

Remarks on Departure for Tokyo, Japan, and an Exchange With Reporters

June 7, 2000

Clinical Trials/Patients' Bill of Rights

The President. Good morning everyone. We are here at this early hour to talk about a vitally important issue to the health of America's senior citizens—indeed, eventually, to the health of all of us.

We must help more seniors participate in clinical trials that test new therapies for illnesses, from cancer to heart disease to Alzheimers. These trials may prolong lives, and they are central to finding cures for deadly diseases.

Today, America's seniors are badly under-represented in clinical trials, yet they bear the heaviest share of illness. More than half of our cancer patients are over 65, but only a third of those in clinical trials are seniors. For breast cancer, the statistics are even worse.

Today, thousands of important clinical trials don't have enough patients because so few seniors are able to take part, and that means slower progress towards curing or treating illness. One major factor keeping seniors out of clinical trials is patients lack of certainty that their expenses will be covered by insurance. Because Medicare's policies on payment for clinical trials have been unclear, seniors cannot be sure of coverage if they volunteer for experimental care. Many assume they'll be saddled with thousands of dollars in routine medical costs if they participate, and they clearly cannot bear such a heavy burden.

For several years, Vice President Gore has led our efforts to clean up the confusion and help seniors and people with disabilities into clinical trials. We've had bipartisan support in Congress, led by Senators Rockefeller and Mack and Congresswoman Johnson and Congressman Bentsen and Congressman Cardin.

Today, after careful study, I am signing an executive memorandum directing Medicare to change its policy and remove a major barrier to seniors' participation in these trials. Within a week, Medicare will begin to cover

all the routine medical costs of participation in a clinical trial.

The Department of Health and Human Services and the Health Care Financing Administration will begin outreach programs so that patients, as well as doctors, researchers, and administrators, all are aware of the change. We'll ask for the help of advocates for patients and research who have done so much to publicize this issue. We believe that with good outreach, thousands of seniors could join trials this year and make a dramatic contribution to the progress of medicine, as well as to the health of older Americans.

I am also directing today the Department of Health and Human Services to report back to me on ways we can provide additional support to clinical trials that are especially relevant to senior citizens and am requesting that the National Institutes of Health look for ways we can encourage even more seniors to speed science's progress by participating in new clinical trials.

As America ages, we must provide all our seniors affordable, quality health care, and we should be using our cutting-edge science to meet that challenge. Simply put, the more seniors we enroll in trials, the faster we'll be able to use these advances to save American lives. We've done this successfully with cancer in children. For decades now, more than half of all the children with cancer have joined clinical trials, giving us a wealth of evidence about how the disease works and how best to fight it. Now we can cure three-quarters of childhood cancers. That could never have happened without the participation of children in these trials. We should be doing the same for Americans of every age.

Today I've authorized Medicare to help seniors participate. Private health care plans should be doing the same for their members. But it won't happen also unless Congress takes the next step and passes a strong Patients' Bill of Rights. Congress has had that on its agenda for 6 months now in the Norwood-Dingell bill, which includes a requirement that every private insurer cover the cost of participation in clinical trials.

This month, before the summer recess, Congress has a window of opportunity to take

another real step to make our country stronger and safer and healthier. I hope that window will be used, because we need this. If we do the Medicare participation in clinical trials and pass the Patients' Bill of Rights, then all our citizens will be able to participate in these trials, and that will hasten the day when all age groups will be more likely to recover from the most serious illnesses.

Thank you very much.

2000 Election

Q. Mr. President, could you disabuse us of the notion that this is an attempt by the Vice President to curry favor among a group of individuals which have been, in recent years, starting to move away from the Democratic Party during an election year?

The President. Well, I think the only way I can disabuse you of the notion is 7½ years of activity on this and the fact that it has been well known that I have been working on this issue, and so has he, for several months now, trying to work through all the legal and administrative issues necessary to get this done. It's not as if this is just an issue that popped up on the radar screen. We've been working this clinical trial issue alone for years, not only the seniors but with children. This is by no means the first action we've taken in this area.

And indeed, there has been a strong bipartisan interest in this with all the people involved. I mentioned Senator Connie Mack, Congresswoman Nancy Johnson; they are the two most visible Republicans who have been working on this. But we've been—all of us have been working on this for some time now trying to get this done. And if I could have gotten it done a month ago, 2 months ago, 6 months ago, I would have done that.

Thank you.

NOTE: The President spoke at 8:09 a.m. on the South Lawn at the White House.

Memorandum on Increasing Participation of Medicare Beneficiaries in Clinical Trials

June 7, 2000

Memorandum for the Secretary of Health and Human Services

Subject: Increasing Participation of Medicare Beneficiaries in Clinical Trials

Promoting biomedical research and ensuring that Medicare beneficiaries receive the highest quality care possible are longstanding priorities of my Administration. Over the past 3 years, with the invaluable assistance of the Vice President, my Administration has advocated and secured funding for a budget proposal that explicitly provides for Medicare coverage of services associated with cancer clinical trials, assuring that seniors and disabled persons with cancer have access to cutting-edge treatments and helping promote the research necessary to find new treatments and cures.

Research shows that only about 1 percent of American seniors participate in clinical trials, although the elderly bear the majority of the disease burden in the United States. For example, although 63 percent of cancer patients are over 65, these older cancer patients constitute only 33 percent of all those enrolled in clinical trials. The disparity is greater for breast cancer patients—elderly women comprise 44 percent of breast cancer patients, but only 1.6 percent of women over the age of 65 are in clinical trials for the disease. These low participation rates hinder efforts to develop new therapies, because they mean that scientists often need between 3 and 5 years to enroll enough participants in a clinical trial to generate scientifically valid and statistically meaningful results.

Experts believe that coverage of all clinical trials—not just those for cancer—can lead to breakthroughs in diagnostics, treatments, and cures for many of the most devastating diseases afflicting millions of Americans of all ages. For example, we have made striking