

**Remarks of Congressman Henry A. Waxman for the
7th Annual Generic Drugs Summit
Strategic Planning For Growth in the Competitive Generics Marketplace
September 28, 2006**

When Americans are asked to name the most important health problem that the government should address, they typically say it's the cost of health care. In fact, many say they worry more about health care costs than they do about losing their job, paying their rent or mortgage—or even being a victim of a terrorist attack.

And when they are asked why the cost of care is so high, they overwhelmingly believe that it's the high profits being made by the drug and insurance companies.

They're right. Prescription drugs are one of the fastest growing components of our health care spending. Our dependence on medicines is increasing—and so is the price.

Retail prescription prices increased an average of 8.3% a year from 1994 to 2005—from an average of \$28.67 per prescription to \$64.86—a rate that is more than triple the average annual inflation rate.

I have always known that 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, Hatch-Waxman has been a great success, providing consumers and healthcare providers with much-needed cost savings.

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. Patents on many biopharmaceuticals have already expired 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.

I embarked on this effort in February with full knowledge 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.

We also must be vigilant against attempts by brand-name companies to game the Hatch-Waxman system. Many companies have successfully found and exploited loopholes in the law.

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, and enrich only the companies involved.

In the international arena, we have also recently seen widespread misuse of the principles of Hatch-Waxman.

Millions of people around the world—and in the developing world in particular—are dying of diseases for which highly effective, life-saving drugs exist. Yet, behind closed doors, the Bush Administration has been diligently working to obstruct access to these life-saving medicines in these countries. As a means of protecting the intellectual property interests of the brand name industry, this Administration has entered into several trade agreements with developing nations that include provisions on intellectual property and pharmaceuticals.

Some of these provisions reflect concepts that are in Hatch-Waxman. But although I am proud of the accomplishments that Hatch-Waxman has made in the United States, I will be the first to say that it would be wrong to impose a Hatch-Waxman-like scheme in developing countries.

The reason is that these countries are in a very different situation from where the U.S. was in 1984. When we fought to enact Hatch-Waxman, there was almost no access in the U.S. to generic drugs because FDA had no mechanism for approving generic versions of new drugs. So we included patent protections and exclusivity rewards as a trade-off for the new authority to approve generic drugs on the basis of bioequivalence studies. Americans got rapid access to generics in exchange for limitations on economic incentives to drug companies.

The truth is Hatch-Waxman took away monopoly rights from the brand-name drug industry by putting an end to the permanent monopoly created by the drug approval system in effect at that time.

In the developing world, the situation could not be more different. For most of the citizens of these developing countries, generic drugs are already widely available. In fact, they are typically the only drugs they can afford. Imposing a Hatch-Waxman-like scheme in these countries will actually undermine generic competition and will benefit only the brand-name drug companies.

What's more, the recent trade agreements lack protections that exist in the U.S. system, apply patent extensions and market exclusivity in ways that will ultimately delay or prevent access to more affordable generic drugs. For example, under CAFTA and many other agreements, many developing nations with current access to generic drugs will now be prohibited from approving a generic drug until five years after the brand name drug is first approved in that country. Many of these agreements also require these countries to grant patent extensions to compensate for any delays in the approval processes.

Notably absent from many of these agreements are the important limitations on the duration of patent extensions that we have in the United States. So if the approval process takes longer in a developing country than it does in the United States, the patent term will actually be longer in that country than it would be in the U.S.

The U.S. adopted the 2001 Doha Declaration, agreeing that trade obligations should be conducted in ways that promote public health and access to medications. But in blatant disregard of the agreement, this Administration has repeatedly used trade agreements to restrict the ability of developing countries to acquire generic medicines that could prevent and treat a host of deadly diseases. The ironic upshot of these agreements is that these developing nations, which need lower cost drugs the most, will now have to wait the longest to obtain them. At a time when we need to be focusing on increasing access to medicines, including costly second-line AIDS drugs, this Administration is consistently prioritizing protection of the brand-name companies above access.

I shudder to think of how many lives will be lost as a result of these policies.

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.