Remarks of Congressman Henry A. Waxman for the
Generic Pharmaceutical Association's Annual Policy Conference 2006
Leading America Into a Healthy Future
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The Census Bureau recently released the 2005 data on income, poverty and health care. It confirmed what average American families already know -- that Americans have not fared well during the Bush Administration. Since President Bush took office, there are 5.4 million more people living in poverty in the United States. And while health care, energy and college costs are all soaring, the overall median household income has plummeted by $1,300.

In the United States, we pay more for our healthcare than any other country. Americans often pay more than two (2) times what the rest of the world pays for their medicines. Yet, on President Bush's watch, 6.8 million more Americans have joined the ranks of the 46 million uninsured in our country. One out of every nine children has no insurance coverage.

This must change. Americans know we simply cannot sustain a healthcare system like this.

One of the most effective ways to lower drug prices is to increase the presence of generic drugs on the marketplace. As you know, the 1984, the Drug Price Competition & Patent Term Restoration Act –commonly known as Hatch-Waxman—established the generic drug approval system. By almost any measure, it has been a great success in promoting competition and lowering drug prices where we have generics. But in 2005, even though generics accounted for 56% of all prescriptions dispensed, we spent only $22.3 billion on generic drugs—compared to $229.5 billion spent on brand-name drugs.

Clearly the bulk of our drug expenditures continues to be on brand-name drugs—and this is evidence that Hatch-Waxman is not working as it should. So we have to do better.

One of the most important steps we can take now is to ensure that Hatch-Waxman applies to *all* types of drugs.

Biologics, or biotech drugs, have emerged as a major component of rising drug prices. These products are now among the most expensive and important medications for U.S. consumers. Patients who need these drugs often have to pay hundreds of thousands of dollars a year for them.

As you know, the original Hatch-Waxman Act did not apply to generic biologics. Many biopharmaceuticals are already off-patent and more than $10 billion worth of these drugs will come off patent over the coming years. But under current law, there will be no generic competition. FDA has no mechanism for evaluating and approving copies of biological products. So these products are effectively given a near permanent monopoly.

The time has come to break this monopoly. I intend to introduce legislation that will establish a clear pathway for generic biologics very shortly.

When I embarked on this effort in February, I knew that this would be a complicated and delicate task.

A system for approving generic biologics must ensure there are, on the one hand, adequate incentives for innovation and, on the other, 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.

Biologics raise sensitive scientific questions that are unique to these products. Some would argue that this means that a system for approving generic biologics should not exist. I believe they're wrong. Instead, the uniqueness of biological products suggests only that we need a case-by-case approach for evaluating each type of product.

We cannot afford to wait the many years it would take to develop a universal test that works for all biogenerics, like the bioequivalence test for traditional drugs. That makes no sense since these products range so widely in complexity. This means that the types of studies necessary to prove that the safety and effectiveness of these products are similar to that of the innovators will also vary.

In creating this case-by-case approach, it is critical that we have the science right. If the science behind approving generic biologics is open to reasonable doubt, the brand name industry will make it their mission to destroy the credibility of those generics. This kind of doubt can seriously undermine the value of a generic drug approval system.

I have been working diligently on developing legislation that speaks to these concerns. And I'm nearing the last stretch in this effort.

Clearly, advancing this legislation will be an uphill battle. The innovator companies have already begun their crusade against any system for approving generic biologics—it can't be done, they say. We need to respond to them with one voice: yes, it can.

You and I might have some differences of opinion about the best way to construct this system. But I believe we can—and must—achieve consensus around an approach and move forward united around one bill. Indeed it is critical that we do so. Remember, when we try to enact this legislation, we will be facing a common enemy—and they will be united in fighting us.

The time to move forward is upon us. Congress can no longer stand by and watch while our reliance on biologics increases, and the cost of these medicines continues to soar with no end in sight.

I believe we will be successful in creating a legislative scheme in which the methods of establishing equivalence for each class of biologics are left to be developed by the FDA, as the science evolves.

Let me turn now to some other issues that Congress will be facing in what promises to be a very busy 2007. Several critical pieces of FDA legislation are up for reauthorization next year—wherever people stand on these issues, Congress will have to act or these programs will come to an end.

The Prescription Drug User Fee Act–or "PDUFA"—is one of the laws that must be reauthorized.

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First enacted in 1992, PDUFA authorized FDA to collect fees from the companies seeking FDA approval of their drugs or biologics. The fees provided a substantial increase in the resources available for the Agency's review of these products, and have enabled FDA to conduct faster reviews, bringing drugs and biologics more quickly to the market.

However, I'm concerned that this increased speed has shortchanged drug safety—that a shorter review period may have caused FDA to miss important safety problems before marketing. And that there has been no attempt to compensate for shorter reviews with more rigorous post-market safety oversight.

FDA's post-market drug surveillance system has got to be strengthened. The reauthorization of PDUFA gives us a chance to address this.

It is inevitable that some safety hazards will not be discovered until a drug is used in the general population. To protect consumers from unsafe drugs, FDA must place equal emphasis on post-market surveillance and pre-market reviews. FDA must be given the resources and the authority to detect and respond to post-approval safety problems quickly and efficiently.

For example, we need to ensure that FDA can erect appropriate restrictions on the distribution of risky products so that the public is not unnecessarily exposed to them. And it is critical that FDA have the ability to restrict advertising directed at consumers while safety issues are resolved.

When safety issues do surface, FDA must also have the authority to require that a manufacturer conduct additional studies of their drugs to determine their cause and extent.

Americans deserve to have complete confidence that FDA is vigilantly protecting them from unsafe drugs both before they are approved—and after they are on the market.

The Best Pharmaceuticals for Children Act also expires next year. This legislation was designed to get more drugs tested for safety and effectiveness in children. Every parent knows the frustration of not knowing the proper dose of medicine to give to their children. So companies were rewarded for doing the testing by being granted 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.

Further, too often, the studies that allow the companies to get the exclusivity do not produce any clinically useful information. Several companies were given exclusivity for conducting studies on anti-depressants in children for example. But because the studies failed to show effectiveness, no information was added to the drugs' labels. Consumers paid these companies hundreds of millions of dollars in higher drug prices and received nothing in return.

We need to ensure that, when these pediatric studies are conducted, they produce useful results—we should not continue to reward companies for studies that don't contribute in a meaningful way to our understanding of the benefits or safety concerns of these drugs for children.

We also have got to be concerned about the staggering *cost* of drugs in this country. Brand-name drug prices have been rising at an unprecedented rate. Obviously, Americans won't have real access to these products, if they can't afford to buy them.

As you well know, one of the most effective ways to lower drug prices is to increase the presence of generic drugs on the marketplace. By almost any measure, the 1984, the Drug Price Competition & Patent Term Restoration Act –commonly known as Hatch-Waxman—has been a great success in promoting competition and lowering drug prices where we have generics. But in 2005, even though generics accounted for 56% of all prescriptions dispensed, we spent only $22.3 billion on generic drugs—compared to $229.5 billion spent on brand-name drugs.

Clearly the bulk of our drug expenditures continues to be on brand-name drugs—this is evidence that Hatch-Waxman is not working as it should. So we have to do better.

We know that pharmaceutical companies have now found loopholes in the law that they can exploit.

As you know, one of the most recent tactics used by brand-name companies is the practice of so-called "authorized generics." Brand-name companies have increasingly been re-launching their own drugs in generic form just as the first generic competitor enters the market—during its 180 days of exclusive marketing.

The number of authorized generics on the market has drastically increased over the past few years. Clearly, brand name companies are doing anything and everything they can to hold onto their market share in the face of what has become stiff generic competition. The authorized generic tactic is designed to reduce the exclusivity reward to the generic company that has put in the time and resources to challenge the patent.

If the consequence is to discourage challenging of patents, and inappropriate patents are left in place, generic competition will be delayed, and consumers, businesses, and governments

will be forced to pay monopoly drug prices for much longer periods. This has got to be a concern.

As I'm sure you know, the FTC is in the process of conducting a study on the economic impact of authorized generics that I, and others in Congress, requested. I am hopeful that they will complete the study in a timely manner because we simply cannot afford an unnecessary loss of generic competition.

You no doubt recall that it was partly a result of the FTC's 2002 study, that we were able to pass legislation in 2003 closing loopholes in Hatch-Waxman. Similarly, with authorized generics, we need the best information available to inform our actions.

The FTC has also recently highlighted another concerning trend. Over the last year, there has apparently been a resurgence in potentially anti-competitive patent settlement agreements between generics and brand name companies.

Beginning in the late 1990's, these settlement arrangements began to include agreements by the generic firms to stay off the market in exchange for compensation from the brand-name firms. In 1999, FTC challenged some of these agreements as being anti-competitive. Shortly thereafter, we saw the use of these types of agreements plummet.

In 2005, however, two appellate court decisions reversed the FTC and upheld settlements that included these kinds of reverse payments. These court decisions appear to have prompted the recent resurgence in these potentially anti-competitive settlement agreements.

Unfortunately, the Supreme Court has decided not to hear FTC's appeal of the case that condoned these types of agreements. I think that's a source of great concern.

I recognize that there are situations in which patent settlement agreements can provide great benefits across the board. The parties involved can avoid protracted litigation and consumers can get access to generic drugs that might otherwise have been deferred by this litigation.

But too frequently these agreements are anti-competitive and improperly postpone generic entry. So I believe Congress needs to act to prevent the subversion of the goals of Hatch-Waxman. And I urge all of you to uphold the spirit of Hatch-Waxman by avoiding participation in agreements that serve to delay consumer access to generic medications, while enriching only the companies involved.

I commend all of you for the good work you do each day in providing Americans with much-needed relief from the skyrocketing prices of medicines in our country.

I look forward to working alongside all of you in the coming year as we continue our struggle for affordable and safe medicines. The American people deserve no less.