

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.

*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, prior to his departure for Tokyo, Japan.

## 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 explic-

itly 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 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 Medicare payment 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, contributing to low participation rates and slowing 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 your recommendations, as well as our shared commitment to promoting critical biomedical research and to assuring that older

Americans and millions of people with disabilities 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 routine patient care costs associated with 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 to 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 clinical trials designed to test the efficacy of devices or therapies that have significant implications for the Medicare program to structure those trials to produce information to inform subsequent Medicare coverage decisions.
- *Review and report back to me within 90 days on the feasibility and advisability of additional actions to promote research on issues of importance to the Medicare population, including:*
  - as recommended by IOM, supporting 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;
- increasing the participation of seniors in clinical trials. Specifically, the NIH should evaluate additional action to increase seniors' participation 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 ways 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.

WILLIAM J. CLINTON

## Remarks Following a Memorial Service for Former Prime Minister Keizo Obuchi of Japan in Tokyo

*June 8, 2000*

I would like to begin by thanking Ambassador and Mrs. Foley for welcoming me back to the American Embassy and the Ambassador's residence, along with our American party.

I came here today to pay my respects to a friend. And on behalf of the American people, I want to extend our deepest condolences to the Prime Minister's family, especially to his wife and his three children, as well as to the people of Japan.

Two years ago Prime Minister Obuchi took office in a difficult time for Japan and the world. There were many who wondered if any person could meet the tremendous challenges brought on by the global economic crisis we faced. I think history will record that Keizo Obuchi rose to the challenge with courage and confidence.

Thirty-seven years ago he was the youngest person ever elected to the Japanese Parliament. Over time, it's clear that he learned a profoundly important lesson, how to reach out to all sides and bring people together. As Prime Minister, he became known for imitating the art and skill of an orchestra conductor, in finding harmony among people of different views.

From his first days in office, he took swift steps to put Japan on firmer economic ground, and he gave strong support to the cause of peace, from East Timor to Kosovo. He worked to strengthen our alliance and to place it on a solid foundation for the 21st century. He believed in a U.S.-Japanese partnership built upon mutual respect and shared values of democracy and human rights, economic freedom and secu-

rity, and that this partnership must remain the cornerstone of stability in East Asia.

Prime Minister Obuchi touched hearts around the world in simple, human ways. His telephone calls are legendary. I remember his human touch when he came to America last spring; when he threw out an unhittable pitch to the Chicago slugger, Sammy Sosa; when he told us of the honor he felt in meeting Robert Kennedy as a young man; and how much he appreciated the dinner we hosted in his honor when he shared a table with Mrs. Robert Kennedy.

Early in his career, Prime Minister Obuchi competed for votes in the same district as two former Prime Ministers. He used to describe himself as a "noodle shop sandwiched between two skyscrapers." As usual, he was being modest. Prime Minister Obuchi represented to the whole world the Japanese virtues of honor and loyalty, vision and determination, love for and commitment to ordinary people. Our world is a better place thanks to the life that he lived and the work that he did.

On his last day in Washington, Prime Minister Obuchi gave me a beautiful painting of Mount Fuji. I will cherish it always. And whenever I look at it, it will always remind me of him. I hope very much that, in his memory, Japan and the United States can work together as partners and friends to lift humanity to a new mountaintop in the 21st century.

Thank you very much.