Remarks of Congressman Henry A. Waxman
Generic Pharmaceutical Association's 2007 Annual Policy Conference:
Generics: Prescription for Affordable Health Care
September 6, 2007

I am pleased to have the opportunity to join you once again at your Annual Policy Conference. Generic drugs give millions of people access to life-saving medicines they wouldn't otherwise be able to afford. And I am proud of the role that the Hatch-Waxman Amendments have played in making generic drugs widely available.

I have addressed this conference each year for many years now. Although the passage of Hatch-Waxman is decades behind us, there have been an endless series of battles to expand the public's access to generic drugs, so there has always been something to talk about.

Looking back, I can see that many of the battles have been defensive, fighting the efforts of the manufacturers of brand name drugs to reduce the public's access to medicines by creating and exploiting loopholes in Hatch-Waxman. It's practically a cliché, but it's all too true, that the brand name companies often spend more energy trying to delay generic competition for their older drugs than they do developing new ones.

So even as I can come before you each year and laud the important role of generic drugs in bringing down our nation's drug bill, I can also be sure that there will always be a new delaying tactic to denounce:

- A new method of evergreening their patents;
- A new spate of petitions to delay FDA approval of generics;
- A new scheme to undermine incentives to challenge patents; or
- Another misleading campaign to cast doubt on the safety and effectiveness of generics.

All too often, the political battles have been merely to try to hold onto the ground we had already won.

I'm glad to say that this year feels different. For the first year in a long time, we are affirmatively moving towards improving the public's access to vital medicines, not just trying to keep from going backwards.

Since this time last year, we have made remarkable progress toward a goal I have long sought: creation of a pathway to approve generic biologics. In 2006, U.S. biotech sales grew by 20% to $40.3 billion. By way of comparison, this 20% growth in biotech sales is far greater than the 8% sales growth experienced by traditional pharmaceutical.

Biotech drugs may be the future of medicine, but they are also dramatically more expensive than traditional drugs.

The cost of biotech drugs could overwhelm our health care system unless we introduce competition into this market. A pathway for approving generic biologics is essential if millions of people are going to be able to afford these life-saving new drugs.

With your help, and the help of a growing coalition of businesses, consumer groups, and purchasers who are no longer willing to tolerate permanent monopolies for biologics, we have, in the last year, come much farther towards the enactment of that pathway than I had expected.

Many of the people in this room did a lot of the ground work in making this accomplishment possible, and you should all take great pride in your role in this battle. I applaud you for the hard work you do each day to ensure that currently marketed generic drugs are safe, effective, and affordable.

In the coming years, your hard work will become even more critical. It's estimated that medicines with combined US sales of $25 billion to $30 billion could lose patent protection over the next three years.

So we must continue to do all we can to ensure that safe and affordable generics — for all types of medicines — are sped to market at the earliest possible moment.

So far, the 110th Congress has been extremely active in efforts to make sure this will happen. In many areas, we have made significant progress toward putting generic-friendly policies in place. In other areas, we still have work to do.

FDARA

We are currently in the midst of conference negotiations on The Food and Drug Administration Amendments Act of 2007, or the so-called "FDARA."

- That legislation will reauthorize the Prescription Drug User Fee Act, the Medical Device User Fee Act, the Best Pharmaceuticals for Children Act, and the Pediatric Research Equity Act.

- Further, it incorporates critical improvements in FDA's oversight of drug safety and will establish for the first time a mandatory clinical trials registry and results database.

Citizen Petitions

In addition, this legislation — which has already passed both the House and the Senate — addresses one of the longstanding battles against the efforts to gut Hatch-Waxman.

FDARA contains provisions that I hope will go a long way toward eradicating one of the many tactics used by brand companies to delay the entry of generic drugs: the abuse of FDA's citizen petition process. Brand companies have been filing citizen petitions raising frivolous safety issues about a generic drug just before FDA is poised to approve the generic drug.

The brand companies know that FDA's practice is to automatically delay the approval of the generic to give the Agency time to develop a comprehensive administrative response to the petition. FDA is forced to make this decision to delay, because it knows that the moment it approves the generic, the brand company will haul the Agency into court and FDA will have no administrative record to back up its decision to deny the petition.

I believe that the language in the House-passed version of FDARA provides greater protection against delays in approval of generic drugs than the Senate's version. The House version would give FDA the time it needs to respond to a frivolous petition, without fear of being dragged into court — through the so-called exhaustion of administrative remedies provisions. Under this approach, the FDA would be able to go ahead and approve the generic drug and then take its time to work on a response to the petition. FDA would not have to delay approval of the generic unless the petition raised a true safety issue. I'm hopeful this language will remain in the final conference version.

But both bills contain language that would greatly curtail the use of the citizen petition process as a tool for delay. Both bills prohibit FDA from delaying approval on the basis of a citizen petition, unless there is a compelling public health reason to do so. Both bills would require the person submitting the citizen petition to certify that all information — both favorable and unfavorable to the petitioner — has been provided to FDA in the petition. Petitioners would also be required to disclose the source of any payment they received for filing the petition. These steps will go a long way toward increasing FDA's ability to more efficiently separate out those petitions which indeed raise valid safety issues, from those that don't.

I am extremely encouraged that these provisions were included in this legislation. The American consumer will benefit from these provisions, because more generics will be available sooner.

BPCA Cap

On the other hand, I am much less encouraged about another section of the House-passed version of FDARA — the reauthorization of the Best Pharmaceuticals for Children Act. I am very disappointed that the House failed to include a measure to address the windfall profits that brand companies have been receiving under the pediatric exclusivity provisions of the Act.

The Best Pharmaceuticals for Children Act was designed to get more drugs tested for safety and effectiveness in children. We reward companies for doing this testing by granting them an additional six months of market exclusivity.

In some ways the law has been highly successful. It has encouraged the development of important new information on many drugs. But the Act has also been far more costly to consumers than anticipated. It has rewarded some companies with profits that are often hundreds of times the actual costs of the studies themselves. Because exclusivity delays generic competition, those profits come from the pockets of consumers who must pay higher drug costs. And, unfortunately, it is usually the uninsured who shoulder most of this burden.

I believe that we need a sort of sanity test for drug profits. There have to be some limits to the prices that can be charged for the most profitable drugs.

Six months of exclusivity for a drug that earns $50 million per year in sales is worth perhaps $20 million to the company.

For a company with a $5 billion drug, though, exclusivity is worth 100 times that amount.

In this example, let's assume that each of those companies spent $10 million on the pediatric study.

If that assumption is fair, the first company has received a generous 100% return on investment. The second company, though, has received an outrageous 10,000% return. When we have millions of Americans who cannot afford life-saving medicines because they just cost too much, a 10,000% rate of return adds up to a windfall that Americans just can't afford.

Nonetheless, despite my efforts to draw SOME lines, the Committee on Energy and Commerce rejected all attempts to curb those windfall profits for blockbuster drugs.

PhRMA somehow managed to convince both Republicans and Democrats that drug companies would use the huge profits on blockbusters to carry out pediatric studies on smaller drugs that wouldn't otherwise be studied.

Forgive me if I'm not familiar with this business model. Since when does a business with fiduciary responsibilities to its shareholders carry out revenue-losing development programs on its smaller drugs simply because another of its drugs reaped huge profits?

The Senate-passed version of FDARA does contain a measure to address windfall profits. I hope that our final conference product will incorporate the Senate approach. We simply cannot stand by and watch as the American people foot the bill for these unfair windfalls.

Generic Biologics

Let me return to the issue I began with — creating a pathway for approval of generic biologics. Biologics are one of the fastest growing and most expensive categories of drugs, frequently costing tens of thousands — even hundreds of thousands — of dollars per year. These drugs are often life-saving.

A recent CNN Money article describes at least part of the reason for the tremendous growth in biotech drugs' share of the market, and I quote: "Biotech drugs are an attractive investment for Big Pharma for two reasons: the industry is fast-growing, and generic competitors can't touch it."

As you well know, the article correctly describes the current state of the law. Biologics were not covered under the original Hatch-Waxman Act. So FDA currently lacks a clear pathway for approving low-cost competing versions of these drugs, even after patents have expired.

Until and unless we in Congress act to give FDA this authority, the biotech industry will continue to enjoy permanent monopolies, "untouched" by generics. And employers, insurers, and the federal government will continue to pay the staggering monopoly prices we have today.

There have been huge changes to the landscape on this issue in the last 12 months. Before last September, despite years of hypothetical musings on the subject, no one had ever even introduced a bill to permit approval of generic biologics. I am proud to have been the first member of Congress to do so, along with Senators Clinton and Schumer, who introduced the bill in the Senate. But I must confess that I initially assumed that the bill would inaugurate a long debate on the topic and that progress would be inevitable but it would take time.

I clearly underestimated the strength of demand for affordable biotech drugs now. Within a few months of the introduction of the bill at the end of the last Congress, an impressive and effective coalition of businesses, consumer and patient groups, and purchasers had come together to push for the rapid passage of a generic biologics pathway. Many of you in this room can take a lot of credit for that.

Against all odds, we came close to getting the legislation included in FDARA. We were much closer, in fact, in the Senate than in the House. Though the prospects for this legislation being included in FDARA are now extremely slim, nonetheless the issue is squarely on the table — and I remain very hopeful that before this Congress ends, we will see legislation enacted.

Many members of Congress have joined me in recognizing that something must be done. The success of the Senate HELP Committee in passing a bill out of Committee is one sign of this. But another sign is that we now have a total of three different legislative proposals that have been circulated.

To be sure, I do not agree with many aspects of the proposals that have been introduced to compete with mine. And I do not underestimate the role of BIO, the biotech industry trade association, in one of those proposals. But it is still striking that this issue has become so important that that we have three proposals pending at the same time, after decades when there were no bills on the topic at all.

The entire framework of the debate is changing. After years of championing the Flat Earth Society on this issue, BIO has finally abandoned its argument that generic biologics are impossible. Even BIO itself now understands that they have to address this issue, even though there is less than meets the eye to their current self-serving proposal.

It is extremely encouraging to see this major shift occur in an extremely short time period, so we can't let the probable failure to get this in FDARA discourage us too much. But

we also can't let this feeling of encouragement about the interest in generic biologics cause us to take anything for granted. There is obviously a great deal of work left to do.

We need to make sure that there are, on the one hand, adequate incentives for innovation and, on the other, rapid competition by generic products once the patents have expired.

Obviously, we learned some valuable lessons about how to balance these competing needs 20 years ago when we drafted the Hatch-Waxman Act.

If Congress ignores the lessons we learned about balance in Hatch-Waxman and passes a bill that puts too much weight on one side of the scale — the side of giving huge profits to the brand manufacturers — we will lose a huge opportunity.

The industry is calling for 10, 12, or even 14 years of exclusivity. Those periods are so long that they are not only not balanced, they make the bill a huge give away. Brand companies should receive a reasonable term of exclusivity, but not one that is so long that it would rob the American people of the cost-savings appropriate generic competition brings.

BIO's arguments for the need for those ever-increasing terms of exclusivity have morphed over time. Early on, we heard that 10 years was the appropriate term because that's what the EU has. Of course, that argument disappeared when it was pointed out that the EU also has price controls. The economic value of 10 years of exclusivity in our system with no price controls would far exceed the value of 10 years of exclusivity in the EU's market.

Later on, we heard that 14 years was necessary because that's what brand companies receive in patent term restoration under Hatch-Waxman. And I've even heard the argument that Congress intended that companies always get 14 years.

This last claim is simply not true. I have some experience with that law, and I feel confident stating that Congress did not intend for every company to get 14 years in patent term restoration. We intended for that to be a ceiling on patent extensions — not a floor. Moreover, we recognized that FDA-enforced exclusivity is significantly more valuable than patent extensions, because exclusivity is unbreakable.

If we had thought exclusivity was interchangeable with patent protection we would have provided a comparable ceiling of 14 years of exclusivity for those products lacking patent protection. We did not. We determined that 5 years of exclusivity was adequate.

Given that the industry sources on this issue have not been trustworthy, we need better information to guide our decisions. I believe that the Congress should demand that the brand industry demonstrate — with specific data — what they need to continue to innovate and to explain why they need it.

Exclusivity issues are ultimately focused on the price for these medicines. As important as that issue is, though, we can never let it be our only concern. We have got to ensure that generic versions of biologics are as safe and as effective as their brand-name counterparts. So

whatever legislative pathway we put into place must establish a scientifically rigorous process for approval of copies of biotech drugs. We need to authorize FDA to determine, on a product-by-product basis, what studies will be necessary to show that a new product is clinically indistinguishable from the brand name product.

But giving FDA — the scientific expert here — the flexibility it needs to make this decision is critical. We should not tie FDA's hands and require that there be a clinical trial in every case.

In some cases, this would not only waste a lot of resources, but could also put patients at risk unnecessarily. A knee jerk requirement of trials in every case would violate all ethical standards of science. Present and former FDA officials have made clear in Congressional testimony that they agree with me on this point.

Congress has taken a giant leap forward on generic biologics. We are no longer standing by and watching as our reliance on biologics increases, along with their cost. These medicines save lives. I believe that we are finally ready to do something to address the fact that often the only thing standing between patients and the drugs they need to survive is the price tag.

But I cannot emphasize too strongly that the job of focusing on competition to address the cost to the consumer is critical. If that concern is not front and center, the bill will only protect the monopoly position of the brands, and do more harm that good. That is where the influence of consumers and insurers, business and labor, state and local government, and the generic industry itself become so crucial. With that help, I am optimistic that we will be successful in establishing an effective and safe generic biologic approval system.

I encourage all of you to continue to spread your message on the Hill and to explain to the American public the many benefits that can, and will, come from with our success on this.

Together, we will see the establishment of the biogenerics approval system very soon.

I thank you for the good work you do to provide Americans with access to safe, affordable, and life-saving medicines.

I look forward to continuing to work with you in our shared struggle to provide affordable health care.