June 6, 2000

STATEMENT ON CLINICAL TRIALS PARTICIPATION FOR MEDICARE BENEFICIARIES

DATE:	June 7, 2000
LOCATION:	South Portico
BRIEFING TIME:	7:30am – 7:45am
EVENT TIME:	7:45am – 7:55am
FROM:	Bruce Reed, Chris Jennings

I. PURPOSE

To direct the Department of Health and Human Services to revise the Medicare policy to authorize payment for the cost of routine patient care associated with participation in clinical trials, and to promote Medicare beneficiary participation in clinical trials for all diseases.

II. BACKGROUND

The actions you are taking today follow the completion of a legal review conducted by the Department of Health and Human Services (HHS) after a recent Institute of Medicine report recommending policy changes to encourage greater use of clinical trials by older Americans. In your remarks, you will single out the longstanding commitment of the Vice President on this issue and commend Senators Rockefeller and Mack and Representatives Johnson and Cardin for their leadership in sponsoring legislation on this issue. You will also call on the Congress to extend similar enforcement provisions to all private plans for all types of clinical trials, underscoring that the Norwood-Dingell Patients' Bill of Rights legislation that is now stalled in the Congress has such provisions.

ACTION IS NECESSARY TO INCREASE THE PARTICIPATION OF SENIORS IN CLINICAL TRIALS. Today, you will highlight that:

Too few seniors participate in clinical trials. About one percent of seniors participate in clinical trials, despite the fact that the elderly bear the majority of the disease burden experienced nationally. For example, 63 percent of cancer patients are older than 65, but they constitute only 33 percent of those enrolled in clinical trials. The disparity is greater for breast cancer patients – elderly women make up 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.

Scientists believe that higher participation in clinical trials could lead to faster development of therapies, as it often takes between three and five years to enroll enough participants in a clinical trial to make the results scientifically valid and statistically meaningful.

Current Medicare reimbursement policies often discourage seniors from participating in clinical trials. Because clinical trial investigators cannot guarantee that Medicare will pay for the care associated with participation in their clinical trial, seniors considering whether to enter these trials must assume that they may be responsible for costs simply because they are participating in a clinical trial. In addition, investigators and research centers are often reluctant to recruit them because of the uncertainty of Medicare reimbursement.

Increased participation is likely to have significant rewards. Striking progress made in treating and curing pediatric cancers was largely possible because of widespread participation in clinical trials. For decades now, well over 50 percent of pediatric cancer patients were enrolled in clinical trials, and today, 75 percent of cancers in children are curable. Experts believe that coverage of all clinical trials – not just those for cancer – is critically important to ensuring new breakthroughs in diagnostics, treatments, and cures for many of the most devastating diseases afflicting millions of Americans of all ages.

NEW EXECUTIVE ACTION TO ENCOURAGE PARTICIPATION IN CLINICAL TRIALS. Your Executive Memorandum directs HHS to:

Revise Medicare program guidance to explicitly authorize payment for routine patient care costs associated with clinical trials. This week, the Health Care Financing Administration (HCFA) will inform all claims processing contractors that Medicare will immediately begin to reimburse for the routine patient care costs and costs due to medical complications associated with participation in a clinical trial and remove this barrier to participation.

Launch activities to increase beneficiary awareness of the new coverage option. HHS will launch an effort to educate beneficiaries and providers about this policy change, including adding information on clinical trial coverage to the Medicare handbook and posting information on their website.

Establish a tracking system for Medicare payments. Before the end of the fiscal year, HCFA will implement a system to track spending in trials for which Medicare contributes financial support.

Ensure that the information gained from important clinical trials is used to inform coverage decisions. Beginning this summer, HCFA and the National Institutes of Health (NIH) will work with researchers prior to the beginning of a clinical trial in order to structure the trial to produce information necessary to inform subsequent Medicare

coverage decisions when the therapies or devices under review have significant implications for the Medicare program.

Review the feasibility and advisability of taking additional action to promote research on issues of importance to the Medicare population within 90 days. HHS should review the feasibility and advisability of:

The Institute of Medicine's recommendation that HCFA support certain clinical trials that are of particular importance to the Medicare population. Certain health care interventions are unique to the Medicare population and clinical trials on these issues could lead to more effective or less costly treatments. HHS should review the feasibility and advisability of providing additional financial support for monitoring and evaluation, device implantation, and other non-covered costs for trials of importance to Medicare beneficiaries.

Taking action to increase the participation of seniors in clinical trials. NIH should evaluate the feasibility and advisability of taking additional action to increase the participation of seniors in clinical trials to ensure that researchers can determine the best therapies for older as well as younger patients.

Developing a registry of ongoing clinical trials receiving Medicare reimbursement. In addition, HHS will review the feasibility and advisability of using the information contained in current NIH and FDA clinical trial registries to develop a national registry of all clinical trials receiving Medicare reimbursement. This new registry would provide a comprehensive picture of the types of trials ongoing, the participation rates, and how patients can access the trials, in addition to facilitating HCFA's ongoing review and oversight activities to ensure that only covered services are billed and reimbursed.

III. PARTICIPANTS

Briefing Participants:
Bruce Reed
Joe Lockhart
Joel Johnson
Loretta Ucelli
Gene Sperling
Chris Jennings
David Beier
Heather Hurlburt

Statement Participant:
YOU

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- **YOU** will proceed to the podium in the Rose Garden.
- **YOU** will make remarks and depart.

VI. REMARKS

To be provided by speechwriting.

[The New York Times, June 7, 2000]

Clinton to Order Medicare to Pay New Costs

Plan Bridges Gap, Advancing Clinical Research on the Elderly

By ROBERT PEAR

WASHINGTON, June 6 — President Clinton will order Medicare to start covering most of the costs of clinical trials testing the value of new drugs and medical treatments for millions of elderly and disabled people, administration officials said today.

Mr. Clinton plans to take the action by issuing an "executive memorandum" on Wednesday, the officials said.

People with chronic diseases have long sought such a policy change. White House officials said the change was needed to increase the number of elderly people who participate in studies of ways to prevent, detect and treat all sorts of ailments, including cancer, heart disease, stroke, Alzheimer's, arthritis, diabetes and eye disorders.

About 1 percent of the elderly now participate in clinical trials, even though the burden of many diseases falls disproportionately on the elderly, administration officials said. The comparable figure for younger people participating in clinical trials is higher, officials said, although they could not provide an exact figure.

Patients, insurance companies and drug companies now often share the costs of clinical research, with much uncertainty about who actually pays how much. That uncertainty often deters people from participating or can mean thousands of dollars in unexpected expenses for people who join the trials.

The Medicare statute has been widely interpreted to bar reimbursement for the routine medical care that beneficiaries need when they participate in clinical trials. Many private insurers have also denied coverage, saying the treatments were experimental or "investigational."

The federal policy is significant not only because Medicare covers 39 million Americans, but also because many private insurers follow its example in deciding what to cover.

In a draft of his new directive, President Clinton says, "I hereby direct the Department of Health and Human Services to revise Medicare program guidance to explicitly authorize payment for Medicare-covered services for clinical trials."

Moreover, Mr. Clinton declared, "Medicare will immediately begin to reimburse for the routine patient care costs, and costs due to medical complications associated with participation in a clinical trial."

Such routine care accounts for the bulk of the cost of most clinical trials. The sponsors of clinical research, including drug companies, would continue to pay for the analysis of data and other expenses beyond the costs of routine care.

The new policy, recommended by the National Academy of Sciences and strongly advocated by Vice President Al Gore, applies to treatments for all diseases and disabilities, not just cancer, as in some legislation pending in Congress.

In a report in December, the Institute of Medicine, an arm of the National Academy of Sciences, said, "Medicare should pay for routine care of beneficiaries enrolled in clinical trials in the same way it pays for this care outside of clinical trials."

Several members of Congress had introduced bills authorizing Medicare to help pay the costs of clinical trials in cancer patients. The Institute of Medicine said the government might already have the authority to cover such costs. That prompted a legal review. Administration officials concluded that they had the necessary authority and that the president did not need to wait for Congress.

Researchers often complain that they cannot find enough patients for clinical research, in part because Medicare reimbursement is uncertain. The White House said that 63 percent of cancer patients were 65 or older, but that the elderly accounted for only 33 percent of the people in clinical trials. Scientists say that higher participation could lead to faster development of effective treatments. Researchers say it often takes three to five years to enroll enough participants in a clinical trial to make the results scientifically valid and statistically meaningful.

In an interview this evening, Mr. Gore said: "Exciting new discoveries are occurring almost weekly. We can't afford that kind of time lag for clinical trials. Speeding up enrollment can accelerate the discovery and use of cost-saving, life-saving new therapies."

In a paper explaining the rationale for its new policy, the White House says: "Too few seniors participate in clinical trials. Current Medicare reimbursement policies often discourage seniors from participating. Coverage of all clinical trials, not just those for cancer, is critically important to ensuring new breakthroughs in diagnostics, treatments and cures for many of the most devastating diseases afflicting millions of Americans of all ages."

Researchers have made great progress in treating children with cancer. One reason, they say, is that more than half of pediatric cancer patients are in clinical trials. About 75 percent of cancers in children are now curable, the administration said.

Mr. Clinton instructed Donna E. Shalala, the secretary of health and human services, to inform Medicare beneficiaries, doctors, hospitals and other health care providers of the new policy. In addition, the White House ordered federal health officials to track Medicare spending on clinical trials.

Even after new medical procedures and devices are found to be safe and effective, there is no guarantee that Medicare will cover them. Under the new policy, Medicare officials and the National Institutes of Health will help researchers design clinical trials so they produce the information needed for decisions about coverage.

F.D.A. Plans Limits on RU-486, Group Says

WASHINGTON, June 6 (AP) — The government is considering rules for use of the abortion pill RU-486 that could restrict access to the early abortion option, Planned Parenthood's director said today.

The Food and Drug Administration said in February that it would approve RU-486, also known as mifepristone, once some final but undisclosed requirements had been met.

Gloria Feldt, national president of Planned Parenthood, said the organization was concerned about any restrictions that limit the pill's use.

Ms. Feldt said she was particularly concerned that the F.D.A. could require doctors who administer RU-486 to be part of a registry, which would deter those worried about anti-abortion violence.

She also said the agency was considering long-term study of at least some RU-486 recipients, something she called unnecessary.

F.D.A. officials declined comment.

PRESIDENT CLINTON TAKES NEW ACTION TO ENCOURAGE PARTICIPATION IN CLINICAL TRIALS

Medicare Will Reimburse For All Routine Patient Care Costs For Those in Clinical Trials

June 7, 2000

Today, President Clinton will issue an Executive Memorandum directing the Medicare program to revise its payment policy and immediately begin to explicitly reimburse providers for the cost of routine patient care associated with participation in clinical trials, and to take additional action to promote the participation of Medicare beneficiaries in clinical trials for all diseases. These actions, strongly advocated by the Vice President and initiated through his leadership, follow a recent Institute of Medicine report recommending policy changes to encourage greater use of clinical trials by older Americans and the completion of a review of Administration policy. With the fast pace of medical advancement and continuing efforts to make evidence based medical decisions, clinical trials serve as the first step towards providing new clinical innovations to the forefront of medical practice. President Clinton's announcement builds on legislation sponsored by Senator Rockefeller, Senator Mack, Congresswoman Johnson, Congressman Cardin, and Congressman Bentsen, and he will thank them for their exceptional leadership on this issue.

ACTION IS NECESSARY TO INCREASE THE PARTICIPATION OF SENIORS IN CLINICAL TRIALS. Today, the President highlighted that:

- **Too few seniors participate in clinical trials.** About one percent of seniors participate in clinical trials, despite the fact that the elderly bear the majority of the disease burden experienced nationally. For example, 63 percent of cancer patients are older than 65, but they constitute only 33 percent of those enrolled in clinical trials. The disparity is greater for breast cancer patients – elderly women make up 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. Scientists believe that higher participation in clinical trials could lead to faster development of therapies, as it often takes between three and five years to enroll enough participants in a clinical trial to make the results scientifically valid and statistically meaningful.

- **Current Medicare reimbursement policies often discourage seniors from participating in clinical trials.** Because clinical trial investigators cannot guarantee that Medicare will pay for the care associated with participation in their clinical trial, seniors considering whether to enter these trials must assume that they may be responsible for costs simply because they are participating in a clinical trial. In addition, investigators and research centers are often reluctant to recruit them because of the uncertainty of Medicare reimbursement.

- **Increased participation is likely to have significant rewards.** Striking progress made in treating and curing pediatric cancers was largely possible because of widespread participation in clinical trials. For decades now, well over 50 percent of pediatric cancer patients were enrolled in clinical trials, and today, 75 percent of cancers in children are curable. Experts believe that coverage of all clinical trials – not just those for cancer – is critically important to ensuring new breakthroughs in diagnostics, treatments, and cures for many of the most devastating diseases afflicting millions of Americans of all ages.

PRESIDENT CLINTON DIRECTS HHS TO TAKE NEW ACTION TO ENCOURAGE PARTICIPATION IN CLINICAL TRIALS. Today, President Clinton will issue an Executive Memorandum that directs HHS to:

- **Revise Medicare program guidance to explicitly authorize payment for routine patient care costs associated with clinical trials.** This week, the Health Care Financing Administration (HCFA) will inform all claims processing contractors that Medicare will immediately begin to reimburse for the routine patient care costs and costs due to medical complications associated with participation in a clinical trial and remove this barrier to participation.

- **Launch activities to increase beneficiary awareness of the new coverage option.** HHS will launch an effort to educate beneficiaries and providers about this policy change, including adding information on clinical trial coverage to the Medicare handbook and posting information on their website.

- **Establish a tracking system for Medicare payments.** Before the end of the fiscal year, HCFA will implement a system to track spending in trials for which Medicare contributes financial support.

- **Ensure that the information gained from important clinical trials is used to inform coverage decisions.** Beginning this summer, HCFA and the National Institutes of Health (NIH) will work with researchers prior to the beginning of a clinical trial in order to structure the trial to produce information necessary to inform subsequent Medicare coverage decisions when the therapies or devices under review have significant implications for the Medicare program.

- **Review the feasibility and advisability of taking additional action to promote research on issues of importance to the Medicare population within 90 days.** HHS will review the feasibility and advisability of:

    - The Institute of Medicine's recommendation that HCFA support certain clinical trials that are of particular importance to the Medicare population. Certain health care interventions are unique to the Medicare population and clinical trials on these issues could lead to more effective or less costly treatments. HHS will review the feasibility and advisability of providing additional financial support for monitoring and evaluation, device implantation, and other non-covered costs for trials of importance to Medicare beneficiaries.

    - Taking action to increase the participation of seniors in clinical trials. NIH will evaluate the feasibility and advisability of taking additional action to increase the participation of seniors in clinical trials to ensure that researchers can determine the best therapies for older as well as younger patients.

    - Developing a registry of ongoing clinical trials receiving Medicare reimbursement. In addition, HHS will review the feasibility and advisability of using the information contained in current NIH and FDA clinical trial registries to develop a national registry of all clinical trials receiving Medicare reimbursement. This new registry would provide a comprehensive picture of the types of trials ongoing, the participation rates, and how patients can access the trials, in addition to facilitating HCFA's ongoing review and oversight activities to ensure that only covered services are billed and reimbursed.

PRESIDENT CLINTON PRAISED THE BROAD BIPARTISAN SUPPORT FOR CANCER CLINICAL TRIAL COVERAGE IN MEDICARE AND CALLED FOR EXTENSION TO ALL PRIVATE PLANS. The President singled out the longstanding commitment of the Vice President, Senator Rockefeller, Senator Mack, Congresswoman Johnson, Congressman Cardin, and Congressman Bentsen in advocating for Medicare coverage for cancer clinical trials. Their support for this policy, in addition to the recently released Institute of Medicine report, made a significant contribution towards this policy revision. The President also called on the Congress to extend similar enforceable provisions to all private plans for all types of clinical trials, underscoring that the Norwood-Dingell Patients' Bill of Rights legislation that is now stalled in the Congress has such provisions.

LONGSTANDING COMMITMENT OF THE CLINTON-GORE ADMINISTRATION TO PROMOTING BIOMEDICAL RESEARCH. Today's announcement underscores the longstanding commitment of President Clinton and Vice President Gore to promoting biomedical research and removing barriers to participation in clinical trials providing access to cutting-edge treatment for Americans with diseases such as cancer, heart disease, Alzheimer's, Parkinsons, and diabetes. Since the beginning of the Clinton-Gore Administration, funding for NIH has increased by $7.3 billion since 1993 – an increase of 73 percent. Last year, NIH received $2.3 billion, a 15 percent increase over FY 1999 funding levels, to build on the Administration's commitment to biomedical research. As a result, NIH now supports the highest levels of research ever on nearly all types of disease and health conditions, making new breakthroughs possible in vaccine development and use and the treatment of chronic and acute disease. President Clinton recently announced that HHS is taking new steps to strengthen federal oversight and increase the accountability of researchers conducting clinical trials with human subjects in order to protect the safety of individuals participating in all clinical trials. Actions include: issuing new guidelines stating that investigators must obtain new informed consent from participants after any event related to their clinical trial that may affect their willingness to participate, and proposing new civil monetary penalties of up to $250,000 per individual and $1 million per institution to promote compliance with current regulations. Finally, President Clinton signed an Executive Order prohibiting every civilian federal department and agency from using genetic information in any hiring or promotion action, removing any fear of repercussion in the workplace and making individuals at risk of hereditary diseases more likely to participate in clinical trials.

Ellen E. Olcott
06/07/2000 08:51:37 AM

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To: See the distribution list at the bottom of this message

cc:
Subject: 2000-6/7 POTUS remarks upon departure

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release June 7, 2000

REMARKS BY THE PRESIDENT
UPON DEPARTURE

The South Lawn

8:09 A.M. EDT

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 six 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.

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 seven and a half 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, two months ago, six months ago, I would have done that.

Thank you.

END 8:15 A.M. EDT

Message Sent To: