

Statement of Rep. Henry A. Waxman
Prepared Remarks on Health Care in the New Congress
December 8, 2008

I am delighted to be with you today.

As many of you know, it is a time of big change for me. Next January, I will assume the chairmanship of the Energy and Commerce Committee. That Committee has sweeping jurisdiction over health care, which has been a primary interest of mine since I first was elected to the state legislature in California and from the first day I came to Congress 34 years ago.

While I have worked on legislation as a member of the Commerce Committee since I've been in Congress, for the last two years, I have been Chairman of the Oversight and Government Reform Committee.

In that role, I've had the opportunity to put a spotlight on problems of fraud, abuse, and mismanagement of government programs, of the private sector, and of our regulatory agencies.

I have been able to examine what happens when our regulatory agencies have become politicized and when ideology replaces science.

I have tried to use the power of oversight to make government work better and more effectively carry out its intended functions. Government activities have a critical impact in all of our lives, and we need to assure that it works to serve and protect the public interest as intended.

Let me talk about my new role.

I laughed recently when a new member said to me I really didn't know you had any interest in health care, I thought all you were interested in is baseball.

That certainly came as a surprise to my family. Those who know me well know I'm not particularly a sports fan – although we did have high profile hearings on steroids and sports.

Like that member, some of you may not remember or know about the work I did when I was the Chairman of the Health and Environment Subcommittee of the Energy and Commerce Committee. That was before I became the Ranking Member and then later the Chairman of the Oversight Committee. I was Chairman of the Health and Environment Subcommittee from 1979 through 1994. That subcommittee was one of the most productive subcommittees in the Congress at the time and it developed a broad spectrum of health legislation as well as environmental legislation and put them into law.

I want to mention just some of the things that came out of that subcommittee during that period, and none of them involved baseball! What we did included:

- Medicaid coverage for all children and pregnant women below poverty;

- Assistance for low and moderate income seniors with their Medicare premiums, better preventive benefits under Medicare, and other improvements as well;
- Nursing home reform. No one would say there isn't more to be done, but we set some standards in place and we made strides in reducing the inappropriate restraint and over-drugging of patients that was so prevalent at that time;
- The Waxman-Hatch legislation. We established a pathway for approval of generics which brought generic drugs — and competition — to the pharmaceutical market;
- A program to allow Medicaid to get the same price advantages as other large purchasers of drugs;
- A nutritional labeling system, which we take for granted because it is so familiar to us now it is hard to remember what a break-through it represented;
- A program to bring vaccines to all low-income children;
- A childhood vaccine compensation system, designed to assure the continued development of life-saving vaccines and also to fairly compensate the rare cases where injury occurred;
- Orphan drug legislation to encourage the development of drugs to treat what we call orphan diseases, diseases that affect only a small portion of the population.

The subcommittee had the first hearings to focus attention on the AIDS epidemic, before we even knew the word AIDS. We heard from the Centers for Disease Control about a new, rare cancer that was breaking out among gay men in few cities including Los Angeles, San Francisco, and New York. Through our hearings and our efforts we were able to devote more money to research and eventually enact the Ryan White Act, which provides drugs and services to people with AIDS and HIV.

And we've had the now-famous hearing on tobacco where the tobacco executives came before us and took an oath to tell the truth and immediately lied about how cigarettes are not harmful, the nicotine is not addictive, and that they would never think to manipulate the nicotine levels in cigarettes, and never market to children. Of course, we found out afterwards that every one of those statements was inaccurate according to their own internal documents.

Those were some of the major areas we addressed, and ones for which I remain very proud.

I have been amused of late because when I became Chairman of the Energy and Commerce Committee, a lot of people started began to speculate about what would I be like legislating. They forgot or didn't know about the time when I was involved in legislation. I think

if people want to know how I am going to behave as Chairman of the Committee all you have to do is to look at how we handled things when I was Chairman of that Subcommittee.

I mentioned those legislative initiatives – in order to get them into law, it required members to work together. It required an extremely able and productive staff and strong support from the Committee Chairman.

It required commitment, perseverance, and a lot of hard work. It required a willingness to listen to and respond to points of view of Members within the party, and reaching across the aisle for advice and support. One characteristic of every bill that I proposed that became law is each one of those bills had some Republican support. It may not have been their priority and they may not have initiated it, but once it was on the agenda we did get Republican support.

It meant we had to continue to be open to identifying problems where government could help and being creative in fashioning solutions. And it meant staying focused on what we were trying to accomplish and finding a way to get it done.

The Orphan Drug Act is a perfect example of that. This bill started with a phone call to my office from a constituent suffering from Tourette's syndrome, who couldn't get access to a drug that could help because the company didn't see that it made financial sense to market the drug for so few people suffering from this disease. It led us to delve into this question. Why do we have a situation where a vibrant pharmaceutical system neglected people with rare diseases? It obviously wasn't profitable for them. We looked at a lot of different ideas on how to approach the issue and we finally came up with the right mix of providing the incentives necessary to solve what had seemed an insurmountable problem. So we adopted the Orphan Drug Act, one of the most successful bills that Congress has ever passed.

That's what I intend to continue. That doesn't mean we aren't going to look at oversight. We are certainly going to have a very strong oversight presence. Oversight informs the legislative process and makes government work better. Our Committee has had a great tradition of oversight under the Chairmanship of John Dingell and I intend to work with him to maintain it.

So let's look to the future.

I am honored to chair the Committee on Energy and Commerce at such a critical time for our country.

I am particularly pleased to have the opportunity to work at this critical spot with a new President, President Obama and his Administration on so many issues, but particularly to ensure affordable, accessible health care coverage for all Americans.

The situation is critical. Every year we have seen the problem get worse. Now we have 46 million Americans without health care coverage. We have many more Americans who are underinsured. And, until we can get out of the recession, we are going to see more and more people lose their jobs and their health care coverage.

We have costs that are too high. Workers, families, and businesses alike are paying more, and too often, getting less. And too frequently, we are not getting the quality care and appropriate care that we should get for our money.

We have people with chronic diseases like diabetes who don't take their medications because they can't afford the cost-sharing.

We have adults who don't have access to vaccines that could prevent illness and even death.

We have people who put off care until they get so sick that they end up in emergency rooms, costing the system much more and preserving their health care less.

I don't need to tell this audience how critical the problem is. But what I want to say to you is that I think the opportunity we have now, at this time, to change this system, is the greatest we have ever had.

We will have President Obama, leading the fight to secure good, high quality health care coverage for all Americans.

We have a Speaker in the House and leadership in the Senate that's determined to move forward. Across the committees and subcommittees that share jurisdiction, Ways and Means, the Education and Labor Committee, and their subcommittees. We have people in power who want work together.

On our own committee, I intend to work hand in glove with the Chairman Emeritus of the Commerce Committee, John Dingell, and with the Subcommittee Chair Frank Pallone.

I look forward to working with the new Secretary of HHS — and I'm not going to break the secret because it's already out that he is about to be appointed — Tom Daschle, and the talented and committed teams we will have at the Department of Health and Human Services and throughout the Obama White House that will work on this issue.

We will have very impressive commitments from everyone involved. We certainly know in the Senate that Senator Kennedy has been a legend. When it comes to the question of health care for all Americans, no one is more committed to the goal of universal coverage than he is. And Senator Baucus has, in my view and in many others, made a tremendous contribution with his thoughtful and progressive White Paper.

I am embracing this opportunity to be part of this effort. I will do everything in my power to be a strong and helpful partner in securing affordable, accessible health care for all.

There are some who say that with this devastating state of the economy, we must put this goal off. I look at it in a completely different way.

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It is absolutely critical to restoring the health of our economy to act to solve the problem of millions of Americans without health care. That costly failure of our health care system affects the financial health of our businesses. It affects the productivity of our workers. It affects every American family, insured and uninsured alike. We will not successfully address the problems of our economy unless and until we address health care reform.

Now there are many ways to go about doing this and there will undoubtedly be a vigorous debate about the best approach. To me, the best approach is what we can pass and that secures the goal of universal coverage, sensible controls on cost, and assurance of quality care.

But we don't have to look too far because President-elect Obama has laid out a workable and thoughtful blueprint to achieve this end.

It builds on and protects the employer-based coverage that is now in place. It lets people who have coverage that works for them keep it.

It strengthens the safety net of our vital public programs — Medicare, Medicaid, and the Children's Health Insurance Program.

It gives people a place to go to get good, accessible, affordable coverage either through a private plan or a public alternative — the choice is theirs.

It works to improve quality and efficiency and the development of a much-needed health care technology system.

It stresses the importance of good coverage of prevention and wellness services and the management of chronic diseases, which makes such good sense from both a health and a cost point of view.

The job is a big one. But that only makes it more critical that we act. Clearly, this is the time. This is the opportunity that has eluded us. We simply cannot fail.

We've got some additional tasks that will require very early action by the next Congress. We have to pass economic recovery legislation and a very important component of that will be the health care area, including increased federal assistance to the states to maintain and support their Medicaid programs and to individuals losing their jobs and health care.

Further, while we work on more comprehensive reform, we have to act immediately to maintain the Children's Health Insurance Program that currently serves six million American kids — with a lot more out there that lack coverage that we don't yet reach. This program is going to be expiring soon and we've got to reenact authority for it and expand it. We had bipartisan legislation to support and extend this program. It passed overwhelmingly in both Houses last Congress, but it was vetoed by President Bush. One of our first tasks will be to give President Obama the opportunity to sign this bill into law.

There will be a lot more on our agenda, of course. I am strongly committed to providing clear and effective legislative authority to bring generic biologics to the market, with sufficient incentives to protect innovation to be sure, but also assurance that we will get the appropriate and timely competition in the market that generic biologics can bring.

I want to provide FDA with authority to regulate tobacco, the largest single killer of any legal product.

And we've got a lot of work to do to restore the effectiveness of many of our public health agencies, from FDA to the Centers for Disease Control. They've been starved for resources and too often, they had the scientific judgment of their professionals interfered with. They need help to do their job better, and they need our support — and constructive criticism — to do it.

Let me just focus on some of the issues that I know are of special concern to you at this conference and that I've had a long interest in as well. One of those is marketing of new drugs.

As you know, we cannot discuss drug marketing without first discussing our drug safety system.

Americans must face an "inconvenient truth" about drug safety. The truth is that we inevitably must allow drugs on the market whose risks are not yet fully known, even with the new authorities we granted the agency under the FDA Amendments Act in September 2007.

Unless we require companies to conduct massive, lengthy, and prohibitively expensive clinical studies in hundreds of thousands of patients before marketing, the full risks of a drug will not be truly understood in the first few years after a drug goes on the market.

But it is in these first few years of a drug's life that drug companies often aggressively market their products and engage in direct-to-consumer advertising. This increases the number of consumers exposed to safety risks of new products, long before those risks are truly understood.

That argues for moving cautiously with new products, particularly when existing drugs are working well.

That is why I have supported legislation that would grant FDA the authority to restrict direct-to-consumer advertising for an initial period for new drugs on a case-by-case basis. That approach was recommended by the Institute of Medicine. I think that concept makes a great deal of sense and could provide FDA an important tool to protect the public health.

We've also got to be concerned about how drugs are advertised to physicians, not just to consumers — after all, physicians are the ones who prescribe the drugs. We know that it is inside the doctors' offices where the most persuasive and effective advertising really goes on. Companies have exploited the unseen nature of this marketing to physicians to engage in so-called "off label marketing."

Because many of these unapproved uses lack scientific support, off-label marketing can lead to the unsafe use of drugs and devices.

The fundamental principle of the Food Drug and Cosmetic Act is that FDA should review the safety and efficacy for a drug or device before it is marketed. We have to ensure that companies have the proper incentives to test new drug uses, just as they have incentives to test new drugs.

Physicians also deserve the best, most accurate information. We've repeatedly seen drug companies cherry-pick what information they'll give to the physicians and in some cases distort vitally important clinical trial information about the safety and efficacy of their drugs. This is a grave disservice to physicians and patients, undermining the scientific basis of drug prescribing.

The FDA Amendments Act we passed last year will for the first time require drug companies to register their clinical trials they are conducting and to make the results of those studies public when they are completed. We want to monitor closely how this is working.

But that information still needs to get into the hands of the physicians. For too long, most of the information physicians receive to make prescribing decisions has come from the marketing representative — and only from the marketing representative — of the drug companies.

We need to have a balance of this information from the manufacturers. Senator Kohl has had some great ideas on this and I've been pleased to join him on legislation proposing an academic detailing program.

In conclusion, let me turn to the big issues facing us. We all have a big job ahead of us. I want to stress that all of you who care so deeply about our health care system must be involved and you are vital to the process. We need and want your help.

This nation has waited far too long for this opportunity to fundamentally change our nation's health care system, and assure coverage for all. But with the help of advocates and experts like yourselves, we can deliver the changes that has been too long delayed.

