Remarks of Congressman Henry A. Waxman
Generic Pharmaceutical Association
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As you all know, last year was the 20th anniversary of Hatch-Waxman, the law that streamlined access to generic drugs in this country. As a result of that anniversary, I was asked on several occasions to look back on what Hatch-Waxman has accomplished and where it has fallen short.

Of course, I have always felt pride in Hatch-Waxman's success in promoting competition and lowering drug prices. By almost any measure, Hatch-Waxman has had a tremendous impact on the prescription drug market, greatly benefiting consumers and healthcare providers. Before 1984, there were relatively few generic drugs on the market, and very little true competition in the prescription drug marketplace.

Since the year the law was passed, generics' share of the market has grown steadily. In many cases, generic competition has lowered drug prices by over 2/3.

In my reflections, however, I have also had to acknowledge that Hatch-Waxman fell short of a perfect solution to the problem of high drug prices. You just have to look at the high-profile battles over reimportation of drugs and the Medicare prescription drug benefit to see that the high cost of prescription drugs remains a central problem in American health care.

Drug prices have remained higher than they should in part because of efforts by the brand-name industry to exploit loopholes in Hatch-Waxman for the purpose of delaying generic competition. And, in part, drug prices have remained high because Hatch-Waxman was not designed to address many inequities in our system. As you all know, we unfortunately have a system where the poorest and most vulnerable members of our society pay the highest prices for drugs.

I'm sure that many of you have had to sit through one or more of my ruminations in the last year on the successes and failures of Hatch-Waxman. Today, however, I want to look forward rather than backward. In particular, I want to look at some looming proposals that may affect the public's access to generic drugs.

The most important proposals deal with two topics of special interest to the generic drug industry. The first of these topics involves the future of biogeneric drugs. The second involves a proposal called "Bioshield II," which would provide incentives for the development of drugs to counter bioterrorism. These proposals both build on the concepts originated in Hatch-Waxman, although they do so in nearly opposite ways.

Proposals to encourage generic competition for biological medicines obviously build on the generic drug approval scheme for synthetic drugs created in Hatch-Waxman. Perhaps less obviously, the Bioshield II proposals builds on the "other half" of Hatch-Waxman: the incentives for innovation, including market exclusivity and patent term restoration.

It will come as no surprise to you that I am quite a bit more enthusiastic about one of these "sons of Hatch-Waxman" than the other.

Defining the regulatory requirements for approving biogenerics would be an important step forward.

I believe that improving competition in the biotech marketplace will be critical to improving access to life-saving drugs and lowering healthcare costs in the coming years. And I believe that there is already a solid scientific foundation for moving forward with a biogenerics approval system that will benefit American consumers.

In contrast, I believe that the bills referred to as "Bioshield II" will harm consumers and the public health, without any real benefits in the fight against bioterrorism. These proposals are a misguided give-away to the big pharmaceutical companies. They provide the name-brand pharmaceutical companies with monopoly rights worth billions of dollars – money that will come from the public in the form of higher prices – but no one has established that the incentives are needed or will actually accomplish the goal of producing drugs useful in the fight against bioterrorism.

Let's start with a potential positive step forward: biogenerics.

As you well know, there is no recognized standards for obtaining approval of generic versions of biological products. The emergence of biological drug products was not something we anticipated in 1984 when we drafted the Hatch-Waxman Amendments.

However, as biological drug products become more widely available to patients, and at the

same time are among the most expensive drugs for many patients to use, and as patents on many of these products have begun to expire, we are facing many of the same dilemmas with these drugs that we faced 20 years ago.

In order to address this situation, we will need to balance competing concerns that we faced 20 years ago. On the one hand, the biotech industry needs incentives for innovation. But, on the other, once patents have expired, consumers should have access to affordable medicines; competition is needed to bring down drug prices.

Current law does not strike the right balance. We cannot continue to have a system that effectively enshrines permanent monopoly status for some of our most important medicines. Of course, some intellectual property protections are needed to encourage innovation by brand-name manufacturers. But permanent monopolies are neither needed nor wise.

I believe that the time has come to design a system for testing and approving biogenerics. Certainly there are contentious scientific issues surrounding such a system. And we must be mindful of getting the science right. We must get the science right because if the science behind approving biogenerics is not sound, the brand name industry will make it their mission to destroy the credibility of those products in the eyes of physicians and patients.

Fortunately, the science of establishing the safety and effectiveness of biogenerics is evolving faster than many in the biotech industry would have us believe. Although recent news stories have suggested that I believe that a scientific foundation for biogenerics is lacking, in fact I believe that an adequate foundation has already been laid.

Two important facts give me hope. First, the FDA may soon set out the studies it will require for approval of generic versions of insulin and human growth hormone, two of the simplest biotech drugs. Since these products are regulated as drugs rather than biologics, approval of biogenerics would be on sound legal footing.

If the FDA issues guidance on approval of these drugs, it will demonstrate for the first time that there is sufficient scientific knowledge to establish safety, effectiveness and equivalence of at least some biogenerics.

It will also provide the first test of the FDA's ability to create a defensible case-by-case approval process for biogenerics.

Because, ultimately, that seems to be where we are headed. If we wait for a universal test that works for all biogenerics, like the bioequivalence test for traditional drugs, it could be decades before a patient sees the first generic. That makes no sense since these products range in complexity and in the type of studies that will be necessary to demonstrate the safety, effectiveness and equivalence of their generic counterparts.

The second fact that heartens me is that experience suggests that we can go without a universal test. Within a few years of passage of the Hatch-Waxman Amendments, the FDA was faced with applications for topical and inhaled generic drugs for which traditional bioequivalence studies were not useful.

The FDA was forced to establish and defend new methods for establishing the comparable bioavailability of topical and inhaled drugs in order to approve generic applications for these drugs.

This case-by-case approach to establishing equivalence, while not without controversy, was successful. This suggests to me that we will be able to create 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.

Perhaps the trickiest part of developing a biogenerics scheme will be in reaching agreement on an incentive to the biotech industry to support continued innovation that doesn't break the bank.

Which brings me to Bioshield II. These bills use the concepts of exclusivity and patent restoration to encourage innovation of drugs to counter bioterrorist attacks in ways that would dramatically limit access to generic drugs and raise the price of prescription drugs.

As you all know, just last July, Congress passed a bill commonly referred to as Bioshield. Bioshield 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 bill 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.

When he signed the bill, President Bush declared that it represented a bi-partisan consensus about the best way to prepare for a bioterrorist attack. He said that it represented "the collective foresight and considered judgment of United States senators and members of the House of Representatives from both political parties." He went on to add that the bill represented "18 months of hard work and cooperation by many dedicated public servants in Congress and in the White House."

Just 3 months later, however, before the bill has been given any chance to work, the supporters of the largest drug companies are already claiming that the incentives in Bioshield were insufficient.

They contend that the pharmaceutical industry needs billions of dollars of additional monopoly profits or it won't develop medicines that would counter terrorism.

I am not here to talk about liability protection, which raises very complex issues. Done the right way, with adequate compensation for consumers, it's possible that some kinds of liability protection could be appropriate in the unusual circumstances raised by developing countermeasures to bio-terrorism. In their present form, however, the liability protection provisions of the Bioshield II bills raise concerns.

There are other provisions of the Bioshield II bills that raise even more significant concerns. Indeed, these provisions should disturb all Americans who are worried about run-away health care costs, because they would create significant increases in market exclusivity and patent term restoration for countermeasures.

As I said, I believe these are indefensible give-aways to the pharmaceutical industry. Is it coincidence that the exclusivity provisions that appear in the Lieberman-Hatch bill are from PhRMA's long-standing wish list for standard drugs? I doubt it. The bill increases to 10 years the length of marketing exclusivity for new countermeasures.

This is exactly the increase for which PhRMA has been lobbying for <u>all</u> new drugs for years.

But this increase is only for countermeasures, you say? How many drugs could really be covered, after all? Just a handful of drugs, right? In another coincidence, the bills change the definition of the term "countermeasure" that was in Bioshield I. Under the new definition, the

term will suddenly encompass a wide range of new uses and dosage forms of drugs that are already on the market. And it would cover many new other drugs that would have even a tangential application in a bioterrorist attack.

The magnitude of this give-away is not widely understood. Instead of involving just a handful of drugs, the Bioshield II bill would give 10 full years of marketing exclusivity, an increase of 5 or even 7 years over the current length, to a very large number of medicines.

Perhaps the most egregious give-away of the Bioshield II bills, though, is the so-called "wild-card" patent extension. Under this provision, a company that develops a countermeasure would be entitled to a patent extension of up to 2 years on any drug or other product the company markets.

In other words, if Pfizer developed and obtained approval of a countermeasure, it could obtain a two-year patent extension on Lipitor [Lĭp'-ĭ-tōr], the world's best selling drug. 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. A two-year patent extension on Zocor [Zō'-kor], which had U.S. sales of $4.6 billion last year, would be worth about $6½ billion to Merck.

No doubt the major brand-name drug companies would like to make billions of dollars in additional profits. But there is no reasonable argument that a drug company needs returns of this magnitude to develop a countermeasure. More importantly, Pfizer's and Merck's gain will be consumers' loss. And the loss is particularly severe for lower income consumers. The unfortunate truth about exclusivity and patent extensions is that these rewards to drug companies are paid for disproportionately by uninsured Americans.

I take no comfort in the fact that the concept of encouraging pharmaceutical innovation through periods of exclusive marketing originated in the Orphan Drug Act and in Hatch-Waxman.

Though exclusivity has been very successful in producing new medical products, it has become clear that it is not the fairest way for society to subsidize innovation.

First, the size of the reward often bears little relationship to the importance of the innovation. A five-year exclusivity period may reward a company that develops the 10th hypertension drug in its class far more highly than the company that develops a cure for multiple sclerosis. This is because the value of 5 years of exclusive marketing is determined not by the

amount of suffering that will be ended, but by market share.

The idea of wild-card exclusivity takes this disconnect between innovation and reward to an absurd level. Pfizer could get a multi-billion dollar extension on Lipitor even if its contribution to our biodefense was a third-line treatment for a minor side-effect of the anthrax vaccine.

The second way in which exclusivity is unfair, as I explained a moment ago, is that extending exclusive marketing periods has the effect of placing the biggest share of the cost of drug development on those least able to pay for it.

Exclusivity rewards drug companies by allowing them to charge higher prices. Unfortunately, as our health care system works today, the pharmaceutical industry charges the highest prices to those without insurance, while those with bargaining power pay much less. It's hard to argue that drug innovation, which benefits all of us, should be largely subsidized by a segment of society that has to choose between buying medicines and paying the rent.

I mentioned earlier that one of the Bioshield II bills happens to increase the length of exclusivity by exactly the amount of time for which the brand-name industry has been lobbying for all drugs. In seeking this increase, the brand-name drug companies always cite the fact that, in Europe, drugs are given 10 years of exclusivity, or twice what they get in the U.S. What PhRMA never points out is that in Europe there are both price controls and universal drug coverage. Ten years of exclusivity may be a reasonable incentive in Europe, where initial prices will not be sky-high, and where all citizens equally share the burden of higher prices. If and when we have such a health care system here, exclusivity will be a far more equitable form of reimbursement for drug development costs.

In the American system, however, we should all scrutinize proposals that rely on exclusivity to reward innovation very closely. And we should oppose such proposals unless there is the strongest evidence that (1) additional incentives are needed, (2) more equitable incentives like tax credits will not work, and (3) the size of the incentive will approximate the benefit to society. I see evidence of none of these in the Bioshield II proposals.

In sum, the proposals to encourage biogenerics and the Bioshield II proposals reflect the two different strands of the compromise that lay behind Hatch-Waxman. Hatch-Waxman was an effort to balance the need to encourage competition from generic drugs, so that more Americans

could afford the medicines they need, and the need to encourage innovation for new drugs.

The proposals to encourage biogenerics are necessary, because right now there is no balance in biologics. The name-drug companies have essentially unfettered monopoly power now, and we need to introduce a balance. As I look toward the future of generic drugs in this country, I am hopeful we will not have to wait too much longer for a system for approving biogenerics with appropriate, but not unfair, incentives for innovation.

I supported the Bioshield I legislation last year, because it helped create the proper balance with respect to medicines that would counter biological terrorism. The bill that we passed would provide drug companies with a fair mix of incentives to encourage them to develop these important medicines.

The new Bioshield II proposals would throw that balance out of whack. They would give incentives out of all measure to the value they would produce for American citizens. They would block generic competition not only for medicines that would address biological terrorism, but also for a wide variety of unrelated drugs. These proposals undermine the entire premise of balance that lay behind Hatch-Waxman, and I will work hard to see that they do not become law.