Remarks of Congressman Henry A. Waxman

Center for Business Intelligence

5th Annual Forum on Generic Drugs

November 17, 2005

Last year was the 20th anniversary of the law that is commonly referred to as Hatch-Waxman. It was an important step towards creating common sense limitations on the monopoly power of large pharmaceutical companies. Although there is certainly room for some improvements in the law, I'm proud to say that, over the past 20 years, it has enjoyed a great deal of success in promoting competition and lowering drug prices.

Despite the significant achievements of the Hatch-Waxman Act, however, there has also been a counter-reaction, a step backwards. We have seen efforts by the major pharmaceutical companies to find loopholes in the law and turn them toward their advantage. Their efforts have had the unfortunate consequence of significantly slowing our progress toward rapid access to low-cost generic drugs.

Authorized Generics

Let me first turn to one of the more recent tactics used by brand-name companies to delay generic competition: the practice of so-called "authorized generics."

Brand-name drug companies have increasingly been putting "authorized generics" onto the market just as the first generic competitor is set to begin its 180 days of exclusive marketing. As you know, the Hatch-Waxman Amendments created this incentive for generic companies who challenge patents on the brand name drug – in exchange for undertaking the costs and risks of patent litigation, the successful challenger is given 6 months of marketing without any other generic competition.

The practice of using authorized generics could substantially reduce the value of the 180-day exclusivity to the generic drug manufacturer who challenged the patent. The practice raises the serious possibility that generic drug manufacturers may stop challenging patents -- at least in the substantial numbers they have up until now.

The consequences of leaving inappropriate patents in place are far-reaching: it threatens to significantly delay generic competition, forcing consumers, businesses, and governments to unnecessarily pay monopoly drug prices for much longer periods. This has got to be a concern.

So I have recently asked the FTC to conduct a study of the economic impact of authorized generics and I was joined in this request by others in congress. We learned last week that the FTC has agreed to conduct this study.

As you may remember, in 2002, the FTC issued a similar report detailing the variety of tactics then being used by the pharmaceutical industry to delay generic competition. In part as a result of the FTC study, Congress passed legislation in 2003 closing loopholes in the Hatch-Waxman Amendments.

I do not believe it is a coincidence that, soon after these loopholes were closed, we witnessed the rise of the new tactic of authorized generics.

We have recently seen a growing recognition by members of Congress that if brand-name companies are going to use authorized generics to thwart generic competition, at the very least, they should be forced to account for the profits they receive. For example, the House Energy and Commerce Committee's budget reconciliation package included changes to the Medicaid drug reimbursement program that would require brand-name companies to include the price of "authorized

generic" versions of their own products in their reports of the best price calculations. The Senate's reconciliation bill includes a similar proposal.

As we did with many of the other tactics designed to thwart generic competition, I'm confident we will work to address the practice of authorized generics and the many others that will inevitably sprout up in its place. The pressure to bring down drug prices is growing in the United States. We cannot afford inaction.

International Trade Issues

We have also recently witnessed, on both a global and a national scale, a misuse of the most important tools created by the Hatch-Waxman Act. Patent extensions and market exclusivity have been used in ways that significantly delay or prevent access to more affordable generic drugs.

In recent years, the Bush Administration has negotiated several trade agreements with developing nations that contain provisions that hinder generic competition. The Administration's actions in negotiating these agreements reveal a terrible truth: Even in developing countries where access to low-cost generics is a matter of life and death, the Bush

Administration is willing block access to those medicines in the name of protecting the intellectual property interests of the brand name industry. For most of the citizens of these developing countries, generic drugs are the only drugs they can afford. Requiring them to buy brand-name drugs is tantamount to removing their access to any drugs at all.

Millions of people around the world are dying of diseases for which highly effective, life-saving drugs exist. The World Health Organization estimates that three (3) million people died of AIDS in 2004 and two (2) million died of tuberculosis. All told, infectious diseases kill over 14 million people each year. These diseases are primarily diseases of the developing world.

Yet, in blatant disregard of the spirit of the 2001 Doha Declaration, this Administration has repeatedly used trade agreements to restrict the ability of developing countries to acquire generic medicines that could prevent and treat these diseases.

For example, under CAFTA and many other agreements, developing nations, most of which currently depend on generic drugs, are now prohibited from approving a generic drug until five years after the brand name drug is first approved in that country.

CAFTA and other agreements also delay access to generic drugs in developing nations by requiring these countries to grant patent extensions to compensate for any delays in the approval processes. Furthermore, these trade agreements lack the important limitations on the duration of these types 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 perverse result of these trade agreements is that these developing nations, which have the greatest need for lower cost drugs, will now have to wait the longest to obtain them. It is haunting to imagine how many lives will be lost as a result of these policies.

As you well know, when we fought to enact Hatch-Waxman, there was almost no access in the U.S. to generic drugs. At that time, there was no legal way to approve generic versions of new drugs. The patent protection and exclusivity provisions of Hatch-Waxman were included 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 limited 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. Many developing countries have current access to generic drugs. Imposing a Hatch-Waxman-like scheme in these countries benefits only the brand-name drug industry by undermining generic competition. It provides no corresponding benefit to the citizens of these countries.

The Administration's track record in negotiating trade agreements with developing nations exposes its true priorities: when faced with a choice, this Administration will protect the profits of brand-name pharmaceutical companies. They will not hesitate to deny access to critical life-saving medicines for thousands of people in developing nations.

"Bioshield II"

Here at home, we have also seen attempts to use the concepts in Hatch-Waxman in ways that could appreciably limit generic competition.

As you all know, in July 2004, Congress passed Bioshield I, which was intended to provide incentives for private companies to develop countermeasures to biological, chemical, and nuclear agents that Americans might face in a terrorist attack. The legislation also provided billions of federal dollars for private research and development, as well as expediting grants and purchasing rules to assure that these countermeasures would be available as rapidly as possible.

The Senate HELP Committee recently approved the Biodefense and Pandemic Vaccine and Drug Development Act of 2005—which incorporates some of the concepts from the so-called "Bioshield II" legislation introduced earlier this year. This legislation uses the concept of exclusivity as a means of incentivizing the innovation of drugs to counter bioterrorist attacks. Unfortunately, it creates these incentives in ways that could dramatically increase the price of many prescription drugs and limit access to generic drugs.

This proposal would grant 10 years of "orphan drug" market exclusivity to new "countermeasures." However, this lengthy increase in monopoly status would not apply to just a handful of products we would usually think of as "countermeasures" for bioterrorism. Regrettably, the Biodefense Act also greatly expands the definition of "countermeasure." The newly defined "countermeasure" would

encompass (1) drugs that are already on the market that are simply indicated for new uses or provided in new dosage forms; and (2) drugs that are only tangentially useful in a bioterrorist attack.

An earlier version of this legislation also included a so-called "wild-card" patent extension. Under this provision, a company that developed a countermeasure would have been entitled to a patent extension of up to 2 years on any drug or other product the company markets, regardless of whether that product is related to bioterrorism.

In other words, if Pfizer developed and obtained approval of a countermeasure, it could obtain a two-year patent extension on Lipitor. With U.S. sales of $7.7 billion last year, a two-year patent extension on Lipitor would be worth over $10 billion to Pfizer.

We witnessed a strong public reaction against the wild-card concept and, as a result, this provision was ultimately dropped from the most recent version of the Biodefense Act. There simply is no reasonable argument that a drug company needs a windfall of this magnitude to develop a countermeasure.

I also believe that the overly broad definition of "countermeasure" that was included in the recently approved bill would similarly provide unwarranted rewards to drug companies.

Medicaid Rebates

In the recent Senate reconciliation bill, we saw another policy emerge that could drastically decrease the availability of generic drugs. In an effort to create savings in the Medicaid program, the Senate included a provision that would increase the rebates on generic drugs from the current federal Medicaid standard of 11% to 17% -- making the amount of these rebates equivalent to those required on brand-name drugs.

The problem with this provision is that it fails to recognize that price competition is more active among generic drugs and that the profit margin for generic drugs is slim. As a result, there is a fear that, in order to compensate for the cost of higher rebates, generic manufacturers may be forced to raise the price of generic drugs for all consumers, resulting in increased costs to the entire healthcare system. There is even a fear that increasing rebates could force generic manufacturers to discontinue products or drop out of the Medicaid program entirely.

CBO estimates that a mere 1% increase in generic utilization in the Medicaid program will result in an estimated $380 million in savings. We will see cost savings in Medicaid by increasing access to and utilization of low-cost generic medicines—not by increasing the rebates generic manufacturers must pay.

Generic Biologics

Finally, let me turn to an area in which the concepts embodied in Hatch-Waxman have yet to be applied. A category of drug products that barely existed in 1984, and that we completely ignored in drafting the legislation, has slowly emerged as a major source of new medicines. Unfortunately, these products have also emerged as a major force causing drug prices to rise. I'm talking, of course, about biological drug products.

These products are among the most expensive and important medications for U.S. consumers. Patients who need these drugs often have to pay tens of thousands of dollars a year for them.

Over the next few years, patents are set to expire on a number of costly biologics.

Yet, as you well know, these products will not face generic drug competition because FDA currently has no mechanism for evaluating and approving copies of biological products. As in 1984, companies seeking approval of copies of marketed biologics must repeat all of the safety and effectiveness studies conducted by the innovator. Our regulatory system, as it stands now, effectively grants a permanent monopoly for these medicines.

It is time for us to change this situation. We need to create a system for testing and approving generic biological products

As you know, creating a generic biologic approval system will be a complicated and delicate task. But it is work we have done before. In creating this system, we will need to balance the competing need for sufficient incentives for innovation with the need for competition once the patents have expired. Obviously, these are the same concerns we faced 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, we must ensure 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.

For evidence that this type of system is workable, we need only look to the European Union. The European Agency for the Evaluation of Medicinal Products has already created a regulatory mechanism for approving generic biologics on a case-by-case basis and is currently working to refine that system. The EMEA has proposed that "comparability studies" are needed to prove the similar nature of what it calls the "new similar biological medicinal product" and the original product. The EMEA has begun the process of issuing product-class specific guidelines setting forth the requirements to demonstrate the

safety and efficacy of the generic biologic product. Although the EMEA has yet to approval a generic biologic under this system, some companies have already submitted applications.

I believe we, too, 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.

It will take a bipartisan effort to pass meaningful reform in this area. We had a bipartisan effort with the Hatch-Waxman Amendments in 1984, as the name alone tells you. I think it's possible that we will be able to craft a new bipartisan approach to encouraging generic biologics as well.

I know that there are people in some of the large brand name biotech companies who want to simply block any kind of reform. They argue that if Congress does anything to limit the duration of their monopoly status, it will spell the doom of all research into new biologics. The strategy of opposing any change may have worked for the big drug companies in the past. But it can't succeed much longer.

With the rapid spread of biologics and the meteoric rise in the price of biologics, I believe that it simply will not be possible for Congress to stand by and do nothing.

The important thing will be to make sure that the reforms that will inevitably come are thoughtful, careful, and strike the right balance between encouraging innovation and encouraging competition. And I'm hopeful that I'll be able to join together with thoughtful colleagues on the other side of the aisle to find that balance.