Remarks of Congressman Henry A. Waxman for the
Generic Pharmaceutical Association's Annual Meeting 2006
Challenges and Opportunities for Generic Drugs in an Ever-Changing Healthcare System
February 17, 2006

We are living in a tumultuous time. People are wondering whether government can do anything right—especially when it comes to our nation's healthcare system. A host of forces has coalesced to push our healthcare system to its limits. We live in a country in which Americans pay more for their healthcare than any other country. Consumers in the U.S. often pay more than two (2) times what the rest of the world pays for their medicines. And yet the number of uninsured is at an unprecedented high—one in seven Americans lack health insurance. During the tenure of the Bush Administration, this number has increased dramatically. More and more employers are struggling with the high cost of insurance premiums and have opted to shift the costs of coverage to their employees. For the companies that have maintained coverage, paying the cost of insurance often places them at a significant economic disadvantage both at home, and internationally.

Americans know that a healthcare system like this must change. We have got to find a way to provide insurance coverage for the more than 46 million uninsured. One viable approach is to broaden the Medicare program to make it available for all—I am joined by my colleagues Representative Dingell and Senator Kennedy in my support of this idea.

I believe Americans are also increasingly recognizing the significant role the Bush Administration has played in getting us to this dire point. For this, and many other reasons, I predict that this year, Americans will ask the Democrats to take back control of the Congress. Americans know that greater Democratic strength will give us a real opportunity to push forward on one of the most important issues facing America—the unreasonably high cost of health care.

As you know, the skyrocketing cost of prescription drugs is one of the major drivers of the high price of healthcare. I have always viewed broad access to generic drugs as one of the most important ways to lower the cost of medicines—and if the Democrats take control of Congress this year, it will certainly make it easier to improve access to these drugs.

But regardless of whether my predictions about the elections turn out to be accurate, we know that we have several challenges ahead of us in our efforts to make affordable medicines widely accessible.

Politicization of FDA/OGD Failures

One of the most significant challenges may be at the FDA itself. During the last five years, the FDA has had a permanent commissioner for only 18 months. In September of last year, only 10 weeks after becoming FDA Commissioner, Dr. Crawford abruptly abandoned his position for reasons that to this day remain unclear. President Bush then made the decision to appoint the director of the National Cancer Institute, Dr. Andrew von Eshenbach, to be the Acting Commissioner of FDA—but, inconceivably, did not ask Dr. von Eshenbach to give up his

responsibilities at the NCI. After much public criticism, Dr. von Eschenbach announced that he would cut back on his day-to-day duties at the NCI—in all other respects, however, he would remain its leader. But this modified arrangement did not adequately address the inherent conflicts of interest that result from Dr. von Eschenbach's dual role at these agencies—both of which have critical and independent roles in the drug safety system. The FDA and the NCI each play far too important a role in protecting our nation's public health to permit one person to simultaneously head both agencies. And yet, the Bush Administration appears to be comfortable permitting this untenable arrangement to linger—even now, over six months later, we have yet to see any movement on the appointment of a permanent FDA Commissioner.

This absence of leadership comes at a time when FDA faces significant emerging challenges, such as new threats of terrorist attacks on our food supply, regulation of new drugs and devices that use advanced biotechnology and nanotechnology, and cutting edge techniques of cloning and gene therapy. FDA cannot address these challenges without a permanent commissioner who will make difficult decisions based on the best scientific evidence.

Plan B

Indeed, we have seen recent evidence that, far from basing its decisions on the best scientific evidence, the FDA has instead allowed politics to guide its actions. I'm referring, of course, to the Plan B decision. Recently, both an FDA advisory committee and FDA scientific staff agreed that Plan B would be safe and effective for all ages if sold over-the-counter. Yet, despite this overwhelming consensus, FDA rejected an application to switch the drug to over-the counter, citing concerns—but no scientific evidence—that over-the-counter sales could promote greater sexual activity among girls under the age of seventeen.

Along with several of my fellow members of Congress, I asked the Government Accountability Office (GAO) to investigate this decision. The GAO report revealed that the decision to reject the application was preordained from the outset, long before FDA completed its scientific review. GAO also found that the decision was made with the highly unusual involvement by the highest echelons of the Agency. In this instance, politics clearly trumped science and impeded women's access to this important drug.

OGD

The Bush Administration has repeatedly shown more concern about protecting the profits of the brand-name pharmaceutical industry than with keeping drug costs manageable. We see more unfortunate evidence of this pattern in the Administration's failure to devote adequate resources to the ailing generic drug review program at FDA. Figures from FDA show that, over the past five (5) years, there has been a drastic increase in the number of generic drug applications received by FDA's Office of Generic Drugs (OGD)—yet the Administration has not provided or fought for a corresponding increase in the number of staff to handle this influx of applications. We hear from FDA staff that OGD's resource needs are particularly dire because no other office within the Center for Drug Evaluation and Research (CDER) has seen the same rapid growth in workload as OGD.

There are other indications that the Administration is not placing generic drugs high on its list of priorities. The Administration declined to take any action to stop the so-called 'authorized generics" from undercutting the 180-day exclusivity period. And last fall, FDA splintered the office of Office of Generic Drugs into different buildings for the second time. We've learned from FDA employees that this separation has resulted in increased inefficiency—staff now have to devote time traveling between buildings to maintain "critical" face-to-face contact with their colleagues. This move has clearly created more difficulties in what was already a strained generic drug review process.

Generic drugs have played a critical role in reducing drug prices in the United States. Over the years, the generics' share of the market has grown steadily, lowering drug prices by up to 2/3 for those drugs with generic competition. Given these successes, it is particularly disheartening to see that the Administration has contributed to delays in access to generic drugs by failing to ensure that FDA's Office of Generic Drugs (OGD) is functioning at its highest level of productivity.

We all know that the brand-name drug companies have spent significant amounts of time and money on strategies to delay access to generic drugs—including frivolous patent filings, endless litigation, and collusive settlement agreements. We must ensure that the FDA itself does not become yet another roadblock in Americans' access to generic drugs.

Authorized Generics

Let me turn to some of these efforts by the pharmaceutical industry to hinder or slow the emergence of generic drugs. One of the more recent tactics is something I alluded to a moment ago, the strategic launching 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 launching 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 consequence of leaving inappropriate patents in place is 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 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. The FTC agreed and is currently in the process of conducting this study. Unfortunately, we've recently learned that FTC will require a lengthy

time to complete the study and we may not expect to see the results for at least a year from now. I am hoping to work with FTC to achieve an earlier release date.

As you may remember, in 2002, the FTC issued a landmark 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 authorized generics.

We have recently seen a growing recognition by members of Congress that, if brand-name companies are going to use authorized generics, at the very least, they should be forced to account for this practice. The budget reconciliation bill, recently signed into law, contains 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.

If the FTC concludes that authorized generics thwart generic competition, I'm confident we will work to appropriately address the practice and any others that sprout up in its place. The pressure to bring down drug prices is growing everyday in the United States. We cannot afford inaction.

Bioshield

We have also seen efforts by the pharmaceutical industry to push for legislation using the concepts in Hatch-Waxman in ways that could appreciably limit generic competition.

As you all know, in July 2004, Congress passed Bioshield I. This law 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. And it expedited 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. This bill incorporates some of the concepts from the so-called "Bioshield II" legislation introduced earlier last year. The Biodefense Act uses exclusivity to promote innovation of drugs to counter bioterrorist attacks. Unfortunately, the exclusivity granted under the bill 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," instead of the current 7 years. However, this lengthy increase in monopoly status would not apply to just a handful of products we 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.

But, unfortunately, 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 push by the pharmaceutical industry for a policy that threatened to drastically decrease the availability of generic drugs. In an effort to create savings in the Medicaid program, the Senate Finance Committee included a measure that would have increased the rebates that the brand-name drug companies were required to provide. Mysteriously, before the bill went to the Senate floor, this provision had been changed. Instead, the new provision would have increased the rebates on both generic drugs and brand-name drugs—bringing the amount of the generic drug rebates up to the same level as that of brand-name drugs. As you know, the problem with requiring large rebates from generics 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 was legitimate concern 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—and increasing rebates could also force generic manufacturers to discontinue products or drop out of the Medicaid program entirely.

Ultimately, in the recently enacted reconciliation bill, the rebate provisions were dropped entirely—for both brand-name and generic drugs. That was a poor policy outcome, eliminating a sensible increase in brand-name drug rebates that would have benefited the American tax payers.

But it's no secret that the brand-name industry fought tirelessly against this provision in the bill. Their strategy to add a provision requiring generics to pay a rebate equal to that of the brand-name in order to drive both provisions out of the bill, unfortunately, worked. In this instance, although generic drug companies escaped unscathed, we witnessed the vulnerability of the generic industry to the power of the brand-name lobbying forces.

Importation

If successful, the types of proposals we saw in the biodefense and reconciliation bills would result in increases in what are already exorbitant prices in the United States. Americans are currently paying more for drugs than almost anyone else in the world. They're fed up and want to see prices lowered. This frustration has led to the push to import lower-cost medicines from foreign countries.

In other industrialized countries, consumers are protected from drug price discrimination because the government uses its bargaining power to affect prices. For example, in Canada, prices of new brand-name drugs can't exceed the average price of those drugs in seven other industrialized nations.

And yet, in this country, not only do we not use the bargaining power of the government, we have actually forbidden the Secretary of Health and Human Services from using it to lower drug prices for Medicare beneficiaries.

So it is not at all surprising that people are looking for other avenues to get drugs at affordable prices.

While it is my belief that importation of drugs from abroad has never been an ideal solution to the problem of price discrimination, on either safety or economic grounds, I certainly understand the drive to import foreign drugs. No American should be forced to choose between paying for medicine and paying the rent.

Rather than looking to foreign nations, we need to take steps *in this country* to assure that drug manufacturers charge no more for prescription drugs here than the average foreign price for those same drugs. We need a much more meaningful Medicare prescription drug benefit for seniors, and we need to address the shameful fact that in the richest country in the world 46 million people have no health insurance at all.

Generic Biologics

We also need to make sure that the Hatch-Waxman Act is applied to all types of drug products so that Americans have access to the cost-savings it provides. There is a class of medicines that, under current law, will never face generic competition. I'm talking, of course, about biological drug products.

I realize that I have been talking to you about the need for generic biologics for years. But, now, more than ever, I recognize the need to move forward and I am currently putting a high priority on this effort.

With the rapid spread of biologics and the meteoric rise in the price of these products, I believe that it is simply no longer possible for Congress to stand by and do nothing. Biologics have emerged as a major force causing drug prices to rise. These products are 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.

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

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.

Indeed, FDA has already begun the process of creating this kind of a case-by-case approach to generic biologics. In 2002, FDA officials drafted guidance documents for two of the simplest types of biologics —human growth hormone (HGH) and insulin. To date, however, FDA has refused to release these guidance documents, without ever having given a scientific reason for its failure to do so. So Senator Hatch and I have recently asked FDA to issue these documents. We are hopeful that they will be released in the near future.

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 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.

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 am hopeful that we will be able to craft a new bipartisan approach to encouraging generic biologics as well.

None of this will be easy. We will not give all Americans access to affordable drugs in a single step. But I am convinced that we must do more than we have done.

We cannot continue to have a system in which monopoly profits are extended through legal shenanigans. We cannot continue to have a system that enshrines permanent monopoly status for some of the most important medicines. And we cannot continue to have a system in which the United States surpasses the rest of the world in the price we pay for our healthcare and our drugs.

Step by step, we can and will do better. And I hope that you will all walk this path with me.