Remarks of Congressman Henry A. Waxman
November 21, 2002

This is a timely moment to talk about generic drug issues. To say the least, there have been a number of significant developments on this issue since I spoke here last year.

But before we discuss recent developments, let's step back for a moment. I think it's important to remind ourselves of how we got where we are today, and more specifically, to remind ourselves of the twin goals we were trying to attain when Congress first enacted generic drug legislation back in 1984: increasing competition while maintaining innovation. I believe those goals are as important today as they were 18 years ago.

The law that became known as Hatch-Waxman represented a careful balance between competition and innovation. Because both are vitally necessary to our nation's health. Our citizens need effective new medicines to treat their illnesses. The pharmaceutical industry is responsible for tremendous advances in health care and we would not want to do anything to interfere with their ability to produce important new medicines. Yet those medicines are useless to many of our citizens if only the insured and the rich can afford them.

Before 1984, there were very few generic drugs on the market, and very little true competition in the prescription drug marketplace. The 1984 law that has become known as the Hatch-Waxman Amendments set out to encourage competition and lower drug prices by streamlining the process for approval of generic drugs.

At the same time, the law protected innovation: it guaranteed brand name companies generous patent protection and monopoly periods. The law provided not only restoration of patent life lost during the drug approval process, but several periods of additional non-patent exclusivity. These monopoly protections were intended to allow brand name companies to recoup their research and development costs and to support future innovation.

For many years, the Hatch-Waxman Amendments worked well; the balance held. The generics' share of the market grew steadily, lowering drug prices by over 2/3 for those drugs with generic competition. Meanwhile, the pharmaceutical industry continued to flourish. Throughout the 1980's and 1990's the industry continued to produce innovative medicines (as well as enviable profits).

But more recently, some companies began to deliberately undermine the balance. At a time when drug company pipelines were running dry (for reasons unrelated to Hatch-Waxman), some of them saw delaying generic competition as the answer to keeping their profits high. So, rather than innovate new drugs, they began to innovate new legal strategies. Through such tools as eleventh-hour filing of new, often invalid or irrelevant patents, as well as collusive agreements, these companies kept generics off the market for months and even years beyond the time Congress intended.

When I spoke here a year ago, these abuses of Hatch-Waxman had begun to come to light. Although I did not want to stand by while loopholes were being exploited, I was also concerned that new legislation could easily spin out of control with amendments that would unbalance Hatch-Waxman even further.

Fortunately, my ability to predict the legislative process was not at its peak that day. A lot of progress toward positive reform of Hatch-Waxman has been made in the last year, some of it a surprise even to me.

- At my request, the FTC investigated and issued a report documenting serious abuses of the Hatch-Waxman Act, the 1984 law that opened the door to widespread generic competition.
- A major bill to address these abuses passed the Senate, with broad bipartisan support.
- Although we tried unsuccessfully to get the Republican-led House to act on the legislation, even the President now agrees that there have been abuses of Hatch-Waxman that should be addressed. Within the last month, he issued a proposed rule to curb some of those abuses.

A year ago, I don't think I predicted that we would have come this close to Hatch-Waxman reform. (I didn't, did I?) How did we get to this point so quickly?

It was an election year. There was mounting pressure, for both Democrats and Republicans, to address soaring prescription drug prices. Drug prices have risen at more than twice the rate of inflation in recent years, placing great financial burdens on the uninsured and particularly on seniors. The drive to create an affordable Medicare prescription drug benefit, and to find the

money to pay for it, produced a commendable desire in both parties to consider methods of bringing down drug prices.

At the same time, a rising chorus of voices was urging Congress to speed up access to generics. These voices came not just from consumers, but, for the first time, from businesses, insurers, and State governors. This unlikely coalition came together because each realized that the health care benefits they paid for were being driven up by deliberate attempts to delay generic competition. Together, these groups formed a powerful alliance in favor of Hatch-Waxman reform.

Adding weight to these political forces was a growing body of evidence documenting abuses of Hatch-Waxman. In May, Senator Kennedy held a hearing on abuses of Hatch-Waxman. Evidence presented at that hearing demonstrated that some companies were generic competition was being substantially delayed . And in July, the FTC published the report of its investigation into competition in the prescription drug marketplace.

At my request, the Federal Trade Commission recently investigated and then issued a report on abuses of the Hatch-Waxman Act. What they found confirmed many of my fears about how some companies are gaming the system.

Here is what the FTC found:

- Since 1998, companies have increasingly begun to file multiple late patents, triggering successive 30-month stays of generic competition. This tactic has been used for 8 blockbuster drugs, and has delayed the availability of generic competition between 4 and 40 months *beyond* the initial 30-month period.
- Moreover, the patents used to achieve these delays were completely undeserving of protection. In all 4 cases in which there has been a court decision on one of these late-filed patents, the patent has been found invalid or not infringed. And the FTC questioned whether the patents in the other 4 cases should ever have been listed at all.
- In that same time period, there have been a significant number of agreements between brand and generic companies with the potential to delay competition. The FTC has taken action against at least 3 of these agreements.

These illegitimate delays in competition are costing consumers, the States, the Federal government, and insurers billions of dollars a year. The games being played by some members of the pharmaceutical industry to delay competition affect some of the top-selling drugs in America. Paxil, Neurontin, Buspar, Hytrin, Platinol, Taxol.

Every day that generic competition on these drugs is delayed costs consumers tens of millions of dollars. It has been estimated that a one-year delay in generic competition for Prilosec would cost State Medicaid programs $300 million. For a single drug. The Congressional Budget Office has estimated that elimination of these delays in competition would save consumers $60 billion over 10 years.

So, what can or should Congress do about this? Although I have been reluctant to reopen the Hatch-Waxman Act, I have come to believe that something must be done about such clear abuses.

In fact, the Senate has already passed, with a large bi-partisan majority, legislation to close the some of the biggest loopholes in the Hatch-Waxman Act. Unfortunately, the Republican-controlled House, responding to great pressure from PhRMA, has prevented a vote on this bill.

PhRMA has many objections to closing these loopholes, but the argument they voice most loudly is that the legislation will destroy their incentives for innovation. They say that limiting them to one 30-month stay per drug will so undermine their intellectual property rights and their profits that they will be unable to carry out research and development on new products.

I must say I find this hard to believe. The FTC looked at the patents on 8 blockbuster drugs on which companies managed to get multiple 30-month stays. Not one of these patents appeared to represent a significant innovation deserving of a 30-month stay.

PhRMA itself has not provided Congress with any examples of late-filed patents that actually covered the drug in question and represented any significant benefit to patients.

And there's a good reason for this. To be eligible for a 30-month stay under the Act, a new patent must cover the approved drug. However, there's also a rule of patent law that says that you can't get a patent on a product that has already been on the market for more than a year.

So what kind of patent can you get on a drug that has already been on the market for several years? Generally, these patents can be one of two things: First, they can be on the approved drug, and represent such a trivial change that FDA did not require a new approval for the change. FDA recently testified that there are very few changes that can be made without approval, and gave as examples changing the color of a label, or extending the expiration date of a drug. Neither of these meets my test for a significant innovation.

Second, late -issued patents can be on an unapproved version of the drug. But these patents are not eligible for a 30-month stay at all under the Act.

So, I don't believe that research and innovation will really suffer if we limit companies to one 30-month delay of generic competition. Recently one generic drug company official said that "some of the most outstanding research happening at certain brand-name drug companies is in the field of law." I think we would all agree that this is not the kind of research that should be rewarded. At best it's a misinterpretation of the law, and at worst it's a scam. Unlike other pharmaceutical research, it makes no one healthier and improves no products.

The kind of research we should reward is research that produces significant benefits for patients. And the bill passed by the Senate does not eliminate any of the incentives for this kind of innovation that we included in the 1984 Act, from restoration of patent life lost during the drug review process at the FDA, to 5-year guarantees of exclusive marketing for new drugs.

Congress has not yet succeeded in passing legislation to end the abuses of Hatch-Waxman. This is not to say that we won't ultimately succeed. I believe that we will. We will succeed because consumers, insurers, businesses, and State governments have become more sophisticated about why their drug costs are so high.

Even the President now agrees that something needs to be done about multiple 30-month stays. Last week, he announced that FDA would issue a proposed rule to limit manufacturers to one 30-month stay per drug.

I have some doubts about whether the rule will truly solve the problem and some bigger doubts about whether the rule will survive administrative hurdles and court challenges. But I am pleased that the Administration has recognized the problem and tried to move forward. Having recognized the problem, I hope that the Administration will now support legislation, a faster and

more certain remedy than regulation.

If this brief account of generic drug developments in the last year suggests that we are poised on the brink of legislative reform of Hatch-Waxman, there is one more development to consider. In the last election, the brand-name pharmaceutical industry spent tens of millions of dollars to support ads that favored Republican candidates. We all know what happened in that election. Will the pharmaceutical industry's generosity to Republican candidates have implications for Congressional action on generic drug issues in the 108th Congress? Let's just say I think it would be naive to underestimate the influence of the big pharmaceutical companies on the next Congress.

And if Congress does pass such legislation, will we have solved the problem of high prescription drug prices? Not entirely. We will have increased access to affordable generic versions of older drugs whose basic patents have expired.

But most new drugs are not subject to generic competition for several years. The prices of these drugs will remain high and out of reach for many of the uninsured, especially seniors on Medicare. To really address high prescription drug prices, we need to do more than amend Hatch-Waxman. We need to address the disparity between what Americans pay for drugs and what the citizens of other countries pay. And we need to pass a meaningful Medicare prescription drug benefit for seniors.