Remarks of Congressman Henry A. Waxman for the
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I'm pleased to join you here today at your Eighth Annual Health Care Policy Conference.

It is obvious why the investment community is interested in health care issues. Health care expenditures represent 17 percent of the GNP, an amount that continues to grow. As long as I've been involved in health care issues, we've heard that this growth can't continue. Yet it does.

Similarly, health care represents a major part of the Federal budget—at last count, Medicare and Medicaid alone account for 22% of Federal spending. When we talk about deficits and budget balancing and spending and revenues, health care programs are in the middle of the debate.

When we pass bills to repeal the estate tax, that affect only the richest in America, and when we lose over $600 billion dollars in potential revenues as a result, then all of us better understand that this is having a major negative affect on our ability to meet the health care needs in this country.

You can't lament the number of uninsured and our inability to finance programs to address that problem if you want to repeal the estate tax. You can't really be worried about the financial health of Medicare when you are willing to throw away potential revenues of that magnitude.

That's my view, and I make no secret of it.

What we did on the House floor last week was probably in its own way about the most significant action we've taken in this Congress on health care. We decided to spend our resources elsewhere.

And to me, that is really a tragedy.

Because there's something else about health care: there are few things that matter more to people.

Health is central to the quality and productivity of people's lives. And when they are sick, they need and want and—yes—expect high quality care.

That makes the tragedy of nearly 47 million people without health insurance coverage in this country truly indefensible.

Unfortunately, there is every indication that this situation will get worse.

In my view, the policies that have been pursued by this Administration and the Republican controlled Congress have taken us in precisely the wrong direction.

Instead of policies that strengthen public programs that we know reach the hard to cover, we see, particularly in the case of Medicaid, proposals that reduce the Federal commitment and take away the protections in the program that have helped it effectively serve the most vulnerable and needy among us.

And we see continuing interest in capping Federal Medicare expenditures. Most of the American public doesn't realize that we now have *in the law* special provisions designed to force cuts in Medicare if general revenue expenditures exceed 45% of program costs. Now that we have a drug benefit, that is sure to happen.

We see the same philosophy in the Gregg budget reform proposals currently being considered in the Senate. Make no mistake, that proposal is designed to do one very basic thing: cut entitlement programs. In this day and age, that means slash the expenditures on Medicare and Medicaid.

We also see that instead of policies that expand and strengthen employer-based coverage, we have more tax incentives for HSAs, which will undermine it. And of course those tax incentives are another area where we lose vitally needed revenues. Is it a coincidence that we lose $60 billion in tax incentives over the next 10 years to encourage more HSAs, and then we have proposals to cut Medicare by a similar amount?

Instead of strengthening the concept of a broad-based pool of people that is the bedrock principle of insurance, we pursue policies that will fracture the insurance pool and take the healthy out into their own cheaper plans, making it harder and harder to have adequate, affordable coverage for people with real health problems.

There are two very obvious trends in where health care policy has been going over the last five or more years.

First, we rely more on coverage through commercial plans.

We see that in the design of the Medicare prescription drug plan. We see it in the push to get people into Medicare Advantage plans, where we provide lucrative financial advantages to the plans. We even see it in various State Medicaid programs where they are moving to give people vouchers to select among private plan alternatives.

Our fascination with the so-called advantages of the private commercial market seems to exist even in the face of evidence that private plans are not particularly effective in controlling prices. We know that when we go this route we are paying for their profits and for their marketing costs. We know they frequently have a history, particularly in the individual and small group market, of skimming to cover the healthier and the cheaper.

To me it is instructive that over the 5-year period ending in 2004, administration and net cost of private health insurance increased from 7.5% to nearly 11% of private personal health expenditures. In fact, during that period, expenditures for administration and net cost of private health insurance increased faster than any other component of health care expenditures—over 15% a year. That's not the growth of what we spend on benefits. That's what we pay for insurance that doesn't go to benefits!

Surely this is a trend that cannot—and should not—continue.

The second major trend I have seen is that in the name of providing health care coverage—certainly a worthy goal—we seem very willing to follow strategies which in fact lead people to have very inadequate coverage. We seem to think we will be solving the problem of the uninsured by causing many millions of people to be underinsured.

That is surely a likely result of the Shaddeg bill which undermines effective State regulation of insurance. It is definitely part of the underlying principle of HSAs, with large deductibles that are liable to leave people of moderate means without the coverage they need. And even the current trend in Medicaid, of reducing coverage of one set of very poor people to provide limited coverage to slightly less poor people is all part of that trend.

All this becomes particularly relevant when you start to evaluate the prospects for the financial health of hospitals, or physicians, or device manufacturers and drug companies.

Unless current trends are reversed, we can look for more reliance on private plans, but less effective regulation and less comprehensive benefits. We can expect less encouragement for business to provide comprehensive health care coverage and more efforts to shift the cost to the individual.

And most importantly, we will have a reduced revenue base at the Federal level to address the problems in the health care system, whether in the form of adequate payment to

physicians, better payments for new technologies, filling in the coverage gaps in the Medicare drug plan, improving emergency care capacity and support, or providing coverage for the uninsured.

So that's the way I see the over-all picture in health care.

Now let me talk about an area where I know you've got a particular interest—FDA.

In 2007, some critical FDA legislation is up for reauthorization—wherever people stand on these issues, Congress will have to act next year or these programs will come to an end.

PDUFA

First, the Prescription Drug User Fee Act–or "PDUFA" [Pronounced "Puh-Doo-Fah"]—will expire in September 2007. First enacted in 1992, PDUFA authorized FDA to collect fees from the companies seeking FDA approval of their drugs or biologics. The fees provided a substantial increase in the resources available for the Agency's review of these products, and have enabled FDA to conduct faster reviews, bringing drugs and biologics more quickly to the market.

However, I'm concerned that this increased speed has shortchanged drug safety—that a shorter review period may have caused FDA to miss important safety problems before marketing. And that there has been no attempt to compensate for shorter reviews with more rigorous post-market safety oversight.

FDA's post-market drug surveillance system has got to be strengthened.

It is inevitable that some safety hazards will not be discovered until a drug is used in the general population. To protect consumers from unsafe drugs, FDA must place equal emphasis on post-market surveillance and pre-market reviews. FDA must be given the resources and the authority to detect and respond to post-approval safety problems quickly and efficiently.

But the fact is, today, FDA's record on enforcement is deplorable.

This week, I released a report detailing the precipitous drop in FDA enforcement actions during the Bush Administration. In the last five years, the number of warning letters issued by the agency has fallen by over 50%--a 15-year low. During the same period, the number of seizures of mislabeled, defective, and dangerous products has declined by 44%.

This decline in enforcement actions is not a result of increased compliance by manufacturers—the number of violations observed by FDA's field inspectors has remained constant.

Americans deserve better than this. The reauthorization of PDUFA gives us a chance to address it.

MDUFMA

A similar user fee program for medical devices also requires congressional action next year— the Medical Device User Fee and Modernization Act of 2002 or "MDUFMA" [pronounced "Muh-Doof-Muh"]. That program was originally enacted to provide FDA with the resources necessary to better—and more quickly—review medical devices. The legislation specified both the amounts that Congress was expected to appropriate, as well as the revenues that the user fees were expected to generate.

Unfortunately, the Republican-controlled Congress has failed to uphold its end of the bargain—it has repeatedly failed to appropriate the necessary dollars to provide adequate funding for the program. As a result, we've put FDA in an untenable position: we've insisted that the Agency continue to meet specified performance goals and timelines, but haven't given them the necessary funding.

We need to fix this problem too.

BPCA

The Best Pharmaceuticals for Children Act also expires next year. This legislation was designed to get more drugs tested for safety and effectiveness in children. Every parent knows the frustration of not knowing the proper dose of medicine to give to their children. So companies were rewarded for doing the testing by being granted an additional six (6) months of market exclusivity.

In some ways the law has been highly successful. It has encouraged the development of important new information on many drugs. But the Act has also been far more costly to consumers than anticipated. It has rewarded some companies with profits that are often hundreds of times the actual costs of the studies themselves. Because exclusivity delays generic competition, those profits come from the pockets of consumers who must pay higher drug costs.

Further, too often, the studies that allow the companies to get the exclusivity do not produce any clinically useful information. Several companies were given exclusivity for conducting studies on anti-depressants in children for example. But because the studies failed to show effectiveness, no information was added to the drugs' labels. Consumers paid these companies hundreds of millions of dollars in higher drug prices and received nothing in return.

We need to ensure that, when these pediatric studies are conducted, they produce useful results—we should not continue to reward companies for studies that don't contribute in a meaningful way to our understanding of the benefits or safety concerns of these drugs for children.

Drug prices/Authorized Generics

These programs all address the need for *access* to drugs and medical devices. An equally critical concern, however, is the staggering *cost* of drugs in this country. Obviously, Americans won't have real access to these products, if they can't afford to buy them.

Brand-name drug prices are rising at an unprecedented rate.

One of the most effective ways to lower drug prices is to increase the presence of generic drugs on the marketplace. 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, it has been a great success in promoting competition and lowering drug prices where we have generics. 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 continue to be on brand-name drugs—evidence that Hatch-Waxman is not working as it should. So we have to do better.

We know that pharmaceutical companies have now found loopholes in the law that they can exploit.

One of the more recent tactics used by brand-name companies to delay generic competition is the practice of launching so-called "authorized generics." Authorized generics are generics marketed under the approved application of the brand name company.

Brand-name drug companies have increasingly been putting "authorized generics" onto the market just as the first generic competitor enters the market—during its 180 days of exclusive marketing. This action 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.

So, last year, I joined other members of Congress in asking the FTC to conduct a study of the economic impact of authorized generics. I hope they can complete it in a timely manner because we simply cannot afford an unnecessary loss of generic competition.

FTC/Patent Settlement Issue

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.

We learned on Monday that 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 unfortunately, too frequently these agreements are anti-competitive and improperly postpone generic entry. Congress must act to prevent the subversion of the goals of Hatch-Waxman. We cannot afford to stand by and watch these agreements delay consumer access to generic medications and enrich only the companies involved.

Generic Biologics

There's another area that needs action. The original Hatch-Waxman Act did not apply to generic biologics. At the time, these products represented only a small portion of the market. Today that is no longer the case.

Biologics, or biotech drugs, have emerged as a major component of rising drug prices. 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.

Further, 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. This has got to change.

Right now, companies seeking approval of copies of marketed biologics must repeat all of the safety and effectiveness studies conducted by the innovator. This effectively grants a near permanent monopoly for these medicines.

I think there's no question that FDA needs a mechanism for evaluating and approving copies of biological products. I intend to introduce legislation this summer to help accomplish that.

Creating a generic biologic approval system will be a complicated and delicate task. 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.

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.

Step by step, in this as in so many other areas of health care, we can and will do better. The American people deserve no less.