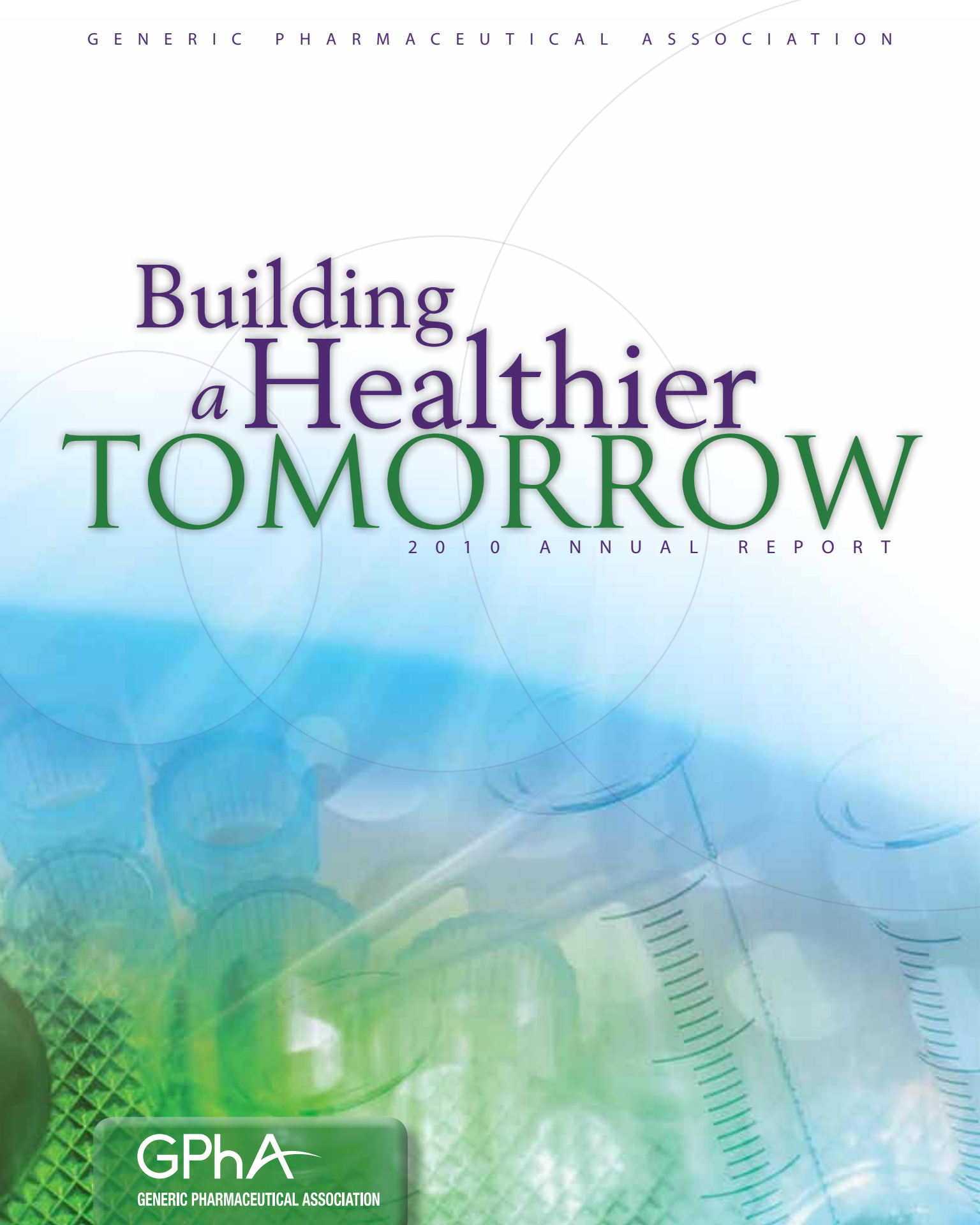
GENERIC PHARMACEUTICAL ASSOCIATION

Building a Healthier TOMORROW

2010 ANNUAL REPORT



GPhA
GENERIC PHARMACEUTICAL ASSOCIATION

VISION 2011

To execute a winning advocacy strategy that optimizes the growth and benefits of generic and biogeneric medicines.

from the CHAIRMAN

PAUL BISARO
Chairman

As I was sitting down to write this to the members of our Generic Pharmaceutical Association, the thought I kept coming back to was one of heartfelt appreciation to our GPhA professional staff and to all of our members for their commitment during this transformational year for our Association. Despite the challenges presented by our governance and leadership changes during 2010, the level of support from every member company, from my colleagues on the Board of Directors and the Executive Committee, and from the hard-working and committed staff of the GPhA has never been in question, and never been more appreciated.

Our Association was challenged internally this year to take our legacy structure and seek ways to make it more impactful and effective, given the legislative and regulatory challenges we have faced in 2009 and 2010, and which we anticipate in 2011 and beyond. I am pleased that we have completed that difficult transition to a new structure that will make our Association a more potent advocate for our industry issues.

I am proud that throughout this process, which has affected every member company, that rather than a divisive debate, we have had constructive, thoughtful and supportive dialog. I am proud that we have been able to set aside at times conflicting individual and company positions to focus on the greater good – namely ensuring that GPhA's mission to be on the forefront of increasing access to affordable medicines for all consumers is achieved. Our shared purpose, to present a strong, vibrant, and responsive single voice in formulating health care policy that supports our mission has been a touchstone during challenging and difficult times. I am convinced that an organization of less committed individuals may have surrendered to those challenges.

We start 2011 as a stronger organization. We start 2011 with renewed vigor, with a sharper focus, and with an appreciation of the power that a single, unified voice can have in the din of debate and disagreement. We start 2011 with the resources – financial, intellectual and structural – to get the job done. We start 2011 with clear vision of the issues in which we must be leaders and with an understanding that together we can forge an exciting future.

Again, I want to thank all of the members for their continued support of GPhA, and I want to encourage your continued involvement in the work ahead. I also want to thank Bob Billings, Gordon Johnston and the other members of our professional staff for their hard work and focus. Throughout our transition, they continued to focus on the "business of the business"

and made important progress in defeating efforts to ban patent settlements, initiated the formal process of negotiating user fees for our industry, and ensured that the codification of generic biologic regulations reflects the input of our industry and will permit competition that will lower prices on expensive biopharmaceutical products for consumers.

It has been said that "nobody can go back and start a new beginning, but anyone can start today and make a new ending." For GPhA and our member companies, we start today, and every day, focused on creating an ending that includes increased access to an ever growing number of generic and ultimately biogeneric pharmaceuticals that will continue to deliver billions of dollars in savings to consumers.

Paul Bisaro
Chairman of the Board, GPhA

Board of Directors

At table from left: Rosendo Ferran, William Marth, Paul Bisaro, Tony Mauro, Christine Mundkur, Joseph Renner **Standing from left:** Thomas Murphy, Vincent Ursino, George Zorich, Doug Boothe, Miles Davis, Siobhan Barr, Steve Brugger, Ed Maloney, Jeffery Glazer, David Hanson, KL Spear, Ambrose Stafford, Chuck Caprariello, Andras Csontos, Tom Silberg, Patrick LePore, Bill Seiden

from the VICE CHAIRMAN

TONY MAURO
Vice Chairman

2010 was a defining year for GPhA. By transforming our association to better reflect the industry's challenges and opportunities, we have positioned ourselves to represent very powerfully the interests of our members and the millions of people who rely on our products.

Our timing couldn't be better. Generic pharmaceuticals represent one of the best ways to meet the nation's growing demand for expanded access to high quality, affordable health care solutions and services. By communicating even more vigorously the tremendous value generic pharmaceuticals offer and working with our allies to shape associated laws and regulations, our strategic initiatives will advance our ability to collaborate, advocate and build industry relevance to stakeholders.

Among our top priorities for 2011 is further globalization of the U.S. Food and Drug Administration (FDA). We want to ensure that all drug products sold in the U.S. meet one standard of quality. Today, approximately 40 percent of the drugs Americans take are imported and the FDA lacks the resources to ensure this standard. That's why we are championing a holistic user-fee proposal, which includes registration, inspection and application fees. This proposal will help keep our drug supply safe while enhancing productivity towards new development.

We also will work hard in 2011 to establish a viable patent and regulatory pathway for biogenerics. We believe that a progressive framework which balances the need for innovation with that of affordability and access is imperative. Indeed, this very balance was the basis for the extraordinarily successful Hatch-Waxman legislation of 1984, which created the modern generic pharmaceuticals industry in the U.S. – and saved the nation's health care system more than $824 billion over the last 10 years.

The members of GPhA have united eagerly behind these and other important initiatives, and we look forward to achieving our shared goal of improving the lives of consumers by providing timely access to affordable generic pharmaceuticals.

Tony Mauro
Vice Chairman of the Board, GPhA

2010 Year *in* REVIEW

The road that leads to success is always under construction.

2010 was a year of profound change. The enactment of new healthcare laws radically altered state and federal regulations governing medical care. New legislation authorized the FDA to create an approval process for generic biologic products. The escalating use of generic prescription drugs pushed annual U.S. sales of generics to a record high $50 billion. And at GPhA, we implemented a comprehensive restructuring plan that positioned the Association as a stronger, and more focused advocate for its membership.

When we chose last year's theme "A steady course in a sea of change," we did not envision the magnitude of change 2010 would bring. As we look back at 2010, we realize that the events of last year laid the foundation on which we now have the opportunity to build a healthier future for our industry and the consumers we serve. We move into 2011 with a clear vision of our critical mission: *To execute a winning advocacy strategy that optimizes the regulatory and political environments to fully expand the advantages offered by generic and biogeneric medicines.*

Health Care Reform

Congress ended more than a year of contentious debate by narrowly passing legislation in March intended to reform U.S. health care laws and guarantee medical coverage to all Americans. Supporters argued that reform was needed to fix a broken system and contain soaring healthcare costs. Opponents argued that for every ounce of reform there was a pound of access and that the costs of the new programs were unsustainable.

Despite public opinion polls showing weak support for the bill, House and Senate leaders guided the legislation through Congress and in late March President Obama signed health care reform into law. "Today, after almost a century of trying—today, after over a year of debate—today, after all the votes have been tallied, health insurance reform becomes law in the United States of America," President Obama said March 21 as he signed the 2010 Health Care and Education Affordability Reconciliation.

GPhA and our member companies were intricately involved in many critical aspects of health care reform. Working with our coalition partners, we engaged in every battle that threatened our industry with unwarranted costs and regulations or that

President Obama signs the Health Care and Education Affordability Reconciliation Act. March 21, 2010.

would bear the unintended consequence of delaying consumer access to affordable generic medicines. Among specific efforts by GPhA and its allies were:

- Blocked repeated efforts to add patent settlement ban language in the reform bill
- Participated in several Town Hall meetings across the country
- Organized CEO fly-ins to discuss key issues with Members of Congress and staff
- Met with White House officials to push the value of generics
- Conducted a Medicaid rebate training presentation to the Senate Finance Committee
- Provided a biogeneric savings presentation to the Congressional Budget Office
- Circulated numerous educational packages to key Committee members
- Issued more than two dozen press statements
- Disseminated to media and Hill staff an economic analysis of "PhRMA deal"
- Published updates and white papers for member companies to provide a constant stream of timely and relevant information
- Offered testimony supporting a science-based biogeneric approval process
- Compiled and distributed documents showing the positive affect competition has on future innovation

Through the entire healthcare reform debate our message was clear: using generics is the proven way of bending the healthcare cost curve downward. Although we did not prevail in every battle, we were successful on several significant fronts including: keeping dual eligibles out of the rebate formula, derailing a proposed $5 billion excise tax on generic manufacturers, and winning a science-based biogeneric process that gives FDA flexibility when setting review and approval standards.

Biogenerics

After passage of the Biologics Price Competition and Innovation Act, part of healthcare reform legislation, GPhA and its member companies began working with the FDA in developing regulations to define the biogeneric approval process. Though various presentations at the FDA, we pushed for the

THE MAKING OF HEALTH CARE REFORM

- **Sept. 17, 2009** – H.R. 3590 Patient Protection and Affordable Care Act introduced in House
- **Oct. 8, 2009** – H.R. 3590 passes in House of Representatives
- **Dec. 24, 2009** – H.R. 3590 passes in Senate by 60-39 vote
- **Jan. 19, 2009** – Scott Brown wins Mass. Senate race; alters strategy
- **March 17, 2010** – H.R. 4872 Health Care and Education Reconciliation Act introduced in House
- **March 21, 2010** – H.R. 3590 reconciliation passes in House by 219-212 vote
- **March 21, 2010** – H.R. 4872 passes in House by 220-211 vote
- **March 23, 2010** – House passes H.R. 4872 resolving differences 220-207
- **March 23, 2010** – H.R. 3590 enacted as Public Law No. 111-148
- **March 25, 2010** – H.R. 4872 passes in Senate by 56-43 vote
- **March 30, 2010** – H.R. 4872 enacted as Public Law No. 111-152

scientific feasibility of a regulatory scheme that is not a barrier to competition, but rather would ensure the robust competition needed to lower costs and spur future innovation. Among the key issues we are working with the FDA are:

- **Comparability:** FDA should use the same standard of "highly similar" for biogenerics as it does when approving post-approval changes to the reference product.
- **Naming:** The new biogenerics law does not require different names for products approved via the abbreviated biogenerics pathway; the regulations must honor this intent of Congress. Otherwise, a finding of interchangeability or biosimilarity will count for very little among healthcare providers.
- **Interchangeability:** Interchangeability is the engine that drives generic competition. It is the reason why generic drugs have generated savings of $824 billion over the past decade. The way that FDA deals with interchangeability will be directly responsible for the market dynamics generated by the biogeneric pathway.

Settlements

Both Congress and the Federal Trade Commission (FTC) spent a considerable amount of time trying to pass legislation that would ban patent litigation settlements. Settlements are a proven way to bring generic medicines to the market months, if not years before patent expiry and save patients and federal and State governments millions of dollars annually. GPhA and its member companies were successful in staving off legislation that would ban pro-consumer patent settlements.

Senator Herb Kohl's Preserve Access to Affordable Generics Act, S.369, and Congressman Bobby Rush's Protecting Consumer Access to Generic Drugs Act, H.R.1706, would have created a bright line ban on settlements and made the FTC, the very agency that is adamantly opposed to these settlements, the judge, jury and arbiter of all patent settlement cases.

This legislation, if enacted, would have had the unintended consequence of limiting the number of patent challenges brought by generic drug manufacturers. GPhA'S full-page ad in *Politico* "Patients Before Profits" (below) called attention to the backroom dealing of settlements ban proponents to get

their legislation attached to any possible piece of legislation…even the war funding bill.

User Fees

GPhA is supportive of generic drug user fees and contends that a program containing clear performance goals and metrics will benefit industry by enhancing certainty for Abbreviated New Drug Application (ANDA) approvals while also providing FDA with much needed additional funding. The added revenue generated from a user fee program that includes establishment registration and inspection fees must be used to support critical Agency activities related to generic application reviews. Added funds also will enable the Agency to carry out its responsibility of ensuring the safety of a global supply chain by providing money to conduct adequate foreign and domestic inspections. A workable, holistic generic drug user fee program ultimately will reward American consumers with more timely access to affordable generic prescription pharmaceuticals.

Funding for OGD

Through a targeted Congressional lobbying and education campaign, GPhA was instrumental in increasing funding for the Office of Generic Drugs (OGD) by $10 million in FY10, bringing OGD's total budget to approximately $51 million. GPhA built on this significant increase in FY11 when the House and Senate Agriculture Appropriations Committee increased OGD's funding by $14 million and $4 million respectively. Although Congress did not pass any of its appropriations bills for FY11, there continues to be a strong desire by those on Capitol Hill to provide OGD with the necessary funding and resources to eliminate the backlog and approve generic drug applications within a reasonable period of time. GPhA will coordinate its advocacy efforts for increased funding for the Office of Generic Drugs with its user fee discussions so that Congress and FDA recognizes that user fees alone do not solve the problem and there must be a sufficient appropriations component to the solution.

Quality by Design

The generic industry provides 75 percent of all prescriptions dispensed in the U.S. GPhA member companies take this responsibility seriously and strongly support initiatives to continually assure that all medicines are of the highest quality. In 2010, GPhA and its membership worked with the FDA to better define a systematic approach of "quality by design" (QbD) for pharmaceutical products. The goal of this initiative is to give the industry a better roadmap to optimize advances in manufacturing science and apply this knowledge to the production of generic medicines. Process engineers, formulation and analytical scientists, and other specialists from GPhA member companies engaged in several in-depth seminars to develop a workable approach to advance applied pharmaceutical science. These efforts culminated in a major training conference for the generic industry. These ongoing scientific exchanges between industry and FDA help assure that product quality is designed into every generic medicine.

Risk Mitigation and Management Strategies

The Food and Drug Administration Amendments Act (FDAAA) authorizes FDA to require firms submitting certain applications to submit a proposed risk mitigation and management strategy (REMS) if the FDA determines such a plan is needed to ensure that the benefits of a drug outweigh its risks. Implementation and coordination of REMS within the pharmaceutical industry has been challenging for FDA. To assist the Agency, GPhA and its members engaged in several meetings to provide a representative voice on REMS programs and issues. These meetings and presentations are improving the FDA's timely implementation of REMS, which in turn provides consumers with additional assurances about the safety of the prescription medicines they take.

Supply Chain Security

As the pharmaceutical sector has become more and more global, new challenges have risen related to supply chain safety. With vendors and suppliers reaching all points on the globe, GPhA has actively supported FDA supply chain initiatives and assisted the Agency in developing best practices for vendor qualification programs. GPhA was a major player in 2010 in several supply chain safety meetings and contributed to the global initiative, working to secure the drug supply chain. These efforts brought together national and international experts to examine how the industry can become even more vigilant in its oversight of the trade channels. GPhA advised FDA on current practices in the supply chain, which gave Agency officials a "hands-on" understanding of strategies currently used to protect drug product shipments. GPhA also provided pharmaceutical supply chain informational documents to Members of Congress.

Through these collective actions, the generic industry remains an important voice in shaping future practices for the industry.

Medication Errors

Medication errors are a major contributor to unnecessary morbidity and mortality. In reports from the Institute of Medicine (To *Err is Human: Building a Safer Health System*), the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), the Institute for Safe Medication Practices (ISMP) and others have indicated that labeling of injectable products may be linked to medication errors in the administration of these products. In 2010, GPhA's long-standing commitment to public health activities, including medication error prevention, was evident on many fronts. GPhA participated in a major FDA public meeting on strategies to reduce medication errors and engaged regularly with NCC MERP to work with the broader health care community to develop strategies to help assure patient safety. GPhA's contributions to NCC MERP, as well as to the FDA, demonstrate the generic industry's commitment to patient safety.

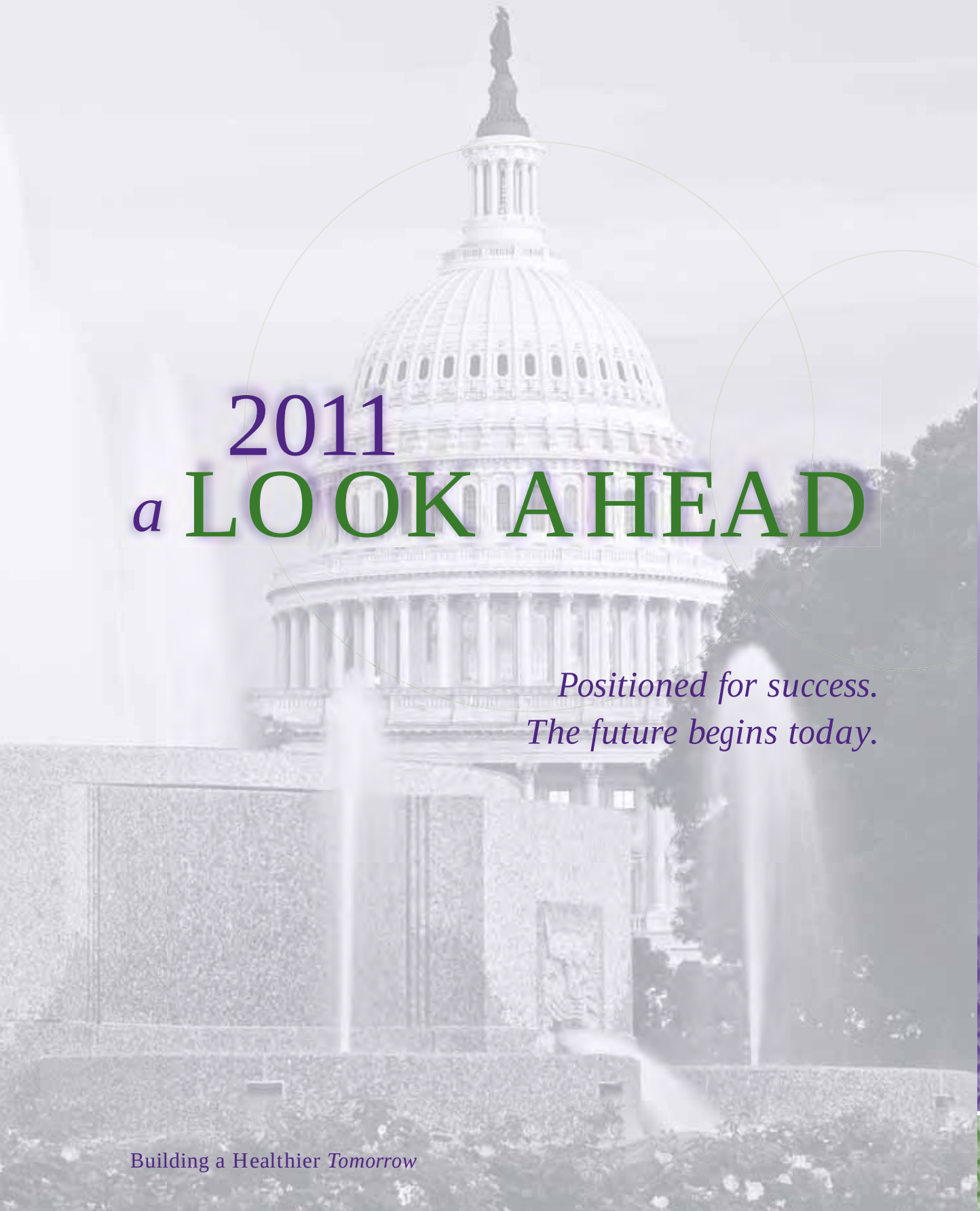
Advocacy in the States

2010 legislative session in the 50 states were very active in two recurring generic issues— carve-out legislation (78 anti-substitution bills were introduced in 25 states) and product stewardship in the form of pharmaceutical waste take-back programs. GPhA worked closely with its member companies and allies to defeat every carve-out initiative introduced countrywide. In several states, considerable effort was made by some brand interests to raise doubts about generic safety, primarily using anecdotal accounts. GPhA and its member companies successfully fought these attempts and ensured that the sound science underlying generic substitution policies prevailed in the carve-out debate. GPhA coordinated with stakeholders to reign in efforts by proponents of "extended producer responsibility" legislation to mandate pharmaceutical take-back programs that would impose the burden of funding entirely on drug manufacturers. We engaged in two national coalition efforts to educate the public on proper disposal of unused drug products and gave substantial support to the American Medicine Chest Challenge, an effort to provide a safe, secure and inexpensive means to dispose of unwanted or unused medicine. Although many issues are expected to return with great intensity in the 2011 session, the generics industry had a successful year advocating in the states in 2010. Finally, our state advocacy program included the education of state officials concerning the value of increasing generic utilization to bend the cost cure in state-sponsored prescription drug benefit programs.

International Advocacy

The international face of the U.S. generic industry changed in 1994 after the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). This was the first time that intellectual property rights were included in trade negotiations, making it easier for the innovative pharmaceutical industry to introduce changes in U.S. law and in the laws of other countries at the expense of generic sales and subsequently, consumers. Recently, trade agreements negotiated by the U.S. have begun to gradually increase intellectual property rights (IPR) protections.

While Congress mandated that USTR follow U.S. law when negotiating treaties, IPR protections have continued to grow, setting new precedents that might lead to future changes in U.S. patent law. By extending exclusivity periods, imposing patent linkage with no "paragraph IV" type recourse, and eliminating "best mode" requirements, some trade agreements are imposing IPR standards in other countries that severely limit the approval and marketing of generic drugs. If GPhA does not actively seek balance in U.S. trade policy, and these anti-generic policies become standard in the majority of overseas countries, there eventually will be a push to bring U.S. in line with foreign countries. The result would be additional delays in the marketing of affordable generics in the U.S.



2011 *a* LOOK AHEAD

Positioned for success.
The future begins today.

Arriving at one point is the starting point to another. Never since the founding of our Association have we been better positioned to accomplish our mission. Restructuring our governance to reflect current market and industry realities has generated a record revenue base for 2011, eclipsing the previous high by nearly 40 percent. Reorganizing our Board of Directors will facilitate timely action in servicing the needs of all member companies. And our renewed focus on execution first, execution always, will assure we optimize our resources in advocacy and action.

In 2011, more than 11 million prescriptions will leave pharmacies across America every day. An astounding 76 percent of those will be dispensed using safe and effective generic drugs. Yet the generic share of prescriptions account for less that 25 percent of the money consumers and the government spend on medicine. This reliance on affordable generics will generate nearly $150 billion in savings to the U.S. healthcare system by the end of 2011.

As the manufacturers and suppliers of these drug products, we have a humbling responsibility to the millions and millions of consumers and patients we serve. Our objective, therefore, is to continue assuring that everyone has timely access to safe, effective, high quality, affordable generic medicines. This means effective advocacy to maintain a political and regulatory climate in the states and federal government that is pro-generic, pro-consumer and pro-savings.

The 112th Congress. The November 2010 elections produced some of the largest gains for a single party in the history of our nation. At final tally, Republicans gained 63 seats, the largest increase for a single party since 1948, and the majority (242-193) in the House of Representatives. On the Senate side of the Capitol, Republicans gained six seats, but still are in the minority 53-47. One of the key themes that arose out of this past November's elections is that Americans are dissatisfied with the large amount of government spending both at the federal and State levels.

As the 112th Congress begins, GPhA is in the perfect place to capitalize on this sentiment towards government spending. Congress will spend considerable time looking for ways to cut government expenditures, save taxpayers money, and bring down the $14 trillion national debt. We will take our message to every office in the House and Senate—the message that safe, effective, and less costly generics are the solution to controlling health care costs.

Biogenerics. While GPhA applauds Congress for establishing an abbreviated approval pathway for biogenerics, the hard work of assuring that FDA implements regulations that do not create unintended barriers for biogenerics will be a critical activity in 2011. GPhA will engage with all stakeholders supporting access to affordable biogeneric medicines in an effort to assure that unnecessary regulatory obstacles do not thwart the intended benefits of greater competition in the biologics marketplace. We will urge member companies to also join in the work. Capturing the opportunity to make lifesaving biologic medicines available to millions of patients at lower cost is a priority objective for our industry.

Patent Settlement Ban. Settling patent litigation often is a desirable option in patent dispute cases. A settlement typically guarantees early generic market entry. There are no examples of patent settlements that delayed generic market formation beyond the patent expiration date, but there are many examples in which settlements proved to be pro-consumer by enabling generic competition prior to the expiration of patents. In 2011, GPhA will continue its full court press against all attempts to ban settlements of patent litigation.

Generic Drug User Fees. The generic industry currently is experiencing some of the longest delays in review and approval of ANDAs since the 1984 passage of Hatch-Waxman. The current uncertainty surrounding review timelines has lead to unprecedented challenges for the generic industry. The number of pending ANDAs, and a median approval time that is approaching 30 months, is in large measure the result of inadequate resources at OGD. In 2011, GPhA will be discussing generic user fees with the FDA in efforts to design and implement a user fee program that will enhance FDA resources dedicated to the generic drug program. The objective is to give our industry better predictability related to FDA review and approval timeframes.

Patent Reform. Legislation to reform our nation's patent system will demand GPhA's attention in 2011. Senate Judiciary Committee Chairman Patrick Leahy (D-Vt.) already reintroduced patent reform legislation for the 112th Congress and passed it out of Committee. However, this legislation faces an uphill battle in the House of Representatives. Furthermore, several industries, including the generics, oppose numerous provisions in the bill. GPhA will continue to coordinate opposition to any attempts to weaken or eliminate the inequitable conduct doctrine and best mode requirements of current patent law. The inequitable conduct doctrine is vital to the health of our nation's patent system. If Congress weakens the inequitable conduct doctrine, patent applicants have absolutely no incentive to comply with their duty of candor on an application. The best mode requirement is the "bargain" that was struck between inventors and the public. In exchange for 20 years of patent protection, the inventor must disclose the best mode of manufacturing the invention. Eliminating the best mode requirement would hinder scientific advancement and deprive consumers of new and improved therapies.

FDA Collaboration. GPhA's Fall Technical Conference drew the largest attendance for any event in our Association's history. This conference, which is the premier generic industry technical conference in the U.S., continues to offer unique value to the industry by addressing the top line issues that affect our industry on a daily basis. In 2011, we again will use every opportunity, including conferences, seminars, and face-to-face meetings to collaborate with FDA on all important issues. GPhA's detailed workshops with FDA staff, including Project Management, Labeling, ANDA Basics and Quality by Design will provide member companies with unique opportunities to learn directly from the FDA and interact with Agency experts.

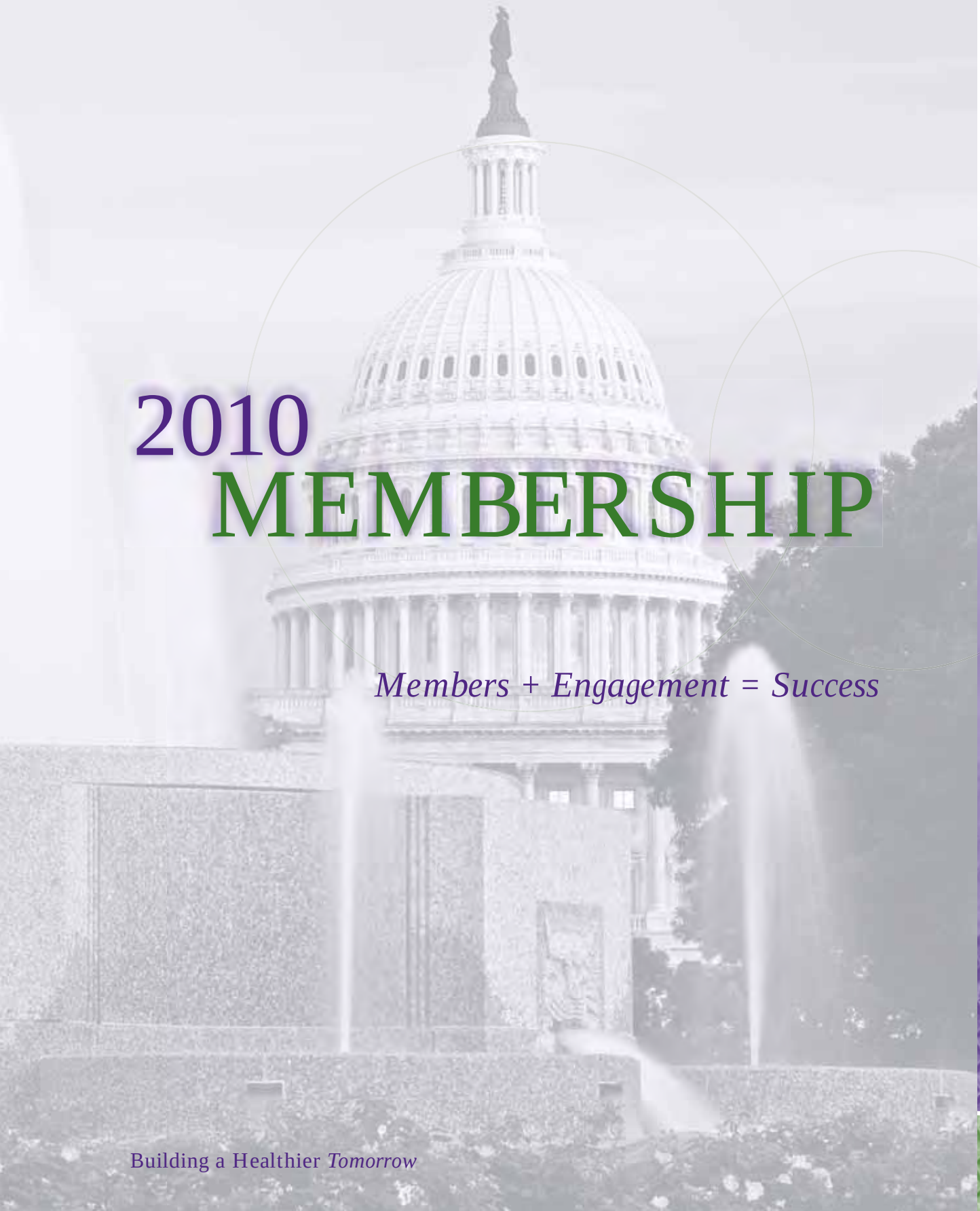
Quality and Equivalence. Regulatory science is a dynamic process with constantly emerging advances in knowledge and technology. These advances lead to improvements in regulatory, manufacturing and clinical science. With the continual progress of science, related regulatory activities will be a priority focus for GPhA and its member companies in 2011. FDA and the generic industry will continue to examine optimal bioequivalence approaches for drug

products, changes in manufacturing science, and quality by design approaches for a variety of product classes. With the extensive expertise of our members in the areas of pharmacokinetics, product development and analytical technologies, our industry will continue to take a leadership role in shaping drug product quality standards and ever more sophisticated approaches to bioequivalence.

Foreign Inspections. GPhA recognizes that globalization of the pharmaceutical industry has created new challenges in how we manage our materials supply chain. The generic industry continues to focus on strategies, alliances and technologies to assure that the U.S. drug supply remains the safest in the world. Our industry, working with the FDA and other stakeholders, will continue collaboration to provide a secure supply chain and assure that patients can count on safe, high quality products. Our efforts in 2011 will enable us to identify and employ best practices for vendor and supply chain management.

State Action. GPhA anticipates another active session on carve-out legislation in several states. As in prior years, our goal is to defeat every carve-out bill introduced. To achieve this, GPhA will rely on its member companies and allies who have a presence in the various states. GPhA will continue to strengthen the National Generic Carve-out Coalition. Regarding product stewardship, or the extended producer responsibility legislation, we will continue to dialogue with stakeholders—both proponents and opponents—to find a reasonable way to address challenges stemming from this issue. Throughout 2011, GPhA will continue its engagement on behalf of our member companies in supplemental rebates; drug pedigree; pharmaceutical marketing and advertising reporting rules; e-prescribing; and other issues.

International Affairs. While the U.S. pharmaceutical market is expected to grow between 3% and 6% over the next four years, the emerging markets of Brazil, India, Turkey, Mexico, Russia, South Korea and China are expected to grow between 14% and 17% over that time. The potential for new growth in our industry is clear. And because the majority of GPhA member companies have operations outside the U.S., we have created a specific budget line item for allocating funds to international activities. Building on the momentum gained from the New Trade Policy, GPhA will help change the provisions of intellectual property agreements that affect our industry. The immediate focus in 2011 will be the Trans-Pacific Partnership (TPP), which involves Australia, Brunei Darussalam, Chile, New Zealand, Peru, Singapore, Malaysia and Vietnam…and possibly other nations in the coming months. Because TPP likely will become the blueprint for future trade negotiations, specifically in the area of intellectual property rights, it will impact our member company bottom lines for years to come. Therefore, we will stay on top of all TPP action, beginning with IP negotiations in Chile early in 2011. We will cooperate with our member companies in protecting the interests of our industry in trade policies.



2010 MEMBERSHIP

Members + Engagement = Success

2010 GPhA Member Companies

Aceto Corporation
ACIC
Actavis Inc.
A.J. Renner
Algorithme Pharma Inc.
All-Pak Inc.
Amerigen Pharmaceuticals Inc
Amneal
Anapharm, Inc.
Anchen Pharmaceuticals, Inc.
ANDA Inc.
Aon Corporation
Apicore LLC
APP Pharmaceuticals Inc.
Baker, Donelson, Bearman, Caldwell & Berkowitz
Ben Venue Laboratories Inc.
Biddle SawyerBiogenerics
Bioniche Pharma Group Limited
Caesar Rivise Bernstein Cohen & Pokotilow
Capsugel
Caraco
Cardinal Health
Caremark Rx, Inc.
Celerion
Cetero Research
ChemWerth Inc.
DAVA Pharmaceuticals, Inc.
Dr. Reddy's Laboratories Inc.
Duane Morris LLP
Eagle Pharmaceuticals
Endo Pharmaceuticals, Inc.
ETHEX Corporation
Express Scripts
Fougera
Frommer Lawrence & Haug
Gedeon Richter USA
Greenblum & Bernstein PLC
Great Southern Laboratories
GYMA Laboratories
Harris Pharmaceutical, Inc.
Hartmann Pharmaceutical
Harvest Moon Pharmaceuticals USA
Haynes and Boone, LLP
Heritage Pharmaceuticals
Hi-Tech
Huahai US, Inc.
Impax Laboratories
Ind Swift Laboratories, Inc.
Interchem Corporation
Katten Muchin Roseman
Knobbe Martens Olson & Bear, LLP
Kremers-Urban LLC
Laboratorios Silanes
Lachman Consultant Services, Inc.
McKesson Corporation
Midlothian Laboratories
Momenta Pharmaceuticals
Mylan Inc.
New Chemic Inc.
Novel Laboratories, Inc.
Novum Pharmaceutical Research
Paddock Laboratories
Par Pharmaceutical, Inc.
Pegasus
Pharma Medica Research, Inc.
Prasco, Inc.
Putney, Inc.
QPS LLC
Qualitest Pharmaceuticals
Ranbaxy Inc.
Ren-Pharm International Ltd.
Rexam Plastic Packaging
Rhodes Technologies
Rising Pharmaceuticals, Inc.
River's Edge Pharmaceuticals
Roxane Laboratories
RRI Consulting Inc.
RTI Health Solutions
Sagent Pharmaceuticals, Inc.
Sandoz Inc.
Schwegman, Lundberg & Woessner
Sciregs International
Sovereign Pharmaceutical
Spear Pharmaceuticals
St. Onge Steward Johnston & Reens
Strides Inc.
Symbio LLC
Synomics Pharmaceutical Services
Synthon Pharmaceuticals
Taro Pharmaceuticals
Tedor Pharma Inc.
Teva Pharmaceuticals, USA
The Pharma Network, LLC
Three Rivers Pharmaceuticals
Tolmar, Inc.
VersaPharm Inc.
Vijuk Equipment
Vinchem, Inc.
Watson Pharmaceuticals, Inc.
Zydus Pharmaceuticals

2010 GPhA Committee, Task Force, and Working Group Members

Audit Committee
Impax · New Chemic
Zydus Pharmaceuticals

Biogenerics Task Force
ACIC · Actavis · Amneal
APP · Ben Venue
Dr. Reddy's · Endo
Gedeon Richter
Kremers-Urban
Momenta · Mylan
Pharmanet Canada
Ranbaxy · Sandoz
Taro · Watson

Foreign Inspections Task Force
Actavis · Amneal
Anchen · Ben Venue
Caraco · Dr. Reddy's
Endo · Fougera
Interchem
Kremers-Urban · Mylan
New Chemic · Putney
Ranbaxy · Roxane
Sandoz · Sovereign
Synthon · Watson · Zydus

Generic Cost Containment Working Group
ACIC · APP · Ben Venue
Endo · Fougera · Huahai
Sagent

International Affairs Task Force
Amneal · Endo
Gedeon Richter
Huahai · Ind Swift
Interchem · Mylan
Ranbaxy · Taro · Watson

Membership
Amneal · Apicore
Caesar Rivise · Celerion
Greenblum & Bernstein
Interchem · Ranbaxy

Patent Reform Task Force
Actavis · Amneal
Ben Venue · Caraco
Dr. Reddy's · Eagle
Endo · Fougera · Mylan
Par · Ranbaxy · Sandoz
Taro · Watson

Patent Settlement Task Force
Actavis · Amneal
Ben Venue · Caraco
Dr. Reddy's · Eagle
Endo · Fougera · Mylan
Par · Ranbaxy · Sandoz
Taro · Watson

Pedigree Task Force
Actavis · Amerigen
Amneal · Ben Venue
Caraco · Dr. Reddy's
Endo · Hi-Tech · Mylan
Paddock · Par · Putney
Ranbaxy · Sagent
Sandoz · Sovereign · Taro
Three Rivers · Watson

Risk Evaluation & Mitigation Strategy
Amneal · Ben Venue
Dr. Reddy's · Ethex
Impax · Kremers-Urban
Mylan · Par · Ranbaxy
Roxane · Sandoz · Taro
Watson · Zydus

State Affairs
Actavis · Amneal
Endo · Mylan · Sandoz
Sovereign · Taro · Watson

Technical Advisory Committee (Paperless Labeling)
Mylan · Sandoz

Technical Advisory Committee (Quality by Design)
Kremers-Urban · Mylan
Par · Roxane · Sandoz
Synthon · Taro · Watson

User Fees Working Group
Amerigen · Amneal
Ben Venue · Caraco
Dr. Reddy's · Endo
Fougera · Heritage
Kremers-Urban · Mylan
Putney · Endo · Ranbaxy
Roxane · Sagent · Sandoz
Sovereign · Spear
Taro · VersaPharm
Watson · Zydus

Executive Committee
Paul Bisaro
Tony Mauro
Rosendo Ferran
David Klaum
Joe Renner
Craig Wheeler

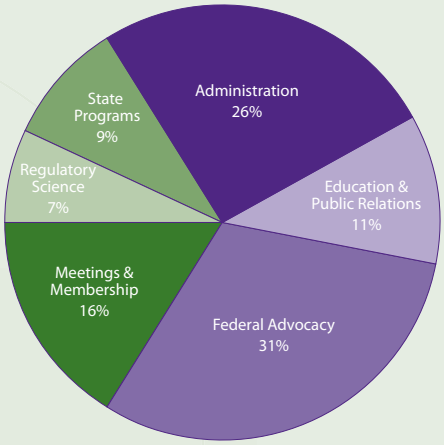
2010 Year *in* PHOTOS


2010
GPhA FDA
Fall Technical Conference

GPhA 2010 Operations

Total Income

2010 Expense Allocation



GPhA Staff

Robert Billings
Vice President of Policy

Gordon Johnston
Vice President of Regulatory Sciences

Shawn Brown
Vice President of State Government Affairs

Jason Money
Senior Director of Federal Government Affairs

Rachelle Kosky
Senior Director of Finance and Operations

Cookie Cottrell
Administration and Membership Services

Katie Dysart
Director of Events

Jennifer Nguyen
Events Coordinator

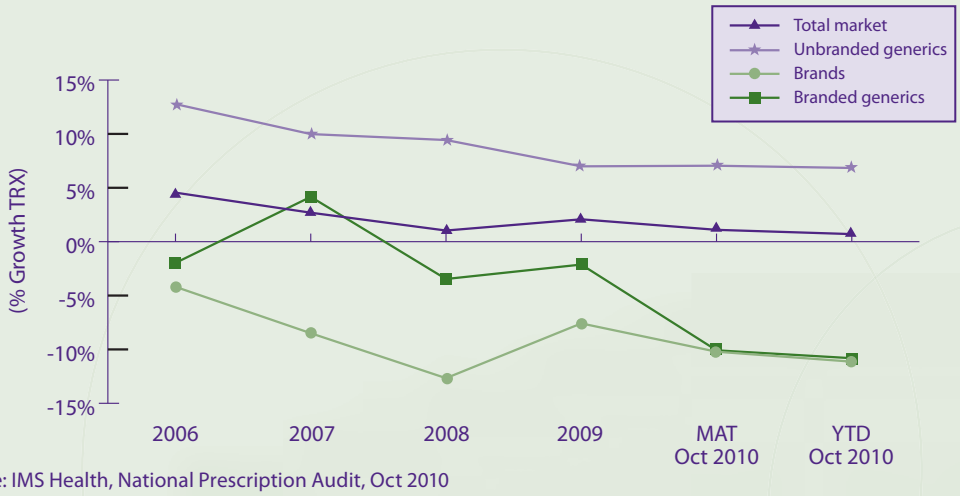
Ashlee Koonce
Associate Manager of Regulatory Affairs

Aquera Agee
Administrative Assistant

Jacqueline A. Henson
Legal Counsel

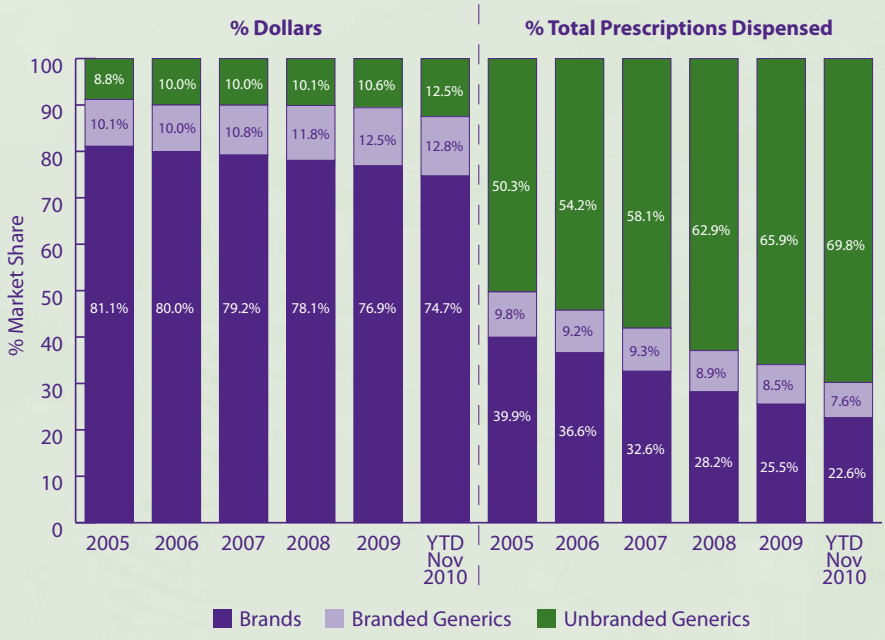
Industry at a Glance

Unbranded Generics Drive Prescription Growth



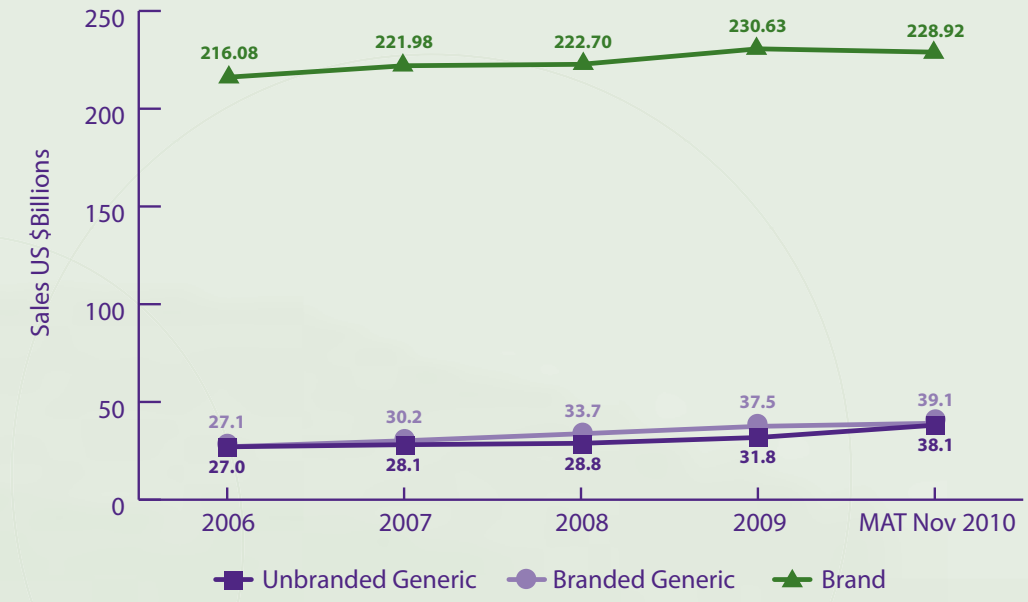
Source: IMS Health, National Prescription Audit, Oct 2010

US Sales and TRX Share



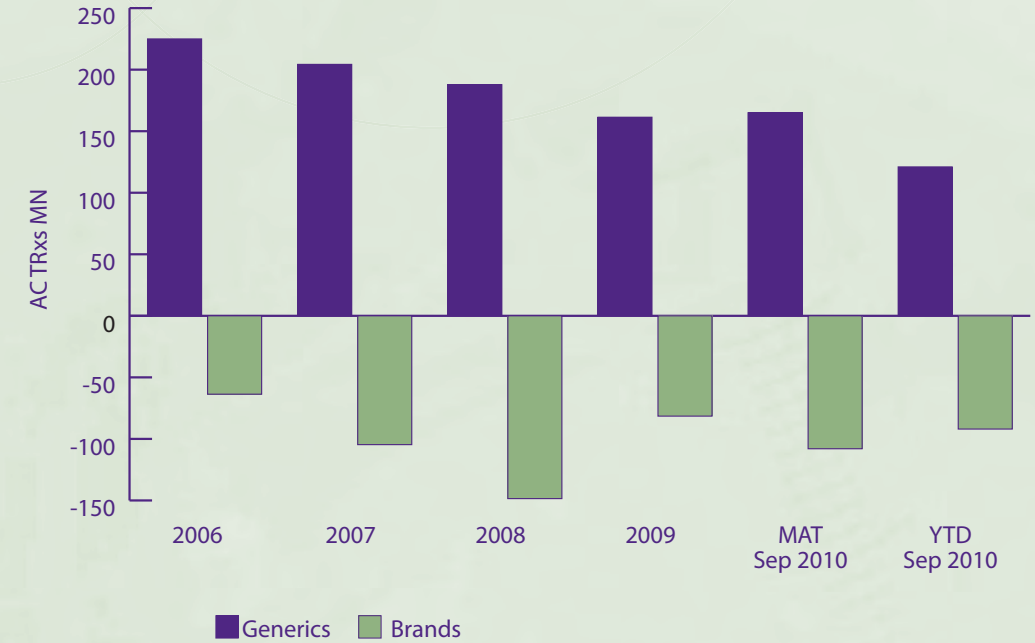
Source: IMS Health, National Sales Perspectives, Nov 2010, National Prescription Audit, Nov 2010

Sales by Brand/Generic



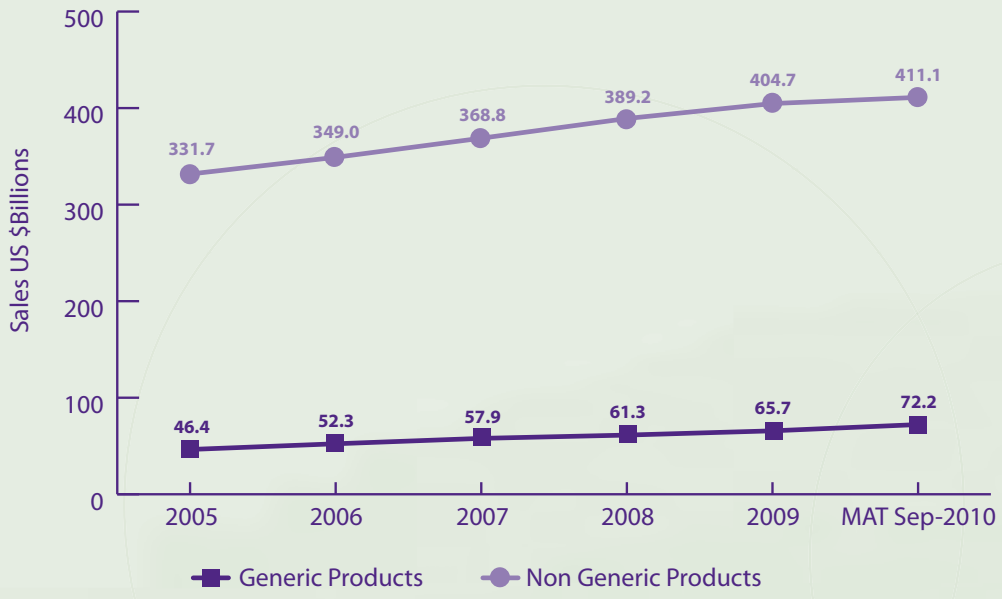
Source: IMS Health, National Sales Perspectives, Nov 2010

Generics Growth Outpaces the Market



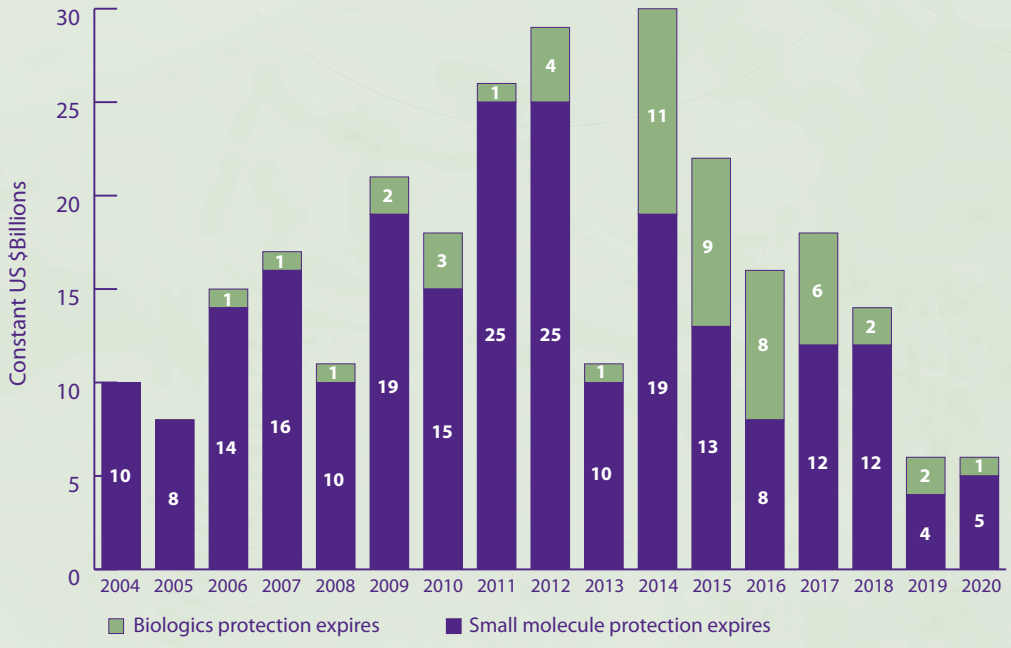
Source: IMS Health, National Prescription Audit, Sep 2010, Branded Generics Disaggregated

8 Key Markets Brands and Generics Sales



Source: IMS Health, MIDAS, Sep 2010

Long Term Loss of Exclusivity Exposure



Source: IMS Health, MIDAS, Market Segmentation, Jun 2010

Dispensed Generic RX by Leading Companies

Prescriptions of unbranded generics by leading corporations	MAT Nov 2010 TRxs mn	% Market Share	% Growth
US Industry	2,758	100.0	7.2
1 - Teva	574	20.8	3.3
2 - Mylan Labs, Inc.	368	13.4	9.6
3 - Sandoz (Novartis)	208	7.5	15.4
4 - Watson Pharma	200	7.3	0.9
5 - Lupin Pharma	126	4.6	40.8
6 - Qualitest Products	120	4.4	24.7
7 - Greenstone (Pfizer)	109	3.9	-0.3
8 - Amneal Inc	95	3.4	47.9
9 - Covidien	79	2.9	-11.9
10 - Actavis US	66	2.4	-1.6
Top 10	1,945	70.5	8.9

Source: IMS Health, National Prescription Audit, Nov 2010

Top 20 Monthly Sales and TRX

	MAT NOV/10 TRx
Acetaminophen/Hydrocodone	131682
Levothyroxine	103647
Simvastatin	92950
Lisinopril	86056
Metoprolol	74390
Metformin	57479
Amlodipine	57424
Omeprazole	56787
Albuterol	55406
Azithromycin	52969
Amoxicillin	52040
Alprazolam	47245
Hydrochlorothiazide	47103
Atorvastatin	45479
Zolpidem	43478
Furosemide	42996
Acetaminophen/Oxycodone	37718
Atenolol	36021
Sertraline	35963
Warfarin	35528

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