2011

# a year of PROGRESS

GENERIC PHARMACEUTICAL ASSOCIATION ANNUAL REPORT

**prog·ress** (prä-grəs). n. 1. Movement toward a goal; advancement. 2. Development and growth. 3. Steady and continual improvement.

# from the Chairman

**Paul Bisaro**
Chairman

The great English author Lewis Carroll wrote, "If you don't know where you are going, any road will get you there." But motion and activity are not progress. Progress, like that demonstrated over the past two years by your GPhA, has a clear goal and a defined direction. The road we have chosen, while challenging and difficult at times, has taken us a long way toward achieving the vision for our Association: To be a vibrant and proactive advocate for the interests of our members and for American consumers of generic pharmaceuticals.

For GPhA, 2010 was a year of transition. In 2011, with the transition behind us, the Board and staff were focused on delivering a demonstrable return on investment for our member companies. When I look at our accomplishments, I can say with confidence that we have shown the value of our reinvigorated Association. We have demonstrated that together much can be achieved, and that the power of speaking with one voice and engaging across all levels of public policy and scientific regulation can generate substantial results.

Throughout this annual report, you will read about the specific endeavors and significant advancements made by GPhA over the past year. Rather than repeat these, I want to highlight how our renewed vigor and enhanced member participation made 2011 a year of substantial progress for our Association.

On the regulatory front, the incredible involvement of member companies in our task forces and negotiating teams delivered generic drug user fee and biosimilar user fee plans that, I believe, will provide substantial and measurable benefits for all generic companies once enacted in 2012. On the legislative front, member engagement enabled us to take a leadership position in defining a pathway for the resolution of the drug shortage issue.

Working as a team, we blocked onerous legislative proposals that, if enacted, would have disrupted the competitive environment of our industry. In state after state we prevented local pedigree laws that would have created a burdensome patchwork of regulatory requirements.

And with renewed focus, we worked to ensure that international treaties and harmonization activities did not become fertile ground for initiatives designed to disadvantage generic utilization in the U.S. and around the world.

I want to thank the members of the GPhA Executive Committee and the Board of Directors for the countless hours they spent in 2011 to define our objectives and chart our course. I want to thank the GPhA staff for their extraordinary efforts and their exceptional strategic and tactical execution throughout the year. And I want to congratulate Ralph Neas on joining our organization. His leadership will advance us toward the goal of being what we must be for our member companies, our industry and all Americans who rely on the affordable medicines we provide.

Finally, as I end my term as Chairman, I want to thank each of our member companies who gave support and advice as we remade our Association. You challenged our staff and leadership to go further than we thought possible and, with your engagement and commitment of resources, we progressed to a higher level of success and excellence. It has been a privilege to serve as Chairman and I look forward to supporting the new leadership of GPhA in 2012 and beyond.

Paul Bisaro

Chairman of the Board

# GPhA 2011 Board of Directors

*From the left:* Paul Bisaro (Watson), GPhA Chairman of the Board; Chuck Caprariello (Ranbaxy); Thomas H. Silberg (APP); David Klaum (Fougera); Doug Boothe, *standing* (Actavis); Tom Murphy (Ben Venue); Paul Campanelli (Par); Craig Wheeler (Momenta), GPhA Secretary-Treasurer; Debra Barrett (Teva); Don DeGolyer (Sandoz); Tony Mauro (Mylan), Vice Chairman of the Board; Joseph Renner (Zydus).

# from the President and CEO

**Ralph G. Neas**
President & CEO

What a way to begin! When I look back over the first few months as your President and CEO, it's hard to believe what a ride it has been. From giving a speech at the FDA on my twelfth day on the job, to joining industry executives from around the globe in South Africa, to testifying before Congress—the phrase "hitting the ground running" only begins to capture this incredible beginning. More than anything else though, this whirlwind start is a testament to the magnitude and importance of the issues facing our industry and the remarkable year we had in 2011. As you will read in this report, we negotiated two landmark user fee programs that will help shape the future of our industry. We staved off numerous attempts to ban pro-consumer patent settlements. We led efforts to minimize shortages of critical drugs. And we continued our remarkable string of successes in the states. But those efforts represent just a fraction of our achievements. As shown in the GPhA/IMS annual savings analysis, our work and the use of our products generated $158 billion in health care savings in 2010 alone, a remarkable rate of $3 billion every week.

As we move into 2012, GPhA will be on the front lines like never before, ensuring that as those in Washington look for savings, they recognize that generics lower costs while providing the same quality care patients have come to rely on. We will enhance communication with the FDA as the agency works to implement a biogeneric approval pathway. We will assure that, as Congress acts on the user fee bills, it keeps intact the fundamental provisions we negotiated with the Agency. And, we will launch the Affordable Medicine Research Institute to help educate both the public and policymakers about the safety and efficacy of generic drugs.

Since my first day at GPhA, I have stressed that our continued success rests on our ability to work together with all health care stakeholders. Unlike the partisanship that is prevalent in election years, our issues are neither Republican nor Democrat, conservative nor liberal. They are national economic security issues that need the support of everyone. In 2012, our mission is clear: We will work with all health care sectors to protect the interests of our members and increase access to affordable medicines.

Ralph G. Neas
President and CEO

# **2011** A Year of Progress

*Without continual growth and progress, such words as improvement, achievement, and success have no meaning.*

Benjamin Franklin

# A YEAR OF PROGRESS

***Progress.*** *A common word used to express development, growth, advancement, change for the better. More than simple movement, progress results from executing a designed strategy focused on reaching an improved position. Progress is the ideal word to sum up 2011 for GPhA. It denotes headway on the road to achieving our mission while acknowledging there still is more to do. As we reflect back over the events of 2011, we remain challenged by the mandate to stretch our efforts and press on to higher goals in 2012 and beyond.*

## The New Look

Last year marked the beginning of our second decade as an association representing the manufacturers and distributors of finished dose generic pharmaceuticals and the suppliers of bulk pharmaceutical chemicals. We began the year with a new look, having completed the implementation of a significant restructuring program in late 2010. Under the redesigned GPhA, a determined effort was launched to enhance the Association's influence and effectiveness in advocating the interests of member companies.

**GPhA Government Affairs Team.** *L to R:* Dave Belian, Media; Shawn Brown, VP State; Brynna Clark, Director State; Jason Money, Sr. Director Federal; Jim Fenton, Sr. VP Government Affairs; Chris Davis, Director Federal; Havi Glaser, VP Policy; Mark Hendrickson, Associate Director of Government Affairs.

Plans called for doubling the size of the federal and state Government Affairs teams, boosting the resources allocated to legislative and regulatory initiatives, and hiring a new President and CEO with the leadership skills and experience needed to drive the message that the use of generic and biogeneric medicines is key to the sustainability of health care and of our economy. We are pleased to report that all of these milestones were reached in 2011. And the equatized membership dues structure established under the restructuring program generated record high revenues for the year and helped attract more than a dozen new member companies into the Association.

# GDUFA: Event of the Decade

The summer of 2011 will be remembered as the time we finally completed the generic drug user fee program (GDUFA). Negotiations between industry and the FDA began in 2008 but soon ended as there were significant differences between the parties in the structure of performance metrics. Then, in early 2011, the talks resumed with the goal of completing GDUFA work by the end of summer. After three months of very difficult and intense discussions over program standards and performance goals, stakeholders reached agreement on the guidelines for the GDUFA statutory language.

By September 8, GPhA had formally ratified the documents outlining the agreed upon performance goals and legislative language needed for Congress to authorize GDUFA. The next day, both the European API industry and the Bulk Pharmaceuticals Task Force of SOCMA ratified the user fee documents. GPhA Chairman Paul Bisaro called the moment "the most monumental event for the generic industry in the past decade."

The GDUFA program is built on three foundational principles: safety, access and transparency. The safety component assures that industry participants, foreign or domestic, who participate in the U.S. generic drug system are held to consistent high quality standards and are inspected biennially using a risk-based approach to provide foreign and domestic parity. Access means expediting the availability of affordable, high quality generic drugs by bringing greater predictability to the review times for generic drug applications. Transparency enhances FDA's ability to protect Americans in the complex global supply environment by requiring the identification of facilities involved in the manufacture of generic drugs and associated active ingredients.

While the user fee program for small molecule drugs captured the majority of the headlines, we also completed negotiations on principles for a biogeneric use fee program (BSUFA). The most critical issue associated with biogenerics is to ensure that the performance metrics and the regulatory pathway for approvals will provide timely access to these lifesaving treatments. This means that the regulations cannot be fraught with unwarranted obstacles to approval.

***The most monumental event for the generic drug industry over the past decade.***

GPhA is confident that these two user fee programs will improve the quality of applications and the review process, and give the assurance of certainty of approval timing. The new programs will provide all companies, regardless of size, with measurable returns on investment.

GPhA sincerely thanks FDA for the substantial commitment it made in collaborating with all industry stakeholders to assure a successful negotiation process for both the generic and biogeneric user fee programs.

# The Drug Shortage Crisis

GPhA and its member companies led the efforts in 2011 to find workable and effective solutions to alleviate drug shortages. In a September presentation to FDA's Center for Drug Evaluation and Research, GPhA President and CEO Ralph G. Neas called for "unprecedented multi-stakeholder collaboration" to address the complex shortage crisis. He said, "The solution must come from all stakeholders—brand and generic drug manufacturers, active ingredient suppliers, wholesalers, distributors, GPO's, health care providers and the FDA."

On December 15, Mr. Neas testified at a drug shortage hearing before the Senate Health, Education, Labor and Pensions Committee. He told Senate members that GPhA is committed to working with all stakeholders to find solutions to shortages because "at its core, GPhA's purpose is to improve the lives of consumers by providing timely access to affordable medicines."

***"Solution requires collaboration; generic makers take a lead role."***

*USA Today*

Mr. Neas also unveiled the Accelerated Recovery Initiative (ARI), a program to establish an independent third-party clearinghouse of information related to the available supply of critical drugs in short supply. By the end of 2011, GPhA had begun planning the ARI. The information collected by the clearinghouse would be used to identify potential gaps in drug supplies compared to market requirements. A high-level "SWAT team" within FDA with the ability to quickly respond to critical shortages and work with the current Drug Shortage Staff expanded through President Obama's drug shortage initiative.


GPhA President & CEO Ralph G. Neas addresses FDA workshop on drug shortages, September 2011.

The basic mission of the ARI is to increase early visibility and communication between the FDA and industry relating to both current and potential drug shortages. The Healthcare Supply Chain Association (HSCA) commended GPhA for advancing ARI, calling it "an innovative, constructive, private-sector solution to the growing problem of drug shortages." Time will prove that the Accelerated Recovery Initiative and the

stakeholders it brings together will be the catalyst to the drug shortage solution.

## "The dog ate my homework!"

House and Senate lawmakers spent considerable time in 2011 deliberating legislation that would reform U.S. patent laws. Much debate focused on H.R. 1249, the Leahy-Smith America Invents Act (AIA). Included in that bill was Section 37—"The Medicines Company amendment"—intended to retroactively change the time period to apply for a patent term extension under the Hatch-Waxman Act.

The provision, frequently referred to as "the dog ate my homework act," was an egregious example of an earmark designed to benefit a single brand pharmaceutical company (The Medicines Company) extend the monopoly of a single drug, Angiomax®, at significant expense to American consumers and patients. Because The Medicines Company's legal team failed in 2001 to file on time the patent term extension application for Angiomax, the company spent millions of dollars last year lobbying Congress for passage of Section 37.

Although significantly less funded, GPhA fought against inclusion of Section 37 in the AIA because it potentially could delay the launch of several generic drugs in the future. Thanks to the support of Senators Jeff Sessions (R-AL) and Joe Manchin (D-WV), we forced a vote on the Sessions-Manchin amendment that would have stripped the provision and preserved the timely access to generics. While we failed to gain passage of the amendment, we came so close that several Members of Congress took notice. Against all odds, we had not only forced a vote but we had missed winning by only four votes, 47-51. The summer-long legislative fight had proven that the influence of GPhA and its member companies on Capitol Hill is growing and our effectiveness in advocating for generic interests and our industry is stronger than ever before.

The New York Times

**Patent Bill Viewed as Bailout for a Law Firm**

By Andrew Pollack
September 8, 2011
The New York Times

A bill to overhaul the patent system that is before the Senate contains a provision that could get an influential law firm off the hook for a possible $214 million malpractice payment.

The provision clarifies how much time pharmaceutical companies have to apply for patent extensions that can provide extra years of protection from generic competition.

But critics, who have labeled the provision "The Dog Ate My Homework Act," say it is really a special fix for one drug manufacturer, the Medicines Company, and its powerful law firm, WilmerHale. The company and its law firm, with hundreds of millions of dollars in drug sales at stake, lobbied Congress heavily for several years to get the patent laws changed.

The patent office initially said that the company had missed the deadline for applying for a patent extension by a day or two, potentially losing nearly four years of patent protection on its main

changes could jeopardize the entire legislation.

J. Scott Applewhite/Associated Press

"The key question is whether we will vote to bail out a law firm that made a mistake and now wants consumers and taxpayers to pay the freight for that error," said Senator Jeff Sessions, above, and Senator Tom Coburn, in a letter to colleagues.

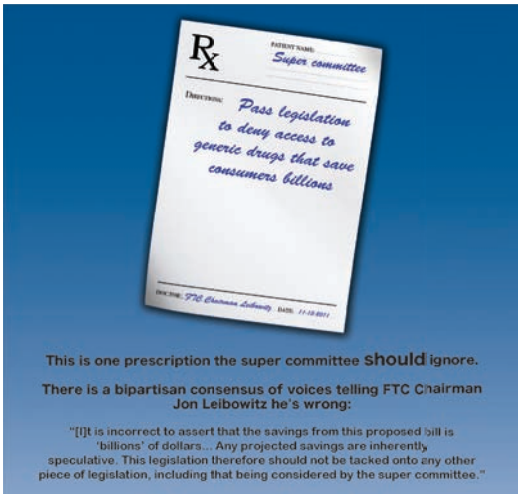
David E. Redlick, co-chairman of the life sciences practice at WilmerHale, said other companies, including Bayer and AstraZeneca, might also now

*The New York Times* was one of several major media sources to carry GPhA's message that the Angiomax provision was a bailout.

## Patent Settlement Ban

Prodded by continual pressure from the Federal Trade Commission (FTC), Congress repeatedly attempted to pass legislation that that would ban patent litigation settlements. Settlements are a proven way to bring generic drugs to the market months, if not years before patent expiry and save patients and federal and state governments millions of dollars annually. GPhA successfully staved off legislative initiatives aimed at barring pro-consumer patent settlements. Throughout 2011, we heralded the message that if a ban

were imposed, it would have the unintended consequence of limiting the number of patent challenges brought by generic drug manufacturers.

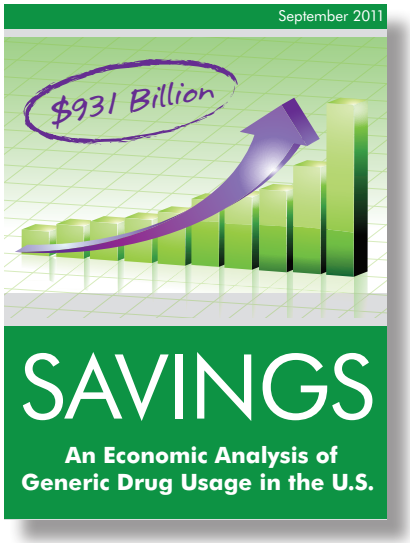



GPhA full-page ad in *The Wall Street Journal* urges super committee to reject ban on patent settlements.

GPhA ran a full-page ad in *The Wall Street Journal* depicting a prescription to the super committee with the instruction "Consumers can't afford higher healthcare costs. Tell Congress to 'First, Do No Harm.'" The ad quoted several experts who oppose an outright ban on settlements, including one of the FTC commissioners, J. Thomas Rosch, who said, "Any projected savings are inherently speculative. This legislation therefore should not be tacked onto any other piece of legislation, including that being considered by the super committee." House Judiciary Chairman Lamar Smith (R-TX) said about the settlement ban legislation, "Not only does the bill make bad policy… but claims that it might modestly reduce the deficit are highly doubtful…indeed, we believe the bill is as likely to increase the deficit as decrease it." GPhA urges policymakers to focus their efforts not on banning pro-competitive settlements but rather on initiatives that promote, not hamper, consumer access to safe and effective generic drugs.

## OGD Funding

In late 2011, Congress passed the "minibus" bill (as opposed to an omnibus bill) that boosted FDA funding for FY2012 by $50 million, to $3.8 billion. With lawmakers under considerable pressure to cut federal spending across the board to lower the national deficit, it was a victory for the generic industry to get even this minimal increase in appropriations for the FDA. Most importantly, it preserved funding for the Office of Generic Drugs (OGD). During the debate, our message to Congress was clear: cuts in FDA's budget would further encumber the timely approval of generic medicines, which have proven to provide savings for the government, health care providers and




In September, GPhA released its third annual savings study showing that generic drug use has saved the U.S. health care system $931 billion over the past decade, $158 billion in 2010 alone.

consumers. Our message was supported by the September 2011 IMS savings study showing that the use of generics generates $3 billion in health care savings every week.

We believe congressional action with respect to the FDA and OGD budget reflects an understanding of our message of savings and of the vital role a fully funded Agency plays in containing health care costs. The funding increase approved by Congress will reap significant dividends by helping ensure that the FDA and OGD continue to receive the resources they need to provide Americans with safe, effective and affordable generic medicines.

## Influence in the States

GPhA's State Affairs team represents the generic industry's interests in all 50 states. In addition to our in-house staff, GPhA employs independent consultants in the seven states that are active in drug-related initiatives. Further support comes from GPhA member companies that have state-based government affairs employees or consultants in an additional 18 states.

Through the national legislative and regulatory tracking service, StateSide Associates, we receive up-to-the-minute alerts about the movement of legislative initiatives and regulatory developments in every state. In 2011, GPhA was active in several state associations and coalitions, including the Democratic Governors Association, the Republican Governors Association, and the National Council of State Legislatures.

Through these alliances, GPhA and its member companies were successful in blocking 51 anti-generic substitution bills (carve-out legislation) introduced in 22 states. These bills were intended to limit generic utilization in specific therapeutic classes and were being pushed by special interests seeking to protect brand monopolies. For instance, GPhA managed to contain a concerted effort by brand companies in Tennessee to require prescriber notification prior to dispensing AB-rated generic drugs. This would have created an onerous process for pharmacists, prescribers and patients, and could have reduced generic substitution by between 4 percent and 5 percent, according to the Centers for Medicare and Medicaid services. Last year, we engaged in dozens of face-to-face meetings with governors, state Medicaid agency regulators, and state legislators. We testified before 13 state assemblies and distributed educational materials and best practice guides in more than 40 states.

## Drug "Take Back" Initiatives

Onerous and burdensome pharmaceutical waste proposals that would have required manufacturers to fund costly "take back" programs for unused medicines were launched in dozens of states in 2011.

GPhA and its allies blocked all of these initiatives. There is no guarantee that such take back laws would reduce the trace amounts of chemicals detected in ground water. So instead of expensive take back programs, GPhA, along with the Pharmaceutical Research and Manufacturers

of America, led efforts to educate consumers on proper disposal methods for unused medicines. We worked with the U.S. Fish and Wildlife Service, the American Pharmacists Association and community based disposal efforts, such as the "American Medicine Chest Challenge," to find workable solutions.

## Track and Trace Legislation

GPhA's goal has been to establish a national, uniform, cost-effective and workable drug tracking system. Without a national drug tracking system, more states may follow California's lead in imposing state track and trace laws. Complying with a patchwork of 50 different state drug tracking regulations would be impossible for pharmaceutical manufacturers.

GPhA's State Affairs team, along with the federal Government Affairs staff, have been advocating for legislation that would implement an end-point authentication system, similar to that in Europe, to add security to the supply chain. The system would rely on 2D barcodes as the standard technology for serialization, a well-established and more affordable technology than RFID.

GPhA's end-point authentication model for increasing supply chain security is a more efficient alternative to the track and trace model envisioned by California's law. The GPhA Pedigree Task Force is also working with multiple stakeholders to develop a national uniform model that would pre-empt the California law, set to take effect in 2015.

In addition to endorsing end-point authentication, we also support the Pharmaceutical Distribution Security Alliance in developing the RxTEC model, a multi-stakeholder effort to create a track and trace system based on a consensus of participants in the supply chain. Both models could help achieve the goals GPhA shares with FDA: to prevent the introduction of counterfeit drugs into the supply chain and assure accountability for the movement of prescription drugs in the U.S.

| 2012 Issues List |
|---|
| GDUFA legislation |
| Drug shortages |
| Carve-Outs |
| e-Prescribing |
| AMP reporting |
| BSUFA legislation |
| Pharmaceutical take-back |
| Patent settlements |
| Free trade agreements |
| Bioequivalence |
| Public education |
| Biogeneric approval regulations |
| QbD implementation |
| Regulatory overreach |
| OGD funding |
| Medicaid rebates |
| Drug safety |
| National pedigree |
| Product labeling |
| Stability requirements |

# **2012** The Year Ahead

*Progress lies not in enhancing what is, but in advancing toward what will be.*

Khalil Gibran

# THE YEAR AHEAD

***We work in a rapidly changing industry.*** *Shifting fundamentals, such as increased competition, the rising role of emerging markets, and targeted opportunities in niche segments, have begun a transformation away from the typical generic business of a decade ago to an industry of global companies competing in both the generic and the brand market spaces. This evolution within the generic industry is expected to accelerate over the next five years as leading companies continue consolidating to build economies of scale, develop proprietary pipelines to boost post-patent cliff revenues, and enhance technological expertise to compete in specialty and biogenerics markets.*

*For GPhA, this change creates a challenging mandate: We must be responsive to the evolving needs of our member companies. This requires that we do more than simply react to change. To be successful, we have to anticipate change and be on the cutting edge of shaping a pro-growth environment for our members. And we must execute a winning advocacy strategy that optimizes the use of generic and biogeneric medicines needed to sustain affordable health care.*

## Defending Hatch-Waxman

Pending congressional action on the landmark generic and biogeneric user fee programs has provided an opportunity for some in the pharmaceutical sector to call for a revamping of the Hatch-Waxman system. These critics of the current generic program argue that the 1984 law has tilted the rules in favor of the generic industry at the expense of brand innovation. But nothing could be further from the truth. Competition from generics has spurred unprecedented innovation of new and improved classes of drugs and delivery systems among brand companies. It was competition from generics that resulted in proton pump inhibitor such as Nexium®, replacing the older H2 antagonists like Zantac®. Competition from generics prompted the innovation of selective serotonin reuptake inhibitors like Prozac® to replace amphetamines for the treatment of depression. It was competition that led to the development of new cholesterol drugs like Lipitor® and Zocor®, antipsychotics Zyprexa® and Risperdal®, the blood thinner Plavix®, and more.

Very few, if any, pieces of legislation have delivered the benefits to consumers that Hatch-Waxman has—both in the development of new and better medicines and in delivering nearly $1 trillion in savings over the past decade. GPhA is resolute in its commitment to defend Hatch-Waxman against any efforts to lessen the effectiveness and value of current regulations governing generic approvals and use.

## User Fee Legislation

A priority for GPhA in 2012 will be to assure that Congress enacts generic drug user fee (GDUFA) and biosimilar user fee (BSUFA) legislation that is in line with the principles negotiated by industry with the FDA. Our federal affairs team already has begun that process by conducting briefings for Hill staff to explain the value of each component of GDUFA and BSUFA in assuring that the programs facilitate the timely approval of generic and biogeneric medicines.

Specific to GDUFA, we will intensify our advocacy for legislation that creates a balanced approached to safety, access and transparency. And with respect to BSUFA, we will be relentless in guarding against the inclusion of any provision that serves only to erect an obstacle to FDA approval of biosimilars and biogenerics.

## Alleviate Drug Shortages

GPhA is committed to minimizing current and future shortages of critical drugs. In 2012, we plan to implement the Accelerated Recovery Initiative (ARI) to establish a voluntary communication between an independent third party and stakeholders involved in the manufacturing and distribution of generic injectable medicines. The ARI is designed to provide real-time supply and distribution information to manufacturers, wholesalers, Group Purchasing Organizations and the FDA and identify supply gaps, with a focus on those products where a shortage is expected to last longer than 90 days. This information would enable stakeholders to take the appropriate steps needed to minimize the shortage of critical medications to patients in need.

> ***"The shortage crisis compels unprecedented multi-stakeholder collaboration…to include manufacturers, API suppliers, wholesalers, GPOs and the government."***
>
> *GPhA President & CEO Ralph G. Neas*

We will urge that a high-level SWAT team be formed within FDA with the ability to quickly respond to shortages and work with the Drug Shortage Staff, expanded through the President's drug shortage initiative. The generic industry has taken a leading role in responding to the shortage crisis, and the ARI marks a significant step in those efforts.

## Regulatory Sciences

GPhA is adding clout to its regulatory efforts in 2012. The budget for our Regulatory Sciences department has nearly doubled and we are focusing on greater company involvement in the Technical Advisory Committee (TAC). Plans call for GPhA to sponsor three technical workshops to give member companies unique opportunities to learn and gain insight directly from FDA staff in a small group environment. And the GPhA/FDA annual Fall Technical Conference will again attract the largest attendance for any similar industry meeting.

The activities of our Regulatory Sciences department could not be more critical as we work to assure a safe drug supply chain, an equitable inspection process, workable REMs and Quality by Design programs, fair labeling, bioequivalence standards, and timely ANDA approvals from the Office of Generic Drugs. Continual collaboration with FDA on these and other issues will be our goal in 2012.

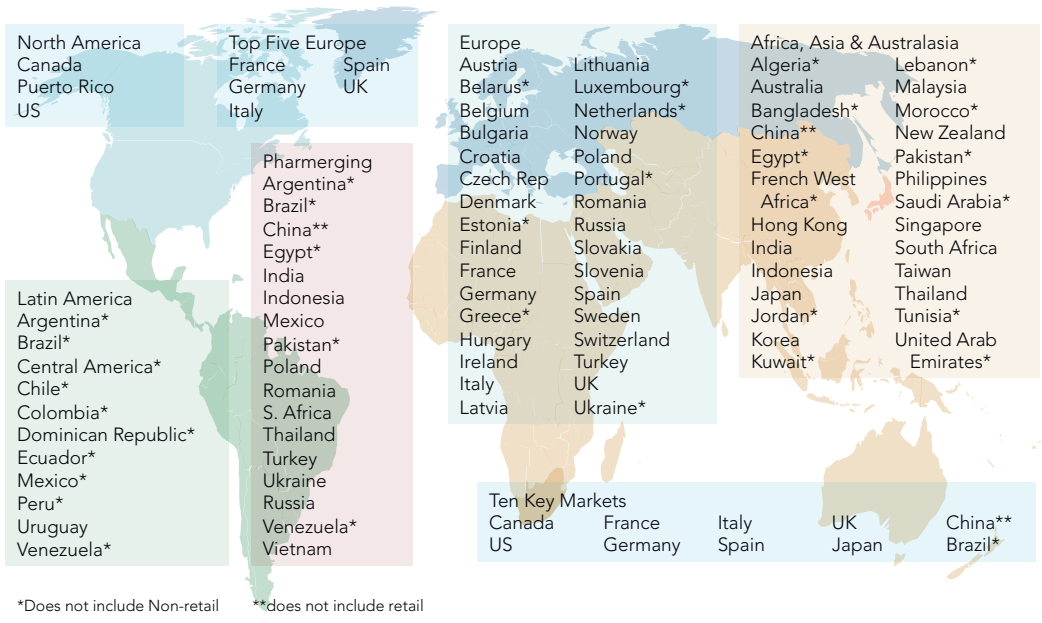
But perhaps the top priority of Regulatory Sciences in 2012 will be working with the FDA to implement a regulatory approval pathway for biogenerics and biosimilars. It is essential that the approval process be science-based with any clinical trials applied on a case-by-case basis, not mandatory across the board. Naming regulations must not impede interchangeability, and innovator exclusivity provisions cannot provide unwarranted monopolies for branded biologic products.

# Global Presence

Generic companies increasingly operate in a global marketplace. Consequently, we must be instrumental in helping shape international laws and regulations that impact the development, approval, manufacture and marketing of generic drugs.

Working through the International Generic Pharmaceutical Alliance and our allies in the European Union, Canada, India, South Africa, Mexico and South America, we will implement a strategy to expand GPhA's international influence. And we will provide our member companies with international-related services, including representation within international bodies and protection against anti-generic laws in trade agreements. We will assure that trade pacts are free of interchangeability restrictions and unwarranted brand exclusivity provisions.

## Generic Pharmaceuticals: A Global Marketplace




*Does not include Non-retail **does not include retail

# *In Memoriam*

*2011 saw the passing of three pioneers whose visionary leadership helped shaped the present day generic pharmaceutical industry. While they rose from widely diverse beginnings, they each had an intense commitment to providing consumers and patients around the world with safe, effective and affordable medicines. Very few of us in the generic industry were not at some time touched by one of these memorable leaders.*

**Agnes Varis (1930–2011).** Ms. Varis used her chemistry degree and $50,000 to build a profitable pharmaceutical business, which included founding Agvar Chemicals and Aegis Pharmaceuticals. Her successes allowed her to become a prolific philanthropist. An ardent fan of opera, Ms. Varis was at her death a managing director of the New York Metropolitan Opera, to whom she donated $21 million. In 2010, President Obama appointed her to the President's Committee on the Arts and the Humanities. Agnes often shared that she "deliberately avoided learning to type so as never to drown in a typing pool."

**Milan "Mike" Puskar (1934–2011).** Mr. Puskar was a great American entrepreneur. After returning from military service in the Korean War, he turned an idea for a pharmaceutical company into one of the largest generic drug manufacturers in the world. Known today as Mylan Inc., the company still is guided by "Mike's commitment to excellence." He also was a generous philanthropist, giving millions of dollars to various universities. His $20 million donation to West Virginia University is the single largest gift in the school's history. Mike's dictum "We do it right or we don't do it at all" continues to define Mylan's business.

**Eli Hurvitz (1932–2011).** Mr. Hurvitz was an Israeli industrialist who, in 2005, was named Business Leader of the Decade by Dun & Bradstreet. He was a recipient of the Israel Prize, for lifetime achievement and special contribution to society. Mr. Hurvitz served as chairman of the Israel Export Institute, was president of the Israel Manufacturers Association, and was chairman of the Jerusalem Development Authority. At the time of his death, he was Chairman of the Board of Teva Pharmaceutical Industries.

# Fall Tech...the world's most unique generic drug conference.

*GPhA's annual Fall Technical Conference attracts 600 regulatory and science experts each year from around the globe. Co-sponsored with the FDA, Fall Tech provides unique educational sessions on such issues as bioequivalence, CMC requirement, drug labeling, Quality by Design, and many more. There simply is no conference in the world like Fall Tech.*


*Clockwise from top left:* Crowd of 600 registrants attend the 2011 GPhA/FDA Fall Technical Conference in Bethesda, Maryland, October; Gordon Johnston, GPhA Vice President of Regulatory Science addresses Fall Tech attendees; Donna Kaye Wilson, Ph.D., Director, Standards Acquisition, United States Pharmacopeia; One of several specialized Breakout Sessions at Fall Tech; Soo Jin Park, Pharm.D., Regulatory Compliance Officer, Office of Compliance, FDA; Keith Webber, Ph.D., Deputy Director, Office of Pharmaceutical Science and Acting Director, Office of Generic Drugs, CDER, FDA.

# **2011** Operations

*Whenever a business decides that success has been attained, progress stops.*

Thomas J. Watson

# 2011 GPhA Membership

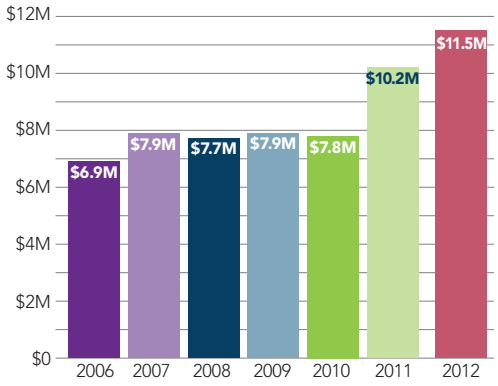
A.J. Renner & Associates
Aceto Corporation
ACIC
Actavis Inc.
Alvogen Inc.
Amerisource Bergen Corp.
Amneal Pharmaceuticals
ANDA, Inc.
Apicore LLC
Apotex Corporation
APP Pharmaceuticals, Inc.
Baker, Donelson, Bearman, Caldwell & Berkowitz, P.C.
Bausch & Lomb
Ben Venue Laboratories Inc.
Capsugel
Cardinal Health
Caremark Rx
ChemWerth Inc.
DAVA Pharamceuticals, Inc.
Dr. Reddy's Laboratories Inc.
Duane Morris LLP
Dykema Gossett PLLC
Endo Pharmaceuticals Inc.
Express Scripts Inc.
Fougera
Gedeon Richter USA
Greenblum & Bernstein
GYMA Laboratories
Haynes and Boone, LLP
Heritage Pharmaceuticals Inc.
Impax Laboratories, Inc.
Ind Swift Laboratories Inc.
Interchem Corporation
JHP Pharmaceuticals LLC
Johnson Matthey Pharmaceutical Materials
Katten Muchin Rosenman LLP
Knobbe Martens Olson & Bear LLP
Kremers-Urban Pharmaceuticals Inc.
Lachman Consultant Services Inc.
McKenna Long & Aldridge LLP
Mckesson Corporation
Medco Health Solutions Inc.
Midas Pharmaceuticals Inc.
Momenta Pharmaceuticals Inc.
Mylan Inc.
Novum Pharmaceutical Research Services
Par Pharmaceutical, Inc.
Perrigo Company
Pharma Medica Research Inc.
Pharmanet Canada Inc.
Prasco Laboratories
Putney Inc.
Ranbaxy Inc.
Ren-Pharm International Ltd.
Rising Pharmaceuticals Inc.
Roxane Laboratories
Sagent Pharmaceuticals, Inc.
Sandoz Inc.
Schwegman, Lundberg & Woessner, PA
Sovereign Pharmaceutical
Spear Pharmaceuticals
Symbio LLC
Synthon Pharmaceuticals, Inc.
Teva Pharmaceuticals USA
ThePharmaNetwork, LLC
Vijuk Equipment
Vinchem Inc.
Watson Pharmaceuticals Inc.
Zydus Pharmaceuticals USA

# Committees, Task Forces & Working Groups

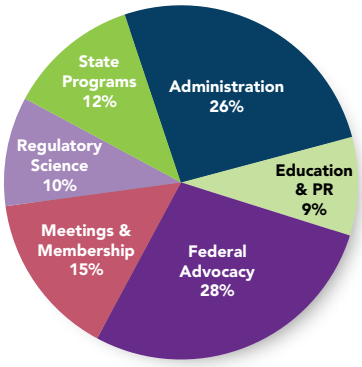
API Supplier Task Force
Audit and Investment Committee
Bioequivalence Group
Biogenerics Task Force
Carve-Outs Task Force
Cost Containment Modeling
Drug Shortage Working Group
Foreign Inspections Group
Government Affairs Committee
International Affairs Committee
Legal Affairs Committee
Membership Committee
Patent Settlements Task Force
Pedigree Working Group
Pharmaceutical Waste Group
Reimbursement Modeling
REMS Working Group
State Affairs Subcommittee
Supply Chain Security Group
Technical Advisory Committee
User Fee Task Force

# GPhA 2011 Financials

Total Income




2011 Expense Allocation




# GPhA Staff

## Office of the President & CEO

**Ralph Neas**
*President & CEO*

**Cookie Cottrell**
*Executive Assistant to the President; Senior Manager of Membership*

## Government Affairs

**Jim Fenton**
*Senior Vice President of Government Affairs*

**Shawn Brown**
*Vice President of State Government Affairs*

**Havi Glaser**
*Vice President of Policy & Strategic Alliances*

**Jason Money**
*Senior Director of Federal Government Affairs*

**Chris Davis**
*Director of Federal Government Affairs*

**Brynna Clark**
*Director of State Affairs*

**Mark Hendrickson**
*Associate Director Government Affairs*

## Regulatory Science

**David Gaugh**
*Vice President for Regulatory Sciences*

**Ashlee Koonce**
*Associate Manager of Regulatory Affairs*

## Operations

**Bob Billings**
*Executive Vice President*

**Rachelle Kosky**
*Senior Director of Finance and Operations*

**David Belian**
*Director of Media Relations*

**Katie Dysart**
*Director of Meetings and Events*

**Jennifer Nguyen**
*Senior Manager of Events and Marketing*

**Aquera Agee**
*Receptionist*

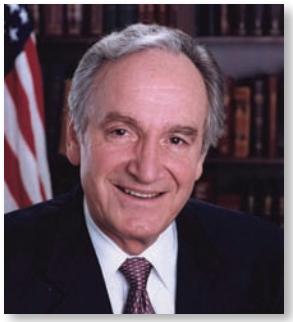
# Memorable Moments of 2011

Representatives from the Mexican generic pharmaceutical industry pay visit to GPhA's Washington, DC, office.

GPhA conducts Quality by Design workshop at GPhA's offices.

A record crowd attends GPhA's 2011 Annual Meeting in Orlando, Florida.

Ranbaxy's Chuck Caprariello welcomes Annual Meeting guests.



U.S. Senator Tom Harkin addresses GPhA's CEO Summit.


CEOs Unplugged session at GPhA 2011 Annual Meeting.


FDA Commissioner Margaret Hamburg shares her perspectives with Annual Meeting attendees.

# **2011** Industry Review

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

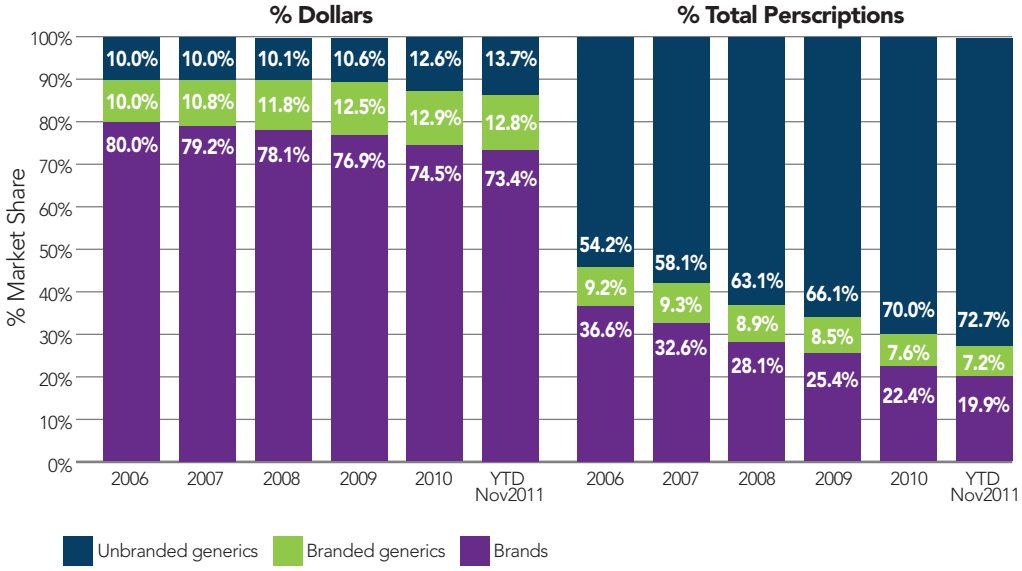
Henry Ford

## Dispensed generic Rx by leading companies

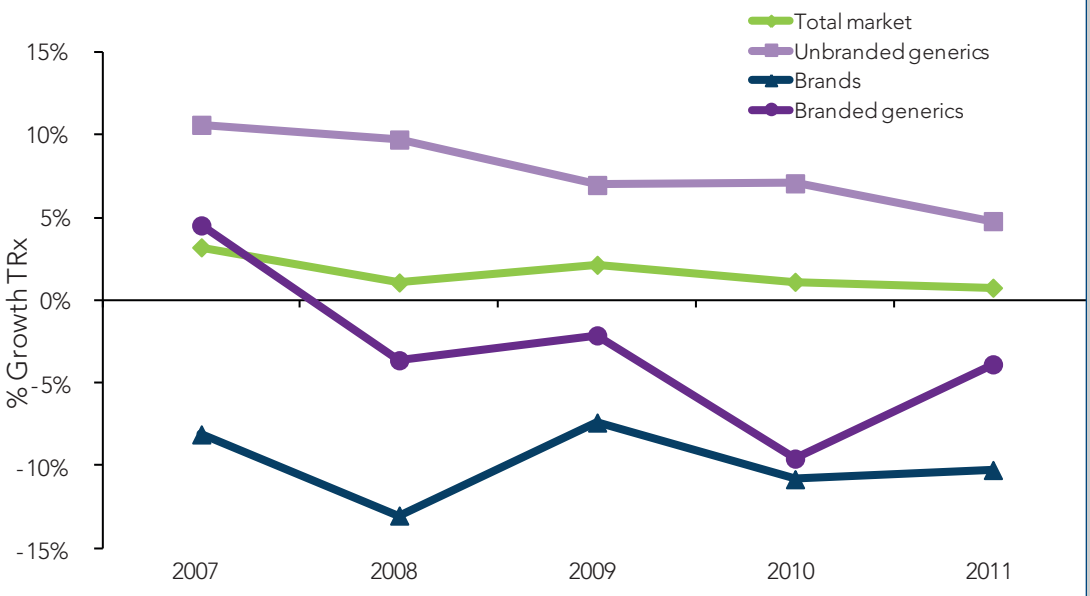
| Prescriptions of unbranded generics by leading corporations | MAT Sep 2011 TRxs mn | % Market Share | % Growth |
|---|---|---|---|
| **US Industry** | **2,907** | **100.0** | **5.9** |
| 1 Teva | 517 | 17.8 | -9.6 |
| 2 Mylan Labs, Inc. | 370 | 12.7 | 0.1 |
| 3 Watson Pharma | 212 | 7.3 | 5.3 |
| 4 Sandoz (Novartis) | 203 | 7.0 | -0.1 |
| 5 Lupin Pharma | 152 | 5.2 | 23.6 |
| 6 Endo Pharm Inc. | 142 | 4.9 | 22.2 |
| 7 Amneal Inc | 112 | 3.8 | 23.9 |
| 8 Greenstone (Pfizer) | 103 | 3.6 | -7.6 |
| 9 Covidien | 74 | 2.5 | -8.9 |
| 10 Dr Reddy Inc. | 72 | 2.5 | 12.1 |
| **Top 10** | **1,957** | **67.3** | **1.3** |

*Source: IMS Health, National Prescription Audit, Sep 2011*

## Unbranded generics with almost 73% of the Rx volume account for only about one eighth of sales

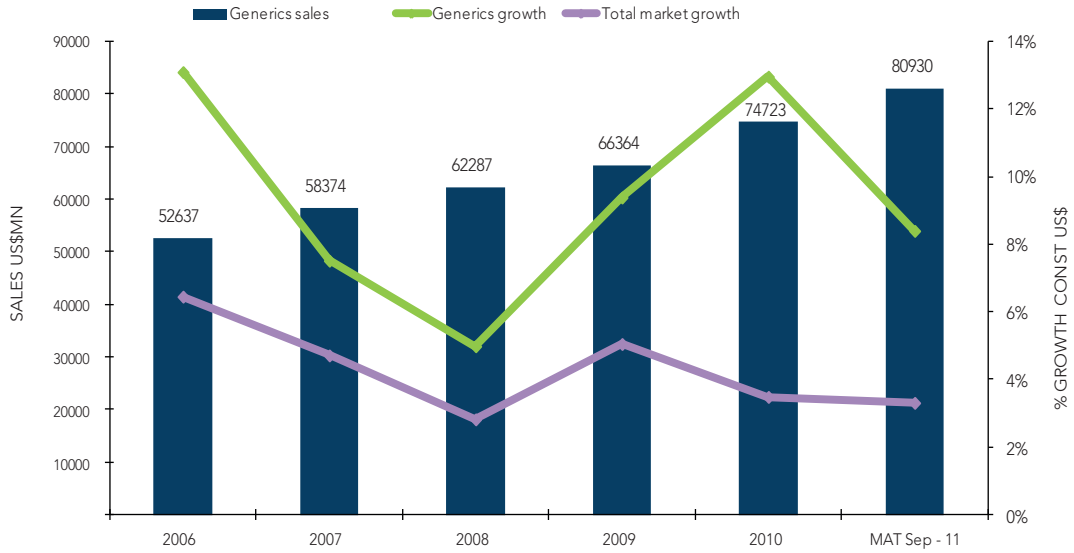


## Unbranded generics continue to drive perscription growth




Source: IMS Health, National Prescription Audit, Dec 2011

## Generics sales and growth - 8 Key Markets



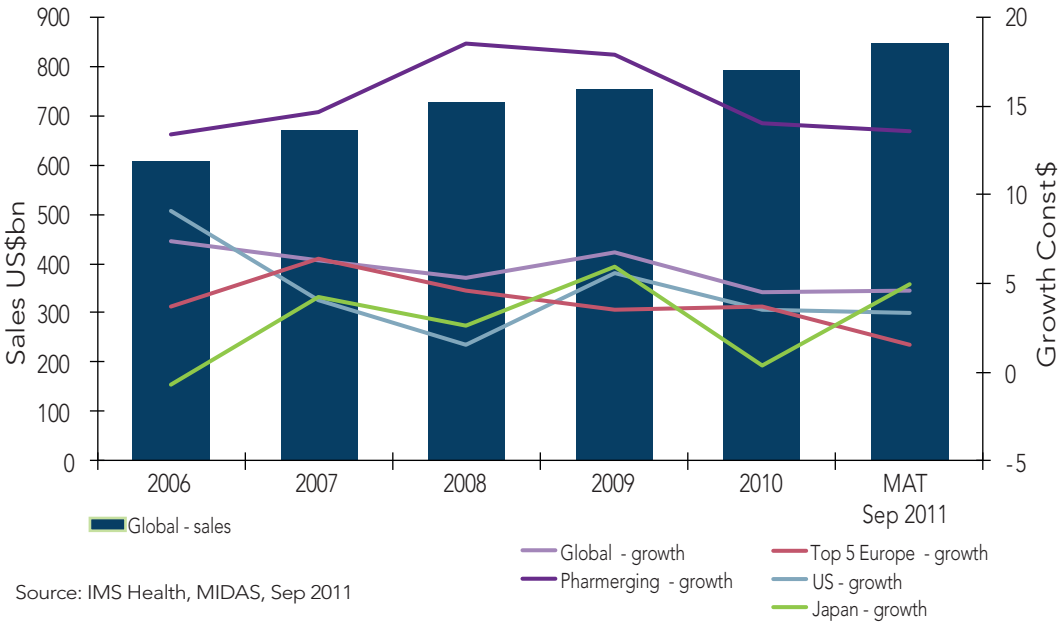

Source: IMS Health, MIDAS, Market Segmentation, MAT Sep 2011, Rx only. *Market Segmentation universe

## Top 10 market sales and growth
## Audited markets in MAT Sep 2011

| Country | MAT Sep 2011 Sales, bn | % Market Share | % Growth |
|---|---|---|---|
| **10 Key Markets** | **655.6** | **100.0** | **4.2** |
| 1 United States | 319.7 | 48.8 | 3.4 |
| 2 Japan | 97.1 | 14.8 | 4.9 |
| 3 Germany | 44.4 | 6.8 | 2.5 |
| 4 France | 41.1 | 6.3 | 0.8 |
| 5 China | 38.3 | 5.8 | 18.1 |
| 6 Italy | 26.9 | 4.1 | 1.6 |
| 7 Spain | 22.9 | 3.5 | -0.8 |
| 8 Canada | 22.3 | 3.4 | -1.5 |
| 9 United Kingdom | 21.6 | 3.3 | 2.7 |
| 10 Brazil | 21.3 | 3.3 | 18.9 |

*Source: IMS Health, National Prescription Audit, Sep 2011*

## Global sales and growth
## The audited market in Sep 2011




Source: IMS Health, MIDAS, Sep 2011

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