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LONG-TERM CARE AND DRUG BENEFITS UNDER HEALTH CARE REFORM

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

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LONG-TERM CARE AND DRUG BENEFITS UNDER HEALTH CARE REFORM

TUESDAY, APRIL 19, 1994

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:04 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Daniel Patrick Moynihan (chairman of the committee) presiding.

Also present: Senators Pryor, Rockefeller, Conrad, Packwood, Dole, Chafee, Durenberger, Grassley, and Hatch.

OPENING STATEMENT OF HON. DANIEL PATRICK MOYNIHAN, A U.S. SENATOR FROM NEW YORK, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. A very good morning to our distinguished colleague and opening witness. This is another in the series of hearings on health care, which the Committee on Finance has been conducting this whole year. We are now down to some specifics of the President's proposal. We are going to have a discussion of the question of long-term care and prescription drug benefits in the President's plan.

But first we have what I believe is the first in such an event. One of our colleagues, Senator Cohen of Maine, has a proposal, and has some thoughts of his own on the subject of long-term care which we are anxious to hear and we welcome you, sir.

Senator Packwood?

OPENING STATEMENT OF HON. BOB PACKWOOD, A U.S. SENATOR FROM OREGON

Senator PACKWOOD. Mr. Chairman, thank you.

Today we are into two very sensitive and expensive topics. Long term care and prescription drugs are not minor issues and at some stage we are going to have to face the issue in this committee when we talk about health insurance. Now whether health insurance should mean what insurance normally means, and that is to protect you against unexpected losses that you cannot afford, or whether it really means basic, across the board health care for everybody, whether they can afford it or not with relatively marginal deductions and relatively marginal co—payments, and we include in that long-term care and prescription drugs.

Prescription drugs for many people are a burden. By burden I mean they are expensive. Long term care for some people is not just a burden, it is a catastrophe. Most people cannot afford it. So

you take care of Aunt Minnie at home as best you can. You hope there is some adult respite care some place where you can get a day off. But the bulk of long-term care is still uncompensated care by friends or relatives or churches or something like that.

Should the government get into it? If so, how? How much is it going to cost? How are we going to pay for it? And Senator Cohen has probably done more on the Republican side on this issue than any other member and I look forward to hearing from you.

The CHAIRMAN. I am sure we do, as does Senator Chafee. Senator Chafee, do you want to comment?

OPENING STATEMENT OF HON. JOHN H. CHAFEE, A U.S. SENATOR FROM RHODE ISLAND

Senator CHAFEE. Thank you, Mr. Chairman.

I do not want to interfere with Senator Cohen and am ready to go ahead. There is a witness on the next panel that is from Rhode Island, Mr. Rudnick, I wonder if he is here yet and perhaps if he could just step up.

The CHAIRMAN. I think Mr. Rudnick is on our third panel.

Senator CHAFEE. All right. I will look forward to seeing him then.

I want to welcome our distinguished compatriot who has been deep into health care matters generally and pharmaceuticals specifically.

The CHAIRMAN. And long-term care in this instance. Good morning, Senator Cohen.

STATEMENT OF HON. WILLIAM S. COHEN, A U.S. SENATOR FROM MAINE

Senator COHEN. Thank you very much, Mr. Chairman. Senator Packwood. Senator Chafee. First of all, let me thank you for allowing me to testify before you this morning. Mr. Chairman, for many older Americans and individuals with disabilities and their families I think the most personal way that health care reform could touch their lives would be to make affordable and more appropriate long-term care services available and to provide some relief from the relentless increases in prescription drug prices.

On the Senate Aging Committee, Senator Pryor and I have seen, I think, first hand the devastating toll that high prescription drug and long-term care prices are taking on families. Just last week we had a very poignant moment when a woman and her daughter appeared to talk about her husband, the child's father—I think he was age 62—who has advanced Alzheimer's Disease and requires 24-hour, around-the-clock service at home. They cannot afford to even continue the service they themselves are providing.

They are having to put their home up for sale and they have no idea where they are going. This is the sort of story that can be told over and over again. The fact is that while Medicare helps over 30 million older Americans with their acute care costs it covers only half of the elderly population's health care costs.

Prescription drugs and long-term care account for the largest gap in coverage for older citizens. In fact, 64 percent of all prescription drug costs for older Americans are paid out-of-pocket—64 percent come out of the pocket.

Only about 3 percent of our population now have insurance against long-term care expenses. I might say that as we are moving forward with the entire discussion on reforming our health care system, long-term care has been something of an afterthought, a step-child of this debate. And our current system, I think you all would agree, is a system of fragmented inequitable Federal and State programs.

Long-term care is the fastest growing segment. State budgets are now breaking under the weight of these costs. Our system clearly is biased toward institutional care such as nursing homes.

And secondly, and perhaps equally important, is the fact that families have to impoverish themselves in order to qualify for Medicare coverage at the State level. So the problem, as Senator Packwood has indicated, is large and the need is real, but there is another reality. That is, I believe that we can no longer afford to construct new, unrestrained, non-means tested programs.

I think such an approach is not only fiscally irresponsible, but also impedes a creation of a private long-term care insurance market and fails to encourage individuals who are financially able to plan and save for their own future long-term care needs.

The costs and the magnitude of the administration's long-term care benefit program, as I understand it, is $62.2 billion over a 5-year period. My concern is that because of the large price tag associated with it, when it comes time for those final votes in the debate, that will be one of the first items that will be considered to be dropped from the bill, which I think will be a mistake.

Senator Chafee has a "Heart" proposal, and legislation has been introduced by Senator Packwood and Dole and, indeed, the administration. They all provide for important tax incentives for the purchase of long-term care insurance and each would provide important consumer protections on these policies so that fair, affordable, long-term care policies will be made available.

I think it is extremely important to encourage the private sector. Private market insurance programs are going to be the ones we have to turn to in order to ease the financial burden on the Federal Treasury in the years to come. We have seen recent reports on what is happening in our Social Security Trust Fund. I know the Chairman is familiar with those reports.

I was with Pete Petersen just recently and, of course, he has written a book which I think many are familiar with. He mentions that when Lyndon Baines Johnson came to, I believe, the Finance Committee at that time and said we need to have a Medicare program, the costs at that time were estimated at $500 million.

Today I believe those costs approach about $150 billion. So we can see the kind of explosive growth in the programs that we have to be concerned about. So I think in addition to helping individuals plan for their own long-term care needs we also have to explore improving the public safety net to better protect those at low income levels against a catastrophic—that is the word that Senator Packwood used—catastrophic expense of long-term care services.

We have to end the current bias toward nursing home care by providing adequate coverage under Medicaid for home care and we have to better integrate long-term care with the rest of our health care system.

I have legislation I am working on. I hope to introduce it in the next several days, hopefully by the end of this week or perhaps next week, that will incorporate some of these recommendations.

Let me just turn quickly to the issue of prescription drugs. This is an issue which the Aging Committee, under the leadership—I should say tireless leadership—of Senator Pryor, has devoted much attention to. We have had hearing after hearing in which doctors, pharmacists, and social service professionals have expressed concern about the choices that our senior citizens have to make.

They are being forced to choose between their medicine or food or fuel. Many times individuals will take half of what they need in order to stretch out their medications. Some will take a quarter of what they need in order to stretch it out because they simply cannot fill up their fuel tanks or buy food. So they are being placed in a terrible situation.

Fortunately, I think the bright spotlight that we have placed on the ever-increasing levels of pharmaceuticals has had some effect. In 1993 pharmaceutical inflation dropped to the lowest level in 20 years. I think the pressure from Congress, and the public as well to lower the prices, and the changes we have had in managed care plans, buying groups, use of formularies, and the huge boom in the availability of generic and "me too" drugs have injected an element of competition into the market which has had a salutary impact.

The CHAIRMAN. Senator, we are developing a lexicon of strange terms that we do not fully understand. A "me too" drug?

Senator COHEN. They are just generic reproductions of existing high priced drugs. But in any event, let me shorten this up. Even though we have had these reductions in prices it really has not filtered down to the consumer level. They have gone to hospitals or HMOs, but at the consumer level the prices are still relatively high.

In fact, the drug prices are continuing to rise faster than other health care sectors in the overall economy and the pharmaceutical manufacturers enjoy profits that far exceed in many cases the average Fortune 500 company profits.

But once again we have a dilemma. We cannot allow costs to continue to escalate well beyond the reach of the average citizen, but we have to make sure that as we try to contain these costs to keep them in check that we do not come up with a manner of checking them that defeats the very purpose that the drugs provide. That is one of the major dilemmas that we have to resolve.

We know, for example, that pharmaceuticals have brought us closer to cures for devastating diseases like Alzheimers, AIDS and cancer, and yet we have the unique situation and our pharmaceutical manufacturer will tell you, we have saved you—the American people, the Federal Government—billions of dollars by saving you from the expensive care that might be required if you have to be hospitalized. Drugs do keep you out of hospitals, and hold down costs. That is true.

But it is also in my mind the equivalent of having a drowning person 50 feet away and tossing that person a life jacket or a lifesaver with a cord that is only 30 feet long. If you cannot afford the prescription drug, it does not matter whether it is saving you

money in the long term by saving you from going into an institution or into a hospital.

So I believe the same applies in the case of long-term care. If we have unlimited Federal resources that were available, a solution would be easy—let Medicare pay for it. But offering Medicare coverage without some kind of adequate cost containment mechanism built in is simply going to shift the higher cost of these prices to the Federal Government, something that I think that we are not eager to do.

Both the administration's plan and the "HEART" proposal of Senator Chafee would expand prescription drug coverage through the standard benefits package. The "HEART" plan, or Senator Chafee's plan, would allow Medicare beneficiaries to enroll in qualified plans to obtain prescription drug coverage. As such, I think the drug coverage is used as a carrot to bring Medicare beneficiaries into health care alliances and qualified plans that contain costs through effective managed care techniques.

There are several other proposals now being promoted. What I am suggesting is, if we are going to include in this health care reform debate coverage for prescription drugs, we have to be sure that we have some kind of cost containment. Otherwise, you are going to have this escalation of prices simply passed on through Medicare or through the health care reform itself and the costs will be astronomical.

As I recall looking at the President's plan for prescription drug coverage, it approaches something in the neighborhood of $69 billion or so. So, if you start adding these figures up, you are going to find that public support or political support in the Congress will dwindle.

That is why as we approach health care reform, long-term care and prescription drug coverage should be included, but included in a way that we can minimize the costs certainly initially, but hopefully in the long term. With that, Mr. Chairman, I conclude my five minute plus presentation.

The CHAIRMAN. Very well said. Can I make the point, and then I wonder if you would not comment on it, a very distinguished student of American government was speaking at a conference at the National Academy of Social Insurance just a while back and said that if in 1965 you had thought about the way our health care provisions would proceed once Medicare had been enacted, you would have assumed Medicare would have been expanded gradually over the next generation to have covered everyone. And yet, that did not happen.

We spent money in other ways and now we have an effort to put in place a universal health care system with no new money or as near as makes no matter. There is no money. You said very properly that the prescription drug provision would cost about $69 billion over 5 years. That is $4 billion more than the revenue we will get from the tobacco tax, which is the only new revenue we have.

That is an anomaly in this arrangement, do you not think?

Senator COHEN. Exactly. That is the problem we are faced with. I think that is why Senator Chafee's proposal is one that is pay as you save. He would not propose expanding the coverage until we find ways to pay for it. This is perhaps unique in Federal legisla-

tion that we actually do not adopt a new program until we find the savings.

There are savings, as you know, to be found. We have heard this idea tossed about by virtually everyone, that one way of saving money would be to simplify the insurance forms. We have some 1,100 different insurance forms to date. If we could have a single unified filing system, perhaps electronic, the estimates are that about $100 billion would be saved by going to a simplified system.

There are other needs in the field, obviously, of tort reform, malpractice reform, that will be controversial, but which may save money. So I think what we have to do is, in looking to reform our health care system to make sure that everyone is either covered or has access to coverage. That debate is yet to be resolved or concluded.

But nonetheless, it is important that we do it in a way that we can afford it. I think to adopt in the long-term care system an uncontrolled non-means tested program is going to put us in the same position we have now with Medicare.

The CHAIRMAN. Uncontrolled non-means test.

Senator COHEN. I think we have to means test these new programs. That is the key test for me.

The CHAIRMAN. This is something you follow.

Senator COHEN. And it is not going to be enough to say that, well, everyone should have coverage regardless of income. We simply are not in a position to afford it.

And, therefore, if you leave that figure of $62.2 billion hanging out there during the debate——

The CHAIRMAN. We have already spent that on prescription drugs.

Senator COHEN. It is gone. And I think that will be one of the items that is dropped out. It is one of the most important items that we have to focus on. I see Senator Pryor is here now.

The CHAIRMAN. Senator Pryor is here.

Senator COHEN. I was just telling them about our experience of just last week, Senator Pryor, of how moving and painful and poignant the testimony was of people who are confronted with the issue of unaffordable long-term care day in and day out. And here it is wreaking havoc upon their personal lives.

I saw an item last evening on one of the news casts were elders are now subject to more abuse because of just the total frustration of people who do not have the money to care for them properly, cannot put them in institutions, and are simply besides themselves, which causes them to take their anger out on the people whom they are caring for.

So it is a very important issue that we have to resolve and I think we have to do it in a cost conscious way as best we can.

The CHAIRMAN. Could I just offer a suggestion in the way of a question? We hear a lot about savings we are going to have on forms. In this committee we deal with the Internal Revenue Code, which is far too complex. But it is pretty hard to have a Code that is not complex, with so many hugely different sets of activities and interests.

And, you know, one form will save money. We will take it out of waste, fraud and abuse. That is a common budgetary tactic that has not helped much.

My impression is that the great savings that come along in our system result from advances in medical knowledge and practice. We are going to have a panel on prescription drug provisions, during which Dr. Charles Sanders, who is head of Glaxo, will be a witness. That firm came out with the pharmaceutical Xantac when a quarter, or thereabouts, of all operations that took place in American hospitals involved peptic acid disease of one kind or another, ulcers.

Those operations have almost ceased just with one pill. Now that is a real savings, when suddenly a quarter of your operating room activities are no longer needed.

Senator COHEN. That is one savings that will be realized through those kinds of advances, which is why I suggested we——

The CHAIRMAN. You mentioned Alzheimers. We probably can say with some confidence that in 10 years or 20 we will have broken that code, will we not? I am speaking far beyond my knowledge, but you have studied this.

Senator COHEN. I think that is the case, which is why I suggested we move carefully when we talk about controlling the costs of prescription drugs because it does offer us one of the best hopes for breakthroughs in the future.

Let me suggest another major savings that I think will be important in health care reform. It is called the wellness ethic. It is something that we have not talked about for a long time.

I recall introducing a piece of legislation back in 1981—which met a predictable fate. I encouraged changing the Tax Code in order to encourage employers to provide wellness programs for their employees with a notion that if they, in fact, had anti-smoking campaigns or educational programs or provided perhaps even on-site physical exercise programs or purchased memberships in health clubs, that this would result in a much better work force.

You would have less absenteeism due to illness, less smoking, and a much happier, productive work force. And, of course, the answer was it was such a great idea, Cohen, why do they not just do it anyway.

Well, we are going to, I think, do it anyway. We cannot devise a health care reform system that will be able to pay for all of the ills that afflict us unless we are willing to start taking measures to take better care of this wonderful God-given machine that we have called the human body.

I watch Willard each morning on the morning news and the weather and he talks about those who have reached 100 plus years. The fact is that we, as a society, eat too much, drink too much, smoke too much and do not exercise enough. And then we complain about the high costs of getting well again when we could have taken preventive measures on our own.

If we educate ourselves about the right foods to eat, and the right amounts, and the right amount of exercise, we will reduce substantially the kinds and amount of drugs that we take. We look at our health care system and wonder why it costs so much. Well

how many other countries pour into their health care system the kinds of problems that we do? Not many.

That is one of the primary reasons that we have such outrageous costs imposed upon our health care system—what we do to ourselves. So if we change that, we can make substantial savings without worrying about the insurance forms or about waste, fraud and abuse. We are the biggest wasters in the business because of what we do to ourselves.

So that is one major change. I believe the President's program has an element in it dealing with wellness. I think all of our health care reform proposals should focus very significantly on this issue.

The CHAIRMAN. Thank you, Senator.

Senator Packwood?

Senator PACKWOOD. There is a discouraging factor to taking care of yourself, however. We have been very successful with seat belts over the last 30 years. Thirty years ago you could barely buy them, and now most people use them.

Now it turns out that it is more expensive because people are being injured, but not killed, and the injury is cheaper than the death. I mean, the injury is more expensive than the death. Yes, the death is cheaper than the injury. So now because of seat belts, we are saving lots of lives.

You know, what Senator Cohen said reminds me very much of what Dr. Sullivan, our past-HHS Secretary would say time and again when he was here, he would go down the same four litanies you did—drinking, smoking, drugs and exercise. And he opined that we could probably save half of our costs if we would do that for ourselves. We paid no attention. We have not done anything. But that is a thesis that is being echoed more and more.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Packwood.

Senator Chafee?

Senator CHAFEE. Well, thank you, Mr. Chairman.

First, I want to commend our colleague who always does an outstanding job, and obviously he feels deeply about the pharmaceutical side of this and the wellness side. I guess few people here use the gym more than he does to keep fit.

I might say I would like to add to the list of those items—smoking, drinking, and so forth, drugs—violence in our society. I have still got room for a few more signatures on my bill to ban all handguns.

But I just think the tragedy that comes with this, along with the health costs, the violence in our society from handguns is a health care cost as well as a tragic cost. It is an educational problem likewise. Namely, schools that cannot afford proper books are having to set up elaborate metal detectors and man them. Here I am on the soap box, I know, a little bit.

How many minutes did you give me?

The CHAIRMAN. As many minutes as you desire on this subject.

Senator CHAFEE. Well, in any event, Mr. Chairman, again I want to commend our colleague and thank him for his testimony here.

The CHAIRMAN. Thank you, Senator Chafee.

I believe Senator Conrad is next.

Senator CONRAD. Thank you, Mr. Chairman.

I would just join my colleagues in saying your testimony was excellent as always and I think useful to the committee. In the interest of time, I will yield back whatever time I have remaining, Mr. Chairman.

The CHAIRMAN. Senator Pryor?

Senator PRYOR. Thank you, Mr. Chairman.

I would like to add my accolades also to the distinguished Senator's appearance here. I think that having the privilege of serving with him on the Aging Committee, we have had a lot of very fine hearings. I think he has mentioned one last week on long-term care.

I would just like to say to my colleagues that I will always remember the poignant testimony of last week of at least two of our witnesses—the mother and her 13-year-old daughter—who are caring for the father and husband in their home with Alzheimers at age 53. They have now spent down. They have lost everything.

And on May 15—we all ought to remember May 15 because a woman with great pride and great bearing, and her beautiful daughter, are going to be evicted from their home. They have lost their home. This is one of the real sad areas of long-term care that we face. So May 15 we will see this woman and her daughter evicted from the home and we will see, I assume, the husband and father with Alzheimers become, I guess, a ward of the system. They are taking care of him now in their home.

The second witness I remember, Mr. Chairman, was a woman from the District of Columbia. And Senator Cohen and I heard her tell about taking care of her father who evidently is in his eighties or nineties. She refuses to put him in a nursing home. She is the only person there to care for him as the care giver. And we asked a following question to her at the last of the hearing. We said, what can we do for you. What do you need more than anything else? She says a few hours rest. A few hours rest.

No big, huge program what have you did she talk about or understand, just give me a few hours of rest so that she can continue the care giving of her father.

But, Mr. Chairman, I know that I am kind of rambling. But I wanted to thank Senator Cohen for that.

I would like to make two points, Mr. Chairman. One, price discrimination in prescription drugs is something I want to talk a little bit more about today. We have cases, Mr. Chairman and colleagues, of 90 percent price discrimination, sometimes against our community pharmacists.

And by the way, the community pharmacists recently in a survey, local pharmacists, they are judged to be the most cared for and respected person in the health care chain, the community pharmacist. The most highly regarded in the whole health care chain is the community pharmacist.

The pharmaceutical companies, however, discriminate against their pharmacists by charging them the highest prices for their drugs that they in turn sell to the consumer, in most cases to the elderly consumer not covered by Medicare.

Relative to Medicare under the Clinton proposal, we are about to see Medicare become the largest single purchaser of prescription drugs and I strongly believe that there must be a rebate back to

the system by the companies and I hope that rebate will be substantial and that those savings can be passed on, not only to the taxpayer, but also certainly to the consumer.

Mr. Chairman, I really appreciate you holding this hearing and thank you for allowing me this opportunity.

The CHAIRMAN. Thank you, Senator Pryor.

Senator Durenberger?

Senator DURENBERGER. Mr. Chairman, I regret not having been here for Bill's presentation but part of having made a decision far in advance of an election not to be part of it, that I sort of occasionally do things spontaneously. So this morning I went down—this was an unspontaneous part—I went down to meet with my building trades folks for breakfast at the Hilton. They told me I could only speak for a minute or something like that. They told me this right in the middle of my presentation.

Senator COHEN. Is that because you are leaving?

Senator DURENBERGER. Yes, a sense of urgency.

No, it was because they wanted to get to hear Hillary Rodham Clinton speak on health care. So I said, well, "can I join you?" I mean, this is the spontaneous part of not operating on a rigid mind set or schedule anymore. So I am late because I took the time to go listen to Mrs. Clinton talk to the building trades.

I am pleased that I did. I regret that I did not hear Bill's presentation but I got back here in time to hear him say something as important as everything I heard this morning and he said it all in one sentence. How many countries pour into our health care system the kinds of problems that we do in the United States?

I heard Mrs. Clinton say, we have the best health care in the world. We do. I mean, it is fantastic. But the structure of it and the financing of it is a disaster. This additional point in defining what is health in America is really critical for us to keep in mind. I think it is a very special colleague who can capture it all in one sentence. How many countries pour into our health care system the kinds of problems that we do in the United States?

That is a reality that no single health care reform bill, no insurance company, no mandated benefit is going to solve. It is a much bigger problem.

The CHAIRMAN. And very much, if I could say, in the tradition of American medicine which for a couple centuries now has discussed whether too much doctoring and too much drugging is not the problem. I will not get into homeopathies yet.

Senator COHEN. Well, I will not indulge as I usually do in talking about my mother and father, but my father is now 85. He continues to work 18 hours a day, 6 days a week, and he has a total aversion to doctors and hospitals and refuses to go to either of them unless carried there. He has done remarkably well on his own.

The CHAIRMAN. Good for him. Send him the greetings on the Committee on Finance. [Laughter.]

The CHAIRMAN. And spread the gospel. Thank you very much, Senator.

Senator COHEN. Thank you.

The CHAIRMAN. We are now going to have a panel on these two subjects that Senator Cohen has introduced for us, if our panelists would come forward. Deborah Briceland-Betts, who is the National

Director of the Long Term Care Campaign; Richard C. Ladd, who is the Commissioner, Texas Health and Human Services Commission, and Mr. Packwood will introduce him when the time comes; Dr. Stephen McConnell, who is Senior Vice President for Public Policy of the Alzheimer's Association; and Stanley Wallack, Chairman of the Coalition on Long Term Care Financing and Director of the Institute for Health Policy at Brandeis.

May I just say for the record that we asked the Department of Health and Human Services if they would not wish to send us an official spokesman on these two areas and the Department declined on grounds of—what is it? They think administration witnesses should not be asked to sit on panels. We could have them sit on stools. [Laughter.]

The CHAIRMAN. That is what it says here.

Anyway, Ms. Briceland-Betts, you are an administration witness, whether you know it or not. They said get you, that you do not mind sitting on panels and we welcome you.

STATEMENT OF DEBORAH BRICELAND-BETTS, NATIONAL DIRECTOR, THE LONG TERM CARE CAMPAIGN, WASHINGTON, DC

Ms. BRICELAND-BETTS. Good morning, Mr. Chairman. I am Deborah Briceland-Betts. I am actually not the administration witness. I am with the National Long Term Care Campaign, which is a coalition of 137 national organizations dedicated to enacting legislation to protect people against the devastating costs of long-term care and I am happy to be here today.

The groups that I represent would find it very hard to support a plan to reform our Nation's health care system that does not include long-term care. Long term care is not just an issue for aging Americans; it is an issue for the American family.

It is a family issue because families not only provide the care—84 percent—but also because they pay out of pocket for the majority of the purchased care. Our current system is based on the family. We have heard a few stories about that this morning from our previous hearing.

But changing demographics and other pressures are causing that structure to crumble under the strain. It does not need to be replaced, but it needs support, which is exactly what the plan proposed by the President would do.

There are certain features of the President's proposal that The Long Term Care Campaign considers absolutely essential, including that it is for people of all ages and incomes. It assures coverage for persons with cognitive and mental impairments as well as physical disabilities. It allows consumers to choose and direct the services. It is flexible and it has real financing.

We all recognize congressional concern about the cost of including long-term care in health reform. But you must understand that we will end up spending even more money if we do nothing about long-term care—through increased hospitalizations and emergency room visits to people who have no care and to care givers who have no help. Or, we will force them into the most expensive setting—nursing homes.

There is mounting evidence that the kind of long-term care plan the President is proposing will yield real savings in nursing home costs and avoidable hospital expenditures.

There are those who say that private insurance is the answer to long-term care crisis. The long-term care campaign feels strongly that the next Federal dollars spent on long-term care should not go to providing tax incentives for those who purchase long-term care policies.

There are several reasons why, but the two most prominent are that most people cannot afford it and those who need it the most, it is unavailable. A 1990 study of the affordability of private insurance found that 94 percent of those between the ages of 65 and 79 cannot afford to pay the average cost of basic nursing home insurance policies from nine leading companies, even when their are available assets are annuitized to help pay for insurance premiums. And 73 percent of that same group cannot afford to buy even the lowest priced nursing home policy that meets minimum standards.

My colleagues sitting at this table will tell you that the issue is not affordability, but it is the willingness to buy. However, the survey to which they will refer is evidence of people's willingness to spend more money on insurance came from surveying those who are in the private insurance industry who depend on sales for their livelihood. I do not really think we can tell much about how much the general public has to spend on insurance by a survey of those who sell insurance for a living. I think we still have to look at the hard numbers.

Josh Weiner of Brookings Institute tells us that long-term care insurance is expensive for two reasons—young people do not buy it; and the older people who buy it are most likely to end up needing the services they have purchased.

While the solution seems to be to encourage younger people to buy the policies, there are many competing demands on their disposable income and they often deny their risk of needing long-term care or faultfully believe that their health insurance or Medicare will cover its costs. And it is not logical to assume that employers will provide long-term care insurance as a benefit because many companies already face huge liabilities for retiree health insurance benefits and they are unlikely to want to take on another costly and unpredictable expense. Long term care insurance is a solution for only the very rich.

The other major problem with private long-term care insurance is that the people who need it the most cannot buy it. It is the reality of insurance. It has nothing to do with fraud and abuse. There are currently 10 million people in this country with Alzheimer's Disease, Multiple Sclerosis, spinal cord injury, development disabilities, birth defects, heart disease, asthma, arthritis and more who need long term services and not one of them could purchase a long-term care policy that would provide the benefits they need.

If there is anything in a person's medical history that signals a potential future need for benefits, they are not allowed to purchase a policy. That is why we need this public program.

Senator Moynihan, I know that you are concerned both about long-term care and welfare reform. The data shows that a new pro-

gram like the one proposed by the President would create one million new jobs, real jobs. Eighty-five percent of those jobs would be in the private sector while some are for professionals. Many would be entry level and could provide training and productive work for those who might otherwise end up on welfare.

I would like to conclude by pointing to recent surveys which indicate that people are much more supportive of reform that includes long-term care. An ICR Research Group survey found support increased from 46 to 82 percent when long-term care is included. That is why I believe that the groups I represent would have a hard time mobilizing a grassroots support effort for any health reform plan that does not include substantial long-term care benefit.

Thank you for holding this hearing.

The CHAIRMAN. Thank you, Ms. Briceland-Betts.

[The prepared statement of Ms. Briceland-Betts appears in the appendix.]

The CHAIRMAN.Senator Packwood, I believe you would like to introduce Mr. Ladd.

Senator PACKWOOD. I would love to introduce Dick Ladd, who I have known for many, many years when he was the Oregon Senior Services Division Director in Oregon before Texas stole him to become the Director of their entire Health and Human Services Program.

He and I first worked together when Oregon was attempting to get a waiver to allow Medicaid funds to be used for home health care. And Jackson County was the first county in Oregon as I recall, Dick, to apply for it. We got it for Jackson County. Then the State of Oregon got it.

And what we discovered is this. We could take the Medicaid funds we had and just about double the population we could treat if we could treat them at home with the same money. But we had to fight tooth and nail to get the waiver to do it. And the people were happier. They liked being at home if they could be at home; and it has worked out very, very successfully for Oregon. And Dick Ladd, more than any other single person, is responsible for that and now Texas has him.

The CHAIRMAN. Well, there you are. Welcome, Mr. Ladd.

Mr. LADD. Thank you, Mr. Chairman. Thank you, Senator Packwood.

The CHAIRMAN. All statements will be placed in the record as if read. I want to make that clear.

Mr. LADD. Yes.

STATEMENT OF RICHARD C. LADD, COMMISSIONER, TEXAS HEALTH AND HUMAN SERVICES COMMISSION, AUSTIN, TX

Mr. LADD. It is a pleasure to be here. The last time I testified in front of this committee I believe it was 1985–86 when it was changing the system and it is true that you do not really need a lot of new money to do a lot of changes in long-term care. We did it in Oregon. We did primarily by a law that was passed in this committee in 1987, added to the Reconciliation Act. Senator Packwood sponsored it. It was called Section 1915(d).

Now only Oregon has implemented that. But essentially what that did was give Oregon flexibility on setting up their long-term

care system. And they were able to end the bias in nursing homes. And when we ended the bias in nursing homes, we were able to expand the community programs tremendously, to the point that Oregon today probably takes care of twice as many people in their long-term care system as they did before with less money.

The CHAIRMAN. You did that, Bob Packwood?

Senator PACKWOOD. Yes, we did. Mr. Ladd and I.

Mr. LADD. The major problem in long-term care from my perspective is two-fold. One is that because of the way it has been funded. We funded with Medicaid through default. Medicaid, when it was first enacted, was not designed to fund long-term care.

When the Miller Amendments were added in 1967 nursing homes then became eligible for Medicaid funding. What has happened since then is an explosive growth in nursing homes. We went from 2.6 beds per 1,000 age 65 plus in 1966 to about 5.4 beds per 1,000, 65 plus today.

The CHAIRMAN. Almost double.

Mr. LADD. It is double in a percentage basis. It is way more than double because the elderly population has grown tremendously.

The CHAIRMAN. Yes.

Mr. LADD. And we have come to think of nursing homes as our primary source of long-term care. In fact, if you look at what the government pays for, 85 percent of what we pay for goes to nursing homes out of Medicaid. And only 2 percent goes to our home and community based waiver program that is to provide home care or care in substitute settings like adult foster homes and assisted living facilities.

So we are still in a mode that pushes us towards nursing homes. Now nursing homes are an entitlement. States cannot deny a nursing home placement. But none of the alternatives, even though they are funded by Medicaid, are entitlements.

Indeed, the home and community based waiver program has some very strict formulas that limit the number of people you can serve in the community. Now what you did in 1987 when you passed 1915(d) was you allowed Oregon to say we are going to sign up for a cap on long-term care and in trade for that we do not want the Federal Government to tell us how many people we can serve in the community.

Oregon did that. We have had that out there since 1987. To date, they have not ever reached that cap. Although, before I came here I talked to them and they said it was getting pretty close. But they still have not reached that cap.

And Oregon nursing homes today in Medicaid have had about a 15 percent reduction since 1981 in the number of people in those nursing facilities. In 1981 when we really got the program going, we had about 3,500 folks out there that we took care of in the community. Today that number is above 20,000.

So you can make it work without new money. You just need to recognize a couple things in my mind. One is that long-term care is not a medical problem. Long term care is a social, functional problem. If any of you live long enough, if I live long enough, we are going to need long-term care.

And in most cases it is going to be helping you do what we call activity daily living. Things like eating and dressing and grooming,

things that you are no longer going to be able to do for yourself and you need somebody to help you do that. That is not a medical problem.

Indeed, most people in nursing homes today in the United States are suffering from limitations of activities of daily living and have no more medical problems than other people in their age cohort. We have answered that with a medical program, primarily Medicaid, which has led us to believe that long-term care is a medical problem when essentially it is not. There is a small percentage that is medical, but most of it is functional.

And we have made nursing homes our primary delivery service out there when it really ought to be home care. I remember I was at a conference and some of the people at this table were at the conference with me in Chicago about 6 years ago where we had a professor who was an expert on aging programs, but primarily in Scandinavia, started the conference out by saying, I think you folks have got it backwards. Why are you waiving home care, you ought to be waiving nursing home care and make home care your primary service.

And home care has a cost of about 25 percent, on average, 25 to 33 percent of what costs are in nursing facilities. There is plenty of money to operate the system if you would just change the rules a little bit.

Thank you, Mr. Chairman.

The CHAIRMAN. Well, you guys get things done. You are ahead of your time. Thank you very much, Mr. Ladd. That is a very important statement.

[The prepared statement of Mr. Ladd appears in the appendix.]

The CHAIRMAN. Dr. McConnell, who will speak on behalf of the Alzheimer's Association, we welcome you, sir.

STATEMENT OF STEPHEN McCONNELL, PH.D., SENIOR VICE PRESIDENT FOR PUBLIC POLICY, ALZHEIMER'S ASSOCIATION, WASHINGTON, DC

Dr. MCCONNELL. Thank you, Mr. Chairman and members of the committee. I am here officially representing the Alzheimer's Association which works on behalf of 4 million victims of Alzheimer's Disease, their families and care givers. Alzheimer's disease is the single most uninsured problem facing the elderly.

I am also unofficially here representing all people who need long-term care, whether they be children with Cerebral Palsy or mental retardation, young adult accident victims, people with MS or paralyzed veterans.

I would like to pick up on the example that Senator Pryor eloquently described, the family that testified at his hearing last week, the Chapmans. Tom Chapman is age 53 and because the programs that exist out there in the community under the Older American's Act are age limited, he does not qualify for those because there is a cutoff at age 60.

The CHAIRMAN. What is the curve, the distribution of Alzheimer's?

Dr. MCCONNELL. Well, most people, of course, it affects over age 65.

The CHAIRMAN. What is the median?

Dr. MCCONNELL. Between the ages of 65 and 74, for example, a couple of percent are affected.

The CHAIRMAN. What is the median age of onset?

Dr. MCCONNELL. It is probably about 72 or 74.

The CHAIRMAN. And the standard deviation is what? [Laughter.]

Dr. MCCONNELL. 1.5. [Laughter.]

The CHAIRMAN. No, how far is that 53-year-old on the left side?

Dr. MCCONNELL. Onset at age 53 is not the most common. But there are many people under age 65 who do get Alzheimer's Disease. It is most common in people over 85. Roughly 50 percent of people over age 85 have Alzheimer's Disease.

But the point is that he does not qualify for existing services. Because the family had a few assets they did not qualify for Medicaid. And as Senator Pryor said, they are now losing their home.

The President's plan would address the needs of the Chapmans and others with long-term care by changing the system in several ways. One, it levels the playing field so that the Chapmans could get help at home where they want to keep Tom.

Second, there are no age, income or type of disability restrictions. So that whether one has Alzheimer's Disease or a stroke, as Mr. Reed has, an individual still qualifies for help.

Third, it is a flexible program, so that the Chapmans could hire a neighbor to come in and watch Tom while she ran errands to provide some respite. Or they could get assisted living in a community-based facility.

Fourth, it allows for broad eligibility requirements so that Alzheimer's Disease is covered, as are other mental and cognitive impairments as well as physical disability.

And finally, as Dick Ladd has pointed out, the States are doing a lot of very innovative things out there and the President's program builds on what the States are doing. It does not establish a program and rigid requirements at the Federal level, it builds on State innovation.

Now the President's long-term care plan is not perfect. But compared to the alternatives, it is clearly superior. If we limit a program by type of disability, it perpetuates the current system that says if you have heart disease, insurance coverages you; but if you have Alzheimer's Disease, you are out of luck.

If we picked off several diseases and said, these will be covered by a long-term care program and left out other diseases, we discriminate on the basis of diagnosis. If we limit it by income, we would leave all middle income Americans without protection. They would have a little more income than would qualify them for the public program, but they would not have enough to purchase private insurance. So we would be saying to middle income Americans who are going to be impoverished by long-term care experience, you are out of luck.

Limiting the program by level of disability makes the most sense, because it is connected to the needs of the individual. When a person reaches a severe need, there will be a program there to help them. All families would have the reassurance that help would be available at some point.

Asking people with higher incomes to pay more, as the President's plan does, is fair. Targeting resources for those with the

greatest health care needs is appropriate. Placing a cap on overall expenditures is responsible. This is not an unbridled program because there are not unlimited resources.

But restricting access based on age, income or type of disability is a recipe for failure. On behalf of Tom Chapman, Hazel and his 13-year-old daughter, on behalf of 10-year-old Walter Dawson who testified a year ago before your committee, Senator Pryor, whose college savings were spent on his father's care, on behalf of the 10 million disabled Americans who cannot qualify for private long-term care insurance because they now have a disability, and on behalf of the countless millions of others who cannot afford long-term care, I urge you to enact the President's long-term care program as part of health reform.

The CHAIRMAN. We thank you, Dr. McConnell.

And now to conclude our panel, Stanley Wallack, who is the Director of the Institute for Health Policy at Brandeis University. We just had Dr. Altman here last week, so we are hearing a lot from Brandeis these days and we much appreciate it. Mr. Wallack.

STATEMENT OF STANLEY S. WALLACK, CHAIRMAN, COALITION ON LONG-TERM CARE FINANCING, AND DIRECTOR, INSTITUTE FOR HEALTH POLICY, BRANDEIS UNIVERSITY, WALTHAM, MA

Mr. WALLACK. Thank you, Mr. Chairman. I am here today in my capacity as Chairman of a Coalition made up of long-term care insurers and providers. But as Chairman of that Coalition, I am going to take a prerogative to sort of expound on the things that I think are important and highlight some things.

The CHAIRMAN. That is the Chairman's prerogative.

Mr. WALLACK. And, of course, I have the testimony which is given to you, which goes into a great deal of detail on some of the program elements dealing with long-term care.

I would like to focus a lot of my time, my limited time here, on issues that I think are very fundamental to this debate. Really the philosophical issue is the private and public roles because, in fact, that issue will drive our policies which will then drive the programs. And we need to really have a full discussion as Senator Packwood said that, as well as Senator Cohen.

And I think in the context of that, we all have to ask ourselves what is fiscally responsible and what is really practical today. I would only like to comment that a lot of the people—and Senator Cohen has talked about the costs—but I would like to remind this committee that our real sort of change in demographics in this country are going to occur after the year 2010.

We have not seen the long-term care expense and the long-term care problem yet. It is going to hit us out there in the future. What we need to do today is plan for that.

The other comment I would like to make with regard to fiscal responsibility—although Dick Ladd is right and there are potential savings in home care—I think it is interesting to note that the fastest rising expenditures in this country in our Medicare and Medicaid program are for home care.

Home care is rising very fast. And if you sort of tip that line and extrapolated it to the 10 years out, it is frightening. If you just take

the current rate, it could exceed physician expenditures. It is going up very fast. We do not know how to control home care in this country very well.

And I do agree with what Steve said, you need to have some controls. But we do not know a lot about home care.

The CHAIRMAN. Can we use the last names, because the audience will not necessarily know Steve.

Mr. WALLACK. Oh, I am sorry. It is Dr. McConnell.

The CHAIRMAN. Steve McConnell.

Mr. WALLACK. I am sorry.

So I think there are some clear issues around fiscal issues what this country can afford. But the other question is, is it practical at all to look at the private market. We did not have a private market to speak of in this country a few years ago. But over the last few years the private products have developed.

There are a number of companies that are now moving to offer very comprehensive products that offer home care and nursing home combined, an integrated product that is managed in the way acute care is now being managed and we could all argue about what is affordable, but a policy that, in fact, provides 3 years of nursing home care, 6 years of home care, and really very good protection for most of your risks.

It costs about $100, which is about the price of a MediGap policy. Now that is for a 70-year-old. So the real question is not I do not think the price of this policy—in fact, overall the prices are coming down. The real issue, I think, is why so few are buying.

And there, I think, really, we did do some surveys, and those of us concerned about this issue, and looked at, in fact, the non-purchasers, not the purchasers, and asked them why they are, in fact, not buying long-term care insurance.

The reasons were quite clear. They did not think the products necessarily had value and they also thought the government was going to finance long-term care; and, therefore, why should I, in fact, buy it.

I do not believe we will have a private long-term care insurance market of any significance unless the government wants to support it. It really is up to the government, because older people as well as the business community look to the government for signals and look to the government for leadership.

I think really the government has to deal with the issues of value and the issues of what is its financing role. What is it really going to finance if we are going to develop a private market and have the full potential of the private market?

To get at value, I think we are talking about standards and we are talking about a tax clarification. The coalition supports Federal regulation. We need something. We have lemons out there and we need lemon laws. It is important that we have regulation over insurance.

Senator Packwood has introduced in his legislation the kind of standards and the kinds of tax clarification that make a great deal of sense to us.

I think we should learn from some of the problems we are now seeing in the health care field with regards to the health insurance, the importance of linking together tax clarification and standards.

The Federal Government did tax clarification and yet we did not really control the kinds of health insurance products that we wanted.

If we integrate them, we put the right signals out there, and encourage the right kinds of products. As we move into the standards area, the important issue to us is really what are we trying to do. It seems to us a system of good standards. It is trying to do two things.

It is, in fact, trying to provide real protection to consumers but also to maintain choice. The benefits of a private market is we have choice out there. Not everybody wants the same thing. And, in fact, our standards, the ones we have developed, really, in fact, try to combine consumer protection and, in fact, consumer choice.

We think that is very important. A good, well—designed tax clarification policy which treats long-term care like health and a set of good standards could, we think, significantly change the market.

Tax clarification only reduces the price slightly. But it sets a signal for people that the government sees long-term care as something which has potential. It creates a different market out there.

The second issue in my last 30 seconds or so is really the issue of the one of financing, because that is the second piece of this. And the real question out there is what signal are we going to set as move to financing. And the Coalition does believe that we should do more about the financing of long-term care.

But what, in fact, signal are we going to send out to the public with regard to what the Federal Government is going to do? The Clinton proposal is really in some way the first step. It is almost like putting something away on lay-away. I mean, if you know you are going to, in fact, get more later, why would you go out and buy a private product. It, in fact, can really do great harm to anybody really considering the purchase of something way off in the future.

This is not the time to get into a full debate, obviously, of the Clinton plan, and we are not here to debate the administration's plan, but I think one of the problems with that is that it just identifies and provides home care and leaves nursing home care out. So it does not really allow you, in fact, to integrate services very well.

From an analyst perspective, you will see all sorts of gaming and shifting of people. And from someone who is interested in managing care you really want to integrate the services for, in fact, individuals. The coalition is very supportive of the kinds of things that Senator Packwood has been thinking about and Senator Cohen, that we need an alternative, an alternative that really, in fact, shows the public is going to be responsible for people who cannot afford to pay for private insurance.

In my testimony I have given you tables of a plan that has the government targeting its dollars on 150 percent of poverty. One of the most important things in that table, if you were to compare a program like that and who gets the benefits to the administration's program.

In our plan, all the benefits go to people below 150 percent of poverty. In the administration's plan, over 50 percent go to people above 200 percent of poverty. In fact, the benefits are not really being targeted on those who can afford to buy a program.

My concluding comment is the following. We are now developing long-term care legislation, hopefully, and we think it is important to include it now in 1994. This is not in 1964 when we were thinking about Medicare, in 1934 when we were thinking about Social Security. We need to plate this in the context of the improvements the elderly have seen in terms of their income and the improvements in terms of the private market.

I find it very difficult to understand why you would want to subsidize a home care product which in the private market would cost something between $35 and $45 a month for a 65 or a 70-year-old. And that is about what, if you went to the private market and said, I want to have a private system for the Clinton package, it would cost you.

So I think we are today, today as we move forward, Senator, I think it is very important today to plan for what is going to happen 20 and 30 years out. And I think to do that we have to have a set of standards that encourage private insurance and a balanced public and private financing system.

The CHAIRMAN. Thank you, Mr. Wallack.

Mr. WALLACK. I appreciate your giving me the time.

[The prepared statement of Mr. Wallack appears in the appendix.]

The CHAIRMAN. Mr. Ladd has some time left over for you.

Senator Chafee's proposal involves provisions on liberalizing the tax treatment of private long term health insurance also. I want to make that point.

Senator Dole, we welcome you once again, sir. Would you like to make a comment?

Senator DOLE. Well, thank you very much. I think there was some reference to a bill that I introduced, along with Senator Packwood, in August of 1991, which we called Secure Choice, in which we addressed many of the concerns expressed and tried to redirect some of the Medicaid funding. I am not certain, but we did specifically target Alzheimers in that proposal.

The purpose of the hearing was not to address that bill, but I think there is a basis at least for I hope some support. Maybe we do not go far enough. But there are three different parts of that provision and we think it was a step in the right direction a couple of years ago and we have not changed our mind. So it may be the basis for some discussion later on.

Hopefully, we can work with the witnesses and others who have an interest because long-term care—and it has always occurred to me that somehow we are going to have to encourage employers and employees when they are 21, 22, 23, 24 to start looking down the road to the golden years. I mean, it would seem to me that it would be very inexpensive at that point in time to start talking about long-term care.

I am not certain whether unions include that in their bargaining or not on health care benefits. Maybe not. But it seems to me it is pretty obvious that most people hope to get older and if they do get older, as Mr. Ladd indicated, they are going to have a problem in doing certain things.

So there must be some way, maybe through the Tax Code or some initiative, where the people in the work force, which would

be most Americans, or self-employed you could provide it there, too, some tax incentive would take a look when they are in their early years of productivity rather than till they are 70 or 75 years of age.

What concerns me is we are maybe looking at another big new entitlement program, open-ended entitlement program, when the year 2010 arrives we will be blown out of the water. We are already told that the Medicare Trust Fund is in some degree of difficulty or will be soon. So it is a question of how are we going to contain it knowing the importance of long-term care.

I think there is a role for insurance. I think Ms. Briceland-Betts indicated it was too expensive, it was only for the rich. You have indicated the contrary. It has been indicated maybe only 20 percent would participate.

I have to believe that if certain changes were made in the Tax Code, which would not cost a great deal of money—I think CBO estimated the cost of our bill at $26 billion, but we do not think that is an accurate estimate. We do not think it is that much.

But does anybody have any comments on this? Yes, Mr. Wallack?

Mr. WALLACK. I would like to first of all say that the fastest growing part of the long-term care insurance field right now is the under 65, the younger, the employer and the employee. That is growing very fast. The average person is around 40 years of age.

Again, I do think that tax clarification will, in fact, help both the employer and the employee even, in fact, the employer may decide to contribute if, in fact, they get the tax clarification and treat them in cafeteria plans and other ways. I think that, in fact, could be very important. I really think it is not like when we have had other kinds of tax policy.

It is not sort of the effect of a tax change that reduces the price that is very important. It really changes the whole attitude that the Federal Government is sort of putting a seal of approval on the idea of that there is a role for private insurance or private sector in solving a social problem.

That is a very important statement and a very important signal to set up. So it does more than just reduce the price, it really changes the attitude. So I think you are right, Senator Dole. I think it could make a significant change out there.

Senator DOLE. In fact, I might just add with reference to Dr. McConnell's testimony under our federal/State program we indicate the impairment must be evidenced by limitation performing activities of daily living or by the presence of Alzheimer's Disease or a similar dementia. So we did try to address that concern.

As far as the tax clarification on out-of-pocket expenses, tax deductible above 75 percent of adjusted gross, payments for LTC services under insurance policy would not be taxable, employer paid LTC service and insurance will be a tax-free employee fringe benefit, in the view of many people, I think as I remember when Bob was putting this together—I am the junior partner in this effort—we had a lot of employers tell us that what was hindering them was they needed clarification on what the tax impact would be.

Ms. BRICELAND-BETTS. A couple of comments. In terms of the affordability of long-term care insurance and talking about a policy that costs $100 when a person is 70 years old, I think there are

two things to look at in that policy and one is to remember when you are purchasing a long-term care policy that the large print giveth and the small print taketh away.

There are a couple of ways you can control costs with long-term care insurance. You either have to put restrictions on the face of the policy—that means the people who really need it will never be able to collect on the benefits—or you cannot control those costs and you have to raise the price of that policy. It is beyond the affordable range of most people.

The other thing to point out is that a person at 70 years of age probably will not use that policy for another 15 years. And what about inflation over that time, even that 4 or 5 percent inflation factor, a policy that is purchased when they are 70 will probably not provide much coverage at all for what they need by the time they get ready to use it.

I would tell you that the industry's own reports, the Health Insurance Association of America, recently reported that premiums increased dramatically when a life-time 5 percent compounded inflation feature is added. In terms of this being available through employers, I think that I pointed out that younger people have a lot of demands on their income.

Again, by the industry's own admissions, HIAA, he talks about the dramatic number of increase of policies being sold through employers. That was about 566 employers who offered that benefit last year and usually it is a choice between something in their current benefit and——

The CHAIRMAN. Ms. Briceland-Betts?

Ms. BRICELAND-BETTS. Yes,sir.

The CHAIRMAN. Would you let Senator Dole speak?

Ms. BRICELAND-BETTS. I am sorry. I was trying to finish my point, sir.

The CHAIRMAN. That is all right. We are giving all the time anybody wants.

Senator DOLE. I think I understand, but we are just trying to find some way to do it.

Ms. BRICELAND-BETTS. Right.

Senator DOLE. I know there are a lot of demands on incomes, but there are a lot of demands on the Federal Government and how we are going to raise the money and how we are going to pay for it.

You suggest there are 11 million people that need long-term care. That may be totally accurate. I do not know how many with the limitations, even in the President's bill, how long that would take to cover 11 million people. By then there would be 11 million more.

It just seems to me that if we are going to avoid the problem long after most of us are gone, there ought to be something in place now to encourage if we can. Maybe we cannot. It seems to me it is fairly important to somebody in their thirties and forties to start looking at when they are going to be in their seventies and eighties. Maybe not. Maybe it is something that they do not worry about and they think the government is going to take care of it.

But the government cannot take care of everything because we are having difficulty right now with the Federal budget. So I do not have any—I think the point I would make first of all, I think we

have recognized on this committee that there are certain needs that ought to be met.

As always the case on this committee, we try to be responsible in meeting those needs and try to make certain that when we do it, we are not going to leave a big, big problem for somebody who is maybe sitting here 10, 15, 20 years from now and say why did they do this. Why were they irresponsible?

So we are prepared to work with the Chairman and others, and obviously the witnesses, because I think we have had some excellent testimony and I appreciate it very much.

I do have some questions I might like to submit for the record. I do not want to take any more time.

The CHAIRMAN. By all means. Thank you, Senator Dole.

[The questions appear in the appendix.]

The CHAIRMAN. I have a very brief question. I do not know that it is necessarily even fair to ask our witnesses, but I would just like to pose it. Which is, it is not an accident, as we used to say at City College, that the administration has not appeared on this panel, did not wish to be seen here.

But the simple fact is that despite all the advance statements to the effect that the Medicaid formula was a very agreeable formula to Wilbur Mills of Arkansas when it was put in place in 1965, Joe Califano has said to us, and he now records Lyndon Johnson saying, "Wilbur, none of this money is going to go up north. It is all going to be taking care of those mamas and babies down our way."

And as you know, it not just compensates for the difference between the median income of different States but for the square of that median, of the two medians. So that if the median was 10 in the nation and Arkansas was 5, why, it would be 2 to 1, if you square it it is 4 to 1.

And almost the first thing I proposed when I got to this committee 17 years ago was to make it square root. You know, if you are going to put algebra in the Tax Code, why not put some of our algebra.

So it was with some dismay that when I got to page 1139, or whatever it was, of the President's bill, what did I find but that old double Medicaid formula, right there in the midst of having been told now we are going to treat everybody equally here.

And that means that on our committee there will be eight States in which the State match is 5 percent. And there will be three States in which the State match is 22 percent. And guess what Senators Bradley, Roth, and Moynihan get—78 percent. It just introduces the question, why did we do that? We are one country.

So I am going to ask our witnesses, and you do not have to answer, do you not think we ought to have a uniform State matching provision in long-term care?

Let us see, I guess we will ask Ms. Briceland-Betts, you are first. You do not have to answer. You can say you do not know.

Ms. BRICELAND-BETTS. I would point out that this is a very rich federal/State match and that most States would stand to save money by participating in this program.

The CHAIRMAN. Fair enough.

Mr. Ladd?

Mr. LADD. Well, Mr. Chairman, I am real glad you asked that.

The CHAIRMAN. I might as well look you up. Texas gets 92.18, sure enough.

Mr. LADD. That is right, Mr. Chairman. But the basic formula is unfair. The basic Medicaid formula really does not recognize it properly.

The CHAIRMAN. Stop right there. [Laughter.]

Stop right there.

Mr. LADD. I will skip that part and just answer your question. Even that is unfair, because Mississippi, for example, is at 83 and they can only go to 95. So they just pick up 12 percentage points, where other States can pick up the full 25. So anybody that is below the 60 mark or the 70 mark is treated unfairly in this, in the Clinton formula.

The CHAIRMAN. I just think it complicates.

Let us see, Dr. McConnell?

Dr. MCCONNELL. I think my understanding is the administration did not pay a lot of attention to that. They simply sweetened the Medicaid match and now I suspect they are paying a lot of attention to it.

The CHAIRMAN. No. No, they are just not showing up. [Laughter.]

Mr. Wallack, you probably have not thought much about this matter.

Mr. WALLACK. I will pass. I will pass on this one, I think.

The CHAIRMAN. That is prudent. Thank you all very much.

Senator Packwood?

Senator PACKWOOD. Ms. Briceland-Betts, if we do not do anything on long-term care but we otherwise have a decent reform bill, will your group oppose it?

Ms. BRICELAND-BETTS. I think it would be very hard for most of the groups that I represent to mobilize any effort behind a reform bill that did not address this issue, yes, sir.

Senator PACKWOOD. Even if it was otherwise a good reform bill?

Ms. BRICELAND-BETTS. I think it would be very hard for groups to mobilize, because public support is so strong in favor of addressing this issue. You have to realize that these decisions are not just made nationally, it is the membership. And the membership of these national groups want to see something done to help their families.

Senator PACKWOOD. I know you made the argument that this would save money in the long run, but unfortunately that is an argument we hear from almost every group about everything that we might either spend money on or give tax exemptions for, that in the long run it will save us money.

Ms. BRICELAND-BETTS. We know this is not new money, Senator.

Senator PACKWOOD. I understand that.

Ms. BRICELAND-BETTS. Families have this coming out of their pockets already. They are paying it in a very inequitable way. What they want is to be able to put something into a pot that if that unlucky thing happens to them they can be able to draw on that.

Senator PACKWOOD. When I say us, I mean it is going to save the Federal Government in the long run.

Ms. BRICELAND-BETTS. Well, I think if we do not address it now, we are going to see some cost shifting. We are going to see things

labeled long-term care that have not been labeled long-term care before. You know, we need to address it or we are going to spend that money anyway.

We are going to see people in emergency rooms because they are not getting appropriate care when and where they need it and we are going to see some exhausted care givers who are not able to care for themselves. So I really believe that if we do not address this issue going in, that we are going to spend more money on long-term care in the long run.

Senator PACKWOOD. I know about your redefinition.

Mr. Chairman, what was that program we had that Senator Long started, where we would give money to local governments? I want to say for sort of a social service program. And pretty soon highways will become——

The CHAIRMAN. Title 20.

Senator PACKWOOD. Highways were becoming social service.

The CHAIRMAN. Well, you had to get to the hospital.

Senator PACKWOOD. They reclassified everything they could conceivably think of until we put a cap on the program or it would have exploded beyond belief.

The CHAIRMAN. Mississippi was building highways.

Senator PACKWOOD. Mr. Wallack, what kind of a long-term care insurance policy can you buy for $45 or $50 a month at age 65?

Mr. WALLACK. Well, I was referring there, if I was not clear, I apologize, I was really—when I mentioned that $35 or $45, I was really equating that to sort of a program that provided about $800 in home care benefits per month. So that was the home care only policy which, in fact, is available.

Senator PACKWOOD. All right.

Mr. WALLACK. It depends on the age. As you said before, and as other people I think recognize here, the age at which you buy a policy is terribly important.

Senator PACKWOOD. But my hunch is that when Ms. Briceland-Betts said an average person at 65 cannot afford it, they probably cannot afford life insurance either if you do not start buying it until you are 65. My hunch is the premium is pretty high for most people.

But do you sell policies that you can start to buy at age 65?

Mr. WALLACK. I am sorry, I do not sell policies.

Senator PACKWOOD. No, I know you do not sell policies.

Mr. WALLACK. I actually do a lot of looking at sort of the potential and the pricing. There are policies that are sold from very young ages, starting at age 20 or something when you go through the employer market up into the nineties. And, in fact, different companies sell for different ages, and the policies really start—they are usually priced at the age of entry if it is an individual policy. Most policies are really individual policies still even though they are sold through a group.

So the price is very tremendously based on the age at which you start to purchase the policy and, therefore, it is terribly advantageous to purchase it before, you know, certainly as we were talking before, before 75 or 80 when the curve really starts to rise.

Senator PACKWOOD. Just give me a rough idea. What can I buy at age 65 that would insure me? I thought her point about the 5

percent premium or the 5 percent inflation factor adds immensely to the premium, but costs escalate on that basis.

Dr. MCCONNELL. Senator, if you do not mind, I have a chart here that is prepared by the Health Insurance Association of America that answers your question.

Senator PACKWOOD. Good.

Dr. MCCONNELL. At age 65 for a base plan, it would be $983 a year. Now that does not——

Senator PACKWOOD. What does that give you?

Dr. MCCONNELL. Well, it does not give you inflation protection.

Senator PACKWOOD. I understand that.

Dr. MCCONNELL. So you are probably not going to need it for another 15, 20 years. That means it is going to be worth a lot less. I think that has generally been about $100 a day for nursing home coverage and usually half of that for home care coverage. I think that is a fairly typical plan.

Senator PACKWOOD. So on that basis, without inflation, you buy it age 65 now for roughly $1,000 a year, you can get about a $3,000 a month policy. It pays about $3,000 a month for nursing home care.

Dr. MCCONNELL. That is close. Now, if you add inflation protection and nonforfeiture, it goes from $983 a year to $2,228 a year. The problem is, as you——

Senator PACKWOOD. Nonforfeiture meaning what?

Dr. MCCONNELL. Meaning that if you have been paying in your benefits and you stop paying say at age 70, if a policy does not have nonforfeiture protection, you have nothing, unlike a life policy that accumulates some value.

So what the insurance industry is doing is taking the money that they save from not having to pay you benefits because you discontinued and they are giving them to people who continue to pay their policy.

Senator PACKWOOD. Was that policy at age 65 or 70?

Dr. MCCONNELL. At age 65. Now, if you go to age 79—the typical age I think now is age 67 for purchasing the policies. But if you go to age 79 with inflation protection and nonforfeiture protection, it is $7,200.

Senator PACKWOOD. A year.

Dr. MCCONNELL. Well, when you add those provisions, which improve the policies, it more than doubles the costs.

Senator PACKWOOD. I realize that $7,000 a year is beyond most people, although it is a rational price if you are age 79 and if you are getting an inflation factor, if you can afford it. That is not a bad price, if you can afford it. If you cannot afford it, it is a moot point.

Mr. WALLACK. Can I just make one note, which is one of the things that bothers me. I do not any insurance policy, I do not know anybody who would insure for inflation. And it does not make an awful lot of sense to pre-fund inflation.

In fact, I would not do that. I would much rather put my money in a savings account or bonds or something. Find me a good investment. But you do much better by, in fact, you know, putting your money somewhere else and then getting the more money and then buying a few—put more money into insurance later.

One of the key points, I think, is do we want to price this product out of the market. You can. And I think a lot of people want to do that. I do not think putting inflation in and mandating it makes an awful lot of sense.

I also think—and this is, I know, a very important issue to Senator Pryor—is this whole issue of nonforfeiture. A lot of people who want insurance do not want to basically build up accumulation. They want insurance.

To mandate that, in fact, raises the price of the policy. And you have to have a debate between real consumer choice out there and protection. So I would be very careful if we start to talk—if we needed all these things on. You can make this a real Christmas tree and put it out of the reach of almost everybody.

Senator PACKWOOD. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Packwood.

Senator Chafee?

Senator CHAFEE. Thank you, Mr. Chairman. This is a subject I am greatly interested in. I was a co—sponsor of Senator Packwood and Senator Dole's bill in 1991 and prior to that Senator Mitchell had a bill in that I was a co-sponsor of.

Let me just say that these situations are so tragic. Particularly the situation that Senator Pryor was talking about, where the individual had to lose her home because she is, I presume, unable to pay the mortgage on it. Perhaps the taxes. And so it ends up that her husband whom she has been caring for goes into a nursing home paid for by Medicaid, which is much more expensive than should she be able to keep him at home.

I think Mr. Ladd or Dr. McConnell, said that it is 25 percent, the cost to care for somebody at home as it is to have the individual——

The CHAIRMAN. Mr. Ladd said that, did you not?

Mr. LADD. Yes.

Senator CHAFEE. Mr. Ladd said that—to have the individual in a nursing home. So you get into these challenges of paying for that individual. And, indeed, maybe in some instances it would be paying the person's mortgage off so that you would save the money by not having the person in the nursing home.

But then, of course, from that you get all kinds of follow-ons and people could game the system. I really find it shocking, and I have discovered, that there are lawyers and reputable lawyers, who spend their time telling their clients how they can dispose of their assets to their children so that individual will become eligible for Medicaid and thus nobody will have to pay for them.

I mean, this is fraud. And yet it is going on to a far greater extent than I ever previously imagined. So if we have the situation such as Senator Pryor was describing in which it makes common sense. Let us use Medicaid, pay off this person's mortgage, and thus she can stay in the home. Thus, she can look after her husband and within 2 years we will save a lot of money.

Well, that makes sense. The trouble is, somebody down the road will hear about it and regrettably game the system to some extent. So I end up in a quandary in this.

Let me ask a question of the panel. Are there any studies done on the efficacy of non-medical services helping to keep people well and out of—and I am talking elderly—nursing homes?

Well, Mr. Ladd said, this is not a medical problem. You had another term. You said it was a structural problem or something.

Mr. LADD. Functional problem.

Senator CHAFEE. Functional. I am not sure what that means.

The CHAIRMAN. Function.

Senator CHAFEE. But anyway, it is not a medical problem. I understand that part of it.

We have quite active senior centers in our urban State. Ours is a very urban State. Kansas maybe could not do it, but in an urban State you can have these senior centers where they can care for people every day. We have Meals-on-Wheels.

Now are there any studies that have indicated that these really pay for themselves because in the senior center when somebody does not show up, then the person who runs the senior center is aware there is a little problem at home for the individual. He might be living in a senior housing. And there that senior center or an assistant goes out and checks on the person.

Now all this is much less expensive than having the individual in a nursing home on Medicaid. Have there been any studies that show, indeed, this is true? This might be apocryphal for all I know.

Mr. LADD. Senator Chafee, I do not know if there have been studies, and perhaps the panel members can talk to that. But having been an Aging Director for about 12 years, I can tell you what you said is absolutely true. It does happen. That without reaching—with working with people through home delivered meals, just making a visit to check on people, you know, socialization, telephone calls, friendly visiting, all that stuff works and keeps the prices down.

Senator CHAFEE. I would just say that in our modern society because of the mobility of our population we, indeed, do have many people who have children, but their children have moved away and their spouses died and that person is truly alone.

I believe there is a great connection between physical condition and mental health and vice versa. So, thus, if these people can have some sense of belonging or know that somebody is caring for them, the chances of them remaining physically healthy is far greater. But if somebody asked me to prove that, I could not, except as Yogi Berra said, you can see a lot by looking, and I have seen it.

Dr. MCCONNELL. Well, there is evidence that care givers, because of the stress on them, develop physical ailments. So that leads to costs in the acute care system. There is evidence that answers your question in part from the on-lock program, which this committee is familiar with out in San Francisco. It is being replicated in a number of States.

What they have found is that through home community—based care they are able to reduce hospitalizations substantially so there are savings. I think we have to be careful about pretending, as Senator Dole said, that we are going to save enough money to offset the costs of this program.

I mean, this is going to be new Federal expenditures. But what we have to look at is that the long-term care system that we have in this country now is families and it is beginning to come apart. More women are working. They are typically the care givers. The stress on care givers, the aging on care givers. The average age is close to 60 of the care givers themselves.

So we may not want to spend the money, but that system of long-term care that is out there based on families is beginning to come apart and it is going to cost some place.

Mr. WALLACK. There are some studies, Senator Chafee, that would support your perspective, looking around in terms of what leads people to be institutionalized and be in nursing homes. One of the best protectors is, are you living with family. If you are married and you have a spouse there, there is a much lower chance you are going to go into a nurse home.

If, in fact, you have other kinds of income, there is a lower chance you are going to go into a nursing home. So I think the alternatives—it is both emotion and it is financial—can really create that. And I think a program, any program we develop, should develop the opportunity to provide a continuum of services.

The home and community and the nursing home care, to allow that kind of potential to happen, because I do believe if we would manage this in the appropriate way, we will have at least people appropriately placed and I think we will over time reduce it, nursing home use.

Senator CHAFEE. Could I just ask one question?

The CHAIRMAN. Of course you can.

Senator CHAFEE. This is of the panel. Do you believe that we, by legislation, have made the requirements for the nursing homes too onerous, if you would, for the type of the care of the patients that are in there?

In other words, is there enough differentiation between that section of the nursing home that should have an RN on duty 24 hours a day versus the section of the nursing home where indeed medical care is not the primary concern. It is as Mr. Ladd said, a functional situation, they are living there. Have we overdone it here in so-called nursing home reform?

Mr. LADD. Mr. Chairman and Senator Chafee, I think that—and I am going to get in trouble with a lot of advocates—but I think that is absolutely true. Nursing homes today, next to nuclear power plants, are probably the most regulated industry in the United States.

It has all been in our chase for safety. You know, it is a funny thing about us. We want all our loved ones to be safe. We are willing to take risk ourselves, but we want loved ones to be safe.

We are not willing for people, old people, to take risk. I see it in my own family. My wife's mother is in her mid-80's. She lives 3,000 miles away. My wife worries constantly about her and she wants to put her in a nursing home where she will be safe.

Now my wife's mother, you know, she has made it abundantly clear that is the last place she ever wants to go. But I see her bending to the family and it is not because my wife has got a problem with her mother. She loves her mother, but she cannot stand

to think about her mother falling and not being able to get up or being hurt and she is 3,000 miles away from her now.

We tried to make that safety thing on nursing facilities to the point that nursing facilities today probably cost us about twice as much as they ought to because of all the laws and regulations, both Federal and State, that have been put on this industry that really restrict what they are able to do.

We have a new model called assisted living and it is used in some States as a nursing home replacement. It is able to come in at around 80 percent of nursing home costs on the average. Oregon has got it. It is 61 percent of nursing home costs in Oregon. That includes your own private room, something you hardly ever see, except in the very high level nursing homes. Usually you share your room with three or four other people. I have seen as high as eight in a room in a nursing home. They must do that because——

Senator CHAFEE. Well, my time is up here. But I know when you say you may get in trouble with the advocates, I am sure you will.

But, Mr. Chairman, we are talking a part of the Medicaid program here that represents 61 percent of total Medicaid spending. As Senator Dole and others have pointed out, we have got the babyboomers coming along with this tremendous increase in the number of elderly. I think it behooves us to be pretty conscious of not only the general Treasury of the United States, but also the need to take care of these folks.

So I think at some time we ought to give another look at that.

The CHAIRMAN. I think that is very properly said.

Senator CHAFEE. Thank you.

The CHAIRMAN. Thank you, Senator Chafee.

Senator Conrad?

Senator CONRAD. Thank you, Mr. Chairman.

Mrs. Briceland-Betts, you testified you support a federally-funded long-term care program without means testing. My first question is, would you oppose any long-term care program that included means testing?

Ms. BRICELAND-BETTS. The groups in the campaign have worked hard for a number of years to look at the way to limit costs. They have dealt very realistically and honestly with he need to look at budget limitations and figure out that the best and most reasonable way to contain costs of a program and the groups I represent felt strongly that to contain costs and to limit access based on degree of disability was a much more appropriate way to control those costs than to means test.

Senator CONRAD. Can you tell me how we would explain to a low income middle-aged couple with children who are struggling to clothe them, to house them, to educate them, and to have some decent living standard who may be on an income of—it is not unusual at all in my State for people to have $18,000 income, why should they pay one penny to provide care to somebody earning a million dollars a year or with a net worth of $200 million? How can that possibly be justified?

Ms. BRICELAND-BETTS. I think the beauty of social insurance programs that we see with Social Security and Medicare is that people pay in and then they draw out as they have need, and that we see with programs that our means tested that the lack of public sup-

port is not there, that the programs are stigmatized, people report and studies show that people are afraid to access those programs because of the stigma attached. And, we tend to see a resistance to funding those programs because people do not feel like they are putting anything into a program that they are likely to get something back out of in return.

I think that one of the beauties of social insurance is that everybody pays and everybody benefits and no one gets left behind.

Senator DOLE. Senator Conrad, I think you have a good point. Part B Medicare is a good example. It is about $40 billion out of general revenues and we pay 75 percent of everybody's premium, whether they are millionaires or paupers, poverty. It does not make any sense to me. We ought to be able to save $20 billion just in that program.

Ms. BRICELAND-BETTS. The President's proposal, the numbers that you look at, that the administration has, shows that only 5 percent of the total benefits would go to people who are above 200 percent of poverty, a very small fraction.

Senator CONRAD. I understand that argument. Let me just say, I guess it resonated with me until we get into more and more of a budget crunch. And none of this adds up. I tell you, I think really we need a tremendous dose of reality.

A study just came out last week, done by two economists. I shared it with my colleagues in Virginia this weekend. It says that if we continue on the course we are on, the next generation is going to have an effective tax rate of 82 percent—82 percent. And that is because we have this huge babyboom generation coming along that are going to be on Social Security. They are going to have tremendous increases in health care costs unless we do reform the health care system.

We are just on a collision course with reality here. And it seems to me we are going to have to find a whole series of things that previously were unacceptable in terms of policy that we are going to have to do if we are going to have any chance of saving this country from what is clearly an unacceptable result.

I would ask other members of the panel—and again, you know, it is off in the future. And so we always do what brings us—we react to the pressure of the moment. That is politics—react to the pressure of the moment. There is almost no looking over the horizon and seeing what is coming.

And what is coming is a time bomb. We are going to see intergenerational conflict in this country that is stunning. In this study, you know what they said? One of the policy prescriptions to save the situation will be in the year 2,009 to cut Social Security and all Federal health care benefits in half—in half. There is nothing liberal or progressive about that.

I would just say, I hope we keep our eye on the ball here and recognize we have got to reform the health care system. We have to hold down the growth, the cost; and we are going to have to look in other areas as well because it did not all add up. It does not add up.

Ms. BRICELAND-BETTS. Senator Conrad, I would have to reply to that that ignoring it does not make it go away. And titling it gov-

ernment money versus what people pay out of pocket does not make it different money. It all comes out of their pocket.

And if the majority of the people in this country who are in long-term care problems could sit at this table and look at you today, they would say they would much rather address this paying a small amount at a time where they could collect on it when they needed it, than to have to try to figure out, as we have heard earlier today, how to sell the home or, you know, to go on Medicaid.

Those families would say to you that their tax dollars are not any different than the dollars that they are trying to scrape up to pay, you know, for these services—$20,000 is $20,000 and they just do not have it.

Senator CONRAD. Let me just say to you, I think that you are correct in that we have to find a way to get a small amount of people over a longer period of time rather than wind up with a program in which the government is expected to bail out the whole situation late in the game.

That is a policy prescription that simply does not work and I think the underlying strategy of doing a little bit at a time helps you get ready for the time when some percentage of us need the assistance. Yes?

Dr. MCCONNELL. Senator, I agree with that. I think those of us that have been working on this issue for years feels that is, in fact, what the President's plan does. We have been pushing for social insurance for nursing home care and full home and community-based care. This is a step. This is not the whole thing.

It also recognizes the point that you are making, that wealthy people should pay more. And, in fact, people will pay up to 25 percent of the cost based on their income, which is a much more sensible way to means test. Because if you take your example of a person earning $18,000, what if they were just over the line that qualified them for a means tested program. With that kind of an income they are not going to be able to afford private insurance, they are going to be unprotected.

It is much better to cover everybody and then ask people with more money to pay more. It is a much more sensible way to do it. I think that is the point you are making and I would agree with that, Senator.

The CHAIRMAN. Thank you, Senator Conrad.

Senator Pryor?

Senator PRYOR. Mr. Chairman, thank you. It is 15 minutes until 12:00 and we have another distinguished panel.

The CHAIRMAN. We do indeed.

Senator PRYOR. And this panel has been absolutely excellent. They are so good I am not even going to ask a question. But I am going to follow along with a few written questions if I might, Mr. Chairman.

The CHAIRMAN. Good.

Senator PRYOR. If our panelists would agree to accept those and to respond.

The CHAIRMAN. I wish you would and I thank you, Senator Pryor.

[The questions appear in the appendix.]

The CHAIRMAN. Senator Durenberger?

Senator DURENBERGER. Mr. Chairman, I was fortunate along with Dave Pryor and Jay and a couple of others to serve on what was called the Pepper Commission. By at least those of us who were on it, it will be remembered as the Rockefeller Commission. At that time, we could not make up our minds whether the biggest problem in the country was long-term care or acute care.

And actually, I think we switched from long-term care to the uninsured as a sort of a political buzz word sometime right after the Pepper Commission concluded its work. We went in with long-term care being the big concern; came out with the uninsured. I am here to say that they are both as important today as they were then.

And also to suggest that there is a common solution, one which people on this committee share and which we share as far as I can tell with both the President and Mrs. Clinton in its resolution. It is very difficult to see it sometimes, because in the way in which the administration's plan is presented it seems to have a solution for practically every problem all wrapped up in one bill in one time frame and everyone said it is impossible to get there.

One of the values of serving on the Pepper Commission was we defined our terms. I think we began by defining what is long-term care. And then we defined a number of people who at any given time would be eligible and then we struggled with what are the kinds of services or what are the particular kinds of needs that define it and ended up with an 11 to 4 vote, which was a lot better vote than we had on the other half of the issue.

One of the things that I learned from that is to raise another question, which is why do we want the national government determining what kinds of health and medical services are most appropriate in every one of our cases. That is the heart of this issue and this concern.

The Federal Government today supplies 70 percent of the money for nursing home care. I mean, the decision is made here and in the bureaucracy's determining you are stuck in a nursing home. And I have said before, if my 87-year-old dad is left without a wife—I am just one of those lucky people with two living parents—bang, he is a $36,000 a year liability and it is a liability to him as well as to the Federal Treasury and the State Treasury.

But we are determining all these things right here. And the question is why. Why is that our business or why would you even trust the national government to decide what is best for your parent or for yourself or for a kid who is profoundly retarded or whatever the case may be?

I think that is the tough issue. All health care is local as far as I know. It is my mom and my dad and whoever is in their particular community and it is the same thing in every one of our communities. I think that is the thesis of Clinton's health reform—the use of accountable health plans which are local in nature, which compete with each other for informed consumers' choices, not on the basis so much of price as they compete today, but on the basis of service.

And as Dick has said, and others have implied, those services will differ from one community to the other and they will differ from one person to the other. And a national government cannot keep up with SHMOs and ON-LOK and assisted living and all the

creative things we could do in our local community if only the reimbursement system gave us a chance.

So what is the role of the Federal Government? The role of the Federal Government is to set some national standards and then to do equity. Take that Medicaid program and say it is not working. You know, we need to find a better way in tax policy and social insurance policy to make accountable health plans affordable for all Americans, so that they can add to what we call acute care benefits, chronic care services, long-term care services.

And then as Jay led us to believe in the Pepper Commission, we need to decide whether the job of the social insurance system is to pick up the first 18 months or the first 24 months and then leave for private insurance the catastrophic coverage or should the first 18 months or 24 months be decisions that we make in our families and with regard to our assets and insurance and leave catastrophic costs to the social insurance system.

Does anybody on the panel agree that that ought to be our goal and objective? We can wrestle with how to get there. But should that not be our goal and objective?

Mr. WALLACK. You mentioned two things which you know we have dealt with—social HMOs and UN-LOK over the years. I think one of the major first priorities of this committee must deal with Medicare and the reforms of Medicare into some of these chronic care issues, because clearly some of what we—when we talk about home care and nursing home care really belongs within that acute care system. It is part of that. It is the rehabilitation part.

I think that is very important to make sure we have a solid Medicare program. So I think that is certainly a very important thing with regards to what you are suggesting.

I guess the other point you were getting at was the one dealing with—two points is hard for me at this point.

Senator DURENBERGER. I think the catastrophic.

Mr. WALLACK. Oh, the catastrophic. I am sorry. Thank you, Senator.

It is a very interesting point actually because if what we say is when people have certain amounts of income, we can name all the prices of these plans—a $100 plan; a $50 plan; a $200 plan; a $400 plan. If you go out and ask what people are buying, they are buying plans for about $100, $125.

Well, that turns out to give you a lot of protection for maybe 3 years. It is the back end. And it is sort of what Senator Moynihan—the public/private partnership plan in New York looks like, where in fact it is done with Medicaid dollars and we can argue about that. But that is what says people are willing to give themselves that flexibility and choice. And, in fact, the back end is picked up in there through the Medicaid program.

So it makes sense with what people are purchasing. They make their choices. I think there is some logic, I guess, with regards to giving people choice and flexibility and what they are willing to pay in having the Federal Government come in.

This was Senator Mitchell, I guess, a number of years ago proposed and maybe others here, this sort of back end kind of program.

The CHAIRMAN. Mr. Wallack, I think that is not the end. I do not remember the second question, possibly the onset of early Alzheimer's or fatigue, because we do have another panel and we want to get to each.

Senator Rockefeller?

Senator ROCKEFELLER. Mr. Chairman, I thank you and I will not really ask questions. I would like to make two statements. One is Senator Dole and Senator Conrad raised an interesting and important point. But there is a big difference between means testing and income-related premiums. There is a big difference between that.

Means testing, in a sense, says that certain people are out based upon income. Income-related premiums try to make sure that people contribute on their ability to pay. I think Senator Dole's point on Part B is that we should make premiums income-related as opposed to means tested. I am not sure that is true, but there is a big difference between the two.

The CHAIRMAN. That is what he said.

Senator ROCKEFELLER. All right. My comment is this, that under the Clinton plan, the way it appears here, there will be about 3 million people who need long-term care in this country who will benefit. And my guess is, if you went down to one ADL, you would get up to 20 to 22 million—I have no idea—people.

There are fewer people who could be helped by what Clinton is suggesting than there are, for example, people who have Alzheimer's in this country alone, forget every other problem. And what strikes me as disturbing in this talk, Mr. Chairman, about long-term care is that when we get to the subject of long-term care, yes, the President's program does include long-term care, prescription drugs; and, yes, John Chafee cares desperately about long-term care. He just said so and it is true.

I think it would have been in his bill had he felt that it would not have cost him support of his side. I believe that. That it would have been in his bill. He does not have to respond to that. But I believe he would want it in his bill but he felt he would not have gotten the support. But it is not in his bill.

It is not in John Breaux's bill at all. What strikes me as disturbing is that all of a sudden we get to long-term care and you are talking about living human beings going through absolute, sheer agony. I have had many conversations with myself and the public about what it means to die from Alzheimers, that we start talking about babyboomers and all of a sudden we start talking about responsibility to the next generation.

It is long-term care and immediately we start talking about that and that it is too expensive. Yet, these are people. In some cases you are not even talking about health care, you are just talking about care. You are talking about living tragedies being acted out on the American scene in terms of long-term care. We have not even gotten to prescription drugs.

We are only doing a tiny part of it, a minute part of it in the Clinton plan. Home and community-based care. Home care is a third as expensive as hospital care. And EBRE or somebody comes along and tells us——

The CHAIRMAN. That is hospital care or nursing?

Senator ROCKEFELLER. It is hospital care. Well, probably more for hospital than for nursing. I mean, in West Virginia the average nursing home is $35,000. In Los Angeles, was is it, $100,000?

Dr. MCCONNELL. Probably $70,000.

Senator ROCKEFELLER. $70,000.

Dr. MCCONNELL. New York is pushing $80,000.

Senator ROCKEFELLER. I mean, it is highly cost effective; it is highly psychologically important. It is what people want. We are talking about only doing a tiny portion of it. Then all of a sudden we jump to, "We cannot afford it," and babyboomers and costs.

It almost is discrimination. I mean, it is almost like that of aging or long-term care. Of course, 40 percent of long-term care needs are for people who are younger than 65 years old. All of a sudden it is peripheral.

I mean, if you are talking about health care, that is important. But if you are talking about long-term care, that is not as important. I really get that sense from having heard what I have heard particularly from—not from you all—but from around the table.

Of course money counts and of course Medicare is in terrific trouble. But the President's plan, I think we have to put it on the record, is the only plan that does something about long-term care, the others do not. They do not. The President's does.

If we are going to get health care passed and we do not have any long-term care in it, I think Ms. Briceland-Betts is not being extravagant when she says it would be hard to mobilize. I think it would be incredibly hard to mobilize.

So is there a relationship between having long-term care and actually getting health care, as Bob Packwood mentioned a good health care bill passed at all. Can you do one without the other? I doubt it. And then I slightly resent, to be honest with you, the implication that long-term care means less than the American health care scene or the American care scene.

My mother died from Alzheimers and she was wealthy and so were her kids. So we could get her all the home health care she needed, but to get, Senator Moynihan, in New York City to get a nurse in the process of dying over six or 8 years, to get a nurse, one Alzheimers trained nurse is $50,000 a year. My mother was 5'10". She was a big, strong woman.

When Alzheimers patients start getting violent, they start hitting and they start throwing plates. They do not know they are doing it, but they do it. And you have to have two. You could not take my mother to the bathtub with one person. You could not do that. Or take her to the toilet with one person, you could not do that. There had to be two. So that is $100,000. That is one eight—hour shift. And Alzheimers is 24-hours a day. Start doing the math.

It is a horrible way to die and we are doing less than just Alzheimers, the numbers of Alzheimers patients in this country. It is sort of a cliche, you should not have to be a Rockefeller to take care of your mother or your father. How do these people do it? They go broke. Families break up. The family structure is breaking down anyway. Do you want to break down family structure? You put Alzheimers into that family and watch generations—three generations—break down financially, psychologically—trying to give care to that person.

Now that is personal and emotional. I understand all of that. But long-term care is not peripheral. Long term care is fundamental in health care and what we are proposing in this is cost saving and it is as much health care as anything else and it ought to be in there.

The CHAIRMAN. We thank you very much, Senator Rockefeller.

Now, Senator Hatch.

Senator HATCH. Thank you, Mr. Chairman. I will just ask one short question. I understand in Japan long-term care costs are quite minimal in relation to their overall spending on health care. This relates somewhat to Senator Rockefeller's statement. I wish there were the money to do everything we can for long-term care, as the distinguished Senator does.

But as I understand it, the reason why long-term care costs are down in Japan is because of the value they place on the family as well as their culture which embraces the concept of family unity. When a family member, young or old, requires long-term care, that individual is usually taken into the home and looked after by other family members.

And while medical services are provided by trained medical providers, significant cost savings are achieved by taking the individual out of the nursing home environment, or hospital, and the care is administered at home.

Now, are there any lessons we can learn from Japan? You know I am an advocate for home health care. I really believe it is the least expensive, the most efficient and, frankly, the most caring form of long-term care. And yet I recognize that there are situations where we have to, as a society, take care of people who cannot be taken care of in the home.

That is all I will ask.

Dr. MCCONNELL. Two responses to that, Senator. One, I think that is what we are talking about, propping up the family, providing some respite, some help. Not replacing the family but supporting it so it can continue to provide care.

And the second is to learn, in fact, from what is happening in Japan. With low birth rates married couples, for example, have two sets of parents to care for in old age. That is four parents they have to take care of. You know what the price of real estate is in Japan. Getting housing that is big enough to contain those parents the entire family is becoming a serious problem. They are now confronting enormous problems because of the changing demographics, which is exactly what we are facing in this country.

I think if we can provide some minimal supports for families to continue doing what they do best, there is no question it is better care and it is less expensive.

Ms. BRICELAND-BETTS. I would like to make a follow-up point, just to kind of defend the American family just a little bit here. You know, 84 percent of all long-term care that is given in this country is given by family members.

This morning when I was getting dressed to come to the hearing I looked at my two-year-old daughter and I toyed with the idea of bringing her in and sitting here on the witness table and calling her Exhibit A, and saying to you, you know, the majority of care given in this country is given by spouses and daughters and daugh-

ters-in-law. And I would like to be able to know that we have helped develop a system that would support my daughter and support the families who are out there and to help us to be able to continue.

I think that we said a number of times that we have a family-based system here and we do not want to replace that. We want to support it.

Senator HATCH. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hatch.

May I thank this panel. We have kept you a long morning. You obviously are hugely informed on the subject that is central to so much of our consideration. We do very much appreciate you.

While our other panel is gathering, could I make a point here that on this whole long-term care we have to watch our birth rate, by which I mean pay attention to. The United States is now below replacement level, is it not? I think it is.

Jay, you indicate?

Senator ROCKEFELLER. Yes, 1.9.

The CHAIRMAN. 1.9. In Japan that most permissive of societies they do not allow the pill to be sold because they are down to about 1.5. They have concluded that the pill has not been proven pharmaceutically or whatever.

But all populations of modern societies that do not reproduce themselves are going to have that imbalance and in great numbers.

Now, let us see who is coming forward. I see Dr. Sanders. We welcome you, Dr. Sanders. Dr. Wagner. John Rother, a familiar, friendly face. Mr. Rudnick. We are looking for Dr. Schondelmeyer. There is Dr. Schondelmeyer. Very well.

We welcome our panel. Here we go just past the midday. We assure you that we will be done by 1:00. We appreciate your patience in waiting and I will ask now, John Rother, you are first, representing the American Association of Retired Persons.

This is essentially a panel on the provision of prescription drugs in the President's proposal, and as a general subject of health care.

STATEMENT OF JOHN ROTHER, DIRECTOR, LEGISLATION AND PUBLIC POLICY DIVISION, AMERICAN ASSOCIATION OF RETIRED PERSONS, WASHINGTON, DC

Mr. ROTHER. Good morning, Mr. Chairman. Thank you and other members of the Finance Committee. My name is John Rother with AARP. I am going to speak today to prescription drugs. We have also submitted testimony on long-term care as a separate item.

The CHAIRMAN. Which will be placed in the record.

Mr. ROTHER. Thank you.

[The prepared statement of Mr. Rother appears in the appendix.]

Mr. ROTHER. Today about 70 million Americans have no coverage at all for the cost of prescription drugs. About 16 million of those are over 65. This clearly compromises their health status, makes them more likely to receive unnecessary and more expensive care and it is also, of course, a financial, in some cases a considerable financial risk to the family.

The problem is probably most severe for older Americans as the combined effect of high prices, heavy utilization and the absence of

affordable private insurance coverage for prescription drugs has substantially reduced their access to needed drug therapies.

In this regard, AARP is quite pleased that the President's proposal includes a prescription drug benefit for all Americans—those under 65 as well as those over 65—and addresses the special needs of older Americans by expanding the Medicare program to cover outpatient prescription drugs.

The basic elements of a Medicare prescription drug benefit must include in our view guaranteed access to needed drug therapies, effective cost containment, stable and equitable financing, a parallel benefit structure for those of all ages, protection for low income beneficiaries and provisions that encourage appropriate prescribing, monitoring and use of medications.

I will only have time today to touch on the first two—access and cost containment.

The CHAIRMAN. Mr. Rother?

Mr. ROTHER. Yes.

The CHAIRMAN. Can I just ask, because it does not quite say, are these your signs?

Mr. ROTHER. Yes, they are.

The CHAIRMAN. All right. Fine.

Mr. ROTHER. I will refer to them in a second. In fact, the first—I am not sure really which one is which—but in the first one, the key point here is that prescription drug coverage today does decline rapidly with age. That is a function of the loss of employment-related insurance. It is also a function of affordability. As people get older and their need for the coverage goes up, their ability to obtain that coverage goes down.

A recent survey that we conducted found that 58 percent of older Americans said that they had a problem paying for their prescriptions. Over half of those said it was a major problem. About 10 percent of those over 65 said they had to cut back on necessary items, such as food and heating fuel to afford their medications. So it is a substantial problem, precisely for those people who would have the most benefit from taking medications in an appropriate way today.

Now I know that there are many proposals, unlike the President's plan, that would tie prescription drug coverage to enrollment in some kind of managed health care plan. And AARP has long supported the same kinds of options for Medicare beneficiaries to enroll in managed health care as for everyone else.

However, we do object to proposals that would tie or condition prescription drug coverage to enrollment in managed care because this really unfairly penalizes beneficiaries who for good reason want to remain in a fee—for-service environment.

Many Medicare beneficiaries, particularly in rural areas, simply do not have access to managed care plans. I believe there are today eight States in which there are no HMOs that will enroll Medicare beneficiaries. So if we tie a drug benefit to enrollment in an HMO, we are excluding many people from that option entirely.

The CHAIRMAN. Do you want to say that once more?

Mr. ROTHER. Today there are eight States where there is no HMO that will enroll a Medicare beneficiary. Today. So, I mean, we have a problem today. It is partly a function of the——

The CHAIRMAN. Give us those when you get a chance.

Mr. ROTHER. I would be happy to furnish that to you, of course.

[The information appears in the appendix.]

Mr. ROTHER. For many other Medicare beneficiaries where managed care is available they have a long time relationship already established with a physician and it is extremely important at this age often to maintain that continuity. It is certainly better quality care to maintain that continuity. So we do not want to do anything that is going to impair that.

On the issue of cost containment we believe strongly that effective cost containment is an essential part of this. Our experience in that comes from the very painful repeal of the Medicare Catastrophic Coverage Act, which we believe was in part due to the lack of cost containment with respect to the prescription drug component of that program.

It was the ever escalating estimates of that cost that really started to undermine the public as well as the Congressional confidence in the financing of that program.

We believe that the administration's proposal provides effective and reasonable way to control these costs. Given the enormous purchasing power of the Medicare program, we believe Medicare should receive discounts comparable to those that manufacturers currently provide to other major purchases. So we think the 17 percent rebate is an appropriate level and comparable to what is now given to other large purchases of prescription drugs.

Given the fact that prescription drug prices in the U.S. have increased at nearly three times the rate of inflation over the past 12 years, we believe that the inflation rebate proposed by the President is necessary to restrain the excessive price increases that would otherwise, I believe, occur in the future.

One last comment, Mr. Chairman.

The CHAIRMAN. Please.

Mr. ROTHER. That is that there are many ways to address the issue of cost containment in prescription drugs, as there are many ways of addressing the issue broadly.

I think that while we believe the President's proposal employs a reasonable approach to cost containment, other cost containment mechanisms may be effective as well. We know that there are some in the pharmaceutical industry who are proposing some alternatives. We are very interested in looking at those. We have not seen them costed out.

I think the bottom line effectiveness is the key question. But along with the cost projections I think we also have to make sure that we are maintaining the accessibility and the ability to provide counseling and drug utilization review that is an essential part of any good prescription drug benefit.

So we are still talking to those in the industry and we are open at this point to counter proposals that would achieve the same results that the President has already specified how to achieve in his legislation.

Thank you very much.

The CHAIRMAN. Thank you, sir.

Now, Dr. Seth Rudnick, who is the Chairman of the Board of CytoTherapeutics, which must be cell related matters and I believe Senator Chafee would like to introduce Dr. Rudnick.

Senator CHAFEE. Yes, thank you very much, Mr. Chairman.

I just want to introduce to the committee Dr. Seth Rudnick, who is a graduate of the University of Pennsylvania and received his M.D. from the University of Virginia. Previously, he was with the Pharmaceutical Research Division of Johnson & Johnson and is now Chairman, President and CEO and also a Director of CytoTherapeutics which is located in Providence, Rhode Island.

It is so splendid that Dr. Rudnick is here because this gives an idea of what we are talking about when we are talking about biotech companies. The total employment in his company is 95. It is not some giant that is located somewhere dominating the industry, but it is a small company—he can correct me on this—but as I visited and had the chance to tour the facility, they know they may need to invest $700 million before they will sell their first product.

Am I correct in those statistics?

Dr. RUDNICK. Across all the products that we are developing, you are correct, sir. So it is the essence of venture capital in this country, not a nickel back before they invest $700 million. So when we talk about—I see these charts here and the suggestion is that when there is a marketing and advertising and somehow that is bad, I will tell you, these companies are scrambling to get the money to develop the products that they are trying to develop which deal with Alzheimers and other neurological diseases.

I just feel very, very fortunate that Dr. Rudnick and his company are in our State. I just hope they find the cure, both to help relieve the suffering that is taking place and that they will flourish and grow, and make a profit.

The CHAIRMAN. And make a profit. And with that jubilant note, we welcome you, Dr. Rudnick.

STATEMENT OF SETH A. RUDNICK, M.D., CHAIRMAN OF THE BOARD AND CHIEF EXECUTIVE OFFICER, CYTOTHERAPEUTICS, PROVIDENCE, RI

Dr. RUDNICK. Thank you, Senator Chafee. My name is Seth Rudnick and my company CytoTherapeutics has a product which holds out hope for millions of Americans—hope to stop Alzheimers Disease literally in its tracks.

Mr. Chairman, members of the committee, to get this product to patients I need your help. To me, health care reform should be synonymous with developing new medical therapies. Right now I often see it moving in almost the opposite direction.

Let me make three points about that, if I can. First, as a physician, the discovery and development of new medicines is both a medical and a moral imperative. We must do it.

Second, the risks in developing any one of these projects are astronomical. And, in fact, almost every one we undertake will fail.

And third, the threat of price controls, real or perceived, has already harmed our industry immensely and slowed the race for cures in a number of companies.

Let me try and illustrate this to you from the perspective of CytoTherapeutics. My firm was founded in 1989 in Providence. We focused the research of our company on neurologic disorders, on pain control, on ALS, on Parkinson's Disease and on Alzheimer's Disease.

You know about Alzheimer's Disease. You have heard about it today. More than 4 million people are afflicted with this disorder in the United States.

The CHAIRMAN. We do know about it, it was discovered by Aley Alzheimer, a German physician, in 1906.

Dr. RUDNICK. Right. Thank you, sir.

The absolute number of suffers will probably double in the United States over the next 30 years. So everything that Senator Pryor commented on——

The CHAIRMAN. That is a function of age distribution.

Dr. RUDNICK. It is indeed. Everything that Senator Pryor commented upon earlier will become ever more prevalent.

We at CytoTherapeutics are investigating a literally one-time treatment that we believe will attempt to defeat this scourge. Today my firm has a little bit over $30 million in cash. It is not enough to even run for 3 years. And as you heard from Senator Chafee, it certainly is only a very small fraction of what we will need to take any of these products to market.

A few years ago this state of funding would have been absolutely fine, because as we were successful and progressed, more money would have been available and that would have been appropriate. And yet today my company, and many others in my industry, face very grave problems in raising the necessary funds to move forward.

Problems that some of the health care proposals have actually created. Problems that exist because the investment community has concluded that the price controls, whether real or perceived, in many of the pending health care reform proposals are simply too great to justify the value of these companies.

Let me give you an example of how this is affecting CTI. In 1992 we went to the public markets. We wanted to raise money to fund our research programs. I should comment that over 70 percent of the funding of my company goes directly into research, not into the "overhead," parenthetically—I am overhead.

As the fear of price controls rose during 1993 we, indeed, needed to go back to the market. This time, despite being a public company, we had to raise private money. It is a very, very expensive way to raise money. Often done at a severe reduction in price.

What is the consequence of that? Less money means fewer research products, which means fewer drugs. We in the company have had to kill off several programs that were very promising simply because we could not afford to delay the more advanced programs. Why is that wrong?

What is wrong with the administration's treatment of new and breakthrough drugs? Finally, today I spend most of my time chasing after investors who are scared of perceived price controls. I would much rather spend most of my time tracking down cures for disease.

Mr. Chairman, when I opened up my remarks I told you about the hope that we offered, both as a company and as an industry to Alzheimer's patients. Who am I to make such a statement? In the past 15 years I have been partly responsible for the development of the two most successful biotechnology growths. I am absolutely convinced that this industry can address the issue of Alzheimers within the decade.

The CHAIRMAN. Within the decade?

Dr. RUDNICK. Within the decade. But only if you let us be successful.

Thank you very much for letting me make these remarks.

The CHAIRMAN. Do not stop. You have not even gotten your yellow light. Tell us more about what makes you think within the decade. Then we will see if Dr. Sanders agrees.

Dr. RUDNICK. I would hope that Dr. Sanders would agree that the overwhelming rate of medical progress is partly a consequence of what has been done in the Senate and the House for the last 20 years. We have growth factors. We have gene therapy. We have the ability to deliver these into the central nervous system, better understand the pathophysiology today of Alzheimers and Parkinsons and ALS than we even remotely thought possible a decade ago.

Yet money needs to be funneled into the companies to push these development programs. I cannot tell you that we at CTI will be the ones who succeed, but I can tell you that the odds are now in favor of someone succeeding. If you want true health care reform, if you want the drug that removes that patient from the nursing home, that takes that patient away from being a burden to their family, that is the drug that I think you insure will succeed technically and progress to the market.

The CHAIRMAN. Do you want to tell us where, in what range of work you are looking at Alzheimers? It is not gene therapy.

Dr. RUDNICK. Our company actually does molecularly alter cells.

The CHAIRMAN. CytoTherapeutics.

Dr. RUDNICK. CytoTherapeutics. It alters the cells, wraps them in a semi-permeable membrane that blocks recognition of the cells by the body. These are very small devices. They are implanted into the central nervous system and they, in fact, act like miniature pumps for years on end and in this case produce a particular growth factor that we are co—developing with Genentech.

Senator CHAFEE. Mr. Chairman, I would refer to you on the bottom of page 7 of Dr. Rudnick's testimony where he says, "First, biotechnology firms tend to be small." And as I pointed out, he has 95 employees. Then he says, "Of the 800 biotech firms in human health care, only 4 make a profit."

The point here is that he survives and he can keep going because people are out there willing to risk their money. They are risking their money not solely for altruistic reasons; they are risking it because they think they can make a return, which has never been considered immoral in this country.

The CHAIRMAN. Oh? [Laughter.]

The CHAIRMAN. You really do not know much about New York City, do you? [Laughter.]

The CHAIRMAN. That is very helpful. Could I just say, Dr. Rudnick, in our hearing last week this whole question of what is a breakthrough drug was discussed and to no very great satisfaction. It is not a definition that would sustain any careful inquiry and the FDA told us they do not know what a "breakthrough drug" is.

Dr. RUDNICK. I think there was a famous Supreme Court Justice that might help you though, sir. And I think that when you see one, you will recognize it.

[The prepared statement of Dr. Rudnick appears in the appendix.]

The CHAIRMAN. Right.

Well, Dr. Sanders, we welcome you, sir. Dr. Sanders is the Chairman of Glaxo, Inc., down at the Research Triangle in North Carolina, former head of the Masters General Hospital. We are very pleased to have you, sir.

STATEMENT OF CHARLES S. SANDERS, M.D., CHAIRMAN, GLAXO, INC., RESEARCH TRIANGLE PARK, NC

Dr. SANDERS. Thank you, Mr. Chairman. As you note, I am Charles Sanders and I am the Chairman of Glaxo, Inc., which is the second largest research-based pharmaceutical company in the United States. I agree entirely with Dr. Rudnick in terms of his hope and expectation for the future and the promise that research is going to bring.

As you know, I have been in health care all of my life and around medical research—first, as a cardiologist; later as a Professor of Medicine at Harvard; then as General Director of Massachusetts General; and now as a pharmaceutical company Chairman.

I am convinced based on my experience that America in many ways has the best health care system in the world for many people, but not for everybody. I am equally convinced that we have the opportunity to really make the system a lot better through health care reform. We have to address the issues relating to cost, relating to access, relating to insurance coverage, and at the same time, maintain quality in the system. Most importantly, we have to sustain innovation and the promise of finding new medicines for the diseases that afflict us.

My message to you is very straightforward. I hope that as we go through health care reform that we will be able to foster an environment that has already made the United States the biomedical research laboratory of the world. That is to the great credit of this Congress, through the years that we have fostered innovation at the National Institutes of Health and the seamless interface of support in the private sector to develop product space that has been developed in the basic research area.

Now through innovation we are going to achieve cost savings and we will enhance quality. The pharmaceutical industry depends upon research to find new products. Innovation is our life blood. What we find is what we are.

This past year Glaxo, for example, invested $1.3 billion in research and development. That is 16.7 percent of sales, which is about the average for the whole industry and this whole industry

invests about twice as much in R&D as any other industry in the United States.

We have had a number of successes. You have already pointed out one this morning in terms of the treatment of ulcers. There are others to treat high blood pressure and lower cholesterol and so it goes. There are examples of those in my written testimony.

But let us build as we embark upon health care reform, Mr. Chairman, upon what is good in the present system. This is a particularly appealing strategy because it uses the market forces which already are at work in reforming the health care system today. These forces have led to the lowest prescription drug price increases in the past 20 years and to lower introductory prices of new drugs as well.

But as you all know, there has been a significant shake-out in our industry, notably a loss of more than 30,000 jobs as the industry has restructured itself to deal with its changing marketplace.

We recognize that these changes are the inevitable consequence of a harsh competitive marketplace. But I am very concerned that as we move into health care reform there are a couple of areas in the administration's proposal which will affect the economics of our industry as well as our ability to realize the promise of innovation.

The first of these, and the most troubling in many ways, is the anti-discounting provision that would prohibit the discounting of pharmaceuticals based solely on a buyer's leverage in the marketplace. In my estimation, it would undermine competition and we can go into that later in the Q&A if we wish.

Another is a proposed 17 percent rebate for Medicare. There is no question that we should provide prescription drug care for Medicare patients. But Price Waterhouse, for example, has done an independent study looking at the effective tax rate of our industry. And if we add on a 17 percent rebate our effective tax rate will go to 55 percent, which I would argue is inimicable to a robust R&D investment.

Now there are other proposals in the administration's bill that would threaten our ability to sustain the high risk R&D which is necessary for continued biomedical innovation. Of specific concern are the Advisory Committee on Breakthrough Drugs. I call it the anti—breakthrough committee, quite frankly and the HHS's Secretary, actually the Secretary's power to "black list" certain medicines for the Medicare population that the HHS Secretary deems are unreasonably prices.

Each provision in effect puts the government imprimatur on a specific pricing level. If we know as a pharmaceutical company that we are going into a high risk area wherein the Secretary or committee may determine in their wisdom that the product is unreasonably priced, we would have to think very carefully about whether or not we are going to undertake a high risk strategy. We would tend to adopt a low risk, relatively short-term strategy.

Let me give you one example. Twenty-2 years ago now, in 1972, Glaxo entered into a program investigating serotonin, a neurotransmitter that is ubiquitous in the brain. We did not have any idea of what serotonin did, but because it was there in such prevalence, we knew it was important.

So we went into a basic research program to determine what it did. Out of that program 18 years later came Zofran, which is a compound that effectively treats the nemesis associated with cancer chemotherapy. Now it is so effective that it has become the standard of treatment in the oncology centers around the country.

Today, if we were facing the prospect of a breakthrough drug committee and the power of the Secretary to blacklist the drug, I questioned whether we would take on that 18-year time horizon to bring a drug to the market. There are countless diseases out there whose cures remain to be found—Alzheimers being but one. You already have, I think, in the record examples of that.

But I would argue once again that if we are going to meet the needs of our society in dealing with the diseases whose needs are still unmet, we have to foster an environment here in R&D in this industry that really promotes innovation.

I would urge that as you go forward in health care reform that we deal with a market-based reform system and no price controls or highly regulated processes that will impede our innovative strengths.

Thank you very much.

The CHAIRMAN. Thank you, Dr. Sanders, most especially.

[The prepared statement of Dr. Sanders appears in the appendix.]

The CHAIRMAN. Stephen Schondelmeyer, a professor at the University of Minnesota College of Pharmacy, who will be introduced by Senator Pryor, if he would wish to do.

Senator PRYOR. Mr. Chairman, this is news to me. I am glad to introduce Dr. Schondelmeyer. I appreciate him coming. He is no—

The CHAIRMAN. Well, if you are glad to introduce him, introduce him.

Senator PRYOR. He is certainly no stranger to this committee and other committees in the Senate. I am honored to present him today. I think he was called by your very competent staff at short notice and he dropped everything to appear here today. I think he is probably one of the authorities in this whole country on the pricing system for prescription drugs. It has been a pleasure to work with him.

Mr. Chairman, I appreciate you allowing Dr. Schondelmeyer to testify.

The CHAIRMAN. Thank you.

Doctor, good morning, sir.

STATEMENT OF STEPHEN SCHONDELMEYER, PH.D., PROFESSOR AND DIRECTOR, PRIME INSTITUTE, COLLEGE OF PHARMACY, UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MN

Dr. SCHONDELMEYER. Good morning. Thank you, Mr. Chairman, for inviting me here. I just received the notice yesterday morning that I would be appearing on this panel and I was traveling at the time. I do apologize, but I did not have a chance, given that time frame, to prepare a written statement. I will submit a written statement within two weeks of the hearing.

The CHAIRMAN. It is very gracious of you to be here. You do not have to.

Dr. SCHONDELMEYER. I am pleased to do that.

I sincerely believe that pharmaceutical products and services are among the most cost-effective therapies we have in our health care system today.

Pharmaceuticals and their related services contribute to the health of our Nation and to the health of our Nation's elderly in particular.

Our elderly, are especially sensitive to the price of pharmaceuticals because they tend to have greater need for medications. They tend to have to pay for their medications out of pocket, and the process and system through which they pay for those medications results in them paying the highest price in the market.

It is difficult for me to totally accept the notion that our pharmaceutical market is becoming more competitive and that price sensitive buyers can get a better price. I do not think there is anybody in our Nation who is more price sensitive in purchasing prescriptions than an elderly person on a fixed income, particularly if they have one or two chronic medications that may cost anywhere from $600 to $1,200 per disease to treat. An elderly person may be spending $1,000, or $2,000 a year for prescription drug therapy to treat a chronic condition when they only have a fixed income of $16,000 or thereabouts.

That would result in such an elderly person paying as much as 10 or 20 percent of their entire income on prescription drugs alone, not counting other health care services.

Today I would like to address several points of the administration's plan, and put them in the context of the role of pharmaceuticals in health care reform no matter which plan you decide to go with as a Senate and as a Congress. I think these principles apply in whatever health care reform plan you consider.

This committee knows all too well that the Medicare program does not cover the cost of prescription drugs. And, in fact, you had a program several years ago, the Medicare Catastrophic Coverage Act, that attempted to cover prescription drugs. Because of some misconceptions and misunderstandings, that program was repealed.

I would remind you that that program would have covered only about 17 percent of the nation's elderly, in any given year. The program presented by the President at this point would cover prescription drugs for about 58 percent of the Nation's elderly in any given year. So it certainly provides much broader and better coverage.

Costs management provisions affecting the pharmaceutical industry will undoubtedly be one of the most controversial issues you deal with as a Senate committee. Coverage of prescription drugs for the elderly is critical for their health care. Such coverage, however, must also be provided by Congress in a way that wisely uses the resources of Medicare beneficiaries' premiums, as well as the resources that taxpayers provide to you.

To provide prescription drug coverage under Medicare without providing cost management tools for that program would be the equivalent of this Congress telling the defense industry to go out there and find us the best and newest defense and technology systems that you can find for defense and we will pay for anything you bring to us. Do not worry about the cost. Bring it all in and the Defense Department will cover it all.

The CHAIRMAN. Doctor, that is the present arrangement.

Dr. SCHONDELMEYER. Yes, it is. [Laughter.]

Dr. SCHONDELMEYER. I hope you can change that as well while you are reforming health care. Use the same principle for both. The point is that this is almost like wanting a blank check for the drug industry. I do not at all oppose funding research and development that is productive and brings us new and effective therapies and new products. But I do not think any taxpayer or any Congressman would advocate a system that opens up more "blank check" systems out of our Federal coffers.

The cost management systems proposed in the President's plan mimmick the provisions used in the marketplace. In fact, many in the drug industry advocate shifting this Medicare benefit to the private market, such as the private pharmacy benefit management companies and HMOs in managed care and managed competition. In fact, the cost management methods used by these organizations I think are even more severe. They have lists of drugs that they do not cover. They set pricing conditions and evaluate drugs on cost effectiveness and decide to cover certain products but not other products.

The cost management provisions are much more severe in the private sector of the market than they are, in the plan proposed by the President. The Breakthrough Drug Committee offers to the Secretary advice on how to evaluate new drug therapies and how to hold drug companies and biotech companies accountable for the value of what they brought to the market.

It would be a mistake to limit that evaluation only to cost-effectiveness. The provisions listed in the current breakthrough committee include a number of methods that would be used, including the manufacturer's costs of research and development, and other factors.

In fact, if we limited the evaluation only to cost effectiveness, I would remind the industry that cost effectiveness studies do not take into account research and development costs. The current provisions of the breakthrough drug committee would allow that committee to take into account not only the cost effectiveness, but if there were extraordinary research and development costs, those costs could be added into a higher price that would be allowed for that product.

In summary, I would tell you that I think a lot of the issues that are being raised and framed as anti—competitive are actually quite competitive and that is why they are of concern to the pharmaceutical industry because it adds to their competition.

I would just remind you, with all of the furor and discussion and threats—in fact, we do have price controls already. These come from the private market and managed care plans that are out there in the marketplace. Their cost management techniques are more severe and account for more of the effect that we have seen in the biotech industry than the "threats" that the government has offered.

The recent Fortune 500 magazine still rates the pharmaceutical industry as the most profitable industry by percent return on sales, percent return on assets, percent return on equity, and the phar-

maceutical industry has been in that position for a number of years running.

So I would argue that even though this has made them a leaner, meaner industry as most every other industry in our country has had to become over the last few years, the impact on the industry at least to this point has not been overly severe.

Thank you, sir.

The CHAIRMAN. Thank you, Dr. Schondelmeyer.

[The prepared statement of Dr. Schondelmeyer appears in the appendix.]

The CHAIRMAN. And now to our last witness from our Office of Technology Assessment, Dr. Judith Wagner, who is going to give us some objective discussion on the forces in the market that produce pharmaceutical prices.

STATEMENT OF JUDITH WAGNER, PH.D., SENIOR ASSOCIATE, HEALTH PROGRAM, OFFICE OF TECHNOLOGY ASSESSMENT, WASHINGTON, DC

Dr. WAGNER. Thank you, Mr. Chairman. I am here to report to the committee this morning on the current status of the prescription drug market and its implications for drug prices and for the costs of a prescription drug benefit.

Today the prescription drug marketplace is undergoing a rapid and in my opinion an exciting transition from a fee-for-service market to one of managed competition. Like a newborn baby that grows fast but looks tiny after one or 2 years, the pharmaceutical managed care marketplace is growing fast but still has a long way to go before it matures.

The pharmaceutical industry sees this future though and is already positioning itself to deal with the realities to come and most interesting to me is the fact that this transformation of the prescription drug marketplace is occurring independently of the discussions or future of health care reform.

The shape of health care reform will, of course, have a major impact on the transition to managed care competition in the prescription drug market, either speeding it up, slowing it down or perhaps derailing it altogether.

At the heart of the new prescription drug marketplace is the managed care pharmacy program, which manages the drug benefit on behalf of employers, insurers or HMOs and exploits the wide array of product choices that are currently available to encourage less costly prescribing and dispensing patterns for plan enrollees and even forces manufacturers to compete for business by lowering prices or offering discounts.

The weapons in the arsenals of these managed care pharmacy plans are still under development, but they include incentives to patients and to pharmacists to dispense cheaper generic drugs and the use of formularies to encourage less costly choices among different but therapeutically very similar compounds in crowded therapeutic classes.

An entire industry of firms called pharmaceutical benefit managers has developed in the last 5 years or so and these firms can administer the benefit, not only for HMOs, but also for indemnity plans.

The CHAIRMAN. Would you say that just once again? That is a new idea to us. There is a new class of business—

Dr. WAGNER. There is a new industry of pharmaceutical benefit managers—called PBMs in our Washington world of acronyms—that have essentially developed over the last 5 years. There are dozens of such firms today.

The CHAIRMAN. And this firm says what to whom?

Dr. WAGNER. The pharmaceutical benefit manager is a firm that sells its services to insurers, employers or sometimes to HMOs to administer the pharmaceutical benefit for the employer or the insurer and it also sells to indemnity plans.

In other words, even when an employer can offer a fee-for-service indemnity plan for its general health care services, it can carve out the pharmaceutical benefit and have it be administered separately by this managed——

The CHAIRMAN. And these PBMs bid for this work?

Dr. WAGNER. Yes, with the insurance companies and particularly with HMOs today.

Now the potential for moderating drug expenditures is great in my opinion. For example, today or in the next 3 years, between 1993 and 1996, 4 out of the 10 top selling drugs in the United States are slated to loose patent protection. These drugs in 1993 had a combined U.S. sales of over $3 billion.

So these four drugs alone offer, if in fact a large number of consumers switched to low-cost generics, the potential for huge savings.

So from generic substitution alone, I think there is a real potential for savings. When savings from switching from high cost to low cost drugs when narrow therapeutic categories through the use of formularies are taken into account, it is my opinion that prescription drug expenditures will moderate substantially as the frequency of use of these plans grows.

Competition among managed care pharmacy plans will also send signals to the R&D community that imitative R&D—that is, R&D for new drugs in therapeutic classes where there are already a number of compounds on the market—will not be nearly so profitable as it was in the past; and companies are likely to rethink their R&D strategies to redirect resources away from this imitative me-too research.

In the long run, the main problem for competition in the managed prescription drug market will be the problem of breakthrough drugs. Though there are different definitions and we do not know exactly how to define a breakthrough, from the market's point of view a breakthrough drug is one which is so uniquely beneficial that it must be accepted onto a formulary regardless of its price.

These drugs could ultimately put pressure on the pharmaceutical benefit costs. OTA, at the request of Senator Pryor's Senate Aging Committee, is actually currently doing a study on breakthroughs to ask questions such as: How often will we expect them to come along? How long will they stay on the market alone without close competitors developing? Just how beneficial will such drugs have to be to operate as breakthroughs in the market? And just how price insensitive will health plans be to such products?

I am running out of time.

The CHAIRMAN. Take your time, Dr. Wagner.

Dr. WAGNER. Thank you, sir.

A pharmaceutical benefit under health care reform will be layered on top of the emerging marketplace that I have described. If the prescription drug benefit is compatible with managed care pharmacy approaches, it will share in the cost moderating forces that are at work.

If the prescription drug benefit is structured as a fee-for-service benefit, then more direct regulation of prices and utilization will be necessary to control the costs of prescription drug benefits.

The choice between the market approach to cost moderation and the regulatory approach deserves careful consideration by this committee and the Congress. The chief problem with price regulation is that it is very difficult to know what the right price of a drug is, and any price control structure runs the long run risk of creating unintended incentives that may lead to inefficient patterns of prescription drug pricing, utilization and ultimately innovation and new drugs.

Thank you for your consideration.

The CHAIRMAN. Thank you.

[The prepared statement of Dr. Wagner appears in the appendix.]

The CHAIRMAN. Now you are not going to get away that easy. What are those four "compounds," patents which expired?

Dr. WAGNER. I will have to get that list to you later. Actually, I am sitting on the list right now, sir, and I will get it to your staff at the end. [Laughter.]

The CHAIRMAN. I think we will just drop that. [Laughter.]

I just want to ask a general question, if anybody wants to respond. I am hearing what Dr. Wagner just said, that price moderating factors are moving all across this system.

We have heard Dr. Schultze from UCLA talk about running his hospitals down there and talking in just these terms and markets emerging. He said there is practically a spot market for bone marrow implants.

There are those who attribute this to the prospect of new health care legislation, but I think we have heard it as something that is just happening because there are those who have an interest in it happening.

Dr. Sanders?

Dr. SANDERS. Yes, Senator. I would say that, you know, this has been going on for some years. There is no doubt that health care reform has accelerated the process. But managed care has been evolving in a very significant fashion starting in the late 1980's.

The CHAIRMAN. The late 1980's is not that far back. It is relatively new.

Dr. SANDERS. No, the marketplace really for the first time in health care is beginning to work. The reason is multiple. But it is primarily because businesses really got interested in health care reform because of the very significant amount of fringe benefits that they were having to pay as an increasing percentage.

And managed care began to evolve in ways which have made it a very tough marketplace.

The CHAIRMAN. I know nothing of these things. But is this part of the general downsizing of management systems and corporations that we have seen a lot of or heard a lot of? They become very cost conscious and so forth. This would be part of it.

Dr. SANDERS. Well, certainly I think if you talk to the auto makers, they would argue that one of the reasons that they were noncompetitive in terms of the foreign imports would be the fact that their fringe benefits packages were so rich, and health care was certainly part of that. There is no question about it.

The CHAIRMAN. And so when you begin to look at this from a managerial point of view, you have to do something about this whole system. You find yourself thinking about this in a way you had not done?

Dr. SANDERS. That is correct.

Mr. ROTHER. Senator.

The CHAIRMAN. John Rother?

Mr. ROTHER. Yes, thank you. I agree that there are many changes happening in the market that are happening regardless of what happens here. But one consequence of what is happening is that those people who are outside of group purchasing arrangements are getting costs shifted to them, very substantially now.

And those are often the people who have the greatest need for the drugs. That is why the price at the retail level for the Medicare beneficiary, for example, has been skyrocketing. It is in part because the overall prices are going up.

But on top of that there has been this cost shifting phenomenon, just like in the rest of the health care system, where those who have organized buying clout are getting a good deal at the expense of those who do not, which is why we need to really think about Medicare as a way to put that buying power together and get the same good deal there that we are getting other organized buying arrangements.

The CHAIRMAN. A nice point.

Dr. SCHONDELMEYER. And, Mr. Chairman, I would like to tie that to the elderly also. In my own area in Minnesota, in the Twin Cities area, a number of the HMO and benefit plans do not cover prescription drugs for the elderly at all. And, in fact, one or two of the plans that had covered prescription drugs for the elderly stopped covering them because they said they could not afford to do it.

So in some areas, prescription drug coverage for the elderly is not available as a part of their health plans. Other HMOs have even dropped that coverage because they could not afford to continue it.

The CHAIRMAN. Dr. Sanders?

Dr. SANDERS. I would just make the point in following on John Rother, as he mentioned in his testimony, there are other alternatives to a rebate. One is using the pharmacy benefit management approach. Another is using a benefit which would be administered through——

The CHAIRMAN. That is PMB.

Dr. SANDERS. PBM.

The CHAIRMAN. PBM.

Dr. SANDERS. Another would be administering such a benefit through the accountable health plans, which Mr. Rother, I think, is opposed to. But it is suffice to say that these are market-based approaches and I think a much healthier approach as opposed to a flat rate discount.

The CHAIRMAN. Thank you.

Senator Packwood?

Senator PACKWOOD. Dr. Wagner, are you reasonably satisfied we will get continuing moderating pharmaceutical prices with no Federal price control?

Dr. WAGNER. If one has to make assumptions or predictions about what a prescription drug benefit plan would look like, if the Medicare population is brought into prescription drug benefits, given prescription drug benefits with a fee-for-service benefit, then I do not believe we will be able to achieve cost control.

Senator PACKWOOD. Because you have no management then.

Dr. WAGNER. Without active management, without active efforts to restrain prices, restrain utilization. So I really think the issue is if the Medicare population is to be given this important benefit for them, what is the best way to structure the cost control mechanisms. Is it to structure it through regulatory approaches or to structure it through a market-based approach? In other words, to build on the emerging——

Senator PACKWOOD. What do you think?

Dr. WAGNER. Well, at OTA we are trained not to have—— [Laughter.]

The CHAIRMAN. Trained not to think. You just state the facts.

Dr. WAGNER. Not to take stands, but to lay out the options. I think it is an important option. I think that there are problems in bringing the Medicare population into a pharmacy benefit—PBM type managed care approach. There are problems to that.

But that approach has not been fleshed out enough to really examine those problems in detail. I think that approach should be given some consideration.

Senator PACKWOOD. The reason I ask, when you sit through enough of these hearings there is sort of a common thread that perhaps competition does work.

Dr. Ellwood, who is probably one of the gurus who has no particular axe to grind that we listened to has backed off of the mandate and he has almost backed off of any plan. He has not really said that. But I was on the plane with him 1 day just inadvertently and he says he has seen so much reform in the last 2 years that he is hesitant to adopt a wrong bill. That, indeed, the pressure on the medical providers and on the pharmaceutical companies and on the hospitals is so great that we may not need much Federal push to get them there.

Then we had Dr. Schultze from UCLA heading the medical center here last week and he has a medical center and a hospital. He has to do primary treatment, secondary treatment. He needs tertiary patients for his research people. And he says there is no indemnity payment left in southern California. It is gone. It is all managed care.

The Chairman refers to the spot market. He says that is exactly it. You can have a managed care program that will pay you

$80,000 for a bone marrow transplant. Here comes one and they come to you and say, hey, how about doing it for $60,000, even though the insurance coverage is $80,000. They will negotiate it. You may meet it and you may do it.

Your testimony is sort of of the same genre, that we are coming to this kind of pressure on the providers—count the pharmaceuticals as a provider—on the providers from basically the equivalent of a farm co-op purchasing arrangement.

Dr. WAGNER. I want to make two points. One is that this managed competition in the prescription drug market is almost uniquely placed as a little microcosm of what managed competition can do because of the nature of the products and the situation that the industry found itself in.

So I think it is important to recognize that this is undergoing a transition to managed competition within even a larger indemnity market.

The second point I might make is to reiterate Dr. Schondelmeyer's point, which is, there are over 50 percent of the elderly and a smaller number of nonelderly people who are totally uninsured for drugs—who cannot take advantage at the present of all of this cost moderation because they are out there in a completely fee-for-service unrestrained costing situation and something should be done to deal with that problem.

Senator PACKWOOD. Well, I think Dr. Schultze could head General Motors as far as I am concerned, in terms of his understanding the market. He has been head of the school for the last 12 years and he saw what was coming; and either the school is going to fold or is going to have to adapt to a market system. And it has adapted wonderfully in the pharmacy. They are looking at cutting costs.

They are talking about inpatient prescriptions now obviously, but they are looking at cutting costs. And even for the primary patients on which they teach because it is a cost reduction for them.

Dr. WAGNER. Yes.

Senator PACKWOOD. Dr. Sanders has something to say. I can tell.

Dr. SANDERS. I was just going to say the Medicare issue is a very poignant and urgent problem as far as I am concerned, as far as prescription drugs is concerned. But it is not the price of the drugs that is the big problem, it is the coverage that is the problem.

Whether a prescription costs $1 or $100, if the patient does not have the money, we have a problem. We spend thousands of dollars for doctors and hospitals, but we have a real problem when we do not cover people for a $100 prescription.

The CHAIRMAN. Could I just say, following Senator Packwood, that we have found we were getting testimony, Dr. Schultze, to the degree that academic health centers are beginning to find that this new pressure on competitive prices and so forth was putting at some risk their capacity to run expensive hospitals because you teach doctors. That is how you get nurses and doctors and new ideas. It is a curious thing.

We are sensitive, I hope, to the same question of pharmaceuticals that Dr. Rudnick raised.

Senator Pryor?

Senator PRYOR. Yes, thank you, Mr. Chairman. Mr. Chairman, I know the time is late, but once again this panel is a very remarkable panel.

I would just like to say a work about Dr. Sanders if I might. I had the privilege of meeting him a few months ago and we had a nice little visit. He reminded me that I had known his brother earlier when his brother worked in the White House. His name is Judge Barefoot Sanders of Texas, a legendary character that many of us here in the Senate and the House know.

Dr. Sanders, we are very proud that you could come today.

Dr. SANDERS. Thank you.

Senator PRYOR. I would just like to say, Mr. Chairman, I have said this before, but it is kind of gnawing on me, I do not know of one Congressman or Senator or anyone that I know of, Dr. Rudnick, who want set drug prices. I do not know of anybody who thinks it will work. It will not work.

Senator HATCH. I would like to introduce you to some then.

Senator PRYOR. Thank you.

Senator HATCH. Some in the White House.

Senator PRYOR. It is not going to work and we all know it. But we do deal in a great deal of frustration because the system that we have now is not working. It is working, by the way, pretty well price wise in other countries at our expense.

We are subsidizing, the American consumer according to the GAO report, we are subsidizing the other countries. We see an average of 8.5 percent inflation—not as much last year, I grant you, but say over the last 10 or 12 years 8.5 percent inflation rate in drug prices. Not for new drugs, but for present drugs on the market, just automatic increases up to about 8.5 percent on the average.

But yet in Europe we see 2.5 percent over the same period of time. And the Chairman, very rightly, pointed out the cost effectiveness of Xantac, by your company, one of your big sellers, cost effective, yes, but it costs 40 percent more for the American consumer than it costs in Europe and that is hard for us to explain. It may not be hard for others to explain, but it is hard for me to explain.

I just think that these are some areas that are of great concern. I have had the opportunity in recent weeks to have visited with some of the CEOs of the major pharmaceutical companies. Generally they say, what do you want? In other words, why do you not get out of our hair, I guess. Why do you not just bug off? What do you want? We will see if we can accommodate you.

I say, well, to start with, I would like to have the same prices here that you sell those drugs for in Europe. If you would start off with that and then we will see if we can negotiate that. I do think that we are subsidizing the other countries.

Let me ask a question, if I might, of Dr. Sanders, I guess. We see an enormous price discrimination by the pharmaceutical companies in selling to the community pharmacists where most of the elderly have to buy their drugs. Now why does this discrimination have to occur?

Why can you not give that pharmacist the same good deal that you give an HMO or to the Veterans Administration or to the big buyers?

Dr. SANDERS. Well, Senator, as we both know, that has been a source of major concern and irritation on the part of the community pharmacist for some time, the fact that there is this differential in pricing.

The difficulty, I think, in pricing relates really to the fact that you give discounts to large buyers to gain access to markets, such as an HMO, or to gain market share.

If you give a discount to a pharmacist, essentially the pharmacist is filling a prescription in response to a doctor and you are not generating demand. That is really the principle point for which discounting is made.

Now what the pharmacists are beginning to do, and there is a good example of this in Tennessee, where they have formed their own pharmaceutical benefit management company and that is something that we respond to in terms of discounting. Under those circumstances, the pharmacist will do very well in terms of the pricing structures.

But at the moment, servicing those small accounts is very costly and that is why they do not benefit, because the larger buyers that allow you to get market share and access do not have those high administrative costs associated with them.

Senator PRYOR. Mr. Rother, I think, brought up some very good points on discrimination, basically against the elderly in purchasing their drugs. We see they are not covered by Medicare and we see only about 40 percent of those over 75 having drug coverage.

I just think that we are looking, as Dr. Wagner said, we are looking at sort of a separate nitch out there when we look at the overall health care concerns as it relates to the issue of pharmaceuticals.

We see here also, and I think that this is a fairly recent chart here, Mr. Chairman, the increase in pharmaceutical sales—blue line—and going up in sales dramatically. But the research and development seems to be going up, but not nearly as dramatically as the increase in pharmaceutical sales. Could that be explained? Perhaps Dr. Sanders or Dr. Wagner or any of the panelists, or Dr. Schondelmeyer might be able to.

Dr. SANDERS. Well, since it is my industry maybe let me have a crack at it. The current average, Senator Pryor, is 16.7 percent of sales. What has happened in the past year, that 6 of the 15 leading companies have dropped their rate of growth. This is the first time this past year that companies began to drop their rate of growth. That is not what that graph shows. I would like to look at it.

But I think that right now we are spending $12.6 billion in this industry and the NIH is spending $9.7 billion in terms of R&D. So we still have a very healthy commitment.

Mr. Rudnick. Senator, may I?

The CHAIRMAN. Dr. Rudnick?

Senator PRYOR. I may be out of time, but go ahead.

The CHAIRMAN. No, please, Dr. Rudnick. It is your industry, too.

Mr. Rudnick. May I go back to a comment you raised earlier? I appreciate the fact that most people in the Congress do not wish

to regulate drug prices. I do think it is important to look at what has happened with more recently introduced drugs, and biotechnology drugs are really quite representative of that.

In the years since those drugs have been launched, I think if you looked at the vast majority of them, and looked at their worldwide pricing, they are very much equalized or, in fact, you would often find that their prices are higher overseas.

I think it is because the times have changed. I think Dr. Sanders pointed out that there has been a sea change over this last six or 7 years. I think in general price pressures will be maintained on all of the newly introduced, whether breakthrough or not, drugs.

I would also like to thank you for considering this issue about control on the pricing of breakthrough drugs, because I think it is really important. When you look at Alzheimer's Disease alone and the tens of billions of dollars that are spent on medical care, let alone the issues of long-term care that you discussed earlier today, I think what you want is a breakthrough drug. And I think the whole goal is to get the industry to price it responsibly. And to worry about whether there will eventually be such an outrageous price when today we do not even have such a drug, seems a little bit premature.

The CHAIRMAN. I certainly follow that and I do not follow things like that easily. If I can say, not to get too close to home, but the Walmart in my part——

Senator PRYOR. Arkansas is coming under a lot of scrutiny because of that. [Laughter.]

The CHAIRMAN. When a Walmart appears outside of town in the Hudson Valley, it is referred to as the Angel of Death. It means those stores on main street are not going to do very well anymore. So it has something to do with volume and purchasing and so forth.

Senator PRYOR. This is beyond my pay grade to discuss this. [Laughter.]

The CHAIRMAN. Senator Durenberger?

Senator DURENBERGER. Mr. Chairman, I want to just begin with your favorite exercise in lexigraphics or whatever the most appropriate word is. But I want to just make a brief comment about Dr. Sander's definition of managed care, but to put it in perspective that it is all over the place.

I mentioned earlier that I played hooky this morning after the building trades to go listen to Mrs. Clinton's speech to all of the building trades members. She uses this line that I think my colleague Paul Wellstone invented, but it is the greatest applause line ever. That is, you should have the same health plan as members of Congress. And everybody in the audience goes crazy.

And I look around these guys and everyone of them has a better health insurance plan than I have. He is buying it in a better marketplace probably. Certainly the Minnesotans are buying in a better market. They have better access. It is cheaper prices. These guys all have first dollar coverage and all this sort of thing.

It just means that when we say these things, you know, they mean different things to different people. If I were defining managed care, for example, I would go back to group health in the 1930's, Kaiser beginning in the 1930's, the Mayo Clinic, Cleveland

Clinic, Ochsner Clinic, a lot of people like that, and recognize the reality that around us over the time of our sort of growing up there have been a lot of people who have been trying to give us some sense of direction in how we as individuals should participate in health, selection of medical service and so forth.

But somehow or other in the last 40 years we have so distorted the market signals that we are now sitting here debating how much of what we ought to have and who ought to pay for it.

Let me get back to the thesis I articulated earlier, which is that all health care is local. It is a relationship at a local level between people and providers of care.

As I understand the beginning of the solution to our problems that is incorporated in the Clinton plan, and in a couple of others, there is a mechanism called the accountable health plan, which is in every community—we all are going to own one of these. In fact, I got a mock health security card this morning. They were on every chair down at the AFL–CIO.

It has their own version of it on the back, which does not relate to universal coverage or any of the other things since they already have it. But the reality is, I think the thesis is the same in all of these plans, an accountable health plan, we will all own one.

And those plans will provide us access to appropriate services at a competitive price because there will be more than one plan to choose from. But the decisions about what particular services we get are not going to be made by the Senate Finance Committee and they are not going to be made by—I think it is 300,000 pages of Medicare regulations or by budget reconciliation around deficit time. They are going to be made by people in local communities in a service or a needs specific basis.

So, you know, sitting as I did going through the Medicare catastrophic experience, I know we will never be able to prescribe a way to do drugs as a benefit, because they are not a benefit. They are a service. They are a tool. They are a means to an end. And they are a means to an end which are better put in the hands of this relationship between me, a person in need, and somebody who has some responsibility for helping me solve my health problem.

So that is one of the reasons in just following this over the years, that I finally introduced the Medicare Choice Act, which enables the elderly and the disabled in America to have the same choice that people in Minnesota have been struggling with, as Steve pointed out, for a long time and getting penalized.

We used to have drugs available through our TEFRA risk contractor. George Halverson was in here last week saying we used to send scales home with people who had congestive heart problems, so they could weigh themselves and report in and did not have to go to a hospital in order to have a heart—they used to be able to do all these sort of things.

But the more they did and the more popular it became, the more HCFA decided to penalize them, because that is the way that we have set up the law apparently, penalized them for doing the right thing.

But it strikes me, and maybe, John, I can start with you since you said we need to organize, we need a better system in organizing this thing more appropriately is the better way. Tell me, what

would be the most appropriate way as long as we are doing health care reform to make sure that the elderly and people with disabilities in America cannot just get another "benefit" added to Medicare, but can actually have access to the variety of benefits that all other Americans are going to have and services as well.

Mr. ROTHER. Well, we strongly support the goal of having the same choices available to Medicare beneficiaries that any other American would have, and having the same standard benefit package available. I think that is also part of that choice.

But as I said in my opening statement, there are some people who for very good and appropriate reasons, whether it is the lack of an HMO in the area or whether they want to continue the kind of care with the practitioner who has served them well for many years when they turn 65, they want to continue that. And we need to respect that.

That is really all I am saying. I think that if we have a system where everyone has an accountable health plan available to he or her, their family, if all doctors are members of those plans so that you can have continuity of care, then we are in a different environment and I think we can talk about how Medicare beneficiaries should be part of that.

We have always thought of Medicare as its own health alliance, a national health alliance. It has some of the same, it seems to me, responsibilities for arranging for the best possible choices and the best deals, if you will, that other health alliances would have. It is really comparable to a corporate health alliance for the very large employer.

So, you know, for those people in managed care, I think we have very good bargaining tools. But we need to have something for those people who for good reason elect to stay in fee-for-service.

With hospitals we have DRGs. With doctors we have relative value scale. We need to have something that addresses that part of the drug market as well as opening up new choices for people to go into managed care environments.

Senator DURENBERGER. Then can I ask you the same question that was asked of other witnesses on the previous panel as to what you would support. If we are going to commit to get the universal coverage as part of health care reform, and if we are going to do that this year, we are not going to get there with an employer mandate. We are going to only get there—and I can say that with certainty. An employer-paid mandate as an excuse not to reform Medicare appropriately and give the elderly and disabled access to the same care as everybody else gets is not going to fly.

An employer paid mandate to pay without reforming access for the low income is not going to fly. An employer paid mandate without some reform on the tax subsidies for the guys I was sitting around with this morning is not going to fly. I mean, an excuse not to do what I think I have heard you say we need to do. We need equal access to quality care for everybody in this country on as equivalent a basis as we can.

As I read that in the Clinton plan and many of these other plans, that is something called an accountable health plan. And it is a locally based plan. We need a way to make sure that the public sub-

sidies for those plans are fair to the elderly and the disabled as we planned them to be or people who are working.

I think it is really critical in your particularly unique role that, you know, the sooner you can come to grips with the reality that we cannot wait to see whether there is an accountable health plan in every town, you have to make a decision you are going to support fee-for-service reimbursement forever or begin with an alternative to fee-for-service.

And in those communities where it works or it is possible to work, encourage it to.

Mr. ROTHER. Senator, with all respect, I think we are talking about a drug benefit as part of a standard benefit package for younger people who are in fee-for-service environments.

All I am asking for is that we give older people the same choices and the same incentives, if you will, that we are going to give to every American under health reform.

The CHAIRMAN. We heard you.

Senator DURENBERGER. Thank you, Mr. Chairman.

The CHAIRMAN. I think it would be useful to get it clear that the health care plans that Congress has are the health care plans that the Federal civil service has. I finally found what it was—Blue Cross/Blue Shield.

Senator Hatch?

Senator HATCH. Thank you, Mr. Chairman. I want to commend you for the manner in which you have conducted these hearings. It has been fair and I think very even-handed and I think very informative to all of us.

The CHAIRMAN. Thank you.

Senator HATCH. I am very concerned about the impact of the President's Health Security Act, especially on the pharmaceutical industry. I believe that the future of health care to a large degree depends upon finding the breakthrough drugs to cure Alzheimers and so many other debilitating illnesses that are affecting not only our senior citizens but others as well.

The industry has been subjected to some dramatic reversals ever since this administration has come into power. It takes about $359 million and approximately 12 years to go through the safety and efficacy process to bring a drug to market in this country. And only one out of three of the FDA approved drugs will ever earn back its research and development costs—that $359 million.

The pharmaceutical industry has been one of our great industries; it has had a positive balance of trade. It has been a healthy industry. But even that is changing. For instance, between 1980 and 1991, job growth in the pharmaceutical industry was rising at 36.2 percent per year. That is seven times all industry average.

Yet in the last 2 years the industry has announced job cuts or job reductions of over 40,000 people. That is all correct, is it not, Dr. Sanders?

Dr. SANDERS. Yes.

Senator HATCH. All right. A lot of that is attributable to what we are doing right here on this committee. The administration mentioned the words "price controls" and, of course, pharmaceutical stocks went down. The big investment houses and companies steer investors away from pharmaceutical stocks.

As Dr. Rudnick has illustrated so well, this could sound the death knell for these small biotechnology firms. There are 800 of them. Only four of them make a profit. But they are the future for breakthrough drugs in this country and we are killing them as we make these attacks on the pharmaceutical industry.

The pharmaceutical industry has been singled out as one of the targets of the Clinton administration and this is abundantly made clear in the Health Security Act. No other health care provider or industry would be subject to such a deathly array of regulatory activity as will affect the pharmaceutical industry, if this bill passes.

In effect, a new government bureaucracy would be created basically to run what has been not only a private sector industry but a source of national pride and leadership unparalleled throughout the whole world.

Now I think my fears are well founded when I hear the comments from the administration on how drug companies have gotten away with making huge profits at the expense of our Nation's children and elderly.

If you go through the Clinton proposal, you see it is going to have a chilling effect on innovation which will lead to rationing of medical services and probably the end of promising new drug therapies.

Let me just make a list: the premium cap; the Council on Breakthrough Drugs, which will do away with breakthrough drugs by and large; the minimum 17 percent rebate on existing drugs; the negotiated rate for new drugs; black listing of new drugs; prior authorization, generic substitution and unitary pricing as a condition of Medicare participation.

All of these are supposed to address the cost issue. But what I find particularly troubling is their ultimate impact on the industry and the ability of the industry to deliver the best health care for all of us.

So I would have to caution all of my colleagues that the potential cost of a breakthrough drug will be irrelevant when there will be no breakthrough drugs at all. That is what this type of over-regulatory, heavy handed government intrusion and approach will do.

This situation is particularly critical when we are literally on the threshold of promising new lifesaving drugs and other medical technologies which may be withheld from the American public because of what I consider shortsightedness.

Now let me just ask you one question, Dr. Sanders. In your testimony you discuss aspects of the administration's bill and the impact on research and development. You mentioned a drug called "Zofran" in your testimony.

The CHAIRMAN. Could you help us on that?

Dr. SANDERS. Zofran.

The CHAIRMAN. Spell it.

Dr. SANDERS. Z-o-f-r-a-n.

The CHAIRMAN. Got you.

Senator HATCH. Now you pointed out that the research on that drug began back in 1972.

Dr. SANDERS. Yes.

Senator HATCH. You also mentioned that Glaxo is involved in some recent research on tuberculosis.

Dr. SANDERS. Yes.

Senator HATCH. And we have strains of that now that are more resistant than any in the history of mankind.

Dr. SANDERS. Yes.

Senator HATCH. And other viruses and other problems are starting to become very, very difficult to handle. As you look at the President's "reform" recommendations, and if by some miracle they were enacted by Congress today, what would be the first thing you would do when you got back to your office today?

And I especially want to know the impact on R&D. I want you to feel free to comment on ancillary impacts as well.

Dr. SANDERS. Well, the first thing I would point out is that we talk a lot about breakthrough drugs. But if you look at the actual costs of breakthrough drugs in terms of health care costs, it is one-five hundredth of the total cost.

Senator HATCH. The average cost of pharmaceuticals is about 7 cents on a dollar.

Dr. SANDERS. Thereabouts. About 7 percent of the total. If you take all that away, we still have a 90 percent problem in terms of the trillion dollars.

So that penalizing the research and innovative industry really is counterproductive because that is the hope of the future in terms of cost savings. What I would do faced with that particular scenario is, I would go back and I would look at every possible area of expense control that I could, starting with sales and marketing, which by the way we are already doing. And the jobs that have been lost is 30,000 through October of 1993. It is between 35,000 and 40,000 now on the basis of new announcements that have been made.

Of the 30,000 almost 12,000 were sales and marketing. So we are beginning to cut back in that particular area in terms of expense control. But in the final analysis, once you have done all of your cutbacks in other areas, you will have to turn to your R&D program and then begin to cut back on that. That is already happening in 6 of 15 companies here at least in terms of the rate of growth.

And under those circumstances, I would foresee that we would then take a strategy which would not be a breakthrough high risk expensive program, where there would be no return guaranteed. We would take a more modest incremental approach to drug development. We would take molecules that had been discovered by someone else, like the Japanese, improve them in a way which made them beneficial, better than they currently are, but not achieving the breakthrough that we all would hope for in attack diseases such as Alzheimers, et cetera.

So it would make us really rethink our entire strategy.

Senator HATCH. And it would defer resolving a lot of these problems that we are on the verge of resolving at this time.

Dr. SANDERS. Well, it would certainly put a chill upon our enthusiasm to enter areas that are currently black boxed and are in need of discovery.

Senator HATCH. Mr. Chairman, could I just ask a couple more questions?

The CHAIRMAN. You can ask as many questions as long as you can get answers.

Senator HATCH. My goodness.

The CHAIRMAN. The only limit on your questions is the supply of answers.

Senator HATCH. You are the first Chairman who has ever given me that opportunity.

The CHAIRMAN. They may go to lunch, you know.

Senator HATCH. I will not keep you any longer, Mr. Chairman, except for one thing.

Who provides most of the funding for these 800 biotechnology companies from which we are hoping we can get a lot of these breakthroughs?

Dr. RUDNICK. Perhaps I might answer that, Senator.

The CHAIRMAN. Dr. Rudnick.

Dr. RUDNICK. That funding comes almost entirely from the equity capital markets and the private venture investors, primarily in the United States, although occasionally overseas.

I think the answer to your question from the perspective of the biotechnology companies is quite different than the answer that Dr. Sanders gave you. You would see the stock prices plummet. You would see forced consolidation. You would see the loss of research opportunities. You might see many of these projects moved off, if they could be unloaded, to overseas companies. You would, in fact, see a major restructuring of what up until now has been one of the bright lights of American entrepreneurial technology.

Senator HATCH. I do not disagree one bit. And I have to tell you that it has already been predicted that if something like the President's program passes, instead of the huge number of major pharmaceutical companies—what are there, 16?

Dr. SANDERS. Well, there are about 30 here in the United States—33.

Senator HATCH. No, but I am talking about the big ones.

Dr. SANDERS. The big ones, about 10 to 15.

Senator HATCH. Ten or fifteen. It is going to come down to four, five or six. And the biomedical companies will basically be gone because the funding will be dried up for them.

And, frankly, senior citizens will be hurt more than any other group of people because these are where most of these pharmaceutical therapies have to come.

The CHAIRMAN. Senator, once again our lexicon. Biomedical companies as against pharmaceutical.

Dr. SANDERS. Biotechnology.

The CHAIRMAN. Biotechnology.

Senator HATCH. Excuse me, biotechnology.

The CHAIRMAN. Comments?

Dr. SCHONDELMEYER. I would comment that the President's plan, as people imagine it implemented, might have some of these affects that we have heard. I fully acknowledge that. On the other hand the pharmaceutical industry argues that the private marketplace and the managed care and managed competition plans are creating price consciousness and competitiveness and getting lower, or even better, prices in the marketplace than the government could get with the President's proposed plan. I find a link missing in the argument of the pharmaceutical industry that the private marketplace is not going to have an equal or even more severe effect.

I share their concern about choking off research and development and would ask that we need to begin examining how these pharmacy benefit management companies exercise their provisions in controlling drug costs.

Because as I see it, most of the benefit management companies I am aware of do not cover new drugs automatically when they come on the market and many of them delay a year or more before they consider whether they will put new drugs on the formulary and others do not even cover them ever.

Every provision that was named by Senator Hatch that is the President's plan is also present out there in the private marketplace in these private pharmacy benefit management firms. These provisions in the private market have an equally chilling effect on this industry.

The underlying issue is that we have to examine how are we going to fund research and development in our pharmaceutical industry. It is essential. We need it. But I do not think our old methods of funding it in the marketplace are going to survive and we have to adapt that mechanism as we move ahead both in our economy and in our health care reform process.

The CHAIRMAN. Well, if I can say, Senator, that this is a pattern we have heard, this issue has been raised in the context of academic health centers. A rationalization of the market can be very punishing to really what are basically not market activities.

I mean teaching is a ministry not a business. And the more rational the economic decisions are made the more they reach the point where they might be injurious to your basic purpose which is discovery and training.

Senator HATCH. That is right. In 1994 for the second year in a row the rate of increase in pharmaceutical R&D has gone down.

Dr. SANDERS. That is right.

Senator HATCH. Between 1980 and 1992 R&D investment had increased on an average of more than 16 percent a year. Now it is going down. Six companies this year actually expect to invest less in real terms in R&D this year than last.

What will it mean for our senior citizens, and to others in our society if this continues? And frankly, it is the bad mouthing of this administration and the actual language of their legislation that is causing an awful lot of this decline.

Let me just point out one other thing. Not many people are aware a recent Price-Waterhouse study found for every dollar that cash flow is reduced, R&D goes down 30 to 40 cents on a dollar. Now pharmaceutical companies have been going through this and it is primarily because of some of the comments that have been made.

So even if every dollar of rebate, new taxes and other financial burdens we pile on the pharmaceutical industry does not all come out of R&D as Mr. Rother has said here today, a big chunk of it is going to. There is no use kidding about it.

I do not think that a country with an aging population can afford to invest substantially less in medical research and especially biotechnology research. It is going to be very expensive in the long run and we cannot be pennywise and pound foolish on this issue.

I am sorry to keep you so long.

The CHAIRMAN. I am not sorry in the least. This is an absolutely fundamental question. For what it is worth, I can tell you we have a prior issue which is the approval processes that we have put in place over the century.

I see Dr. Sanders nodding and Mr. Rudnick.

We have all met and spoken with heads of major pharmaceutical companies of late. The one I spoke with said to me, they have gotten so discouraged by the FDA that they are really putting all their efforts into a cure for baldness, which is something the Romans worked on and never did solve. So you never know.

Senator HATCH. You may want to go on my dietary supplement bill. [Laughter.]

The CHAIRMAN. We have to end on a positive note. Dr. Rudnick, is the nature of Alzheimer's Disease understood?

Dr. RUDNICK. I think increasingly it is understood.

The CHAIRMAN. So the question is what do you do about it.

Dr. RUDNICK. The developments in the disease, the ability to diagnose it has gone up immensely in the last couple of years alone. I think as a result of much of your support in terms of basic research.

The CHAIRMAN. All right. You get out there and we want CytoTherapeutics to win the prize.

Thank you all very much. We do very much appreciate it.

[Whereupon, at 1:28 p.m., the hearing was adjourned.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED

PREPARED STATEMENT OF DEBORAH BRICELAND-BETTS

INTRODUCTION

Good morning, Mr. Chairman. I am Deborah Briceland-Betts, National Campaign Director of The Long Term Care Campaign. I appreciate this opportunity to appear before you today.

The Long Term Care Campaign is a seven-year-old coalition of 137 national organizations dedicated to enacting legislation to protect American families against the devastating costs of long term care. The Campaign's cooperating organizations represent a diverse community, including: seniors, people with disabilities, organized labor, nurses, veterans, women, and the elderly. Their combined memberships include more than 60 million Americans.

The groups that I represent would find it very hard to support a plan to reform our nation's health care system that does not include long term care.

THE NEED

An estimated 11 million Americans, young and old, need long term care. While two-thirds of those are seniors, one in three are children and adults under the age of 65. The fastest-growing segment of the population is the group aged 85 and older, now about three million and projected to almost triple by 2030.

Long term care is not just an issue for aging Americans, it is an issue for the American family. It is a family issue, because families provide the care. Eighty-four percent of the people who need help live at home. At least seven million Americans are involved in caring for a parent at any given time. Long term care is particularly an issue for women in the family. Most care is provided by spouses, daughters, and daughters-in-law. The average caregiver is a 57 year-old woman who is often in poor health herself. Women who are now in our mid-lives will spend more time caring for our parents than we have for our children.

Long term care is a family issue because currently it is families who are paying out-of-pocket for that care and they are paying in a very inequitable way. The only help available to families under our current system demands that they spend down to be eligible, and then for the most part it only provides help in paying for institutional care.

Long term care is a family issue because, regardless of the age of the person who needs care, every person in the family—parent, spouse, sibling, child, grandchild, even great-grandchild—is affected.

We have a health system now that discriminates by disease and disability. If you have a heart attack and need surgery, or if you have cancer and need chemotherapy, the system recognizes your health care needs and insures them. But, if you get Alzheimer's Disease, if your child has cerebral palsy, if you suffer a spinal cord injury, the system ignores you because the type of health care you need is long term care.

The following are brief descriptions of people who need long term services. These cases are representative of the millions of families for whom long term care services and support are an essential part of health care reform.

- Kate and Tom Miles from Lusby, Maryland are the parents of a nine-year-old boy, Robbie. Robbie had epileptic seizures when he was two-years old which left him retarded and physically limited. He spends much of his time in a wheelchair and needs physical help bathing, dressing, toileting, and moving around. His parents and his eleven-year-old sister provide all of his care. Both of his parents have developed back problems helping their growing son. Tom works

two jobs so that Kate can stay at home. They have already sold their house to help pay Robbie's medical bills, and their insurance copayments have just increased to 50%. They have nothing left to pay for someone to help with Robbie's physical care. They will not put Robbie in an institution, even through Medicaid would pay for his care if they did.

- Mrs. Shirley Reed of Washington, D.C. is a 60 year-old retired government worker and mother of seven who cares for her 83 year-old father, Clarence Spring. He suffered a stroke almost two years ago that left him paralyzed from the neck down. When he left the hospital, Mrs. Reed brought her father to live in her home. Mr. Spring is totally bedridden and needs complete help bathing, toileting, dressing, and eating. He needs attention at all times of the day and night and cannot be left in the house alone. Mrs. Reed has difficulty getting away, even to run errands and pays a friend to help on weekend and some evenings. She rarely gets a night of uninterrupted sleep. Mrs. Reed's three adult daughters who live in the area help by staying overnight when they can.
- Before he was 25, Billy owned his own contracting company and had purchased a home. He paid his health insurance premiums out of his own pocket, until an accident a year ago. Now, at the age of 26, he is a quadriplegic. His health insurance will not pay for the extended rehabilitation he needs to become independent again and return to work. He lives with two friends, who help him eat, bathe, dress, and move in and out of his wheelchair. Billy uses almost all of his disability income to pay for his care.
- Seven years ago, at the age of 55, Judy quit her job to care for her husband, Otto, who has Alzheimer's Disease. Even though he is still physically strong, Otto needs help eating, bathing, dressing, and moving from place to place, because he has forgotten how to do these things on his own. And because Alzheimer's has taken his judgment and reasoning, he needs constant supervision and cannot be left alone. Judy is using all of her extra funds to pay for adult day care, to provide a therapeutic program for her husband during the day and some respite for herself.

We need a health system that will offer a range of support—from acute to long term services—to individuals and families like these. Real national health reform must include long term care benefits.

THE CLINTON PLAN FOR LONG TERM CARE

The President's health care reform plan will make an enormous difference, by finally bringing health care costs under control, so state and federal dollars will go further, and by providing major new funding for home and community long term care. Finally, the states and the federal government may be able to stop robbing Peter to pay Paul, and address all of a family's health care needs—including long term care.

We know that we are at the beginning of the legislative process and that changes will be made. But, there are certain features of the President's long term care proposal that The Long Term Care Campaign considers absolutely essential:

- First, it is a program for persons of all ages and incomes, with protections for low-income families and cost-sharing for those who can afford to contribute.
- Second, it includes specific eligibility language to assure coverage for persons with cognitive and mental impairments as well as physical disabilities.
- Third, it provides consumer choice of services and providers, and allows consumers or their families to direct those services.
- Fourth, it is flexible, so that services can meet individual needs, rather than a "one size fits all" program.
- Fifth, it provides real financing for the new program.

I think it is important to point out that the President's program is *not a new* entitlement program. Certainly, the groups that I represent would have liked to see a more comprehensive program that was more of an entitlement, but we have declared this limited program a responsible and very major step forward in the light of current budget realities.

LONG TERM CARE SAVES HEALTH CARE DOLLARS

We all recognize Congressional concern about the cost of including long term are in health reform. But, you must understand that we will end up spending even more money if we do nothing about long term care, increased hospitalizations and emergency room visits to people who have no care and to caregivers who have no help. Or, we will force them into a setting where we know we will spend the most money—nursing homes.

There is mounting evidence that the kind of long term care expenditures the President is proposing will yield real savings, in nursing home costs and in avoidable hospital expenditures. For example:

- In Wisconsin, a leader in providing home and community services through its community options program, Medicaid nursing home bed use went down by 19%, at the same time bed use was rising 24% nationally.
- In the Independent Living for Seniors program in Rochester, New York, use of adult day care has cut hospital utilization by participants in half.
- Nearly half of hospital emergency room physicians report an increasing number of elderly persons left in emergency rooms, not because they need medical treatment, but because their families are exhausted and there is no where else for them to go.
- According to the National Institute of Medicine, delaying admissions to nursing homes by just one month would save three billion dollars a year. Wisconsin's experience proves this is an achievable goal.
- Studies have shown that one in three caregivers experience health problems. This problem is compounded by the fact that many caregivers themselves lack health insurance to help pay for the treatment of injuries and illness.

WHY PRIVATE INSURANCE ALONE DOESN'T WORK

There are those who say that private insurance is the answer to the long term care crisis. The Long Term Care Campaign feels strongly that the next federal dollar spent on long term care should not go to providing tax incentives for those who purchase long term care policies. While we believe that there is a role for private long term care insurance and we support national standards for private insurance, we do not believe that this alone is the answer to our long term care crisis. There are several reasons why, but the two most prominent reasons are that most people can not afford it and those who need it the most cannot purchase it.

Even under the best of circumstances, appropriately standardized and regulated, private long term care insurance is too expensive for most families—even its most enthusiastic proponents concede that at best is could meet the need of only 20% of the population. (We think those estimates are overly optimistic.) (Riviln and Wiener of Brookings 1988; Friedland 1990).

According to the industry's own information (Health Insurance Association of America, HIAA), the average annual premiums for a long term care insurance policy with a four-year benefit period paying only $80 a day for nursing home care, and $40 a visit for home care (with inflation and nonforfeiture protection) in 1991 were: $1,252 per year for a 50 year-old; $2,525 for a 65 year-old; and $7,675 for a 79 year-old. The average American buys long term care insurance at about age 70. And, recent reports by HIAA indicate that those premiums increase dramatically when a lifetime 5 percent compounded inflation feature and/or non-forfeiture benefits are added to the base' policy. Certainly long term care insurance is an option only for the very rich.

Another problem with long term care insurance is that people who need it the most cannot buy it. It is the reality of the insurance. It has nothing to do with fraud and abuse. An individual voluntary program will not work for millions of people with disabilities, diagnosed diseases, or health histories that signal a future need !0 draw on policy benefits. That includes approximately three million people with evelopmental disabilities, nearly half a million people who happen to have multiple sclerosis, four million people diagnosed with Alzheimer's Disease, and millions more disabled from birth, accident, or other illnesses, like epilepsy, heart attack, or even asthma, alcoholism, and others. Many companies also refuse to sell policies to people over 80 years of age because of the increased risked of using benefits. If there is anything in a person's medical history that signals a potential future need for benefits, they are not allowed to purchase a policy.

There are currently 10 million people in this country who need long term care services and not one of them could purchase a long term care insurance policy that would provide the benefits they need. That is why we need this public program.

LONG TERM CARE INCREASES SUPPORT FOR NATIONAL HEALTH REFORM

Finally, including long term care increases popular support for general health care reform. According to recent surveys by the Alzheimer's Association and AARP, people are much more supportive of reform that includes long term care. The Gallup survey conducted by the Alzheimer's Association showed that nine out of ten Americans—of all ages—believe that health care reform must include long term care. These findings are consistent with other polls taken in January of this year showing that:

- 48% would be more likely to support a health care reform proposal that included coverage for home and community-based care, and
- 43% would be much less likely to support a proposal that does not include long term care coverage.

These polls are not surprising. Millions of American families are already dealing with long term care and most believe they will at some time in the near future. They understand, as you do Senator Moynihan, that health care reform will not be comprehensive, it will not offer universal coverage, and it will do almost nothing for the people we represent, unless it includes long term care.

LONG TERM CARE MEANS JOBS

Senator Moynihan, I know that you are concerned about both long term care and welfare reform. The data shows that a new program, like the one proposed by the President, would create one million new jobs. Those are real jobs. Eighty-five percent of these job would be in the private sector. And they would be new jobs. Jobs that could provide training and productive work for those who might otherwise end up on welfare.

CONCLUSION

The Long Term Care Campaign, a diverse national coalition representing more than 60 million Americans nationwide, believes that long term care must be part of any effort to reform our national health care system. We need a program—like the one proposed by President Clinton—that begins to offer options for individuals and families to get and receive care where they want in the most, at home and in the community.

Ignoring the need to address long term care now will not save money. In fact, including long term care in national health reform can save dollars by avoiding cost shifting, unnecessary hospitalizations, emergency room visits to those who have no care and injury and illness to caregivers.

We believe that while there may be a role for private insurance, insurance alone simply cannot address this problem. Even in the best regulated market, insurance premiums would still be too expensive for all except the very rich.

And finally, public opinion polls repeatedly show that Americans want and are willing to pay for a national health reform plan that includes long term care.

Thank you for holding this hearing, Senator Moynihan. And, thank you for your leadership on long term care and its important place in the health reform debate.

RESPONSES OF MS. BRICELAND-BETTS TO QUESTIONS FROM SENATOR DOLE

Question 1. What might be the role for private insurance and what can the federal government do to expand the availability of affordable private long term care insurance?

Answer. Private insurance is expensive because the pool is not large enough to cover the liability. If a policy maker wanted to create a role for private insurance, there must be a market carved out that would limit the liability of the industry and drive down the cost of individual policies, thereby increasing the affordability and opportunity of more people and younger people to purchase policies. The combination of the larger pool and limited liability would allow the private market to thrive. Several pieces of legislation have been introduced over the years reflect this strategy. Those approaches have used a public/private mix—a public program with a private insurance wrap-around. Those discussions have included front end and back end financing (either a delay in accessing the public program for a specified period of time, say 6 months to 2 years, or immediate access to the program with a limit on the amount of benefits available), and enhancements to the existing Medicaid program and tax incentives for purchase of private insurance (such as the Robert Wood Johnson approach), among others.

However, The Long Term Care Campaign believes that a public program is the best way to insure protection for all Americans. Insurance companies are becoming increasingly active in their efforts to market private long term care policies. As of December 1991, approximately 135 companies sold long term care insurance. According to the Health Insurance Association of America (HIAA), about 2.4 million private long term care insurance policies have been sold. However, many of these policies are no longer in force because they have been dropped, or "lapsed." Still, many politicians and some policy makers, argue that private insurance can solve the long term care crisis. It cannot do the job alone—not without assistance from a public long term care program like Social Security or Medicare. Why?

- **Availability**—An individual voluntary program will not work for millions of people with disabilities, diagnosed diseases, or health histories that signal a future need to draw on policy benefits. That includes approximately 3 million people with developmental disabilities, nearly half a million people who happen to have Multiple Sclerosis, 4 million people diagnosed with Alzheimer's Disease, and millions more disabled from birth, accident, or other illnesses like Epilepsy, heart attack, or even asthma, alcoholism, and others. Many companies also refuse to sell policies to people over 80 years of age because of the increased risk of using benefits. *If there is any indication in a person's medical history that indicates a potential future need for benefits. they are not allowed to purchase a policy.*
- **Affordability**—According to the insurance industry's own information IAA), the average annual premiums for a long term care insurance policy with a 4-year benefit period paying only $80 a day for nursing home care and $40 a visit for home care, with inflation and nonforfeiture protection, in 1991 were:

  $1,252 per year for a 50 year old;
  $2,525 for a 65 year old; and
  $7,675 for a 79 year old.

The average American buys long term care insurance at about age 70. Only 10–20% of the elderly can afford long term care insurance. (Rivlin and Wiener of Brookings 1988; Friedland 1990). It is not that older Americans are unwilling to buy policies. Recent studies indicate that of married people 65–79 who are willing to spend as much as 25% of their discretionary income on long term care insurance premiums, 38% would be willing to boy a policy that provides 4 years of coverage with a $100 daily benefit, no inflation protection, and a $2,000 deductible (Crown, Capitan 1992). *As the cost of long term care insurance premiums increases with age, the income of older Americans decreases. The Census Bureau reports that the income of the disabled elderly is disproportionately low.*

The long term care insurance market is also untested. These policies have been on the market for about ten years. It may be an additional twenty years before the beneficiaries begin to draw on the policies and only then it become evident whether the premiums were appropriately priced. If they were underpriced, it could result in an insurance crisis.

- **Coverage**—*Even those who can afford the premiums of a private long term care insurance policy do not have the security and peace of mind that the benefits will be available when they need them.* A recent Alzheimer's Association study, *Don't Count on It,* examined 11 of the leading insurance policies on the market and found that even after spending as much as $4,000 a year on a policy, the policy holder faced with Alzheimer's Disease may find she or he has little if any protection against the heavy cost of the long term care they need.

Many policy holders cannot afford to pay the premiums over a long period of time, therefore, many policies are dropped or "lapse" with the consumer never receiving any benefits. The insurance industry's own reports show a higher lapse rate for long term care insurance than any other kind of insurance. According to the U.S. General Accounting Office "On average, insurers we reviewed expected that 60% or more of their original policyholders would allow their policies to lapse within 10 years; one insurer expected an 89% lapse rate." Lapsing occurs because of increased premium costs for long term care or Medigap policies, death of a spouse, or other financial problem. Very few policies include nonforfeiture benefits, which provide some protection after a policy lapses.

Most plans lack inflation protection and rapidly lose their value over time. This is a serious problem for long term care policies because of the long interval between purchase and ultimate use. A policy purchased in 1993 that provides an $80 a day benefit and no inflation protection will cover only a small amount of the daily cost of care when the purchaser needs it in ten to twenty years.

Private insurance is too expensive for the vast majority of Americans. Even those who can afford it have no guarantees that the high premiums they pay will produce a policy that provides the long term care coverage they will ultimately need.

Public long term care coverage, like Social Security, is the only way all Americans can be protected from the financial burden of providing long term care for a loved one. Everyone would pay and everyone would benefit, no one would get left behind. It would provide the peace of mind and security that you never really get with a private insurance policy.

Question 2. What options, other than the Clinton Administration's plan for long term care, can you recommend for providing long term care—for example by modifying Medicaid long term care programs?

Answer. See answer number 1.

Question 3. How many people would realistically not receive long term care under the Clinton plan?

Answer. As you know, Senator, we are in an era of tight budgets. In an effort to save precious dollars, the Clinton Administration has proposed a program that is aimed at serving those who are in the most need—people who would probably face much more costly institutionalization if they did not receive services proposed through the Clinton plan.

Analysts of the Clinton administration's proposal suggest that it would serve approximately 3.1 million people with severe disabilities. It is difficult to ascertain how many additional people would receive services under existing state and local programs, but a sizable number, certainly somewhere near 50 percent of those who need assistance, would not receive help under the Clinton proposal.

Question 4. What in your view will happen to the existing family network of care if a new public program. becomes available?

Answer. There is almost no hard data on what would happen if a public program were implemented, but there are a few studies that lead to the conclusion that families would not abandon their members to the public system, rather they use it as a support mechanism that appears to allow them to perform such duties over a longer period without illness or injury to themselves. The US experience with the National Long-Term Care Channeling Demonstration offers some evidence of such.

The Channeling demonstration was implemented by the federal government over a five-year period beginning in 1980 to evaluate the ability of home and community-based services in a case management system to control long term care costs. After 6 months in a carefully constructed program, one of the two case management approaches did lead to some minor substitutions among services. However, the total analysis revealed that the amount of community care increased from formal and informal caregivers combined increased as a result of the addition of the new program. (For a more detailed explanation, see *Facing the Costs of Long Term Care,* Robert B. Friedland).

Similar results were evidenced in a Minnesota study. Overall, that study found that the availability of formal services did not affect the amount of informal caregiving with any statistical significance. The study showed that services tended to supplement rather than substitute for informal services. (Friedland, pp. 119–122.)

Substituting Formal Care for Informal Care

The high price of formal care, the limited number of services available, and the dislike of nursing homes may explain why so much long-term care is provided by family and friends. Critical to insurers and to public policy decisions is the question of how much care already provided by the family would be replaced by formal or paid services if these services were affordable or subsidized and available. This important question is difficult to answer. At best there may be a few select examples of what happens to informal care when services become available. In the United States, the experience with the National Long-Term Care Channeling Demonstration and, in Canada, the addition of long-term care to the national health plan offer some indication of what may happen.

The channeling demonstration was implemented by the federal government over a five-year period commencing in 1980 to evaluate the use of comprehensive case-managed, community-based care to contain long-term care costs. Two fundamentally different case management approaches were used in ten sites (five sites for each model) throughout the country. Frail elderly at risk of needing nursing home care were either assigned to one of the two case management programs or became a part of the control group. The control group did not receive the services provided in the demonstration project but continued to use those available in the community.

Compared with those in the channeling program, the control group received substantially fewer in-home services. The increase in services in the channeling program resulted in a small amount of substitution for informal care in one of the two case management approaches used in the study. However, the substitution of formal for informal care occurred due to the withdrawal of friends and neighbors, not of spouses, children, siblings, or other relatives, who continued to provide the same amount of care regardless of whether or not their dependent was in the program (Kemper et al., 1986).

After six months in the program, one of the two case management approaches did lead to some minor substitutions among services. Meal preparation, housework, laundry, and/or shopping, other in-home care, delivered meals, and transportation were found more

likely to be replaced with formal care. However, therapy, help with taking medicine, personal care, general supervision, chores, and other medical treatments were not decreased and, therefore, recipients received more care. Altogether, the total amount of community care from formal and informal caregivers combined increased as a result of the channeling program (Kemper et al., 1986).

A similar result was observed in Minnesota, where applicants to Medicaid-certified nursing homes and related facilities must undergo a health and psychosocial needs assessment prior to admission. The recommendation based on the assessment is not binding, but if the individual chooses to remain in the community, the assessment team will develop a care plan and assess financial eligibility for services within their community-based program. This program includes adult day care, respite care, homemaker services, home health aide services, foster care, personal care, and case management.

One study attempted to evaluate the extent to which the availability of informal caregivers influenced the care plan provided and the extent to which the services provided affected the amount of care given. The simultaneity of these two decisions, however, created some measurement problems, which may have affected their findings. Overall, the study found that the availability of informal caregivers did not alter the allocation of formal services and that the amount of informal caregiving was not affected by the amount of formal services provided in a manner that was statistically significant. This suggests that formal services tended to supplement, rather than substitute for, informal services (Moscovice, Davidson, and McCaffrey, 1988).

The experience of Canada, which has, under the direction of each province, universal health insurance that includes federal funding for long-term care, has led to a similar conclusion (Fletcher, Stone, and Tholl, 1987). Examining the implementation of publicly financed long-term care in three Canadian provinces (Ontario, Manitoba, and British Columbia), one study found that from 1977 to 1980, health care expenditures as a percentage of Gross National Product declined, as did the percentage of public expenditures (except for 1980). In general, the changes in health care use through 1982 have led researchers to conclude that there was a stronger case for the substitution of long-term care beds for hospital beds than for the substitution of community-based care for nursing home beds. The growth in community-based services that did emerge enabled communities to restrain the growth in nursing home beds that might otherwise have occurred based on the growth of the elderly population (Kane and Kane, 1985a).

More notably, providing community-based homemaker and nursing services did not lead to runaway utilization.[10] There was no evidence of overinstitutionalization; in fact, the elderly in Canada may be less likely than those in the United States to use long-term care facilities (5.5 percent compared with 5.6 percent in 1985) (Doty, 1986b). Families in Canada are just as dedicated as those in the United States to maintaining the independence of the elderly, who are just as desirous of remaining independent as are elderly Americans (Doty, 1986b).[11]

Conclusion

The organization and delivery of long-term care is not systematic. Sources of care and the services provided vary considerably. The best-organized delivery system, however, is the nursing home. But even nursing homes vary tremendously, as evidenced by the wide range of types of facilities and of bed and staffing ratios that exist among states. Furthermore, despite the fact that nursing homes are relatively well-financed and are the most regulated and best understood source of long-term care, there is widespread concern about the quality of life they offer to residents.

Formal in-home care services have not been found to be a cost-effective substitute for nursing home care. Furthermore, *additional* services have not demonstrated substantial improvements in the recipient's quality of life. Nevertheless, home health services are highly desirable. The absence of any informal services makes formal in-home services imperative, and these services do improve the quality of life of the primary caregiver. This suggests that private or public coverage of in-home care should be flexible enough to assist primary caregivers in providing long-term care. The evidence is limited, but it suggests that children and spouses will not substitute formal services for their

[10]It should be noted that the use of these services in two of the three provinces (at the time of the study) was controlled by a case management approach. Case management is discussed in detail in chapter VII.

[11]It is quite conceivable that the moral hazard arising from a publicly financed program is different from that arising within an environment of private insurance. (See chapter VI for a discussion of moral hazard.) If individuals feel compelled to "get their premiums' worth of services," then it might not be relevant that within public programs individuals show little, if any, tendency to substitute formal services for informal services. However, there is no evidence that the attitude concerning publicly financed services would be considerably different, since, after all, beneficiaries did pay their taxes.

PREPARED STATEMENT OF RICHARD C. LADD

Before any reform of the long-term care system in the United States can be undertaken, we should be sure that we know what problems need to be fixed. We should also be sure that these problems are severe enough that reform of the long-term care system is necessary In my opinion, long-term care in the United States is an unique American tragedy. This opinion is based on my experience in developing, implementing and operating the highly touted Oregon long-term care system for twelve years, and for the last two years in the state of Texas.

Long-term care is even more of a tragedy than health care. I say this because there are no good ways to protect oneself from financial disaster for the millions of Americans who live long enough that long-term care becomes necessary. For a variety of reasons, the United States spends most of its long-term care dollars in nursing homes. These facilities are very expensive and generally cost private clients over $2,000 per month.

A great many elderly Americans will spend a few months or even a few years in nursing homes. Most of these people will become eligible for Medicaid. In New York, about 90 percent of those in nursing homes are eligible for Medicaid. In my state of Texas it is nearly 75 percent. Most retired elderly persons cannot afford more than a few months in nursing homes as private clients. Indeed, most will become eligible for Medicaid during the first year of their stay in a nursing home. A great many of the people who live in nursing homes worked hard and paid taxes all of their lives. They never expected to spend the last few years of their lives on a public welfare program.

Medicaid was designed as a program for poor people. It has become the major funder of long-term care in this country by default. Medicaid requires that the beneficiaries be poor before it will pay for care. Medicaid has the highest co-payment system in existence. In nursing homes for example, it essentially requires that you spend all of your income each month on a co-payment (except for a small amount usually $35 that you may keep for personal incidentals).

Much of this financial suffering could be avoided if a viable insurance program was available. Unfortunately, most, if not all, available long-term care insurance plans are unaffordable for the average retired person. Indeed, like myself, almost all experts on long-term care do not own a long-term care insurance policy. In fact, most of us advise elderly relatives not to buy such policies. Long-term care insurance in the United States remains too expencive and too restrictive to become a viable alternative funding source.

Tax credits or expanded allowable tax deductions would be of some help, but will not solve the problem. Senator Packwood has introduced such plans on several occasions in the past, and in my opinion they should be included in any reform package.

The major tragedy in long-term care in the United States is the method in which we deliver most of these services. Long-term care was not included in either Medicaid or Medicare when they were enacted. After the so called "Miller" amendments were passed by Congress in 1967, long-term care institutions, i.e., nursing homes, could be funded by Medicaid. Between 1967 and 1981 growth in nursing homes in the United States went from about 26 beds per 1,000 persons over the age of 65 to nearly 54 beds per 1,000.

Because Medicaid is an entitlement program, any individual who meets the eligibility criteria is entitled to nursing home care. This is not true for other services such as home care that provided alternatives to nursing homes. Indeed, until 1981 essentially the only long-term care service eligible for Medicaid was nursing homes.

During the period 1967 to 1981, all states greatly expanded their nursing home programs. Private developers were encouraged to build and operate nursing homes, and we as a society talked ourselves into believing that old people needed to be placed in nursing homes when they became frail.

Because Medicaid is a medical program, we began to think of long-term care as a medical service. Mostly through federal statutes and regulations, we began to medicalize nursing homes. Indeed, before 1967 most of the facilities that would later become nursing homes, were social model facilities with a medical component, and were generally not thought of as medical facilities. We as a society began for the first time in our history to think of aging as a disease that needed medical attention.

It is very hard to find an individual who wants to enter a nursing home. In fact, nursing home placements are very seldom made by the individual, they are made mostly by family members and hospitals. Study after study tells us that the largest fear of most elderly people in this country is being placed in a nursing home. There is no denying that the care needs of some people will require a medical setting such as a nursing home, but the number of such people is far less than the number cur-

rently residing in nursing homes. Some studies have shown that as many as 50 percent, or more, of those currently in nursing homes could benefit from an alternative setting.

The 1981 Reconciliation Act included a provision for Home and Community Based Waivers that allowed for Medicaid funding for alternatives to nursing homes. Unfortunately, during the first seven or eight years, only a few states were able to take major advantage of this program. Today 48 states have waivers, but they only account for about 2 percent of long-term care expenditures. The Home and Community Based Waivers, while funded by Medicaid, are not an entitlement program. The amount of funds each state can spend on alternative care is strictly regulated by a complex formula.

We have created a major bias in our long-term care system: Nursing homes are an entitlement program for eligible clients, while alternative services are not. This has caused almost all states to strictly limit the number of persons that can be served in alternatives. Once this number is reached, waiting lists are established, and persons needing long-term care services must either wait or enter a nursing home.

Oregon has established a nursing home replacement model using a social model facility with a medical component. These are called assisted living facilities, and are funded through Medicaid Home and Community Based Waiver funds. This program is enjoying a high degree of success, and is very popular with the residents of these facilities. They also cost less, about 80 percent of nursing home costs, even though each resident has their own private room. Oregon, Texas and most other states have also found that a great many former nursing home residents can reside safely and happily in their own homes, with homecare being provided when needed.

No one is more responsible for the success of the Oregon program than Senator Packwood who in 1987 sponsored legislation that created section 1915(d) of the Social Security Act. Only Oregon has so far chosen this option, which allows a state more flexibility in designing its long-term care system. Under this section there are no limits placed on the number of persons that can be served in alternative services. In exchange for this flexibility, Oregon has agreed to a cap on the amount of federal funding available for long-term care. To date, Oregon has been able to expand the number of persons served, and still not exceed the federal cap, although because of growth factors used in determining inflation, that cap may be reached this year.

If ever a system needed reform it is long-term care. Because we have invested so heavily in the most expensive type of long-term care, i.e., nursing homes, we spend much more than necessary for long-term care services. A better balanced long-term care system, where only people with medical long-term care needs were placed in medical long-term care facilities would save billions of tax dollars.

The Oregon long-term care system, for example, serves many fewer people today than it did in 1981 in nursing homes, but several times more people in alternative long-term care services. Oregon has estimated that overall more people in need of long-term care are served at a much lower cost.

The most important long-term care reform that Congress can enact is to eliminate the nursing home bias. Elderly and persons with disabilities in need of long-term care services must be allowed to choose where they can receive those services. States must be allowed the flexibility needed to design long-term care systems that provide reasonable choice between alternative services and institutional services.

Long-term care reform must allow us to return to the idea that aging is not a disease, it can not be cured, it is a natural condition that all of us will suffer if we live long enough. We should not be punished for aging and required to live under conditions we do not choose. We should also not have to suffer the indignity of impoverishment before help becomes available.

I firmly believe that long-term care reform is possible without expending large additional amounts of new federal dollars. We will never be able to achieve this, however, as long as the nursing home industry enjoys special status among all long-term care providers. I also believe that meaningful reform can only be accomplished if states are given the flexibility they need to design balanced long-term care systems. The current long-term care system is too expensive, too restrictive, and too intrusive. I hope you will be able to achieve reform of this system this year.

RESPONSES OF RICHARD C. LADD TO QUESTIONS FROM SENATOR PRYOR

Question. In your testimony, you point out that while we treat nursing home services as an entitlement, we do not view alternative services such as home care in the same light. If we make these alternative services an entitlement, won't we see a whole new set of recipients, who haven't received services in the past, come out of the woodwork—the so-called "woodwork effect?"

Answer. Studies done by GAO in the late 1970's showed that for every person receiving formal long-term care (in a nursing home or other paid program), there were at least two other persons, at the same degree on impairment, who were being cared for by family or friends, or were simply surviving by themselves. Although it has never been researched, the result of this GAO study led many people to think that expanding the long-term care system (especially the home care component) would cause this latent population in risk of long-term care to come out of the "woodwork."

Oregon has had an open system (no waiting lists, no nursing home bias, and no differences of eligibility between nursing homes and the community programs) since 1981. If the "woodwork" effect was real it would have been seen in Oregon during this time. Oregon has seen a greater increase in long-term care cases than would otherwise have been expected, but this increase was not great and was easily absorbed. When home care is costing between 25% and 33% of nursing home care, you can provide services to 3 or 4 people at home for the same cost of serving one person in a nursing home.

Question. You mention in your testimony the difficulties inherent in the Medicaid waiver program as it currently exists. Under the President's proposed changes to the health care system, States will still be able to use Medicaid to serve poor people who do not meet the disability test of the new home and community-based care program. How can we improve the Medicaid regulations to make it easier for States to do this?

Answer. Currently, and under the President's proposal, home care and other alternative services can be offered either through the Personal Care option, or through the Medicaid waiver program. Both of these programs have serious limitations:

Personal Care allows states to offer home care and other alternatives without regard to the number of people using this service, however it does not allow institutional eligibility.

Most states have set the institutional eligibility income level at 300% of the SSI standard. Personal Care only allows that eligibility level to be 100% of the SSI standard. This means people needing long-term care services who have an income of between 100% and 300% of the SSI standard will not qualify for home care, but will qualify for nursing home care.

Medicaid waiver programs are limited as to the number of people they can serve, but do allow eligibility up to 300% of the SSI standard. Medicaid regulations require that no more people can be served in a waiver program in a state than there are empty nursing home beds in that state. This has been termed the "cold bed rule," because eventually the only way to expand the home and community bases services are to build nursing homes and then keep the beds empty.

Both of these options produce a strong nursing home bias. This bias has been, and continues to be, a powerful disincentive for the expansion of home care. The best thing Congress could do for the states and for the federal government, would be to make home and community based care an optional program within Medicaid, and allow that program to make persons eligible who have income up to 300% of the SSI standard.

This option will cost more money, but since we now predominately use nursing homes as our chief long-term care service, the most expensive long-term care option is not changing the current system. If home care is allowed to expand, it should become the chief long-term care service in five to ten years. This will allow the large expected increase in the elderly population to be able to receive long-term care services in a less expensive, less restrictive environment.

Question. In both Oregon and now Texas where you have helped set up innovative and comprehensive long-term care systems, how did long-term care insurance play a part?

Answer. Long-term care insurance has played little or no part in either state. Current policies are too expensive for most people to afford, and younger persons who could purchase this insurance at cheaper rates, seem reluctant to do so. Until long-term care insurance companies lower rates, provide inflation protection, and broaden the services that can be insured, it will continue to be a very small player.

Question. When we consider providing a long-term care component in health care reform to create a more comprehensive continuum of care for people and address the wishes of the majority of the population who would prefer to receive services within their own homes, there is always the question of how much will it cost. I know that some studies have shown that there is not a significant cost difference between home and community-based care services and nursing homes.

However, your testimony says that costs for home and community-based care services are 80 percent less than nursing homes. Can you expand on that statement?

Answer. The studies that you mentioned were conducted mostly in the' late 1970's and early 1980's. They showed that home care was just as expensive as nursing home care. The reasoning behind these conclusions is quite convoluted, and hardly anyone who operates a state long-term care system gives them any credibility. In Texas for example, the 1994 budget for nursing homes is $1,201,744,808, and we expect to serve 68,144 persons (or about $1,470 per person, per month). The 1994 budget for home and community based services is $386,226,094, and we expect to serve 78,536 persons (or about $410 per person, per month). The cost of home and community based services is 27.9 percent of the cost of nursing home care in Texas.

The 80 percent figure I gave in my testimony applied to the Assisted Living Facility program now being operated in a few states. This program is a nursing home replacement model, and as such is more expensive than home care. A recent study in Oregon by the University of Minnesota showed that Assisted Living Facilities in Oregon were 61 percent of nursing home costs.

The simple fact of the matter is that home and community based services cost less than nursing home services to whomever is paying the bill. If you want to confuse the issue by studying life time costs (home care recipients tend to live longer and use more services), or by trying to add to home care the cost of maintaining a home; then you might come up with the same conclusions that were made over 10 years ago.

Question. In your testimony, you state that long-term care reform is possible without spending large amounts of new federal money. Do you have any specific recommendations that you can provide to us on how we can achieve this in health care reform?

Answer. The following recommendations are made:

1. Form a national long-term care committee similar to those suggested in the Clinton Health Plan. This committee should be time limited, and its main activity would be to decide several issues connected with the following recommendations:

2. Limit nursing home placements to sub-acute patients. The definition of sub-acute would be decided by the national long-term care committee, but would be much higher than admittance levels to nursing homes are today, and would require the need for complex medical care.

3. Allow no Medicaid or Medicare certification for new nursing homes in geographic areas where the number of beds is above a certain level per 1000 persons age 65 plus. The defined geographic areas should be left to each state to decide, but should be no greater than the state itself.

Currently, the national bed ratio average is about 52 beds per 1000, but this varies widely between states. Florida has the smallest ratio at about 26 beds per 1000, and several states exceed 75 beds per 1000. The national long-term care committee should determine an appropriate number.

4. Move the current 1915 waiver programs (including "Frail Elderly") into the regular Medicaid program. Remove any requirement for limiting the number of clients to be served or other such formulas that restrain growth. A state should be able to start or expand alternative services simply by submitting a state plan amendment.

5. Allow for institutional financial eligibility to apply to home and community based services. To do otherwise maintains a nursing home bias.

6. Allow for much lower impairment levels for eligibility in home and community based services than in nursing homes. The national long-term care committee should make this determination.

7. Alternative services should include:
   a. Home care,
   b. Adult Foster Homes,
   c. Assisted Living Facilities,
   d. Adult Day Care,
   e. Chore services,
   f. Personal Assisted Services,
   g. Minor adaptations to the home, and
   h. Other necessary services as approved by HCFA.

8. National definitions of the above services should be completed by the national long-term care committee. These definitions should be broad enough to allow some flexibility for different areas of the country. Social congregate living facilities (Adult Foster Homes and Assisted Living Facilities) should not be subject to the Boren Amendment and should not include board and room as a part of their Medicaid reimbursement rate.

9. National quality standards should also be developed for the alternative services, but should not be allowed to become too burdensome as is the case with nurs-

ing homes today. The national long-term care committee should develop these standards.

10. Since this program can be expected to reduce the demand for nursing homes, they should be encouraged to remodel to assisted living facilities (which should require single occupancy). One method of doing this would be to give a tax credit to nursing homes that remodel.

11. Maximum financial eligibility for Medicaid long-term care should be the same for home and community services and for nursing homes. Both should have a maximum income eligibility of no higher than 300 percent of the SSI standard. Asset limits should be increased to $12,000. Spousal impoverishment should be retained. Current Asset exceptions should also be retained.

12. Coverage of long-term care services for those who do not meet the Medicaid financial eligibility tests, should be provided through Medicare. This should be included in a new title (C or D). This Medicare coverage should be time limited (perhaps 2 to 4 months for nursing homes and 4 to 8 months for alternative services). If deductibles or copayments were instituted this time limit could be extended.

13. For longer coverage, long-term care insurance should be encouraged. This item could have tax breaks as described in the Packwood-Dole bill.

These recommendations will cost additional state and federal dollars, but it should be remembered that anything we do in long-term care will cost more. Over the next 20 years these recommendations should save considerable dollars from our current, nursing home dominated, overly expensive, long-term care system.

RESPONSES OF RICHARD C. LADD TO QUESTIONS FROM SENATOR DOLE

Question. You mention HCBS waivers and the 1915(d) option in your testimony. Two questions. Why haven't the states pushed for more money and flexibility with HCBS waivers? Why is Oregon the only state to use the 1915(d) long-tern care option?

Answer. From the middle 1970's to the late 1980's the states pushed extremely hard for more flexibility in providing home and community based services through Medicaid. Federal Medicaid law was changed significantly in 1981, 1985, 1987, and 1989, and all states moved aggressively toward expanding home and community based services. However, the federal government has set limits (through regulation) on the number of people that can be served in home and community based services. These limits are based on the number of empty nursing home beds and have severely restricted the growth of alternative services. This has resulted, in most states, in the creation of waiting lists for home and community based services. When these waiting lists are in effect, anyone who has an immediate need for long-term care services usually has no other choice but to enter a nursing home.

Oregon is the only state to have a 1915(d) home and community based waiver in effect. This option trades flexibility for a cap on the federal share of the states Medicaid long-term care expenditures. This means that while there is no cap on the number of people that can be served in home and community based services, there is a cap on the amount of federal funds available. The only way to make such an arrangement work is to maintain or reduce the number of nursing home beds and allow growth only in alternative services. While Oregon has done this to date, it will reach a point where nursing home beds can no longer be maintained or reduced. When this happens, Oregon will probably exceed the federal cap, and be in the position of having to finance a growing portion of long-term care with only state general revenues. For this reason, other states are highly reluctant to apply for a 1915(d) waiver.

Follow up. What could Congress do to increase? To what extent would greater this meet the goals of the Clinton LTC plan?

Answer. The follow up questions are not understood.

Question. what would it take to create a market for private long-term care insurance?

Answer. Long-term care insurance seems to have little appeal for the general public, and is purchased mainly by elderly persons in risk of long-term care services. Most current policies are too expensive, do not provide inflation protection, and pay mostly for nursing home care. Younger persons can purchase long-term care insurance for much less but, to date, have been reluctant to do so. This insurance is really based on a "term life insurance" model, with payment before death and only for long-term care services.

Two things would help market long-term care insurance: First, tax credits for those purchasing such policies should increase their sale somewhat. Second, a new insurance model for long-term care should be developed. This model should be more

realistically priced, provide for inflation protection and allow for coverage of a wide variety of long-term care services.

In my opinion, long-term care insurance is never going to be a viable option for most people. Life insurance is a more feasible option for most people because we all know we will die. Although almost half of us will eventually use long-term care services, most of us are convinced that we will be in the other half.

Question. You mention that nursing home coverage under Medicaid is an entitlement, but community alternatives are not. What would happen to demand for community long-tern care services and the resulting cost if we went to an entitlement?

Answer. Costs will increase. The only way an increase in long-term care can be avoided is to severely restrict the use of this service to only those most impaired. If we continue to serve the same percentage of people at risk of long-term care services that we do today, there is no way to prevent cost increases. Of all the options available for long-term care, the most expensive is maintaining the current system. This is so because 85% of the long-term care dollars are spent on the most expensive service (nursing homes), and because the growth of home and community options are rigidly limited.

Allowing home and community based services to become an entitlement program would make it available to all those who meet the eligibility criteria. Oregon essentially did this in 1981, and since that time has had no waiting lists for home and community based services. This has resulted in increased caseloads, but not to the extent many people thought. The bottom line is that in the aggregate 3 to 4 people can be served in home and community based services for the cost of serving one person in a nursing home. The Oregon long-term care system did not see a 3 or 4 fold increase in caseloads, indeed they did not even see a 2 fold increase.

Allowing equal access to home and community based services will increase costs because this is the service that most people prefer, and they will tend to use it more often than nursing homes. This increase will, however, not be as great as some have prognosticated. Future costs of long-term care will be much less because we will be able to direct most of the expected growth in these programs to home and community based care.

Response of Stephen McConnell to a Question From Senator Dole

Question. The President's bill makes a clear distinction between breakthrough drugs and all other forms of medical intervention—new surgical techniques, new medical devices, generic drugs, etc. Do any of you see any reason why price controls should apply to these so-called brearthrough drugs but not to advances in other areas of medicine?

Answer. The Alzheimer's Association is opposed to any policy changes which will prevent or inhibit research into the causes, treatments or prevention of Alzheimer's disease and related disorders.

At the same time, we also recognize the pressing need to provide health and long term care coverage for all Americans and to bring costs under control in every part of the health care sector.

No breakthrough drug, surgical technique or medical device will mean much to American families if they do not have insurance to pay for it, or if the cost is so high it is priced out of the market.

At present, there is only one drug on the market that begins to treat Alzheimer's disease and there are no surgical techniques, medical devices or generic drugs available.

The real key to finding the breakthrough and effective Alzheimer treatments still lie in basic medical research funded through the National Institutes of Health, research that will discover the underlying mechanisms of this disease. Once those mechanisms are understood, the path to treatment will be clear for the biotech and pharmaceutical research industry to pursue.

Prepared Statement of Senator David Pryor

Mr. Chairman, I want to thank you for holding today's hearing on long term care and prescription drug issues in health care reform. As you know, these are issues in which I have had a long-standing interest. Health care reform gives us the unique opportunity to address my long-standing concerns about the ability of all buyers—older Americans, hospitals, federal programs, managed care plans—to buy prescription medications at reasonable prices. In addition, our health care reform

efforts would be woefully inadequate if we were to not do our level best to address the serious long term problem which faces our nation's families.

PRESCRIPTION DRUGS

Mr. Chairman, thus far in discussions on health care reform there has been a lot of talk about competition and letting "market forces" work to relieve us from the spiraling health care inflation we have been experiencing. There is no sector of the health market where there has been more discussion along these lines than with respect to prescription drugs. I believe that we should let competition and the marketplace work where it can to contain drug prices. Where it cannot work, other mechanisms should be put in place to assure that drug prices are reasonable.

For example, community retail pharmacists—both independent and chain—have often paid the highest prices for prescription medications in the market, even though they purchase millions of dollars in drugs each year, and at the same volume as other purchasers. Drug manufacturers simply refuse to negotiate in good faith with retail pharmacy buying groups. As a result, these higher drug prices then have to be passed along to the average consumer—including millions of older Americans—who buy their medications out of pocket. The market has not worked for these buyers, and I believe that we should address this issue as part of health reform.

A meaningful pharmaceutical cost containment mechanism must also be included in any Medicare prescription drug benefit that is enacted. Medicare will become the single largest purchaser of drugs in the United States, and should have access to discounts and rebates like other large purchasers. The rebate mechanism included in the President's proposal is, in my opinion, a logical way to contain the Medicare program's drug costs. Many of my colleagues through the years have expressed repeated concerns over growth in Medicare spending. I can think of no better way to guarantee runaway costs in the drug program than to NOT allow Medicare a rebate for the drugs it purchases. Refusal to enact a rebate will also create a tremendous shifting of prescription drug costs from the private market to Medicare, because the Medicare program will be footing the bill for the discounts and rebates private purchases receive.

In 1990, Congress enacted a program to contain the Medicaid drug program's costs, and it has saved billions of federal and state dollars during that time. Without a Medicare rebate, beneficiaries and federal taxpayers will have to shoulder more of the burden of providing this drug benefit. However, if there are other options to provide a Medicare drug benefit that contains costs as well as assures beneficiaries' access to drugs and pharmacy services then we should explore those as well.

We also need to assure that the prices of new, breakthrough drugs are reasonable. The prices of some of the new drugs that have come to market over the past few years have been staggering. New drugs and biologicals are our best hope for curing illness and diseases, yet they help no one if they are unaffordable. Under health reform, health care plans will have no choice but to cover these drugs, and will literally be at the mercy of the manufacturer when it comes to the price of the product. Manufacturers can charge whatever price they want because there are no competitors to breakthrough drugs. Therefore, I believe that the proposed Advisory Council on Breakthrough Drugs in the Health Security Act strikes the right balance between assuring that a product will be priced fairly and provi[illegible]ncentives to manufacturers to develop the drugs we need.

LONG TERM CARE

The most compelling reason to address long-term care in health c[illegible]eform is its impact on families. The goal of health care reform is to give all Am[illegible]ans health care coverage, responding to the true needs of families and individuals. Universal coverage will ensure that a serious illness, such as cancer, will not financially devastate a family. But the great untold tragedy of our current health care system is that even people who have generous health insurance coverage can lose everything to a long-term care chronic illness.

Currently, millions of people go without needed support and services in the home and community because little or none are available. And once their physical and financial resources are nearly exhausted, they must further impoverish themselves to become eligible for Medicaid nursing home coverage. I am pleased that the President's long-term care proposal goes beyond the limited, incremental approaches that this Committee has considered in the past.

In the past, many of us on this Committee have been part of efforts to strive to meet the long-term care needs of our citizens. The Pepper Commission, for example, spent hours and hours on this issue. In 1991, with the support of many members

of this Committee, I introduced legislation that would require private long-term care insurance policies to meet basic Federal consumer protections, similar to the way we regulate the Medigap policies. Also, along with our former Chairman Bentsen, I sponsored legislation to clarify the tax law that applied to long-term care expenses.

A major change has occurred since the crafting of those incremental approaches. Now, with the leadership of President Clinton, we have an historic opportunity to truly address the long-term care needs of our nation. As we craft this Committee's health reform bill, we must not neglect the important area of long-term care. Any health reform proposal that passes this year must include a long-term care benefit. It is clear that private insurance will not meet the needs of a majority of Americans.

Further, as we address the long-term care needs of our nation's families, we must do it in a meaningful way. It would be a grave disservice to do some tinkering around the edges but speak as if we have truly addressed the problem. The families who bear the tremendous burden of providing care for their chronically ill family members deserve more than that.

So, Mr. Chairman, I look forward to today's hearing. And I also look forward to this panel taking this historic opportunity to improve the lives of all Americans through health care reform in the areas of long-term care and prescription drug coverage.

PREPARED STATEMENT OF JOHN ROTHER

The inclusion of long-term care in health care reform legislation is vital to Americans of all ages and is critical to AARP's support for any health care reform proposal. Historically, many Americans have equated long-term care with nursing home care. Long-term care, however, is much more than just nursing home care. It includes a wide range of home and community-based care as well as residential alternatives.

Long-term care is typically considered a benefit for the elderly. This is a myth. The need for long-term care crosses generational lines. An estimated 10 million persons need some form of long-term care. Approximately one-third of these individuals are under age 65. Many are children. Moreover, the need for long-term care is felt not just by those requiring care, but also by their families—often those providing and paying for care. This is particularly true in the case of those in the "sandwich generation," caught between meeting the needs of their children and their parents.

Over the past several years we have listened closely to what the American people, including our diverse membership, tell us they want in a health care system. Despite their differing circumstances, the vast majority of Americans, old and young, have consistently stressed the need for broader protections against the high costs of health *and* long-term care. How is it, they ask, that we cover the cost of a lengthy hospitalization, costing tens of thousands of dollars, but we do not help with the cost of nursing home or home care? Some assume that concern about and support for long-term care coverage is confined primarily to the older population, but, in fact, strong support exists across all age groups. The 50–64 age group is particularly concerned, both for their parents and themselves. It is this middle generation, particularly the women, who see and feel the staggering costs—financial and emotional—of long-term care. It is they who bear the costs of providing care in the home and then the costs of institutional care when it can no longer be avoided.

The President has offered a bold and constructive plan for accomplishing reform. The First Lady, Congressional leaders in both parties, and this Committee are to be commended for their commitment to addressing this issue *now*. The nation has waited too long for comprehensive reform. We must use this unique point in history to enact true reform which covers everyone, includes coverage of both long-term care and prescription drugs, maintains high quality care, and makes health care costs affordable.

AARP is very pleased that the President's proposal includes coverage for home and community-based care for persons of all ages and incomes. The new home and community-based program in the Health Security Act would be a serious start towards addressing the unmet long-term care needs of millions of American families.

Too many reform proposals focus only on acute care and simply ignore the long-term care needs of American families, as if these needs were so easily compartmentalized in the lives of these families. Such proposals are fundamentally flawed because they fail to address the need for a full *continuum* of care throughout an individual's life. Without long-term care coverage, no family has real security against the crippling costs of serious illness or disability.

Health Care Reform Must Include Long-Term Care

While approximately 38 million people lack basic medical insurance, virtually all Americans lack protection against long-term care expenses. With average annual nursing home costs of approximately $37,000 (in some areas $60,000 or more) and home health care costing from $50 to $200 per day, the need for long-term care can often devastate a family. For most people, the cost of long-term care is an unmanageable financial burden. Many families are also shocked to find—too late—that neither Medicare nor private insurance covers long-term care to any great extent. To a family sitting around the kitchen table, there is no difference between spending $20,000 on hospital care and spending $20,000 on home care. It is still $20,000 they do not have. Therefore, to achieve true security, savings, and quality in our health care system, care must not be limited to the provision of services by a hospital or doctor; long-term care must also be included.

The need for comprehensive services—It makes little sense to provide financial protection against the cost of an acute illness but leave people vulnerable if they suffer from a chronic and disabling condition, especially since the need for these services often is so interrelated. Results from research conducted on the Social Health Maintenance Organization (SHMO) demonstrations in the late 1980's illustrates why integrated care is so important—custodial and skilled services are often needed to complement one another. Almost 70 percent of initial referrals for community-based long-term care originated from hospitals and other parts of the medical care system. Moreover, 37 percent of the care plans developed for home and community care included concurrent authorization for medically necessary skilled services. In addition, individuals' levels of disability frequently changed and were tied to acute episodes of illness. Without comprehensive benefits, effective patient care will not be achievable, and costs "avoided" in long-term care may instead show up as costs in the acute care setting.

Caregivers are being unfairly burdened—Family members, particularly women, provide the vast majority of long-term care to persons of all ages. Caregivers place their own health in jeopardy and frequently are forced to leave the labor market, thereby suffering not only short-term loss of income, but also long-term reduction in Social Security and private pension benefits.

In a recent focus group, a woman in her 50's related her story:

> Rose had held a good job with a large corporation until her mother needed long-term care. Unable and unwilling to place her mother in a nursing home, Rose quit her job—6 months before her pension would have vested—to care for her mother. She saw her future income potential and retirement security disappear as she made the painful decision to take care of her mother—for the next seven years.

There are many stories just like this. They typically involve women in their 50's—primarily spouses and daughters—who sacrifice financially, physically, and emotionally to assure that a loved one is cared for. One-half of caregivers spend at least 12 hours per week providing care. At some point in their lives, nearly four out of ten women (37 percent) will care for a disabled adult; approximately 25 percent of these caregivers—part of the "sandwich generation"—must simultaneously care for their children. Institutionalization of loved ones often occurs because of caregiver "burnout" if no outside help is available. The Association believes that caregivers deserve strong support.

Private sector solutions cannot work—The private market has not provided, nor can it provide, adequate and affordable protection against the cost of long-term care. Private long-term care insurance that provides meaningful coverage is very expensive and generally excludes people with pre-existing conditions or mental disorders. Few people can afford the cost of private long-term care insurance for any length of time, particularly if the policy provides meaningful protection. A decent policy bought by the average age purchaser (about 70 years) would cost approximately $3,000 per year—too expensive for most prospective purchasers, even if tax incentives were included. Private long-term care insurance policies have done a particularly poor job in trying to cover home care because insurance companies are not confident of their ability to control the risks and demand involved.

Public Support for Long-Term Care

Americans of all ages strongly support health care reform that includes coverage for long-term care. A random sample survey of 2,020 adults conducted for AARP by the ICR Survey Research Group in April, 1993 found that 90 percent of the respondents felt that including long-term care in a health reform proposal was important. Support for health care reform increased from 46 percent to 82 percent when long-term care was included (see Attachments 1 and 2).

The most recent survey by the ICR Research Group, of 2,012 adults conducted between January 26 and February 1, 1994 found that 64 percent of respondents were more likely to support a health care reform proposal that included comprehensive long-term care coverage and 42 percent were much less likely to support a health care proposal with no long-term care coverage.

According to a survey conducted in the fall of 1991 by DYG, Inc., three-fourths of Americans (18 and older) were "very concerned" about paying for the cost of long-term care. The concern, which is felt sharply by both men and women, extends to all income and age groups. In fact, concern about long-term care was greatest among persons age 50–64—those most likely to be caring for older parents and worrying about their own futures (see Attachments 3–7).

In a Harris survey conducted during December 1992 and January 1993, 91 percent of the respondents said they could not afford long-term care when they were told it would cost $15,000 to $60,000 a year, or $40 to $160 a day. With regard to a federal program providing long-term care in the home for the chronically ill or disabled, over 80 percent of these same respondents favored such a program not only for people 65 years of age and older, but for younger adults and children as well.

AARP Views on Long-Term Care

To make long-term care coverage affordable and accessible to all Americans, the Association believes that the ideal solution is a social insurance program, similar to Medicare and Social Security, that would provide a comprehensive set of benefits in the home and community, as well as in nursing homes. A social insurance program would require financial contributions from all members of society and would provide protection to all who need long-term care, regardless of age or income. Such an approach would spread the risks so that the costs to any one person would be small, while offering protection and appropriate care to all. Under such a social insurance system, private sector initiatives would supplement the public system by covering coinsurance, deductibles, and additional needed services.

Other fundamental principles that underlie AARP's views on long-term care include: (1) provision of a comprehensive range of services, including institutional and home and community-based care; (2) effective cost containment mechanisms; (3) financing which is equitable, broadly based, and affordable to all individuals; (4) coordination between the acute and long-term care systems to assure a continuum of care across an individual's lifetime; (5) assurance of high quality care; and (6) support for informal caregivers.

These principles are at the foundation of AARP's proposal for comprehensive health care reform—"Health Care America." The proposal, which was developed with the extensive involvement of AARP members across the country, would create a new Medicare-like program to provide comprehensive coverage for both acute and long-term care for individuals of all ages and incomes. The nursing home component of the proposal would be available over the entire length of an individual's stay, excluding coverage for room and board.

AARP believes firmly that any new long-term care should be available to persons of all ages and incomes. The Association strongly opposes means-testing—tying *eligibility* for benefits to the recipient's income. We already have a means-tested long-term care program—Medicaid—which has proven to be seriously inadequate. A new long-term care program must not repeat these mistakes. Income-related financing, where middle and upper income people are eligible to receive benefits but pay relatively more for them, is a logical way to pay for a program progressively.

There are many reasons why a means-tested program would provide seriously inadequate coverage and leave many Americans in need:

- Historically, may people do not apply for means-tested benefit programs because of the stigma attached to welfare programs, the complexity of the application process and the lack of information on program benefits due to inadequate outreach. For example, in 1993, 1.8 million low-income older Americans eligible to receive benefits under the Qualified Medicare Beneficiary (QMB) program but *did not enroll.* This represents over half of the total eligible beneficiaries. Reasons specifically cited in a January, 1994 GAO report [HEHS–94–52] include welfare stigma, the complicated application process and lack of outreach;
- Middle income persons have a difficult time affording home care visits, especially if they are needed on a regular basis. For example, a middle class couple with a combined annual income of $20,000 (the median income of over 65 households in 1992 was $17,160) must pay for housing, food and other living expenses from this modest income, which is just above 200 percent of the federal poverty line. Annual home care costs of $5,000 (assuming 100 visits at $50 each) would be unaffordable, yet this couple would not be eligible for any help

under a means-tested system. Ironically, this couple probably would be helping to pay for the means-tested program through their taxes;

- Means-testing would produce few savings because most people who need home care have low or modest incomes. Only about 5% of the dollars under the Presidents's home and community-based care proposal would be spent on those with an annual income above 400% of poverty (over $29,600 for singles and $38,000 for couples—see attachment 8);
- Means-tested programs require extensive administrative overhead. They also require that applicants file lengthy and complex forms and comply with burdensome eligibility verification requirements. Moreover, the lack of convenient locations and transportation to the application sites further impedes participation;
- The public does not support means-testing long-term care. In a survey of over 2,000 adults conducted in April, 1993, 69 percent preferred a government program for long-term care similar to Social Security or Medicare, while only 25 percent preferred leaving it to individual savings and private insurance, with government only providing coverage for the poor; and
- Because they assist only a segment of our nation's population, welfare-based programs such as Medicaid and SSI do not have as much support in the Congress as Medicare and Social Security. This makes these means-tested programs much more vulnerable to budget cuts.

The President's Proposal for Home and Community-Based Care

The Health Security Act includes a significant, much-needed proposal to provide home and community-based care to millions of American families. The proposal represents a dramatic improvement over our current "non-system."

In basing eligibility for the new home and community-based program on levels of disability, rather than age or income the President has taken a very significant step forward. Moreover, given the limited resources available, it is appropriate that the program target the most severely disabled individuals. An eligibility assessment and determination based on level of disability, when combined with the proposed care plan, would begin to address the serious problems of fragmentation and unmet need that currently exist for disabled persons of all ages. Age is not a viable eligibility criterion because approximately one-third of persons with severe disabilities who need home and community-based care are under age 65. In addition, while the program does ask persons with greater income to pay more for their long-term care services, it is not based on a welfare model. Therefore, those in need would not be forced to bankrupt themselves before getting help, as they must do now, to be eligible for Medicaid.

The President's proposal for home and community-based care would provide much needed support to caregivers who are shouldering enormous burdens by taking care of their loved ones and often missing work to do so. Many caregivers perform these services out of a strong family commitment and a desire to postpone nursing home placement for as long as possible.

The President's proposal also would begin to provide to disabled persons and their families real *choices* about how to arrange for and where to receive the most appropriate care. Today, people are forced into nursing homes prematurely or go without care because they do not have access to affordable home and community-based care. Historical patterns in public spending reflect a perverse bias, where approximately four out of five dollars spent on long-term care go to institutional care. This creates situations in which families are broken apart and Americans are denied care in the most appropriate and preferred setting. For the first time, under the President's proposal, many disabled Americans could receive services through the full continuum of care.

The Health Security Act proposal also includes reasonable cost-sharing and low-income protections which will discourage over-utilization and yet help ensure that care is affordable for those who need it.

The President's home and community-based care proposal will also have a positive impact on the economy. For example, Lewin-VHI has estimated that the proposal would ultimately crate over one million new jobs. Approximately 85 percent of these jobs would be in the private sector. Working caregivers would be better able to stay in their jobs and absenteeism would decline, thereby improving productivity. Many adult disabled persons would, for the first time, be able to work and become productive, taxpaying members of society with the proposed assistance available to them.

It is important to point out that the Health Security Act would strictly limit new federal expenditures for home and community-based care by (1) not providing an individual entitlement to services; (2) capping federal expenditures; (3) leaving nursing home coverage largely to the private market, with new standards and tax incentives for long-term care insurance policies; (4) imposing stringent eligibility criteria;

(5) providing for a long seven-year phase-in period; and (6) providing for income-related copayments. It is also important to note that most states will realize significant savings from this provision due to Medicaid offsets derived from the greatly enhanced federal match rate under the proposed new program (on average, 85 percent vs. 57 percent under Medicaid).

While the President's proposal includes an important, much needed starting point on long-term care, many of the other health care reform proposals—most notably S. 1770, the Health Equity and Access Reform Today Act, and S. 1579, the Managed Competition Act—unfortunately fail to include meaningful long-term care reform.

Suggestions to Strengthen the President's Home and Community-Based Care Proposal

The Association strongly applauds the President for recognizing the need to expand coverage and options for home and community-based care.

We agree with the need to contain long-term care costs and to keep federal expenditures under control, given limited resources. Effective care management and appropriate provider reimbursement should help in this regard. However, certain elements of the proposal that are designed to limit program costs and others relating to the role of the states ruse particular concerns. In this regard, the Association has a number of specific suggestions for strengthening the proposal.

Proposals to Limit Program Costs

Caps on Funding—The proposal is, in effect, a matching grant program to the states. We have questions about how this would work. The capped nature of the proposed program makes it all the more critical that the data and criteria used to estimate full funding over time are accurate. Otherwise, funding shortfalls could easily occur, resulting in potentially serious levels of unmet need. To help prevent this from occurring, baseline estimates must include accurate cost and utilization assumptions for all groups of eligible persons, including severely disabled children.

The adequacy of inflation and trending factors are a concern because they do not seem to account sufficiently for future changes in the intensity of service needs or real wage growth among workers in the very labor intensive home care area.

To help address these concerns, we recommend that the caps on funding for home and community-based care be accompanied by the same safeguards as caps on low-income subsidies for acute health care services. Specifically, an additional 15 percent cushion should be included as a margin of error, and any excess funds should be permitted to be carried forward and not be charged toward the next year's cap.

Definition of Disability—The Association is pleased that the proposal would cover persons who need stand-by assistance or cueing to perform 3 or more ADLs. However, we would ultimately like to see a 2 of 5 ADL standard.

Issues Regarding the Role of the States

Option for the States—Under the proposal, states would have the option of not participating in the program. This could pose serious problems for consumers. Some states may elect not to establish a program or may postpone participation until much later in the phase-in schedule. Consideration should be given to strengthening incentives for state participation.

State Accountability—While we agree with the Administration that there is merit in state administration of the home and community-based program, the Association believes that, to ensure accountability, state flexibility must be balanced by a clear federal framework for state participation and strong, effective federal oversight. Standards should ensure that federal dollars are being spent appropriately, that consumers are protected, and that a range of services are available. Federal oversight should include review of state plans and monitoring of compliance with standards. Careful reporting of substandard performance should be accompanied by strong enforcement tools. Particular attention should be paid to monitoring states so that they do not simply shift eligible Medicaid recipients into the program during the phase-in period, without extending services to other vulnerable persons.

State Incentives for Residential Care Alternatives—One way to promote savings through competitive market forces would be to provide strong incentives to assist the development of residential alternatives to nursing home care, such as assisted living. Experience in Oregon, for example, has shown assisted living to be a cost effective, preferred alternative to nursing home care for many frail elderly. The program has permitted more people to receive services under the state's budget constraints. Although we are pleased that the proposed home and community-based care benefit would be portable and available to eligible persons in these settings, more needs to be done on the capital and housing side of the equation. Ways to make such residential options affordable to persons with low and moderate incomes should be specifically addressed.

Nursing Home Care and Medicaid Improvements

In addition to a new program for home and community-based care, the President's proposal also would include modest improvements for those who need nursing home care. Specifically, it would: (1) require all states to have medically needy programs under Medicaid; (2) give states the option to increase the level of protected assets for single persons from $2,000 to $12,000 for purposes of Medicaid eligibility; (3) increase the minimum Medicaid personal needs allowance from $30 to $50 (scaled back from $100 in the September 1993 draft); and (4) create new uniform federal minimum standards for private long-term care insurance policies, together with certain tax clarifications.

Although AARP is supportive of these modest attempts to improve Medicaid, millions of Americans would remain vulnerable to impoverishment due to lack of protection against enormous nursing home costs. The cost of a nursing home stay now averages $37,000 a year and can exceed $60,000 in some parts of the country. Studies conducted for AARP in 1989 and 1991 by DYG, Inc. found that while people *prefer* home care, it is the cost of nursing home care which individuals fear most when they consider their long-term care needs, and it is this concern that appears most related to their willingness to pay increased taxes to finance new benefits.

If sufficient funding for a comprehensive nursing home program is not available at this time, less expensive incremental reforms could help many people. For example, one option would be to reduce the inappropriately high $87 Medicare Skilled Nursing Facility daily coinsurance payment and make it more consistent with the extended car benefit available in the President's proposed basic benefit package through the alliances.

We also strongly urge that the proposed optional increase in the level of assets protected under Medicaid for single persons (from $2,000 to $12,000) be made mandatory, as was originally proposed in the September 1993 draft, since states are very unlikely to provide such protection voluntarily. Further, in our view, the amount should be increased beyond $12,000 so that people need not spend-down to such a low level before receiving protection.

The President's proposal should also do more to promote the key principles of savings and choice for Americans who need nursing home care. For example, nursing home costs must be contained. Hospitals and other providers will have incentives to shift costs to this sector if it is the only one not subject to some form of spending limits. Cost containment could be accomplished, in part, by making charge data available to consumers. In addition, the access problems that low and middle income applicants experience in gaining admission to the nursing home of their choice must be addressed. Nursing homes should be prohibited from discriminating in admissions on the basis of wealth and source of payment.

Long-Term Care Insurance Standards and Tax Incentives

AARP strongly supports the requirement for uniform federal standards for private long-term care insurance. Such reform is long overdue. Findings from studies conducted by the U.S. General Accounting Office, the Office of the Inspector General, and by Project Hope for AARP clearly demonstrate that the current state regulatory system has failed to provide sufficient consumer protection throughout the nation. We do, however, have some questions about the costs and distributional effects of the tax clarifications proposed in this area, particularly for those selling insurance policies.

AARP agrees with many of the proposed standards in the President's proposal. We are particularly pleased by the Administration's approach on two key issues: inflation and nonforfeiture protection. In our view, inflation protection should be *offered* to all prospective buyers and nonforfeiture protection should be *mandatory* for all long-term care insurance policies. These views are consistent with the current standards proposed by the National Association of Insurance Commissioners (NAIC).

With regard to the proposed long-term care insurance tax incentives, in general, the proposed tax incentives to encourage individuals to purchase long-term care insurance policies would help only a limited number of persons. For the most part, the benefits would be far more available and worth more for higher income individuals.

The Association believes that it is only appropriate to consider certain tax changes in the context of a comprehensive long-term care financing package. It would be premature to enact tax changes in isolation that would result in lost revenues and which, by their nature, are directed primarily to a limited number of individuals with relatively high incomes. We recommend that distribution tables detailing the extent and distribution of proposed tax changes be developed. Such tables will permit evaluation of the efficiency and equity of tax code incentives for long-term care.

Conclusion

On June 8, 1988, the late Senator Claude Pepper brought a bill covering home and community-based care to a vote on the House floor. Much was said by many members about the need to provide this kind of protection. Even opponents, who argued that the timing was not right, spoke eloquently about the importance of covering services in the home. Just before the proposal was defeated by a 169–243 vote, Congressman Pepper stated:

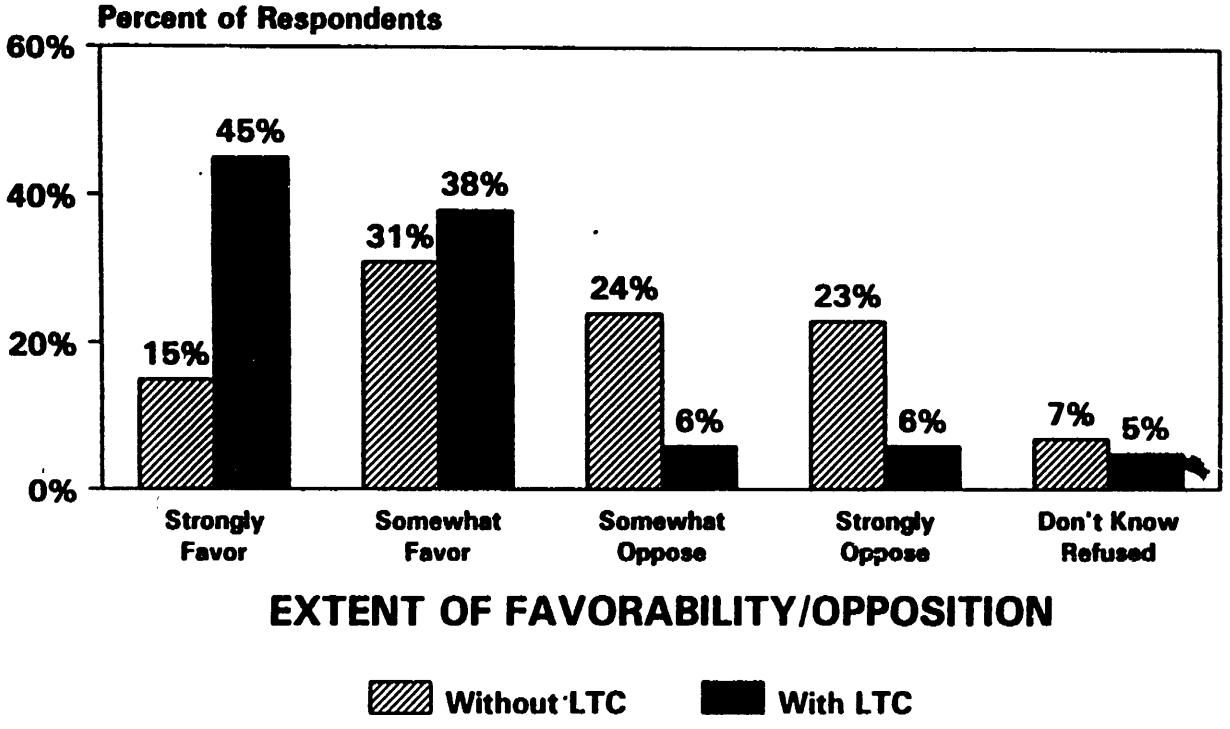
> This is a day for which I have waited and worked, and I might say prayed for, for 50 years—a chance to lighten the burden upon the masses of the people of this country, trying to help those saddled with a long-term illness . . . . We can help millions of people to meet crises in their homes that are heart-rending in their character. When are we going to have another opportunity if we lose this one?

The opportunity has now come. We have a chance to begin to create a new system that removes the existing bias in favor of placing people in institutions for the rest of their lives; a system that does not force people to bankrupt themselves and go on welfare in order to receive help; a system that does not force caregivers to quit their jobs or jeopardize their own health to continue caring for loved ones; and a system that is not as intimidating for those who need to use it.

As advocates and policymakers we need to be clear with the public that most current long-term care proposals are a beginning. The public must understand the specific benefits of and limits to the President's proposal. The limitations of this program will loom larger in the public's eye in the future if they come to believe that there is more coverage and protection in the program than really exists. *But the fact that it does not provide all the answers for everyone in need. cannot be an excuse for doing nothing.* The President's proposal is a very important, significant start and a vast improvement over our current long-term care "non-system." Our job is to shape and improve the proposal so that it will provide real protection now and a solid foundation for the future.

AARP looks forward to working with members of this Committee to help realize these goals and ensure that long-term care remains an integral part of whatever health care reform package is enacted.

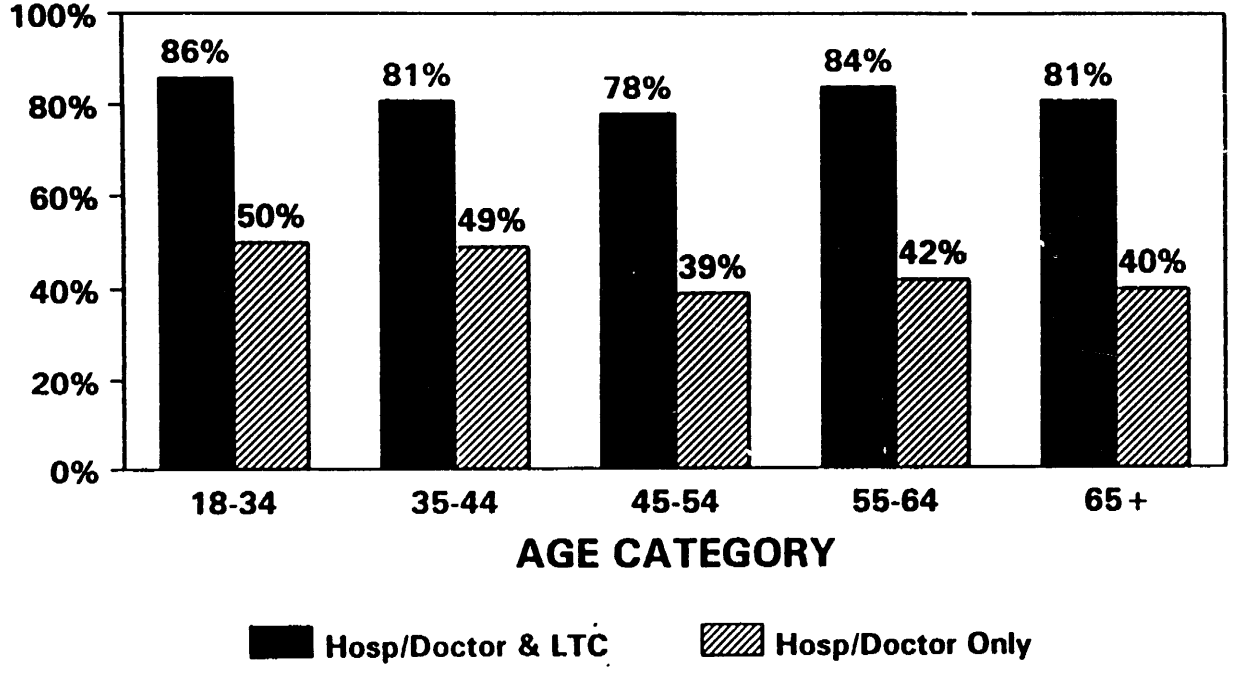
FAVOR/OPPOSE HEALTH CARE REFORM PLAN WITH AND WITHOUT LONG-TERM CARE COVERAGE



AUS/ICR Survey Research Group
Excel Omnibus Study
April 21-27, 1993 (N = 2,020)

ATTACHMENT 1

PERCENT FAVORING HEALTH REFORM PLANS WITH & WITHOUT LONG TERM CARE COVERAGE (BY AGE CATEGORY)



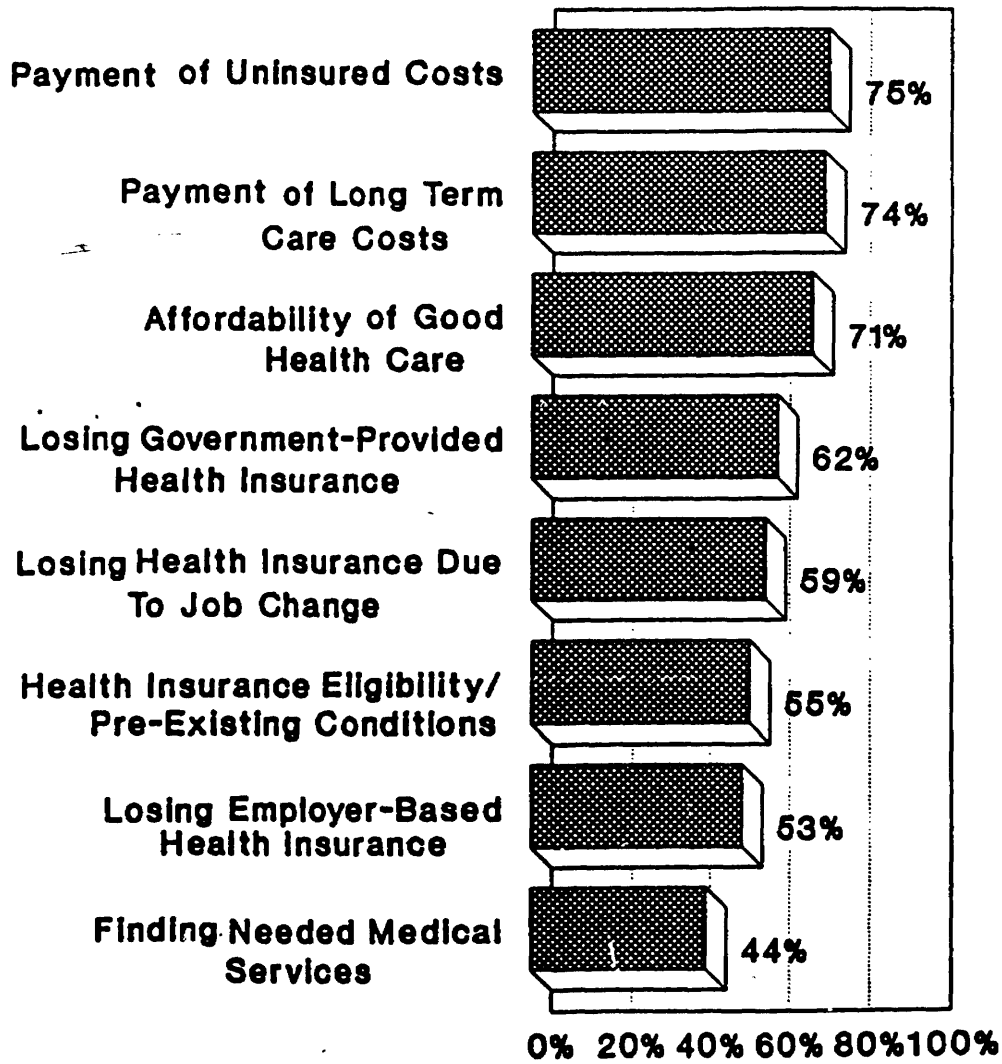
AUS/ICR Survey Research Group
Excel Omnibus Study
April 21-27, 1993 (N = 2,020)

ATTACHMENT 3

Ratings of Health Care Concerns

Total Sample

Very Concerned About:



ATTACHMENT 4

Ratings of Health Care Concerns

	Total %	Total Women %	Total Men %
Very Concerned[1/]			
Being able to pay for costs of health care not covered by insurance/government	75	75	75
Being able to pay for the cost of long term care such as nursing home care	74	76	73
Being able to afford good health insurance	71	70	71

Continued...

1/ Rating of "4" on a 4-point scale

ATTACHMENT 5

Ratings of Health Care Concerns

	Total Women	Women: Age 18-49	50-64	65+
Very Concerned 1/	%	%	%	%
Being able to pay for costs of health care not covered by insurance/ government	75	74	82	70
Being able to pay for the cost of long term care such as nursing home care	76	72	85	78
Being able to afford good health insurance	70	69	85	60

Continued...

1/ Rating of "4" on a 4-point scale

ATTACHMENT 6

Ratings of Health Care Concerns

	Total Men	Men: Age 18-49	Men: Age 50-64	Men: Age 65+
	%	%	%	%
Very Concerned 1/				
Being able to pay for costs of health care not covered by insurance/ government	75	75	76	76
Being able to pay for the cost of long term care such as nursing home care	73	69	80	79
Being able to afford good health insurance	71	73	75	58

Continued...

1/ Rating of "4" on a 4-point scale

ATTACHMENT 7

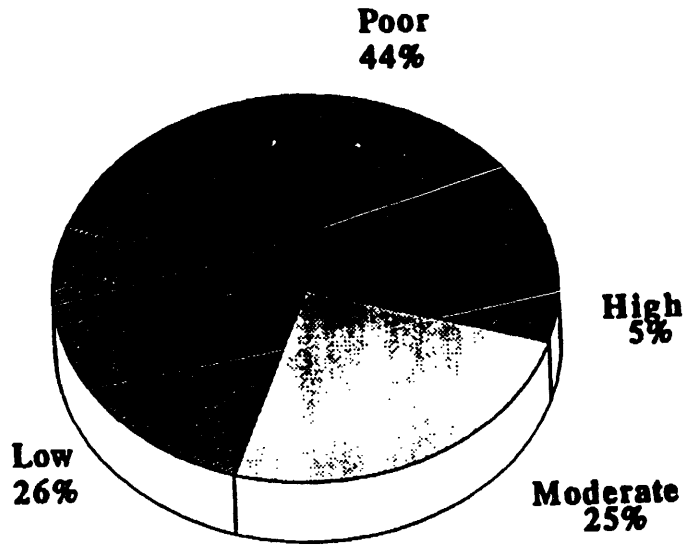
Ratings of Health Care Concerns

		Income ($Thousands)		
	Total	Under 25	25-49.9	50+
Very Concerned[1/]	%	%	%	%
Being able to pay for costs of health care not covered by insurance/ government	75	80	78	59
Being able to pay for the cost of long term care such as nursing home care	74	77	74	68

Continued...

1/ Rating of "4" on a 4-point scale

Projected Expenditures of Public LTC Funds by Income Group Under HSA



Poor: below $7,400 for singles or $9,500 for couples; Low: $7,400-$14,800 for singles or $9,500-$19,000 for couples; Moderate: $14,800-$29,600 for singles or $19,000-$38,000 for couples; High: above $29,600 for singles or $38,000 for couples.

Source: ASPE, prepared by AARP's Public Policy Institute

ATTACHMENT 8

AARP

Bringing lifetimes of experience and leadership to serve all generations.

April 20, 1994

The Honorable Daniel Patrick Moynihan
Chairman
Senate Finance Committee
205 Dirksen Senate Office Building
Washington, D.C. 20510-6200

Dear Chairman Moynihan:

Thank you for giving AARP the opportunity to testify at your April 19 Senate Finance Committee hearing on Prescription Drug Coverage Under Medicare. As you will recall, during my oral statement I mentioned that many Medicare beneficiaries do not have access to managed care plans, and that eight states currently do not have HMO coverage available to Medicare beneficiaries. You asked for the names of those eight states, which I did not have available at that time. The purpose of this letter is to provide you with an answer.

According to the Health Care Financing Administration's Office of Prepaid Health Care, Operations and Oversight, the following eight states currently do not have any contracts (under either section 1876 risk/cost contracts or section 1833 Health Care Prepayment Plan contracts) to cover Medicare beneficiaries in HMOs:

Alaska	Maine	Mississippi	Montana
South Carolina	South Dakota	Tennessee	Wyoming

According to HCFA, however, the status of Medicare HMO contracting is very fluid. HCFA currently has approximately 50 pending applications.

Thank you again for including AARP in your hearing on Prescription Drug Coverage Under Medicare. We look forward to working with you to ensure the passage of comprehensive health care reform.

If I can be of further assistance, please feel free to call me at (202) 434-3701, or have your staff contact Kirsten Sloan of our Federal Affairs Department at (202) 434-3781.

Sincerely,

John Rother
Director, Legislation and Public Policy

RESPONSES OF JOHN ROTHER TO QUESTIONS FROM SENATOR PRYOR

Question. The manufacturers are saying that the proposal which requires manufacturers to pay a rebate to Medicare is a "tax." Can you explain the rationale behind including a rebate in Medicare? What other Medicare cost containment options might be considered? For mlexample, do you think a Medicare drug formulary would work?

Answer: The President's proposal would establish three types of rebates that drug manufacturers could potentially pay to Medicare:

(1) a *basic rebate* equal to 17 percent of the average manufacturers retail price (AMRP) or the difference between the AMRP and the price paid by non-retail purchasers (e.g., hospitals and HMOs), whichever is greater;

(2) an *inflation rebate* paid by manufacturers for each drug whose retail price increases faster than general inflation; and

(3) a *special rebate* that is negotiated by the Secretary of Health and Human Services (HHS) for a new drug that is determined to be excessively priced.

We believe that the President's rationale behind including these rebates is to provide an effective and reasonable way to contain prescription drug costs for the Medicare program while retaining adequate incentives for research and development. Given the enormous purchasing power of the Medicare program, we believe Medicare should receive discounts comparable to those that manufacturers provide to other major purchasers. A recent study by the Boston Consulting Group for the pharmaceutical industry showed that the average private market discount in 1992 was about *16 percent*, and that more than half of the U.S. pharmaceutical market received discounts of greater than *25 percent*. As a result, we believe that a minimum basic rebate of 17 percent for Medicare, as proposed by the President, is reasonable.

In addition, given that prescription drug prices in the United States have increased at nearly three times the rate of inflation over the past twelve years, we believe that the Medicare inflation rebate proposed by the President is necessary to restrain excessive price increases in the future. This rebate would also help to stop manufacturers from gaming the system by inflating their prices to compensate for the cost of the basic rebate.

Moreover, to assure that Medicare reimbursement for new drug products is reasonable, AARP believes that the special rebate provisions included in the President's plan are warranted. In negotiating this rebate with manufacturers, the Secretary would have to consider a number of factors including the prices of other drugs in the same therapeutic class, cost information from the manufacturer, and the prices of the drug in other industrialized countries. AARP believes that this provision will ensure that Medicare is paying fair and reasonable prices for new drugs that offer meaningful improvements over existing products.

Although AARP believes the President's proposal employs a reasonable approach to cost containment while retaining adequate incentives for research and development, other cost containment mechanisms may be effective as well. For example, a few major pharmaceutical manufacturers are offering potentially meaningful alternatives for providing drug coverage to Medicare beneficiaries while controlling costs. At the same time, AARP believes that such cost containment mechanisms must not impede convenient beneficiary access to needed medications or pharmacy counseling. Although we have not seen the details of these alternative proposals, we have expressed a willingness to review them.

With regard to a Medicare formulary, AARP believes that on the one hand drug formularies have been used very effectively for years by providers (hospitals and HMOs, etc.) to keep their costs reasonable. These providers typically establish their drug formularies through a committee made of physicians and pharmacists that make educated decisions on what drugs to include and where therapeutic substitution is appropriate. They also periodically update their formularies based on the latest information regarding the effectiveness of comparable drug therapies.

On the other hand, formularies can harm patient care when a specific product, which is not included in the formulary, is needed to treat a patient. Such problems can be avoided if an appropriate procedure for physician overrides is established and enforced, allowing the appropriate drug to be provided to the patient in a timely manner.

If a formulary is included in a Medicare drug benefit proposal, AARP would have take a close look at how it could affect patient care before we would take a position on it.

Question. There are some manufacturers that are advocating that we use a "managed care" approach to providing a Medicare drug benefit, for example, the Merck-

Medco proposal. What do you think of this approach? What would the impact of such an approach be on senior citizens?

Answer. We believe that the Medicare drug benefit structure proposed by the President offers effective cost containment without impeding convenient access to prescription drugs for Medicare beneficiaries. We are open to considering other structures, but firmly believe that they must include effective cost containment mechanisms that do not impede beneficiary access to needed medications or pharmacy counseling.

We believe that all Medicare beneficiaries should be guaranteed access to needed drug therapies. Therefore, we would not support proposals that means-test the benefit or would only provide drug coverage to Medicare beneficiaries who enroll in HMOs or other managed care plans and leave those who remain in Medicare fee-for-service without drug coverage. We believe such proposals are inadequate and would probably not be satisfactory to the older population.

Although we have not seen many of the details of the alternative "managed care" proposals offered by manufacturers, we have expressed a willingness to review them and believe a number of important questions need to be answered regarding such proposals in order to determine their impact on senior citizens, including:

- How will beneficiary access to needed medications be protected, and what type of appeals process will be incorporated? Will the appeals process include objective reviewers who do not have a financial interest in the beneficiary's plan?
- How will beneficiaries be protected against the various perverse incentives that could influence a private firm that manages their pharmaceutical benefit and is only concerned about the cost of the drug benefit and makes decisions based solely on the prices of drugs?
- If the marketplace fails to control the cost of the drug benefit, who is responsible for the additional costs? The beneficiary? The federal government? The drug manufacturers or the plan?
- If a variety of private plans offer the drug benefit, how will they adjust for risk, and how will beneficiaries know which plan is best for them?

Question. Some consumer and elderly groups don't think that the Advisory Council on Breakthrough Drugs that is established under the President's plan goes far enough to contain new drug costs. On the other hand, the manufacturers think it goes too far. Can you tell us the purpose behind the Advisory Council and why you think it will work to contain new drug costs?

Answer. We believe the President's proposal does include effective cost containment mechanisms. For Non-Medicare beneficiaries, the President's plan would rely primarily on private sector competitive price negotiating mechanisms currently used by many hospitals, HMOs and other large purchasers to contain prices. In addition, formularies, generic substitution, and drug utilization review are mechanisms that health plans could use to contain prescription drug costs. Given the success of these various mechanisms for containing prescription drug costs, AARP believes that health plans under the President's proposal would have a strong incentive to use similar techniques to contain drug costs.

The President's proposal would also help health plans make informed decisions on the potential role of "breakthrough" drugs (new drugs which represent a significant advance over existing therapies and, therefore, have little or no competition) through an "Advisory Council on Breakthrough Drugs." The Council would be responsible for:

(1) reviewing the launch prices of breakthrough drugs;

(2) reporting on the cost-effectiveness and therapeutic value of these new products; and

(3) determining whether the price is reasonable based on such factors as the price charged in other countries, Cost information supplied by the manufacturer, and projected sales volume.

Under the President's proposal, AARP believes that the activities of this council are essential given that individual health plans would have difficulty evaluating the appropriateness of prices for new drug therapies on their own.

Question. How does the AARP respond to the manufacturers' concerns that these proposals will have a negative impact on new drug research and development?

Answer. Most manufacturers insist that every dollar in revenue reduced by policymakers' efforts to contain drug prices will come directly out of research and development of important breakthrough medications. AARP believes that this is simply false. Much more than legitimate research and development activities go into a manufacturer's price of a drug; therefore, a drug manufacturer has many choices as to where it can be more efficient and cut costs.

In fact, according to a 1993 study by your Special Committee on Aging, only *16 percent* of the manufacturer's price of a drug goes toward research and development

compared to the 36 percent that goes toward profits, marketing, and advertising. In addition, estimates based on a recent Office of Technology Assessment report indicate that during the 1980s, pharmaceutical companies on average earned 15 to 30 percent *more* profit each year than needed to attract adequate investment in capital. Given this, AARP believes the industry could accept profits of a more reasonable level and eliminate excessive promotional activities without harming legitimate research and development endeavors. Moreover, because research and development is the lifeblood of the pharmaceutical industry, it is most likely the last area manufacturers would look to cut.

Question. It may be a few years before all Americans have drug insurance under the health care reform plan. Until that time, millions of older Americans will still be paying for the drugs out-of pocket. The manufacturers want to use "voluntary" restraints to contain drug costs during this period of time. From a consumers point of view, do you believe that these manufacturers' "voluntary" approaches are the most effective ones to use?

Answer. AARP is very concerned about the "voluntary" price restraint proposals currently advocated by the pharmaceutical industry. The industry claims that its "voluntary" efforts are working, and backs its claim by citing the Producer Price Index (PPI) for pharmaceuticals, which was 3.1 percent in 1993. According to a recent report by your Special Committee on Aging, however, drug manufacturer price inflation at the retail level—where most older Americans buy prescription medications—continued to increase much faster than general inflation in 1993. In fact, according to the report, "forty of the top 200 drugs increased in price at the retail level more than twice the rate of general inflation, which was 2.7 percent in 1993."

Clearly voluntary cost containment is entirely inadequate and merely perpetuates cost-shifting from the inpatient market, where HMOs and hospitals negotiate deep discounts from manufacturers, to the outpatient or retail market, where similar discounts are not offered. AARP is pleased that the President's proposal includes provisions which would reduce such cost-shifting, particularly to the retail sector of the market.

AARP looks forward to working with you to ensure the passage of comprehensive health care reform. If I can be of further assistance, please feel free to call me at (202) 434-3701, or have you staff contact Dan Durham of our Federal Affairs Department at (202) 434-3772.

RESPONSES OF JOHN ROTHER TO QUESTIONS FROM SENATOR HATCH

Question. In your statement, you note that research and development are the lifeblood of the pharmaceutical industry. As you may be aware:

- This year, for the second year in a row, the rate of increase in pharmaceutical research and development has gone down;
- This year's increase in pharmaceutical R&D is expected to be 9.3%. Between 1980 and 1992, by contrast, R&D investment increased by an average of more than 16% per year; and
- Six companies actually expect to invest less in real terms in R&D this year than last.

What is this going to mean for America's elderly down the line? Won't less R&D investment mean fewer breakthrough drugs, just when they're needed to meet the needs of the older population explosion that will occur with the aging of the baby boom generation?

Answer. We believe that the reduced rate of growth in R&D investment by the pharmaceutical industry does not mean fewer breakthrough drugs, but it may mean fewer "me-too" drugs which offer no real therapeutic advantage over other drugs on the market. In fact, market forces have reduced the demand for "me-too" drugs. According to the Office of Technology Assessment (OTA), the willingness of the market to pay high prices for prescription drugs during the 1980's sent signals to the pharmaceutical industry that new products would be handsomely rewarded, "even when a compound was a 'me-too' drug." The OTA cites a recent European study which found that more than one-half of the new compounds introduced to the U.S. market between 1975 and 1989 were judged to offer no therapeutic benefit over compounds already on the market.

The recent growth in restrictive formularies used by hospitals and HMOs to lower their drug costs, however, has caused intense price competition among "me-too" drugs, thereby reducing the industry's incentive to invest in R&D on "me-too" products. Moreover, the OTA notes that breakthrough drugs have been "immune" from this price competition. Thus, the industry now has a much greater incentive to invest in R&D on breakthrough products rather than "me-too" drugs.

Question. A recent Price Waterhouse study found that, for every dollar that the cash flow of pharmaceutical manufacturers is reduced, R&D goes down by about 30 to 40 cents. Yet, some argue that the effect of the proposed new rebates and other pricing policies in the President's proposal should not affect pharmaceutical R&D. Do you agree, and if so, why?

Answer. Most manufacturers insist that *every* dollar in revenue reduced by policymakers' efforts to contain drug prices will come directly out of research and development of important breakthrough medications. AARP believes that this is simply false. Much more than legitimate research and development activities go into a manufacturer's price of a drug; therefore, a drug manufacturer has many choices as to where it can be more efficient and cut costs.

In fact, according to a 1993 study by the Senate Special Committee on Aging, only *16 percent* of the manufacturer's price of a drug goes toward research and development compared to the *36 percent* that goes toward profits, marketing, and advertising. In addition, estimates based on a recent Office of Technology Assessment report indicate that during the 1980s, pharmaceutical companies on average earned 15 to 30 percent *more* profit each year than needed to attract adequate investment in capital. Given this, AARP believes the industry could accept profits of a more reasonable level and eliminate excessive promotional activities without harming legitimate research and development endeavors. Moreover, because research and development is the lifeblood of the pharmaceutical industry, it is most likely the last area manufacturers would look to cut.

Question. Do you acknowledge that pharmaceutical prices are already moderating without government intervention?

Answer. The pharmaceutical industry claims that its "voluntary" price restraint efforts are working, and backs its claim by citing the Producer Price Index (PPI) for pharmaceuticals, which was 3.1 percent in 1993. According to a recent report by the Senate Special Committee on Aging, however, drug manufacturer price inflation at the retail level—where most older Americans buy prescription medications—continued to increase much faster than general inflation in 1993. In fact, according to the report, "forty of the top 200 drugs increased in price at the retail level more than twice the rate of general inflation, which was 2.7 percent in 1993."

Clearly voluntary cost containment is entirely inadequate for cash-paying consumers and merely perpetuates cost-shifting from the inpatient market, where HMOs and hospitals negotiate deep discounts from manufacturers, to the outpatient or retail market, where similar discounts are not offered. AARP is pleased that the President's proposal includes provisions which would reduce such cost-shifting, particularly to the retail sector of the market.

Question. In your statement, you noted that manufacturers' prices increased by only 3.1% last year, but you expressed disapproval that these savings were not passed on to consumers. Why is that? What role should manufacturers be expected to have in the pricing policies of pharmacies? Were these savings passed on to consumers in the drug benefit plan that AARP manages for its members?

Answer. As stated above, these "savings" were not passed on to cash-paying consumers who must buy their medications at the retail level. In fact, costs were merely shifted from HMO's and hospitals, who extract deep discounts from manufacturers, to consumers who do not have the ability to demand from manufacturers.

The same is true of the Medigap policies that AARP offers to its members at group rates through the Prudential. Under the Medigap reforms enacted in OBRA 90, three of the standardized Medigap policies include prescription drug coverage. Under these polices, beneficiaries still buy their drugs at the pharmacy of their choice and are reimbursed for 50 percent of their costs after they meet a $250 deductible. Two of the plans ("H" and "I") have an annual benefit limit of $1,250, while the third ("J") has a limit of $3,000. Since the beneficiaries of these plans pay cash for their medications at the retail level, they have not benefitted from the deep discounts manufacturers provide to the non-retail market.

AARP does offer a mail order pharmacy service to its members which can provide significant savings on prescription drugs. The AARP Pharmacy Service, administered by Retired Persons Services, Inc., is a non-profit mail service pharmacy that buys prescription drugs (primarily generic drugs) in large volumes and passes on the savings to AARP members through lower prices. Since the Pharmacy Service does not have the ability to establish a drug formulary, which hospitals and HMOs use negotiate deep discounts from manufacturers, the discounts it receives from volume purchases are not nearly as great as those provided to the inpatient market.

AARP strongly believes that any viable health care reform proposal must included effective cost containment that reduces the extraordinary amount of cost-shifting that occurs in the current system and makes health care affordable to all individuals. In this regard, health care reform must include a mechanism that prevents

prescription drug manufacturers from shifting costs onto consumers through charging higher prices to pharmacies. AARP believes the best way to accomplish this is by including a universal drug benefit in health care reform that effectively contains drug costs.

AARP believes the President's proposal employs a reasonable approach to prescription drug cost containment while retaining adequate incentives for research and development. However, other cost containment mechanisms may be effective as well. For example, a few major pharmaceutical manufacturers are offering potentially meaningful alternatives for providing drug coverage to Medicare beneficiaries while controlling costs. At the same time, AARP believes that such cost containment mechanisms must not impede convenient beneficiary access to needed medications or pharmacy counseling.

PREPARED STATEMENT OF SETH A. RUDNICK

EXECUTIVE SUMMARY

The biotechnology and pharmaceutical industries are on the verge of significant biomedical breakthroughs. To fulfill this promise we are prepared to accept the risks inherent in our scientific research, the risks of FDA regulation, and the risks of the marketplace. Our chances of improving human health care are jeopardized if we are required to accept the risk of government regulation on our rate of return.

The biotechnology and pharmaceutical industries strongly support many of the consensus changes proposed in the various health care reform measures pending before you, including insurance reform, ending the use of "preexisting condition" clauses and required portability. In addition, we believe that because our products are an essential, and cost effective, ingredient to our health care system, comprehensive drug benefits should be available to as many Americans as possible.

I support the goal of assuring health care security for all Americans while assuring quality of care. To accomplish this goal, comprehensive health care reform is needed. Total health care costs have risen too fast. And too many people lack coverage for necessary medical care, including prescription drugs. These problems must be addressed.

I offer the Committee three specific recommended goals in fashioning a health care reform bill. First, the Congress should firmly and unequivocally reject any form of discriminatory price scrutiny of our products. The proposed advisory council on breakthrough drugs has the net effect of discouraging innovation and investment in medicines for serious unmet medical needs. The proposed "special rebate negotiations" and "blacklisting authority" should be rejected as unwise and unnecessary.

Second, in fashioning any drug benefit the Congress should—to the maximum extent feasible—rely on private sector delivery mechanisms. As the Congressional Office of Technology Assessment recently pointed out—and as the managed care-dominated market proves—this approach maximizes cost containment.[1] It also eliminates the need for government to set or review prices or to impose arbitrary rebates to the government.

Judith L. Wagner, Ph.D., Senior Associate of the Health Program at the Office of Technology Assessment (OTA), testifying on November 16 before the Senate Special Committee on Aging, concluded that growing market competition in the pharmaceutical industry will continue to restrain drug price increases:

> "Together, these developments have created a new market place in which employers and insurers have both strong incentives *and* the power to contain the

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[1] The new market environment was succinctly described in these terms in the May 3, 1993 edition of Fortune magazine:

"No matter what happens in Washington market forces are already bringing the lower drug prices that politicians and consumers seek. Two factors have converged to change the prognosis for the industry: The onset of managed care has altered demand, and a profusion of low-cost alternatives to high-priced drugs has increased supply."

According to an April 1993 study by the Boston Consulting Group (BCG),

"Managed care grew explosively in the 1980s. . . . Managed care organizations use a number of tools to reduce drug budgets, including formularies, drug utilization review, generic substitution, aggressive discount negotiations, and demands for demonstration of the economic value of the products. Their success, particularly in more active therapeutic areas where several competitive compounds are available (e.g., H2 antagonists, ACE inhibitors), has put intense pressure on the pharmaceutical industry to delivery high value for low cost."

The generic share of the prescription drug market doubled from 15 percent to 30 percent during 1983–1989. This year, more than 50 percent of all new prescriptions in the U.S. are expected to be filled by generics. Continued strong growth in the generic industry is anticipated as more than 200 drugs with $22 billion in 1991 sales will come off patent during the 1990s.

costs of prescription drugs by forcing drug companies to compete more vigorously on the basis of price . . . . Thus, over the next few years, growing price competition can be expected to provide a strong moderating influence on the rise in prescription drug expenditures."

Third, the Federal government should improve its existing ability to collect and disseminate information about outcomes research and practice guidelines. I am not advocating a new regulatory hurdle. I do support a new emphasis and application of increased resources to the process of assessing the value of various forms of medical intervention. I am confident that fair assessments of the products of the biotechnology and innovative, research-based pharmaceutical industry will establish their value and justify their use by providers of health care.

Just as medicines have conquered diseases of the past, including tuberculosis polio, syphilis and diphtheria, the industry's new therapies will succeed in combatting the diseases of the present—if the incentives for pharmaceutical innovation are preserved. Pharmaceutical breakthroughs, including those from biotechnology, provide the best hope that new cures and treatments will be developed. The rise of biotechnology follows earlier scientific advances that also led to better understanding of disease and ultimately more effective medicines. Pharmaceutical innovation has followed a pattern in the treatment of disease—from relief of symptoms, to control of disease mechanisms and finally to cure or prevention. Products now in the pipeline could provide more cures and better controls for many of today's most intractable and costly diseases.

For example, the industry has almost 300 medicines in human clinical trials or awaiting approval at the Food and Drug Administration for just eight diseases that afflict older Americans. These eight diseases alone—osteoporosis, diabetes, stroke, depression, arthritis, Alzheimer's, cancer and cardiovascular disease—cost the United States more than $430 billion a year, as shown in the attached chart. A cure for just one of these diseases would produce enormous benefits by improving patient health and cutting health care costs.

PRICE REGULATION OF DRUGS WOULD SLOW INNOVATION

Price regulation of pharmaceuticals would be particularly harmful. Studies show that price regulation of pharmaceuticals stifles innovation—which harms patients and increases overall health care costs. The U.S. International Trade Commission, in a 1991 study of the pharmaceutical industry, stated:

"The enactment of cost-containment programs, price controls, or both, on a national level often results in decreased levels of R&D spending in that these programs reduce revenues that can be reinvested in R&D programs. Several countries that have implemented such programs have seen their pharmaceutical industries weaken or shift their research efforts outside their borders."

Regulation of drug prices would be especially harmful because it would bias research towards low-risk, low-benefit new products. Heinz Redwood, an industry analyst, wrote in a recent study:

"Price regulation causes drug industry decisionmakers to shorten their time horizons and to reduce the scientific risk inherent in their research projects. The search for relatively quick, predictable results safeguards a satisfactory, if uninspiring, financial performance. In the long run, such policies produce an industrial formula that seeks to imitate rather than innovate."

An editorial in the April 2, 1993 edition of the journal Science summed up the impact of drug price regulation in this way: *"The major casualties of excessive price pressure on drugs would be the small biotechnology companies, the rate of development of new drugs to relieve human suffering, and global leadership of the United States in creating new pharmaceuticals."* (emphasis added)

CONCLUSION

In conclusion, I believe three principles—coverage, competition and cures—are fully consistent with the six goals specified by President Clinton for his health care reform plan. I firmly believe we can contribute significantly in helping to meet these worthy goals. I look forward to working with this Committee in your efforts to achieve health care reform in a way that will accommodate our major concerns.

BACKGROUND

I am the Chairman of the Board and CEO of CytoTherapeutics, a biotechnology company based in Providence, Rhode Island.

CytoTherapeutics (CTI) is a development stage biotechnology firm located in Providence, Rhode Island. The company was founded in 1989, went public in 1992 and currently has 95 employees.

CTI was created as a result of research originally conducted at Brown University and Washington University in St. Louis, Missouri. Our basic enabling technology focuses on cell therapy or the use of transplanted living cells to provide sustained delivery of therapeutic proteins and neurotransmitters to treat chronic diseases.

The company's primary Research and Development focus is in the treatment of chronic pain, Parkinson's disease, ALS, Huntington's disease and Alzheimer's.

I am testifying today solely on behalf of CytoTherapeutics. But, CTI does not exist in a business or marketplace vacuum. We are part of the biotechnology industry and aspire to become a fully integrated pharmaceutical firm. By way of background let me outline some information about the biotechnology industry. I do so, not because of a sense of superiority over the traditional pharmaceutical firms—from which I came—but rather to highlight some of the differences:

- First, biotechnology firms tend to be small. Of the 800 biotech firms in human health care only 4 make a profit, and virtually all of them have fewer than 50 employees.
- Second, the funding sources for much of their research comes from the capital market rather than the sales of existing products.
- Third, the young biotech industry does not have the history of international price differences or price increases above the rate of inflation.

This is *not a claim of moral superiority,* rather a statement of fact that discloses that because our products are more recently approved—and that the market has changed during the last 7 years—that our products have been priced more like the recent products of the traditional pharmaceutical industry, than the older products of that sector of the industry.

- By definition, orientation and market focus biotechnology products are predominantly *"breakthrough"* drugs. Thus, *the biotechnology industry will suffer more from a breakthrough drug committee* and we can bear this risk less well because of our greater dependence on outside capital.
- In the long term, the type of product made by the biotech and large pharmaceutical sector of the industry will be similar, and over time, their structure and financing will become more similar. Thus, there is no practical or logical reason to make a statutory difference between the two groups. Rather, the more valid distinctions have to do with whether Congress wants to *create incentives or disincentives for the development of innovative, breakthrough products.*

I am pleased to have the opportunity to appear before this Committee today to discuss the Medicare prescription drug benefit in the Administration's health care reform proposal. Before I turn to the specifics of health care reform and the drug benefit, however, I would like to provide the Committee with some background on the biopharmaceutical industry. Through its rapid growth it has helped to create the beginning of a therapeutic revolution.

BACKGROUND ON BIOPHARMACEUTICAL INDUSTRY

Let me begin by mentioning some of the milestones in the genetic revolution. In 1961, a technique for recombining genes was patented, setting the stage for the development of the industrial biotechnology industry in the United States. In 1975, the first biotechnology company, Genentech, was founded in South San Francisco and, in the same year, the first cancer-causing gene was identified. With that, industry scientists began a series of remarkable discoveries of the underlying causes of, and treatments for, some of the most costly and debilitating diseases threatening the health of Americans.

There are currently 23 biotechnology therapeutics and vaccines approved for sale by the Food and Drug Administration (FDA). The first of these was approved in 1985 and the latest was approved in February of this year. The biotech products currently on the market treat a wide range of diseases: AIDS, diabetes, dwarfism, hepatitis, heart attacks, anemia, leukemia, renal cancer, organ transplant rejection, cystic fibrosis, multiple sclerosis, and Kaposi's sarcoma. Drugs and vaccines now being developed by emerging biotechnology companies will treat such intractable diseases as cancer, arthritis, Alzheimer's, heart disease, osteoporosis, and genetic disorders.

The risks for companies like mine which are developing these kinds of biopharmaceutical products on the way to the market are enormous. Only an estimated five of 4000 compounds screened in preclinical testing will make it to the human testing phase, and only one of those five tested in people is approved for sale.

I am proud to tell you that in spite of these risks the U.S. biotechnology industry dominates international markets, due in large part to the convergence of outstanding basic science and sophisticated capital markets. Without scientific breakthroughs combined with patient investment from venture capitalists, public investors and others this industry would never have developed. But the long odds against a product making it past the scientific risks and through the regulatory process have made it difficult for executives in the biotechnology industry to convince investors that their company one worth gambling on. This set of obstacles make an investment in the industry truly a high risk venture. It is important to demonstrate to investors that potential rewards are commensurate with the risks.

COST OF DEVELOPING A DRUG

The Office of Technology Assessment found that the average cost per new chemical entity (NCE) is $359 million[2]. This survey did not cover the cost of developing a biotechnology drug, but analyses done by our industry suggest that the product developments costs in our industry are similar. We know for instance that Genzyme and Amgen, two BIO member companies, raised $328 and $264 million, respectively, in equity before they brought their first products to market. In addition, Genentech has spent $1.6 billion on R&D and has four basic products on the market.

Biotechnology companies are the most research intensive industry in this country, spending on average $60,000 per employee in research. Recent surveys have shown that the *biotechnology industry spends more on research and development,* based on R&D as a percentage of revenues and on a per employee basis, *than any other industry.* Our research is expensive for one simple reason: to accelerate our products into patient care we are advancing basic and applied science at the same time.

Financing this level of research and development is my biggest challenge and it is one which I share uniformly with my colleagues in the industry. Very few biotech firms are profitable or can fund their activities from sales of existing products, and we have found that most banks will not lend money to a biotech firm. Our industry is therefore dependent to an extraordinary degree on the equity capital markets to fund research and development.

Biotechnology companies were able to raise a total of $2.8 billion in the capital markets in 1993, compared with $2.5 billion in 1992. However, if you look closer at these figures, you will understand why only segments of the market were open and that the cost of capital increased. A significant portion of the money that was raised last year was in the form of private placements. My firm participated in such an offer. Taken together, venture capital firms, institutions and even individuals came up with a full 40 percent of all monies flowing to biotech in 1993.[3]

Venture capital and private placements are usually seed money that allow companies to begin their research. When a venture capitalist invests in a company, he or she betting millions of dollars on the promise of the science of biotechnology. But as a company gets closer to commercialization of a product, it requires hundreds of millions of dollars—substantially beyond the range of the most generous of the increasingly scarce venture capital funds—to fund the large-scale animal and human clinical studies, regulatory requirements, and manufacturing commitments it needs to complete in order to bring a product to the market.

Companies at this more advanced stage turn to the public markets to raise funds from shares traded on the NASDAQ, NYSE or AMEX stock exchanges. But unlike venture capitalists, public investors are investing based on their belief that an individual company will be profitable.

Public financing was especially difficult for biotechnology companies in 1993, because the industry was viewed by investors as threatened by price controls, as demonstrated by the fact that the American Stock Exchange Biotechnology Index lost 32.6 percent last year. These difficulties are further illuminated by comparing this year's figures for total public offerings and initial public offerings (IPOs) to last year's. The size of the average public offering in 1993 was down to $23 million, from $28.2 million in 1992. IPOs were down to $22 million in 1993, compared with $26 million in 1992.[4] Several public biotech companies were forced to do Private Investment in Public Equity (PIPE) financings, deals in which public companies sell stock to private investors at a discount to their current stock price.

As this Committee is aware, markets are cyclical and financing windows open and shut. While there are a variety of factors that contributed to the present difficult

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[2] U.S. Congress, Office of Technology Assessment, Pharmaceutical R&D: Costs, Risks and Rewards, OTA-H-522 (Washington, DC: U.S. Government Printing Office, February 1993).

[3] Van Brunt, Jennifer, "1993 Tops Out at $2.9 Billion—and It's Still Coming," BioWorld Financial Watch, 1 (January 10, 1994).

[4] Feinstein Partners Incorporated, January 19, 1994.

financial circumstances in which the biotechnology industry finds itself, experts assert that mezzanine investors were scared by the pharmaceutical cost containment provisions in the Administration's health care plan.

Our investors are sophisticated enough to understand and, in the past, able to accommodate the not insignificant risks inherent in our industry: the scientific risk involved in the development of genuine breakthrough products; the financial risks of having to attract capital sufficient to fund extensive research; and the regulatory risks faced in the process of FDA approval. But they feared that some widely discussed points of health care reform would present a final and insurmountable risk that would mean that they would not recoup their investment in companies that were close to bringing products to market.

The biotech industry is in a critical stage of development and research. Two hundred and seventy biotech therapeutics and cures are now in human clinical trials, the advanced stage in the FDA review process. According to the accounting firm of Ernst and Young, two thousand potential therapies and cures are in earlier development stages.[5] Now is the time when the biotech industry needs increasing amounts of capital to bring these products to market where they can improve our quality of life. The failure to fund a significant portion of these products will harm human life and decrease price competition; the exact opposite of the goals we all share.

But according to a recent report by Dr. Robert Goldberg of the Gordon Public Policy Center at Brandeis University, fully 75 percent of biotechnology companies have 2 or less years of capital left. Ernst & Young reports that biotech companies are raising capital now at 25 percent of their "burn" rate, the rate at which capital is being expended. There are approximately 1,300 U.S. biotechnology companies, which means that a staggering 975 companies will need to go to the financial market in the next two years or face going out of business, merging or selling rights to a larger firm.

HEALTH CARE REFORM

I would now like to turn to the issue of health care reform, and to my specific concerns about the Administration's proposal.

I recognize the need for health care reform in this country, and appreciate the challenge facing the Congress and this Committee of trying to fashion effective legislation that is responsive to this complex problem. We in the biotechnology industry believe that our companies can play a constructive role in a reformed health care system, by lowering health care costs through the development of effective treatments and cures for the currently untreatable diseases which cost America billions of dollars each year.

The medicines we produce are innovative, breakthrough technologies which lower costs and improve our quality of life. I believe that these kinds of products can and should be a critical element of any cost containment strategy. As we are all well aware, alternatives to drug therapy, such a hospitalization and surgery, can be vastly more expensive.

I will just note for the Committee that if you could eliminate all the costs—not just profits, but all costs for breakthrough drugs, you would be able to impact only 3% of the 7% of the total health care budget that these drugs represent. Three percent of 7% is 0.2%, a few billion dollars. If you eliminated only the profit attributable to breakthrough drugs, the savings would be a fraction of that amount.

But the effectiveness of biotech medicines is high. GM-CSF, a treatment for low blood counts, Hodgkin's disease, has an annual cost of $6,700. However, use of this treatment for a patient with Hodgkin's disease results in a net savings of $16,000 'when compared with other treatments.[6] Interferon Alfa-2B—a product I was responsible for in an earlier part of my career—a treatment for hairy cell leukemia, has a cost of $3,364. However, if this treatment is used instead of other existing therapies, the net savings to the health care system are $9,019.[7] Neutropenia, a biotechnology medicine which treats cancer patients who develop low white blood cell

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[5] Ernst & Young, *Biotech 94 Long Term Value Short Term Hurdles, Eighth Annual Report on the Biotech Industry* 28–31 (1993).

[6] Gulati, S.C. and Bennett, C.L.: "Granulocyte-macrophage colony-stimulating factor (GM-CSF) as adjunct therapy in relapsed Hodgkin's disease." Annals of Internal Medicine, Vol 116, No 3 (1992 February 1): 177–182.

[7] Ozer, H. et al.,"Cost-Benefit Analysis of Interferon Alfa-Ab in Treatment of Hairy Cell Leukemia." Journal of the National Cancer Institute, Vol 81, No 8 (1989 April 19): 594–602.

counts and fevers as a result of chemotherapy, costs $2,300 per cycle. However, since Neutropenia reduces hospitalization, its use can save $8,470.[8]

I support the goals for health care reform, but I have not supported or opposed any specific health care reform legislation. I have chosen instead to focus on the key issues that affect our sector of the health care industry. Before I turn to the issue of the Medicare drug benefit, let me briefly outline my position on the key issues that have been raised in the pending proposals.

Innovation: I believe that preserving innovation must be one of the first principles of health care reform. We do not have enough therapies and cures for diseases like cancer, AIDS, Alzheimer's, cysticfibrosis, multiple sclerosis, and a host of other deadly and costly diseases, and we must encourage continuing research on these therapies and cures. While I appreciate the pressing need to insure that health care reform provides both universal coverage and cost containment, I also believe that our public policymakers must also insure that health care reform will continue to provide the powerful incentives for innovation which have helped this country develop some of the best and most effective medical treatments, procedures and cures in the world.

Universal Coverage: I support the development of a reform proposal that will provide for universal coverage, because we recognize that, without it, we will continue to see cost shifting from those who do not provide, to those who do provide, health insurance coverage. Universal coverage will also allow us to expand preventative heath care, which will go a long way toward lowering overall health care costs. A country that provides K–12 education cannot fail to provide health care for all.

Market Based Competition and Cost Containment: I support market based competition to contain health care costs. I am confident that the unique and innovative biotech medicines being developed will be found to be both effective and cost effective by payers, doctors and patients. Our companies are ready to compete in the current health care marketplace and to compete in a marketplace where buying groups are empowered to operate even more efficiently powerful.

Prescription Drug Benefit: I support inclusion of a drug benefit as a part of a standard benefit package, and the provision of a prescription drug benefit for Medicare beneficiaries. Without a drug benefit, we will continue to find that some Americans, both elderly and non-elderly, will be unable to afford the medicines that will improve their quality of life and thus cause continued cost shifting between medicines and other medical costs.

Medicare Drug Benefit: I have some serious concerns about the prescription drug benefit outlined in the Administration's health care reform proposal. As this Committee knows, the President's plan provides for prescription drug coverage for Medicare beneficiaries but new drugs will not automatically be reimbursed by the program. They will be covered only if a rebate can be negotiated with the Secretary of HHS. The base rebate amount will be 17 percent of the average manufacturer's retail price.

Manufacturers of new products already marketed in one or more of the specified countries, at prices significantly lower than the average manufacturer retail price, must negotiate a special rebate. Manufacturers of new drugs not marketed in any other specified foreign country for which the Secretary believes the average manufacturer's retail price may be excessive must also negotiate a special rebate. The bill sets out a series of factors that the Secretary must consider in determining whether the price is excessive and in negotiating rebates. If the Secretary is unable to negotiate an acceptable rebate, the Secretary may exclude the drum from coverage.

I believe that this Committee should delete the authority provided to the Secretary to exclude "excessively priced" new drugs from Medicare reimbursement. This proposal will have a marginal impact on health care costs: As I noted earlier, only seven percent of the health care dollar is spent on drugs, and breakthrough drugs—the products targeted by this proposal—account for only three percent of that seven percent. That means that these mechanisms are aimed at 1/500th of one percent of health care spending.

While they offer little potential for savings, this mechanism presents a great threat to continued investment in the high-risk, innovative research conducted by the biotechnology industry, which will lead to products that improve health care outcomes and lower health care costs for all Americans, including the elderly covered under the Medicare program. Increasing risk to investors must increase returns investors expect.

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[8] Glaspy, J. et al., "The Economic Impact of Recombinant Granulocyte Colony-Stimulating Factor." Health Systems—The Challenge of Change. Proceedings of the 5th International Conference of Systems Science in Health Care. Editors: Chytil, M.K. et al. Omni Publishers. Prague.

Less research means fewer cures—for diseases like AIDS, cancer, cystic fibrosis, and especially for diseases affecting the elderly, like Alzheimer's and osteoporosis. Less research means fewer effective therapies which can reduce overall costs for the health care system.

In addition, excluding drugs from the Medicare system, from an elderly patient's perspective, substitutes a bureaucratic judgment for a medical one and targets this population for what will be in effect second class medicine. The industry's goal is to improve the lives of our aging population. Retaining the exclusionary authority will have a deleterious impact on the research and development of drugs for the Medicare population. Fear of potential exclusion in the future—which, in the case of drug development, can require predictions of circumstances more than a decade away—will cause companies to scrutinize the development of drugs for the elderly especially carefully.

Decisions which are presently made on the basis of scientific data and results will be skewed, since the exclusionary language provides a significant disincentive for the development of new drugs which may attract the attention of the Secretary under this provision. For example, a company may chose to focus scarce R&D resources on a drug for the treatment of rheumatoid arthritis—which has a mixed patient population of all ages—rather than on a treatment for Alzheimer's disease, which will be used solely by an elderly patient population. Because of the possibility that future pricing of the Alzheimer's product may be unacceptable to a future HHS Secretary, the risk that the company will not be able to sell the drug to the Medicare market could make development less likely.

CONCLUSION

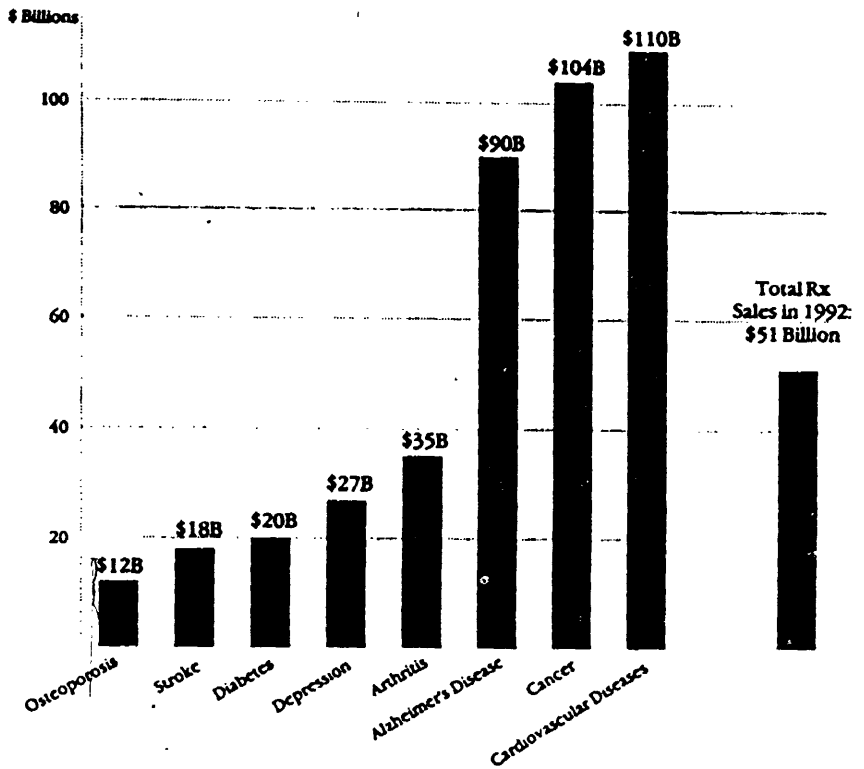
Mr. Chairman, we appreciate the opportunity to appear before your Committee today to discuss these important issues. The biotechnology industry knows that it will create breakthrough medicines that are effective and cost effective. That is our business, our inspiration, and our contribution to reducing the cost of health care in America. I look forward to working with you in a constructive manner to develop health care reform legislation that will respond compassionately and well to the needs of all Americans, today and in the future.

Thank you. I am happy to answer any questions you may have.

Uncured Diseases Cost Much More Than Drugs

For just eight uncured diseases, the cost to society amounts to an estimated $419 billion annually. This compares to just $51 billion in 1992 for all prescription pharmaceutical sales in the U.S. Drugs and vaccines successfully treat hundreds of other diseases – such as typhoid fever and polio – that once were as costly as any of today's major illnesses.

Cost of Uncured Diseases, Total Annual Cost: $419 Billion



Source Alliance for Aging Research; American Heart Association; American Diabetes Association; National Institute of Mental Health; Alzheimer's Association; "The National Economic Burden of Cancer," 1990; PMA New Medicines in Development for Older Americans Survey

PREPARED STATEMENT OF CHARLES A. SANDERS

Mr. Chairman, I am Charles A. Sanders, M.D., chairman of Glaxo Inc., the second largest research-based pharmaceutical company in the United States. Glaxo Inc. is a subsidiary of British-based Glaxo Holdings p.l.c., with U.S. headquarters, including a 1.5-million-square-foot research and development center, in Research Triangle Park, N.C. Glaxo employs approximately 6,500 people in the U.S.

Like all health care companies, Glaxo has a keen interest in the ultimate shape of health care reform. We are interested because it obviously will affect our business, but more importantly, we are interested because it will affect our mission We exist to discover and develop innovative medicines to treat unmet medical needs, an effort to which Glaxo will devote $1.4 billion worldwide this fiscal year.

Because we are convinced that the products resulting from such research efforts will play an even more important role in high-quality, cost-effective health care in the future, we firmly support the inclusion of prescription drug coverage in any standard benefits package that may emerge from current reform discussions. It's especially important that this coverage be extended to those covered by Medicare, who consume a disproportionate share of all medical services, including pharmaceuticals.

Today I will explain how our mission to discover new medicines is consistent with the health care needs of this country, and in fact serves as the foundation for solutions to many of the problems that continue to vex our current health care system. I also will discuss how we might achieve the goals of health care reform in a manner that preserves the vital role of biomedical innovation Finally, I will point out some concerns with aspects of the Administration's reform plan that might diminish innovation in the medical sciences and, along with it, the hopes of thousands of people suffering from diseases, like Alzheimer's, osteoporosis and cancer, that are inadequately treated now.

As a participant in and observer of the health care system for more than 35 years, I have gained a broad-based perspective on both the problems facing our health care system and on some of the potential pitfalls we may encounter as we seek to reform it As a practicing cardiologist, and later as a professor of medicine at Harvard University, general director of Massachusetts General Hospital and now chairman of a major pharmaceutical company, I am convinced that health care in this country is second to none. However, I am also convinced that reforms are needed.

It is plainly not acceptable to allow 35 to 40 million uninsured Americans to live an ambulance ride away from financial ruin. It is plainly not acceptable to ration health care based on an individual's ability to pay. But it is also not acceptable to compromise the quality of the health care services we have come to depend on and can look forward to in the future.

It is clear that we must contain costs, expand access and preserve and improve quality, and I commend the efforts of President Clinton and Members of Congress who have offered various proposals to address these important issues.

As we grapple with them, however, it is also not acceptable to overlook the vital role of biomedical innovation in providing solutions. Whatever direction we take, we must recognize and encourage innovation, because innovation impacts every point of the cost-access-quality triangle.

As pharmaceutical companies make strides in unlocking the secrets of disease and in designing more effective medicines, innovation will enhance quality. As these new medicines keep more people out of the doctor's office, out of surgery and out of the hospital, innovation will help contain costs. As technological advances improve efficiencies in health care delivery, innovation will help expand access.

Recent history provides us with abundant examples, but I would like to mention one that originates close to home in North Carolina.

At the Duke University bone marrow transplantation program, the use of a new therapy has had a dramatic impact on the lives of many cancer sufferers. Use of this new therapy has also turned what was a high-mortality, inpatient procedure into a highly successful procedure performed largely on an outpatient basis.

The Duke program has performed autologous bone marrow transplants on more than 850 patients. Under the earlier approach to bone marrow transplant, patients were required to spend weeks in isolation units while their bone marrow engrafted and began producing new blood cells. The cost per patient was about $140,000 in 1990 and rising.

Today, largely because of a product of biotechnology that stimulates the growth of bone marrow a compound called granulocyte colony stimulating factor, or GCSF—most patients are able to be hospitalized for only 4–5 days, and the per-patient cost has dropped by $75,000. Even more important, improved drug therapies are contributing to decreasing mortality rates, which in the program's first decade ranged from 21 to 25 percent in the first 100 days of treatment, compared to about 2 to 3 percent

now. The value of biomedical innovation in this area was summarized by no less an authority than Dr. William P. Peters, director of the Duke Bone Marrow Transplant Program, who has cited his experience as "an example of where a new technology not only improved outcomes but decreased costs."

This case is a dramatic example of the payoff of biomedical innovation. But it is not unusual. It joins a host of other achievements demonstrating the same effect: cardiovascular drugs that allow patients to avoid $40,000 coronary bypass surgery; psychotropic drugs that reduce schizophrenia patients' need for institutionalization and other treatment, saving costs of $25,000 per patient per year; ulcer drugs that have made expensive and uncomfortable gastric surgery largely a thing of the past; new treatments that have drastically reduced the cost of care and increased the rate of survival of premature infants with respiratory distress syndrome.

My purpose here is not simply to provide a laundry list of solutions to health care problems made possible by pharmaceutical industry innovation, although the effects of the innovations are clear. Rather it is to point out that these innovations were not coincidence. They were the direct result of significant investments undertaken with innovation as the goal, with the clear expectation of reward should innovations result.

It is not coincidental that of the 97 new drugs marketed worldwide in the 15 years ending in 1989, 47 originated in the U.S. It is not coincidental that a 1992 General Accounting Office report examining global competitiveness of 11 major U.S. industries cited the pharmaceutical industry as the only one that had maintained its leadership position throughout the 1980s. It is not coincidental that industry analyst Heinz Redwood concluded that "the American pharmaceutical industry has a clear and outstanding lead in developing major, medically innovative, globally competitive and therapeutically accepted new drugs" and that there exists "an indisputable link between pricing freedom and successful innovative research and development in the pharmaceutical industry."

While the U.S. has earned a leadership role in pharmaceutical innovation, it is clear that productive research also occurs in companies based in countries with some sort of government mandated price restraint It is also clear, however, that to sustain the increasingly expensive investments necessary for continued discoveries, the major players in the international pharmaceutical industry must have vigorous U.S. operations. My own company is an example.

Glaxo's worldwide headquarters is in the U.K. Since entering the U.S. market, however, Glaxo's R&D investments worldwide have increased more than 2800 percent, supporting the research and development of innovative products like Zofran (ondansetron hydrochloride), our anti-nausea drug used in cancer chemotherapy, and Imitrex® (sumtriptan succinate), used to relieve the severe pain of migraine headache. Indeed, in fiscal 1993, our R&D expenditures exceeded the total revenues realized in the U.K. by more than $375 million.

In addition, our R&D investments have allowed Glaxo to build and equip a 1.5 million-square-foot research center in North Carolina, part of a capital investment over the last 10 years of more than $1 billion in the U.S. alone. Our number of employees in the U.S. has grown to approximately 6,500, as I mentioned before. And we are one of the largest taxpayers in North Carolina.

They also have allowed us to establish a significant presence on university campuses. The R&D investments of Glaxo and other pharmaceutical companies fund the vast majority of pharmaceutical clinical research performed at leading academic research centers and teaching hospitals.

Such investments make prescription pharmaceuticals part of the solution to the health care issues we face today in this country. They have achieved that status because we operate in a free market that rewards the high-risk enterprise of pharmaceutical discovery and development. So if we accept, first, that this country's competitive market has allowed the U.S. industry to become the world's leader in the discovery of innovative medicines, and, second, that we must achieve the cost-containment, access and quality goals of health care reform, the question becomes how to reconcile these sometimes competing agendas.

Mr. Chairman, we have a model for comprehensive reform that will allow us to reach all of our shared goals. It is the concept of market-based managed competition advocated by the Jackson Hole Group, in which I have been an active participant That concept has been embodied in legislation sponsored by Senator Breaux, Senator Durenberger, and others. The strength of this approach is that it relies on the marketplace and builds on many of the changes that are already occurring to widen access and further contain costs. Importantly, because market forces would not be substantially impeded, it also would preserve the incentives for innovation that will be the key to overall cost savings in the future.

These market forces have led to the lowest prescription drug price increases in twenty years. In addition, many new products in established therapeutic categories are being introduced at prices well below the category's market leader. Unfortunately, these forces have also led to over 30,000 job losses in the U.S. industry, representing a work force reduction of more than 10 percent In addition, they have slowed the rate of growth in private R&D investments, with the 1993 increase in R&D budgets the smallest in 16 years.

Enactment of health care reform legislation based on the principles of market-based managed competition may lead to further significant adjustments in the way the pharmaceutical industry approaches its discovery, development and business practices. We recognize, however, that under meaningful reform all players in the health care industry must accommodate change. So while the changes would be challenging, they are reasonable if we are to reach our health care reform goals.

Indeed, the changes already taking place in the U.S. health care industries are evidence that the marketplace is far ahead of the rest of us in this area. They are proof that health care reform is already taking place, especially in the pharmaceutical industry. It is now the challenge of society in general and Congress in particular to arrive at a plan that will build on these incremental changes in a positive way to further the cost-access-quality goals of reform.

If we are successful in that effort, we will maintain the incentives for innovation that are so essential for continued biomedical advances. The pharmaceutical industry's ability to deliver those advances is far less certain, however, under some of the provisions of the Administration's version of managed competition. While the proposal's incorporation of the terminology and some of the structures of managed competition is encouraging, its reliance on regulation is concerning. Especially concerning are the price controls, both implicit and explicit, that would fundamentally change the economic equation in health care delivery. They also would change fundamentally the nature of the industry's decisions about what sort of research and development to pursue.

It is a sad fact that many of industry's research projects never make it out of the lab, yet consume enormous resources before enough is known to decide whether to proceed or abort. With such failures an unfortunate part of life in biomedical research, the ability to realize fair returns on successes is crucial. In a health care system in which a pharmaceutical company's ability to realize returns is less certain, the industry simply will not be able to continue its current approach to investments in innovation. One telling indication of this is the slowdown in the rate of growth of the industry's R&D budgets, which I mentioned earlier.

Contributing to the uncertainties are the enormous powers given to various offices and entities in government Among the most concerning is the authority given to the National Health Board to establish and enforce global budgets through control of premium rates.

Such budget caps would inevitably lead to a cost-focused line-item approach to medical decision-making, forcing tradeoffs of costs vs. quality.

An example of the effect is the 30-year-old patient with high cholesterol, but who is vigorous and otherwise healthy. A formulary committee operating under a global budget may argue that it can't justify coverage of lipid-lowering medications. Such coverage would only add to this year's expenditures, with no discernible improvement at year's end in the patient's health. The patient still suffers from high cholesterol; he still must take the medication Unexamined are the questions of how the lack of coverage today will affect this patient in 10 years. Will coronary bypass surgery be required? How much greater will his health care costs be over his lifetime?

As a developer of innovative drugs, we recognize that formularies will remain part of the health care landscape for some time to come. However, the interests of patients, physicians, budget directors and pharmaceutical companies all would be served by formularies that consider not just acquisition costs, but also overall economic and quality-of-life outcomes. Artificial budget caps force a distortion in health care decisions that may well lead to higher costs over time.

Similar concerns are presented by the proposed Advisory Committee on Breakthrough Drugs. This is a panel that would be empowered to examine the launch prices of new drugs that represent significant advances over existing therapies. It would determine the "reasonableness" of the price by studying, among other things, projected prescription volume, manufacturing costs and research expenditures.

There are tremendous difficulties with this approach, a fact recognized by Judith Wagner, senior associate in the health program of the Office of Technology Assessment, in her comments last November to the Senate Special Committee on Aging. "Unfortunately it is extremely difficult, perhaps impossible, to know what the 'right' price for a breakthrough drug is," Ms. Wagner said. "Every criterion for evaluating the entry price of a new drug is problematic. For example, even at high prices, some

breakthrough drugs may save overall health care costs by reducing the need for other expensive care." At the same time, she recognized that "many breakthrough drugs will offer major improvements in mortality or morbidity but at a net increase in health care costs even when the price is at the minimal level required to assure its availability on the market."

Putting aside these difficulties, putting aside the terrible precedent of a committee of this sort rummaging through a company's books, the power exercised by this so-called advisory committee would be extraordinary. While it would not have direct price-setting powers, it would be putting a government imprimatur on a specific pricing level. By emphasizing costs exclusively, it would discourage the health plans and individual physicians from considering the benefits of a new medicine objectively and arriving at their own independent opinions of its value.

Perceptions of value are at the heart of another troubling aspect of the Administration's proposal, the provision that gives the Health and Human Services (HHS) Secretary power to blacklist a drug for the Medicare population. If the Secretary deems a new drug "inappropriately priced," he or she may exclude it from Medicare coverage, or negotiate an extra discount in addition to the one that would be mandated for all pharmaceuticals.

While Glaxo recognizes the importance of providing prescription drug coverage for the elderly, this provision conceivably could discourage research into pharmaceutical treatments for diseases affecting that portion of the population. These diseases—Alzheimer's, for example—are among the most puzzling to understand, and therefore are among the most costly to explore in terms of drug discovery and development They also are among the most expensive in terms of costs to society. If, however, a drug company knows that after its huge investments of time and resources, the resulting compound may not be available to the very people for whom it was designed, it would have to consider carefully whether it wants to invest the time and money to begin with. Indeed, it may be the case that the entire market for some compounds lies within the Medicare population, making the negotiation with HHS not a true negotiation at all because of the unilateral leverage the Secretary would bring to the table.

But putting aside the problematic effects of such blacklisting power, the method by which the HHS Secretary would determine the "reasonableness" of prices is significantly flawed—a flaw also found in the powers of the Advisory Committee on Breugh Drugs. In addition to the criteria I already mentioned, "reasonableness" would be determined in part by comparing the U.S. price of a drug with prices in other countries. When even academics and others with vast experience in international economics cannot agree on a fair method of comparison, allowing the HHS Secretary to control a substantial part of the market based on such a comparison is particularly unwise. The U.S. introduction of the tablet form of our innovative anti-nausea drug, Zofran®, illustrates part of the problem.

In December 1990, Glaxo launched 30-count bottles of Zofran tablets in the U.K. at a price that was equivalent at the time to $315. We introduced the same product in the U.S. in March 1993 at a price of $262, 17 percent below the U.K. launch price. Even though the price in the U.K. had not changed in the 27 months since its launch, the U.K. price equivalent at the time of the U.S. introduction was only $240. This demonstrates the effect of varying exchange rates, only one of the difficulties with international price comparisons. Due to exchange rate fluctuations alone, at various points in time the U.S. product at launch was either significantly less expensive than the U.K. product, or about 10 percent more expensive.

Like the power to blacklist, the proposed Medicare rebate scheme adds an element to the R&D decisionmaking process that may tilt the balance further toward conservatism. The rebate seems to be predicated on the idea that companies will see a windfall of revenue from the increased use of pharmaceuticals in the Medicare population. Based on Glaxo's analysis, however, the induced demand will be far lower than that estimated by the Administration, largely because Medicare recipients as a group are already using pharmaceuticals. The Administration proposal would simply change the method of parent Support for this view comes from an October 1993 comment from the securities analyst firm of Bear Stearns, which said that much of the induced demand from pharmaceutical insurance coverage for the Medicare population would be offset by pharmacy management programs, resulting in net revenue increases to the entire industry of $1 billion to $2 billion.

In addition, it is possible that the revenue realized by increased demand will be further offset by the rebate, resulting in a net negative financial impact. Indeed, independent securities analysts have already recognized this. A September 1993 report from Lehman Brothers, for example, asserts that "a 15% discount off this segment of drug sales [the proposed rebate amount has since increased to 17%] would

completely negate the volume gains generated in the initial years, and in the out years, the pricing discounts would outweigh any volume gains."

Again, if a company must subject the revenues it receives from medicines developed for diseases of the elderly to a minimum 17 percent tax—a tax that could apply to more than 40 percent of its business—that company would have to ask itself whether it makes financial sense to invest the hundreds of millions of dollars and staff hours such a project requires.

Another troubling aspect of the administration bill is the very complex provision that prohibits discounting to hospitals, HMOs, and other entities that have leverage in the marketplace because of their ability to expand or contract market share. This provision is totally inconsistent with the Administration's stated desire to stimulate competitive market forces.

Price competition is central to any market-based effort to restrain health care costs. The ability of a health care plan to offer higher quality health care within a fixed premium will depend in part on the plan's ability to negotiate with product suppliers as well as service providers. Mandating that discounts negotiated in one sector of the market be applied in other sectors of the market would act as a disincentive for manufacturers to provide such discounts. At a time when market forces are moderating health care costs, such a mandate would be a step backward, particularly in light of the Federal Trade Commission's finding that the pharmaceutical industry's practice of offering different prices to different classes of trade is consistent with the U.S. anti-trust law.

Such a market dislocation would add to the conclusion created by the provisions I described earlier, perhaps further dampening the industry's willingness to support long-term investments in innovation. Nevertheless, this does not mean the research-based pharmaceutical industry would end its research. Research is what we do. It defines us. Iris central to our mission.

At the same time, we would not be blind to the environment in which we do our research. We would not be blind to the marketplace forces and economic realities that would determine our success and stability as a company. The ultimate effect, then, may well be a bias away from long-term, high-risk projects to shorter-term, lower-risk projects. The probable result would be a stream of new products that may not advance the pharmaceutical sciences significantly. They will be products representing incremental improvements and refinements in medicines in familiar therapeutic categories.

This is not to diminish the value of incremental gains, which are an important way science progresses. It is only to point out that in a highly regulated environment, the big stretch in R&D would be the exception rather than the rule. Only with incentives that reward high-risk ventures can pharmaceutical companies justify the sort of revolutionary research that may lead to wholesale changes in the way a disease is treated, for example, the search for a medicine that works at the genetic level to eradicate a disease as opposed to a palliative treatment that targets the symptoms of the disease.

My company, Glaxo, may provide a glimpse of how these forces would be translated into realities. Earlier, I spoke of one of our newer products, Zofran, our anti-nausea drug, which has quickly become a standard therapy in oncology wards across the country.

Zofran is the result of basic research into the role of the neurotransmitter serotonin that Glaxo began in 1972. It was not until 1990, when Zofran was introduced into the market, that we were able to realize a return on our investment in research and development that spanned approximately 20 years. It is easy to forget the internal debates that occurred when the effort encountered seemingly insurmountable obstacles and the soul-searching discussions on whether to continue its funding. Given the significant difference the medicine is making in patients' lives, it seems almost unimaginable that anything could have sidetracked it. Yet we have to ask ourselves, if the project were beginning in an environment dominated by regulation and cost containment, would we pursue it? Fortunately I don't have to answer that question. Yet the fact remains, many similar questions are around the corner.

Some of those questions will be basic ones involving the industry's R&D choices. Last year, Glaxo announced a five-year $15 million international research collaboration to find better treatments for tuberculosis. This initiative was launched because the company realized that although modern medicines and vaccines have done much to control the disease, TB has re-merged as a major health risk in this new effort, called "Action TB," Glaxo scientists are working with scientists from three academic institutions in an attempt to develop vaccines to prevent infection and identify novel targets for new antibiotics to combat resistant strains of TB.

Mr Chairman, I don't have to tell you about the magnitude of the problems posed by the resurgence of TB. New York City is one of the areas hardest hit by this dis-

ease. In fact, New York City accounts for approximately 15 percent of the national caseload and 61 percent of the cases that are resistant to drugs. In the last three years, the city has spent more than $70 million, tripled the staff at the Bureau of Tuberculosis Control to 600 woikers, and implemented the most rigorous quarantine program in modern history to attempt to get the disease under control. These massive efforts appear to be taking an effect, as the 1993 reported cases declined 15 percent from the previous year; nevertheless, in 1993 there were 3,235 new cases reported in New York City alone.

Lack of compliance with proper drug therapy combined with the increasing incidence of AIDS infection has led to this deadly resurgence of TB. According to some authorities, approximately 15 percent of the cases are resistant to at least two of the best TB drugs on the market Patients infected with those have a substantial risk of dying, estimated at approximately 50 percent Consequently, it is essential that we continue to search for new vaccines and treatments in addition to increasing our efforts to ensure full compliance with available drug therapy.

In deciding whether to initiate the "Action TB" venture, Glaxo had a choice: Should we invest in a therapeutic area in which well-fined drug regimens already exist? Should we be satisfied with existing therapy, or should we attempt to take the therapy to the next level? We chose to go forward, but our answer might have been different in an environment dominated by regulation and cost containment.

In another collaboration, Glaxo is investigating some exciting, promising yet futuristic work in anti-sense research, which involves blocking the genetic messages that actually cause disease. This research has a potential to one day prevent herpes, cancer, the common cold, and even AIDS. This is an area of science that has wondrous potential, yet it will be years—some say as many as 15 years or more—before we know whether we can successfully translate antisense research into medicines.

Again, our choice was clear: Do we embark on what is clearly a long-term, high-risk project? Or do we play it safe, investing in discovery efforts in which the research pathway and the possible product are more well-defined? While we are firmly committed to our anti-sense project, an environment in which our potential for return is limited would make these questions far more difficult.

Such an environment would force yet other, perhaps more fundamental choices as well. If the exigencies of a regulated marketplace and the realities of business cause investments in innovation to slow or shrink, which project gets the funding? Would it be the one offering hope to cancer patients whose vomiting is so severe that many choose to forego the chemotherapy treatments that may save their lives? Or would it be the one holding the potential to wipe out tuberculosis worldwide? Or would it be the one that might save thousands of lives otherwise lost to AIDS? Or would it be the one that might save billions of dollars of lost productivity costs associated with the common cold?

If society is to continue to realize the. benefits of innovation, free market forces must be allowed to work. Market-based managed competition provides an excellent framework for reform, and may well be the solution we all are looking for. However, in a highly regulated setting such as the one proposed in the Administration's plan, we may see short-term cost-containment, but some very significant long-term costs.

What will those costs be? If the pharmaceutical industry must become more conservative in its R&D decision-making, what will be the costs to the thousands suffering from arthritis and osteoporosis? What will be the costs for thousands more Alzheimer's sufferers, diabetics and heart disease victims?

As a physician, a former hospital administrator and pharmaceutical company chairman, I'm convinced the costs of curtailing pharmaceutical research—both in economic and human terms—would be tremendous. But how do we as an industry or we as a society quantify that cost? How do we count expenses associated with a medicine that might have been discovered, but wasn't?

We obviously cannot look into the future and find the answers. We can say with certainty, however, that we must not enact health care reforms that diminish the promise of continued biomedical innovation For it is innovation that holds the key to lower medical costs, improved health, and better and longer lives for us all.

RESPONSES OF CHARLES A. SANDERS TO QUESTIONS FROM SENATOR PRYOR

Question. The pharmaceutical manufacturers appear to be opposed to any efforts to contain costs in the Medicare program. They are opposed to the Medicare rebate. They are opposed to the Secretary's authority to negotiate new drug prices. Yet manufacturers negotiate rebates with other purchasers: hospitals, HMOs, and give discounts to Medicaid, VA, DOD and Public Health Service clinics.

- Do you support any mechanism to contain the costs of drugs for Medicare?

- Do you think it is fair to focus Medicare cost containment on the beneficiaries and pharmacists only?
- Would you support the use of a Medicare drug formulary instead of the rebate mechanism that has been proposed?

Answer. The research-based pharmaceutical industry supports the goal of assuring healthcare security for all Americans. To accomplish this goal, healthcare reform is needed. Total healthcare costs are rising too fast. And too many people lack coverage for necessary medical care, including prescription drugs. These problems must be addressed.

The industry supports strengthening consumer choice among competing private plans rather than mandating a single-Government payer. The industry supports continuous coverage regardless of illness. The industry supports greater emphasis on prevention and medical outcomes. The industry supports strong safeguards to ensure quality care.

In addition, the industry believes that market competition can and must be relied on to control costs, without Federal government price regulation or other unnecessary and anticompetitive Government intrusion in the market.

Finally, the industry believes that the discovery of new cures must be encouraged as the best way to maintain and improve the quality of care for patients and to contain healthcare costs, now and for future generations.

Question. Do you know of any pharmaceutical manufacturers who offer the same discounts and rebates for volume purchase that manufacturers offer to hospitals and HMOs? Does PMA support the President's proposal that manufacturers must offer discounts and rebates to all pharmaceutical buyers on equal terms and conditions?

Answer. For antitrust reasons, the Pharmaceutical Research and Manufacturers of America (PhRMA) does not become involved in the pricing practices of its member companies and has no knowledge of any such practices.

In addition, PhRMA strongly opposes the President's proposal that manufacturers must offer discounts and rebates to all pharmaceutical buyers on equal terms and conditions as anti-competitive, anti-consumer and antithetical to the integrity of the country's antitrust laws.

Question. The PMA has a new ad indicating that drug companies are not increasing their spending on R&D as fast as they were. If I remember correctly, the ad combines the years of 1980 through 1992, and estimates pharmaceutical R&D at 16 percent for those years. For 1993 and 1994 the ad cites figures of 10.2 and 9.3 percent respectively. Now these figures are growth figures, measured against the previous year's investment. A recent Fortune magazine article found that the drug industry was, once again, one of the most profitable industries in the United States by all indicators. If profits are going up, and R&D spending is going down, what are the drug manufacturers doing with their revenue? Where is the money going?

Answer. While the rate of growth of the industry's investment in research and development is slowing, the industry continues to invest more money each year in discovering and developing new medicines. It is incorrect to state that R&D spending is declining.

From 1980 through 1992, the industry's average annual increase in R&D investment was more than 16 percent. In 1993, that rate dropped to 10.2 percent. This year, it is anticipated that the rate will be 9.3 percent—the smallest increase since 1972.

In addition, PhRMA's survey shows that 20 major member companies are projecting a decline in their R&D growth in 1994 when compared to 1993. When research and development spending is adjusted for inflation using the NIH Biomedical Research and Development Price Index, six of those companies actually expect to invest less in real terms in R&D this year than they did last year.

Nevertheless, the industry will invest $13.8 billion in research and development in 1994, up from $12.6 billion in 1993 and $3.5 billion more than the National Institutes of Health will spend on all biomedical research. The industry's R&D investment this year represents a higher percentage of sales—18.8 percent—than last year's rate of 18.3 percent. The industry's rate is more than four times the average rate for all U.S. industries engaged in R&D.

Question. It seems that the Advisory Council on Breakthrough Drugs serves as a reasonable compromise between those individuals that believe that drug prices should be controlled and those that believe that there should be no restraint on drug prices. The Advisory Council can only make findings—it has no regulatory authority—and can only make a finding when a product is priced excessively. PMA opposes this Council. Manufacturers have opposed this body on the grounds that its establishment will discourage R&D, and will result in less investment and innovation. Yet, even with the specter of health reform hanging over the manufacturers' heads, a December lead headline in BIOWORLD Financial Watch declares "1993 tops 1992

for Biotech Investments," and a September 1993 article in Pharmaceutical Daily states "Analysts Don't See Near Term Drug R&D Reductions Despite Risks." We have also been told that (as has been shown in some European nations) that there are many more factors that go into decisions about R&D investment than whether or not some price control mechanism exists in a country.

Answer. What does the drug industry recommend we do to ensure that Americans don't pay excessive prices for their new drugs?

Answer. The pharmaceutical industry fundamentally believes that the market place is the best judge of what value a particular medication provides and hence what its price should be—not some arbitrary finding by a government board. There is ample evidence that over the last several years—spurred by the growth of managed care programs and increased generic and name-brand competition—direct price competition in the industry has increased dramatically. This has had a real impact on prescription drug prices at all levels, as can be evidenced by a decline in both the CPI and PPI for prescription drugs.

As reported in a January 18 article in The Wall Street Journal, these market trends have put a squeeze on pharmaceutical company profits to the point that "the pharmaceutical industry is expected to post the slimmest quarterly profit gain in more than a decade. Securities analysts predicted fourth-quarter earnings will rise on average 3% to 6% as compared to 15% to 20% increases generated by major drug makers from the mid-1980s through 1992." Companies have responded by attempting to streamline their operations, in manufacturing and marketing, as well as in MD. The result has been that 14 leading companies have announced job cuts of more than 30,000 employees in just the past 14 months. And, according to a recent PMA survey of member companies, the growth in expected MD spending this year will be the slowest in over 20 years.

The bottom line is that the market is working to moderate prescription drug prices. A Breakthrough Drug Committee which only focused on the price of a new drug and not the overall value to the healthcare system would not only cause distortions in the market, but could also negatively impact MD investment in innovative new medicines.

RESPONSES OF CHARLES A. SANDERS TO QUESTIONS FROM SENATOR DOLE

Question. The President's bill makes a clear distinction between breakthrough drugs and all other forms of medical intervention—new surgical techniques, new medical devices, generic drugs, etc. Do you see any reason why price controls should apply to these so-called breakthrough drugs, but not to advances in other areas of medicine?

Answer. We would question the advisability of the government imposing arbitrary price controls on any sector of the health care system. Certainly this is true with regard to the pharmaceutical sector. Over the past few years it has become increasingly clear that government intervention is not needed and that market competition has already significantly moderated the inflation rate for prescription drugs. Every indication is that these trends represent structural changes in the market which are likely to intensify in the future.

There are tremendous difficulties with the approach taken by the Clinton bill which would establish an Advisory Council on Breakthrough Drugs. As stated by Dr. Judith Wagner of the Office of Technology Assessment before the Senate Special Committee on Aging last November, "it is extremely difficult, perhaps impossible, to know what the 'right' price for a breakthrough drug is. Every criterion for evaluating the entry price of a new drug is problematic. For example, even at high prices, some breakthrough drugs may save overall health care costs by reducing the need for other expensive care." And while the Advisory Council might not have direct price-setting powers, it nevertheless would put a government imprimatur on a specific pricing level. By focusing exclusively on price, the Council's findings would serve to discourage health plans and individual physicians from considering the benefits of a new medicine objectively and arriving at their own independent opinions of its value.

Question. I understand that it takes between 10 and 12 years to complete the research needed to bring a new compound to market. On average, how much of that time is attributed to the FDA approval process?

But you usually file for a patent on the compound as soon as it is discovered. Do you have any suggestions about steps we can take to try to speed up that process and, in doing so, extend the patent life of new drugs, without sacrificing safety standards?

Answer. If one looks at the total time that FDA has possession of the New Drug Application, the answer would be an average of 2.5 to 3 years. This figure can be

misleading, however, since there may be times when additional studies and/or clinical trials may be asked for by the agency. This could extend the period of study by the company—without the application actually being in the possession of the FDA.

Some steps have already been taken to try ad shorten the time of development, such as meeting with the company to help design protocols, etc. very early in the process, thus avoiding some unnecessary work and aiding to streamline the process. The primary way, however, to truly speed up the process would be to provide the FDA with increased finding and adequate manpower devoted to conducting drug reviews. This would go a long way in helping the FDA to carry out its mission to approve new medicines as quickly as possible for the benefit of those patients in need.

Question. Let's say that price controls are enacted this Congress. And let's say that four years from now, for example, we discover that it was a big mistake—R&D has slowed dramatically, we've lost our internationally competitive edge, people have lost jobs.

In your estimation, how long would it take the industry to recover from such a measure?

Answer. While it is impossible to predict how long it would take or even whether the industry would recover from such a scenario, the situation in Canada offers some interesting insights. Canada recently began to reverse its policy of promoting artificially low drug prices at the expense of pharmaceutical R&D. This reversal has mainiy been pursued through the restoration of patent protection similar to that found in the U.S. and in Western Europe.

As a result, pharmaceutical companies have significantly increased their level of R&D spending in Canada, yet, many influential researchers believe that it will take at least several more years to achieve a reasonable level of pharmaceutical innovation. As Dennis Gagnon, Ph.D., vice rector of research at Leval University in Quebec noted, "Our biggest problem is that we are weak in basic research." Gagnon also indicated that Canada lost many of its world-class researchers during the intervening years and that it will take to rebuild the infrastructure.

Biomedical and pharmaceutical research and development is a long-range, high-risk enterprise. The negative impact of policies like the imposition of arbitrary price controls can be felt for decades.

RESPONSES OF CHARLES A. SANDERS TO QUESTIONS FROM SENATOR HATCH

Question. We have been told that a rebate to the government for pharmaceuticals used in a covered Medicare population is justified because of the windfall profits that this coverage would afford the industry. How do you answer this claim?

Answer. According to two different studies done by Lewin-VHI and the Policy Research Group, the Administration's bill would result in a substantial net loss of revenue for research-based pharmaceutical companies—even after accounting for any potential increase in pharmaceutical sales due to expanded coverage. These studies indicate that, under the proposed Medicare prescription drug benefit, the average pharmaceutical company would end up losing an estimated 6.7 to 11.2 percent of its revenues due to mandatory Medicare rebates, increased use of generic drugs and an increase in managed health care.

Question. In your written testimony you mention a program at Duke University which is illustrative of what advances in medicine can do to save patients from suffering and at the same time save time and money. Would you briefly describe that case?

Answer. At the Duke University bone marrow transplantation program, the use of a new therapy has had a dramatic impact on the lives of many cancer sufferers. Use of this new therapy has also turned what was a high-mortality, inpatient procedure into a highly successful procedure performed largely on an outpatient basis.

The Duke program has performed autologous bone marrow transplants on more than 850 patients. Under the earlier approach to bone marrow transplants, patients were required to spend weeks in isolation units while their bone marrow engrafted and began producing new blood cells. The cost per patient was about $140,000 in 1990 and rising.

Today, largely because of a product of biotechnology that stimulates the growth of bone marrow—a compound called granulocyte colony stimulating factor, or GCSF—most patients are able to be hospitalized for only 4–5 days, and the per-patient cost has dropped by $75,000. More importantly, the new procedure has decreased the mortality rate dramatically. Dr. William Peters, director of the Duke Bone Marrow Transplant Program, has cited this as "an example of where a new technology not only improved outcomes but decreased costs."

Question. When we discuss pharmaceutical research can you describe what we are really talking about? Would you agree with me that it takes about $359 million and 12 years to bring a drug to market?

Answer. The pharmaceutical research and development process is an exceedingly complex and risky one where the chances of success are quite remote. In fact, it has been that only 1 in 5,000 compounds ever developed actually succeed in making it to the market place. And even for those which do succeed, only about one in three ever recoup the cost of their development. In a recent study by Joseph DiMasi of Tufts University, the average time from drug discovery to the drug becoming available to the patient is 12 years. The average times by stage are:

I.	Preclinical laboratory and animal studies	3.5 years
II.	Phase I clinical studies (safety)	1 year
III.	Phase II clinical studies (efficacy)	2 years
IV.	Phase III clinical studies (large scale)	3 years
V.	FDA review	2.5 years

Last year, the Office of Technology Assessment calculated that the fully capitalized cost of pharmaceutical R&D per successful New Chemical Entity (NCE), taking into account both direct and opportunity costs, averaged approximately $359 million.

Question. We hear constantly about the pharmaceutical industry price increases during the 1980's. Have these increases moderated and, if so, what factors do you credit with change?

Answer. Competition is working in today's pharmaceutical market. Radical changes have occurred and are continuing to intensify, with the result being moderate growth in prices for both existing and new drugs. This new environment was described well in the May 3, 1993 edition of Fortune magazine:

"No matter what happens in Washington, market forces are already bringing the lower drug prices that politicians and consumers see. Two factors have converged to change the prognosis for the industry: The onset of managed care has altered demand, and a profusion of low-cost alternatives to high-priced drugs has increased supply."

In addition to market forces, 18 PMA companies, representing about two-thirds of the U.S. market for prescription drugs, individually and voluntarily have pledged to keep their average price increases at or below the general inflation rate.

PREPARED STATEMENT OF STEPHEN W. SCHONDELMEYER

Thank you, Mr. Chairman and members of the Senate Finance Committee for this opportunity to provide input into your deliberations regarding pharmaceutical coverage and cost management issues. I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Economics at the University of Minnesota where I also serve as Director of the PRIME Institute. The Institute focuses on pharmaceutical research involving management and economics. These remarks are my own views based upon observations of the pharmaceutical marketplace over the past twenty years, during which I have studied the economic behaviors and pricing policies of the pharmaceutical industry and have developed a broad understanding of the dynamics of the pharmaceutical marketplace. In particular, I have also examined the structure and financing of both private and public pharmaceutical benefit programs.

This Committee will be one of the principal Senate committees which drafts major components of the health care reform package that will eventually emerge from Congress. There are several major prescription drug issues which the Committee should address as part of health care reform. I want to address four issues, which are specifically mentioned in the Health Security Act, and which should be incorporated into any other package that emerges to reform health care in the United States:

(1) the need for a pharmaceutical benefit for the elderly;

(2) issues related to the pricing of new, breakthrough pharmaceutical products;

(3) rebate and discount practices of pharmaceutical manufacturers and their impact in the marketplace;

(4) the impact of cost management on research activities and profitability of the pharmaceutical industries.

The Need for a Pharmaceutical Benefit for the Elderly

Pharmaceuticals are one of the most cost-effective forms of medical therapy that are available today. For many individuals, however, necessary pharmaceuticals are inaccessible because of the lack of public and private pharmaceutical insurance cov-

erage. This is particularly true among our nation's elderly. The elderly have the greatest need for prescription medications, yet they are the least likely to have prescription insurance coverage. A majority of the elderly have to pay out-of-pocket for their prescriptions at the highest price drug companies charge in the market. The drug companies argue that the community pharmacy market is charged higher prices because it is not price-sensitive. However, I find it difficult to describe the nation's elderly as not being price sensitive. As any practicing pharmacist can tell you, the elderly frequently call for prescription price quotes, they complain about the cost of their medications and many do not purchase or use their medication properly because they can not afford it.

This Committee knows all too well that the Medicare program does not cover the cost of outpatient prescription medications. As a result, recent surveys and studies indicate that older Americans, many of whom live on limited incomes, are unable to afford all the medications that they need. Persons age 65 and over account for 12 percent of the population, but they consume 34 percent of all outpatient prescriptions. Many of these prescriptions are for medications that have to be taken on a chronic basis for conditions such as diabetes, arthritis, and high blood pressure. The cost of many chronic medications can range from $500 per year to more than $2,000 per year. An elderly person with one chronic disease who has to spend $1,200 per year on prescriptions would be spending 7% of the median income ($16,975) for heads of households age 65 and older on prescriptions alone. If an elderly person has two chronic conditions, the drug bill could consume 10% to 15% of the modest, median fixed income. Because of the heavy burden that prescription costs place on many elderly, it is not uncommon for practicing pharmacists to have patients who do not fill their prescriptions or who ask for only one-half of the prescription to be filled.

The President's Health Security Act proposes that a Medicare outpatient prescription drug program be established for Medicare beneficiaries. After meeting an annual $250 deductible, the beneficiary would pay 20 percent of the cost of the prescription, and the Medicare program would pay 80 percent. A maximum annual prescription expenditure of $1,000 is set as the out-of-pocket expenditure cap. In contrast to the outpatient prescription drug program in the Medicare Catastrophic Coverage Act of 1988, which provided benefit to only 17 percent of the Medicare beneficiaries during any given year, this proposed benefit would cover about 58 percent of beneficiaries each year. In addition, the President's plan contains specific provisions to assure that the program expenditures remain reasonable for Medicare beneficiaries and for federal taxpayers. Specific cost-management provisions in the Act apply to Medicare beneficiaries, pharmacists and pharmacies, and pharmaceutical manufacturers.

The cost management provisions affecting the pharmaceutical industry will undoubtedly be one of the more controversial issues addressed by this Committee. While coverage of prescription drugs for the elderly under Medicare is critical to the health of the nation's elderly, and such coverage should be provided by Congress, it would be unwise for Congress to provide this coverage without providing some tools for the Medicare program to act as a prudent buyer in the marketplace. To assure prescription drug coverage under Medicare without providing cost management tools would be like telling the defense industry to spend whatever they wanted on developing new weapons and defense systems and at the same time guaranteeing that the defense department would purchase an endless quantity of these new systems without concern for the cost or total expenditure obligation. No reasonable Congressman, either hawk or dove, would adopt such an approach to the important defense industry.

In the past, federal health care programs, including Medicaid, and private insurance programs that cover prescription drugs, have contained program expenditures by mechanisms such as increasing beneficiary cost sharing through copayments and deductibles, and by reducing reimbursement to pharmacy providers. For example, during the 1980's, the state Medicaid programs, with encouragement from the federal government, sharply curtailed pharmacy reimbursement in an attempt to control runaway Medicaid drug program expenditures. That effort was largely unsuccessful primarily because the cost of drug products, and not pharmacy reimbursement, was the primary factor causing rapidly-increasing Medicaid drug program expenditures. Up until recently, it was rare for third party prescription drug programs, like Medicaid, to attempt to control their total drug expenditures by focusing on the drug product cost at the manufacturer's level. Since the manufacturer drug product cost constitutes about 70 percent of total prescription drug program expenditures, it seems absurd to expect to manage such expenditures without targeting some effort at the manufacturer's price. Over the past few years, private health care plans have become more aggressive at controlling their overall drug program costs

by focusing on the drug product component. Volume purchasing, discounts, and negotiated rebates are some of the mechanisms that these programs are using to control expenditures for the drug product component.

The cost management tools in the Health Security Act are similar to those used in the private sector for managing the expenditures of prescription drug programs. A drug manufacturer rebate of 17% is required at a minimum. This level of discount is less than many private managed care programs currently receive even though there is no private managed care program that would come close to paying for the volume of prescriptions that would be paid for by the Medicare drug program. Another provision would allow the Secretary to negotiate with manufacturers to establish the amount of reimbursement for new drugs that will be covered under the Medicare program. Such new drugs would be covered under the program unless the Secretary and the manufacturer fail to come to agreement on a reasonable price for the new drug. If no agreement is reached, then the new drug may be excluded from Medicare coverage or subjected to "prior authorization."

These cost management provisions mimic almost exactly the mechanisms used by private managed care programs to manage their prescription drug expenditures. If the 17 percent rebates under Medicare threaten manufacturers' R&D expenditures, why is it that the industry advocates a managed care approach which would supposedly result in equal or greater discounts? Why wouldn't these managed care discounts have an equal or greater effect on R&D expenditures?

Some manufacturers have referred to the Medicare rebate as a "tax." In reality most manufacturers provide rebates and discounts to a variety of pharmaceutical purchasers—managed care plans, hospitals, HMOs, nursing home providers and others. The government is merely acting as a prudent buyer in the marketplace using the same tools as private buyers in a competitive market. These behaviors when used by the government to manage costs in what would be the world's largest prescription drug program are no more a tax than they are when these much smaller private plans use them. These provisions can more accurately be described as aggressive behavior of a large drug program to manage the level of expenditures for prescription drugs whose coverage is guaranteed by the program. *Nothing in the Health Security Act would prevent a drug manufacturer from setting the price they chose and charging that price directly to a private pay patient who wants to pay that price, whether or not the drug is covered under Medicare.*

Congress would be wise to give the federal government and its Medicare program the same cost management tools as those used by the competitive marketplace which we so jealously guard in the United States. This responsibility is especially important because the government will become the largest payer for prescription drugs in the world. Currently, federal and state governments provide reimbursement for more than $6 billion in outpatient prescription drugs through the Medicaid program. The expenditures for prescription drugs in inpatient settings under Medicare and Medicaid are hidden in the cost of hospitalizations and can range from 5% to 15% of total hospital costs. In addition, nearly $2 billion is spent each year for drugs procured by the Department of Veterans Affairs (DVA) and the Department of Defense (DOD). Other government coverage of prescription drugs is found in the health plans of federal and state employees. If a Medicare prescription benefit is passed by Congress, the government may be purchasing 30% to 45% of all prescription drugs used in the United States when expenditures from all government programs are combined.

Up until 1990, the only federal health care programs that received price concessions or discounts from pharmaceutical manufacturers were the DVA and the DOD. Certain Public Health Service clinics and hospitals were able to negotiate some discounts, but not all were able to do so. For many years, state Medicaid programs, often the largest payers of drugs in their states, attempted to negotiate price discounts with pharmaceutical manufacturers. While many generic drug manufacturers did provide price discounts to the state Medicaid programs, most if not all of the brand name manufacturers refused to negotiate. These facts are well documented in the hearings that Senator Pryor held in the U.S. Senate Special Committee on Aging in 1989.

As a result of the refusal of manufacturers to negotiate with most state Medicaid programs, Congress enacted the Medicaid Pharmaceutical Rebate Program as part of the Omnibus Budget Reconciliation Act (OBRA) of 1990. This legislation requires manufacturers to provide rebates to state Medicaid programs as a condition of coverage of their products under Medicaid. To date, this program appears to have worked well. State governments and the federal Medicaid program have saved billions of dollars in drug costs since 1990. To assure that other federal health care programs also receive fair pharmaceutical prices, Congress enacted the Veterans Health Care Act of 1992. This legislation assured that VA, DOD, most PHS-funded

clinics, and Disproportionate Share Hospitals (DSH) also received price discounts from drug manufacturers.

When enacting a much needed drug benefit for the nation's elderly, a pharmaceutical cost management program for the Medicare drug program appears to be a logical extension of the actions that Congress has taken over the past four years with regard to expenditures for pharmaceutical products under other government health care programs. Without cost management tools the Medicare program would be writing a 'blank check' to the pharmaceutical industry. This does not seem to be a prudent way for the world's largest prescription drug program to spend Medicare beneficiaries' premiums or taxpayers' money. The absence of cost management provisions would mean that Medicare beneficiary premiums, or the federal treasury's 6ontribution, or both would be continually increasing with little recourse for control.

Another issue relating to Medicare cost management which I would like to discuss is the proposed program's review of new drug prices. It has been argued by the pharmaceutical industry that the proposed Medicare drug benefit in the Health Security Act establishes a Secretary's "blacklist" for new drugs. If the Secretary and the manufacturer cannot agree on a price for a new drug, the Secretary has the authority to prior authorize, or even not cover, the new drug or biological. While excluding a drug from coverage may seem to be an extreme action to most individuals, this is exactly the procedure used by many managed care and pharmacy benefit programs and by hospitals when determining whether or not they want to cover new drug products as a means to manage drug expenditures. Many new drugs are not covered initially by private health care programs, and some are never covered. Private managed care plans often have 6 month or one year waiting periods before determining whether or not to cover drugs newly approved by FDA. Even those drugs that are significant breakthroughs are often used only under certain protocols or procedures because of safety, effectiveness, and cost issues. Enabling Medicare to use the same tools as private pharmacy benefit plans would be consistent with using marketplace methods to deliver cost-effective health care.

Without such Secretarial authority or leverage over new drug prices, a drug manufacturer would essentially have a 'blank check' to charge the federal government whatever price it wanted for a new drug. The government is quite experienced at purchasing or procurement procedures, and it would seem imprudent for the federal government to pay any manufacturer or distributor whatever price they wanted for their products. The federal government negotiates for and purchases all sorts of products each year from pencils to highly technical defense systems to complex health insurance for its employees. The government should use its experience and its buying clout and its substantial volume of drug purchases to pay reasonable prices for prescription drugs. The determination of these prices should take into account the costs of research and development, but the price cannot be left to the 'market' to price since by definition new drugs will be government-granted, patent-protected monopolies at the time of introduction to the market.

Manufacturers argue that such provisions will discourage investment in new drugs to treat conditions affecting older Americans since the manufacturer will not know whether the drug will ultimately be covered by Medicare. It is my impression that the Secretary would be pre-disposed to covering all new drugs that provide a significant breakthrough because these drugs would, in general, be cost-effective compared to the cost of alternative therapies, if any, available to Medicare beneficiaries. We must remember, however, that one of the principal components of cost-effectiveness is the price cost of the drug A new drug's cost-effectiveness can be doubled, or cut in half, simply by where the price is set. The Secretary has an obligation to assure that breakthrough drugs provide cost-effective choices which will improve the patient's health status. Given the nature of breakthrough drugs, that is that they provide effective therapy where we often have none, it seems likely to me that a manufacturer will continue to have significant incentives to invest in new drug research for older Americans given the potential market for the drug, and the tremendous need among the nation's Medicare population.

As an alternative to the cost management mechanisms in the President's plan, the Congress could consider establishing a restrictive drug formulary for the Medicare program. This is the approach used by most hospitals, HMOs, and other managed care plans to control drug expenditures. In fact, this is the approach used by the pharmacy benefit management firms and managed care, as well as managed competition, plans that many in the drug industry have suggested we entrust with the Medicare drug benefit. It is puzzling to have the drug industry argue that the minimally intrusive provisions of the administration's health plan are worse for them than the more restrictive pharmacy benefit plans in the private market. The federal government could also consider pooling the pharmaceutical purchasing power of all its health care programs—VA, DOD, PHS, DSH Hospitals, Medicaid,

and Medicare—and use this power to negotiate with manufacturers over drug prices just as a private market buyer would do.

New Drug Prices

The issue of new drug pricing will be particularly challenging for the Congress to address. New drugs do represent significant hope for curing many of the diseases of our time. The advent of biotechnology has brought us the ability to cure certain diseases, rather than just find ways to treat their symptoms. However, the price tag for these cures is high, and many individuals legitimately question how these prices are established.

The marketplace does not work efficiently to contain the cost of new drugs, especially those that are considered "breakthrough" drugs. While there is no definition of a "breakthrough" drug, either in the Health Security Act or in the Food, Drug, and Cosmetic Act, these drugs are commonly understood to be drugs or biologicals that are the first in a new class of drugs or biologicals, or a significant treatment advance over drugs already on the market. This definition is consistent with the language included in the Medicaid provisions of the Omnibus Budget Reconciliation Act (OBRA) of 1993. This language permits Medicaid programs to develop a formulary and exclude certain drugs from Medicaid coverage. Just a few examples of such breakthrough drugs are:

Ceredase, a treatment for Caucher disease;
Betaseron, the first treatment for multiple sclerosis;
Cognex, the first treatment for Alzheimer's disease; and
Felbatol, a significant new treatment for epilepsy.

The marketplace can begin to work to set a 'market-based price' for new drugs only when several alternative drugs which are therapeutically equivalent (or similar) to the new drug are already on the market. For example, the marketplace could work in the case of another beta-blocker or anti-ulcer drug because there are already several competing drug products on the market, and the manufacturer would have to price its new product to be 'competitive' with these other products. If the new drug had characteristics that made it superior to these other drugs, then the manufacturer could charge a higher price. If it did not have significant advantages, then it would have to be priced 'competitively' with other drugs on the market in order to attempt to gain some market share.

The need for some form of new drug pricing restraint becomes even more paramount if Congress enacts universal coverage for prescription drugs. Even private health care plans have little leverage over new, breakthrough drugs and this leverage will be even further reduced if universal prescription drug coverage is mandated. The universal coverage of prescriptions drugs under health reform would act as a substantial stimulus to invest in new drug discovery because of the guaranteed coverage of those drugs found to be safe, effective, and reasonably priced including the cost of the research and development.

It is important for Congress to develop a mechanism to establish reasonable new drug prices which does not discourage investment in research and development in effective new drug therapies. Obviously, the federal government does not want to become involved in setting the prices of new drugs, per se, and *nothing in the administration's proposed plan will set the market price or prohibit a drug manufacturer from establishing any price they want to charge to private payers in the market.* The sector of the market underwritten by government, however, will work efficiently only where a price conscious choice related to coverage of new, breakthrough drugs can be made.

The Health Security Act develops what appears to be a logical, balanced approach to assuring that the American health care system pay reasonable prices for new drugs. The Advisory Council on Breakthrough Drugs would have the authority to provide information to buyers about whether the price of a new drug is reasonable based on several criteria including: the price of the new drug in other countries, the cost-effectiveness of the drug, and the contribution of the new drug to improving the patient's quality of life. This approach gives the manufacturer the flexibility in establishing prices, but provides some measure of accountability and provides our health care system with a means to use its limited resources wisely on new, breakthrough drugs.

Some of the drug and biotechnology manufacturers are advocating that, instead of looking at the price of the new, breakthrough drugs, that we look exclusively at the cost-effectiveness of the drug. In fact, the cost-effectiveness of a drug is one of the criteria that the Advisory Council will review when making a determination about the "reasonableness" of a price. *However, cost-effectiveness alone cannot be used to assure that a new drug is priced reasonably because a cost-effectiveness study does not take into account the cost of research and development.* For example, a drug

priced based on its cost-effectiveness may not assure that the manufacturer's research and development costs have been recovered. The administration's proposed advisory council would be able to take these additional factors into account and to suggest how the substantial R&D costs should be accounted for in the price. Pharmaceutical and biotechnology manufacturers deserve a handsome reward on their investment if they are able to discover new, innovative breakthrough drugs. Society should be ready and willing to give them their reward. However, since no market mechanism exists for pricing these patent-protected monopoly products, some form of pricing review is warranted to assure both appropriate reward for the innovator and adequate value for the public.

The pharmaceutical industry often complains that they receive more attention by Congress, the Administration, and the media than other health care providers, such as physicians and hospitals, and that other health care services have not been subjected to cost management efforts. Drug prices are more visible to the public because individuals still pay for nearly one-half of all prescriptions out-of-pocket, while most of the cost of hospital care and physician services is covered by insurance plans. With respect to cost containment efforts the industry suggests that they are the only ones who are being subjected to scrutiny about prices. Congress does not need to be reminded that hospital payments under Medicare are established and limited by the prospective payment system (also known as the diagnosis-related groups payment system, DRGs); physician payments under Medicare are subject to expenditure targets and screens on the usual, customary and reasonable charges; and pharmacists' fees 8 are directly set by state Medicaid programs. The point is that pharmaceutical manufacturers have not been overly picked on by Congress, and, if anything, they have been ignored in cost management for longer than most other health care sectors. While it is important that Congress find a way to assist with prescription drug coverage, especially for the nation's elderly, it is equally important that Congress provide a means to manage the expenditures of such a program. *Prescription coverage balanced with cost management is quite consistent with the way Congress has dealt with other health care products and services.*

Pharmaceutical Manufacturer Discounting Policies

The Health Security Act contains a provision that would require drug manufacturers to offer discounts or price concessions on equal terms to all buyers, as long as such discounts reflect economic efficiencies realized by the manufacturer. Such efficiencies occur when the purchaser buys large quantities (volume) of product from the manufacturer, provides prompt payment, or takes prompt delivery of the product.

Individuals have questioned the need for this particular provision in the legislation. In fact, it has been referred to as "anti-competitive" by the pharmaceutical industry. This approach, however, will address another long-standing inequity in the pharmaceutical marketplace: that is, the largest buyers of pharmaceuticals are often shut out by the manufacturers from having access to discounts that are routinely offered to other smaller purchasers. This issue is commonly referred to by community retail pharmacists as "discriminatory" or "multi-tier" pricing. These pricing policies by pharmaceutical manufacturers have resulted in a see-saw effect in the pharmaceutical marketplace. Lower prices paid by hospitals and managed care plans for pharmaceuticals are often cost shifted to retail community pharmacies, and are ultimately paid for by the average American consumer. It is not uncommon to find a hospital paying $1 for the same product that would cost a community retail pharmacy $10 or $20.

Actually discriminatory pricing is, by definition, evidence of monopoly power and is an anti-competitive behavior. Elimination of discriminatory pricing based on structural criteria in the market (i.e., type of pharmacy such as community pharmacy versus hospital versus managed care benefit plans) will make similar prices available to all pharmacy purchasers who meet the same legally acceptable criteria. Discounts would then be available to those purchasers who offer bona fide business economies of scale savings to the manufacturer. *The legislation proposed by the administration does not mandate 'one price' for all.* However, it does require that 'one policy for price discounts' be offered to all buyers meeting similar legally defendable criteria for discounts. *Under the administration equal access to pharmaceutical discounts provision the manufacturer still sets its own prices and establishes its own uniform price discount policy.*

Contrary to popular belief lower pharmaceutical prices are not driven primarily by purchase volume. Large chains such as Walgreens or Rite-Aid, and community pharmacy buying groups, such as the PACE program in Lawrence, Kansas, purchase pharmaceuticals in far greater quantities than most institutional buyers. Even so, pharmaceutical manufacturers have consistently refused to give the same

level of discount to the large community pharmacy buyers that they give to small and moderate-sized institutional buyers. This market imbalance is causing a cost shift to average Americans—including the majority of older Americans—that have to buy their drugs out-of-pocket. Community pharmacies generally have no choice but to pass on these higher prices to their customers. In contrast, there are some studies that show that institutional buyers do not pass along the discounts that they negotiate with drug manufacturers. For example, we have often heard about a hospital charging $5 for an aspirin tablet which they purchased for a few pennies.

Manufacturers offer discounts to hospitals and HMOs for many reasons. First, many of these institutions do, in fact, buy in large quantities and deserve price concessions just like any other buyer, such as a large chain or a retail pharmacy buying group, which purchases in large quantities. However, a more important reason for manufacturers' providing these discounts is the marketing advantage that is gained by the manufacturer if a patient is started on that manufacturer's drug while in the hospital. If that patient uses the manufacturer's drug while in the hospital, they are likely to use it upon discharge and for many years after, especially if it is being used for a chronic condition. The price concessions offered by the manufacturer for the drug used in the hospital is more than offset by the much higher price that the manufacturer charges at the retail level after the patient leaves the hospital. Any benefit the patient may have through lower prices derived during a short hospital stay is more than lost to the higher prices the manufacturer charges retail pharmacies and their patients for the long term maintenance of the chronic disease.

If the market were working, then all pharmaceutical buyers would have access to the same discounts if they purchased the same quantity of drug. That is not the case in the pharmaceutical market today. There is some question as to whether the language in the Health Security Act would make formularies ineffective in controlling pharmaceutical expenditures. Formularies are one of the most effective tools that health care plans have at their disposal to provide cost effective pharmaceutical programs. The language seems to suggest that formularies can be used to increase a particular institution's use of a drug, and such volume increase can be used to negotiate a rebate with a manufacturer, as long as the same rebates or discounts are made available to all buyers for equal volume. That is, an institution could still use a formulary to increase its volume, but an institution could not receive a rebate simply because it had a drug formulary.

Impact on Pharmaceutical Industry Profits and Research Activities

The pharmaceutical industry is one of our nation's most research-intensive industries. It invests a significant percentage of its sales in research and development. This investment should be encouraged by policy makers. Let me respond to several issues raised by the pharmaceutical industry about the impact of health care reform policies on their ability to do research and development.

First, as a result of universal access for prescription drugs, millions of Americans that do not have coverage for prescription drugs will have such coverage. This includes millions of older Americans who will have coverage under a Medicare drug benefit. Some increased prescription volume will result from this expanded coverage. In Pennsylvania, for example, when prescription drug coverage was provided by the states' PACE (Pharmaceutical Assistance Contract for the Elderly) program, the average number of prescriptions used by the elderly grew from about 15 prescriptions per person per year in the first year (1984) of the program to around 26 prescriptions per person per year in 1993. It is realistic, therefore, to expect that drug manufacturers will experience a substantial increase in sales volume due to Medicare prescription drug coverage. The revenue increase as a result of expanded coverage is expected to provide an even greater source of monies for R&D. This expanded prescription volume will be for drug products whose R&D and marketing costs have already been expensed based on current sales volumes. Consequently, the marginal cost of producing this expanded volume will be only about 30 to 60 percent of the original market price. Rather than cut resources available to pharmaceutical firms, the expanded coverage under Medicare, even at a 17 percent discount, would provide additional dollars for R&D and would still offer a substantial profit margin.

Second, the pharmaceutical industry has complained that the rate at which its annual R&D spending is increasing has slowed down! While this has occurred, one must put in perspective the rate of growth in R&D spending for the pharmaceutical industry. According to Medical Advertising News (Sept. 1993), the Top 50 pharmaceutical firms experienced 18.2 percent growth in their health-related R&D spending in 1992 compared to the previous year. These rates of R&D growth, when compared to the growth rate of inflation in the general economy (about 3 percent), showed that health-related R&D was growing at 6 times the rate of inflation. While this phenomenally high rate of R&D growth is commendable, it is not reasonably sustain-

able. Last year, we had one of the lowest inflation rates (2.7 percent) in more than two decades and *to suggest that a slowing of the double-digit growth rate of pharmaceutical find spending is a decrease in commitment to pharmaceutical find is not a credible assertion.*

Forty-eight of the top 50 pharmaceutical firms spent more on R&D in 1992 than they did in 1991 and the two which spent less were explainable for reasons unrelated to cost management pressures in health care (one firm had a corporate divestiture and the other received FDA approval for its only major product in development). Some slowing in this extraordinary rate of growth in R&D is not surprising when all of the economy has slowed down. *Pharmaceutical R&D has continued to grow substantially in real dollars.* Even if the rate of R&D growth slowed to one-half of its 1992 growth rate, which it has not, it would still represent a growth in R&D spending which is more than three times the rate of inflation in the general economy. More real dollars were spent on R&D last year than in previous years, and the level of spending on pharmaceutical R&D is expected to continue growing faster than the rest of the economy in the next few years.

Third, according to the recent Fortune Magazine, the drug industry was once again the most profitable industry in the United States in 1993 by any one of three measures of profitability. I do not say this to criticize any industry's right to make a profit. However, evidence continues to suggest that this industry has been able to sustain higher levels of profitability over several decades than most any other industry. In fact pharmaceuticals have been America's most profitable industry for more than a decade and this industry has been first or second in return on sales for more than three decades. This excellent performance on the one hand deserves commendation, but on the other had raises questions as to whether or not there is some fundamental difference in the structure of this market versus other industrial markets that has allowed such exceptional performance in the long term.

Certainly, other industries in America also strive to be profitable and they have outstanding talent in corporate leadership. Because pharmaceuticals are a necessity of life this market appears to function differently from other markets. The price feedback system does not seem to work to set market prices as it does in other markets. The patient does not choose the drug product; instead his or her physician does, and that physician is not price sensitive and often does not even know the relative price of the medications being chosen. Also the payer is an insurance company, or in some cases the government, but the payer is not usually directly involved in the choice of a drug. This system of health insurance coverage appears to have led to both over-use of medications and over-priced prescription drugs. If all patients, rather than insurance plans, were paying directly for their prescriptions, it is quite likely that we would either see fewer prescriptions being filled because many patients could not afford needed medications or we would see lower prices that are truly market-based as a result of competition for market volume. Despite the 'cry wolf' complaints of 'gloom and doom' by the pharmaceutical industry as a result of feared health care reform pressures the industry's profitability and R&D expenditures remain above the performance levels of other industries in corporate America.

In conclusion, affordability of prescription drugs by many of the nation's elderly and near poor has become a major access issue. Coverage of prescriptions for these groups is essential to providing appropriate and cost-effective health care. At the same time the government can not guarantee coverage of prescription drugs for disadvantaged populations without the same tools that private health care plans use to manage their pharmaceutical and overall health expenditure levels. The coverage of prescriptions for the nation's elderly can be expected to result in a substantially expanded sales volume (10 to 20 percent) for pharmaceutical firms at relatively low marginal costs. The 17 percent rebate proposed by the administration is no more of a discount than other prudent buyers are receiving in today's pharmaceutical marketplace. Nearly all well-managed health care plans have a process for reviewing new, breakthrough drugs and for determining of the effectiveness and safety of the new drug product provides sufficient value to warrant the price asked by the pharmaceutical firm. Government-financed programs should be no less careful in spending their health care resources than are privately managed health care plans. Policymakers need to continue to work with the pharmaceutical industry to determine what provides appropriate incentives to conduct productive and efficient research and development which results in significant breakthrough drugs. We must remember, though, that the value of pharmaceutical R&D is not measured by the amount of money spent in the process, but rather by the outcome that breakthrough drugs can produce in the health of the nation.

RESPONSES OF STEPHEN W. SCHONDELMEYER TO QUESTIONS SUBMITTED BY SENATOR PRYOR

Question 1: The drug manufacturers have been Unwilling to negotiate with community pharmacy buying groups, yet they negotiate with hospital buying and managed care buying groups. The President has proposed that manufacturers treat all buying groups on the same terms and conditions. The manufacturers are calling this an "anti-discount," "anti-competitive" proposal. Would you label it as such?

Answer: The President's proposal would not be anti-competitive, but would, in effect, level the playing field so that all buyers of pharmaceuticals would have access to the same pharmaceutical manufacturer discounts on equal terms. Nothing in this section of the Health Security Act will prevent pharmaceutical manufacturers from establishing the price of a drug product or from determining the amount and level of discount to be offered on that drug product. The 'equal access to pharmaceutical discounts' provision does, however, require that the criteria for discounts be related to factors which result in lower cost to the manufacturer through economic efficiency or economies of scale and that once the discount criteria are set that they be equally available to all purchasers who meet the same criteria. This provision is proposed to encourage competition by providing all purchasers who use the same competitive behaviors equal access to the same level of discounts.

Presently, some purchasers who buy in very large volume do not receive the same discounts as other purchasers who buy much smaller quantities. It is well known that drug manufacturers, in general, will not negotiate with community pharmacy buying groups, regardless of their size or volume. In fact, testimony presented to the hearing of the U.S. Senate Special Committee on Aging in November, 1993 by Benji Wyatt, Executive Director of the PACE Buying Group in Lawrence, Kansas detailed this fact for the Congress. In addition, hearings that you held as Chairman of the Senate Aging Committee in 1989 found that drug manufacturers, in general, refused to negotiate discounts with the Medicaid program, the largest prescription drug program in the nation. This resulted in the enactment of OBRA 90, which requires drug manufacturers to give discounts to the state Medicaid programs.

Under the President's proposal, drug manufacturers could not arbitrarily decide to whom they would give discounts or price concessions. The same rules would have to be established for all purchasers. Pharmaceutical buyers who purchased the same quantity of drug would receive the same discount. Right now, a large chain pharmacy buying a total of $2 billion in pharmaceuticals a year is charged more for the same product than a hospital buying only $2 million a year. Clearly, the group buying the largest quantity of drug is not receiving a larger, or even the same, discount despite the larger quantity. This current practice appears to be anti-competitive, and discriminatory, and ultimately leads to higher prices for the average consumer.

It is well known that drug manufacturers, in general, will not negotiate with community pharmacy buying groups (either chains or independents), regardless of their size or volume. This practice is known as "discriminatory pricing." The concept of "price discrimination" goes by many names (e.g., multi-tier, discriminatory, differential, or preferential pricing). In the public policy debate, pharmaceutical manufacturers have attempted to confuse the price discrimination issue by labeling this pricing practice as "competitive pricing." Actually, the characterization of price discrimination as "competitive pricing" could not be further from reality. An economics dictionary provides the following definition:

> **"Price discrimination.** The selling of the same commodity to different buyers at different prices. Several conditions must prevail for it to be profitable. First, there must be a separation between markets that does not allow buyers in one to resell the item in another (no arbitrage must be possible). Secondly, the seller must possess some degree of monopoly power in at least one market, for under competitive conditions, prices will be driven down to the level of costs in all markets." Bannock, Graham, R.E. Baxter, and Evan Davis, *The Penguin Dictionary of Economics,* Fourth Edition, (London: Penguin Books, 1987), p. 322–3.

Intense rivalry among sellers, or between buyers and sellers, tends to be confused with competition, to the point that participants often lose site of the real meaning of competition. There is certainly intense rivalry, and intensified technological and marketing competition in the pharmaceutical industry in today's marketplace, but these conditions do not necessarily produce "economic competition." Based upon the above economic definition of price discrimination, it is clear that price discrimination is the result of some degree of moncpoly power held by pharmaceutical manufacturers rather than economic competition. As the pharmaceutical marketplace moves toward fewer buyers and fewer sellers the market will become even less, rather than more, competitive. Mergers of brand name drug companies, or brand

name and generic drug firms, has led to fewer sellers in the market over the past decade. Also, pharmaceutical firms have acquired pharmacy benefit management firms through mergers and acquisitions. This vertical integration in the market removes a key player which has been one of the primary sources of creating some degree of economic or price competition. Again, more of these vertical integration actions will result in less, rather than more competition in the market.

By itself, some degree of monopoly power is not sufficient to establish price discrimination. There must also be different price elasticities of demand among different market segments and it must be possible to keep market segments separate. If one segment of the market can buy at a lower price and can transfer the product at that lower price to other market segments, it is difficult for the manufacturer to maintain price discrimination. However, if the manufacturer can clearly define market segments and prevent transfer of product across market channels, higher prices can be charged to the least price sensitive buyers and lower prices can be charged to the more price sensitive buyers.

Demand for products and services in the health care market, in general, and particularly the pharmaceutical market is uniquely different from most other markets. A consumer can not purchase a prescription drug without the permission of a physician. The physician determines if a prescription drug is needed and which drug product the patient will receive. Physicians are known to be relatively unaware of the price of prescription drugs making them price insensitive, regardless of the patient's price sensitivity. Insurance coverage of prescriptions makes both consumers and physicians even more price inelastic resulting in increased opportunity for pharmaceutical manufacturers to engage in monopolistic price discrimination. In summary, price discrimination separates buyers by some criterion. Criteria are chosen that successfully separate buyers into those with more elastic demand and those with less elastic demand. The seller can then raise the price in the inelastic market and reduce it in the elastic market, increasing total profit. "In general, firms and groups with elastic demand benefit from price discrimination, while those with inelastic demand pay higher prices because of price discrimination" (Managerial Economics, p. 166).

Competitive market pricing is a hallmark of the "free market" system. The existence of substantial price discrimination in the pharmaceutical market is evidence that competitive pricing is not uniformly available to all prescription consumers. The U.S. pharmaceutical market is quite complex and demands a more competitive approach. Some purchasers of pharmaceuticals (such as hospitals, HMOs, and mail order plans) have been able to insist on more competitive prices from pharmaceutical manufacturers. Other prescription drug consumers are disadvantaged in the market because the physicians who make the decision as to which drug will be purchased are relatively price insensitive. This does not necessarily mean that the individual patient is price insensitive, just that the structure of the prescription market does not provide a direct means for consumers to express price dissatisfaction. It would be hard to imagine a more price sensitive consumer than an elderly person on a fixed income of about $16,000 per year who has two chronic conditions requiring prescription medications which must be paid for with out-of-pocket dollars. These medications may cost from $1,000 to $2,500 per year. Yet these consumers are the ones most likely to be paying the highest manufacturer price for prescriptions.

The price charged for prescription drugs to the so-called "insensitive" segment of the market are not competitive "market-based" prices. Other segments of the market may be receiving prices which are closer to a true market-based price. The criteria for determining which purchasers receive lower prices appears to be somewhat arbitrary and are different for each pharmaceutical manufacturer. Manufacturers are very secretive about the definitions of various market segments and the prices they receive which further impedes the competitive market. Because of the extreme importance of prescription drugs to all consumers, the criteria for favored pricing should be standardized and made publicly available so that all manufacturers and purchasers have equal opportunity to meet the criteria for more competitive pharmaceutical pricing.

The Clinton health security plan allows pharmaceutical manufacturers to retain pricing flexibility by establishing the price level and the timing of their price changes. The criteria for segmenting the market and offering competitive prices are made explicit and must be publicly available so that all types of pharmacy purchasers have an opportunity to access these competitive prices. The acceptable reasons for granting more competitive prices through discounts to buyers are: (1) prompt payment, (2) bash payment, (3) volume purchase, (4) single-site delivery, (5) use of formularies by purchasers, and (6) any other terms effectively reducing the manufacturer's costs. Many pharmaceutical manufacturers use these criteria to es-

tablish discounts for certain customers (e.g., hospitals and HMOs), but do not offer similar discounts to other buyers meeting the same criteria (e.g., chain pharmacies or retail buying groups). The danger is that without such a policy manufacturers will define and apply these criteria inconsistently and in a manner that inappropriately disadvantages certain pharmaceutical purchasers and consumers.

Given the facts above, it is clear that competitive pricing offers advantages which should be equally accessible to all purchasers and consumers willing to meet the acceptable reasons for competitive prices. If the pharmaceutical market structure was less complex and less convoluted the competitive market would be able to work normally, but the many inconsistencies in the pharmaceutical market are compelling reasons to establish clear and uniform criteria for equal access to competitive pharmaceutical prices.

Question 2: I am astounded by the differences in prices paid by HMOs versus those paid by community pharmacies for the very same drugs. What do you think are the reasons for these wide discrepancies in price? I understand that these low prices are given for marketing reasons. Can you expand on this?

Answer: It is not unusual to find multiple percentage differences in the pharmaceutical prices paid by hospitals and HMOs versus community pharmacies. There are some very widely known examples of such price disparities, such as Nitroglycerin patches, where a hospital would pay one penny per patch, and a community pharmacy would pay one dollar for the same patch, and asthma inhalers, where similar price differences exist. While many of these institutions buy in volume and are entitled to some quantity discounts, the volume buying does not explain the total differences in prices paid by these institutions.

Manufacturers offer discounts to these institutions on products for which there are multiple competitors on the market so that the institution will use their drug. Once the patient is started on a drug in the institution, it is likely that the individual will use the drug for a long time once discharged from the hospital. Therefore, the significant discount-given to the-hospital to use the drug in the patient for the short-term stay is more than offset by the many years that the patient will use that drug and pay full price at the community pharmacy level. If manufacturers gave the same deep discounts to community pharmacies, who often buy in equal, or even greater, quantities than these hospitals, manufacturers would not be able to recoup the discounts that they provide to these institutions. Ultimately, while the hospital may save money on its drug purchases, consumer, and indeed, societal savings may be negated by the higher prices charged to consumers as a result of cost shifting to the community pharmacy buyers and their customers.

Question 3: The drug industry now contends that the drug marketplace is very, very price competitive. That may be the case for hospitals and HMOs, but it may not be the case for the retail pharmacy marketplace. Is competition working in the retail pharmacy sector right now?

Answer: As the percentage of the pharmaceutical marketplace which uses competitive mechanisms increases, such as formularies and therapeutic interchange, the potential for true pharmaceutical price competition increases. Traditionally, hospitals and managed care plans have been best able to harness these competitive forces, and thus have received some of the best pharmaceutical prices in the marketplace. Manufacturers have also traditionally charged the retail marketplace the highest prices for prescription drugs. These lower hospital prices are "cost shifted" to community pharmacies, and thus to average American consumers, especially older Americans, who buy their drugs at the retail level.

While the rate of growth in pharmaceutical price increases has slowed down over the past year or two in the retail sector, it does not mean that retail pharmaceutical prices have decreased. In fact, the rate of price increases is still above the overall inflation Tate in the consumer economy as measured by the CPI-U for all items. Because the retail marketplace is not structurally organized to use formularies and therapeutic interchange, competitive forces have not been the primary reason for this moderation in prescription drug price inflation at the retail level. I believe that most of the price restraint that we have seen in the retail market has come from "political forces" rather than "market forces." Therefore, the impact that economic competition can have on retail pharmacy prices is limited.

Question 4: A recent GAO report found that citizens of the U.K. pay much less for the same prescription drugs that the citizens of the United States. What accounts for these price differences?

Answer: The GAO report found that there were several factors accounting for the differences in pharmaceutical prices paid by citizens of the United States versus the United Kingdom. The primary reason for the price differences, however, was the fact that the U.K. utilizes a system of regulatory profit and price restraints to hold down pharmaceutical prices, while the United States does not. Because the struc-

ture of the U.K's National Health System is very similar to that of a single-payer system for health care services, including prescription drugs, the government is able to exert considerable leverage over pharmaceutical prices charged by manufacturers.

The U.K. government and the pharmaceutical industry have agreed to limits on both profit levels and marketing expenditures as a way to control total pharmaceutical costs. For example, there are limits to the profits that pharmaceutical manufacturers can earn in the U.K., although the manufacturers have relative freedom when pricing new products. In addition; the government limits marketing expenditures to approximately 9 percent of sales of a company. This is in contrast to the United States, where drug manufacturers spend anywhere from 20–30 percent of sales on marketing and advertising. While some of this marketing and advertising is needed to educate health professionals about new drug products, a good part of it appears to be expensive, wasteful promotion with costs that ultimately have to be passed on to the American consumer in the form of higher prices for pharmaceuticals.

While patents are granted to brand name drug firms as a reward for innovation, these patents create monopoly power for the pharmaceutical firm which is further enhanced through extensive, and expensive marketing, and advertising. Advertising creates habits and brand loyalty to certain products which leads to less competition and higher prices. "Advertising raises prices and reduces output for consumers in monopolistically competitive markets, but in other cases both price and quantity rise" (Ulbrich, Holley E. and Mellie L. Warner, *Managerial Economics* (New York: Barron's Business Library, 1990), p. 159). Either of these effects could be harmful to the public with respect to essential health care products and services such as pharmaceuticals.

Although the U.K. has these pharmaceutical profit, price, and expenditure restraints, pharmaceutical manufacturers in the U.K. still invest a significant amount of their sales in R&D in that country. In fact, three of the world's most successful research-intensive pharmaceutical manufacturers are located in the U.K: Glaxo, Burroughs-Wellcome, and ICI-Stuart. This seems to suggest that meaningful R&D and reasonable cost management on pharmaceuticals are compatible goals.

Question 5: Generic drug manufacturers have been willing to negotiate with buying groups, unlike the brand name drug manufacturers. Why do generic drug companies negotiate and not the brand name companies?

Answer: Generic drug manufacturers operate in a much more price competitive environment than do brand name drug manufacturers. There are often times many different manufacturers of the same generic drug product who have to compete aggressively on price in order to sell their products to purchasers. At the community pharmacy level, pharmacists are able to substitute one generic product for another which gives them negotiating leverage with generic drug manufacturers. Large community pharmacy buying groups can pool their purchasing of generic drugs in order to effectively negotiate with generic drug firms and generic firms have not refused to discount to retail community pharmacies like the brand name firms have done.

Alternatively, community pharmacists cannot, by law, independently substitute therapeutically-equivalent brand name drug products. Therefore, they cannot force brand name drug manufacturers to compete on price, and the manufacturers can literally charge community pharmacists whatever the market will bear for these products. It is not unusual to find new therapeutically similar or interchangeable drug products being marketed at prices that are higher than those already on the market. In recent years, some community pharmacies have taken the initiative to establish their own formularies, and substitute similarly-acting drug products with the permission of the physician, injecting some price competition into this segment of the market. This has met with some limited success, but community pharmacies are, in general, still charged the highest prices in the market. They, then, have to pass along these higher prices to the average consumer.

As a number of very popular brand name drug products come off patent, many brand name drug manufacturer are making their own generic versions of these products. Some are marketing them before the patent expires on the originator product. This phenomenon may have some anti-competitive implications with respect to the pricing of generic drugs, and should be watched closely by Congress and the Federal Trade Commission.

RESPONSES OF STEPHEN W. SCHONDELMEYER TO QUESTIONS FROM SENATOR HATCH

Question 1: I believe that you were a consultant to the General Accounting Office (GAO) study comparing U.S. and Canadian drug prices. What has the reaction been of other researchers to this study? Has there been unanimous agreement among researchers that the conclusions reached by the GAO were correct?

Answer: Just as there are few pieces of legislation that pass unanimously, likewise, there are few major policy studies in which all experts will agree on the methodology, or conclusions, of the study. With respect to the GAO study comparing Canadian and U.S. prescription drug prices, most policy analysts, as well as experts from other government agencies or from consumer-based organizations, agreed with the GAO's study findings. This study's findings were consistent with other studies, such as the study done by the HHS Office of the Inspector General or studies done by the Canadian Patent Medicines Price Review Board. The replication of research findings by other independent researchers provides added assurance of the validity of such findings.

To my knowledge the only major criticisms of the report have come from policy analysts and "experts" funded (by the pharmaceutical industry or by individual pharmaceutical firms) to critique the report. Certainly, there are always challenging issues to be dealt with when doing international price comparison studies, since the exact differences between international prices may vary with such factors as exchange rates. However, I believe that the general conclusion of the study—that Canadian citizens pay less for their prescription drugs than citizens of the United States—is fundamentally correct and has been confirmed by other independent researchers.

Question 2(a): In February of last year, Professor Ernst Berndt from the Massachusetts Institute of Technology testified before the House Subcommittee on Health and the Environment and he raised some interesting questions with respect to the above-mentioned GAO study. For example, he points out that, since the provincial governments buy in bulk, the method used of converting the price paid by the Ontario government for 100 tablets when they bring in a container of 5,000 tablets is simply to divide the price by 50. The price is then compared to the list price of a bottle of 100 tablets in the U.S. Is this a fair comparison?

Answer: The premise of Professor Berndt's comment, concerning "bulk purchasing" by the Ontario Drug Benefit, is not at all accurate. The Ontario Drug Benefit program reimburses community pharmacies for providing prescription drugs to the indigent (much like a state Medicaid program) and the elderly (similar to a state-run drug program for the elderly such as the Pennsylvania PACE program). In other words, the provincial government does not directly purchase from pharmaceutical manufacturers nor does it take drug products into stock in "bulk" quantities as the "for example" portion of the above question implies. The prices listed in the *Ontario Drug Benefit Formulary* are the drug product cost amounts which a pharmacy will be paid for the drug product dispensed in a prescription to an eligible beneficiary.

The drug cost is the "best available price" (BAP) which is the "lowest amount for which a listed originator (nongeneric) drug product (in each dosage form and strength) can be purchased in Canada for wholesale or retail sale in Ontario (GAO Report HRD–92–110, p. 16–17)." Therefore, the drug cost listed in the *Ontario Drug Benefit Formulary* is reflective of the price pharmacists in Ontario pay to wholesalers and manufacturers for the drugs dispensed in prescriptions for program beneficiaries, as well as the prescriptions dispensed to private pay citizens in Ontario.

By establishing 'best available prices' for prescription drugs in Ontario which are based on the prices found in the market, the province not only assures a reasonable price for the ODB program beneficiaries, but it also assures the same reasonable price for its private pay citizens. Consequently, the ODB prices are quite appropriate to compare against when one wants to know the manufacturer's price that is relevant to private pay citizens in Canada and the U.S.

Question 2(b): I also understand that the GAO used the "list" price for drugs in the U.S., excluding any manufacturers' discounts and any Medicaid rebates, and compares these prices to actual transactions in Canada. Isn't this methodology flawed?

Answer: No, the methodology did not use "list prices" and it is not flawed. The premise of this question is based upon a misperception of what was actually done by the GAO. The GAO study did not use "list price" as this question suggests. The U.S. prices for the GAO study were based on the wholesaler acquisition cost (WAC) which is the price found on the invoice for the transaction between the manufacturer and the wholesaler for drug products that are to be sold to retail community pharmacies. This price which does not even include the wholesaler's markup on the drug product is usually 12 percent to 20 percent less than the list price (also known as the AWP or average wholesale price). If the GAO had actually used the "list price" as your question suggests, the difference between U.S. and Canada drug prices would have appeared much greater than those reported in the study.

The intent of the GAO study, according to the Congressional member requesting the study, was to focus on the impact of manufacturer's prices on the amount paid

by the typical individual consumer in the U.S. and Canada. Consequently, this study examined manufacturers' prices to retail community pharmacies where the majority of consumers in the U.S. purchased their prescriptions in 1991 (the timeframe in which the study was done). Since the Ontario Drug Benefit prices are established based on prices at which community pharmacies can purchase drug products in Ontario, these prices reflect the price that community pharmacies would typically pay a wholesaler or the manufacturer for the drug product. Prices similar to those in the *ODB Formulary* were reported to be available in other Canadian provinces according to several governmental and other private sources in Canada.

The issue of including manufacturer's discounts and rebates in this price comparison is not relevant to this study, since cash-paying consumers purchasing individual prescriptions in community pharmacies do not benefit from manufacturer's discounts or Medicaid rebates. No individual paying cash receives a lower prescription price due to Medicaid rebates nor do manufacturer's typically provide discounts or rebates to retail community pharmacies. Accounting for discounts and Medicaid rebates would be relevant only if the research question was attempting to determine the manufacturer's weighted average price for a drug product across all purchasers. However, that was not the research question which the GAO study was designed to answer.

The Canadian and U.S. ex-factory prices compared in the GAO study were at a comparable level and were appropriate to answer the research question posed by the Congressional requestor of the study. The U.S. prices were, if anything, an underestimate of the transaction price paid by U.S. pharmacies because the wholesale acquisition cost used in the study did not include the wholesaler's markup, while the Canadian prices are thought to have had this wholesale markup built in to the prices used: The GAO study method was quite appropriate and was not at all flawed in the way that this question appears to suggest.

Question 2(c): The study looks at the 200 largest selling branded drugs in the U.S. and compares the U.S. to Canadian prices for the 121 drugs for which overlapping data could be obtained. These 121 drugs are then weighted equally without regard to market share. I also believe that generic drugs were not considered at all. Do you believe that this methodology leads to an accurate conclusion?

Answer: Your question correctly notes that the GAO study found 121 comparable drug products in the U.S. and Canada which were used for evaluating differences in prices to the individual consumer in the two countries. Representation of the price differences across a group of individual drug products requires some means of summarization. The initial GAO study design included plans for weighting the differences across these drugs by the respective sales volume of these drug products in the U.S. market. As noted in the study report (GAO Report HRD–92–110, p. 11), the GAO was "unable to obtain U.S. sales information for each of the drugs in our study." At least two pharmaceutical market research firms in the U.S. were contacted by GAO with inquiries about access to sales volume data for use with this study, but a combination of factors including timing, cost, and confidentiality of data resulted in the GAO not being able to obtain such data for use in this study. Althougtrsales volume data would have provided additional useful information, the fact that GAO was not able to obtain that information in a timely and cost-efficient manner does not invalidate the findings of the study.

With regard to generic drugs, the GAO study design considered only drugs which had the same strength, dosage form, and manufacturer in both the United States and Canada. There were relatively few generic drug products in the Top 200 and few generic pharmaceutical firms market in both the U.S. and Canada. Consequently, the drug products included in the study were largely brand name products. As long as one understands the drug products included in the study, the study's methods lead to an accurate conclusion. This study can not answer the question as to whether or not generic drug manufacturers charge higher prices to U.S. retail community pharmacies serving the cash paying public than they charge retail community pharmacies serving the cash paying public in Canada. On the other hand, this study can lead to an accurate conclusion that the brand name manufacturer's price for a brand name drug product sold to retail community pharmacies serving the cash paying public in the United States is generally higher than the same brand name manufacturer's price for the same brand name drug product sold to retail community pharmacies serving the cash paying public in Canada.

Question 3: I understand that you have written that Canadian prices are 12.2% lower than those in the U.S., although the GAO report indicates that the differential is much higher. Could you explain this difference?

Answer: This very same issue was raised at a hearing that was held by Congressman Henry Waxman last year. Attached is a copy of the letter, and related data tables, that I sent to Chairman Waxman subsequent to that hearing in order to ex-

plain how this quote is quite consistent with, and supportive of, the conclusions in the GAO study.

As I concluded in my letter to Congressman Waxman: (1) My statement quoted from the Canadian report is both accurate and not at all contradictory with the GAO findings; and (2) The U.S. prices to typical consumers are 36.75 percent higher than the prices to typical Canadians for a set of identical prescription drug products when weighted by Canadian sales volume. This percentage difference is even higher than the median difference of 32 percent reported in the GAO study.

Thank you for the opportunity to clarify these important issues with respect to the GAO's landmark study of drug prices in the U.S. versus Canada.

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March 2, 1993

Honorable Henry A. Waxman
House Annex #1, Room 512
Washington, DC 20515

Dear Congressman Waxman:

During the recent hearings of the House Subcommittee on Health and Environment on International Drug Prices, a quote from a study I did in Canada was mentioned out of context. Furthermore, it was suggested that the comment was inconsistent with the findings of the GAO study. In fact, the statement made in the Canadian report is accurate and in no way conflicts with the findings reported in the GAO study.

Enclosed for your information, is a printed copy of a spreadsheet which shows how the Canadian statement was derived and its relationship to the GAO findings.

First, all 121 drugs reported in the GAO study were included in the re-analysis from the Canadian perspective and are listed in the printout with product descriptions in columns A through E. The Canadian price (in U.S. dollars), and the dollar difference in price from the GAO study were used and are found in columns G, H and I, respectively. The percentage difference as reported in the GAO study, used the Canadian price as the denominator and this value is shown in column J. As the GAO study concluded, the median U.S. price for a typical consumer was 32% greater than the price available to the typical Canadian.

In order to re-evaluate the data from the Canadian perspective, the percentage difference in price was recalculated using the U.S. price as the denominator (see Column K). This approach would allow a statement regarding the percentage by which Canadian prices were less than the U.S. prices.

For the Canadian analysis, a set of data with the sales volume for each drug was used to calculate a weighted average percentage difference. The weight factor (Column L) was multiplied by the percentage difference which used the U.S. price as the denominator (Column K). The sum of the weighted percentage difference score (Column N) provides the weighted average percentage difference of 12.23%. In other words, the price of identical prescription drugs to the typical Canadian was 12.23% less than the price to the typical U.S. citizen.

GAO was not able to acquire the weighting data based on U.S. sales in a timely and cost-efficient manner and therefore, a U.S. weighted average was not reported by GAO. The Canadian sales weight factor, however, can be used to determine the weighted average difference of U.S. pricing in relation to Canadian prices. This calculation was done by multiplying the weight factor (Column L) times the percentage difference with the Canadian price as the denominator (Column J). The resulting weighted percentage differences are found in Column M. The weighted average resulting from summation of this column is 36.75%. In other words, the U.S. price to a typical consumer is 36.75% higher than the Canadian price for a typical consumer using an identical set of drug products.

100 YEARS OF LEADERSHIP 1892-1992
College of Pharmacy
University of Minnesota

Based on the description provided in this letter, I would like to make two final points:

(1) My statement quoted from the Canadian report is both accurate and not at all contradictory with the GAO findings.

(2) The U.S. prices to typical consumers are 36.75% higher than the prices to typical Canadians for a set of identical prescription drug products when weighted by Canadian sales volume. This percentage difference is even higher than the median difference of 32% reported in the GAO study.

Since this out-of-context quote was mentioned several times during the hearing, I respectfully ask that you include this explanation in the hearing record to clarify any confusion that might have been created. Thank you for your time and interest in this matter. If I can answer further questions or be of service to you or your committee, please let me know.

Sincerely,

Stephen W. Schondelmeyer, Pharm.D., PhD
Professor and Director

cc: Mr. William Schultz
Howard Cohen, J.D., Ph.D.

1991 U.S. vs. Canadian Manufacturer's Price Comparison

A U.S. Drug Rank	B Product	C Manufacturer	D Strength	E Dose Form	F Pkg. Size	G US Price /Pkg(US$)	H Can Price /Pkg(US$)	I $ Diff. /Pkg(US$) (G - H)	J %Diff./Pkg (Diff/Can) (I / H)	K %Diff/Pkg (Diff/US) (I / G)	L Wt. Factor Can Sales $	M Wt. Fct. x % Diff.(C$) (J x L)	N Wt. Fct. x % Diff(US) (K x L)
79	Terazol	Ortho	0.40%	vag cr	45	$15.92	$14.36	$1.56	10.9%	9.8%	0.0020290	0.00022042	0.00019882
69	Zestril	Stuart	10 mg	tab	100	$58.81	$70.24	($11.43)	-16.3%	-19.4%	0.0042379	-0.00068962	-0.00082365
95	Prinivil	Merck	10 mg	tab	100	$58.81	$70.24	($11.43)	-16.3%	-19.4%	0.0037257	-0.00060628	-0.00072411
83	Ceftin	Allen & Hanbury	250 mg	tab	60	$120.74	$69.01	$51.73	75.0%	42.8%	0.0040199	0.00301331	0.00172228
91	Anaprox DS	Syntex	550 mg	tab	100	$87.35	$87.78	($0.43)	-0.5%	-0.5%	0.0031040	-0.00001521	-0.00001528
61	Lotrisone	Schering	1%	cream	15	$10.90	$7.39	$3.51	47.5%	32.2%	0.0009032	0.00042898	0.00029084
174	Suprax	Lederle	400 mg	tab	50	$191.31	$126.34	$64.97	51.4%	34.0%	0.0024558	0.00126287	0.00083399
118	Sinemet	Dupont	25/100mg	tab	100	$45.25	$44.17	$1.08	2.4%	2.4%	0.0109627	0.00026805	0.00026165
98	Buspar	BMS (Mead John)	10 mg	tab	100	$68.79	$77.91	($9.12)	-11.7%	-13.3%	0.0039172	-0.00045854	-0.00051933
84	Transder-Nitro	CIBA (Summit)	5 mg	patch	30	$31.69	$30.35	$1.34	4.4%	4.2%	0.0080340	0.00035471	0.00033971
117	Hytrin	Abbott	2 mg	tab	100	$71.93	$55.17	$16.76	30.4%	23.3%	0.0025826	0.00078458	0.00060177
35	Cipro	Miles	500 mg	tab	100	$213.24	$205.30	$7.94	3.9%	3.7%	0.0208838	0.00080768	0.00077761
106	K-Dur	Scherin (Key)	20 meq	tab cr	100	$22.60	$21.55	$1.05	4.9%	4.6%	0.0007302	0.00003558	0.00003392
19	Prozac	Lilly (Dista)	20 mg	cap	100	$139.85	$129.12	$10.73	8.3%	7.7%	0.0279107	0.00231941	0.00214145
7	Cardizem SR	Marion M Dow	60 mg	cap cr	100	$49.03	$57.51	($8.51)	-14.8%	-17.4%	0.0782082	-0.01157281	-0.01358269
67	PCE	Abbott	333 mg	tab	500	$304.32	$211.98	$92.34	43.6%	30.3%	0.0027580	0.00120139	0.00083685
32	Mevacor	Merck	20 mg	tab	60	$88.49	$85.19	$3.30	3.9%	3.7%	0.0450238	0.00174408	0.00167904
18	Colon	Searle	240 mg	tab sr	100	$85.74	$115.80	($30.06)	-26.0%	-35.1%	0.0167531	-0.00434887	-0.00587356
160	Axid	Lilly	300 mg	cap	30	$59.53	$35.21	$24.32	69.1%	40.9%	0.0049219	0.00339962	0.00201076
154	Tenoretic	ICI	50/25 mg	tab	100	$70.41	$52.20	$18.21	34.9%	25.9%	0.0019494	0.00068004	0.00050416
88	Slo-bid	R P Rorer	300 mg	cap cr	100	$27.00	$22.35	$4.65	20.8%	17.2%	0.0000911	0.00001896	0.00001569
58	Estroderm	CIBA Geigy	0.05 mg	patch	8	$11.72	$15.90	($4.18)	-26.3%	-35.7%	0.0121658	-0.00319829	-0.00433898
11	Vasotec	Merck	10 mg	tab	100	$66.90	$78.75	($11.85)	-15.0%	-17.7%	0.0687335	-0.01034276	-0.01217478
159	Bactroban	SKB	2%	oint	15	$10.15	$6.22	$3.94	63.3%	38.8%	0.0022181	0.00140506	0.00086018
149	Rogaine	Upjohn	2%	top sol	60	$42.50	$52.69	($10.19)	-19.3%	-24.0%	0.0043948	-0.00084993	-0.00105371
57	Pepcid	Merck	20 mg	tab	100	$103.74	$76.72	$27.02	35.2%	26.0%	0.0208814	0.00735423	0.00543876
152	Noroxin	Merck	400 mg	tab	20	$35.09	$35.74	($0.65)	-1.8%	-1.9%	0.0109258	-0.00019871	-0.00020239
190	Betoptic	Alcon	0.5%	ophth	10	$22.50	$18.72	$3.78	20.2%	16.8%	0.0023381	0.00047212	0.00039280
103	Ansaid	Upjohn	50 mg	tab	100	$54.20	$37.87	$16.33	43.1%	30.1%	0.0035816	0.00154441	0.00107909
72	Trental	Hoechst	400 mg	tab	100	$34.03	$51.84	($17.81)	-34.4%	-52.3%	0.0047431	-0.00162953	-0.00248236
24	Augmentin	SKB	250 mg	tab	30	$36.60	$22.29	$14.31	64.2%	39.1%	0.0080421	0.00516294	0.00314431
64	Eryc	Parke-Davis	250 mg	cap	100	$26.55	$24.64	$1.91	7.8%	7.2%	0.0043313	0.00033575	0.00031159
14	Ortho-Novum	Ortho	7/7/7	tab	28	$16.00	$8.75	$7.25	82.9%	45.3%	0.0166182	0.01376935	0.00753011
12	Tenormin	ICI	50 mg	tab	100	$61.68	$47.34	$14.34	30.3%	23.2%	0.0114171	0.00345842	0.00265437
182	Pediazole	Abbott (Ross)	200/600ml	susp	150	$16.63	$12.62	$4.01	31.8%	24.1%	0.0038019	0.00120804	0.00091675
134	Dolobid	Merck	250 mg	tab	60	$39.84	$27.79	$12.05	43.4%	30.2%	0.0033116	0.00143596	0.00100164
39	Triphasil	Wyeth Ayerst		tab	28	$15.60	$9.46	$6.14	64.9%	39.4%	0.0259844	0.01686516	0.01022721
113	Atrovent	Boehringer Ingel	20 mcg	aero	14	$17.87	$13.13	$4.74	36.1%	26.5%	0.0179701	0.00648729	0.00476654
3	Zantac	Glaxo	150 mg	tab	60	$70.19	$53.82	$16.37	30.4%	23.3%	0.0361212	0.01098670	0.00842434
81	Zovirax	Burroughs Wel	200 mg	cap	100	$62.50	$92.88	($30.38)	-32.7%	-48.6%	0.0136122	-0.00445240	-0.00661662
200	Zovirax	Burroughs Wel	5%	oint	15	$24.29	$29.51	($5.22)	-17.7%	-21.5%	0.0048665	-0.00086084	-0.00104583
5	Xanax	Upjohn	0.5 mg	tab	100	$47.81	$16.92	$30.89	182.6%	64.6%	0.0031940	0.00583110	0.00206363

1991 U.S. vs. Canadian Manufacturer's Price Comparison

A U.S. Drug Rank	B Product	C Manufacturer	D Strength	E Dose Form	F Pkg. Size	G US Price /Pkg(US$)	H Can Price /Pkg(US$)	I $ Diff. /Pkg(US$) (G - H)	J %Diff./Pkg (Diff/Can) (I / H)	K %Diff/Pkg (Diff/US) (I / G)	L Wt. Factor Can Sales $	M Wt. Fct. x % Diff (CS) (J x L)	N Wt. Fct. x % Diff(US) (K x L)
13	Procardia	Pfizer	10 mg	cap	100	$39.46	$42.14	($2.68)	-6.4%	-6.8%	0.0594180	-0.00377884	-0.00403549
15	Capoten	Squibb	25 mg	tab	100	$41.73	$43.36	($1.63)	-3.8%	-3.9%	0.0246441	-0.00092643	-0.00096261
94	Isoptin	Knoll	80 mg	tab	100	$32.95	$46.67	($13.72)	-29.4%	-41.6%	0.0041133	-0.00120923	-0.00171273
36	Monistat	Ortho	2%	cream	45	$13.30	$10.56	$2.74	25.9%	20.6%	0.0073477	0.00190650	0.00151373
40	Micro-K	Robins	8 meq	cap cr	100	$9.49	$6.35	$3.14	49.4%	33.1%	0.0019448	0.00096166	0.00064347
122	Intal	Fisons	20 mg	cap	120	$55.10	$46.01	$9.09	19.8%	16.5%	0.0065887	0.00130170	0.00108695
187	Propine	Allergan	0.1%	ophth	15	$24.72	$20.99	$3.73	17.8%	15.1%	0.0020117	0.00035748	0.00030354
41	Feldene	Pfizer	20 mg	cap	100	$167.54	$123.61	$43.93	35.5%	26.2%	0.0024961	0.00088710	0.00065450
143	Moduretic	Merck	5/50 mg	tab	100	$35.40	$28.52	$6.88	24.1%	19.4%	0.0042021	0.00101370	0.00081668
108	Duricef	Mead Johnson	500 mg	cap	100	$200.69	$100.39	$103.30	102.9%	50.7%	0.0012792	0.00131629	0.00064874
129	Restoril	Sandoz	30 mg	cap	100	$45.25	$18.06	$27.19	150.6%	60.1%	0.0030037	0.00452212	0.00180485
30	Inderal	Wyeth Ayerst	40 mg	tab	100	$35.79	$10.21	$25.58	250.5%	71.5%	0.0055252	0.01384268	0.00394897
26	Voltaren	CIBA Geigy	50 mg	tab	100	$64.70	$52.04	$12.66	24.3%	19.6%	0.0376104	0.00914964	0.00735931
191	Anaprox	Syntex	275 mg	tab	100	$56.11	$46.67	$9.44	20.2%	16.8%	0.0331052	0.00662809	0.00552242
20	Ortho-Novum	Ortho	1/35	tab	28	$15.79	$9.05	$6.74	74.5%	42.7%	0.0055909	0.00416384	0.00238650
60	Corafate	Marion M D	1 gm	tab	120	$58.50	$45.94	$12.56	27.3%	21.5%	0.0130136	0.00355791	0.00279402
9	Cedar	Lilly	250 mg	cap	100	$134.18	$84.14	$50.04	59.5%	37.3%	0.0195250	0.01161194	0.00728148
29	Theo-Dur	Schering	300 mg	tab cr	100	$18.70	$22.33	($3.63)	-16.3%	-19.4%	0.0067571	-0.00109844	-0.00131167
76	Nicorette	MMD (Lakeside)	2 mg	gum	96	$26.00	$20.83	$5.17	24.8%	19.9%	0.0087907	0.00218184	0.00174799
82	Clinoril	Merck	150 mg	tab	100	$68.89	$46.61	$22.28	47.8%	32.3%	0.0018848	0.00090094	0.00060957
74	Corgard	Bristol Myers Sq	40 mg	tab	100	$61.19	$37.37	$23.82	63.7%	38.9%	0.0033912	0.00216160	0.00132014
66	E.E.S.	Abbott	400mg/5n	liq.	100	$6.47	$11.62	($5.15)	-44.3%	-79.6%	0.0031744	-0.00140689	-0.00252674
53	Timoptic	Merck	0.50%	ophth	15	$34.99	$37.20	($2.21)	-5.9%	-6.3%	0.0063810	-0.00037909	-0.00040303
33	Halcion	Upjohn	25 mg	tab	100	$47.69	$16.09	$31.60	196.4%	66.3%	0.0015883	0.00311943	0.00105246
54	Retin-A	Ortho	0.05%	cream	45	$34.30	$13.54	$20.76	153.3%	60.5%	0.0009793	0.00150150	0.00059272
93	Flexeril	Merck	10 mg	tab	100	$69.68	$45.74	$23.94	52.3%	34.4%	0.0053533	0.00280188	0.00183924
142	Nolvadex	ICI	10 mg	tab	60	$63.82	$61.33	$2.49	4.1%	3.9%	0.0039334	0.00015969	0.00015346
112	Orudis	Wyeth Ayerst	50 mg	cap	100	$69.99	$28.14	$41.85	148.7%	59.8%	0.0098207	0.01460545	0.00587223
198	Topicort	Hoechst	0.25%	cream	15	$9.66	$7.68	$1.98	25.8%	20.5%	0.0012100	0.00031195	0.00024801
130	Beconase AQ	Glaxo (A & H)	42 mcg/m	nasal	25	$22.82	$14.60	$8.22	56.3%	36.0%	0.0093178	0.00524605	0.00335637
104	Percocet	Dupont	5/325 mg	tab	100	$43.70	$30.35	$13.35	44.0%	30.5%	0.0019032	0.00083718	0.00058143
17	Tagamet	SKF	300 mg	tab	100	$57.16	$34.27	$22.89	66.8%	40.0%	0.0028156	0.00188066	0.00112754
23	Lopressor	CIBA Geigy	50 mg	tab	100	$35.71	$15.80	$19.91	126.0%	55.8%	0.0039449	0.00497107	0.00219947
70	Ativan	Wyeth	1 mg	tab	100	$49.43	$6.16	$43.27	702.4%	87.5%	0.0053002	0.03723074	0.00463972
146	Reglan	Robins	10 mg	tab	100	$34.46	$5.34	$29.12	545.3%	84.5%	0.0007774	0.00423955	0.00065697
196	Tussi-Organidin	Wallace	30/10	soln	480	$35.06	$14.92	$20.14	135.0%	57.4%	0.0000842	0.00011366	0.00004837
133	Klonopin	Roche	0.5 mg	tab	100	$42.16	$15.51	$26.65	171.8%	63.2%	0.0071539	0.01229213	0.00452208
194	Vanceril	Schering	42 mcg/m	inhaler	168	$21.14	$8.71	$12.43	142.7%	58.8%	0.0003714	0.00053005	0.00021839
183	Tobrex	Alcon	0.3%	ophth	5	$11.25	$7.09	$4.16	58.7%	37.0%	0.0024800	0.00145511	0.00091704
1	Amoxil	Beecham	250 mg	cap	100	$17.27	$16.46	$0.81	4.9%	4.7%	0.0092440	0.00045490	0.00043356
102	Wymox	Wyeth Ayerst	250 mg	cap	100	$16.84	$16.46	$0.38	2.3%	2.3%	0.0092440	0.00021341	0.00020859
193	Bactrim DS	Roche	800/160m	tab	100	$77.36	$22.62	$54.74	242.0%	70.8%	0.0008697	0.00210472	0.00061542

1991 U.S. vs. Canadian Manufacturer's Price Comparison

A	B	C	D	E	F	G	H	I	J	K	L	M	N
U.S. Drug Rank	Product	Manufacturer	Strength	Dose Form	Pkg. Size	US Price /Pkg(US$)	Can Price /Pkg(US$)	$ Diff. /Pkg(US$) (G - H)	%Diff./Pkg (Diff/Can) (I / H)	%Diff/Pkg (Diff/US) (I / G)	Wt. Factor Can Sales $	Wt. Fct. x % Diff (Can) (J x L)	Wt. Fct. x % Diff(US) (K x L)
131	Catapres	Boehringer Ingel	0.1 mg	tab	100	$35.51	$22.62	$12.89	57.0%	36.3%	0.0019044	0.00108522	0.00069129
49	Motrin	Upjohn	400 mg	tab	100	$13.85	$15.93	($2.08)	-13.1%	-15.0%	0.0014707	-0.00019203	-0.00022087
137	Ventolin	Glaxo (A & H)	2 mg/5ml	syrup	480	$22.23	$26.21	($3.98)	-15.2%	-17.9%	0.0121911	-0.00185123	-0.00218267
31	Ventolin	Glaxo (A&H)	90 mcg	aero	17	$15.53	$10.24	$5.29	51.7%	34.1%	0.0292303	0.01510043	0.00995676
172	Deltasone	Upjohn	5 mg	tab	100	$2.35	$1.29	$1.06	82.2%	45.1%	0.0001846	0.00015165	0.00008325
73	Macrodantin	Norwich Eaton	50 mg	cap	100	$46.71	$27.14	$19.57	72.1%	41.9%	0.0021835	0.00157450	0.00091483
56	Nitrostat	Parke-Davis	0.3 mg	tab sl	100	$3.77	$2.17	$1.60	73.7%	42.4%	0.0010566	0.00077905	0.00044842
50	Diabeta	Hoechst	2.5 mg	tab	100	$20.42	$9.70	$10.72	110.5%	52.5%	0.0078748	0.00870288	0.00413408
186	Dalmane	Roche	30 mg	cap	100	$40.80	$12.13	$28.67	236.4%	70.3%	0.0007567	0.00178847	0.00053172
21	Tylenol #3	McNeil	300/30mg	tab	100	$19.38	$3.32	$16.06	483.7%	82.9%	0.0087088	0.04212737	0.00721687
68	Slow-K	CIBA (Summit)	8 meq	tab cr	100	$11.58	$5.65	$5.93	105.0%	51.2%	0.0035965	0.00377479	0.00184176
153	Cleocin T	Upjohn	1%	top sol	30	$7.74	$7.08	$0.66	9.3%	8.5%	0.0080456	0.00075001	0.00068605
52	E-mycin	Boots	250 mg	tab	100	$6.42	$10.91	($4.49)	-41.2%	-69.9%	0.0000427	-0.00001756	-0.00002985
77	Tegretol	CIBA Geigy	200 mg	tab	100	$24.38	$20.10	$4.28	21.3%	17.6%	0.0085715	0.00182518	0.00150476
97	Persantine	Boehringer Ingel	50 mg	tab	100	$33.90	$30.03	$3.87	12.9%	11.4%	0.0028260	0.00036419	0.00032262
25	Lasix	Hoechst	40 mg	tab pp	100	$14.20	$9.55	$4.65	48.7%	32.7%	0.0023808	0.00115923	0.00077962
181	Indocin	Merck	25 mg	cap	100	$38.78	$25.84	$12.94	50.1%	33.4%	0.0104067	0.00521140	0.00347248
158	Norinyl	Syntex	1/50	tab	28	$16.17	$8.81	$7.36	83.5%	45.5%	0.0002595	0.00021682	0.00011813
180	Aldomet	Merck	250 mg	tab	100	$24.61	$13.52	$11.09	82.0%	45.1%	0.0012365	0.00101428	0.00055722
46	Valium	Roche	5 mg	tab	100	$40.41	$7.57	$32.84	433.8%	81.3%	0.0010070	0.00436849	0.00081835
37	Provera	Upjohn	5 mg	tab	100	$36.60	$20.79	$15.81	76.0%	43.2%	0.0066037	0.00502184	0.00285257
163	Elavil	Stuart (Merck)	25 mg	tab	100	$27.61	$10.85	$16.76	154.5%	60.7%	0.0015134	0.00233770	0.00091865
120	Isordil	Wyeth	10 mg	tab	100	$17.41	$1.63	$15.78	968.1%	90.6%	0.0023865	0.02310414	0.00216311
167	Questran	Bristol Myers Sq	4 gm	powde	378	$23.27	$26.43	($3.16)	-12.0%	-13.6%	0.0089060	-0.00106481	-0.00120941
8	Synthroid	Boots	.05 mg	tab	100	$11.80	$3.13	$8.67	277.0%	73.5%	0.0035008	0.00969713	0.00257221
48	Coumadin	Dupont	5 mg	tab	100	$36.70	$19.59	$17.11	87.3%	46.6%	0.0063003	0.00550272	0.00293728
161	Achromycin V	Lederle	250 mg	cap	100	$5.46	$4.02	$1.44	35.8%	26.4%	0.0002272	0.00008140	0.00005993
140	Erythrocin Ster.	Abbott	250 mg	tab	100	$11.00	$9.90	$1.10	11.1%	10.0%	0.0019748	0.00021942	0.00019748
28	Dilantin	Parke Davis	100 mg	cap ex	100	$15.03	$4.67	$10.36	221.8%	68.9%	0.0037188	0.00824988	0.00256334
164	Phenergan	Wyeth Ayerst	25 mg	tab	100	$18.43	$9.14	$9.29	101.6%	50.4%	0.0004533	0.00046076	0.00022850
185	Premarin	Wyeth Ayerst	625mcg/g	vag cr	42.5	$20.70	$12.20	$8.50	69.7%	41.1%	0.0026242	0.00182831	0.00107756
4	Premarin	Ayerst	.625 mg	tab	100	$26.47	$10.10	$16.37	162.1%	61.8%	0.0098796	0.01601270	0.00610987
2	Lanoxin	Burroughs Wel.	0.25 mg	tab	100	$7.83	$6.75	$1.08	16.0%	13.8%	0.0069578	0.00111325	0.00095970
141	Tri-Norinyl	Syntex		tab	28	$15.54	$8.39	$7.15	85.2%	46.0%	0.0000265	0.00000261	0.00001221
124	Vancenase AQ	Schering	42 mcg/m	nasal	25	$22.82	$8.71	$14.11	162.0%	61.8%	0.0000012	0.00000187	0.00000071
16	Naprosyn	Syntex	375 mg	tab	100	$72.36	$42.64	$29.72	69.7%	41.1%	0.0057928	0.00403755	0.00237923
114	Erythromycin Ba	Abbott	250 mg	tab	100	$11.16	$4.69	$6.47	138.0%	58.0%	0.0025538	0.00352305	0.00148057
											Sum	Wt Avg % Diff	Wt Avg %
# of Items											Wt. Factor	(Diff/Can Price)	(Diff/US Price)
121											1.0000000	36.75%	12.23%

PREPARED STATEMENT OF JUDITH L. WAGNER

Thank you, Mr. Chairman. I am here today to provide the Committee with information on recent changes in the market for prescription drugs. OTA completed an assessment of the economics of pharmaceutical R&D in February, 1993, and in December we began a small study of the approaches to the problems for cost-containment posed by breakthrough drugs. My comments today draw on what we have learned in the past several years of study of the market for prescription drugs.

The prescription drug marketplace is presently undergoing a transition from a largely fee-for-service market to a market with a major component of managed competition. Furthermore, these changes provide a powerful example of the potential for competition to influence costs in the health care system. This transition is taking place independent of prospects for health care reform, but health care reform will surely affect the pace of the transition and the ultimate character of the market place.

BACKGROUND ON THE TRANSITION TO MANAGED COMPETITION IN PHARMACEUTICALS

The increase in competition in the pharmaceutical market place is occurring because the conditions were ripe for change. Employers are under increasing pressure to contain prescription drug costs for two reasons. First, expenditures for prescription drugs are rising much more rapidly than other components of employers' health care costs, at a rate of 15 percent in 1993, compared with 8 percent for overall employer health care costs.[1] Second, although prescription drugs are a relatively small percentage of overall health care costs (7–8 percent), they represent a much larger proportion—roughly one-third—of employers' costs of retiree health benefits.[2] The recent Federal Accounting Standards Board ruling requiring companies to report their obligations for retirees' health care costs as a liability in their financial statements has made employers feel the pinch of rising drug costs where it hurts most—in their bottom lines.

The rising employer demand for cost containment alone would not have led to the transition in the market had prescription drugs not been a particularly fertile arena for the development of managed care approaches. Today, consumers of prescription drugs have available a wide array of similar alternatives in important therapeutic categories. For this level of choice consumers can thank the traditional pharmaceutical market, which was dominated by physicians who prescribed without much attention to or even knowledge of drug prices, and consumers who were uninformed of alternatives and, in any case, relatively insulated from high prices by widespread prescription drug insurance coverage. These conditions sent signals to pharmaceutical companies throughout the 1970s and 1980s that new products would be handsomely rewarded, even after the lengthy development process and risks of failure were taken into account. Even when a new compound was a "me-too" drug, offering no real therapeutic advantage over others on the market, it could find its niche through advertising and promotion. The result was a steady increase in outlays for pharmaceutical R&D throughout the 1980s and the availability of a wide array of choice among competing compounds within certain therapeutic categories, particularly those with large markets. Table 1 shows, for example, the compounds currently on the market in the United States in 7 narrow cardiovascular therapeutic categories. (Cardiovascular drugs constitute about 22 percent of prescription drug sales in the United States.) The availability of so much choice meant that any pharmaceutical benefit plan that could influence prescribing patterns within these crowded therapeutic fields had a potential vehicle for saving money. Other factors also laid the foundation for managed care pharmacy. The 1984 passage of the Drug Price Competition and Patent Term Expiration Act made entry of generic versions of off-patent pharmaceutical compounds feasible for the first time. Because FDA's Abbreviated New Drug Approval (ANDA) certifies the therapeutic equivalence of generic versions of originators' compounds, substitution between brand-name drugs and their generic equivalents can be made with little concern about impacts on quality of care. The development of an independent generics industry gave pharmaceutical benefit plan managers another potential lever for cost savings.

Finally, advances in interactive on-line computer technology opened up new possibilities for employers to manage their prescription drug benefits and spawned a new industry of Pharmaceutical Benefit Managers (PBMs), firms that administer pharmaceutical benefits plans for insurers or employers. Some insurance companies and HMOs have their own PBM subsidiaries. Benefit managers can process and adjudicate claims on a point-of-sale basis through on-line connections with a network of pharmacies participating in the program. Today, the vast majority—over 90 percent—of community pharmacies are connected on-line to at least one third-party pharmaceutical claims processor. All of the enabling conditions came together in the

early 1990s to produce an increasing number of prescription drug benefit plans that are actively "managed" to one degree or another in the hope of saving money on their prescription drug benefit. The number of benefit plans employing managed care pharmacy techniques is growing rapidly, and the methods of benefit management are themselves evolving under the pressure of competition among PBMs and among health plans.

MANAGED CARE PHARMACY METHODS

The fundamental goal of managed care pharmacy is to reduce the costs of the prescription drug benefit by moving prescribing and dispensing patterns toward lower cost drugs without affecting health outcomes of enrollees. The easiest approach is to encourage or require the substitution of lower-cost generic versions for off-patent brand-name drugs. However, PBMs are increasingly using methods that encourage or require physicians to change their prescribing patterns among therapeutically similar compounds in narrow therapeutic categories.

Generic Substitution: Many health insurance plans encourage or require substitution of cheaper generic products for brand-name pharmaceuticals even when the prescription is written for the brand-name product. The most common incentive in private health plans is a lower patient copayment when a prescription for a multiple source drug is filled with a generic version. Mail-order pharmacy programs are another vehicle to maximize generic substitution, because these pharmacies are often located in States with the least restrictive laws on generic substitution. Some insurers, including the Federal Medicaid program, use a maximum allowable cost limit to cap the payment to pharmacists on multiple source drugs.

Despite the fact that generic drugs are cheaper than their brand-name counterparts and become more so over time, the market share of generic drugs is still surprisingly low. Data provided to OTA on prescriptions for multiple source drugs for long-term therapy by Medco Containment Services, a company that administers health plans' drug benefits, illustrates the point. As Table 2 shows, in the first 9 months of 1992, only 56 percent of these prescriptions dispensed through Medco's participating retail pharmacies were filled with a generic version of the compound. (A much higher proportion—72 percent—of such prescriptions filled in Medco's mail order pharmacies were filled with generics.) By the end of 1992, there was still a great deal of cost to be squeezed out of pharmaceutical benefit plans through more vigorous generic substitution.

The potential for cost savings from generic competition and managed care pharmacy is slated to grow even more dramatically in the next three years as several drugs with high U.S. sales revenue come off patent. Between 1993 and 1996, four compounds whose 1992 U.S. sales placed them in the top 10 drugs in the United States will lose patent protection.[3] Many other drugs with substantial markets will also lose patent protection in the next few years.

Therapeutic Interchange using Formularies: Hospitals pioneered the use of the formulary—a list of drugs in each class that is preferred or required—as a way of managing their drug costs. More recently, HMOs have embraced the formulary as a method for altering the prescribing patterns of their member physicians toward less expensive drugs within narrow therapeutic classes. Very tightly organized staff and group-model HMOs, such as the Group Health Cooperative of Puget Sound (GHCPS), have been particularly successful in enforcing their formulary decisions with their member doctors.[4] This power to move prescribing patterns toward one or two preferred drugs in a category has given such HMOs purchasing clout with manufacturers and over the past few years has led some manufacturers to offer substantial price discounts to some HMOs.

Several classes of drugs have been particularly vulnerable to formularies, because the physicians and pharmacists in charge of formulary development have determined that several drugs within the class have essentially equivalent therapeutic effects. ACE inhibitors, HMG-COA reductase inhibitors (cholesterol lowering drugs), non-steroidal anti-inflammatory drugs (NSAIDs), and H2-Blockers (anti-ulcer drugs) have been targeted most frequently by the Pharmacy and Therapeutics (P&T) committees that establish formularies on behalf of hospitals, HMOs or health plans.

The key to the success of a formulary in reducing the cost of the prescription drug benefit is the power to enforce it. Although most HMOs today have some sort of formulary, only a few require their member physicians to choose formulary drugs; the remainder depend on voluntary compliance with the plan's formulary. In the past year, a number of large indemnity plans have adopted formularies, but so far these are also voluntary. Two large PBMs have recently announced new programs in which the PBM will pay community pharmacists a fee for each time they persuade a prescribing physician to switch from a non-formulary to a formulary drug. In the

future, indemnity plans may give patients incentives (through variable cost-sharing requirements) to encourage their physicians to prescribe from the formulary.

CURRENT STATUS OF MANAGED CARE PHARMACY

Managed care pharmacy programs are growing by leaps and bounds, but when one considers that they started from scratch just a few years ago, they clearly have a long way to go before they reach their full potential for moderating prescription drug costs. The majority of Americans with private prescription drug insurance are in plans that still do not have strong formularies. In 1993, for example, only 15 percent of HMOs had restrictive formularies,[5] and HMOs cover only 17 percent of the population. And the 25–30 percent of Americans with no prescription drug coverage (including 55–60 percent of elderly Americans) cannot benefit at all from the cost savings achievable from managed pharmacy plans.

INDUSTRY RESPONSES TO MANAGED CARE PHARMACY

The pharmaceutical industry is already moving to adapt to the sea change in the prescription drug market. One obvious adaptation is for innovator companies to make generic drugs. Many major pharmaceutical firms have either acquired a generic subsidiary or started their own. Some innovator companies are entering a generic version on the market five or six months before their patent expires, thereby establishing an early lead in the generic business for their product.

Companies may also enter into strategic alliances with PBMs to assure sufficient volume for their drugs. The Merck-Medco merger is, of course, the prototype of such integration. What these strategic changes will mean for the number of pharmaceutical companies or PBMs is difficult to predict, but several market analysts have predicted consolidation of the industry in the future.

Most important in the long-run will be the industry's strategic decisions regarding research and development (R&D). The new market place will change the dynamics of pharmaceutical R&D in ways that are difficult to predict. Because the cost of developing any new compound is high, pharmaceutical companies will be less inclined to invest in R&D to add additional new drugs to a therapeutic category that already contains several drugs. The expected returns from such imitation will certainly be lower than they were in the past. Thus, over time, the number of compounds in new therapeutic categories may thin out, offering managed care pharmacy fewer opportunities for cost savings through restrictive formularies.

In our Pharmaceutical R&D study, OTA studied R&D projects in one new therapeutic class: HMG-COA Reductase inhibitors, whose pioneer compound, lovastatin, was approved for marketing in the United States in 1987. This class of cholesterol-lowering drugs has a world-wide market of over $3 billion. Table 3 shows the status of R&D projects on compounds in this class as of 1992. Although 3 compounds had been approved for marketing and a fourth awaited FDA approval, 12 compounds were still in development, and at least 5 were in the earliest, preclinical stage. What will managed care do to these research projects? It is safe to say that the developers of the drugs still in their earliest phases of research may reassess the wisdom of further investment. Yet, the U.S. market constitutes only 30–35 percent of the world market for prescription drugs, and some countries have policies that reward the entry of "me-too" products. So, the ultimate impact on the array of choice in this category is difficult to predict and may be modest.

Another strategic R&D policy that responds directly to managed care pharmacy is to actively seek FDA approval to market already-approved compounds for new indications. Although physicians can prescribe a drug for unapproved indications, companies cannot promote their use in these cases. If a drug is the first of its class to obtain marketing approval for a new indication, its drug company sponsor may be able to argue persuasively to the PBM that it should be included in the formulary, despite a higher price. Thus, companies may become much more active in conducting clinical research on new indications for existing drugs.

IMPLICATIONS OF MANAGED CARE PHARMACY FOR BREAKTHROUGH DRUGS

The term "breakthrough drug" means different things in different contexts. Most people think of "breakthroughs" as magic bullets that mean the difference between life and death, or between disability and a normal life. However, it is difficult to draw a dividing line between a "breakthrough" and other new drugs that offer some new benefits not previously available. OTA is currently undertaking a study of breakthrough drugs, and one of its goals is to define the term and determine how often such drugs are likely to appear in the future.

In the context of the prescription drug market, a breakthrough drug is any new drug whose therapeutic benefits over other available therapies are sufficiently great

that the pharmaceutical benefits plan must make it available at any price. In the words of the director of pharmacy administration at Group Health Cooperative of Puget Sound, "If a drug is unique and there is nothing else like it which effectively treats the disease, you just have to eat the cost and deal with it."[6]

Just how great must the medical benefits be for a drug to be irresistible regardless of its price, even in tightly-run HMOs? OTA is currently studying this question. Two examples illustrate the difficulty of defining a breakthrough.

- Kaiser Permanente recently announced that tacrine, the first drug approved by the FDA for the treatment of mild and moderate Alzheimer's disease, would not be listed on its formulary because of its modest therapeutic benefits and frequent adverse side effects.[7] Although Kaiser physicians are not barred from prescribing the drug, the message is clear that plan managers consider such decisions exceptions from standard practice. It is uncertain whether this formulary decision to withhold this FDA-approved drug will ultimately stand, as Kaiser officials have themselves acknowledged. Is tacrine a breakthrough? Most experts acknowledge that tacrine is no "magic bullet" that cures or permanently arrests the progression of Alzheimers, but it is the first drug to show any clinical benefit in this major debilitating disease.
- One large clinical trial comparing different clot-busting drugs for heart attacks found that tissue plasminogen activator (tPA) was somewhat more effective than its main rival, streptokinase.[8] Compared with streptokinase, tPA was found in that trial to reduce the risk of death in the hospital from 7.4 per 100 cases to 6.3 per 100 cases, for a gain of one survivor per 100 heart attack cases. The cost of administering tPA is roughly $2000, approximately ten times the cost of streptokinase. Thus, every extra survivor costs about $180,000. To some observers, the survival difference represents a "small advantage",[9] but if the results of the trial hold up under the scrutiny of the clinical research community, this "small advantage" may be great enough to compel its use regardless of its cost.

However the line is drawn in the definition of a breakthrough drug, such drugs will be immune from price competition during the period of patent protection unless and until close therapeutic alternatives emerge to compete with them. (And the incentives to imitate will be lower in the future as price competition grows, so fewer such competitors can be expected to emerge.)

The insulation of breakthrough drugs from pricing pressures means that incentives to engage in R&D on such drugs will be much less affected by managed care pharmacy than will research on imitative "me-too" drugs. It is possible, however, that barring any additions to the number of people with prescription drug insurance, that fewer firms may enter the race to be the first to market compounds in new categories, because potential competitors will realize that the probability has diminished of recouping their investment if they lose the race and enter the market late.

To summarize, managed care pharmacy may reduce the amount of R&D on breakthrough drugs compared with what it would be in the traditional market place, but the reduction in R&D will be much less for important new drugs than it will be for imitative R&D on me-too products. When true breakthroughs do occur, managed care pharmacy will not have much power to constrain prices paid, although this approach to pharmaceutical benefits management will still permit more control over the conditions of use of these drugs. Prior authorization programs, for example, can be used to limit the availability of expensive new therapies to specific indications.

Whether the potential cost savings from managed care pharmacy will ultimately be overwhelmed by rapid development of new generations of important and high priced new drugs I do not know, but increases in the costs of prescription drugs are likely to be slower under the emerging managed care pharmacy system than under the traditional fee-for-service system. In the latter system, there was inadequate price competition among close or virtually identical competitors, and people with insurance were willing to pay very high prices for new drugs. In the new system of managed competition for prescription drug benefits, buyers will turn product choice into a vehicle for cost savings. Given today's array of drug choices, the potential for savings in the short run is enormous.

IMPACT OF HEALTH CARE REFORM ON THE MARKET FOR PRESCRIPTION DRUGS

Several proposals for health care reform call for a prescription drug benefit for both the Medicare and non-Medicare populations. If the benefits for these two populations are compatible with the growth of managed care pharmacy, then both the opportunities and problems inherent in this kind of market place will be compounded under health care reform. The principal advantage of the managed care

approach to administering a prescription drug benefit is the potential for rapidly achieving cost savings by moving prescribing and dispensing patterns to low-cost alternatives. An important secondary advantage of such an approach is that managed care pharmacy sends signals to the pharmaceutical industry that imitative R&D will be less well rewarded in the future. R&D on "breakthroughs" will fare relatively well under a regime of managed competition in pharmacy benefits. Because a universal prescription drug benefit will give drug coverage to a large number of previously uninsured people, health care reform that embraces managed care pharmacy could stimulate R&D on breakthrough drugs.

The chief problem with the managed care pharmacy approach to health care reform is the potential for "breakthrough" drugs to enter the market at very high prices. Managed care pharmacy alone will have limited power to influence the prices of such drugs. (It is, of course, this limited pricing power that will encourage companies to invest in breakthroughs.) The potential problem of breakthrough drugs deserves careful study, because the stakes are high. On the one hand, as a society we clearly value and demand the medical advances that lengthen life and improve its quality along the way. On the other hand, our ability or willingness to pay for such advances may be limited. Paying higher prices than is necessary to induce R&D investors to bring beneficial new drugs to market clearly wastes limited health care dollars. But paying too low a price would stifle R&D and deny us the benefits of breakthrough drugs. Because we know so little at present about how often breakthrough drugs will come along or how difficult controlling their costs will be under a regime of managed prescription drug competition, it may be prudent to engage in "watchful waiting" before addressing the problem with specific direct interventions.

The main alternative to managed care pharmacy under health care reform is a fee-for-service pharmaceutical benefit. Under this approach, the strong cost-moderating features of the emerging prescription drug market will be lost, and other mechanisms, such as detailed regulation of pharmaceutical prices and drug utilization review, will be needed to keep costs in check. The impact of pharmaceutical price regulation on both the cost of the prescription drug benefit and on the level and directions of R&D depends to a large extent on the details of the price regulation scheme. Medicaid's current rebate program is a system that controls price increases on existing drugs but leaves the launch prices of new drug products uncontrolled. This kind of price control encourages the development of new drug products, including imitative me-too drugs, because all new products are immune from the controls. Regulatory mechanisms that control introductory prices of new drugs would change these incentives, but much would depend on the institutional procedures underlying the regulation. In any case, any price regulation of new drugs will add an additional dose of uncertainty to the drug development process, which could to some extent discourage R&D on new products, including research on breakthrough drugs.

Table 1—Number of Unique Compounds Available in the United States in Selected Cardiovascular Categories, 1993

	Number of Unique Compounds
Adrenergic Blockers	6
Adrenergic Stimulants	4
Alpha/Beta Adrenergic Blockers	2
ACE Inhibitors	8
Beta Blockers	11
Calcium Channel Blockers	13
Diuretics	17

SOURCE: *Physician's Desk Reference*, 47th Edition, 1993.

Table 2—Percent of Prescriptions for Multi-source Maintenance Drugs[1] Dispensed with Brand-name and Generic Products, January–September 1992

Market sector and drug type	Rx volume	Rx dollar value[2]
Mail order		
Brand-name	27.60%	53.6%
Generic	72.4	46.4

Table 2—Percent of Prescriptions for Multi-source Maintenance Drugs[1] Dispensed with Brand-name and Generic Products, January–September 1992—Continued

Market sector and drug type	Rx volume	Rx dollar value[2]
Retail[3]		
Brand-name	44.1	67.6
Generic	55.9	32.4

[1] Maintenance drugs are generally used for long-term therapy.
[2] Dollar value is derived from the average wholesale price.
[3] Prescriptions ordered through Medco's retail prescription programs. Some of these programs actively promote incentives to encourage dispensing of generic drugs.

KEY: Rx = prescription drug.

SOURCE: Medco Containment Services, Inc., 1993.

Table 3—HMG-CoA Reductase Inhibitors Currently or Formerly Under Development, 1992

Compound	Sponsor	Approval Status
lovastatin	Merck	IND: April 1984. NDA: November 1986. Approval: August 1987.
pravastatin	Sankyo, Bristol-Myers Squibb	Launched in Canada, Europe, Japan, and Mexico. U.S. NDA: January 31, 1989. U.S. approval: November 31, 1991.
simvastatin	Merck	Launched in at least 17 countries worldwide, including most of Europe. U.S. NDA: November 1986. U.S. approval: December 1 991
colestolone	American Cyanamid	Entered U.S. clinical trials in 1987.
fluvastatin	Sandoz	U.S. NDA filed March 1992.
crilvastain	Pan Medica	Phase II clinical trials.
dalvastatin	Rhone-Poulenc Rorer	Phase III clinical trials.
BAYW6228	Bayer	Phase II clinical trials.
HR780	Hoeschst	Phase II clinical trials.
CI 981	Warner-Lambert	Phase I clinical trials.
BB-476	British Biotechnology	Series of compounds under development; preclinical.
BMY-22566	Bristol-Myers Squibb	Preclinical studies.
SQ-33600	Bristol-Myers Squibb	Preclinical studies, discontinued.
BMY-21950	Bristol-Myers Squibb	Phase I clinical trials.
GR-95030	Glaxo	Preclinical studies, discontinued.
SC-45355	Searle	Preclinical studies, discontinued.
L-659699	Merck	Preclinical studies.
L-669262	Merck	Preclinical studies.
CP-83101	Pfizer	Preclinical studies.

SOURCE: Office of Technology Assessment, 1993.

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RESPONSES OF JUDITH L. WAGNER TO QUESTIONS FROM SENATOR PRYOR

Question. The biotechnology industry claims that the Advisory Council on Breakthrough Drugs is the death knell for their ability to do research and development. Does the marketplace work for breakthrough drug pricing? Is the Advisory Council as awful as the biotech industry says? Aren't there other factors that affect the ability of the Biotech industry to raise capital?

Answer. An Advisory Council on Breakthrough Drugs, whose only function would be to study the prices at which certain important new drugs enter the market and the costs of development and manufacture, and whose only recourse would be to make an "announcement" about the reasonableness of a price, does not have very effective cost-control levers, and therefore would not be likely to pose a major threat to R&D on breakthrough drugs.

In the market for financial capital, there are always firms that are unable to secure funding because their planned investments do not appear to be potentially profitable enough to justify the investment. Therefore, there are always firms that are having a difficult time raising capital. The availability of capital to the biotechnology industry has to be looked at in an aggregate sense, including all possible sources of capital, from public equity markets to the corporate partnerships between biotechnology companies and large pharmaceutical companies. New biotechnology firms continue to be started, and the total number of firms in existence has grown over time. Indeed, 1993 was a record year for biotechnology industry capital financing.

Some, perhaps many, biotechnology firms can be expected to fail—that is the nature of the risky investments they undertake. It can be argued that the huge potential earnings available to those firms who "win" the R&D lottery induce a large number of entities to join the game.

The central question is whether government policy—or expectations on the part of investors about changes in government policy—is altering investors' assessments about the profitability of future biotechnology drugs or otherwise changing the costs of bringing such drugs to market. The uncertainty about the future structure of the health care market place can add an additional barrier to financing, but it is impossible for anyone to know whether this uncertainty surrounds the breakthrough drug committee or other elements of health care reform.

Question. We may establish a Medicare drug benefit for those millions of older Americans who cannot afford their medications. The President has proposed that a rebate mechanism be used. Some manufacturers advocate that we use a "managed care" approach to providing a Medicare drug benefit. What are some other approaches that Congress can consider to lower drug costs for the Medicare program?

Answer. Two general approaches to controlling expenditures for prescription drugs under a Medicare prescription drug benefit are: (1) a fee-for-service system with price control mechanisms; and (2) a managed-care system. Within these two general approaches, however, lie a variety of specific alternatives, and the details of such programs matter! For example, a price control system that controls only the prices of drugs currently on the market and not the launch prices of new drug products, would send signals to the developers of new drugs that new products offering only marginal medical benefits would be the easiest way to circumvent controls. Consequently, R&D dollars would be skewed toward the development of new "me-too" products.

Similarly, the definition of a "managed care" system with respect to the pharmaceutical benefit may be highly varied. One approach would be for Medicare to contribute a set amount to the premium, set minimum benefit requirements, and allow different plans to offer Medicare beneficiaries a pharmaceutical benefit, with Medicare beneficiaries being able to make the trade-off between the quality of the plan and their out-of-pocket premium costs. This approach would give competing plans the incentive to "manage" prescribing and dispensing to get the benefits of lower-prices from generic substitution and formularies.

An approach that falls in between a fee-for-service and a managed care plan is to have Medicare award contracts to companies willing to manage the Medicare pharmaceutical benefit. If these contracts are awarded on a price-competitive basis (where the plan takes the responsibility for meeting a per-patient or per-prescription cost), the approach would contain some elements of managed competition. However, with Medicare comprising such a large share of the prescription drug market, limiting the number of firms who can compete for the business of Medicare beneficiaries might, in the long-run, reduce the level of competition in the managed care pharmacy market place.

Question. There was a recent Wall Street Journal article which had various estimates of the cost of developing a new drug. The manufacturers are saying that your

recent report says that it costs $359 million to bring a new drug to market. Yet, there are other reports that the cost is lower. Can you shed some light on this topic? How much does it really cost to bring a new drug to market?

Answer. There has been more heat than light shed on the issue of how much it costs to bring a new drug to market. First, it is impossible to know how much it will cost the investors in new compounds that are just entering testing today to reach the market. The full cost of developing a new drug is extremely sensitive to the success rate—the percent of all drugs entering testing that ultimately succeed in making it to market. And the success rate can change rapidly over short periods of time.

The best that can be done is to look backward and estimate the full cost of bringing a new drug to market in the past. When OTA reviewed the evidence on the costs of bringing the average new drug to market for drugs first entering testing in the 1970s, we found the amount to be $359 million before tax savings from R&D are considered, and $194 million net of the tax savings from R&D. Since investors make their decisions on an after-tax basis, the more appropriate number is $194 million. Several pharmaceutical companies and associations have emphasized the before-tax number, which is clearly inappropriate.

In addition, the $194 million does not represent actual cash outlays required to sustain the researchers, buy equipment and supplies and build the R&D facilities. The actual cash outlays required are much lower. However, investors demand a return on investment (essentially a risk-adjusted rate of interest on their investments), and more than 1/2 of the entire cost represents the amount of payoff required from the successful products to adequately reward the investors for the risks they took.

RESPONSES OF JUDITH L. WAGNER TO QUESTIONS FROM SENATOR DOLE

Question. The President's bill makes a clear distinction between breakthrough drugs and ah other forms of medical intervention—new surgical techniques, new medical devices, generic drugs, etc. Do you see any reason why price controls should apply to these so-called breakthrough drugs but not to advances in other areas of medicine?

Answer. The concept behind a breakthrough drug committee whose intended purpose is to study the introductory prices of important new drugs and announce whether these prices are "reasonable" is not in and of itself a form of price control. To be a price control mechanism, such information would have to be coupled with provisions giving power to Medicare or some other entity to control entry prices of breakthrough drugs.

The problem with new drugs, including but not limited to breakthrough drugs, is that if they are offered in a prescription drug benefit under Medicare, and the benefit is a fee-for-service benefit without any price controls, the patent protection on the product would give the manufacturer a monopoly position, with an insurer (Medicare) that had no recourse but to pay any price charged. The inevitable result of such a system would be a major escalation of the prices of *all new drugs, including new breakthrough drugs.*

The unique characteristics of prescription drugs that make this issue problematical is that (1) unlike many medical devices, such as imaging equipment or laboratory equipment, they are sold to the patient, not to the provider. MRI equipment, for example, is sold to hospitals or free-standing facilities, who have an incentive to consider the price of the equipment as well as its quality. Although MRI procedures are covered by Medicare, the hospital's surplus depends on whether it can produce images at less cost than the reimbursement rate.

(2) Most medical devices have relatively poor patent protection, because competitors can easily "design around" these kinds of patents. In fact, developers of devices frequently don't even bother to file for patent protection. Thus, the barriers to market entry of closely competing products are much lower for devices than for drugs.

(3) Medicare has controlled the prices paid for technology-intensive procedures for several years. The Medicare fee schedule is essentially a price control system governing physician services. The Medicare allowed amount for a full colonoscopic examination, for example, is about $500. The participating provider must accept that fee as payment in full from any Medicare beneficiary. (In contrast, physicians do not pay for the drugs they prescribe, and until recently, private insurers and Medicaid simply accepted the manufacturer's price.)

Direct regulation of prices is always a different undertaking and may create perverse incentives in the long run, because it is difficult, if not impossible, to know the 'right' price for a given product or service. Regulation of drug prices in other countries has shown that prescription drugs are no exceptions. Price regulations in

Japan, for example, have been structured in such a way as to encourage the proliferation of research on "me-too" drugs, with consequent distortions in the allocation of precious R&D dollars.

The long-run problems associated with price controls, combined with the potential for high launch prices of new drugs under a fee-for-service system lacking such controls, suggest that the Congress might want to consider alternatives to a fee-for-service benefit—one that restructures the market so that prescribing physicians are more sensitive to the prices of alternative therapies. More price-sensitive buyers would encourage pharmaceutical companies to compete for business on the basis of price as well as quality. Although such an approach still leaves open the possibility of high prices for important new drugs that have no close substitutes, such advances occur infrequently and, if the rest of the prescription drug market place becomes more price-competitive, may be affordable.

Question. When you testified before the House Energy and Commerce Committee you said, "it is extremely difficult, if not impossible, to know what the "right" price for a breakthrough drugs is." Based on that, would you recommend that the notion of price controls be abandoned altogether?

Answer. When markets are structured properly, they are always better at determining prices than are regulators, who cannot know all of the conditions of supply and demand that should govern price setting. When markets fail to send appropriate signals to those who sell products, however, regulation of prices may be a necessary action.

If a Medicare prescription-drug benefit is structured as a fee-for-service benefit—where physicians prescribe for patients who pay only part of the cost out-of-pocket and are protected by catastrophic limits on out-of-pocket costs—the inevitable result, in the absence of any price controls, would be a rapid increase in prescription drug prices (as well as increasing advertising and promotional expenditures). Thus, under such a system, price controls would be needed to control prescription drug expenditures.

An alternative approach—one that might be less dependent on price controls—would be a prescription drug benefit that embodies the principles of managed competition. Health plans might compete with one another to offer prescription drug insurance to Medicare beneficiaries. To keep cost of the benefit down, plans could use the techniques of "managed care pharmacy" to inject price sensitivity into prescribing and dispensing decisions.

The key to success of such an approach would be the availability of a large number of competing plans offering the benefit to Medicare beneficiaries. Any proposal whose ultimate effect would be a very few plans competing for Medicare business, and barriers to entry for new plans, would violate the spirit of a managed competition approach.

Question. Let's say that price controls are enacted this Congress. And let's say that four years from now, for example, we discover that it was a big mistake—R&D has slowed dramatically, we've lost our internationally competitive edge, people have lost jobs. In you estimation, how long would it take the industry to recover from such a measure?

It is reasonable to conclude that price controls will reduce R&D, but the nature of the changes in R&D depend on the details of the price control system. A system that controls only the prices of existing drugs, for example, might have little or no effect on R&D on either me-too drugs or breakthrough drugs. Whatever the effects of the price control system are, they might be difficult to undo quickly because of the time and cost of gearing up research programs. How long that lag might be is unknown, but the effects might last up to 12 years, the average time it takes a drug from initial identification to the market.

Because United States policy regarding approval for marketing and pricing of prescription drugs is neutral with respect to the country of origin of a drug, it is not clear at all that the U.S. industry would lose its competitive edge in pharmaceuticals because of an R&D decline. The losses in R&D would be shared among the R&D companies that compete in developing new drugs for the global market.

Responses of Judith L. Wagner to Questions From Senator Hatch

Question. As we discuss the public policy relevance of the cost of pharmaceutical development, are there Federal policies or programs that could be changed to reduce the cost of drug development? In other word's, is there something the Federal government is doing now that has the effect of inflating the costs associated with drug development?

Answer. Any Federal policy that requires firms to spend money and time to test a drug before its entry on a market increases the cost of drug development. Thus,

the FDA's process for approving new drugs has increased the cost of drug development over what it would have been without such regulations, although some experts have argued that much of what is done to test drugs for market would be done anyway, even in the absence of any drug regulations.

OTA did not assess the FDA new drug approval process but many Commissions and Blue Ribbon panels have explored the potential avenues for streamlining and otherwise making more efficient the drug approval process. Currently, FDA is attempting to make greater use of computerized new drug applications as a way of facilitating the review of the masses of data submitted to FDA from drug trials. And, of course, the express purpose of the recent user-fee legislation was to buttress the capability of the FDA staff to expedite the review of new drug applications. The effect of that legislation will need to be evaluated in a few years, after enough experience with the new system has accumulated.

OTA's analysis of the cost of developing new drugs revealed that the average cost of bringing a new drug to market is most sensitive to the success rate (i.e., the percentage of all new drugs beginning human testing that are successful in gaining market approval). The success rate has little to do with how efficient the regulation of new drugs is. It has more to do with the state of scientific knowledge and the ability of pharmaceutical company scientists to predict which drugs are likely to be successful. Thus, although there are clearly changes in requirements that could reduce the cost of conducting research (e.g., requiring smaller trials, less animal testing, etc.) or speed drugs through the review process, unless they were major changes they would not have the kind of impact that an improvement in scientists' ability to predict winners would have.

PREPARED STATEMENT OF STANLEY WALLACK

Good morning Mr. Chairman and Members of the Committee. My name is Stanley Wallack and I am Chairman of the Coalition on Long-Term Care Financing. I am also the Director of the Institute for Health Policy at Brandeis University and a faculty member of the Heller Graduate School at Brandeis University. In 1987, I founded LifePlans a long-term care managed care company. I am here today on behalf of the Coalition which represents a diverse group of researchers, leading insurance companies offering long-term care insurance coverage and providers of long-term care services. Coalition members are united by a common commitment to the establishment of a strong partnership between the public and private sectors in financing long-term care services.

The Coalition appreciates the opportunity to testify on a matter of critical importance in the health care reform debate: namely, ensuring that long-term care (LTC) is not left out of the equation as we move forward in developing a national policy for restructuring the way health care and related services are delivered and financed. Although the center piece of health care reform legislation introduced to date has been reform of the acute care system, problems of access to health care services and containment of escalating health care costs in the acute care system represent only half the picture. While there are close to 40 million individuals under the age of 65 who lack health insurance coverage, there are also 32 million people over the age of 65 who are exposed to the risk of incurring catastrophic expenditures for long-term care services.

I. BACKGROUND

The Problem and Need for Federal Involvement

I want to briefly comment on three aspects of long-term care financing: (1) the problem and need for public sector involvement, (2) the purpose and potential of Federal long-term care insurance consumer protection standards and tax clarification, and (3) the alternative public/private financing strategies for home and community-based care.

I want to begin my testimony by emphasizing the importance of a meaningful public/private approach in the financing of long-term care. All too often those supporting a public-private partnership are only providing lip service to the idea. You are considering legislation today that will establish policies and expenditures far into the future. We are not far from 2010, when the baby boom generation will reach retirement age and the number of disabled accelerates rapidly. Long-term care expenditures will increase exponentially when this happens. There will be pressure for more government assistance in the future, which means that we need to be thinking about public and private sector LTC roles today. Currently, the fastest rising budget expenditure for both Medicare and Medicaid is for home care. In the

next six years, expenditures on home care are expected to double, even in the absence of any major programmatic changes. This growth reflects an increasing need for services as well as our inability to manage acute and chronic populations and to accurately define service norms. If the record growth in Medicare home health care expenditures were to continue, they could exceed Medicare physician payments in the next ten to fifteen years.

Thus, I believe the Federal government should proceed cautiously in this area and not overlook the opportunity and importance of encouraging private sector involvement in the financing and managing of home and community-based services.

The history of social welfare programs in this country, as well as the particular interests of the private and public sector, strongly suggest that, over time, long-term care services will be financed by a mix of public and private programs. To assess what mix of public and private long-term care financing would be best, it is important to determine what each sector can do as well as to evaluate what each sector should do. Private long-term care policies have evolved over the past decade. Market forces have been effective in shaping policy configurations as well as their cost. In general, policies today are more comprehensive and lower priced. However, the number of policies sold continues to be low in comparison with the proportion of elderly who could afford to buy them. This will remain the case until the Federal government clearly and unequivocally defines its own role in this area. Older people look to the Federal government for signals on financing long-term care needs; the employed to their employers. Only when parties are supportive and send the proper signals will the private market approach its potential. The Federal government should take the lead in recognizing the viability of private long-term care insurance and establish private insurance standards that will promote the evolution of the private market. But, even though insurance is less expensive for many, for others it is not a feasible alternative. Government certainly must do more for these individuals, and that is why the Coalition supports an expansion in public benefits for poor and non-poor disabled individuals.

The Coalition supports four key strategies for promoting public-private partnerships in long-term care financing:

- aggressive strategies to educate consumers about long-term care risk and options for financial protection;
- tax clarification of long-term care insurance policies to provide incentives for consumers to plan for their long-term care needs in advance through the purchase of private coverage;
- federal consumer protection standards to ensure that policies provide value to consumers and that this value is maintained over time; and
- public expansions in programs for whose who cannot afford to protect themselves against long-term care risk through private means.

Based on our principles regarding long-term care financing reform, Coalition members have been pleased to note that almost all health care reform proposals have addressed long-term care in some fashion. Furthermore, may of the bills include some or all of the elements necessary to promote public-private partnerships. The inclusion of provisions to clarify the tax status of long-term care insurance products and federal standards for these products suggests that Members of Congress recognize the market potential for private long-term care insurance.

The private market has spearheaded efforts to enhance financial protection against long-term care risk in the past decade. Since 1987, the number of policies sold has increased from 815,000 to almost 3 million at the end of 1992. The number of policies sold has grown an average of almost 30 percent annually. The majority of long-term care insurance policies, about 82 percent, have been sold to individuals or through group associations.

Sales through the employer market and life insurance market, while a smaller percentage of total sales, have increased dramatically. In the past five years, the number of policies sold in the employer market has grown from 20,000 in 1988 to over 350,000 in 1992. This represents an average annual growth of over 100 percent. Employer policies comprised over 12 percent of the market at the end of 1992. During the same period, the number of life riders should has increased to over 157,00 policies, representing an average annual growth of over 300 percent. Life riders now represent over 5 percent of the long-term care insurance market.

Consumer Protection: Federal LTC Care Insurance Standards and Tax Clarification

For private insurance to work appropriately, there is a need for government regulations. Insurance is a complex product in which people buy today for benefits in the future. Government should ensure that purchasers are not harmed and that they receive the value they purchased. The policies established by government must encompass the social goals of consumer protection and encourage the development

of the private market to provide fair and attractive plans. Developing the private market means encouraging choices for consumers which should be entirely consistent with sound well thought-out consumer protection strategies.

Too often, regulation is adopted under the banner of consumer protection when its real objective is to impose a product on consumers which policy makers believe to be in consumers' best interest. I, for example support comprehensive benefits for long-term care plans with continuing personal care management. Yet, many consumers select a nursing home only plan because it is the most effective way to secure financial protection.

Many individuals find insurance rules and policies formidable and, therefore are suspicious of insurance plans. Individuals also may not want to consider the consequences of needing services. Often, governments have established tax incentives, requirements or mandates to increase or assure the purchase of insurance. Given the complexity of insurance, I believe individuals would welcome the government informing them about the need and adequacy of private insurance policies in meeting their long-term care needs.

An adequate long-term care insurance policy must provide benefits when one needs personal assistance because of a physical or mental disability. However, individuals are likely to want different benefits—services and dollar levels—depending on age, sex, marital status and income status. Some people want and can afford lifetime benefits, others want inflation protection on a three year policy duration. In short, individuals demand different types and levels of benefits, and insurers are providing.

The purchase of long-term care insurance should be viewed as one of many steps taken by individuals to protect their assets, ensure a standard of living, and guarantee access to care if and when the need arises. The primary focus of consumer protection should be on assuring policy holders that they receive the value for which they have contracted and for which they are paying premiums. Whereas consumer choice focuses on levels of product value, consumer protection deals with the protection of the value purchased. Consumer protection also should address operational norms of insurance companies, the assumptions underlying premiums and the solvency of insurers.

Federal consumer protection standards should be accompanied by tax clarification as these are critically important for the future growth of the private sector. While tax deductibility only reduces net price of a policy moderately, the impact on consumer attitude toward purchase could be altered dramatically.

II. FEDERAL LONG-TERM CARE INSURANCE STANDARDS

The Coalition supports appropriate federal standards for consumer protection to ensure that long-term care insurance policies have initial and continued value. To ensure access to affordable protection, however, any federal legislation must strike an appropriate balance between the extent of policy requirements and the price of policies.

We strongly urge the establishment of standards that, when combined with effective enforcement mechanisms, ensure that individuals know the value of what they are purchasing and ultimately receive that value. The Coalition believes that LTC insurance plans must be understandable, fairly and appropriately priced and clearly articulated. To assure that value is maintained over time, we support procedures for appropriate policy pricing, establishment of required reserves and disclosure of information concerning the financial strength of insurance companies—areas over which the consumer has little or no control. Additionally, we support the establishment of standards at the outset to ensure that benefits will be paid as promised.

Coalition members support most of the provisions included in the Model Act and Regulation adopted by the National Association of Insurance Commissioners. For example, we support the following consumer protection measures:

- requirements regarding guaranteed renewability, coverage of Alzheimer's Disease, offer of inflation protection, 30 day free-look period, delivery of detailed outline of coverage and shopper's guide, and provision of continuation or conversion coverage for group policyholders;
- prohibitions against post claims underwriting, prior-hospitalization requirements, preexisting conditions exclusions, and marketing practices such as twisting and churning;
- requirement that insurers establish marketing standards that can be audited to assure fair and accurate comparisons of policies;
- sanctions in the form of civil monetary penalties for agents and insurers who violate regulations.

The Coalition also supports numerous consumer protection provisions which exceed requirements in the current NAIC Model Act and Regulation such as:

- requiring insurers to establish: long-term care education and training programs; procedures for monitoring sales practices of agents; meaningful update protection programs; a thorough claims process which includes a written explanation of filing procedures; clear and thorough written definitions of benefit eligibility criteria to be presented at the point of sale.
- establish minimum standards for long-term care insurance reserves and criteria for evaluating insurer reporting data.

While the Coalition supports the majority of requirements adopted by the NAIC included in health care reform legislation, there are several provisions which we believe are not in the best interest of consumers. In fact, we feel strongly that some of the proposed provisions would create barriers to consumer access to private long-term care products. These provisions are addressed below.

Nonforfeiture Benefits

Non-forfeiture provisions ensure that all policyholders receive some benefit for paying premiums. In effect, individuals are creating their own savings account. The underlying assumption is that LTC insurance policies should serve both a risk and savings function rather than just being exclusively risk-relieving instruments. There is a tradeoff, however, between the insurance aspect and the savings aspect of a policy design because non-forfeiture benefits reduce risk spreading.

Non-forfeiture is certainly an attractive benefit for younger individuals who are at low risk and are primarily trying to pre-fund future liabilities. Not surprisingly, the group employer market has evolved this way. In the older market, incidence risk outweighs the importance of savings.

For these reasons, the Coalition supports the requirement to offer all prospective policyholders a nonforfeiture benefit in the event of nonpayment of premium. We oppose mandated nonforfeiture benefits. Nonforfeiture benefits significantly increase the cost of long-term care insurance policies—anywhere from 30 to 200 percent, depending on the age of the policyholder. Since LTC products are extremely price sensitive, this requirement would act as significant deterrent to the purchase of LTC policies. Further, requiring consumers to purchase this protection could force them to forgo other coverage or benefits that would better serve their individual needs. For example, some consumers may prefer longer coverage periods, higher daily benefits or inflation protection.

Rate Stabilization

The Coalition supports reasonable and justifiable insurance premiums which ensure that a carrier's long-term care obligations will be met. The most effective protections include measures which assure that initial premiums, and potential increases, are determined appropriately on the basis of actuarial data. The Coalition also supports sanctions against insurance companies that engage in exorbitant and unwarranted rate increases. However, we oppose the establishment of arbitrary and unreasonable limits on premium increases and do not believe that such limits would achieve the goal of ensuring tat rates are set correctly in the first place. Such limits could have the potential to threaten insurers' abilities to pay future claims which is certainly not in the best interests of consumers.

The Coalition supports the following minimum rate guarantees:

- 3 year rate guarantee from date of issue;
- subsequent rate increases must be guaranteed for at least 2 years from date of increase;
- rate increases may not exceed 10 percent in any 23 month period for individuals 75 or older who have held policy for ten years;
- carriers must offer insured option for benefit reduction 90 days in advance of rate increase to help maintain stable premium level;
- if an insurer increases rates by more than 50 percent in any 3 year period, carrier will be prohibited from issuing policies in state where violation occurred for 2 year period;
- Secretary may modify or waive any requirements related to rate stability if requirements: would adversely affect insurer's solvency or conflict with State or Federal requirements; become inconsistent with mortality or morbidity patterns as a result of new medical developments; judicial interpretations of policy benefits result in unintended claim liabilities.

Relation to State Law

All long-term care standards bills would allow states to impose additional state standards on carriers which exceed Federal requirements. We believe that this provision is inconsistent with the intent of Federal regulations which are aimed at cre-

ating uniformity of benefits to make comparison shopping possible for consumers. Further, additional state standards would require insurance companies to obtain policy approval in any state with regulations exceeding federal standards. This would needlessly increase administrative costs which would be passed on to consumers in the form of higher premiums. If Federal standards include the essential elements needed to protect consumers, additional state standards should not be necessary.

The Health Security Act prohibits carriers from selling insurance policies in states found out of compliance with Federal standards. The Coalition believes it is unfair to penalize consumers and insurers for a state's violation of Federal law. We believe that carriers should have the right to sell any policy meeting Federal requirements, regardless of whether the state in which the policy is sold is in compliance with Federal law.

Independent Assessment

We oppose, a third party determining eligibility for benefits. The insurer is contractually obligated to manage an individual's long-term care needs so that the best care can be delivered most efficiently. Transferring the claims adjudication function to an outside party could expose the insurer to unintended claims liabilities. It also could undermine carriers' ability to maintain stable premiums by changing utilization patterns assumed by carriers in establishing premium rates.

Regulatory Authority

The Coalition believes that too much regulatory authority is vested in the office of the Secretary of HHS under the Health Security Act. We believe that the Secretary's office should play an advisory role to Congress, but that Congress should have the final authority to approve federal standards. Parts of the Health Security Act provide the Secretary wide discretion in implementing final regulations under broad guidelines. There is little or no statutory guidance from Congress on the content of these standards. This legislation effectively delegates these decisions to the Secretary.

Coalition members believe that the legislation should clearly articulate as many of these standards as possible and limit the role of the Secretary to that of policy implementation, not policy development. Furthermore, we believe that the Advisory Council should be established as an independent body, not an arm of the Secretary's office, to ensure objective representation of all pertinent interests.

Agent Compensation Limits

The Coalition does not support the use of agent compensation limits. Problems regarding lapse rates and replacement rates should be dealt with directly by regulating agent sales and marketing practices and extensive agent training and education. Caps on commissions will not remove incentives for unwarranted initial sales or ill-advised policy replacements. Blanket restrictions on sales commissions do not distinguish between agents selling in an ethical, responsible way and those who do not.

The Coalition believes that other safeguards and restrictions adopted by the NAIC are better suited to addressing problems related to ill-advised sales and lapsing, such as the following:

- agent training and education requirements:
- prohibitions against unfair sales and marketing practices such as twisting, churning, high-pressure sales tactics and cold lead advertising;
- penalties consistent with Section 11 of the NAIC Model Act for violations of sales practices;
- requirement that carriers establish marketing procedures to assure fair and accurate comparison of policies by producers and to prevent the sale of excessive insurance;
- requirement to display a prominent notice to consumers on the first page of the policy that the policy may not cover all costs of long-term care and advising the consumer to carefully review all policy limitations;
- requirement that state-approved shopper's guide be delivered to potential insureds at the point of solicitation;
- requirement that consumers answer a series of questions on the application form concerning existing coverage and eligibility for and coverage by Medicaid.

Coalition members believe that these and other standards included in the NAIC Model Act and Regulation and proposed federal standards legislation will be much more effective in assuring agent accountability in the marketing and sales of long-term care products than agent commission caps.

III. TAX CLARIFICATION

The Internal Revenue Service has yet to rule on the treatment of premiums paid for long-term care insurance policies and benefits paid out by such policies. The Coalition believes that clarification of the tax status of long-term care insurance would increase the legitimacy of these policies and could significantly enhance consumer interest in purchasing long-term care protection. Based on surveys conducted by the Washington Business Group on Health, the Health Insurance Association of American and others, we believe that tax clarification would increase employer interest in offering long-term care coverage and, in some cases, making a premium contribution to this coverage. Employees also would be more likely to purchase policies if their premium contributions were tax free.

We believe legislation should accomplish the following:

- treat long-term care insurance as accident and health insurance, assuring that benefits would be excluded from policyholder income and that employer contributions to a long-term care plan would be excluded from the employee's income;
- permit long-term care insurance to be included in cafeteria plans and allow employers to deduct, as a business expense, the value of premiums paid for long-term care insurance on behalf of employees;
- clarify that long-term care expenses and premiums for long-term care insurance qualify for the limited medical expense deduction;
- clarify that benefits paid under a life insurance contract that accelerates the payment of benefits for long-term care services can be excluded from income;
- ensure that disability-based policies receive favorable tax treatment, the law should specify that amounts received for the permanent loss of a bodily function are disbursed tax-free;
- to recognize the high cost of nursing home care in areas such as the northeast, we recommend that the per diem cap be set at $250 per day;
- Medicare must retain primary payer status for those situations it already covers;
- the requirement that companies maintain a capital ratio equal to 25 percent of LTC insurance premium receivable should be eliminated; companies shall, however, be required to have adequate capital to meet their long-term care obligations;
- companies should be required to use the *one-year* preliminary term reserve method where it conforms to state laws;
- benefit eligibility standards should be set at 2 out of 6 ADLs, regardless of the level of care; continence should be included in the list of ADLs as well as state-mandated ADLs.

IV. FINANCING HOME AND COMMUNITY BASED BENEFITS

Over the past few years there have been increasing calls for reforming the financing of home and community-based care and there seems to be a growing consensus that expanding coverage for the functionally disabled is an important and timely policy response to their changing needs as well as to their changing numbers. Yet, these calls have not been occurring in a static service or financing environment. On the elderly disabled alone, more than $10 billion was spent on home and community-based care in 1992. Moreover, similar spending on community alternatives for the mentally retarded/developmentally disabled has grown to more than $2 billion. For both the Medicare and Medicaid programs the fastest growing budgetary item is home and community-based care. In fact, over a period of six years, Medicaid expenditures have more than tripled whereas Medicare expenditures have increased by more than 4 times their 1987 levels. The current HCFA Administrator estimates that by 1999, Medicare will be spending about $23 billion on home and community-based care: a doubling within a six year period. Thus, these entitlement programs are playing increasing important roles in financing home and community based care.

As policymakers think through the structure of a new or reformed financing program for home and community-based care, two important objectives must be balanced: the necessity of targeting benefits to those most in need and the requirement that expenditures be controlled or at the very least, controllable. Moreover, there needs to be a recognition of the fact that there is a rapidly developing private insurance market for such care. Over the past five to seven years, private insurers have been selling long-term care insurance policies, many of which now cover a broad range of home and community-based services.

Since most of you are familiar with the Home and Community-based Care Program outlined in the Health and Security Act, I am not going to review the program

here. My views on the structure and approach of the program will become clear as I outline an alternative for your consideration. While the Administration's proposal and the alternative that I am outlining here today both are designed to encourage an expansion in the financing of home and community-based care for disabled Americans, there are some important differences that relate to the way in which program benefits are distributed, the role of the public and private sectors in financing home and community-based care, and the costs of alternative programs.

The Administration's plan is designed to provide benefits to all severely disabled people without regard to their level of financial resources. The proposal that I want to put before you seeks to create a national financing program for poor and near poor disabled individuals National eligibility criteria, implemented at the state level, would be based on the functional and cognitive status of individuals as well as on their level of financial resources. The program would begin to integrate the financing of home based and institutional care services by promoting uniform income and asset eligibility thresholds. The plan would cover individuals who are limited in their ability to perform at least two activities of daily living, who are at least moderately cognitively impaired, who are severely or profoundly mentally retarded, and who are technologically dependent children. Qualifying individuals would have incomes no greater than 150% of the poverty level and non-housing assets of $12,000 or less.

Given the multitude of social problems facing this country, as well as budgetary realities, it is important to assure that public dollars are well targeted. The Administration's Plan would allocate more than half of all new benefits to disabled individuals with incomes in excess of 200% of the poverty line. Thus, program dollars will be spent on individuals, many of whom could afford to pay for care themselves, or pay for private alternatives for financing such care. The result is that certain existing financing inequities may be exacerbated. The Plan I am proposing targets all benefits to incomes with incomes less than 150% of the poverty line (See Figure 1).

The philosophical underpinning of this proposal is that the government should address the problems faced by those who cannot afford to protect themselves against LTC expenses because of inadequate financial resources. I am concerned that, over time, especially as the baby-boom generation begins to retire in 2010, benefits will be spread a mile wide and a inch deep. Inevitably, the poor, for whom such benefits would comprise the majority of available help, would be hurt the most.

I believe that for the segment of the population with adequate incomes and assets, responsibility rests with individuals and their families. This is not a small segment of the population. The elderly, in particular, have made great strides in the area of income status. Poverty rates among elders have fallen dramatically over the last two decades, in part as a result of actions taken by Congress to strengthen Social Security and to provide additional income support. Many elders can, if they so choose, insure themselves against the costs of home and community-based care through the purchase of private LTC insurance policies. This is consistent with the President's desire that individuals assume personal responsibility and that individuals be provided incentives to purchase private long-term care insurance.

The Alternative Proposal that I am outlining here seeks to clearly define public and private roles. Without question, one of the most important tasks facing health policy makers as they grapple with health care reform is to define the boundaries and roles of the public and private sectors in meeting LTC needs. The Alternative Plan divides the market in terms of population groups. The Administration's proposal defines public and private responsibilities by dividing the market for LTC services: the government assumes overall responsibility for home and community based services whereas private insurers assume responsibility for insuring the market for nursing home care for middle and upper-income individuals. Such a division could lead to a variety of market distortions including gaming and shifting between public programs (e.g. Medicaid recipients being shifted to the new program), between service locations (e.g. from the nursing home to the community), and between markets (private insurance to public market).

Also, insurers will find it extremely difficult to carve out policy coverages that complement the public coverages for care. This could lead insurers to desist from marketing policies that provide meaningful home and community-based care coverage to individuals. Moreover, if individuals come to believe that the government is going to guarantee financing for a comprehensive set of home and community based services, there will be little incentive to purchase private coverage for these services. Clearly, from a program management perspective, the Administration's program does not make a lot of sense; nor is it consistent with other aspects of the Health Security Act which stress personal responsibility and the encouragement of an innovative and meaningful private market for long-term care financing.

The Alternative Proposal would establish a Federal-state partnership in the context of a globally budgeted program with internal budget caps for different groups served by the program. A "home and community-care service basket" would have to be provided by states and contain a minimum set of services needed to meet the needs of the diverse groups served by the program. States could choose to make available additional services beyond the minimum basket. In this way, the Alternative Plan creates an "access entitlement" to poor and near-poor individuals rather than a budgetary entitlement to the states. Moreover, as a way to deal with potential competition for limited program resources among groups with diverse needs, the Alternative Plan proposes that separate internal expenditure caps within the context of an overall budget be maintained. Establishing global budget caps based on per capita service costs and numbers of program eligibles is perhaps the most effective way to achieve macro-efficiencies and assure that expenditures remain controllable over the long-run.

The Alternative plan is to be fully-funded at the time of initial implementation. The Administration's plan is to phase-in the program over a seven year period which means that the program will be grossly under-funded to meet projected needs. Not only will expectations go unmet, but the pressure on the states to provide meaningful coverage will be enormous.

We estimate that 1.5 million individuals will qualify for benefits under the program in 1996 and this number will grow to 1.7 million by the year 2003. Total service users grows from about 1.3 million in 1996 to about 1.5 million by 2003. This represents roughly half of the population that would be served by the Administration Plan. By design, the "half" that would not be covered by the Alternative Plan represent those disabled individuals many of whom could finance care themselves or, with advanced planning, pay for private insurance. The total costs of the program are $18.5 billion in 1996 increasing to $29.6 billion by 2003 (See Table 1). The Administration has estimated the costs of its proposal to be $50 billion in 2003. Thus, the Alternative proposal costs 40% to 50% less than the Administration's Plan (depending on whether one accounts for the fact that not all expenditures under the program are "new"; some represent a net shift in costs from the Medicaid program to the new program.

CONCLUSIONS

The Coalition supports expansions in public financing for home and community-based care and public support for the continued development of an innovative private insurance market through federal consumer protection standards and tax clarifications. Where we differ from the Administration is on the issue of who should be entitled to receive public benefits and who should be expected to assume greater private responsibility. Both the service environment and the financial status of the elderly have improved dramatically over the last few decades but there remain significant numbers of disabled individuals who require public assistance to cope with their disabilities. On the other hand, many other disabled individuals have adequate resources to care for themselves or to access the private market: today, there are insurance alternatives covering home and community based care for individuals who plan ahead for retirement needs. There are now home care-only policies that provide weekly benefits for home care and policies that essentially give a disable individual a pot of money to be spent on home care or nursing home. The premiums for these home care only policies are quite reasonable—a 65 year old could pay $35 to $40 a month to receive up to $800 a month in home and community-based care payments for up to three years.

The Alternative Plan that I have presented today presents a realistic, sensible and fiscally prudent blue print for a meaningful public-private partnership. It encourages an equitable distribution of public funds, maximizes the chance for programmatic efficiencies through managed care and budget caps, and assures that the private market presents high value products to consumers through the establishment of federal insurance standards and tax clarifications.

Table 1: Program Costs for Coalition Proposal: 1996–2003 (Billions)[1]

Budget year	Total program costs	Program costs up to 100% poverty	Program costs 100% to 150% poverty	Net additional expenditures[2]
1996	$18.5	$9.8	$8.7	$12.5
1997	19.9	10.5	9.4	13.4
1998	21.3	11.3	10.0	14.4
1999	22.8	12.1	10.7	15.5

Table 1: Program Costs for Coalition Proposal: 1996–2003 (Billions)[1]—Continued

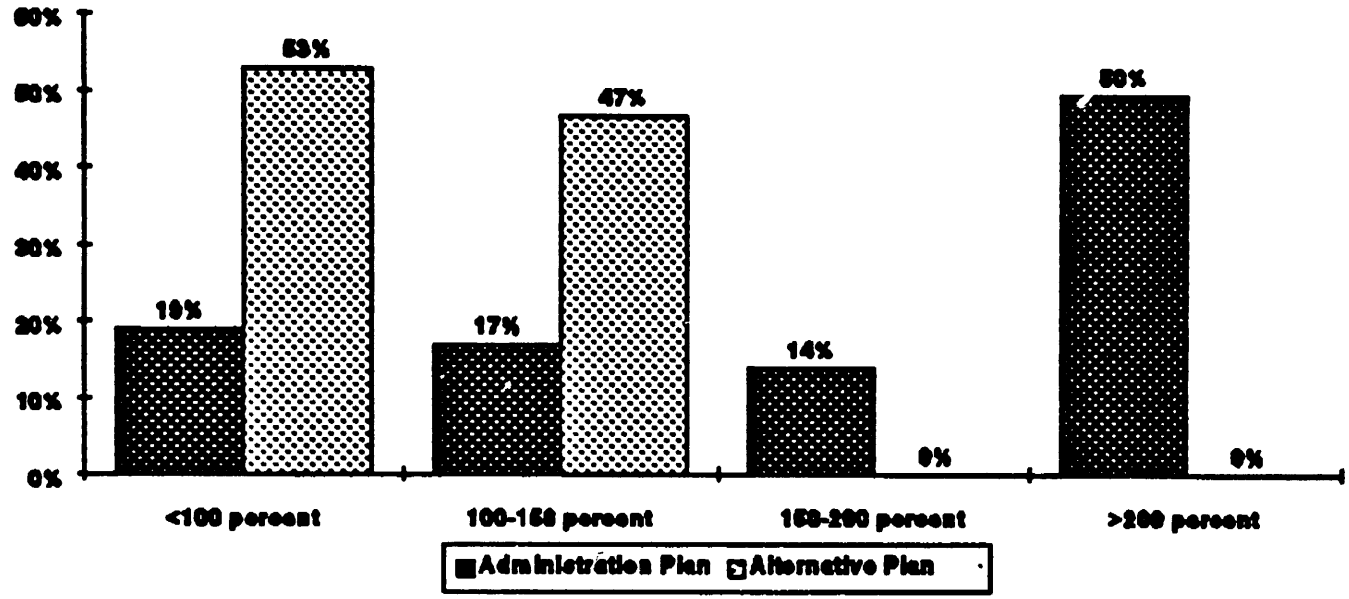
Budget year	Total program costs	Program costs up to 100% poverty	Program costs 100% to 150% poverty	Net additional expenditures[2]
2000	24.4	12.9	11.5	16.6
2001	26.0	13.8	12.2	17.8
2002	27.7	14.7	13.0	18.9
2003	29.6	15.7	13.9	20.3

Source: LifePlans Long-Term Care Services Utilization Model.

[1] Total program costs include the costs of assessments, care plans, all other service costs and administrative expenses which are estimated to be 10% of service costs. These expenditures will be financed by the federal and state governments

Roughly 30% of current Medicaid beneficiaries will qualify for the new program. Therefore, their care represents a net shift in costs from the Medicaid program to the new program. Also 55% of the MR/DD population will also shift from Medicaid. Because of the lack of data on the income and asset status of the technology dependent, they are not treated as part of the overlap population. To evaluate net additional expenditures on home and community-based care, one must subtract these "Medicaid overlap" groups from the eligible population and recalculate program expenditures.

Figure 1: Distribution of Program Benefits by Poverty Line, 1996
(Includes Medicaid Overlap Population)



Source: LifePlans, Long-Term Care Services Utilization Model

COMMUNICATIONS

AMERICAN BAR ASSOCIATION, GOVERNMENTAL AFFAIRS OFFICE,
Washington, DC., April 22, 1994.

Hon. DANIEL PATRICK MOYNIHAN, *Chairman,*
Committee on Finance,
U.S. Senate,
Washington, DC.

Dear Mr. Chairman: I am writing to you in connection with your Committee's April 19, 1994 hearings focusing on long-term care within the context of health care reform. We respectfully request that this letter be included in the record of those hearings.

The American Bar Association supports legislation that would provide every American access to quality health care regardless of the person's income. Further, with respect to long-term care, the ABA has, since 1989, supported the enactment of federal and state legislation providing a co-ordinated and comprehensive system of care and support for Americans of all ages with long-term care needs.

Three ABA policy statements are attached: one on health care, and two on long-term care.[1] The policies provide general principles that should guide the implementation of health care reform. The ABA enthusiastically supports inclusion of long-term care benefits in health care reform legislation.

We urge that procedural due process protections be made part of such a long-term care component. Even if the long-term care component is not envisioned as an entitlement program, procedural fairness is essential. For example, we are pleased to see that President Clinton's proposed "Health Security Act" contains a long-term care component. However, the proposal appears to lack clear procedural due process protections for the long-term care component. This shortcoming can be remedied by ensuring that substantially the same consumer due process rights that accompany health care benefits also accompany long-term care benefits.

We appreciate the opportunity to express the ABA's views on this important effort and would be pleased to provide additional information.

Sincerely,

ROBERT D. EVANS.

STATEMENT OF CARETENDERS HEALTHCORP.

Chairman Moynihan and Members of the Committee: We appreciate the opportunity to present our views and recommendations on long-term care issues as a part of proposals to overhaul the nation's health care system. Caretenders Healthcorp. is a provider of comprehensive home health care services and is the nation's leading provider of adult day health care. Caretenders currently operates 13 adult day health centers (ADHCs) in Maryland and Connecticut under the name Almost Family. In 1993, we provided services to over 1000 disabled adults of all ages.

For purposes of this hearing, we urge you to consider the following issues:

- There is a growing need for home- and community-based long-term care services;
- Long-term care coverage should focus on the most severely disabled, regardless of age;
- There are different types of adult day care;
- Adult day health care must be included in any long-term care package, and

[1] The ABA policy statements were made part of the committee files.

- The federal government and states have defined adult day health care.

THERE IS A GROWING NEED FOR HOME- AND COMMUNITY-BASED LONG-TERM CARE SERVICES

There is an immense and increasing need for home- and community-based long-term care services for disabled. The Administration estimates approximately 3.1 million persons would be served by the Clinton plan's home- and community-based long-term care program. Several factors are fueling this need, including:

DEMOGRAPHICS

Nearly 31 million people were 65 or over in 1989.

Less than 14 percent of those aged 65-74 were disabled in 1985, while over 58 percent of those over 85 were disabled, according to data from the Brookings Institution and the Census Bureau.

The over-85 population is the fastest growing sector of the elderly.

The Urban Institute estimated there to be 9.2 million disabled elderly in the community in 1990.

MEDICAL IMPROVEMENTS

Medical improvements allowing people to live longer and survive accidents and diseases that used to kill have resulted in an increase in morbidity, or sickness rates. Diseases such as Alzheimer's will become increasingly prevalent as more and more individuals live longer.

NEW FAMILY STRUCTURE

The emergence of two-worker and single-parent households means that many families will need assistance in caring for elderly family members.

In the middle of the last decade, only one in five elderly with long-term care needs lived in a nursing home, according to the Brookings Institution. This clearly indicates that individuals prefer to remain in the community for as long as possible. However, as more and more households find it necessary to move to dual incomes, the ability to care for a disabled parent or child at home will lessen. The need for home- and community-based long-term care has been increasing over the past decade, and is only going to get worse under the status quo.

FISCAL CONSTRAINTS

The current system of long-term care in this country is inequitable and inefficient. Public programs, such as Medicare and Medicaid, are experiencing astronomical rates of growth in expenditures, with no relief in sight. The private insurance market is beyond the reach of all but the most wealthy individuals.

Nursing home expenditures are increasing. In 1994, Americans will spend $85.5 billion on nursing home care, according to the Department of Health and Human Services.

Currently, there is an underdeveloped private long-term care insurance market. Several current health care reform bills, including the President's, contain provisions that would make it easier for insurance companies to offer coverage for long-term care services.

The market for home- and community-based long-term care is huge and growing, but supply has not increased to meet demand. If only one percent of the 31 million individuals over age 65 in 1989 needed adult day health care, that would translate to over 300,000 individuals. However, there were only 1200 adult day care centers in 1992, serving 60,000 individuals. This translates to a market where only 20 percent of demand has been met.

LONG-TERM CARE COVERAGE SHOULD FOCUS ON THE MOST SEVERELY DISABLED, REGARDLESS OF AGE

Any long-term care reform package should ensure that at least the most severely disabled—those with limitations in three or more activities of daily living—are granted coverage for those home- and community-based services that can provide for their needs. These services should be offered without regard to an individual's age.

Sec. 2103(a)(1) of the Clinton plan guarantees coverage for home- and community-based care to individuals of any age who—

(A) requires hands-on or standby assistance, supervision, or cueing (as defined in regulations) to perform three or more activities of daily living . . . , and

(B) is expected to require such assistance, supervision, or cueing over a period of at least 100 days.

The Clinton plan also guarantees care to "severely disabled children" and individuals with "severe cognitive or mental impairment" or "severe or profound mental retardation."

There are many non-elderly disabled. They should not be denied eligibility for long-term care benefits because of age. Specifically, 900,000 individuals under age 65 meet the Clinton plan's criteria for home- and community-based care eligibility.

Adult day health care is not a service limited to the elderly. Throughout our Almost Family centers, roughly 40 percent of our guests are under 65.

We recommend that any long-term care proposal adopt the disability requirements as outlined in Sec. 2103(a)(1) of the Clinton plan.

THERE ARE DIFFERENT TYPES OF ADULT DAY CARE

There are many different levels of adult day care. Centers that are staffed and equipped to care for individuals with more intensive medical needs are called adult day health centers (ADHCs). Some centers focus on a specific disability or illness, such as Alzheimer's. Traditional centers, typically run by religious organizations, are called social day care (SDC) centers. They tend to provide more of a social atmosphere for elderly individuals, with less emphasis on health care.

The scarce resources for health care reform should be directed toward individuals with the most severe health needs, i.e., the population best served by an adult day health center. Coverage for home- and community-based long-term care should include those services that can be provided at an adult day health center. Specifically, we recommend that any adult day health center must meet the following minimum requirements to provide services to eligible individuals:

A full-time registered nurse on staff and a physician on call.

A full-time program director.

Open seven days a week.

Staffed at a ratio of one professional for every six guests.

Guests have limitations with at least three activities of daily living (ADLs).

Transportation is provided to and from the center in specially-equipped vans with drivers who are trained to assist disabled individuals.

Given the nutritional requirements of many of the disabled, day health centers maintain the services of a certified nutritionist to monitor guests' diets.

Must be able to dispense and monitor medication, change dressings, change colostomy bags, and perform other light medical tasks. In addition, trained staff are responsible for the coordination of appointments for physical therapy, infusion therapy, dialysis, and any other medical needs and providing transportation to and from appointments.

Many policymakers and health economists have warned that covering respite care services such as adult day care would result in inefficiencies. Specifically, they are concerned that the government would be paying for care that is being provided by family members anyway. This "double coverage," they argue, would be an inefficient allocation of scarce financial resources.

Coverage for adult day health care would alleviate this problem. Only the most disabled individuals, who may require frequent health care services, and without constant care would likely enter a nursing home, should be eligible for adult day health care. Typically, families are not able to care for individuals with higher levels of disability who have more acute health needs. This would limit the duplicative provision of resources.

Families are less likely to be able to provide health-oriented care, given the specialized health needs of the disabled population. Finally, from a social policy perspective, families deserve a respite.

Our Lanham, MD center has several examples of true success stories that underscore the benefits of adult day health care:

Four of their current guests arrived from a nursing home. This immediately and directly reduces long-term care expenditures.

Several families who were considering placing a parent in a nursing home were referred to Caretenders' Lanham center. This has allowed each individual to prolong their stay in the community.

ADULT DAY HEALTH CARE MUST BE INCLUDED IN ANY LONG-TERM CARE PACKAGE

Adult day health care is typically 1/2 the cost of a nursing home. For many persons, adult day health care can act as a substitute for a nursing home. Individuals with three or more limitations in ADLs can be treated in adult day health centers (ADHCs).

Since the adult day health center often serves as a substitute for a nursing home, it can prolong the time that an individual remains an active participant in the community.

In short, adult day health care is a cost-effective substitute to a nursing home for many individuals. It also provides a respite for families whose time and patience are strained while caring for a loved one. It is the most effective community-based service that can meet the long-term care needs of the elderly and non-elderly disabled.

Adult day health care is an integral part of the continuum of long-term care. Any health care reform package enacted by Congress should ensure that families and individuals who could benefit from adult day health care have the option to choose and adult day health center over entry into a nursing home.

THE FEDERAL GOVERNMENT AND STATES HAVE DEFINED ADULT DAY HEALTH CARE

At the federal level, the Clinton health care plan, introduced by Rep. Richard Gephardt (D–MO) and Sen. George Mitchell (D–ME) (H.R. 3600/S. 1757), and the single payor plan (H.R. 1200/S. 491) sponsored by Rep. Jim McDermott (D–WA) and Sen. Paul Wellstone (D–MN) are the only current legislative proposals that include coverage for long-term care services. The Clinton plan does not make a distinction between social day care and adult day health care. Specifically, the bill defines adult day care as follows:

> Clinton plan Sec. 2304(2)—The term "adult day care" means a program providing social and health-related services during the day to six or more adult with disabilities in a community group setting outside the home.
>
> The single payor plan (H.R. 1200/S. 491) makes a distinction between adult day health care and social day care, but neither term is defined in the legislation.
>
> Rep. Pete Peterson (D–FL) and Rep. Jim Cooper (D–TN) have collaborated on a package of long-term care benefits which specify coverage for adult day care. Their proposal makes no distinction between adult day health care and social day care, and neither term is defined in the current proposal.

Many state governments currently make a distinction between medically-oriented adult day health care and social day care. Here are some examples:

> CA—Sec. 1570.7(a): "adult day health care" means an organized day program of therapeutic, social, and health activities and services provided pursuant to this chapter to elderly persons with functional impairments, either physical or mental, for the purpose of restoring or maintaining optimal capacity for self-care.
>
> AR—Adult Day Health Care is a program which provides organized and continuing therapeutic, rehabilitative and supportive health and social services and activities to meet the needs of four or more functionally impaired adults for periods of less than 24, but more than two hours per day in a place other than the adult's own home.
>
> MD—Sec. 14–301(b) of the Annotated Code of Maryland: "day care center for adults" means a place that:
>
> > (1) is operated to provide, with or without charge, care for medically handicapped adults; and [is]
> >
> > (2) (i) designated for group day care for four or more medically handicapped adults[.]
>
> Maryland requires the following services to be provided in adult day care centers:
>
> > (1) Therapeutic arts and crafts
> > (2) Community excursions
> > (3) Hobby cultivation
> > (4) Health services
> > (5) Counseling services for elderly individuals and their families
> > (6) Group dynamics, and
> > (7) Other services that enhance social functioning and develop activities in daily living and personal independence

NJ—Adult day care means a community-based group program designed to meet the needs of functionally or cognitively impaired adults through and individual plan of care structured to provide a variety of health, social or related support services in a protective setting during any part of a day but less than 24 hours.

LEGISLATORS MAY LOOK TO LONG TERM CARE TO FIND SAVINGS TO PAY FOR HEALTH REFORM

As the reform debate unfolds, policymakers are increasingly coming under fire from critics who charge that the Clinton plan to too expensive. Pressures to reduce the cost of the Clinton plan may threaten the proposed scope of benefits, including home- and community-based long term care. The following mechanisms may be considered during the coming months:

Phasing-in coverage

Universal coverage may be pushed back in order to contain costs. Long term care coverage may be delayed even further. Currently, the Clinton plan offers coverage for eligible individuals beginning in 1996 in states whose plans are up and running at that time. There is no requirement that states offer long-term care services, nor are individuals entitled to long-term care benefits.

Means-testing coverage

A new proposal, developed by Reps. Jim Cooper (D–TN) and Pete Peterson (D–FL), which is not yet in legislative form, would reform the long-term care delivery system. Their proposal includes coverage for "adult day care services." However, eligibility for benefits is means-tested. Specifically, the plan would cover individuals with limitations in 2 or more ADLs with income up to 200 percent of the poverty level. Their proposal does not specifically define adult day care.

Scale back covered services

It is possible that Congress will pass a plan that does not includes coverage for any form of long-term care. Especially if employer mandates are dropped, long-term care is in danger of being scrapped.

Perhaps only certain services will be included. Clearly, adult day health care should be included in any long-term care program.

Cost sharing for services

The Clinton plan imposes cost sharing, on a sliding scale basis, upon all individuals whose incomes exceed 150 percent of poverty. The minimum copayment is 10 percent and the maximum is 25 percent.

The Cooper/Peterson proposal imposes copayments based on income and the number of hours per week that an individual uses long-term care services. Copayments would be assessed for all individuals with incomes that exceed 100 percent of poverty, and would range from 5 to 25 percent.

STATEMENT OF THE NATIONAL ASSOCIATION FOR HOME CARE

The National Association for Home Care (NAHC) represents the nation's home care providers—including home health agencies, home care aide organizations, and hospices—and the individuals they serve. NAHC is committed to assuring the availability of humane, cost-effective, high quality home care services to all individuals who require them. Toward this end, NAHC has long advocated the development of a national plan to ensure universal access to basic acute care and long-term care services.

NAHC believes that no health care proposal is complete without ensuring access to high quality home care and hospice in both the acute and long-term care setting. These vital services provide millions of individuals—the aged, infirm, disabled, and children—the ability to receive care in the settings that allow them the highest level of satisfaction, independence, and dignity—in their homes.

REFORM PLANS MUST ADDRESS NEED FOR LONG-TERM CARE

Any action taken on health care reform must not overlook the growing need in the U.S. for a comprehensive long-term care program. It is impossible to separate the need for reform of the current health care system from addressing the need to include a long-term care component.

Long-term care is one of the most devastating problems America faces today. Estimates indicate that between 9 and 11 million Americans of all ages require long-

term care because of chronic illness or disability that render them helpless to perform basic tasks of daily living without assistance. This number could double by the year 2030 to more than 19 million. The need for long-term care is expected to increase substantially as a result of several factors: the burgeoning growth of the elderly population; increased usage of high technology and new medical breakthroughs that may extend the lives of more mentally retarded, developmentally disabled and physically disabled persons; increased survivorship of low birthweight children; greater longevity for children with terminal chronic illness, and earlier detection of chronic health problems; and the growth of the number of persons with AIDS.

Spending for long-term care is currently estimated at $57.8 billion. Yet neither Medicare nor private insurance provides adequate protection against the costs of long-term care. Many families exhaust their emotional and financial resources providing and purchasing long-term care. A million Americans a year are impoverished trying to meet the cost of long-term care left uncovered by insurance. Only the most wealthy of Americans are insulated from the potential financial devastation. The rest can have their lifetime savings wiped out in a matter of months paying for long-term care.

Long-term home care improves the quality of life because it is more humane. It reinforces and supplements the care provided by family members and friends and maintains the recipient's dignity and independence, qualities that are all too often lost in even the best institutions.

Long-term home care services can also be cost-effective. New York State's experience with its Nursing Home Without Walls program is that the great majority of clients who would otherwise need to be placed in a nursing home can be cared for at home for a much lower cost.

Medicaid waiver programs have increasingly relied on home care services as a way to reduce states' long-term care costs. For example, New Mexico's waiver program for people with AIDS estimates a savings of $1,100 a month for patients who use home care rather than skilled nursing facility care. The average patient plan of care costs $1,000 a month for home care compared to $2,100 a month for skilled nursing facility care, according to the program director. Moreover, New Mexico reports that only about 47 percent of patients receiving waiver services are hospitalized in a given year, compared to 70 percent of those not under waiver.

The National Governors' Association (NGA) has recognized the importance of home care services and in a resolution adopted in 1992 stressed the importance of making home- and community-based services a key component of all long-term care policies and programs. NGA recommended elimination of the current institutional bias in public programs for long-term care in favor of home care as a more preferred and cost-effective method of care.

PRESIDENT'S PLAN WOULD ESTABLISH HOME-BASED LONG-TERM CARE PROGRAM

The President's health care reform proposal would establish new federal programs for long-term home care services that would be run by the states and provide additional expansions and improvements in Medicaid long-term care programs. The significance of these provisions cannot be overemphasized. Millions of Americans now go without needed long-term care or are forced to impoverish themselves to qualify for minimal Medicaid coverage.

The President's plan also contains three important provisions that the National Association for Home Care has strongly supported over the years. First, the plan would permit disabled Americans who are under age 65 to qualify for these desperately needed home- and community-based services on the same basis as the elderly. Second, the plan would not require states to use costly external case management procedures that duplicate standard caregiver activities. Third, access to benefits would not be based on income. However, the plan would apply a copayment schedule based on clients' income levels.

The federal government would provide most of the funding for the new long-term home care program and establish minimum eligibility and benefits guidelines. States would administer the program and contribute an amount of funding roughly equal to their current spending on long-term care for the severely disabled. Federal spending on this new program is expected to total $57 billion in the first five years and $38.3 billion a year when fully implemented in the year 2003. To qualify for benefits under the new program, an individual would have to need assistance in performing at least three of five specified activities of daily living (bathing, dressing, transferring, toileting, eating). Individuals who have severe cognitive or mental impairment, or individuals who have severe or profound mental retardation could also qualify. In addition, individuals under the age of six who are dependent on tech-

nology and who would otherwise require hospital or institutional care would be eligible for services.

At a minimum, states would be required to include coverage for personal services for assistance with activities of daily living. States would have the flexibility to provide other home- and community-based services such as homemaker and chore assistance, respite services, and adult day care services.

State Medicaid programs would back up these programs for the severely disabled by providing home- and community-based services for low income individuals with fewer than three ADL deficiencies. Medicaid would also continue coverage for low income individuals who need nursing home care. Enhancements to the Medicaid long-term care program would include: (1) an increase in the personal needs allowance from $30 to $50 a month; (2) an increase in the level of protected assets from $2,000 to as much as $12,000, at the option of the state; and (3) states must set financial eligibility at a point that is no lower than SSI eligibility.

The proposal would establish federal standards and tax preferences for private long-term care insurance policies. The federal standards would not require minimum benefit packages but would require private long-term care insurance plans to: base eligibility for services on functional ability; provide nonforfeiture features (e.g., require a portion of premiums to be refunded when policies terminate); provide inflation protection, and meet additional consumer protection standards. Plans that meet these standards would qualify for tax deductions for policy premiums paid by individuals and employers.

Additional tax incentives would be established to support certain disabled individuals who work. For example, employed individuals who require assistance with activities of daily living and who purchase personal care and personal assistance services could obtain tax credits for up to 50 percent of their costs, up to a maximum of $15,000 per year.

NAHC COMMENTS ON PRESIDENT'S LONG-TERM HOME CARE PROGRAM

The National Association for Home Care applauds the President's commitment to providing needed long-term care to the millions of Americans with chronic disabilities. This crucial component of the Health Security Act will help make the promise of health care for all a reality for the young, the elderly, and all disabled Americans.

We especially applaud the President's reliance on home care as the foundation for this new federal long-term care program. Home care has a long and distinguished history of caring for individuals of all ages in the setting they like best—in their own homes where they can maintain their dignity, their independence, and their individuality.

NAHC has several concerns regarding the President's plan that we think should be carefully considered. First, of primary importance is that the program should be adequately and realistically funded. The promise of long-term home care will not become a reality until real funding sources are proposed to meet the needs. The President's proposal uses massive new Medicare cuts, along with an excise tax on cigarettes for the long-term care program.

NAHC is opposed to the proposed cuts in the Medicare home care benefit contained in the $124 billion in proposed Medicare cuts. Home health care has already been hit hard by administrative cutbacks in the Medicare cost limits and this year's reconciliation bill, and the proposed new cuts could seriously jeopardize patient access to care. We hope Congress will choose not to enact such deep and imposing cuts in the Medicare program. In addition, cost estimates show that revenues from the cigarette excise tax are expected to diminish over time.

Both the near-term and long-term revenues for the long-term home care program are somewhat in doubt. NAHC strongly believes that funding for a long-term care program should be broad-based and progressive, and reliable for many years to come.

A second concern is that the Administration's proposal may not meet the needs of all Americans in need of long-term care. Primarily due to financing pressures, the Administration has chosen to limit the program to individuals with limitations in three or more activities of daily living (ADLs). This is indeed a very needy population, but it leaves on the sidelines a large and growing number with limitations in two or fewer ADLs who are equally in need of care. It is important to note that an individual unable to carry out even one ADL can be extremely disabled and in need of long-term care. For example, an elderly individual, living alone with no family or other caregiver close by, who needs assistance with only one ADL, such as eating, would benefit greatly from a relatively small amount of long-term home care.

We understand the need to begin new programs conservatively, but we hope that the Administration will work to provide long-term care to all those in need within a reasonable timeframe.

A third issue of concern to home care providers is that of case management. The President's long-term proposal would allow all qualified entities, including home care agencies, to perform case management functions. We support this permissive language that would enable each state to choose case managers for their programs. Many home care agencies perform these important functions today and resist the notion that only a separate additional agency can correctly perform important case management functions. Outside case management, in many cases, does little more than increase administrative costs and layers of bureaucracy that are placed between patients and providers.

Finally, NAHC is concerned that health care reform plans use adequate quality assurance mechanisms. The use of outcome-based mechanisms is at this time little more than a theoretical possibility. Until such mechanisms are available, NAHC recommends the requirement of standards for organizations delivering in-home skilled services that can be found in the Medicare Conditions of Participation for home care and hospice. For nonskilled service providers, suitable standards can be based on the requirements developed by the Joint Commission on Accreditation of Healthcare Organizations, the Community Health Accreditation Program and the National HomeCaring Council, which have developed special standards for training, testing and supervision of paraprofessional workers employed by home care aide organizations. These provider standards serve as important protections for consumers.

The President's plan also allows eligible individuals to independently contract and supervise home care aides. While there are a limited number of cases where this may be appropriate, the vast majority of individuals eligible for services under the long-term home care program should receive services from qualified home care agencies. In cases where independent providers are used, the legislation should ensure that they are appropriately trained, tested, and supervised as well as provided with basic employee benefits—including health care coverage—and other support.

SUMMARY

Inadequate access to acute health care and long-term care is the single most devastating problem facing America. And this problem will only get worse unless prompt action is taken. Reform legislation must address the need for access to both basic health care coverage, including home care and hospice services, and a comprehensive array of long-term care services based on home care.

Without federal reform, health care costs will continue to increase while access to basic services and long-term care services deteriorates. Congress should make the most of the current climate of support for change and make health care reform a top priority for action this year.

The President's proposal represents a paradigm shift toward federal coverage for care in the home setting. We are excited and optimistic about the potential for this landmark change. The National Association for Home Care looks forward to working with this Committee toward enactment of a health care reform plan that will contain the increases in health care costs while achieving universal access to high quality care.

STATEMENT FOR THE NATIONAL GOVERNORS ASSOCIATION

THE GOVERNORS' POLICY ON LONG TERM CARE

The nation's Governors recognize that in the absence of a national long term care policy, the burden of the cost of care falls primarily on individuals and their families. Unfortunately, most Americans become aware of the prohibitive costs of prolonged care only when directly confronted by a family illness. For most Americans, it is at that time that they become acutely aware of how unprepared they are to cope with the situation. They quickly learn that public assistance exists for institutional care only when their assets are depleted and learn that even less financial assistance is available for home and community-based care.

As Governors, we are concerned about the high costs of long-term care—care that can ultimately force people to spend their life savings before becoming eligible for public assistance. At the same time, we believe, however, that concern about the cost of care should not wait until the family faces a catastrophic illness. The problem is not just a governmental one and should be dealt with from a number of perspectives including public programs, individual planning through quality private long-term care insurance, and personal responsibility for those who can afford to

pay for care. This multi-faceted approach is essential to address a national need that will grow as our population ages over the next several decades.

Through the National Governors Association, we have called for federal policies that de-emphasize institutional care and encourage home- and community-based care. Institutional care must remain available and be affordable to those who need it. However, we support programs whose goal it is to prevent or delay admission into an institution for as long as possible. Such programs should recognize the essential importance and independence of the individual who has need for such services. The services must maintain and enhance, to the greatest extent possible, that independence. Moreover, these services must work in concert with those support systems provided by family members, friends, and the community. We believe that a federal long-term care policy must include home- and community-based services with adequate consumer protections.

The Governors' commitment to home- and community-based care is reflected in the fact that each of the fifty states now has at least one home- and community-based care program under Medicaid, and many states have state funded programs.

It is within this policy context that we offer, on behalf of the nation's Governors, our comments on President Clinton's new program for home- and community-based care for persons with disabilities as detailed in the Health Security Act (the Act).

PERSPECTIVES ON THE CLINTON PROPOSAL

The nation's Governors support the policy objective of President Clinton's new home- and community-based care program for persons with disabilities. Such a program will begin the important step of redirecting federal policy away from the emphasis on institutional care and moves toward a balance between institutional and home- and community-based care. We believe that federal policy must not force Americans toward the inappropriate use of nursing facilities and other institutional care. If medically appropriate, individuals should receive care and support in the community where they can continue to interact with friends, family, and have access to the social and religious institutions that are the fabric of our society.

Optional Program. Since this program will require the expenditure of state dollars along with federal funds, Governors prefer to have an optional program. In our discussions with the Clinton Administration as well as our reading of the Act, we believe that this program is consistent with that.

Flexibility in Services. As designed, states would have the ability to develop and offer an array of services to program beneficiaries. We support this as an approach that gives us the opportunity to develop a package of services that can address the needs of our citizens in the best way possible. While we understand that this program is intended to provide maximum flexibility for both beneficiaries and the state, another provision of the legislation may limit a state's ability to offer the new program to beneficiaries receiving services under existing Medicaid home- and community-based care waiver programs. Specifically, those "waiver beneficiaries" must receive at least an equivalent benefits package to the package they receive under the waiver program. If states choose to offer different or a more modest array of services under this new program, those individuals would not be able to participate. Rather than deprive those beneficiaries of the opportunity to participate in a program that offers them more control of their care and independence, we suggest that the Act be modified to grandfather the "waiver beneficiaries" so that they can continue to receive the services in this new program that had been part of the waiver program even if the state chooses not to offer those services other new program beneficiaries.

Populations Served. Under section 2102(a)(2)(B)(ii) of the proposed legislation, "the state plan may not allocate such services based on income or other financial resources of such individuals." We cannot comment on the merit of this policy decision since the Governors have no policy on a program that provides for public funding of programs irrespective of one's ability to pay. However, this same provision, for all practical purposes, is inconsistent with section 2102(a)(2)(E)(ii) that requires states to serve low income individuals in "the proportion to the population of the state that represents individuals who are low income individuals." The conflict of these provisions is exacerbated by the fact that states and the federal government are limited in their expenditures of funds. How can a state meet the requirement of service on a first come first served basis as described in (E)(ii) while at the same time keep a tally of low income beneficiaries to assure that it meets the proportional requirements of (E)(ii).

We suggest that either one or the other of the provisions be dropped or include language that holds states harmless if they fall to meet the test of proportionality.

Individual Entitlement to Services. The establishment of a new program, especially a program designed to address an unmet as significant as the one proposed, requires attention to the expenditure of public funds. As designed, this program has a limit on the expenditure of federal funds. Because of this limit, it is essential that the states have the same ability to limit expenditure of their funds. Specifically, states must have the flexibility to expend either a part or all of the federal funds allocated. But if federal funds are exhausted, the state must have the authority to suspend the program until more federal funds are available.

The Act is constructed to assure that there is no individual entitlement to this program. Governors support that position since an individual entitlement to this program, particularly with no income limitations, would be prohibitively costly. Moreover, the Act, as well as statements of Congressional intent, must be sufficiently clear and unambiguous in this regard as to minimize the ability of the judicial system to determine otherwise. We expressed this concern to the President as the program was under development, and we believe that his intent, reflected in the Act, is to give states the same prerogatives and protections in funding this program as the federal government.

Federal Matching Percentage. While the National Governors' Association takes no position on the equity among states of the federal Medicaid matching percentage, we do support the extremely state-favorable enhanced matching strategy for this program, as detailed in the Act. Strategies, such as these, coupled with the state option to implement serve as a strong incentive for states to adopt and implement new federal policy, especially when states have precious little money to implement new programs.

CONCLUSION

In conclusion, we believe that important aspects of this new program are consistent with the goals and policies of the nation's Governors regarding home- and community-based care. More people will be able to receive much needed care in the community with their loved-ones and friends, and this program takes an important step in moving federal policy toward a balance between community-based and institutional care. We reaffirm the importance of establishing this program as a state option and believe that the Act must include language that pre-empts any judicial interpretation of an individual entitlement to services. This is necessary for both the states and the federal government.

Mr. Chairman and members of the Committee, we would like to thank you for the opportunity to submit this testimony.

STATEMENT OF THE NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM CARE

The National Association for the Support of Long Term Care (NASL), represents the interests of nearly 200 companies which specialize in providing an array of medical services, products and supplies to nursing facilities. In addition to our corporate members, NASL has a number of association and associate members many of whom are representatives from the nursing home and long term care sector.

NASL is unique, inasmuch as it brings all the different care programs operating within the nursing home sector together in an integrated, multi-disciplinary view. Our operating coalitions represent six areas of ancillary support: rehabilitation, portable x-ray, clinical laboratory, pharmaceutical, products/supplies and wound care programs. Through our Legislative Council these differing ideas and those of our host industry are brought together into a unified program for improving the quality of services in the extended care and long term care settings.

We wish to emphasize five key points for your consideration:

- ancillary supports (medical services, products and supplies) are necessary components of post-acute caring;
- ancillary support programs are often provided primarily by small, independent businesses;
- the success of these businesses comes because they are meeting identified patient needs;
- healthy competition among these businesses has improved the efficiencies of delivering ancillary support programs; and,
- these ancillary support programs make a major contribution to the quality of patient care.

Our testimony is divided into three parts. First, we will address the broad issues raised by the various reform measures and offer our viewpoints. Second, we will address several of the proposed reductions in Medicare, explaining why we opposed

these changes. Finally, we will focus on the extended and long term care proposals and offer our analysis for your consideration.

I. BROAD ISSUES

After careful analysis our Legislative Council has made the following recommendations:

1. Access: We are supportive of the access goal articulated by the President. Too many Americans are denied health care because of pre-existing conditions and discriminatory insurance practices; too many others cannot afford adequate coverage. Something must be done. While supportive of the goal articulated by the President, we are concerned that the solution proposed in The Health Security Act is too cumbersome and bureaucratic. We urge Congress to focus on the problem of access for those without coverage rather than attempt an experimental rewriting of the total system.

2. Employee Mandates: As small businesses and employers of many part-time employees, we are concerned that an employee mandated system would threaten the economic survivability of our enterprises. Given a large portion of our patients are Medicare and Medicaid eligible, we believe the Congress must make provision for the costs of such mandates. If they are enacted, Congress should enact a direct pass-through in reimbursement.

3. Simplification: We laud this goal. Simplification must occur not only in patient invoicing but in the redundant documentation required to justify our services. Our businesses are drowning in seas of paperwork generated to satisfy the oversight functions of multiple layers of government and insurance scrutiny. Hopefully, the reform system will start with the premise: "pay for caring" rather than "pay for paperwork."

4. Coverage: We strongly believe the Congress should statutorily define the core benefit package. Who gets what, where, and how are policy questions best addressed in an open forum where the politics of the decisions are understood as a given. The individuals responsible for designing coverage must be accountable for their decisions.

5. Cost Containment: As specialized businesses focused on providing services to specialized populations, we are frightened by the simplicity of many of the cost containment ideas advanced in a number of the reform packages. Global budgeting, pricing caps, competitive bidding, mandated fee schedules are great academic concepts which will drive small businesses out of the system. Many of the ideas proposed in the reform packages appear to reinforce the "big dogs eats first" rule. Our businesses grew because the "big dogs" i.e., hospitals, doctor practices, mega-health conglomerates were not meeting the specialized needs of individuals. Unless caution is exercised in segmenting containment initiatives, the net result will be to disrupt services, rather than to contain costs, i.e., the "big dogs" will stay fat, patient services will suffer.

6. Provider Discrimination: An underlying tenet of the free enterprise system is that competition brings cost efficiencies and improves quality. In order for these market forces to work, consumers must have choice. Proposals which attempt to restrict "any willing supplier" or which attempt to impose "single source monopolies" undermine choice. NASL urges the Congress to prevent provider discrimination.

7. Fairness and Due Process: Many of the reform proposals add significant requirements to providers with limited consideration of how these changes will be implemented. Pages of new fraud and abuse requirements are proposed; authorization is provided to new layers of government and quasi-governmental entities to impose rules and standards. The career paths in health care are increasingly away from the playing field of patient care services to the cushy jobs of overseeing and regulating. Measures which strip due process will only accelerate this trend. Balance must be restored; adequate notice, opportunities for public comment, and due process must be preserved.

II. MEDICARE/MEDICAID REDUCTIONS

Members of the NASL Legislative Council are unanimous in their view that health care reforms should not be paid for on the backs of Medicare beneficiaries and Medicaid recipients. The demographics of utilization clearly underscore that prudent decisions must be made to assure the integrity of the services purchased through these two programs. We are particularly concerned about three of the ideas proposed in the President's recommendations.

1. Competitive Bidding: We strongly oppose competitive bidding. Monopolies, whether sanctioned by the government or formed in the absence of vigorous anti-trust enforcement are anti-competitive. The net effect will be a deterioration of qual-

ity, difficulties in beneficiary access, and an elimination of competitive market behaviors. Sole source franchising will destroy small business. In the absence of market alternatives, the initial cost savings will evaporate and government will be locked into arrangements with no market alternatives.

2. **SNF Routine Services Limits:** We strongly oppose the idea of lowering the routine cost limit variance for skilled nursing facilities from 112% to 100% of the mean. This proposal would undermine Congressional initiatives to broaden access to high quality extended care services for Medicare beneficiaries. Racheting down routine cost limits will be a significant disincentive for those facilities which have moved to attract heavier care patients. It will reduce access, not improve access for patients, and its impact would be most felt in major metropolitan areas, especially in the Northeast and California.

Cost limits have been straitjackets inhibiting responsiveness to changing patient needs. As nursing facilities move to meet the needs of patients being discharged quicker from hospitals, an enlightened policy would be for the Congress to ease the routine cost limits, exploring alternative strategies for speeding exceptions from the limits and/or permitting a separate classification of subacute programming.

3. **Clinical Labs:** Policy recommendations should consider the differences between providing laboratory services to residents in long term care facilities from the delivery of such services in the acute and community settings. We are greatly concerned that policy recommendations do not differentiate between the types of services being purchased in the nursing home setting and the unique needs of the beneficiaries receiving the services. Most long term care facilities do not have their own clinical laboratories, and, therefore they must contract with laboratory suppliers to obtain this service. The provision of such specialized services is most demanding and costly. Service demands drive higher operating costs. Specially-trained and experienced lab phlebotornists supervised by senior clinical staff are required to meet the higher acuity levels of nursing facility residents. Additional costs are incurred as these practitioners travel to the facility in order to draw and collect samples. Moreover, facilities are more conscious of their regulatory obligations under the OBRA 87 requirements contracting for labs to be capable-of provided full service 24-hour, 7 day-a-week service.

For instance, stat (emergency) work requires a turn around of between 2–4 hours. Working with the facilities to assure attentive patient caring, many laboratories provide technical assistance in interpreting results and in meeting special patient monitoring needs. It is important to recognize that while the readiness to service costs are built into reimbursement in the acute setting, in the long term care setting these costs are shouldered by the clinical laboratory. As the medical acuity of nursing home patients increase, demands for laboratory performance have also increased, however reimbursement has not kept pace with expectations. In-service education, monthly chart reviews, standing order systems, summaries of test results and clinical data reports ranging from infection control and nutrition reviews to therapeutic drug histories are demands placed upon clinical laboratories in the long term care setting which are not reflected in current and proposed payment systems. Our fear is these specialized services will not be available to nursing facility residents, especially under competitive bidding proposals, and the progress which has been made in improving the quality of laboratory services to nursing home residents will be undermined. Unless separately considered, nursing facilities will have few cost effective options for meeting the needs of their residents.

III. EXTENDED/LONG TERM CARE

As experts in the delivery of ancillary services in the extended care setting, we applaud the consideration which is being given to improving extended and long term care services. Reform initiatives which do not address issues of transition from acute to longer term services will be most disruptive; proposals which do not address long term care are incomplete.

The nursing facility sector has been evolving over several decades from programs oriented to sheltering and protecting to programs oriented to caring and discharging. OBRA 87 reforms accelerated this evolution, imposing a myriad of requirements on nursing facilities transforming them into the mainstream of post-acute services. NASL members currently provide many of the supportive services which help nursing facilities comply with the Congressional directives. Our ancillary supports—rehabilitation, clinical laboratories, portable xray, pharmacy services, specialized products and supplies—bring the medicalized services of the acute setting to the extended care environment.

1. **Preserve Core Benefits for Nursing Facility Residents:** Unless the reforms of the past decade are to be ignored, these services must be required in the

core benefit package, and specific instructions provided to health plans to assure access for subscribers who reside in nursing facilities to necessary ancillary support services.

2. Improve Medicare Extended Care Benefit: Congress has the opportunity to greatly improve upon current Medicare policy. The extended care benefit which is authorized under current Medicare law provides only shallow coverage. Few beneficiaries are covered for more than 30 days of skilled nursing services and many are denied access because of restrictive prior hospitalization requirements. Stringent copayment and medical review criteria have so narrowed coverage as to make the claim of 100 days of extended care coverage a fraudulent statement.

3. Enact meaningful long term care reforms: The reform initiatives offer an opportunity for change. Several of the plans call for a 100 day extended care benefit. We urge the Congress to enact such coverage as a minimum. We urge Congress to remove the three-day prior hospitalization and to alter the copayment requirements under Medicare. Nursing facilities are stepping up to the challenge of caring for heavier care patients and reimbursement and certification requirements should facilitate sub-acute programs.

4. Exercise Caution in developing SNF Prospective Reimbursement: One of the ideas which has been proposed is shifting reimbursement for skilled nursing facility services under Medicare to a prospective payment system. Initiatives are underway within HCFA exploring the appropriate methodologies for categorizing patient needs and grouping these needs for payment. Because of data availability, these demonstrations have focused primarily on routine nursing services; few ancillary needs are being analyzed. Given this significant flaw in the research designs, we urge caution in making the reimbursement transition. HCFA should focus first on completing its design and implementation of a system which captures the routine services, continuing the current reimbursement methodologies for ancillary programs. Separate data collection and analysis will be required to design a more inclusive system which is fair to patients and which capture the evolving role which ancillary services perform. Simply stated, nursing facilities are rapidly becoming something different than they use to be and the change is being driven by ancillaries. Premature conversion of reimbursement systems will stifle change. The potential for error is particularly great because there is so little data to predict what might occur. Let us be clear, NASL supports the movement towards a prospective system for routine services, but we urge that ancillaries be considered separately.

IV. CONCLUSIONS

The health care reform debate challenges the Congress to make a series of major decisions reshaping and restructuring the health care delivery system. We have attempted in this testimony to offer constructive guidance, soliciting your understanding that a very specialized ancillary services structure has emerged meeting the unique needs of the nursing facility sector. These ancillary programs are cost effectively meeting a real market need. These ancillary services might be significantly harmed in the restructuring decisions. Patient care will suffer; nursing home reforms will erode.

NASL stands as a resource to work with you and your staffs so that policy changes will continue to improve the quality of services in the long term care setting.

STATEMENT OF THE NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE

Mr. Chairman, members of the Committee, I am Martha McSteen, President of the National Committee to Preserve Social Security and Medicare. The National Committee is a grassroots advocacy organization representing millions of senior Americans. Both prescription drug and long-term care coverage are important components of health care reform.

Overall, health care reform should result in comparable coverage, tax treatment and cost containment for seniors and non-seniors. We fear anything less will inevitably result in continued unequal treatment and possible access to care problems for seniors. In summary, the National supports the following health care reform principles:

(1) quality health care coverage and equality of coverage for all Americans;

(2) a basic benefit package for both private and Medicare-covered with emphasis on preventive care, reasonable drug coverage and limits on out-of-pocket costs;

(3) individual choice of physicians and other providers;

(4) home and community-based long-term care benefits with equitable, broad based financing;
(5) effective cost containment, both private and public;
(6) equitable, fair financing of health care reform by all sectors, including any means testing of health care benefits; and
(7) effective consumer protections.

FINANCING

The National Committee is well aware that finding acceptable financing proposals to fund health care reform will be the major stumbling block to reform. With this in mind, we are equally concerned about the level of Medicare savings proposed in the President's plan and about making sure that all of these savings be used to fund prescription drug and long-term care benefits.

Medicare may not be able to absorb the level of savings proposed by the President without harming access and quality of care for Medicare beneficiaries. The National Committee urges Congress to heed closely the advice of the Prospective Payment Assessment Commission and the Physician Payment Review Commission which has raised concerns about the Administration's proposed Medicare savings. The Administration's proposal would prescribe an equally strong dose of cost containment for the private sector also. Medicare beneficiaries expect comparable treatment; they do not want to be singled out.

Most but not all of the proposed savings would be reductions in reimbursement to doctors and hospitals, but some of the "savings," would increase out-of-pocket costs for some seniors a net $13 billion over five years. Others have proposed beneficiary cost-sharing triple this amount. Most Americans, seniors included, are expecting health care reform to make health care more affordable, not less. This kind of cost shifting is not real cost containment. Some trade-offs may be acceptable, but the first reaction to increases in out-of-pocket costs will naturally be resistance. The National Committee also continues to oppose increasing the Part B premiums on upper income beneficiaries while leaving the tax deductions in place for employer paid health insurance for upper-income wage earners.

If Congress limits the Medicare cuts, will it come up with the additional financing needed for both a Medicare prescription drug benefit and a new home and community-based long-term care benefit for the severely disabled of all ages and incomes? The National Committee firmly believes that coverage for these benefits is cost effective in the long run. Failure to cover these services when appropriate can mean that some do without treatment, which may lead to more expensive treatment later, or they seek more expensive covered treatment immediately. And long-term care not only benefits disabled seniors but also other disabled individuals as well as caregivers of all ages.

It seems only fair that all individuals should be treated the same, but usually that treatment is not extended to tax deductibility. If an employer or former employer provides health insurance, even insurance which has no deductibles or co-pays, the individual does not pay income tax on the employer contribution. In contrast, workers and retirees who must pay for supplemental insurance or who have out-of-pocket costs must use after-tax dollars. Equal tax treatment would make it easier for individuals who do not have assistance from an employer or former employer to pay for supplemental insurance or out-of-pocket costs.

PRESCRIPTION DRUGS

The National Committee applauds the President's proposal for expanding Medicare to include outpatient prescription drugs. For seniors, prescription drug costs represent an almost universal Achilles' heel, and it's easy to understand why.

In recent years, prescription drug price increases have been triple the rate of inflation. At the same time, seniors need more prescriptions than those under 65 and often have little or no insurance to cover the cost. A 1992 poll of National Committee members shows that medications are their single largest out-of-pocket health care expense. Monthly drug bills amounting to hundreds of dollars are not uncommon for seniors.

For a senior receiving the average Social Security benefit, an annual prescription drug cost of $1,000 eats up almost two entire months of benefits. Among National Committee members with yearly out-of-pocket drug costs of $1,000 or more, one-fourth of them have an annual income of less than $15,000. A Medicare beneficiary who must spend $1,000 a year out-of-pocket on prescription drugs to control some chronic life-threatening disorder may be more vulnerable than a healthy 25-year-old who is completely uninsured.

Being very cost conscious, seniors do have some sticker shock at the proposed additional $11 a month premium. Seniors already pay $41 a month—more than nonseniors would be expected to pay for health insurance under the Administration's plan. They may also worry they will not receive a benefit because they must have more than $250 in prescription drug costs in addition to physician and hospital bills. The Administration estimates that 58 percent of Medicare enrollees can look forward to some benefit annually because they will have more than $250 in prescription drug expenses. Beneficiary support for a prescription drug benefit would erode, however, if the deductible was raised significantly.

Another problem is that thirty percent of seniors have prescription drug coverage included in their retiree health benefits and therefore will experience increased costs without deriving any gain from a new Medicare prescription drug benefit. These National Committee members have asked us to recommend that the new drug benefit be made an optional Medicare Part B benefit. The new drug benefit could work something like the Medicare secondary payer provision. In other words, if the Medicare beneficiary had prescription drug coverage under a retiree health plan, then Medicare would not provide the coverage and the beneficiary would not pay the additional Part B premium.

If the retiree health plan eventually is cut back as many businesses are doing, then the enrollee could sign up for the Medicare benefit without paying a late enrollment penalty which would otherwise be appropriate. The Office of Technology Assessment also points out an additional benefit of preserving drug coverage in retiree health plans is the favorable impact on costs from mostly managed drug plans.

Most other Medicare beneficiaries will ultimately recognize this as a valuable benefit well worth the additional premium. Seniors are generally risk adverse, frequently purchasing medigap policies of marginal value on limited income. This Medicare benefit is a bargain since the premium only covers 25 percent of the cost. It is also a bargain compared to the incremental premium charged for inferior prescription drug coverage provided through medigap insurance.

In a larger sense, the high cost of prescription drugs helps drive up health care costs. Recent studies suggest that seniors who are faced with inordinately high drug bills feel forced to ration by splitting their medication in half, taking smaller doses or doing without it altogether. Additionally, many seniors take medication improperly. Adverse reactions from medication non-compliance and other factors account for 10–25 percent of all hospital admissions for persons 65 years of age or older.[1] If these seniors didn't have to be admitted to the hospital, Medicare could save $4–10 billion annually. This is another good reason for supporting the Administration's proposed drug coverage and drug utilization review.

One controversial feature of the Administration's proposal is cost containment for prescription drugs. Senior citizens should not be at the mercy of drug company retail pricing policies, especially when these same companies provide discount drugs to other large purchasers or citizens of other countries. The Administration proposal would mandate rebates which will save the Medicare program and will keep premiums lower. But it would not reduce out-of-pocket costs for the deductible and copays which will continue to be based on the retail price before the rebate. Medicare beneficiaries do share some of the concern that cost containment, especially the federal committee to review the prices of breakthrough drugs, would discourage research in the cure and treatment of Alzheimer's and other diseases. Safeguards against price gouging are needed, but not to the extent of discouraging valuable research.

LONG-TERM CARE

The National Committee applauds the President for including several long-term care initiatives in his proposal. The awesome financial burden of long-term care for chronic conditions threatens seniors, their spouses and families with bankruptcy. Nursing home care costs an average of $25,000 to $30,000 a year-much more in some places. Few Americans have any protection from this kind of expense. In a nationwide survey of the general public conducted for the National Committee in 1992, seven out of 10 respondents said they could not afford the cost of nursing home care if a family member needed it.

Americans are offered few options when it comes to long-term care. Instead, individuals and families often are forced into poverty before they qualify for government assistance to help pay for nursing home care. Most Americans do not want to see their loved ones forced on to welfare to pay for nursing home care. One key to pro-

[1] Edward, T. Lonergan, Ed., *Extending Life, Enhancing Life,* Committee on a National Research Agenda on Aging, Institute of Medicine. 1991, p. 96–7.

viding cost effective, long-term care is to make available more options to keep frail seniors in the community. In fact, by more than eight to one, National Committee members prefer a comprehensive long-term care home care benefit over a partial nursing home care benefit of equal value.

The most important initiative is the new federal-state matching grant for home and community-based care. In addition to commenting on this plan, we will also discuss Medicaid nursing home improvements and private long-term care insurance regulations.

Community-based long-term care

The Administration proposes a home and community based long-term care program for the severely disabled of all ages and all incomes. This is an important step towards full protection against the financial devastation of long-term care. Except for the single payer reform proposal, the Administration's proposal is the only reform proposal which has long-term care.

This benefit fills in a serious gap between hospital care and nursing home care. Hospital care is financed by Medicare and nursing home care is financed by Medicaid for the poor. But there has been limited public assistance to individuals who want to remain in the community. This is also the first government long-term care program whose beneficiaries are not limited by age or income-a major breakthrough.

On balance, the National Committee supports state flexibility in the Administration's long-term care proposal because many states already have innovative initiatives and new federal dollars can build on these well-developed programs. State flexibility also allows a care plan to be tailored to the needs of the individual rather than the individual being pigeon-holed into a specific benefit category. State flexibility should not go so far that some states do not offer the benefit. It is also essential that a state-mandated, fully-funded, community-based long-term care benefit be available in all state.

Of course, the National Committee would prefer that eligibility was not limited to just the severely disabled and that the program could be phased in faster. But the new funding is bound to help many more people receive the kind of assistance they need and flexibility should help states stretch the new dollars to help as many people as possible.

The National Committee is still concerned about states who have not gone as far as other states in developing home and community-based programs or who may be reluctant to even sponsor the program because of the matching funds the state may have to come up with. The lack of individual entitlement means that adequate financing is imperative so that care is not disrupted at the end of a year.

Other complementary policies should be pursued to provide additional assistance to individuals in need of home care, especially those who are not so disabled as to qualify for this new program. One possibility is the use of reverse mortgages to pay for home modifications or to provide additional services. FHA could provide certain protections for disabled Americans.

Co-Payment The National Committee believes co-payments for home and community-based services of no more than 25 percent could be applied while still protecting the poor from out-of-pocket costs. If there must be a co-payment, the National Committee would limit it to no more than 25 percent. However, the Pepper Commission recommended a 20 percent co-payment.

Consumer empowerment. The National Committee welcomes the strong consumer involvement in the development of the state plans and the emphasis on self-determination in the home and community-based benefit. The plan calls for the disabled to provide, through an advisory council, substantial input into the development of the state plan. It also intends for states to allow consumers of long-term care benefits considerable flexibility through vouchers or cash payment. Consumers could hire their own attendant or buy their own services. They could even pay a family caregiver to take care of them. A cash payment could provide an important sense of independence rather than the guilt that often comes with being a burden to one's family. States should still assure that caregivers are trained and should periodically have certified care managers assess the care.

Choice of services. While the intent of the legislation clearly is for states to offer a variety of long-term care services, it only mandates personal assistance. Some states may therefore limit benefits to the minimum requirement and thereby eliminate consumer choice. A program rigidly limited to personal assistance cannot serve the differing needs of severely disabled individuals. Adult day care, for example, can provide family respite, rehabilitation and socialization. Transportation should be covered because seniors could lose their independence without it. The National Committee believes more services should be mandated.

Federal Advisory Group. The National Committee agrees with the proposal to create a federal advisory group, and we recommend that it be modeled after the Physician Payment Review and the Prospective Payment Assessment Commissions. It should have a staff capable of performing the background work necessary for the advisory group to make decisions and carry out its advisory responsibilities. This panel of experts should begin to make recommendations on the myriad of issues related to long-term care. For example, the development of guidelines or standards for care management, adult day care and other services; development of a standardized assessment tool that would be compatible with the assessment tool used in nursing homes; development of a sensible payment system for different levels of care or case mix; the analysis of the infrastructure of long-term care and the identification and promulgation of best practice models around the country; best ways to assure quality of care; and the development of standardized data systems for collecting data. A central entity is needed at the federal level to move the country towards better integration not only of long-term care services, but also acute and long-term care services.

Approval of State Plans. When states decide to participate in the long-term care program, they are required to submit a plan satisfying at least eleven criteria spelled out in the proposed legislation. These criteria are all relevant and are not likely to be perceived as too burdensome to states. The legislation, however, does not spell out what guidelines—preferably standards—will be used at the federal level for approving plans. A national program—even if state run—should have national standards, but allow for maximum flexibility in a state.

Acute and Long-Term Care Demonstration. The Administration proposes separate programs for acute and long-term care, but that is mostly because we don't yet have enough experience in designing programs that integrate acute and long-term care. The Administration is taking a step in that direction, however, by proposing to expand the demonstrations. Ultimately, the integration of acute and long-term care in a managed care framework may be the most effective way to provide long-term care services to consumers. One of the biggest barriers to consumers currently is the structural fragmentation in the delivery of care. In our current system, providers focus first on whether an individual qualifies for a specific program rather than focusing on designing an appropriate plan of care for that individual.

Medicaid Nursing Home Improvements

The Administration initially proposed several changes in eligibility for Medicaid nursing home benefits but backed off some of them in response to state concerns about the cost. As a result, the proposed changes are very modest, costing only $2.5 billion over five years.

Asset Protection. Under the draft plan, the amount of assets that could be protected and still qualify for Medicaid was going to be increased from $2,000 to $12,000. In the final plan, this became a state option. Given the additional cost to states of raising the asset limit, we are concerned that many states will retain the $2,000 limit. The National Committee frankly regrets that the President's plan would not do more for nursing home residents. For example, the Pepper Commission recommended that Medicaid residents be able to protect $30,000 in assets.

Needs Allowance. The draft plan was going to raise the personal needs allowance for Medicaid nursing home residents from $30 to $100 which was recommended by the Pepper Commission. First it was lowered to $70. Now it is only $50 and the federal government has agreed to pick up the full cost of this proposal rather than imposing a share of the cost on the states. The needs allowance is all that the resident has to spend on personal items. Five states already have a personal needs allowance at or above $50 a month, which is less than $2 a day for spending money. The national average is $35.

Medically needy. The National Committee is pleased that the medically needy provision will be extended to the 15 states who have not approved this option. Under the medically needy program, individuals who have income above the cut-off point could still qualify if their medical expenses, such as nursing home care, were greater than their income. This will be good news for some National Committee members whose incomes are just a few dollars above the limits in these states.

Nursing Home Quality. The Administration's proposal says nothing about the need for increased financing required to improve care in nursing homes. An adequate minimum staffing standard is needed as well as a mechanism to assure appropriate funds are used for direct care. Both licensed nurse and nurse aide staffing is inadequate in nursing homes across the country, according to a National Committee study.

In addition, current federal regulations do not assure protection of the Nursing Home Reform Act to private pay residents. These protections should be extended to all nursing home residents living in Medicare and Medicaid certified facilities.

Long-Term Care Private Insurance

The Administration also proposes to regulate long-term care private insurance and to provide tax incentives for the purchase of long-term care private insurance. While private insurance alone cannot solve the long-term care problem, it is an important piece to the long-term care solution. The number of people willing and able to purchase long-term care policies, while still relatively small, is likely to increase as the baby boom generation matures. Federal regulations, similar to Medigap regulations, however, are needed to protect the consumer. Without reforms such as mandatory inflation protection, mandatory non-forfeiture, simplification and counseling, many will end up with a false sense of security. While many of these regulations have a cost, anything less is not worth the premiums being paid.

Premium Rate Stabilization. Consumers of long-term care insurance—especially older consumers who are out of the job market-need protection against large and unpredictable premium increases. Caps on premium increases control the risk to the purchaser-which is the primary purpose for buying insurance. Policies should be required to at least contain these three features: a cap on life-time premium increases; limits on frequency and size of periodic premium increases; and no premium increases beyond a certain age. For example, policies could be limited to a life time increase of 100 percent, a maximum increase of 20 percent every five years, and no increase after age 75.

Non-forfeiture. The National Committee supports mandatory non-forfeiture benefits. Protection must be awarded policyholders who have paid premiums for years and, perhaps due to declining health and added medical expenses, no longer can afford the policy-often just when they need it the most. The balance is between meaningful benefits and affordability. Life insurance policies are required to have a non-forfeiture clause. There is no reason why long-term care policies should not have to provide similar protection. We support a non-forfeiture benefit design that would guarantee a shortened benefit period after a minimum number of premium payments. This is preferable to a cash benefit which could induce lapses.

Inflation protection. Current generation long-term care policies generally include the option to purchase an inflation protection rider. The National Committee believes it is essential to incorporate in all policies this inflation protection as a standard benefit. If inflation protection continues to be optional, consumers of long-term bare policies need to be educated about the importance of having inflation protection. A nursing home bed that today costs anywhere from $45 to $200 a day may double in price in a few years.

Standardized Benefit Products. With federal standards, insurance products are expected to become easier to understand with simple summaries and standardized language. However, the National Committee recommends that a further step be taken. Long-term care insurance products should follow the Medigap example and be offered to consumers in standard benefit packages to further simplify policy comparisons.

Consumer Complaint and Dispute Resolution. The National Committee is pleased to see that under the Administration's proposal states are required to establish administrative procedures to investigate and resolve consumer complaints and disputes between consumers and long-term care insurers. It is important that State Insurance Commissioners can prohibit the sale of policies that fail to comply with applicable requirements. The Federal oversight in the Administration's proposal is also welcomed.

The National Committee has a long history of advocating for federal standards for private long-term care insurance and is therefore pleased that the Administration plan includes such provisions. The plan establishes an advisory council to develop the standards but requires that certain provisions go into effect six months after the enactment of the law regardless of whether regulations have been published.

CONCLUSION

In conclusion, the National Committee looks forward to working with you to fashion a health care reform bill that is equitable to all Americans. At a minimum, we believe there needs to be prescription drug coverage and a meaningful home and community based long-term care benefit for all Americans. Financing must be fair and cost containment must be across the board.

STATEMENT OF THE PRESBYTERY OF BALTIMORE PRESBYTERIAN CHURCH (USA)

I. INTRODUCTION

This testimony supports the need for, and advantages of, including long term health care as a part of the Health Security Act. The testimony has been prepared for the Senate, Committee on Finance by the Public Policy Team of the Peace and Justice Committee, a standing committee of the Presbytery of Baltimore, a part of the Presbyterian Church (USA). The Public Policy Team is composed of eighteen Presbyterians including both pastors and lay people, with a wide range of background and experience, living in Baltimore and the surrounding area in Maryland. The Public Policy Team, representing a community of faith, seeks to advocate for the common good and to speak for the voiceless in our society.

The Public Policy Team believes that our duty as Christian citizens is to advocate for a national health care reform plan which provides access to health care for all people who live in the United States, provides affordable coverage for all people without regard to employment status or where they live: provides the whole population of the nation with comprehensive benefits, including: prevention services and health promotion, primary and acute care, mental health care and long term health care: guarantees access to care everywhere in the nation; promotes effective and safe innovation and research in health care techniques, research on the delivery of health services, and research on health practices of individuals and families: assures the quality of health care services through monitoring care delivery and evaluating quality based on objective study of outcome: provides funding for nationwide health education and wellness promotion: reduces the financial burden on the health care delivery system of malpractice litigation: significantly curbs the current rapid inflation in the cost of providing medical services: reduces unnecessary medical care; and draws financial support from the broadest possible resource base.

The Team believes the universal availability of long term health care to those in need of it to be an important part of the Health Security Act, or of any other national health care reform plan which may be proposed by the Senate, Committee on Finance for adoption by the Senate and the Congress. This is a need which is currently not being adequately met in the United States, and one which will become increasingly critical as the number of elderly in our population continues to increase in the next several decades. Consequently the Public Policy Team offers the following testimony stating the background from which our interest in the health care reform process springs, our concerns, our desired objectives, the rationale supporting those objectives, and our conclusions.

II. BACKGROUND

The Presbyterian Church has addressed the need for a national health care plan, and identified the critical requirements of such a plan, in statements made by its General Assemblies in 1946, 1976, 1988, 1991 and 1993. All of these statements reflect the strong conviction that based on Biblical and theological convictions the members of the Presbyterian Church, as a part of their Christian commitment, should engage in advocacy for universal access to, and universal coverage under, any proposed national health care plan. It is clear that "universal access" means access by all peoples of all ages and situations; and that universal coverage must include long term health care for the disabled, chronically sick and elderly. On this basis the public Policy Team of the Presbytery of Baltimore strongly advocates a national health care plan that includes long term health care plan for all residents of the United States.

III. OUR CONCERNS

We know that there are in this country many retirement communities and long term health care providers with excellent facilities, unfortunately there are also a good many others with below standard facilities: however, existing capacity may not be adequate to handle all those who need the services of long term health care facilities. The Federal Government already has in place a widespread system for financing long term health care through the social Security, Medicare and Medicaid Programs. These programs pay for the care of about half of the patients now in nursing homes and other long term health care facilities. Supplementing the federal programs are family support, charitable facilities, and the many various commercial insurance plans some of which are of very doubtful value to the insured. The Team wishes to raise the following specific concerns about the present situation and the process through which reform is being attempted:

- That, due to the cost pressure under which the process of devising and adopting an affordable national health care plan is being carried out, the long term

health care provisions of the plan which eventually emerges may be reduced to an inadequate level, or possibly even eliminated, to keep the cost of the overall reform program within acceptable limits.

- That the preexisting level of coverage for long term health care may be inadequate for some situations. In those cases we urge that the level of coverage be increased, as has been proposed by the President, by enhancing benefits under Medicaid.
- That, in view of the financial strain anticipated for long term health care funding through existing programs in the coming years, as the number of elderly in our population-and especially the number of people over 75 years of age-increases, more attention should be given to improving the efficiency of the present long term health care delivery system and to developing alternate means for financing long term healthcare.
- That improvements are needed in the present Medicaid Program to prevent its abuse by persons who have sufficient resources to provide for their own care. On the other hand, the maximum financial resource level to qualify for Medicaid may be unfairly restrictive.
- That although regulations for nursing homes have been recently established, they need to be improved and vigorously enforced; in the past many nursing homes have been operated under extremely poor conditions and have provided woefully inadequate service to patients. to care for persons who are able to care for themselves except perhaps for preparing meals and handling their own medications—in a full service skilled care facility.

Since the federal programs (Social Security, Medicare and Medicaid) already in place provide approximately half the funding for long term health care in the United States the most cost efficient way to extend long term health care financing would be to expand the Medicare and Medicaid programs. This approach avoids creation of a new agency with its attendant administrative overhead. Contrary to popular wisdom, Medicare is an efficient program with about 3 percent overhead. This is borne out by Government Accounting Office reports. For example GAO/OCGXX–93–STR Health Care Reform published in December 1992 states on page 19: "In the United States, nearly 6 percent [other reports put the figure at 5.8 percent] of total health expenditures in 1989 were accounted for by the administration of government health programs and private insurers . . . . Administrative expenses for private insurance plans average about 12 percent . . . ." From this it is clear that the government health care funding bureaucracy, as a whole, is more than twice as efficient as the private health care insurance industry since the average for private health care insurance industry administrative costs is twice the average for all administrative costs, and Medicare is about four times as efficient as the private health care insurance industry.

Existing qualification standards for Medicare and Medicaid would be the logical basis for qualification under a national long term health care plan. These standards and the procedures by which it is possible to protect assets from 'spend down' in order to qualify for Medicare or Medicaid should be examined carefully, simplified and clarified as necessary to make them easily understood, fair and equitable. For example, the amount of assets, excluding a home, household goods and personal effects, the spouse at home can keep when their spouse attempts to qualify for Medicare or Medicaid varies widely from state to state (in 1992 it ranged from $13,740 to $68,700). This needs to be made uniform, and $13,740 seems a very low limit Wherever the limit on assets may be set it seems reasonable for the limit to be indexed to inflation. Existing regulations concerning the type of care covered under Medicare and Medicaid when rendered in the client's home, or at an adult day care facility, should be reevaluated and changed to allow more efficient and cost effective care for the more able clients. Home and adult day care not only conserves resources it improves the quality of life for the older or disabled person who is enabled to live in their home while receiving only the level of assistance needed rather than being forced into an expensive nursing home facility where they need very few of the services available and do not enjoy the accommodations, surroundings or atmosphere of the institution.

Private provision for long term health care should be encouraged. This might be accomplished by creating some form of tax-advantaged investment specifically for the purpose, as has been suggested by some or through other incentives. Private insurance is another possibility; however, the insurance industry must be carefully regulated to prevent the abuse which currently bilks millions from unwary senior citizens through confusing language, tricky provisions which cannot normally be met, and raising rates to force the insured to drop the coverage and forfeit much or all of the premiums paid in.

- That the insurance industry preys on the elderly by marketing many long term health care insurance policies under grossly misleading (if not fraudulent) claims, which do not provide adequate coverage for the insured, contain confusing policy language, include tricky provisions which few policy holders can hope to fulfill and are subject to unaffordably large rate increases.

IV. OUR OBJECTIVES

The Health Security Act, or any national health plan adopted, must include long term health care for all those who need it. This would include all elderly, chronically sick and disabled persons who could not otherwise maintain an acceptable quality of health on their own resources.

Benefits under this plan should include a full range of care without complicated or tricky restrictions which in fact prevent many of those who need the care from qualifying for it. The following benefits should be included:

- Home care including meal preparation; house cleaning; shopping and other errands; help with bathing, dressing and other personal needs; necessary transportation; speech, occupational or physical therapy; low level nursing care provided by health care aides; occasional skilled nursing care performed by registered nurses; and visits by a physician when necessary
- Day care including supervised activities, meals, assistance with personal hygiene needs, low level nursing care, administration of medications and other skilled nursing care, and transportation if necessary
- Institutionalized assisted living care, essentially identical to home care but rendered in an institution or retirement community
- Institutionalized custodial care including feeding, bathing, dressing, routine nursing care which does not require the services of a registered nurse or licensed physician, occasional skilled nursing care, and visits by a physician when needed
- Institutionalized twenty-four hour intermediate nursing care
- Institutionalized, twenty-four hour skilled nursing care

The long term health care benefit package should be supported by an extension of, and improvement of, the Medicare and/or Medicaid Programs with the following considerations:

- Evaluate existing qualification standards and procedures to determine if they should be modified to prevent "hiding" of resources by those seeking to qualify for Medicare and/or Medicaid long term health care services, since hiding resources by those able to pay for their care raises the cost of the service or reduces the benefits offered to all.
- Evaluate the present maximum financial resource qualification requirement to determine if the limit is too low and should be raised as proposed in the Clinton Plan, and also, determine whether the limit should be indexed to account for inflation rather than being an arbitrary amount.
- Evaluate the efficiency and cost effectiveness of the system to determine if sufficient emphasis is being given to support of more home and adult, day care facilities which would permit older or disabled persons to live at home while they receive the care and assistance they need.
- That the government encourage private provisions for long term health care by means of tax incentives for the purchase of insurance and/or by establishing a new tax sheltered investment program specifically to provide savings for long term health care.

V. RATIONALE

Long term health care services should be available to all those who need them as a matter of right as a person without regard to their ability to pay for the services. It is inhumane to force those in our society who are poor and in need of long term health care to live grossly diminished lives. This is especially time for those poor who are elderly and those younger poor people who suffer from debilitating diseases or who are disabled. In particular poor people should be provided adequate medical services and such other related health care and assisted living services as are necessary to enable them to maintain at least a minimum acceptable quality of life.

Home care services should be provided to all those who can benefit from them. Forcing a person into a nursing facility when they need only some one to run errands and perhaps cook meals or do housework is costly and usually degrades the person's quality of life. Being independent is highly valued by most Americans and is important to self-esteem. If a person who wants to live independently in their own home is enabled to do so they will live a much happier and satisfying life than they

would if forced into an institution. Home care services, which allow people to continue to live in their own home rather than moving to a nursing facility even though they are not in need of skilled care, are very cost-effective.

Day care for elderly and disabled people should also be provided to those who need it. Day care will often enable an elderly or disabled person to live at home in the care of family members rather than in a costly institution. Day care is not only cost-effective but also usually provides the person a way to live a fuller more satisfying life with their loved ones for many years. The fact that day care also makes it possible for family members, who want to care for their loved one in their home, to work outside their home, or have the time to run necessary errands, or just have some time off, should not be discounted since this contributes greatly to the care giver's quality of life.

Institutionalized care should be a last resort but must be provided for those who have reached the point where living in their own home is no longer practical for whatever reason. Almost half of those over sixty-five years of age will eventually require the services of a nursing facility. A full range of care should be provided but it should be a priority to see that the care provided suites the needs of the person rather than placing people in institutions which provide unneeded services. It is cost inefficient and a waste of professional health care providers' time

CONCLUSIONS

In view of predictions that the number of elderly (over 65 years) will rise to over 31 million by the year 2000, the necessity of finding satisfactory but affordable long term health care provisions is urgent. A primary problem is how to finance the care needed to provide our older and disabled citizens a satisfactory quality of life. The possibility of reducing the present level of support, in order to extend some care to all who need it, is unthinkable.

Achieving a fair and viable system will require our best thinking and resolve and almost surely an increase in public revenues. Although there is universal revulsion at the idea of increased taxes, it should be remembered that all the costs of the present system for long term health care is being fully borne by the American public in one form or another. The current system is inefficient For example, in some cases it forces people into expensive nursing homes in order to be eligible to receive needed simple care when the needed care could easily be administered by unskilled or low skilled providers inexpensively at home or in adult day care facilities. This would satisfy the need, and would actually be preferable to the client.

To realize an expanded and improved program of long term health care through public financing would free much of the private resources now consumed by long term health care and need not necessarily place a new burden on the taxpaying public. If the long term health care delivery system is improved so that needed services could be provided in a more efficient manner, the burden on the public might even be reduced. As noted earlier the federal agencies which administer health care delivery (Medicare and Medicaid) do so much more efficiently than the commercial health care insurance industry. Federal agencies as a whole, are more than twice as efficient on average and Medicare is about four times as efficient. The difference in administrative cost means a potential savings of many billions of dollars each year estimated by the GAO (GAO/HRD–91–90) at $66.9 billion annually and by others at between 22 and 69 billion dollars per year in 1991 dollars.

The Team believes that it is the responsibility of the Senate, Committee on Finance to craft a national health care reform plan which meets the criteria outlined in the introduction to this testimony and which contains provisions for long term health care coverage as discussed above. Common decency, respect for human dignity and compassion for those in need among us require that we plan and implement a fair and efficient approach to providing long term health care as an integral part of any new national health plan.

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