislation will help to ensure one quality standard for all pharmaceuticals utilized in the U.S. by empowering the Food and Drug Administration (FDA) to assure all drug manufacturing facilities that supply the U.S. market are regularly inspected, regardless of whether they are based inside the U.S. or outside our borders, with the end goal of protecting the health and safety of consumers.

Included within FDASIA was the landmark Generic Drug User Fee Act (GDUFA), which will provide FDA with approximately $1.5 billion over the next five years to support more timely inspections of drug facilities while enabling a faster, more predictable review of generic drug applications for improved access to high quality, affordable generics.

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 great milestones.

Bringing a vision like ours to life is no easy task. It requires an incremental, sometimes painstaking implementation of actions that support our cause. As an association, we must continue to invest our time and energy in this effort in order to ensure our future success.

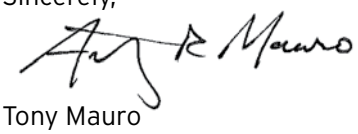
In 2013, our priorities will shift from passing GDUFA to successfully implementing it. Additionally, our efforts must continue focusing on creating transparent federal and state regulatory frameworks for increased access to generic drugs, including the creation of a viable approval pathway for interchangeable biosimilars in the U.S.

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; continue our efforts to secure the supply chain to ensure the reliable availability and delivery of generic drugs; all while providing passionate leadership as a member-focused association comprised of dedicated companies to advance policies that strengthen each of these efforts and fight barriers that seek to limit access to generics.

Continuing to ensure the ongoing development of a successful generic drug system in the U.S. depends on all of us. By further diversifying our membership and making our organization more sustainable, we will better position GPhA to champion our meaningful message: translating vision into action for expanded and more affordable access to life-saving generic medicines.

I thank you again for your ongoing dedication and commitment to GPhA in 2012 and look forward to seeing what exciting developments 2013 will bring.

Sincerely,



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

GPhA 2012 Board of Directors

From the left: Tony Mauro (Mylan); David Klaum (Fougera); Jeff Watson (Apotex); Mike Keenley (*for Joseph Renner,* Zydus), Paul Bisaro (*for Charlie Mayr,* Watson); John Ducker (Fresenius-Kabi); Chirag Patel (Amneal); Juliana Reed (*for Thomas Moore,* Hospira); Doug Boothe (Actavis); Debra Barrett (Teva); Chuck Caprariello (Ranbaxy); Don DeGolyer (Sandoz); Craig Wheeler (Momenta), Carole Ben-Maimon (Impax).

Ralph G. Neas
President and CEO

FROM THE PRESIDENT & CEO

ONE OF THE MOST EXTRAORDINARY CHARACTERISTICS OF THE GENERIC pharmaceuticals industry is the power of our collective vision. The very nature of our vocation—providing affordable, life-saving medicines to patients—requires that we be ever forward-looking. Our industry's vision, by necessity, must extend beyond the life-cycle management strategies of the innovator companies, beyond the limitations of the FDA's regulatory frameworks, beyond current quality requirements, beyond barriers to global competition, and beyond traditional business partnerships to continue seeking growth and opportunity that benefits not only patients, but also the health care system as a whole.

However, vision alone is insufficient; it must be accompanied by a well-developed strategy and specific tactics for execution in order to be meaningful. As you will read in this report, in 2012 we stepped up our close engagement with the FDA to further influence the implementation of two critical laws: the Generic Drug User Fee Act (GDUFA) that was signed into law in July, and the Biologics Price Competition and Innovation Act of 2009 that was part of the Affordable Care Act, both of which are now in the regulatory phase. We also engaged with Congress on GDUFA, appearing half a dozen times before House and Senate Committees to testify on the bill's benefits to patients and other issues. Other Hill efforts included blocking harmful amendments on patent settlements, generic labeling, drug abuse/diversion, reimportation, and drug shortages. Across 50 state battlegrounds, GPhA successfully defeated scores of carve-out initiatives that would inhibit generic utilization and leave savings on the table. And on the international front, we hosted an event centered on the latest round of negotiations of the Trans-Pacific Partnership. And those are just the highlights of the Association's achievements.

As an industry, we excel at harnessing our vision and translating it into measurable results. According to GPhA's annual generic savings analysis—produced again this year with IMS Health—the use of generic prescription drugs saved consumers, patients and the U.S. health care system $193 billion in 2011 alone.

Our industry enters 2013 from the position of the undisputed backbone of the U.S. pharmaceutical market. As we survey the coming year, we see much cause for optimism. Our industry grows ever more technologically sophisticated, with an ongoing commitment to manufacturing practices of the highest quality, further proving the case for increased utilization. The emerging biosimilars opportunity, increased globalization, and the massive "silver tsunami" of aging demographics in America also fuel this optimism.

Although vision is not quite the same thing as having a crystal ball, I hope you all share my confidence and conviction that the generic pharmaceuticals industry and the medicines we provide will continue to be part of the solution to America's health care challenges in 2013 and beyond. GPhA will continue, with pride, our efforts to be at the forefront of these developments on your behalf.

Sincerely,

Ralph G. Neas
President and CEO

The Association

Obstacles are those frightful things we see when we take our eyes off the vision.

HENRY FORD

A Banner Year 2012

2012 was, in every respect, a banner year for GPhA and its members. In addition to the significant progress we made on an array of key legislative and regulatory fronts, we set records in many operational areas: record annual operating revenues of $11.8 million, up 25 percent over the prior year; record attendance of 623 at our Annual Meeting in Orlando, an increase of 50 percent over the 2010 attendance; record number of company representatives participating on committees and task forces; and record attendance of 700 at our GPhA/FDA Fall Technical Conference.

In January, we received extensive media coverage when the FDA submitted to Congress its recommendations for a proposed Generic Drug User Fee Act (GDUFA). Commenting on the accomplishment, GPhA President and CEO Ralph G. Neas said the seminal event "could not have been achieved without the extraordinary efforts of the FDA, my colleagues in the generic industry and all other stakeholders." The FDA's recommendations, which were right in line with the provisions negotiated by industry, became the basis for the GDUFA legislation passed later in the year.

A record crowd of 623 attended GPhA's Annual Meeting in Orlando in February.

In February, we enjoyed a remarkable Annual Meeting that included the keynote by FDA Commissioner Margaret Hamburg (her third consecutive Annual Meeting appearance), the state-of-the-industry address by GPhA President and CEO Ralph G. Neas, a "call to arms" by GPhA Chairman of the Board Tony Mauro (President, Mylan North America), and the popular CEOs Unplugged with host Stuart Varney of Fox News Channel. Also in February, FDA released its biosimilar guidances. GPhA submitted formal comments on the guidances in April, and testified before the FDA in May.

In March, GPhA's Senior Vice President of Regulatory Affairs, David Gaugh, testified before the House Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade on the issue of prescription drug diversion and how we as a nation could best combat the abuse. David also testified at a Senate Health, Education, Labor and Pensions Committee hearing entitled "FDA User Fee Agreements: Strengthening FDA and the Medical Products Industry for the Benefit of Patients." And Vice President of State & International Affairs, Shawn Brown, testified before the House Energy and Commerce Health Subcommittee on the issue of generic drug user fees.

In April, David once again was called upon to testify before the House Energy and Commerce Subcommittee on Health to discuss the draft Prescription Drug User Fee Act (PDUFA) reauthorization legislation, one of a half dozen times GPhA was asked to testify before the House and the Senate in the 112th Congress.

In May, the House Energy and Commerce Committee and Senate Health, Education, Labor and Pensions Committee completed work on the generic drug user fees and biosimilar user fees language as part of the Food and Drug Administration Safety and Innovation Act (FDASIA). In late May, FDASIA, S. 3187, was passed by the full House and Senate. During congressional consideration of this bill, GPhA was instrumental in blocking harmful amendments on patent settlements, generic labeling, drug shortages

and drug reimportation. FDASIA was signed into law by President Obama in July. Also in May, GPhA and FDA co-hosted the 2012 CMC Workshop in Bethesda, Maryland. Registration for the workshop was sold out several weeks before the event.

In August, GPhA received a positive advisory opinion from the Federal Trade Commission (FTC) on the Accelerated Recovery Initiative (ARI)—the generic industry's unprecedented multi-stakeholder initiative designed to accelerate the recovery of critical drugs in short supply to patients in need. The opinion was a critical step forward in addressing drug shortages. Under ARI, generic manufacturers, IMS Health and the FDA will collaborate in efforts to mitigate drug shortages in the U.S. GPhA also released its fourth annual Generic Drug Savings Study that showed the use of generic drugs saved the U.S. health care system more than $1 trillion over the last 10 years (2002-2011). The savings analysis was conducted by the IMS Institute for Healthcare Informatics. And, in late August and early September, GPhA was active in both national political conventions: the Republicans in Tampa, Florida, and the Democrats in Charlotte, North Carolina.

Throughout the summer, our state affairs team hosted numerous events associated with the National Governors Association and the National Conference of State Legislators. The GPhA State Government Affairs team, which includes our staff, in addition to representatives and consultants from many of our member companies, was successful in blocking scores of state anti-generic carve-out initiatives and promoting pro-generic best practices in state-sponsored prescription drug benefit plans.

Executives from GPhA's member companies engaged in strategic planning at the Washington CEO Leadership Summit in September.

In September, GPhA hosted a luncheon for international representatives participating in the latest round of negotiations in the Trans-Pacific Partnership (TPP). Also in September, GPhA conducted the annual CEO Leadership Summit in Washington, DC, at which our member company leaders hammered out strategic plans for 2013.

The GPhA/FDA Fall Technical Conference in Bethesda, Maryland, attracted 700 regulatory and science experts from around the globe.

In October, we conducted the most successful ever Fall Technical Conference, which is co-sponsored annually by GPhA and the FDA. Newly appointed Director of the Office of Generic Drugs, Dr. Gregory Geba, was one of several dozen guest speakers. GPhA also filed an amicus in the critical Upsher-Smith patent settlement case, in which we argued that the Third Circuit erred in its conclusion that the presumption of validity of a patent is not a substantive right of the patent holder.

Following the elections in November, GPhA engaged in educating newly elected members of Congress and their staffs on key legislative issues expected to be introduced in 2013. And, as the year closed, GPhA vigilantly guarded against any potential costly or burdensome language that could make its way into impending sequestration or debt ceiling legislation.

While these paragraphs highlight some of our more significant efforts in 2012, they do not begin to tell the full story of the work GPhA, its consultants and its member companies did throughout the year. Our reward is in knowing that the good work we accomplished together benefits all companies in the generic industry, even those who are not members of GPhA.

GPhA

Generic Savings
The Solution
To Affordable Health Care

One trillion dollars in health care savings over the past decade!

The 2012 edition of our annual Generic Drug Savings Study presented data from the IMS Institute for Healthcare Informatics to quantify the unprecedented savings achieved by using generic prescription drugs. The report validated the dramatic contribution the generic pharmaceutical industry makes every year to assuring the sustainability of the U.S. health care system.

The government's most recent National Health Expenditure Accounts (NHEA) report shows that total U.S. health care spending reached $2.6 trillion in 2010, which translates to $8,402 per person or about 18 percent of the nation's Gross Domestic Product. The federal government financed 29 percent of the total spend—a substantial increase from its 23 percent share in 2007—with state and local governments paying an additional 16 percent of national health care costs. NHEA further notes that the average annual growth in health care spending is expected to be 6.2 percent per year through 2018, outpacing annual growth in the overall economy by 2.1 percentage points per year. By 2018, according to government projections, national health care spending will reach $4.4 trillion and comprise over one-fifth of the GDP. At this rate of growth, within 15 years health care costs would amount to half of the nation's GDP, begging the question whether our yearly spending on health care is sustainable.

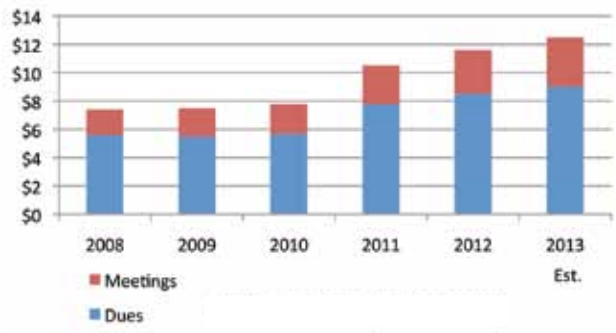
GPhA's fourth annual Generic Drug Savings Study showed savings generated by the use of generic drugs averaged $1 billion every other day in 2011.

Against this backdrop of escalating costs, the Generic Drug Savings analysis showed conclusively that the use of lower cost generic prescription drugs is a vital component to holding down the growth rate of health care spending. As the study showed, generic drugs saved the system $193 billion in 2011 alone, a rate of more than $1 billion every other day. Considering that the government's share of health care spending will soon exceed 30 percent as the oldest baby boomers become eligible for Medicare, the money saved by using generic medicines is critical to bending the cost curve and providing sustainability to our health care system.

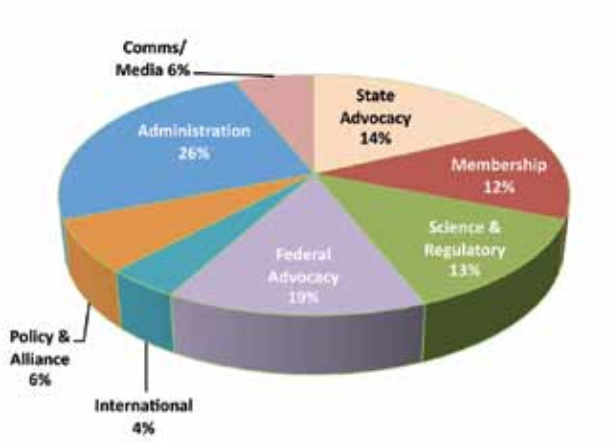
The analysis further highlighted that future savings achieved through generic drug use will climb at an even steeper annual rate as generic versions of expensive branded biologic treatments begin entering the market. Current biologic medicine costs are staggering, putting these lifesaving treatments out of reach for many patients. Even after insurance coverage, co-pays can be thousands of dollars each year. A Congressional Research Service study completed in 2010 concluded that the cost of biologics is often prohibitively high, both for patients and the government. Competition from biosimilar versions of branded biologics will help rein in these escalating costs and deliver sizeable savings while providing affordable options to patients needing treatments for deadly diseases.

2012 Operations

Total Revenue ($ in millions)



Expense Allocation by Cost Center



Allocation of Program Money by Priority Issue

Office of the President & CEO
Ralph G. Neas
President & CEO

Cookie Cottrell
Executive Assistant to the President
Senior Manager of Membership

Kendra Janevski
Senior Director
Human Resources & Administration

Government Affairs
Jim Fenton
Senior Vice President, Government Affairs

Jason Money
Senior Director Federal, Government Affairs

Brynna Clark
Senior Director, State Affairs

Chris Davis
Director, Federal Government Affairs

Mark Hendrickson
Associate Director, Government Affairs

John Zoshak
Manager, Government Affairs

Regulatory Science
David Gaugh
Senior Vice President, Sciences & Regulatory Affairs

Ashlee Koonce
Associate Manager, Regulatory Affairs

Policy
Christine Simmon
Senior Vice President, Policy & Strategic Alliances

Media
Claire Sheahan
Vice President, Communications

Operations
Bob Billings
Senior Vice President
Finance, Planning & Special Programs

Rachelle Kosky
Senior Director, Finance & Operations

Jennifer Nguyen
Director, Meetings & Marketing

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.

AMP Task Force
The Task Force prepares and submits formal comments to CMS with respect to proposed regulations governing average manufacturer price and Medicaid rebate issues.

Biosimilars Working Group
The 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.

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.

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

Patent Settlements Working Group
The Group advocates for allowing pro-consumer patent litigation settlements that ensure generic entry prior to patent expiry.

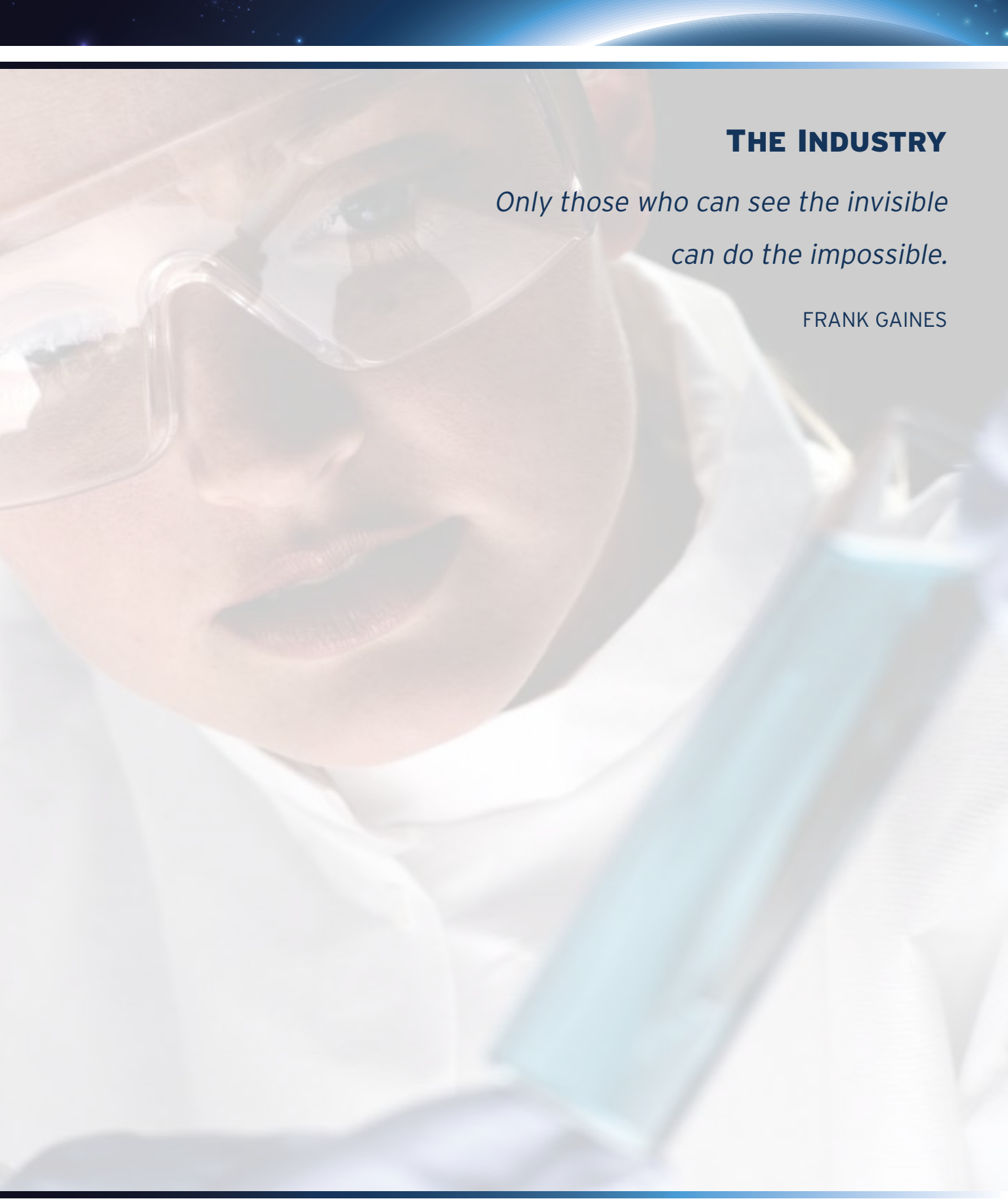
Supply Chain Task Force
The Task Force advocates on the federal level for nationally uniform track-and-trace legislation; on the state level the task force works to prevent burdensome track-and-trace laws.

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

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.

Carve-Outs Coalition (Industry-wide)
The Coalition consists of both GPhA members and non-member allied organizations committed to blocking state regulatory and legislative initiatives that would carve-out select therapeutic classes from generic substitution laws.

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.



The Industry

Only those who can see the invisible

can do the impossible.

FRANK GAINES

How do you sum up the kind of year the generic industry had in 2012 within just a few pages? Perhaps the best way would be to recall the top industry news stories of the year. While this list certainly does not capture all of the events of last year, it does highlight 10 significant stories that grabbed the lion's share of the generic industry headlines throughout 2012.

FDA Releases Biosimilar Draft Guidelines

In February, the FDA issued proposed guidelines for approving biosimilars. "These draft documents are designed to help industry develop biosimilar versions of currently approved biological products, which can enhance competition and may lead to better patient access and lower cost to consumers," said FDA's Center for Drug Evaluation and Research Director, Janet Woodcock. While low-cost copies of biotech drugs are used in Europe, none has yet been approved in the U.S. About $80 billion worth of biologic drugs will lose patent protection by 2013 and face competition from biosimilars.

GAO Highlights Critical Role of Generics

In March, a new General Accountability Office (GAO) report became public, showing that prescription drug spending in the U.S. reached $307 billion in 2010, and made up about 12 percent of all health care spending. GAO said that, until the early 2000s, drug spending was one of the fastest growing components of health care spending. However, over the last 10 years, the rate of increase has declined each year, attributable primarily to the greater use of generic drugs. The GAO study highlighted the savings reported in the annual GPhA/IMS Savings Study, specifically noting that, from 1999 through 2010, generic drug use generated more than $1 trillion in savings. Commenting on the analysis, GPhA President and CEO, Ralph G. Neas said, "We have long maintained that the greater use of generic medicines is an integral part of the solution in reducing costs and ensuring the stability of the US health care system and the national economy."

Generic Makers Win High Court on Patents

In April, the U.S. Supreme Court unanimously sided with GPhA member company Caraco Pharmaceuticals Laboratories, Ltd. in ruling that generic drug manufacturers may argue in court that their brand-name rivals overstated the reach of their patents in regulatory filings. The decision overturned a lower-court ruling that would have enabled brand companies to delay generic launches. Caraco argued in the case that the innovator improperly extended its monopoly over Prandin® (repaglinide) until 2018 by misrepresenting to the FDA the reach of one of its patents. The FDA initially rejected Caraco's application for repaglinide, based on the innovator's patent claim in the Orange Book. But the Supreme Court ruled that generics could invoke a provision in Hatch-Waxman letting them challenge information submitted by innovators to the FDA.

Watson Acquires Actavis

In April, Watson Pharmaceuticals Inc. said it would buy Actavis Group for approximately $5.6 billion. *Reuters* had reported a month earlier that U.S.-based Watson was close to buying the Swiss company to help it compete in the global generics marketplace. "In a single commercially compelling transaction, we more than double Watson's international access and strengthen our commercial position in key established European markets," Watson chief executive and former GPhA chairman Paul Bisaro said.

Supreme Court Upholds Affordable Care Act

On June 28, the Supreme Court ruled 5-4 that President Obama's signature legislation, the Affordable Care Act (ACA), was constitutional. The landmark ruling was a major victory for Democrats. Even though several state governors are balking at setting up the required health care insurance exchanges in their states, implementation of the law is moving forward. Of particular concern to brand and generic drugmakers before the ruling was what would happen to the regulatory pathway for biosimilars if the Court struck down the ACA. In the dissenting opinion, four of the justices said they would have found the entire act invalid if a majority had found the health insurance mandate unconstitutional.

President Obama Signs User Fee Bill

On July 9, the President signed into law the generic drug user fee program, contained in the Food and Drug Administration Safety and Innovation Act (FDASIA), or S. 3187, which passed the House and the Senate with little opposition in late May. "This bipartisan bill shows what Congress can accomplish when we focus on the important work of the American people," Senate HELP Committee Chairman Tom Harkin (D-Iowa) and Ranking Member Mike Enzi (R-Wy.) said in a joint statement. Implementation of the user fee program began in October, with generic finished dose and API manufacturers committed to pay to the FDA $299 million annually in user fees over the next five fiscal years. The program earmarks $50 million in the first year to help clear the backlog of generic applications pending at the FDA.

Crowd gathers outside the U.S. Supreme Court on June 28, awaiting a decision from the Justices regarding the constitutionality of the Affordable Care Act.

Appeals Court Says Settlement is Anticompetitive

In July, the Third Circuit Court of Appeals reversed a lower court ruling that the K-Dur® settlement did not violate antitrust rules. The Third Circuit decision was contrary to previous rulings by federal appeals panels in New York, Atlanta and Washington, all of which upheld settlement agreements as long as they do not delay generic drugs beyond the expiration of the underlying brand patents. GPhA President and CEO said the Third Circuit's ruling was an outlier and that settlements "have resulted in making lower-cost generics available months and even years before patents have expired, saving consumers billions of dollars."

FTC OKs Industry Drug Shortage Plan

In August, the Federal Trade Commission (FTC) said a GPhA plan to have generic manufacturers share information for drugs in short supply with FDA via a third party is not likely to harm competition because of safeguards put in place to protect competitively sensitive data. The FTC decision opened the door for the Accelerated Recovery Initiative (ARI) to move forward. GPhA asked for the advisory opinion from FTC before fully implementing the ARI. The opinion was a critical step forward in addressing the shortages of needed medicines.

FDA Plans Reorganization of CDER

In September, the FDA said it would raise the stature of the Office of Generic Drugs (OGD) to the same level as the Office of New Drugs as part of a reorganization within the Center for Drug Evaluation and Research (CDER). "With the historic passage of the Generic Drug User Fee Amendments and a heightened public focus on generic drugs, I am proposing to elevate OGD to a 'super office' – an office that houses subordinate offices within its organizational structure," said CDER Director Janet Woodcock. In 2009, GPhA proposed to the White House that OGD be moved up in the organizational structure at the FDA because nearly 80 percent of all prescription medicines used in the U.S. were generic drugs.

FDA reorganization elevates stature of the Office of Generic Drugs.

Justices to Hear Settlement Issue

The Supreme Court said in December that it would take up whether patent settlements that include a payment from the brand company to the generic company violates any anticompetitive regulations. The case could settle the decade-long debate between industry and the FTC over patent litigation settlements. Three separate federal circuit courts of appeal have ruled settlement agreements were allowable. But a contrary ruling by the Third Circuit appeals court set the stage for the issue to go to the U.S. Supreme Court.

GPhA

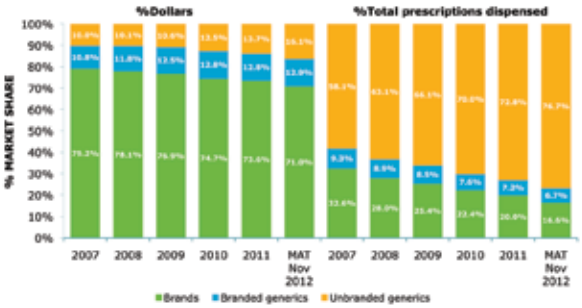
Generic Industry
by the Numbers

Dispensed prescriptions by leading corps in unbranded generics

Prescriptions of unbranded generics by leading corporations	MAT Nov 2012 TRxs mn	% Market Share	% Growth
US Industry	3,118	100.0	6.7
1 Teva	492	15.8	-1.0
2 Mylan Labs, Inc.	364	11.7	-0.4
3 Actavis/Watson	291	9.3	4.7
4 Sandoz (Novartis)	177	5.7	-17.4
5 Lupin Pharma	164	5.3	6.1
6 Endo Pharm Inc.	152	4.9	5.9
7 Amneal Inc	117	3.7	2.6
8 Greenstone (Pfizer)	93	3.0	-8.7
9 Dr Reddy Inc	84	2.7	13.7
10 Zydus Pharm	80	2.6	15.6
Top 10	2,014	64.6	-0.1

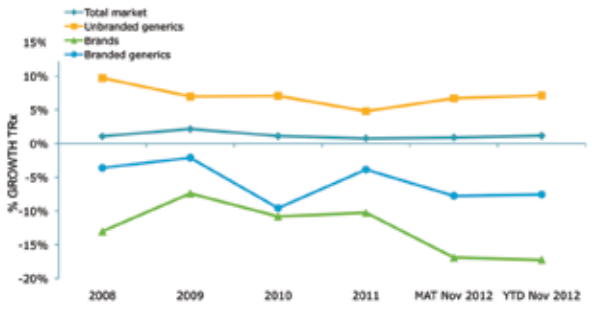
Source: IMS Health, National Prescription Audit, Nov 2012

Sales and TRx Share by Brand/Generic Segment (MAT)



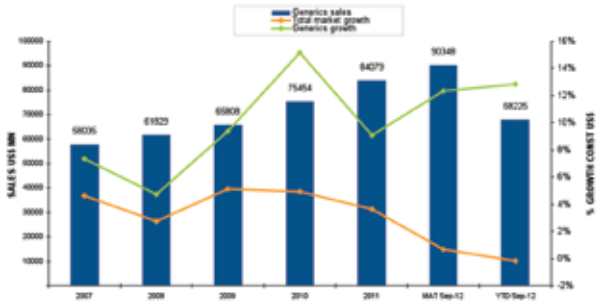
Source: IMS Health, National Sales Perspectives, Nov 2012, National Prescription Audit, Nov 2012

TRx Growth by Brand/Generic Segment



Source: IMS Health, National Prescription Audit, Nov 2012

Generics Sales and Growth - 8 Key Markets



Source: IMS Health, MIDAS, Market Segmentation, MAT Sep 2012, Rx only. *Market Segmentation universe

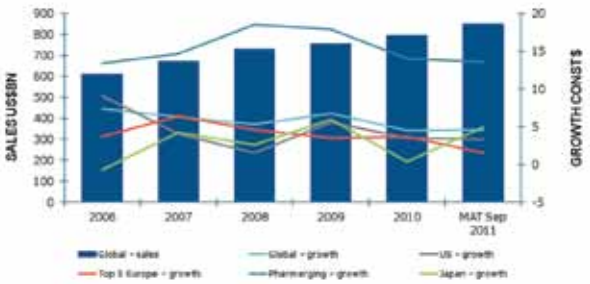
Generic Industry
by the Numbers

Top 10 market sales and growth
Audited markets in MAT Sep 2012

Country	MAT Sep 2012 Sales, Bn	% Market Share	% Growth	CAGR 2008-2012
10 Key Markets	669.5	100.0	2.1	4.4
United States	329.9	49.3	0.3	3.3
Japan	101.5	15.2	1.7	3.5
China	47.8	7.1	21.1	24.5
Germany	42.0	6.3	1.7	4.2
France	37.2	5.5	-0.3	0.8
Italy	26.2	3.9	-0.7	3.4
Canada	21.8	3.3	-0.2	3.6
Brazil	21.7	3.2	17.1	15.9
Uk	21.4	3.2	1.0	3.3
Spain	20.1	3.0	-5.7	2.3

Source: IMS Health, MIDAS, MAT Sep 2012

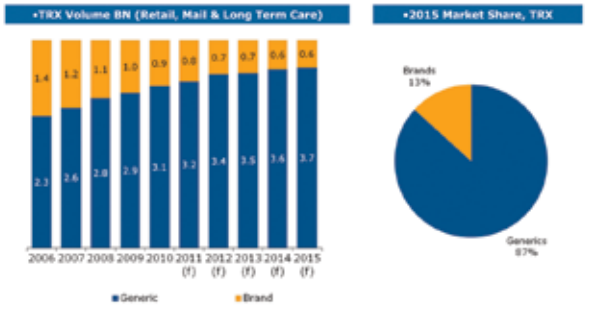
Global sales and growth
The audited market in Sep 2012



Source: IMS Health, MIDAS, Sep 2012

U.S. Savings Generated via Gx Usage
($ in billions)

Prescriptions to become more generic through 2015 with generic share reaching 87%



•Source: IMS Institute for Healthcare Informatics, 2011

The Nation

Some men see things as they are and say "why." I dream things that never were and say "why not."

ROBERT F. KENNEDY

Presidential Elections Dominate Media Coverage

2012. A year that will be remembered for a host of different reasons. For thousands of political campaign workers across the country, 2012 will be remembered as a year with too many late nights, too many tracking polls to keep up with, and, in the end, not a lot of change. For athletes from around the globe, it will be remembered as a year they came together in London to thrill the world with the Games of the XXX Olympiad. For millions of residents living along the east coast of the United States, 2012 will be remembered for the massive devastation caused by Hurricane Sandy. And for families in Newtown, Connecticut, it was a year that ended with unbearable sorrow.

Elections: The Year's Top News Story

The U.S. presidential election of 2012 was the 57th quadrennial presidential election in our nation's history. The presidential election also was the most searched news topic on Yahoo in 2012, dominating news coverage and online conversations beginning with the primaries early in the year.

The Democrat nominee, incumbent President Barack Obama, defeated the Republican challenger, former Massachusetts Governor Mitt Romney, to win a second term in the White House. While many major media outlets reported before the election that the race was too close to predict a winner in advance, some political analysts agreed with Las Vegas bookmakers that Obama was the clear favorite. By 11:15 p.m. eastern time on November 6, most television networks were projecting that the winner would be the incumbent president. At approximately 1:00 a.m. eastern time on November 7, Romney conceded the election to Obama.

In the U.S. House of Representatives, while Democrats won a plurality of the nationwide vote, Republicans were able to retain a solid majority, primarily due to advantages gained in congressional redistricting following the 2010 U.S. Census. This marked only the fifth time since 1900 that the party winning a plurality of the popular vote failed to receive a majority in the House. In the First Session of the new 113th Congress, the House will be comprised of 233 Republicans and 200 Democrats, with two vacant seats.

President Barack Obama and GOP Candidate Mitt Romney engage in debate prior to the November 6, 2012 national elections.

In the U.S. Senate, 33 of the 100 seats were being contested. Of those, 21 were held by Democrats, two were held by Independents who caucus with the Democrats, and 10 were held by Republicans. The elections resulted in the Democrats gaining a net of two seats, the Republicans losing a net of two seats, and the Independents staying at two seats. This was the third consecutive Senate election held in a presidential election year in which the

party belonging to the winning presidential candidate also gained seats in the Senate. The new Senate consists of 53 Democrats, 45 Republicans and two Independents.

Even though the U.S. Supreme Court had upheld the Affordable Care Act by the time the elections took place, health care reform still was among the more debated issues during the campaign. While President Obama defended the new health care law, Candidate Romney said repealing the law would be among his first efforts if elected to office.

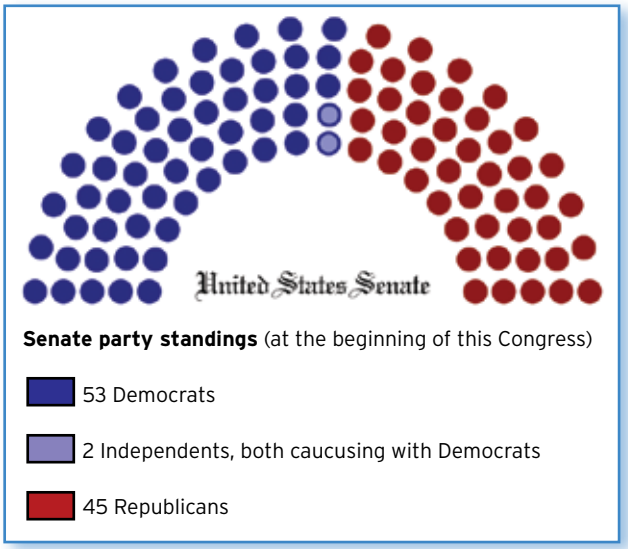
In The States

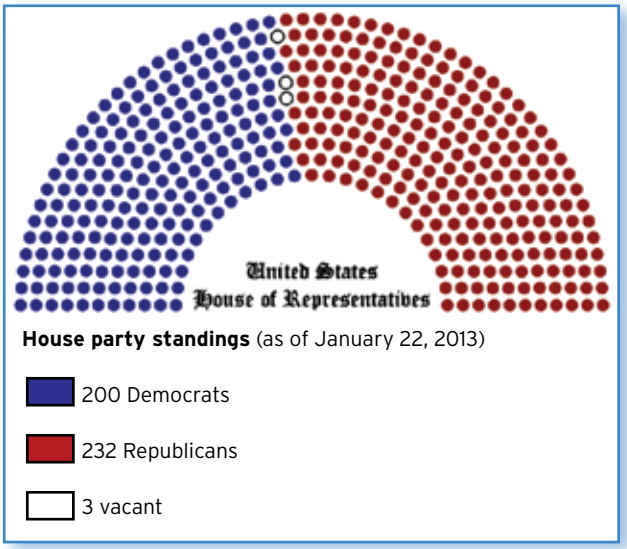
In the 50 states, which often are battlegrounds for generic issues such as therapeutic carve-out legislation, pharmaceutical take-back initiatives and generic bidding, 86 of the 99 legislative chambers held elections. Two-thirds of the country's 1,972 state senate seats were up for re-election and 4,714 (87%) of the country's 5,411 state house seats were up for re-election. Altogether, 6,015 of the nation's 7,383 state legislators had campaigns in 2012.

Elections immediately following redistricting historically demonstrate a higher number of open seats and a higher rate of new legislators than in typical election years. This was true in 2012, as the percent of state legislative turnover reached nearly 25 percent, up significantly from the average 17 percent in other election years.

Gubernatorial elections were held in 11 states and two territories concurrent with other elections during the general election of 2012. In addition, a recall election for Wisconsin was held on June 5. Of the eight Democratic and four Republican seats contested, only that of North Carolina changed party hands, giving the Republicans a net gain of one governorship.

Immediately following the elections, the National Governors Association (NGA) began dealing with the continued strains on state budgets by exploring innovative ways to "do more with less across state government." Included in those budget challenges are the rising health care costs associated with state employee health care benefits. NGA released plans to examine several best practices for controlling costs, including offering wellness programs and incentives for state employees to improve health outcomes and introducing new high-deductible health benefit plans. GPhA will be working closely both with NGA and with individual governors in key states to incentivize initiatives aimed at increasing the use of affordable generic medicines.





Hurricane Sandy Swamps the Northeast

After devastating portions of the Caribbean and the Mid-Atlantic, Hurricane Sandy headed for the Northeastern United States during October 2012. Sandy, classified as the tenth hurricane of the 2012 Atlantic hurricane season, was a Category 2 storm at its peak intensity. Nicknamed "Superstorm Sandy," it became the largest Atlantic hurricane on record, as measured by diameter, with winds spanning 1,100 miles.

Damages were estimated at $65.6 billion, which made Sandy the second-costliest hurricane, behind only Hurricane Katrina. The hurricane affected 24 states, including the entire eastern seaboard from Florida to Maine and west to Michigan and Wisconsin. But most severely damaged were areas in New Jersey and New York. At least 253 people were killed along the path of the storm, from the Caribbean to the North Atlantic.

GPhA member companies played a critical role in assuring that persons in heavily damaged areas could still get their prescription drugs. By participating with the American Red Cross, the brand drug industry and other partners, we enabled RxResponse to meet its goal of keeping the supply chain flowing in the storm-ravaged regions.

Of course, there were several other significant events that helped shaped 2012. From the high drama of the fiscal cliff to the failed IPO of Facebook, from the attacks on the U.S. Consulate in Benghazi to the gun violence at Sandy Hook Elementary School and a movie theatre in Aurora, Colorado, 2012 was a year that will be remembered.

GPhA

Hurricane Sandy, nicknamed "Superstorm Sandy," killed at least 253 people as it moved across seven countries.

Moving Foward

We are limited, not by our abilities,

but by our vision.

KAHLIL GIBRAN

GPhA: A Bright and Shining Future

THOSE NAYSAYERS WHO PREDICTED GENERIC COMPANIES WOULD HAVE A TOUGH TIME MAINTAINING GROWTH IN THE POST-2011/2012 "patent cliff" environment overlooked one important fact—the expert leadership that shapes, guides and secures our industry. By enlarging production capabilities, investing in new technologies, focusing on specialty and alternative dosage form products, and expanding into emerging global markets, our companies have built growth strategies that are not reliant upon the brief periods of one-time exclusivities from brand patent expirations. This forward-looking leadership has made generic prescription drugs the backbone of the pharmaceutical market. Throw in the promise of biosimilars and the key role generics will play in sustaining new health care reform policies and the future of our business could not be brighter.

And this all adds up to good news for patients and consumers! The savings that generics provide year after year are well documented. In 2011, the use of generic medicines saved more than one billion dollars every other day. This is light years ahead of the estimates when Hatch-Waxman was enacted in 1984, which predicted generics could save $1 billion per year. When biosimilars begin entering the market over the next few years, the savings will be even greater and consumers will gain access to less costly versions of biologic treatments for life-threatening diseases.

And this evolution will continue as fundamentals shift, competition increases, "pharmerging" markets grow, and new opportunities in specialty and proprietary sectors arise. GPhA is committed to being on the cutting edge of serving the needs of our member companies. Through effective advocacy of our interests, we are dedicated to creating and maintaining a political, legislative and regulatory environment that optimizes the benefits of generic and biosimilar products and facilitates robust growth of our industry. That is our vision.

2013 Operating Budget

Keeping with our theme for 2013, the current-year operating budget is entitled Vision and Action. Vision because it is the most robust and forward looking budget in the history of the Association; Action because for the first time the budget was driven completely by the priority action plans decided by the membership during the 2012 CEO Leadership Summit. The 2013 mission will be achieved by linking human and financial resources to legislative and regulatory strategies. This will optimally position GPhA to reach its goals for the year. Some of the key provisions of our 2013 budget are:

Revenues—The projected total revenue of $12.5 million is the highest level of Association funding ever.

Staffing—The budgeted staff of 23 FTEs includes eight in government affairs, four in regulatory sciences, two in media and communications and two in policy and alliances building.

Office Expansion—Included in the budget are funds to relocate to larger office space in the August timeframe.

Human Resources—The budget includes a new cost center, Human Resources, to enhance the Association's ability to recruit and retain the professional personnel required to meet our objectives and service staff needs.

Membership—A 150 percent increase in member recruitment and retention activities will facilitate our plans to grow the Association's membership base.

2013 Strategic Plan

To achieve the overall legislative and regulatory goals set by the membership for the Association in 2013, we developed seven priority cross-functional Comprehensive Action Plans (CAPs). The CAPs are cross-functional because successful execution requires the engagement of several departments at GPhA—policy, government affairs, regulatory sciences, media, alliances, etc. The seven CAPs are:

- Prevent the placing of restrictions on the ability of companies to settle patent litigation out of court.
- Achieve effective and timely implementation of GDUFA to assure that negotiated performance goals are attained.
- Strengthen relationships within CDER/OGD to facilitate collaboration in dealing with regulatory overreach, both in approvals and manufacturing.
- Develop potential proactive options to generic drug labeling concerns and guard against efforts to negate the impact of the Mensing decision.
- Assure an industry-centric biosimilar approval pathway with workable regulations that are sufficient to produce market incentives and savings.
- Affect drug shortages through implementation of the Accelerated Recovery Initiative (ARI).
- Defeat state anti-generic initiatives, such as biosimilars, carve-outs, generic bidding, and pharmaceutical take-back programs, and promote pro-generic use programs.

Each CAP details the overall objectives, evaluates the challenges and opportunities, and lists the near- and long-term metrics. The CAPs can be altered as necessitated by changing situations so that leadership can make strategic tradeoffs to allocate resources to core priorities.

In addition to the cross-functional priorities, there are four "ongoing" strategic priorities demanding our attention: (1) enact a national, uniform track-and-trace system to include electronic (paperless) labeling; (2) assure a pro-generic Trans-Pacific Partnership trade agreement that does not disadvantage the marketing of generic pharmaceuticals; (3) secure a favorable and constructive REMS policy; and (4) promote generic and biosimilar utilization in the private and public sectors.

We believe our 2013 strategic plan and accompanying operating budget offer a significant value proposition for all member companies.

Strong Gx Pipeline

With the generic dispensing rate (GDR) now 80%, generics are the backbone of the U.S. prescription drug market. And with the current robust generic pipeline expected to push the GDR to 88% in 2016, generic medicines will be the lifeblood of the health care system. Among the five leading generic companies, the pipeline includes more than 700 ANDAs, with 214 first-to-file opportunities. Blockbuster brands going generic in the next three years include:

Brand (generic name)	Annual U.S. Sales
Niaspan® (niacin XR)	$1.0 billion
Cymbalta® (duloxetine)	$3.5 billion
Nexium® (esomeprazole)	$5.6 billion
Lunesta® (eszopiclone)	$1.0 billion
Celebrex® (celecoxib)	$1.6 billion
Nasonex® (mometasone)	$1.2 billion
Namenda® (memantine)	$1.1 billion
Abilify® (aripiprazole)	$4.9 billion
AndroGel® (testosterone gel)	$1.0 billion

Bright Biosimilar Outlook

Adding to the bullish Gx future is a bright outlook for biosimilars. Between now and 2016, patents will expire on brand biologics with $40 billion in annual U.S. sales. Combining that with the $20 billion in biologics already off patent and the opportunities for biosimilars are abundant.

Biologic	Annual U.S. Sales	Patent expires
Remicade®	$5.9 billion	2013
Rituxan®	$5.7 billion	2015
Humira®	$5.5 billion	2015
Lantus®	$4.2 billion	2015
Neulasta®	$3.4 billion	2015
Rebif®	$2.1 billion	2013
Humalog®	$2.0 billion	2013
Erbitux®	$1.6 billion	2015
Cerezyme®	$1.0 billion	2013

Sources: IMS Health; Express Scripts; GrantThornton; Company reports.

The Who, Why and What of GPhA Membership

Who is GPhA?

GPhA is the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. GPhA is a strong voice in advocating the interests of its member companies before federal and state lawmakers, regulatory policymakers, and international agencies. GPhA's mission is to create and maintain a political and regulatory climate that is most conducive to the continued growth of our member companies.

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, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such a business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections.

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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