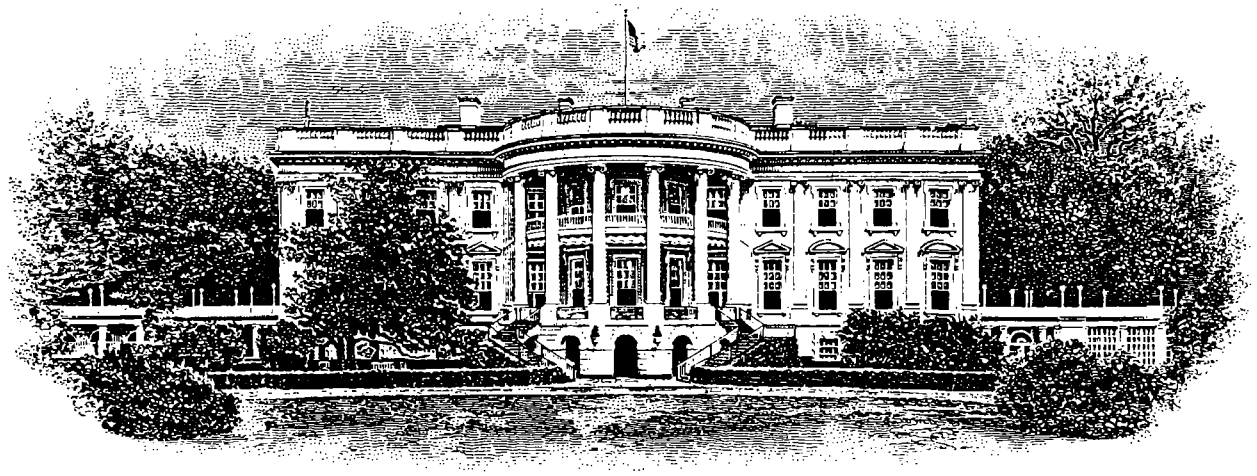
CLINTON TRIALS

The White House



Final 06/06/00 8:10pm
Heather Hurlburt

PRESIDENT WILLIAM J. CLINTON
DEPARTURE STATEMENT ON CLINICAL TRIALS
THE WHITE HOUSE
WASHINGTON, DC
June 7, 2000

Good morning. We're here at this early hour to talk about a vitally-important issue for the health of America's seniors – and every one of us. We need to help more seniors participate in the clinical trials that test new therapies for illnesses from cancer to heart disease to Alzheimer's. These trials may prolong lives, and they are central to finding cures for deadly diseases.

Today, America's seniors are badly underrepresented in clinical trials – although they bear the heaviest share of many illnesses. More than half of America's cancer patients are over 65 – but only one-third of those in clinical trials are senior citizens. For breast cancer, the statistics are even worse. And overall, only one percent of senior citizens participate in clinical trials. Today, thousands of important trials do not have enough patients, because so few seniors are able to take part. And that means slower progress toward curing or treating diseases.

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 that they will be saddled with thousands of dollars in routine medical costs if they participate. Most cannot bear such a heavy burden.

For several years, Vice President Gore has led our efforts to clear up the confusion and help seniors and people with disabilities into clinical trials. We have had bipartisan support in Congress, led by Senators Rockefeller and Mack, Congresswoman Johnson 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 are aware of the change. We'll ask for the help of the 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 and the health of older Americans.

Today I am also directing 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 I 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 such trials. As

America ages, we must provide all our seniors affordable, quality healthcare – 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 will be able to use advances in medicine to save American lives. We've done this successfully with cancer in children. For decades now, more than half of all 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 thousands of children in medical 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 that won't happen unless Congress takes the next step and passes a strong Patients' Bill of Rights. Congress has had before it for six months the Norwood-Dingell legislation, which includes a requirement that every private insurer cover the costs of participation in clinical trials. This month, before the summer recess, Congress has a window of opportunity to take real steps to make our country better. I hope Congress will use that window to make sure that every American can benefit from America's best medical science. And I pledge to do all that I can to make that happen.

Thank you.

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

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MEMORANDUM FOR THE PRESIDENT

Promoting biomedical research and ensuring that Medicare beneficiaries receive the highest quality care are longstanding priorities of the Department of Health and Human Services. We recognize that Medicare beneficiaries should not face barriers in accessing cutting-edge treatments that clinical trials can provide.

However, elderly individuals and their physicians may be deterred from participating in potentially life-saving clinical trials because of the uncertainty of Medicare reimbursement for their patient care costs for the many diseases from which they suffer. Up to now, some clinical trial investigators may have been uncertain about whether Medicare would pay for routine patient care if a beneficiary participated in their clinical trials. Some patients considering whether to enter these trials may have assumed that they could be responsible for routine costs.

Out of these concerns, the Balanced Budget Act of 1997 authorized the Health Care Financing Administration (HCFA) to sponsor a study conducted by the Institute of Medicine (IOM). The purpose of the study was to determine whether there were barriers to Medicare beneficiary participation in clinical trials. Last December, IOM issued a report entitled "Extending Medicare Reimbursement in Clinical Trials" which recommended that Medicare cover the routine patient care costs associated with clinical trials. This new information prompted a review by the Department. Following this review, the Department concluded that it could exercise its administrative authority to provide Medicare reimbursement for the routine patient care costs associated with clinical trials in which Medicare beneficiaries participate.

I recommend that we take the following actions. First, HCFA should immediately prepare a revision to the Medicare manual to authorize Medicare's claims processing contractors to reimburse for the routine patient care costs that are reasonable and necessary during a beneficiary's participation in a clinical trial. Second, HCFA should authorize its contractors to reimburse providers for costs incurred to treat medical complications that may occur after a patient receives experimental services in a clinical trial. This action is consistent with the IOM's primary recommendation and would not include Medicare reimbursement of costs specifically related to non-covered services.

In addition, HCFA, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) will undertake a series of activities to promote the goal of improving older Americans' access to cutting-edge treatments. The Department will launch educational activities to increase beneficiary awareness of the new coverage option; will ensure collaboration between HCFA and NIH so that information gained

from clinical trials is used to inform Medicare coverage decisions; and will establish a system that tracks Medicare payments for costs associated with beneficiaries participating in clinical trials. In addition, HCFA, NIH, and FDA will review the feasibility and advisability of expanding further Medicare's coverage of other costs associated with certain clinical trials.

I am pleased to be able to inform you about these new developments. I know you and the Vice President share my commitment to ensuring that Medicare beneficiaries have access to clinical trials which also serve to promote critical biomedical research. I look forward to keeping you apprised of our progress in this important area.

Donna E. Shalala

Donna E. Shalala

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 promoting 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 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 make the results scientifically valid and statistically meaningful.

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 progress in treating and curing pediatric cancers, largely 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.

One factor contributing to seniors' low participation rate in clinical trials is the Medicare program's failure to guarantee that Medicare will pay for the care associated with participation. This uncertainty regarding reimbursement often deters patients from participating in these trials, and deters physicians and other clinicians from recruiting patients, which contributes to the low participation rate in trials and also slows the development of new medical treatments and diagnostic tests that could benefit the entire Medicare population.

Last December, the Institute of Medicine (IOM) issued a report entitled "Extending Medicare Reimbursement in Clinical Trials," which recommended that Medicare explicitly cover routine patient care costs for participants in clinical trials. This and other recommendations by IOM, combined with your ongoing efforts to modernize Medicare's process to ensure coverage of new technology, prompted a review of Medicare's administrative flexibility to independently remove barriers to participation in clinical trials. Following this review, you concluded that Medicare could exercise its administrative authority to provide reimbursement for routine patient care costs associated with clinical trials.

Based on the results of your Department's review and recommendations, as well as our shared commitment to promoting critical biomedical research and to assuring that older Americans and millions of people with disabilities can have access to cutting edge medical treatments, I hereby direct the Department of Health and Human Services (HHS) to:

- **Revise Medicare program guidance to explicitly authorize payment for Medicare-covered services for clinical trials.** The HCFA should inform all claims-processing contractors that Medicare will immediately begin to reimburse routine patient care costs and costs due to medical complications associated with participation in clinical trials.

- **Launch activities to increase beneficiary awareness of the new coverage option.** The HHS should educate beneficiaries and providers about this policy change, including developing an easy-to-read brochure, adding information on clinical trial coverage to future Medicare handbooks, and posting information on the HHS website.

- **Establish a tracking system for Medicare payments.** The HCFA should implement a system to track clinical trial spending for which Medicare contributes financial support.

- **Ensure that the information gained from important clinical trials is used to inform Medicare coverage decisions.** The HCFA and the National Institutes of Health (NIH) should work with researchers prior to the beginning of a clinical trial designed to test the efficacy of devices or therapies that have significant implications for the Medicare program to structure the trials to produce information to inform subsequent Medicare coverage decisions.

- **Within 90 days, review the feasibility and advisability of taking additional action to promote research on issues of importance to the Medicare population, including:**

  - the IOM's recommendation to support certain clinical trials of particular importance to the Medicare population, including certain health care interventions unique to the Medicare population and clinical trials that could lead to more effective and/or less costly treatments; HHS should review IOM's recommendation to provide additional financial support for monitoring and evaluation, device implantation, and other non-covered costs for trials researching methods of care of particular importance to Medicare beneficiaries;

  - taking action to increase the participation of seniors in clinical trials. Specifically, the NIH should evaluate 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; and

  - developing a registry of all ongoing clinical trials receiving Medicare reimbursement, using the information contained in current NIH and FDA clinical trial registries. This new registry would provide a comprehensive picture of ongoing trials, participation rates, and how patients can access the trials and facilitate the HCFA's ongoing review and oversight activities to ensure that only covered services are billed and reimbursed.

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.

MEMORANDUM FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

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