



GENERIC PHARMACEUTICAL ASSOCIATION

Strategy for Achieving Savings in Health Care:
Bringing Affordable Medicines to Consumers

Policy Initiatives for the New Administration

Strategy for Achieving Savings in Health Care:
Bringing Affordable Medicines to Consumers



This paper summarizes several critical policy initiatives that the New Administration could launch to maximize the savings realized by consumers and the government through the use of generic pharmaceuticals. We applaud President-elect Obama's commitment to greater access to generic drugs and the specific embrace of a workable pathway for biogenerics. We appreciate the recognition that increased use of generic pharmaceuticals will both allow greater consumer access to necessary medicines, and also lower health care costs. The recommendations listed in this document are separated into two priority categories: (1) "near-term" initiatives, which denote those recommendations that should be set in motion within the first 180 days of the new Administration; and (2) ongoing initiatives, which consist of those policies that should be incorporated into the Administration's overall first-year health care strategy. The addendum to this paper details each of these initiatives. The policy goals presented in this paper are in line with the overarching need to protect the critical balance between innovation of new drugs and access to lower cost generics.

Overview

Generic drugs save consumers, state and federal government prescription drug plans and other payors enormous sums of money each year. Consumers who pay for their medicines save approximately \$85 per prescription when buying generics rather than brand drugs.¹ Federal and state Medicaid agencies realized \$2.9 billion in savings in 2006 by using generic drugs.² According to a 2008 study, the average price paid for a generic drug in Medicare Part D fell 9.6% in 2007, while the average price for the same brand product increased 2.8%.³ A Pharmaceutical Care Management Association study in 2007 showed seniors in the Medicare program could save at least \$23 billion dollars over five years based just on 14 major brand-name drugs that will lose patent protection and be open to generic competition between now and 2011.⁴ Numerous other studies attest to the considerable savings achieved by out-of-pocket payers, federal and state employees, small businesses and major corporations as a result of the use of FDA-approved, safe and effective generic drugs. Against the proven record of safety and savings, it is imperative that federal policies minimize barriers to generic competition and facilitate the use of affordable generic medicines.

¹ NACDS: www.nacds.org/wmspage.cfm?parm1=507#pharmpricing.

² Centers for Medicare and Medicaid Services analysis of IMS Health drug utilization data. January 2007.

³ AARP Public Policy Institute and conducted by the University of Minnesota PRIME Institute.

⁴ "Potential Savings to Medicare from New Generic Drugs Becoming Available;" PCMA April 2006.



Near-Term Priorities: Initiatives for the First 180 Days

1. Request Additional Funding for OGD to Address Generic Backlog

Include a request for an additional \$14 million for the FDA's Office of Generic Drugs (OGD) in the President's FY 2010 budget submission to Congress in February 2009. Instruct that this additional funding be specifically targeted for review and approval of Abbreviated New Drug Applications (ANDAs). This increase would bring total OGD appropriations to approximately \$54 million and would enable OGD to reduce the current backlog of generic drug application awaiting action. Expediting the approval of new generics would result in billions of dollars in new savings as each one percent increase in generic use nationwide yields \$4 billion in added savings to taxpayers and the government.

2. Submit Request for Statutory Authority for FDA Biogeneric Approval Process

Include in the FY2010 Budget Request a provision seeking new statutory authority to allow FDA to approve abbreviated applications for biogenics. The request should urge Congress to include three fundamental principles in biogeneric legislation: (1) give FDA discretion to make scientific decisions regarding whether to approve generic biologics; (2) allow generic competitors to resolve patent disputes early; and (3) maintain existing patent extensions and grant marketing exclusivity that is not greater than permitted under the 1984 Hatch-Waxman Act. An early signal from the Administration that biogenics legislation be included in health reform and budget priorities would be enormously constructive in advancing the debate.

3. Reposition OGD within the Center for Drug Evaluation and Research

The organizational positioning of OGD within the Center for Drug Evaluation and Research (CDER) should be commensurate with the national importance of the generic drug program. But despite a 60% increase in generic drug use over the past 10 years, and a four-fold increase in the number of generic drug applications handled by OGD each year, there has been no change in OGD's organizational position within CDER since 1994. As a result, OGD remains two steps removed from the CDER Director and in this position is not part of CDER's Senior Management Team. The Administration should instruct CDER to immediately implement a reorganization plan that would bring OGD under the CDER Director and make OGD a member of the Senior Management Team. This organizational shift should include installment of an OGD liaison in the FDA Commissioner's office to enhance program accountability.

Ongoing Initiatives

4. Patent Reform Legislation

Ensure that any patent reform legislation proposed in Congress does not impede the timely entry of new generic medicines into the marketplace. This would include any attempt to weaken current "inequitable conduct" language in patent law so that inequitable conduct effectively would be eliminated as a defense to patent infringement.



5. Balanced Free Trade Agreements

The Administration should endorse the bipartisan crafted “New Trade Policy for America” as established in the 110th Congress. This policy is one example of the positive steps Congress has taken to assure that Free Trade Agreements (FTAs) do not tilt the scales so heavily in favor of intellectual property protection that they impede the delivery of affordable medicines to patients in need. Principles in the New Trade Policy for America should be applied to all future free trade agreement, such as the pending U.S.-Korea Free Trade Agreement.

6. State Carve-Out Legislation

Each year in the U.S. more than 2.5 billion prescriptions are filled using generic versions of brand drugs. Despite the proven safety and efficacy profiles of generic drugs, attempts persist in some state legislatures to prevent the substitution of certain FDA-approved generics. The White House should: (1) propose policies that would make any state carve-out program inapplicable to Medicaid and other federal drug programs; (2) instruct the Federal Trade Commission to investigate the anticompetitive aspects of carve-out laws and the impact on costs to consumers and the government; and (3) direct the FDA to incorporate on its internet homepage a link dedicated to issues surrounding the equivalence, safety and substitution of generic drugs.

7. Pro-Consumer Patent Litigation Settlements

The Administration should not propose a “bright line” prohibition on all patent litigation settlements between brand and generic companies. Such an approach could have the unintended consequence of preventing pro-consumer settlements that actually enable generic competition sooner than might otherwise be possible. Current law, as enacted by the 2003 Medicare Modernization Act, addresses the settlement issue by requiring that all brand-generic settlement agreements be filed with the Federal Trade Commission to determine if any provisions could have an anticompetitive, anti-consumer affect.

Summary

Two-thirds of all prescriptions dispensed in the U.S. in 2007 were filled using generic versions of the counterpart brand drug. Yet the cost to consumers, insurers and the government for these generics accounted for just 16% of the total amount spent last year for prescriptions medicines. Studies show that the average price for a generic prescription is approximately 80% below the average price for the corresponding brand, or an average of less than \$20 per generic prescription compared with \$115 for the brand. As a result, the use of FDA-approved generic drugs achieves billions of dollars in savings every year.

Implementing the policy initiatives outlined in this paper would maximize the savings generated by the use of generic drugs by minimizing barriers to generic competition. Each of the policy goals presented in this paper are in keeping with the overarching need to protect the critical balance between ensuring incentives to innovate new brand pharmaceuticals and providing access to lower cost generic medicines. These initiatives have the support and endorsement of the generic pharmaceutical industry.



ADDENDUM A

INITIATIVES TO ACHIEVE GREATER SAVINGS IN DRUG COSTS

- Additional Funding for the Office of Generic Drugs
- Regulatory Approval Process for Biogenerics
- Restructuring of FDA's Center for Drug Evaluation and Research
- Patent Reform Legislation
- Balanced Free Trade Agreements
- Generic Carve-Out Legislation
- Pro-Consumer Patent Litigation Settlements

Additional Funding for FDA's Office of Generic Drugs

Over the past six years the number of Abbreviated New Drug Applications (ANDAs) submitted to the FDA for review and approval has nearly tripled, from 307 in 2002 to an estimated 875 in 2008.¹ This influx of generic applications has resulted in an accumulation of approximately 1,300 unapproved filings that now are pending in the Office of Generic Drugs (OGD). As a consequence of this backlog, the median review and approval time for ANDAs has swelled to 19 months – more than a year longer than the statutory six months allowed for approving new generic drugs – and for applications challenging brand patents, the approval delays typically are much longer. Without additional funding for OGD, the unacceptable situation will grow even worse as more than \$80 billion in brand drugs will expire over the next three years, generating even more generic applications.

The FY2009 OGD budget is approximately \$41,900,000.² Compare that investment to the return in billions of dollars each year in savings for consumers and taxpayers. According to data from the National Association of Chain Drug Stores, the average price of a brand prescription is approximately \$119, while the average price of an available generic prescription is less than \$30.³ That difference of \$89 per prescription represents a significant sum of money (more than \$200 billion annually) when multiplied by the 2.3 billion generic prescriptions dispensed in the U.S. each year. The resulting potential return on investment for the government and taxpayers is a staggering 4,700%.



It is obvious that a relatively modest investment in OGD would help make more affordable medicines available in a timely manner to consumers and private health care purchasers, thereby saving billions of dollars each year. And those savings would enable the government to reach more Americans through its priority health care initiatives, such as Medicare, Medicaid and SCHIP. Delays in generic approvals result in millions of dollars of lost savings every day.

Recently, OGD tentatively approved a generic manufacturer's ANDA (meaning the application was complete and approvable). The manufacturer was awaiting a final court decision on the brand patent and subsequent final approval of the generic. Even after the federal appeals ruled that the patent covering the brand drug was invalid and unenforceable, it took OGD 62 days to issue final approval for the generic drug, during which time consumers, insurers and the government were paying \$1,115,735 per day for a brand with an invalid patent.⁴ That single example of a 62 day delay of generic market entry yielded the brand company incremental sales in excess of \$69 million, at taxpayer expense. When final approval was issued and the generic launched, not only did out-of-pocket payers save approximately 30% per prescription, but those who had insurance began paying a generic co-pay, which averages \$7.57, as opposed to the brand co-pay at an average \$19.18.⁵

Recommendation:

In the FY2010 White House Budget Request, the Administration should request at least an additional \$14 million for OGD. This increase in funding would enable the agency to hire more scientists and reduce approval times for generic drug applications. More funding also would permit OGD to continue to expand its program to educate physicians, pharmacists and consumers about the safety, efficacy and affordability of generic drugs. This request would help increase generic utilization and bring more savings to the health care system. OGD has said an increase of \$14 million could allow the addition of at least 34 full time equivalents (FTEs) and enable the agency to significantly reduce the time to conduct ANDA reviews and respond to the growing number of generic drug applications submitted.⁶

A budget request at this level would support the goal of rapidly approving safe new drugs, continually monitoring drug safety after approval, and proactively communicating new information to providers and patients. It would also enable more timely approval of treatments for HIV/AIDS and make them available to the neediest patients under the President's Emergency Plan for AIDS Relief (PEPFAR). The return on investment from increased funding will pay significant and long-lasting dividends for all Americans – individual consumers, employers, state governments and the federal government.



Regulatory Approval Process for Biologic Medicines

Biologic pharmaceuticals (“biologics”), unlike conventional chemically synthesized drugs, are vaccines, blood products and therapeutic proteins that are produced by living organisms. Biologics have been proven to be effective in the treatment of such serious and life-threatening diseases as multiple sclerosis, diabetes, Alzheimer’s, stroke, AIDS, leukemia and other types of cancer. Unfortunately, biologics are expensive and often are cost prohibitive for patients.

Short of price controls on branded medicines, the only successfully proven way to bring down the high cost of these medicines is through marketplace competition from generic versions of brand-name biologics whose patents have expired. But currently, the U.S. does not have a statutory process in place to allow the FDA to approve generic biologics. Congress passed the Hatch-Waxman Amendments creating a regulatory process for approval of generic chemical drugs over two decades ago. A similar avenue for biologic drugs is long overdue.

Current biologic treatment costs are staggering. The *monthly* cost of Remicade®, used to treat rheumatoid arthritis and other inflammatory disorders, is \$35,000 to \$66,000; Enbrel®, also used to treat RA and other inflammatory disorders, \$17,000 to \$25,000; Herceptin®, used to treat breast cancer, \$12,000; Avonex®, used to treat MS, \$7,000; and Avastin®, used to treat colorectal cancer, \$5,500. In some cases, insurance companies are denying much-needed biologics because of their costs. When coverage is available, even the co-pays can be thousands of dollars each year.

What becomes alarming, from the cost perspective, is not only are the prices for these medicines increasing annually, but the use of biologics is growing, as well. Spending on biologics in the U.S. increased 21% in 2006 to reach \$54 billion, more than triple the \$17 billion spent on biologics just 5 years ago. By 2010, spending for biologics is expected to reach \$99 billion, accounting for 26% of the country’s total drug spend.⁷ The dual effect of escalating prices and increasing use is yielding exponential growth in the amount we are spending on biologics. This presents numerous potential problems for the federal government and consumers. The preferred and proven alternative, which has already been successfully implemented in the traditional chemical drug sector, is generic competition.

Competition from biogenerics will provide a market-based mechanism to help reduce private and federal expenditures and achieve significant savings. The American health care system has never needed those savings more than it does today. Just as competition has produced savings in the traditional chemical drug sector, competition from biogenerics will achieve much needed savings in the biologic sector. Without a market for biogeneric alternatives to brand biologics, higher monopoly prices continue. Biogenerics are expected to be priced initially at least 25-30% below the reference branded drug, with steeper discounts coming as additional generics enter the market. These lower prices are projected to produce savings to health care providers and patients of between \$67 billion to \$108 billion over 10 years and up to \$378 billion over 20 years.⁸



Without generic competition, consumers will continue to experience ever-increasing prices which could ultimately have a negative impact on the care they receive.

Of course, the government is not immune from the high costs of biologics. Medicare spending for biologics continues to escalate disproportionately to Medicare funding. In 2005, for instance, Medicare Part B spent about \$2 billion on just the biologic anemia drug Epogen[®].⁹ This is an amount that exceeded FDA's entire annual budget of \$1.89 billion.¹⁰ Saving even 25% with a generic version of Epogen would lower Medicare's drug spend this year by \$625 million. Of course, there are several other biologics that cost the government hundreds of millions of dollars each year; two examples are Aranesp,[®] and Neulasta,[®] which last year cost Medicare approximately \$850 million and \$524 million, respectively. Applying the Congressional Budget Office's projections for Medicare spending to just the subset of biologics in the top 200 Medicare Part B reimbursed categories yields a savings of approximately \$1.5 billion annually, or \$14.9 billion over a standard 10-year scoring period.¹¹

Recommendation:

We strongly applaud President-elect Obama's acknowledgment during the campaign that a workable approval pathway for biogeneric medicines with measured rewards for innovation is long overdue. To achieve this goal, strong White House and Congressional leadership is needed to open the door to affordable biogenerics. Therefore, the Administration should move quickly on this issue and include a request for biogeneric legislation and appropriate funding in its 2010 budget request. Should the Administration include biogenerics in any type of health reform/budget package, it would send a tremendously valuable signal to Congress that this is a vital issue.

It is imperative that Congress act swiftly on that request and pass legislation that enables and compels the FDA to review biogeneric applications and approve safe and effective alternatives to branded products. With generic biologics now approved and marketed in 11 countries around the world, the U.S. cannot wait two or three years longer to create a regulatory pathway that would allow the FDA to approve biogenerics for sale in this country. The savings are needed now. As it did for chemical drugs 25 years ago with enactment of the Hatch-Waxman Amendments, Congress again has the opportunity to increase access to affordable drugs for patients, taxpayers and the government.

The biogeneric framework that Congress creates must be a flexible approval process. FDA must have the authority to use its considerable expertise to decide – *based upon science* – what tests are necessary for approval. Some have proposed that Congress hand down a rigid regulatory checklist of approval requirements, including mandatory human clinical testing in every instance. This is not a scientific approach. FDA should not be statutorily required to demand any type of test, let alone duplicative clinical trials, if the FDA determines such trials are not



necessary. FDA Deputy Commissioner Janet Woodcock described in Congressional testimony the importance of having a flexible framework and not a regulatory checklist, pointing out that evolving technology will enable the FDA to build a proficient approval process for the future.¹² Further, the approval process must empower the FDA to approve biogenerics using their expertise to determine the interchangeability for these biogenerics on a case by case basis.

Additionally, effective legislation must be free of unnecessary barriers and roadblocks in the form of artificial requirements, and must contain a mechanism that allows a generic company to resolve patent disputes without that litigation impacting or delaying FDA approval. The science of comparability between biological products is not new, but rather has been used by FDA and the brand industry for almost a dozen years. Legislation within the proper framework will allow FDA to continue using its expertise to expeditiously approve safe generic biologics.

The generic industry has consistently argued that a sound balance must be struck between innovation and competition in any truly workable biogeneric legislation. That is why GPhA has consistently stated that the landmark Hatch-Waxman legislation enacted 25 years ago serves as a sound model for biogenerics legislation. Hatch-Waxman has been extremely successful for the innovator industry, as well as for the generic industry. It struck a reasonable balance between market incentives and competition which has provided affordable access to small molecule drugs. Hatch-Waxman provided protection beyond that afforded to any other industry and has achieved its goals of innovation and access. A recent paper authored by former House Ways and Means Committee Chief Economist and research fellow at the American Enterprise Institute, Alex Brill, clearly demonstrates that BIO's argument for a long period of exclusivity is not valid, and that a period similar to the Hatch-Waxman market exclusivity period provides the necessary incentives to promote innovation in novel biologics and get needed life-saving medicines to consumers.

To bolster this point, BIO's own economists concluded that there is only a seven month differential in the R&D period for biopharmaceuticals and chemical drugs – an indistinguishable difference in the broadest sense. GPhA believes that a reasonable market exclusivity period, along with the present robust intellectual property protections and the patent restoration provisions included in the Hatch-Waxman Act, provides the proper incentives to foster innovation and, most important, provides patients struggling with health care costs needed medicines.

Lastly, GPhA believes that interchangeability is essential to fostering incentives technology innovators assert they need to invest and develop new and advanced characterization and access control technologies. If legislation prevents FDA from making interchangeable determinations, scientific innovations from technology companies will be held back because the incentive to innovate will not exist. Given the need for affordable, safe, and effective biopharmaceuticals in



the marketplace, and the need to maintain state-of-the-art science and technology to determine, at least for some products, their interchangeability, it is very important that FDA be given authority to use its expertise to make critical judgments to determine that two products are interchangeable.

Interchangeability determinations dramatically reduce the need for firms to engage in comprehensive marketing efforts, thereby reducing the cost of the product. Additionally, smaller firms will be encouraged to compete since interchangeability will provide purchasers with confidence that products are the same as the reference product without the need for special marketing programs, thus allowing them to compete on price and service.

The debate over generic biologics has moved from a question of *if* biogenerics are possible, to *when* biogenerics will become available. Generic manufacturers have the know-how to produce these products and they are ready to move forward with development of biogenerics. Now, Congress must brush aside political maneuvering that threatens progress on this issue and repeat the success of Hatch-Waxman by creating a well-defined, science based generic biologic approval process. Effective generic biologics legislation that helps control rising health care costs would be one of the most important piece of consumer legislation enacted this decade.

Reorganization of FDA's Center for Drug Evaluation and Research.

Despite a 60% increase in generic drug use over the past 15 years, and a four-fold increase in the number of generic drug applications handled by FDA's Office of Generic Drugs (OGD) each year, there has been no significant reorganization of OGD since 1994. OGD needs to be reorganized in a way that reflects the growing generic industry and the increased importance of the generic pharmaceutical industry's significance to our nation's health care system, as well the importance of this industry as it relates to the other functions within FDA's Center of Drug Evaluation and Research (CDER).

Given the critical nature of generic drugs to the federal government and all consumers, OGD should exist in CDER's organization hierarchy at the highest level to assure direct communication and oversight with the Director of the Center for Drug Evaluation and Research. Currently, OGD is under the Office of Pharmaceutical Science where it is two-steps removed from the CDER Director's office. In this organizational position, OGD must compete for administrative and budgeting resources with two programs handling new branded drugs and with the Office of Testing and Research. By reorganizing the structure of CDER so that OGD reports directly to the Director of CDER, top administrative officials could provide closer oversight to OGD management issues. The result of this change would be that OGD would receive appropriations more directly. Given the tremendous value of generics in the U.S. health care system, this organizational shift could allow OGD to have a liaison in the FDA Commissioner's office to enhance program accountability.

***Recommendation:***

OGD's position in the CDER organizational and reporting structure needs to be changed so that the Director of OGD reports directly to the CDER Director. By directly reporting to the CDER Director, the OGD Director would become part of the recognized Senior Management Team (SMT) within the Center. The SMT, which now includes the Office of New Drugs, the Office of Compliance, the Office of Surveillance and Epidemiology, and the Office of Translational Science, is responsible for setting tactical and strategic direction of CDER.

The absence of OGD's representation on the SMT is unjustified given that two-thirds of all prescriptions dispensed in the U.S. rely on the good work of the Office of Generic Drugs. The organizational level of OGD within CDER should be commensurate with the national importance of the generic drug program. The generic industry strongly recommends that FDA create a new organizational structure within CDER to assure that the generic drug program has the requisite priority within the FDA hierarchy. This change could be implemented via executive order and should be achieved within the first six months of the new Administration.

Patent Reform Legislation

Legislation introduced in the 110th Congress would have made the most sweeping reforms to the U.S. patent system since 1952.¹³ Senators Leahy and Hatch, along with Representatives Berman and Lamar Smith, introduced concurrently the Patent Reform Act of 2007. Sponsors of the bills in both the House and Senate have committed to reintroducing patent reform legislation in 2009. While this reform may be well-intended, these bills contained provisions that would have impeded the timely entry of new generic medicines into the market. Specifically, the generic industry is deeply concerned about any renewed effort to enact provisions such as those discussed below:

- Provisions that effectively eliminate the inequitable conduct doctrine as a defense to patent infringement.; Such a provision would create an incentive for companies to act dishonestly before the Patent and Trademark Office (PTO) to obtain patents that would in turn be used to block generic market entry.; Congress should not encourage, let alone reward, fraud and dishonesty in the patent process, particularly when doing so harms consumers and taxpayers.
- Provisions that re-write the novelty requirements for patentability, thus allowing brand companies to prop up weak and suspect drug patents by making it more difficult for generic companies to prove invalidity, thus extending monopolies for branded drugs;



- Provisions that would permit an automatic and immediate appeal of so-called “claim construction” rulings by district courts. Allowing immediate appeals of such decisions will unduly delay resolution of Hatch-Waxman patent cases and thus undeservedly delay consumer access to affordable generic medicines costing tens of millions of dollars for each product approval delay; and
- Eliminating the “best mode” requirement and best mode defense in patent infringement cases. The best mode requirement is a key part of the bargain struck by the patent system – a government-created monopoly granted in exchange for full disclosure to the public of the invention. Unfortunately the PTO does not have the resources to determine whether the patentee has satisfied the best mode requirement. Thus, eliminating the best mode defense, as a practical matter, likely will eliminate the requirement entirely. Therefore the generic pharmaceutical industry urges the new Administration and Congress to reject any effort to have the defense eliminated from the patent code.

Recommendation:

Patent reform legislation, without question, could have a tremendously negative impact on the generic pharmaceutical industry and the public that relies upon that industry to introduce affordable medicines. Thus, any legislation must not be undertaken quickly or without adequate consideration of its impact on consumers and taxpayers. It is critical that any legislation be carefully analyzed to ensure that our health care system is not harmed unintentionally.

Pro-Consumer Patent Litigation Settlements

The 1984 Hatch-Waxman Act provides an incentive for generic manufacturers to challenge weak and suspect brand drug patents. Over the past 25 years, generic companies have successfully challenged scores of patents via the Hatch-Waxman “Paragraph IV” generic application process (ANDA), and as a result have generated tens of billions of dollars in savings for American consumers. Like all types of litigation, some of these patent cases have involved litigation settlements between the parties. There are those that believe these settlements are anti-competitive; however many of these settlements have included countless pro-consumer terms and have guaranteed consumers access to a multitude of generic medicines well in advance of patent expiration. And in any event, Congress already has enacted legislation to address any anticompetitive agreements that might be reached. No new legislation is necessary, and any such legislation could, in fact, harm the public.

The generic industry's mission is to provide consumers with affordable medicines. The fact is that patent settlements unquestionably have proven to be a valuable component in achieving this mission in some infringement actions, as they have brought more affordable products to market



sooner than otherwise would have been possible. But despite the overall success of settlements to resolve patent disputes, there have been efforts to ban settlements that include any form of payment of cash or other consideration from the brand company to the generic applicant. Supporters of these efforts contend that settlement payments constitute anticompetitive pay offs by brand drug companies to delay competition from generic rivals; thus limiting the range of options available to settle patent disputes would have the unintended consequence of preventing pro-consumer settlements. Limiting a generic company's ability to settle patent disputes would lead to fewer patent challenges and, in the end, delayed market entry with a substantial loss in savings for consumers.

Recommendation:

The generic industry opposes an outright ban on settlements as a means of resolving patent litigation. Such a “bright line” approach would have the unintended consequences of preventing pro-consumer settlements that actually would allow generic competition sooner than if the generic company took the case to conclusion and lost – which is a possibility in every single patent case. Further, such an across the board ban would have the perverse effect of reducing the number of patent challenges brought by generics, working contrary to the goal of creating incentives that bring lower cost generic drugs to market sooner.

As part of the 2003 MMA Act, Congress enacted numerous statutory provisions designed to ensure prompt generic market entry and to punish companies that might enter into an anticompetitive agreement. Furthermore, under the MMA, settlement agreements between generic and brand companies must be filed with the Federal Trade Commission and Department of Justice, both of which reviews each agreement for any anticompetitive affect. Taking all of this into account, current law has done an excellent job in policing these settlements; no new legislation is necessary.

Balanced Free Trade Agreements

U.S. foreign trade policy affecting the pharmaceutical sector has begun to shift toward ensuring patient access to lower cost generics, while at the same time protecting intellectual property (IP) rights of innovator drug companies. The bipartisan “New Trade Policy for America” is one example of the positive steps Congress has taken to assure that Free Trade Agreements (FTAs) do not tilt the scales so heavily in favor of IP protection that they frustrate the delivery of affordable medicines to patients in need.¹⁴ The New Trade Policy for America requires expeditious adjudication of patent disputes so that generic drugs are not endlessly tied up in litigation, but also provides sufficient time for patent owners to seek remedies before generic marketing begins. The new policy also creates a strong incentive for innovative pharmaceutical companies to introduce their medicines quickly in the markets of our trading partners.



The New Trade Policy for America also provides assurances that compulsory licensing would be permissible, even when data exclusivity periods are pending. This allows the development and distribution of affordable generic medicines. But there are still outstanding issues in the pharmaceutical and IP sections of many past and current FTAs that should be addressed.

Generic companies remain concerned, for example, with the U.S.-Korea FTA, which has not been significantly altered relating to intellectual property provisions. In particular, the U.S. Trade Representative's negotiating template arguably provides more intellectual property protection to the brand industry than it is afforded under U.S. law, and fails to include critical generic access provisions. Thus, this FTA, like many others before it, fails to achieve a balance between pharmaceutical innovation and access to affordable medicine.

Recommendation:

The generic industry urges the Administration to promote the progress being made to bring balance to FTAs with respect to generic and brand-name pharmaceuticals. The generic pharmaceutical industry endorses a balance in FTAs between generic access and IP protection and believes the New Trade Policy for America has made considerable improvements to the terms of the FTAs that had long been unfavorable to the generic industry and inconsistent with U.S. law. The Office of the U.S. Trade Representative, working with Congress, should assure that future FTAs are not at variance with U.S. law with respect to brand IP and market protections. Current U.S. regulations provide that a patent term extension may be no more than five years for a novel medicine (new molecular entity), with a limit of a single patent extension per product. Unfortunately, some previous FTAs have provided for an unlimited number of patent extensions, even for older drugs.

The Administration also must ensure that generic companies maintain the right to research an innovator company's drug during the patent term so that a more affordable generic version may be developed promptly upon patent expiration. This is commonly referred to as the "Bolar" provision. Some recent FTAs fall short of U.S. law by not requiring the adoption of a Bolar principle, which results in extensive delays in the marketing of affordable generics. It is imperative that the U.S. Trade Representative's office work to restore the balance between drug innovation and access to affordable medicines through generic competition.



State Carve-Out Legislation.

Each year more than 2.5 billion prescriptions are filled in the U.S. using generic versions of brand pharmaceuticals. Yet despite the proven safety and efficacy profiles of generic drugs, attempts persist in some state legislatures to prevent the substitution of FDA-approved, therapeutically equivalent generics. This is especially unfortunate because there are no published studies or scientific evidence to show that the interchangeability of a generic for a brand name drug presents danger to the patient.¹⁵ If efforts to prohibit generic interchangeability are successful, the consequences will be profoundly higher drugs costs with no added safety or therapy benefits.

In recent years, it has become an oft-used strategy of brand name drug companies to advocate so-called state “carve-out” laws to limit generic substitution for drugs soon to lose patent protection. In 2008, more than 60 carve-out bills were introduced in 33 states, each aimed at limiting generic substitution. These “carve out” efforts typically target drugs in certain therapeutic categories, such as anti-seizure medicines, or immunosuppressant drugs that help prevent the rejection of transplanted organs. Proponents of carve-out laws typically argue that generic substitution should be limited to drugs considered to have a “narrow therapeutic index (NTI)”, even though there is no official definition for “narrow therapeutic index,” no general consensus of which drugs fall within this category, and no empirical evidence that such drugs require special treatment in terms of safety/interchangeability.

Moreover, FDA has confirmed on several occasions that current bioequivalence requirements for generics and brands are adequately rigorous to ensure that approved generics are therapeutically equivalent to their brand counterparts. When one therapeutically equivalent drug is substituted for another, the physician, pharmacist and patient can be assured of the same clinical results and safety profile. Further, FDA has frequently pointed out that any differences that could exist between brand and generic should be no greater than would be expected if one lot of the innovator's product was substituted for another.

In addressing the carve-out issue, it is critical to understand that pharmaceutical equivalents, whether brand-to-brand or generic-to-brand, contain the same active ingredient, are administered by the same route in the same dosage form, and are of identical strength and concentration. When two drugs are bioequivalent, their active ingredient works in the same way and in the same amount of time. But FDA's approval process for generics is not limited to the review of this type of data. The generic approval process also evaluates chemistry, manufacturing and controls and includes inspection and auditing of all facilities.

***Recommendation:***

Enactment of carve-out laws would have the effect of extending brand product monopolies well beyond patent expiration, at a high cost – but no increased health benefit – to patients, insurers and state-sponsored drug benefit programs. Carve-out laws limit the consumers’ right to choose affordable generics, which threatens patient access to these vital medicines. This adverse consequence is particularly evident on the Medicaid programs, which generally require pharmacists to dispense generics if the prescriber does not expressly indicate on the prescription that a brand product is medically necessary. The generic industry urges the Administration to:

- (1) Instruct the Federal Trade Commission to study the use of carve-out legislation and the projected impact on costs to consumers and the government.
- (2) Direct the FDA to add to its internet homepage a link dedicated to issues surrounding the equivalence of generic drugs and substitution of generic NTI medicines. A new link on FDA’s homepage would offer rapid access to information FDA has circulated over the years regarding the bioequivalence and substitutability of approved generic drugs. As with FDA’s current webpage links on issues such as pediatric drugs and bioterrorism, the new link would provide “one stop shopping” for state legislators and policymakers grappling with this critical issue.



ADDENDUM B

GENERIC PHARMACEUTICALS OVERVIEW

- Legislative and Regulatory Background of the Generic Industry
- Importance of Balancing Access to Affordable Generics with New Drug Innovation
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Legislative and Regulatory Background

When the Federal Food, Drug, and Cosmetic Act (FDCA) was enacted in 1938, the entire section covering drugs totaled just over five pages. The Act did not even distinguish in any significant way between whether a drug could be marketed over-the-counter or only as a prescription. And the concept of FDA-approved generics was still decades into the future.

Today, there are hundreds, if not thousands, of pages of drug regulations and FDA guidances that govern the approval and marketing of pharmaceuticals. The most significant addition to the FDCA in terms of the cost of medicines was the 1984 Drug Price Competition and Patent Term Restoration Act.¹⁶ Popularly called the Hatch-Waxman Act, named for its two chief sponsors in Congress, the Act created the generic drug industry as we know it today and undoubtedly is one of the most successful pieces of consumer legislation ever enacted.

Balancing Access and Innovation

What has made Hatch-Waxman successful for the past quarter century is the balance this compromise legislation created between the brand and the generic industries. For the brand drug innovators, Hatch-Waxman offered patent term extensions for the new drugs to compensate for any delays during FDA's regulatory review of the new product.¹⁷ It also gave innovators periods of "non-patent" market exclusivity of up to five years as an incentive to develop drug products with new chemical entities.

For generic manufacturers, Hatch-Waxman set forth requirements for a streamlined regulatory submission known as an Abbreviated New Drug Application (ANDA) by which a generic applicant provides FDA with documentation of therapeutic equivalence to a corresponding branded product. This process allows FDA to make a determination regarding the safety and



effectiveness of a generic product without requiring that the generic manufacturer replicate costly and time-consuming clinical trials, thus keeping generic costs lower. The Act also incentivizes generic companies to challenge or invent around brand patents that may be weak or suspect, for the purpose of injecting price competition into the market sooner rather than later, which significantly benefits consumers, employers, and taxpayers.

As a result of the balance between providing incentives to innovate new medicines and opening up access to lower cost generic versions of branded drugs, Americans have benefited from new, life-savings drugs while at the same time realizing billions of dollars in savings through the use of generic drugs.

Approval of Generic Medicines

FDA approves generic drugs using many of the same approval methods as those used for brands. In fact, the rigorous Chemistry, Manufacturing and Controls (CMC) phase is equally applicable to both new brand drugs and generic drugs. Labeling and testing requirements also are identical for both brand and generics. The same FDA field inspectors inspect the manufacturing facilities for generics and for brand products, using the same standards, to ensure compliance with all good manufacturing practices (GMPs). The only meaningful difference between the generic and brand approval process is that human and animal clinical studies to show safety and efficacy are conducted for new brand drugs, whereas bioequivalence studies serve as surrogates for clinical studies in approving generics.¹⁸

A bioequivalence study that shows that the active ingredient in the generic product is absorbed at the same rate and extent as in the brand product allows the generic company to rely on the proven safety and efficacy of the corresponding brand drug, which typically has been on the market for several years for both consumers and taxpayers. As a result of this well-established and successful ANDA approval process, consumers and patients can be sure that generics provide the same medicine and the same results as the brand counterparts, but at a significantly lower cost.

Public Acceptance of Generics

Public awareness campaigns and consumer education programs initiated by the FDA, the Generic Pharmaceutical Association, AARP, Blue Cross and others have greatly advanced the acceptance of generic drugs as safe and effective low-cost alternatives to brand-name medicines. Indeed, as the availability of generics has increased, the percentage of prescriptions filled with generics in the U.S. has grown from about 12% in 1984 to 66% in 2007.¹⁹ While there have been efforts by certain groups to discredit the effectiveness of FDA-approved generics, the fact remains that an increasing number of Americans rightly view generic drugs as a safe and effective alternative to more-costly brand-name drugs.



In 2007, more than 2.3 billion of the total prescriptions dispensed in the U.S. were filled with generics, compared to 1.8 billion prescriptions filled with brand drugs.²⁰ American consumers and patients have come to find that a generic drug delivers the same medicine and produces the same therapeutic effect as the counterpart brand, but at a much lower cost.

Savings Achieved by Generic Use

Generic drugs are less expensive than their brand-name counterpart because, in large part, once generic drugs are approved; there is greater competition amongst companies making their own generic version of the brand product. This competition creates a commodity market in which prices are held in check.

A study released Sept. 25, 2008, by the AARP Public Policy Institute and conducted by the University of Minnesota PRIME Institute showed that average prices for generic drugs in Medicare Part D *decreased* 9.6% in 2007, while the average price for the same brand-name product *increased* 7.4%.²¹ Studies by the FDA show that prices for generics drop an average 80% compared to the brand price when the second generic competitor enters the market.

A Pharmaceutical Care Management Association study in 2007 showed seniors in the Medicare program could save at least \$23 billion dollars during just the next five years based solely on 14 major brand-name drugs that will lose patent protection and be open to generic competition. A Congressional Budget Office estimate from 1998 found that generic drug use saved consumers between \$8 billion and \$10 billion that year at retail pharmacies.²² That savings has increased dramatically over the past 10 years as generic utilization as a percentage of all prescriptions has risen steadily from about 40% in 1998 to 66% today. According to the FDA, the savings are even greater when adding in hospital use of generics.

Against this proven record of safety and savings, it is imperative that federal policies promote the use of generics and minimize barriers to generic competition. Outlined above are ten policy initiatives that this Administration could put forward to maximize the savings that can be achieved for consumer and taxpayers through the use of generic drugs.



REFERENCES

- 1 FDA Office of Generic Drugs presentation at GPhA Fall Technical Workshop; Oct. 11, 2007.
- 2 FY2009 FDA Budget: www.fda.gov/oc/oms/ofm/budget/documentation.htm:
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- 4 The Federal Circuit Appeals Court ruled Sept. 7, 2006, that Ortho-McNeil's patent covering Ditropan XL (oxybutynin) was invalid. At the time, Mylan Pharmaceuticals was holding a tentative approval from the FDA for a generic version of the drugs. The appellate decision permitted FDA to immediately grant final approval and marketing clearance for Mylan's product. However, the final approval was not issued for 62 days (to Nov. 9, 2006) due in part to a staffing level that was insufficient to meet workload needs. During this delay, consumers were paying \$1,115,735 per day (IMS retail audit data) for a brand with an invalid patent. When the generic launched, consumer costs fell significantly as the generic co-pay became available for those with prescription drug coverage, and the generic retail price was up to 40% below the brand price for out-of-pocket payers.
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- 14 House Committee on ways and Means. <http://waysandmeans.house.gov/Media/eNewsLetter/5-11-07/07%2005%2010%20New%20Trade%20Policy%20Outline.pdf>
- 15 Undermining Generic Drug Substitution: The Cost of Generic Carve-Out Legislation Pharmaceutical Care Management Association. October 2008.
- 16 The Drug Price Competition and Patent Term Restoration Act, informally known as the "Hatch-Waxman Act" [Public Law 98-417], is the 1984 federal law that established the modern system of generic drugs. The informal name comes from the Act's two sponsors, Rep. Henry (D) of California and Sen. Orrin Hatch (R) of Utah. Hatch-Waxman amended the Federal Food, Drug, and Cosmetic Act with Section 505(j) 21 U.S.C. 355(j), which sets forth the process by which marketers of generic drugs file Abbreviated New Drug Applications ([ANDAs](#)) to seek FDA approval of the generic equivalent.



17 Hatch-Waxman added Section 156 to the Patent Act permitting patent term extension for patents on products (or processes for making or using the same) that are human drug products, medical devices, food additives, and color additives subject to regulation under the Federal Food, Drug and Cosmetic Act. The Act restores a portion of the patent term (up to a maximum of five years) during which the patentee is unable to sell or market a product while awaiting government approval, such as FDA review of a prescription drug.

18 For a complete explanation of the similarities between the new drug application (NDA) process and the abbreviated new drug application (ANDA) process for generic approvals, see Office of Generic Drugs presentation [June 2007]; www.fda.gov/cder/learn/CDERLearn/genDrugProcess/transcript.htm.

19 IMS Health and the FDA Office of Generic Drugs

20 IMS Health Presentation at GPhA Annual Meeting; February 13, 2008

21 AARP Public Policy Institute Trends in Manufacturer Prices of Generic Prescriptions Drugs Used by Medicare Beneficiaries; Sept. 2008

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