

PRESIDENT CLINTON AND VICE PRESIDENT GORE ANNOUNCE HISTORIC EFFORTS TO RENEW THE WAR ON CANCER

September 26, 1998

Today, the President and Vice President launched a new series of initiatives to redouble our efforts in the war against cancer. The President outlined these new steps in his weekly radio address on cancer and the Vice President delivered the keynote speech to tens of thousands of Americans at the March to Conquer Cancer on the National Mall.

ADVANCING COMMITMENT TO HIGH QUALITY RESEARCH

Called on the Congress to pass the President's historic multi-year commitment to cancer research. Experts believe that we are at the cusp of important new breakthroughs in the war against cancer. Today, the President and Vice President called on Congress to pass the Administration's historic five-year, 65 percent increase in cancer research at the National Institutes of Health. This multi-year investment would ensure that our nation's scientists conduct more extensive and fruitful research than ever before, secure in the knowledge that the research will not be interrupted as the result of funding lapses.

Announced that Federal cancer research programs will fully integrate patients and advocates into research within a year. Cancer advocates and patients provide a unique and critical perspective on the cancer research agenda. Building on unprecedented efforts to integrate patients and advocates into the cancer research program at the Department of Defense and ongoing innovative efforts at NCI, the President and Vice President announced that by next year NCI will fully integrate patients and advocates into activities such as reviewing grant proposals and planning policy.

Issued nationwide challenge for new technological approaches to fight cancer. Winning the war against cancer requires innovative approaches to prevent, detect, treat, and one day cure this disease. Today, the Director of NCI announced a \$48 million competitive grant program for researchers to apply new technologies -- from areas such as computer science, engineering, military defense, and astronomy -- to prevent, detect, and treat cancer.

USING NEW PROGRESS IN GENETICS TO ADVANCE PREVENTION AND TREATMENT FOR CANCER

Announced that in the first year of the Cancer Genome Anatomy Project (CGAP), scientists have identified twice as many genes and gene sequences as expected. In 1996, the Vice President unveiled the CGAP, a comprehensive effort to profile genes in precancerous and cancerous cells and by doing so, to unravel the genetics of cancer. The President and Vice President announced that in the first year of this historic effort, the project already has identified more than 300,000 DNA sequences and 12,000 new genes -- double what the NCI initially expected.

Issued historic challenge to scientists to use the CGAP to develop new diagnostic techniques for every major cancer in the next two years. Efforts to unravel the genetics of cancer should be used to make unprecedented progress in improving detection and treatment for cancer patients.

The President and the Vice President issued a challenge to scientists to use new knowledge about genetics to develop new diagnostic strategies for every major cancer in the next two years, so that doctors can pinpoint cancers in their earliest and often most treatable stages.

Challenged Congress to pass bipartisan legislation preventing genetic discrimination.

According to one report, 63 percent of Americans would not take a genetic test if their health insurers or employers could get access to the results. The President and Vice President renewed their call for Congress to pass bipartisan legislation, similar to legislation introduced by Rep. Slaughter and Senator Snowe, to prohibit health plans and employers from using genetic screening to discriminate against individuals.

SPUR RESEARCH BREAKTHROUGHS BY INCREASING THE NUMBER OF PATIENTS ENROLLED IN NEW NATIONAL CLINICAL TRIALS SYSTEM.

Directed NCI to fully implement its new computer-based clinical trials system for breast, prostate, and colon cancers by next spring. The President and Vice President directed NCI to fully implement a new system to make it easier for physicians to enroll patients in clinical trials. Under the directive, NCI will complete this simplified system for breast, colon and prostate cancer by next spring and expedite the system for other cancers as well. This new system will ensure that physicians are informed about cutting-edge cancer clinical trials and will allow them to enroll patients on the spot. This effort will give tens of thousands of cancer patients improved access to cancer clinical trials. By increasing participation in these trials, the effort will accelerate test results and spur research breakthroughs.

Challenged Congress to pass a bipartisan initiative that authorizes coverage of cancer clinical trials for Medicare beneficiaries. Americans over the age of 65 make up half of all cancer patients, and are 10 times more likely to get cancer than younger Americans. Older Americans, however, frequently cannot participate in cutting-edge cancer clinical trials because Medicare does not pay for experimental treatments. The President and Vice President renewed the call on Congress to pass a proposal, similar to legislation supported by Senators Mack and Rockefeller, that authorizes coverage of clinical trials for Medicare beneficiaries without harming the Trust Fund.

NEW STEPS TO IMPROVE QUALITY OF CARE FOR CANCER PATIENTS AND SURVIVORS

Renewed call on Congress to pass a strong enforceable bipartisan patients' bill of rights to assure cancer patients of high-quality care. The President and Vice President urged Congress to stop delaying and pass a strong enforceable patients' bill of rights this year. The patients' bill of rights would provide many critical protections for patients with cancer including access to the specialists they need and continuity-of-care protections to prevent them from having to change care suddenly in the middle of treatment.

Unveiled groundbreaking research grants to examine how to prevent cancer recurrence, understand the lifelong impact of cancer treatment, and to improve the quality of life for cancer survivors. The Vice President announced that the NCI is releasing \$15 million in new cancer survivorship grants to fund top-of-the-line research to examine the impact of this disease on

patients and their families. Specifically, researchers will examine the long-term effects of cancer treatments and the most effective ways to prevent recurrence of cancer and to improve the quality of life for cancer survivors and their families.

APPROVING NEW CUTTING-EDGE DRUGS FOR PATIENTS.

Announced that FDA has approved a record number of cancer drugs. In 1996, the President launched the FDA Initiative on Reinventing the Regulation of Cancer Drugs. Since that time, the FDA Division of Oncology Drug Products has approved more than twice as many new therapies as in the three years prior to the initiative.

Urged Congress to confirm Jane Henney, the first woman and the first oncologist nominated as FDA Commissioner. The President and Vice President urged the Senate not to adjourn without confirming Dr. Jane Henney, the first woman and the first oncologist to be nominated as FDA Commissioner.

URGING CONGRESS TO PASS COMPREHENSIVE TOBACCO LEGISLATION

The President and Vice President are fighting against the leading cause of preventable cancer -- tobacco. Every day 3,000 children start smoking, and one thousand will die of a tobacco-related disease. Today the President and Vice President reminded Americans that they need a Congress that has the courage to pass comprehensive tobacco legislation to stop kids from smoking.

REMARKS FOR VICE PRESIDENT AL GORE
MARCH TO CONQUER CANCER RALLY
Saturday, September 26, 1998

Every single one of us today has been inspired by our heroes. I'm lucky, because my hero lives under the same roof. Thank you, Tipper.

Today, I have some new heroes. Thank you Renee Cole, for working to save other women from cancer. Thank you Dani Grady, for riding your bike 4,000 miles to make a difference. Thank you Ellen Stoval, for believing that 100,000 people would come to Washington for a March to conquer cancer. And most of all, thank you -- all of you -- for showing America that we can meet, we can treat, and we can beat this horrible disease.

This isn't just a noon rally for cancer. This is high noon for cancer. It was more than a quarter-century ago that America first declared war on cancer. We are here today because we want to be the first generation that finally wins that war. I want to talk to you for a few minutes today about what we are doing to redouble our commitment to make it happen.

As any cancer survivor will tell you: the power to fight cancer comes from the heart and from the soul. But most of all, it comes from being able to imagine a day when you are cancer-free. I want to begin today by asking all of you to imagine a day when America is cancer-free.

Imagine waking up tomorrow morning and reading that not a single American died today from cancer. Imagine waking up in a world where not a single child has ever heard the word "chemotherapy." Imagine waking up in a world where children at the local kindergarten start the school year with a nap, a flu shot, and a routine cancer immunization. And imagine how it would feel to visit the Smithsonian and see a radiation machine next to an iron lung as a relic from the past.

Make no mistake about it: this dream can happen in our lifetime. But to get there, we have to continue to make cancer research a priority today. And it's time: because this disease has haunted this land and hurt our families for too many years.

We meet today in the shadow of the Washington Monument, a short walk from the Lincoln Memorial, and a stone's throw from the Memorial to FDR. Guess what they have in common? George Washington's mother, Franklin Roosevelt's daughter, and Abe Lincoln's great-granddaughter all died from this horrible disease. In America today, more than 40 percent of us will be diagnosed with cancer, and 20 percent of us will die from it. If you're wondering what that means, visit the Vietnam Memorial when this rally is over. If we were going to build a monument to all the Americans who die from cancer this year, it would take ten Vietnam Walls.

Like all of you, when I hear the word "cancer," I don't think of statistics, I see faces. I have spoken often about my family's tragic experience with this disease in the past. Tipper has had similar experiences. We have all seen what cancer does, and we are here today because we hope for a day when it doesn't happen to anyone else.

Thanks to your work, and the breathtaking advances in science, we are closer to a cure than we have ever been. From 1991 to 1995, cancer deaths actually dropped for the first time in history. As we meet here today, the first medicines to prevent prostate cancer, colon cancer, and breast cancer are being tested. You know, I have run the Race for the Cure more than five times, and I love that race. But one of the happiest days of my life will be the day that none of us has to run it again.

President Clinton and I have been proud to play a role in this progress. We have helped cancer patients keep health coverage when they change jobs. We have accelerated the approval of cancer drugs. We have increased funding for cancer research. We are working to end the most preventable form of cancer by stopping our kids from smoking. And today, we are taking unprecedented new steps to build on our progress to make cancer a relic of the past.

First, President Clinton and I have proposed the largest increase in cancer research in history. Somewhere in America today, a young researcher has an idea that will one day lead to a cure for cancer. It would be a tragedy if his idea was lost because we didn't fund his project. This March proves that Democrats and Republicans can come together to conquer cancer. We also need to do more to ensure that patients are involved when research decisions are made. Nobody knows more about this disease than cancer patients and advocates, and your voice must be heard. That's why, today, we are announcing that by next spring, the National Cancer Institute will ensure that patients have a full voice -- at every step of the way.

Second, we need to be sure these advances are used to improve treatment for people with cancer. We are just a few years away from the complete sequencing of all the genes in the human body. In 1996, I unveiled the Cancer Genome Project, a historic effort to unravel the genetics of cancer. I am proud to report that already, this project has more than doubled its original goals. Today, we issue a historic challenge to the scientific community: as we unlock the genetic code, let's make sure we develop new diagnostic techniques for every major kind of cancer by the year 2000 -- so we can catch it at its earliest and most preventable stage. History shows: if we crack the enemy's code, we win the war. We are going to win this war for America's families.

Third, let us do more to improve access for patients to cutting-edge clinical trials. We won't cure cancer if only three percent of America's cancer patients are enrolled in clinical trials. Today, we are directing the National Cancer Institute to speed up the process, to allow patients to be enrolled on the spot with no wait. We are also calling on Congress to pass our proposal to cover the patient care costs for Medicare beneficiaries enrolled in clinical trials. America's seniors make up more than half of all cancer patients. They deserve to have the latest weapons to fight it.

Fourth, we need to continue to improve quality breakthrough medications and treatments for cancer. Two years ago, we launched an historic effort to speed up the drug approval process while maintaining quality.

In just two years, we have more than doubled the number of approvals for new therapies. Today, we have a new weapon in the war against breast cancer. Just last night, the Food and Drug Administration approved a brand new, cutting-edge drug to treat breast cancer. This will help some of the 1.6 million women who are diagnosed with breast cancer each year. There is one more thing we can do to advance this fight. Congress should not go home until it confirms oncologist Jane Henney to be the first woman Commissioner in the history of the Food and Drug Administration.

Fifth, we need to make sure that these advances are used to improve the quality of life of cancer patients. As we crack the genetic code, it should be used to improve treatment, not increase discrimination. No person should have their health care or their job put at risk because they are genetically at risk for cancer. I urge Congress: pass our proposal to give all Americans the protection they deserve. At the same time, no American should feel like they can't go to their doctor because they're afraid of who will see their medical records. Privacy is a basic American value, and it must be upheld. I urge Congress: work with us to keep medical records private. And let's make sure that critical health decisions are made by doctors, not by bean counters in the back room. If you're in the middle of chemotherapy, you shouldn't be forced to stop treatment because your employer changes health plans. I urge Congress: give Americans the quality care they need, when they need it. Pass a strong Patients' Bill of Rights into law.

Some people say it's impossible to find a cure for cancer. But 100 years ago, they said the same thing about smallpox. Sixty years ago, they said the same thing about polio. They were wrong then -- and they are wrong today. The beauty of this March is not just that all of you have come together to conquer cancer. The beauty of this March is that your lives and your stories prove that yes, we can conquer cancer.

When people say that we can't make prevention work, we say, "YES WE CAN." When people say we can't find a cure, we say, "YES WE CAN." When people say we can't get people involved, we say, "YES WE CAN." When people say no we can't, we say, "YES WE CAN."

Can we save lives? [Yes we can]. Can we save families? [Yes we can]. Can we find a cure? [Yes we can]. Working together, marching together, fighting together, I know we will. Thank you.

March to Conquer Cancer

Briefing Prepared by Sarah Bianchi.

Event Time: Saturday, September 26, 1998
12pm to 12:45pm

EVENT

You are delivering the keynote address at "*The March: Coming Together to Conquer Cancer*," a rally to raise awareness about the devastating impact of cancer and the need to renew our efforts to conquer this disease. As many as 150,000 people from around the nation are expected to attend *The March* on the National Mall on Washington DC.

LOGISTICS

Upon arrival, you and Mrs. Gore are doing a photo-op with the Tennessee delegation participating in *The March*;

Sam Donaldson and Cokie Roberts make very brief welcoming remarks;

Sam Donaldson introduces **you** and Mrs. Gore, accompanied by Renee Cole onto the stage;

Renee Cole makes remarks and introduces Mrs. Gore;

Mrs. Gore makes remarks and introduces **you**;

You deliver keynote address;

You and Mrs. Gore depart.

YOUR ROLE AND CONTRIBUTION

This event provides an opportunity to outline a new vision for how we can redouble our efforts to win the war against cancer. It also provides a forum for you to highlight your longstanding commitment to this disease.

In the past several years we have made historic progress in fighting cancer. Cancer incidences and death rates are down for the first time ever, and while 10 percent of children survived cancer in the 1970s, nearly 70 percent do today. There are new cutting edge treatments for cancer and advances in the Humane Genome Project are providing unprecedented possibilities for the ways we detect, treat, and cure cancer. In fact, scientists believe that we will look back on the 1990s as the decade we turned the tide in the fight against cancer.

Cancer continues to affect millions of Americans. About 1.2 million Americans are diagnosed with cancer each year and 560,000 will die from it. In fact, fully 40 percent of Americans are expected to be diagnosed with cancer during their lifetime, and moreover, cancer costs us nearly \$100 billion (indirect and direct costs) each year.

You are outlining a series of new steps to intensify our efforts in the war against cancer. Specifically, you are: (1) calling on Congress to spur new progress in research by passing unprecedented increases in cancer research and initiating new efforts to integrate patients into setting the agenda for Federal cancer research programs; (2) highlighting new advances in genetics, through the Cancer Genome Anatomy Project and issuing an unprecedented challenge to the scientific community to develop, by the year 2000, new diagnostic techniques for every major kind of cancer so we catch it at its earliest and often most treatable stage; (3) increasing the number of patients who participate in cancer clinical trials by directing the National Cancer Institute to speed development of a national clinical trials system --a simple, accessible resource for health care providers and patients across the nation; and renewing the call on Congress to pass our proposal to cover patient care costs for Medicare beneficiaries in cancer clinical trials; (4) initiating new steps to improve quality of care for cancer patients and survivors; and (5) urging Congress to pass comprehensive tobacco legislation to stop children from smoking.

PROGRAM NOTES

Following your departure, there are a number of other speakers at *The March*, including Jesse Jackson, Scott Hamilton, General Norman Schwarzkopf, Michael Milken, Senator Mack, Senator Harkin, Bob Dole, Representative John Porter, and Representative Rosa DeLauro. Performers include Aretha Franklin and Michael Bolton.

You should also note that the President is giving his weekly radio address on cancer. He will be highlighting briefly some of the new steps we are taking to redouble our efforts on cancer. He is also noting that you are attending *The March* today to outline more specifically the Administration's vision for how to advance the war on cancer.

Renee' Cole. You will be introduced by Renee' Cole, a breast cancer survivor. Renee' detected an abnormal mass in her breast, which she brought to the attention of her general practitioner. This led to a diagnosis of breast cancer when she was 31. Early detection was the key to her recovery. After the initial shock of the diagnosis, Renee' went on a personal crusade to raise awareness about cancer. Renee', her husband and her family, began to prepare themselves mentally and spiritually so that they could become medically informed and fight the cancer. Renee' is a native Washingtonian (she currently lives in Lanham, Maryland). She works for IBM and serves on the ministerial staff of Reid Temple A.M.E. Church as minister to women. She is married to Reverend Henry Cole and is the mother of three.

ATTACHMENTS

- Detail on announcements to move ahead on the war on cancer;
- President's weekly radio address.
- List of Tennessee photo op.

NEW STEPS IN THE FIGHT AGAINST CANCER

ADVANCING COMMITMENT TO HIGH QUALITY RESEARCH

Calling on the Congress to pass the President's historic multi-year commitment to cancer research. Experts believe that we are at the cusp of important new breakthroughs in the war against cancer. Today, the President and you are calling on Congress to pass the Administration's historic five-year, 65 percent increase in cancer research at the National Institutes of Health. This multi-year investment would ensure that our nation's scientists conduct more extensive and fruitful research than ever before, secure in the knowledge that the research will not be interrupted as the result of funding lapses. *[You unveiled this proposal in January. You should note that many advocates at The March support even greater increases in cancer research, although they very much appreciate the Administration's efforts in this area].*

Announcing that cancer research programs will fully integrate patients and advocates into research within a year. Cancer advocates and patients provide a unique and critical perspective on the cancer research agenda. Building on unprecedented efforts to integrate patients and advocates into the cancer research program at the Department of Defense and ongoing innovative efforts at NCI, you are announced that by next year NCI will fully integrate patients and advocates into activities such as reviewing grant proposals and planning policy. *[This initiative is a high priority for the leadership at The March, who have fought hard to play a major role in setting the cancer research agenda. The DoD program is well-renowned for including patients in research design. NCI has only recently begun efforts in this area].*

Issuing nationwide challenge for new technological approaches to fight cancer:

Winning the war against cancer requires innovative approaches to prevent, detect, treat, and one day cure this disease. Today, the Director of NCI announced a \$48 million competitive grant program for researchers to apply new technologies -- from areas such as computer science, engineering, military defense, and astronomy -- to prevent, detect, and treat cancer.

USING NEW PROGRESS IN GENETICS TO ADVANCE PREVENTION AND TREATMENT FOR CANCER

Announcing that in the first year of the Cancer Genome Anatomy Project (CGAP), scientists have identified twice as many genes and gene sequences as expected. In 1996, you unveiled the CGAP, a comprehensive effort to profile genes in precancerous and cancerous cells and by doing so, to unravel the genetics of cancer. The President and you are announcing that in the first year of this historic effort, the project already has identified more than 300,000 DNA sequences and 12,000 new genes -- double what the NCI initially expected.

Issuing historic challenge to scientists to use the CGAP to develop new diagnostic techniques for every major cancer in the next two years. Efforts to unravel the genetics of cancer should be used to make unprecedented progress in improving detection and treatment for cancer patients. The President and you are issuing a challenge to scientists to use new knowledge about genetics to develop new diagnostic strategies for every major cancer in the next two years, so that doctors can pinpoint cancers in their earliest and often most treatable stages.

Challenging Congress to pass bipartisan legislation preventing genetic discrimination. According to one report, 63 percent of Americans would not take a genetic test if their health insurers or employers could get access to the results. The President and you are renewing their call for Congress to pass bipartisan legislation, similar to legislation introduced by Rep. Slaughter and Senator Snowe, to prohibit health plans and employers from using genetic screening to discriminate against individuals. *[You unveiled the Administration's support for legislation to prevent employers from genetic discrimination in January at the James Watson lecture].*

SPUR RESEARCH BREAKTHROUGHS BY INCREASING THE NUMBER OF PATIENTS ENROLLED IN NEW NATIONAL CLINICAL TRIALS SYSTEM.

Directing NCI to fully implement its new computer-based clinical trials system for breast, prostate, and colon cancers by next spring. The President and you are directing NCI to fully implement a new system to make it easier for physicians to enroll patients in clinical trials. Under the directive, NCI will complete this simplified system for breast, colon and prostate cancer by next spring and expedite the system for other cancers as well. This new system will ensure that physicians are informed about cutting-edge cancer clinical trials and will allow them to enroll patients on the spot. This effort will give tens of thousands of cancer patients improved access to cancer clinical trials. By increasing participation in these trials, the effort will accelerate test results and spur research breakthroughs.

Challenged Congress to pass a bipartisan initiative that authorizes coverage of cancer clinical trials for Medicare beneficiaries. Americans over the age of 65 make up half of all cancer patients, and are 10 times more likely to get cancer than younger Americans. Older Americans, however, frequently cannot participate in cutting-edge cancer clinical trials because Medicare does not pay for experimental treatments. The President and Vice President renewed the call on Congress to pass a proposal, similar to legislation supported by Senators Mack and Rockefeller, that authorizes coverage of clinical trials for Medicare beneficiaries without harming the Trust Fund. *[You unveiled this proposal with Senators Mack and Rockefeller in January. Currently only 3 percent of cancer patients participate in clinical trials. Scientists believe that if more patients did participate, we would get results faster, as certain trials take three to five years to get enough participants to be statistically meaningful].*

NEW STEPS TO IMPROVE QUALITY OF CARE FOR CANCER PATIENTS AND SURVIVORS

Renewed call on Congress to pass a strong enforceable bipartisan patients' bill of rights to assure cancer patients of high-quality care. The President and Vice President urged Congress to stop delaying and pass a strong enforceable patients' bill of rights this year. The patients' bill of rights would provide many critical protections for patients with cancer including access to the specialists they need and continuity-of-care protections to prevent them from having to change care suddenly in the middle of treatment. The Dingell-Ganske legislation, that the President has said he would sign into law has a provision that would require all health plans to cover clinical trials, an extremely popular provision among the cancer community.

Unveiled groundbreaking research grants to examine how to prevent cancer recurrence, understand the lifelong impact of cancer treatment, and to improve the quality of life for cancer survivors. You are announcing that the NCI is releasing \$15 million in new cancer survivorship grants to fund top-of-the-line research to examine the impact of this disease on patients and their families. Specifically, researchers will examine the long-term effects of cancer treatments and the most effective ways to prevent recurrence of cancer and to improve the quality of life for cancer survivors and their families.

APPROVING NEW CUTTING-EDGE DRUGS FOR PATIENTS.

Announced that FDA has approved a record number of cancer drugs. In 1996, the President launched the FDA Initiative on Reinventing the Regulation of Cancer Drugs. Since that time, the FDA Division of Oncology Drug Products has approved more than twice as many new therapies as in the three years prior to the initiative.

Urged Congress to confirm Jane Henney, the first woman and the first oncologist nominated as FDA Commissioner. You are urging the Senate not to adjourn without confirming Dr. Jane Henney, the first woman and the first oncologist to be nominated as FDA Commissioner.

URGING CONGRESS TO PASS COMPREHENSIVE TOBACCO LEGISLATION

The President and Vice President are fighting against the leading cause of preventable cancer -- tobacco. Every day 3,000 children start smoking, and one thousand will die of a tobacco-related disease. Today the President and you are reminding Americans that they need a Congress that has the courage to pass comprehensive tobacco legislation to stop kids from smoking.

Revised Final 09/24/98 6:30pm
Jeff Shesol

**PRESIDENT WILLIAM J. CLINTON
RADIO ADDRESS ON CANCER
SAN JOSE, CALIFORNIA
September 26, 1998**

Good morning. Cancer, as everyone knows, is the cruelest of fates; and it strikes nearly every family. It struck mine, and I lost my mother to this devastating disease. Losses like these are the reason why tens of thousands of Americans are coming together today, on the National Mall in Washington, DC, with one, common purpose: to focus our nation's attention on cancer. Gathering today are patients and survivors; families and friends; doctors and Americans from all walks of life. The Vice President, who has led our administration's struggle against cancer, will join their ranks, and will speak about the specific steps we are taking to win that fight.

This morning, I want to talk to you about our overall vision of cancer care and research as we approach the 21st century. This is a time of striking progress, of stunning breakthroughs. With unyielding speed, scientists are mapping the very blueprint of human life, and expectations of the Human Genome Project are being exceeded by the day. We are closing in on the genetic causes of breast cancer, colon cancer and prostate cancer. New tools for screening and diagnosis are returning to many patients the promise of a long and healthy life. It is no wonder the scientists say we are turning the corner in the fight against cancer.

For six years now, my administration has made a top priority of conquering this terrible disease. We have helped cancer patients to keep health coverage when they change jobs. We have accelerated the approval of cancer drugs while maintaining safe standards. We have increased funding for cancer research, and, as part of our balanced budget, strengthened Medicare to make the screening, prevention and detection of cancer more available and more affordable.

Still, we know that we must never stop searching for the best means of prevention, the most accurate diagnostic tools, the most effective and humane treatments -- and, someday soon, a cure. To that end, there are several steps we must take.

First, to build on our remarkable progress, I have proposed an unprecedented multi-year increase in funding for cancer research. As studies proceed, we must remember that patients, as much as scientists, have a critical perspective to add to any research program. That is why I am announcing that all federal cancer research programs will, by next year, fully integrate patients and advocates into the process of setting research priorities. Next, as we continue to unravel the genetic secrets of cancer, we must apply that knowledge to the detection of this disease. I am, therefore, issuing a challenge to the scientific community: to develop, by the year 2000, new diagnostic techniques for every major kind of cancer so we catch it at its earliest and often most

treatable stage. Also, we should give more patients access to cutting-edge clinical trials, so they -- and researchers -- can get faster results. That is why I am directing the National Cancer Institute to speed development of a national clinical trials system -- a simple, accessible resource for health care providers and patients across the nation. I am also urging Congress to pass my proposal to cover the costs of those trials for Medicare beneficiaries, who need them most.

Finally, we are fighting against the leading cause of preventable cancer by doing everything we can to stop kids from smoking. America needs a Congress that has the courage to finish the job and pass comprehensive tobacco legislation.

New technological tools; new networks of information; new research priorities: all are part of our overall approach to health care that puts the patient first. On this day, as Americans renew our national fight against cancer, we do well to remember that we are doing more than curing a disease. We are curing the ills that disease may cause -- the stigmas, the myths, the barriers to quality care. The concerned citizens on the Mall today show that we are overcoming those barriers, one by one, and at the same time building a stronger and healthier America.

Thank you for listening.

The Tennessee group will include the following individuals:

Cancer Survivors -

Peggy Earnest

Darren Gish

Sandra Hamilton

Paula Hill

Vada Newcomb

Barbara Christian Sproul

Keith Junior, M.D.

Lori A. Teague

Kimbra Wilder

Dr. Harold Moses, Director, Vanderbilt Cancer Center

Mrs. L. Sykes Martin, Board of Directors, Vanderbilt Cancer Center

Mrs. William Wade Wood, Board of Directors, Vanderbilt Cancer Center

Mrs. Francine Corzine, Board of Directors, Vanderbilt Cancer Center

Dr. Jim Whitlock, Cancer Survivor, Chair, Vanderbilt Pediatric

Hematology/Oncology

Dr. Dennis Hallahan, Vanderbilt Cancer Center

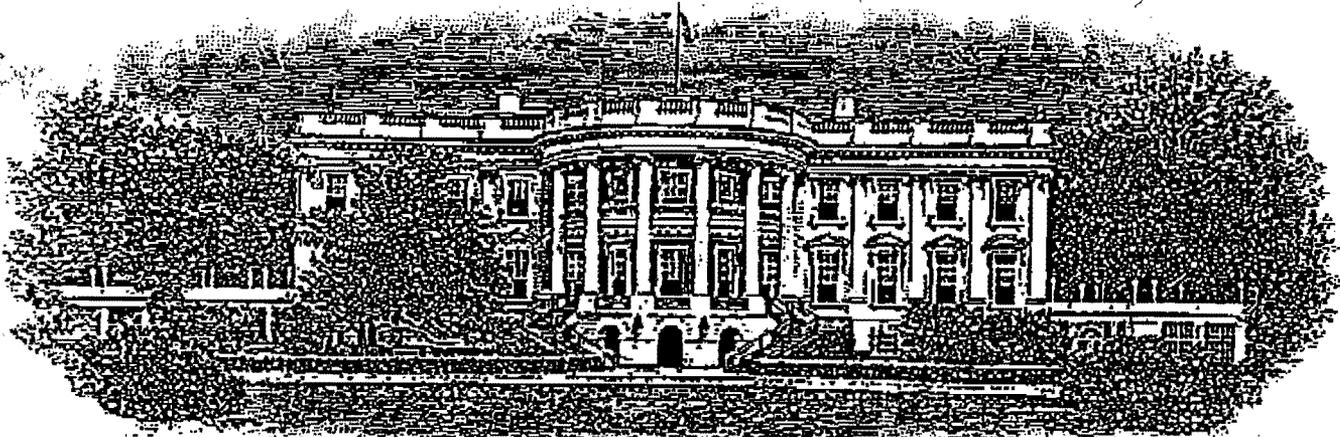
Linda Quigley, Cancer Survivor, Journalist, The Tennessean

Marianne Bouldin, President, Nashville Women's Political Caucus

Dr. Larry Kerr, Vanderbilt Fellow, National Science Foundation

Marilyn Yager, Director, Health Policy Development, Vanderbilt

The White House



925

DOMESTIC POLICY

03
4.7

OW-5750

FACSIMILE TRANSMISSION COVER SHEET

TO:

Chris

FAX NUMBER:

TELEPHONE NUMBER:

FROM:

TELEPHONE NUMBER:

PAGES (INCLUDING COVER):

COMMENTS:

here's where this heliport process

ended.

— 5

4.75 million

750
1900 million OW
5

15 million

14 million
to buy
gas

HHS FACT SHEET

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

September 26, 1998

Contact: HHS Press Office (202) 690-6343

HHS FOCUSES EFFORTS ON PREVENTION, DETECTION AND TREATMENT OF CANCER

Overview: More than 40 percent of Americans will be diagnosed with cancer during their lifetime and more than 20 percent will die of it. But our concerted efforts to battle cancer are making progress. The National Cancer Institute reports that cancer death rates in the U.S. population fell between 1991 and 1995, the first sustained decline since national record-keeping was instituted in the 1930s. In the short term, this decline means that as many as 16,000 Americans will survive cancer this year who would have died if the rates were the same as they were in 1990. The decline in cancer mortality has been greatest among African Americans, although overall cancer rates remain significantly higher among this group than among white Americans. While this news is encouraging, the fight against cancer remains a top priority for the Clinton Administration.

To meet the challenge and continue the progress, the Administration has implemented a variety of initiatives to improve cancer research, encourage cancer prevention and make cutting edge treatment available to Americans through Medicare and Medicaid.

The President has proposed a \$1.9 billion increase over five years in cancer research at the National Institutes of Health, an historic 65 percent increase to \$4.8 billion in 2003. Medicare has instituted important new benefits for prevention and screening for breast, colorectal, and cervical cancers. Americans over age 65 make up half of all cancer patients, and are 10 times more likely to get cancer than younger Americans.

Across HHS, experts are working to understand, prevent and treat cancer. On March 26, 1996, President Clinton announced the FDA Initiative on Reinventing the Regulation of Cancer Drugs, which outlined several initiatives to enhance cancer drug development and to provide opportunities for people to be actively involved in FDA's cancer drug advisory committee process. In the 30 months since the initiative was announced, FDA has approved 24 new therapies to treat more than a dozen different types of cancer, 16 new uses for already available cancer drugs, and 14 new medical devices to diagnose or treat cancer. The Centers for Disease Control and Prevention supports a variety of cancer-related programs, including early detection, surveillance, skin cancer prevention, and education projects.

Finally, the President and the Department of Health and Human Services have worked to prevent tobacco use among youth, step up the fight against breast cancer, decrease environmental hazards, and educate the public about the importance of prevention and early detection of breast, cervical, prostate, colorectal and skin cancer.

- 2 -

RESEARCH AND PREVENTION

Understanding Cancer. The National Cancer Institute at the National Institutes of Health leads the nation's efforts in cancer research. The most remarkable progress made in recent years has been in the knowledge of cancer biology. Research on how cancer develops has shown that cancer invariably involves altered genes and altered gene function. Studies in cancer genetics are providing unprecedented insight into the development and evolution of cancer and are generating knowledge about the most basic processes involved in the onset of cancer — those at the molecular level. In the past few years, scientists have made remarkable progress in the study of cancer genetics, identifying a number of genes that are involved in a number of cancers, including breast, prostate, kidney, skin, and colon.

- In 1994, studies of women with a family history of breast cancer revealed that alterations in two genes, *BRCA1* and *BRCA2*, increase a woman's risk for developing breast cancer.
- Scientists also are honing in on the location of the first hereditary prostate cancer gene, *HPC-1*. Researchers estimate that one in 500 men has an alteration in *HPC-1*. Familial prostate cancer accounts for about 1 in 10 cases, and *HPC-1* may be responsible for about one third of these cases.
- In 1998, NCI established a new Cancer Genetics Network to provide our nation with a network of nearly a dozen institutions that will collaborate in building a research and information technology infrastructure to explore ways to answer the many medical questions raised by discovering the genes responsible for cancer.
- NCI has a multitude of clinical trials underway to test various agents as possible preventive agents against cancers. One of the largest is the Prostate Cancer Prevention Trial which will determine whether the drug finasteride reduces prostate cancer risk.

Treatment. NCI is taking a new approach to conducting clinical research by harnessing the power of computer-based information technologies to speed the application of what is discovered in research to the practice of medicine. Once in place, the new Cancer Informatics Infrastructure will revolutionize cancer clinical research, making it easy for patients, families, at-risk individuals, and physicians to get information about available clinical trials. Using the information superhighway, these programs integrate the worlds of laboratory science, informatics, the World Wide Web, and clinical research to speed the application of scientific discoveries to the real world problems faced by doctors and patients. These projects make scientific information more accessible to scientists, doctors, and the public.

Drug Development. Over the past year, the National Cancer Institute started an ambitious program to help us develop new and effective anticancer drugs. The "Chemistry-Biology Centers Program," brings together the best scientists in these two disciplines to focus their efforts on cancer drug discovery. These Centers promise to help discover truly novel ways to prevent and treat cancer that were previously unimaginable.

For example, Herceptin, a new anti-cancer compound that was approved by the FDA on September 25,

- 3 -

1998, was developed by a biotechnology firm working with NCI and effectively attacks specific cancer cells that produce a protein called HER2. Studies indicate that Herceptin can help 25-30 percent of patients with advanced breast cancer. Also, early findings of a large, NCI multi-center trial show that the drug Taxol, when used in combination with other standard chemotherapy agents, has a small but significant benefit for breast cancer patients whose disease had spread to nearby lymph nodes.

In 1998, an NCI-sponsored study showed a 49 percent reduction in breast cancer incidence among the high-risk participants who took tamoxifen. The tamoxifen study proved for the first time that it is possible to reduce the short term incidence of breast cancer in women at high risk. An FDA advisory panel recently recommend approval of tamoxifen for reduction of short-term breast cancer incidence.

The FDA works closely with both NCI and private industry to make promising products available to patients with cancer. These products included some novel and even breakthrough approaches. Many were available in the United States before they were approved anywhere else in the world:

- the first therapeutic monoclonal antibody for cancer patients with refractory lymphoma;
- The first approval of a lipid encapsulated intravenous chemotherapy to minimize toxicity while preserving efficacy for patients with Kaposi sarcoma – a cancer that affects people with AIDS;
- a new use for chemotherapy that results in a dramatic increase in survival for patients with ovarian cancer.

Vaccine Development. Vaccine development is another major area of research designed to obtain an immune response in patients against their tumor cells. NCI scientists designed a synthetic vaccine to be used in patients with melanoma, an often deadly form of skin cancer.

Another example of targeted treatment, is anti-angiogenesis research. In cancer, tumors cannot grow or spread without developing new blood vessels that supply the cancer with oxygen and nutrients. About 20 compounds that inhibit the growth of blood vessels are being tested in human clinical trials.

Studies of Issues Faced by Cancer Survivors. Although cancer remains among the worst fears of Americans, it is becoming clear that -- thanks to research -- cancer is not the death sentence it once was. More than 8 million Americans today are cancer survivors who have special needs, and to help them, the National Cancer Institute is spending more than \$13 million a year studying the issues and problems they face.

For the first time this year, the National Cancer Institute began including consumer advocates as full voting members of the peer review groups that judge the worth of grant applications. This year the National Cancer Institute also formed a Director's Consumer Liaison Group, a formal committee of 15 cancer survivors who directly advise the NCI director and bring the patient's perspective to bear on the full range of NCI activities.

- 4 -

As part of the March 1996 announcement, FDA also initiated a program to educate and recruit cancer patients and their advocates to participate in meetings of FDA advisory committees – groups of outside experts that advise FDA on cancer-related therapies. More than two dozen cancer patients or their advocates have made important contributions to the advisory committees that review cancer-related therapies.

ENSURING RIGHTS FOR CANCER PATIENTS

With the "Consumer Bill of Rights," the Administration has proposed to protect the rights of all health care consumers and their families by assuring the health care system is fair and responsive to consumers' needs. Among the patient protections are two of special concern to cancer patients: Guaranteed access to specialists, which would allow cancer patients to have direct access to their oncologists without having to see a primary care physician for a referral; and, transitional care, which would allow patients to continue with an oncologist for a period of time, even if their insurance changes or if the doctor leaves or is terminated from the managed care plan. The Administration continues to press Congress to pass a comprehensive Patients' Bill of Rights and has already applied the Bill of Rights to all Federal health care programs and plans.

On September 17, the President announced that HHS had completed work on a new regulation establishing patient protections for Medicaid beneficiaries enrolled in managed care plans. The rule would bring Medicaid managed care in line with Patient's Bill of Rights, and provide the more than 15 million Medicaid beneficiaries enrolled in managed care plans with comprehensive, easy-to-understand information about those plans, along with a list of providers and their locations. The Medicaid managed care regulation fulfills the President's promise to extend the Patient's Bill of Rights to the tens of millions Americans enrolled in public health care programs, including the more than 20 million Americans in Medicare and Medicaid.

MEDICARE PREVENTIVE BENEFITS

On January 1, 1998, Medicare expanded several preventive procedures to detect diseases at early stages when they are most treatable. These new benefits were part of the Balanced Budget Act of 1997. Expanded benefits include: annual mammogram screenings for women age 40 and over; a one-time baseline mammogram for women age 35-39; expanded pap smear coverage to include both a pelvic exam and clinical breast exam every three years for most women; annual pap smear coverage for women at high risk for cervical or vaginal cancer; and coverage for colorectal cancer screening.

ELIMINATING RACIAL DISPARITIES

President's Clinton's Initiative on Race and Health has set, among other goals, a target of eliminating longstanding disparities in cancer rates that afflict racial and ethnic minority groups by the year 2000. Though overall health statistics have improved since 1993, research shows minorities suffer from certain diseases at up to five times the rate of white Americans. For example, African-American men under 65 suffer from prostate cancer at nearly twice the rate of whites; Vietnamese women suffer from cervical cancer at nearly five times the rate of whites; and Latinos have two to three times the rate of stomach cancer.

- 5 -

Surgeon General Dr. David Satcher has launched an outreach program to educate the public about the risks of cancers and other public health problems, and the President's budget proposal contains a \$250 million investment over five years to strengthen public health programs such as prostate cancer screening for African American men and breast and cervical cancer screening for Native Americans. Overall, the plan sets a national goal of eliminating health disparities in six areas by the year 2000: infant mortality; cancer screening and management; cardiovascular disease; diabetes; HIV/AIDS rates; and child and adult immunization levels.

DETECTING AND FIGHTING BREAST CANCER

Breast cancer is the most commonly diagnosed cancer, and the second leading cause of cancer deaths among American women. Early detection through mammography and clinical breast exams are essential to reduce deaths from this disease. For women age 50-69, having regular mammograms can reduce the chance of death from breast cancer by one-third or more. Despite the potential benefit, 33 percent of women ages 50-64, and 45 percent of women age 65 and older reported not receiving a mammogram during the past two years.

National Action Plan on Breast Cancer. The Clinton Administration has responded to the significant threat posed by breast cancer with increased efforts in research, prevention and treatment. HHS Secretary Donna E. Shalala convened a conference in December 1993 to establish a National Action Plan on Breast Cancer, which has awarded more than \$9 million in grants for 99 innovative research and outreach projects. In 1995, First Lady Hillary Rodham Clinton launched a campaign urging older women to obtain mammograms, and, in particular, to promote use of Medicare coverage for mammography. Both the President and the First Lady have appeared in TV public service announcements encouraging older women to get mammography screening.

Breast and Cervical Cancer Early Detection Program. The Centers for Disease Control's Breast and Cervical Cancer Early Detection Program brings critical screening services to underserved women in all 50 states, including older women, women with low income, and women of racial and ethnic minority groups. To date, more than 1.7 million screenings have been provided.

Mammography Quality Standards Act (MQSA). The Mammography Quality Standards Act (MQSA), published October 1997, gives FDA the authority to set high standards for mammography facilities and certifies those which meet the standards. The roughly 10,000 mammography facilities nationwide certified by the FDA must meet quality standards for both equipment and personnel, and are inspected annually. MQSA regulations require facilities to hire capable technologists, use quality dedicated equipment that produces clear images, and employ skilled interpreting physicians to interpret the results both accurately and efficiently. The rules also require that doctors and patients be fully and quickly informed of results so that any follow-up testing or treatment can begin immediately.

- 6 -

PREVENTING YOUTH TOBACCO USE

Each day, almost 3,000 young people in the United States become regular smokers, and nearly 1,000 of them will die prematurely from diseases related to tobacco use. Each year, more than 400,000 Americans die from smoking-related diseases, more Americans than are killed each year by AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.

In August, 1996, President Clinton announced the FDA tobacco rule designed to reduce the incidence of youth smoking. The FDA rule made it a federal violation to sell cigarettes or spit tobacco to anyone younger than age 18, and required retailers to ask for photo identification from anyone under age 27 who attempts to purchase tobacco products. In February, 1998, Vice President Gore announced a new national education campaign to educate consumers and help retailers prevent illegal sales of tobacco products to children. The Vice President also announced progress by the Substance Abuse and Mental Health Services Administration (SAMHSA) in implementing the Synar Amendment, legislation that requires states to monitor retailer compliance to ensure they prohibit tobacco sales to children.

The administration is also working to pass comprehensive national tobacco legislation, encompassing the President's five key principles: (1) a comprehensive plan to reduce youth smoking; (2) full authority for the FDA to regulate tobacco products; (3) changes in tobacco industry policy, including an end to marketing and promotion to children; (4) progress toward other public health goals, including biomedical and cancer research, a reduction of second-hand smoke, promotion of smoking cessation programs, and other urgent priorities; and (5) protection for tobacco farmers and their communities.

OTHER PREVENTION ACTIVITIES

Protecting Children from Environmental Exposures: In April 1997, President Clinton issued an executive order assigning high priority to addressing environmental health and safety risks to children. The executive order established a Task Force on Environmental Health Risks and Safety Risks to Children, which has identified four priority areas: 1. Asthma, 2. Unintentional injuries, 3. Developmental disorders, 4. Cancers. Through this task force, HHS is working with the Environmental Protection Agency (EPA) to promote policies and practices that emphasize child health. On September 3, 1997, HHS and EPA announced that they are creating the first federal research centers dedicated to the protection of the health of children from environmental threats. A total of \$ 10 million has been allocated for the initial year of the centers. The agencies plan to establish six centers nationally.

"Choose Your Cover" Skin Cancer Prevention Campaign. In May 1998 HHS Secretary Donna E. Shalala launched a national, multi-year awareness initiative to prevent skin cancer among Americans. The "Choose Your Cover" public service announcements target 18- to 25-year-olds, an age group that spends many hours out in the sun. The "Choose Your Cover" initiative will also reach out to 9- to 18-year-olds -- a critical time when adolescents set patterns of behavior that they carry with them into adulthood. The campaign was designed by the Centers for Disease Control and Prevention.

Changes to Disability Bill September 24, 1998

The following are two options that replace Sec. 101(b) of the draft bill that had offered all states the option to expand to a group of workers with disabilities as defined by the state.

1. Allowing states to offer eligibility to people with disabilities leaving SSI/Medicaid because of health care: This would narrow the second eligibility option to include only people with disabilities who lose SSI/DI because their disability has improved due to health care provided by Medicaid (e.g., not a natural improvement over time, cure of a condition, etc.)

Example: A person has rheumatoid arthritis. At the time of application for disability benefits, laboratory findings were positive for this condition and the doctor reported persistent joint pain that prohibited work. At the disability review a year later, laboratory tests were still positive for rheumatoid arthritis, but the impairment responded favorably to therapy and a new drug, so that the pain subsided enough for the person to potentially return to work. Although this is a temporary remissions that can be attributed to health care, the improvement would disqualify the person from disability and thus health benefits under current law. This provision would give states the option to allow this type of person to buy into Medicaid at a premium set by the state.

Draft language:

“(v)(1) The term ‘working individuals with disabilities’ means—

“(A) individuals ages 16 through 64 who—

(I) but for medical improvement, would be considered disabled under 1614(a)(3) or 223(d) at the time of a regularly scheduled continuing disability review; and

(ii) is employed, defined as:

(I) earning at least the applicable minimum wage requirement under section 6 of the Fair Labor Standards Act (29 U.S.C. 206) and working at least 40 hours per month; or

(II) is engaged in a work effort that meets substantial and reasonable threshold criteria for hours of work, wages, or other measures, as defined by the State and approved by the Secretary.”

2. Limited state option to cover for people with potentially severe disabilities: Without adequate health care, some moderate disabilities can become severe enough to prohibit work and qualify people for disability and health benefits. This demonstration would allow a limited number of states to create an optional eligibility category for people with such conditions. States would be given the authority to restrict eligibility based on functional status and/or medical listings without the risk of opening up Medicaid to all people with lesser disabilities. Only a limited number of states could participate for a five-year trial period (modeled on the Community Supported Living Arrangements option under 1930). To limit Federal cost liability, states would no longer receive Federal matching payments for additional workers with potentially severe disabilities if a cumulative Federal expenditure target is exceeded.

Example: Some people with diabetes or epilepsy require health care to control their conditions but do not have enough hypoglycemic attacks or seizures to meet the SSA medical listings criteria. Similarly, workers with multiple sclerosis or Alzheimer's disease will likely become eligible for disability benefits but may not have the severity of their condition or functional limitations to qualify. This option would allow a limited number of state to opt cover such people in a Medicaid buy-in.

Draft language:

SEC. 104. MEDICAID BUY-IN FOR WORKERS WITH POTENTIALLY SEVERE DISABILITIES.

(a) Medicaid Buy-In for Workers with Potentially Severe Disabilities.—Under this title, the term “Medicaid buy-in for workers with potentially severe disabilities” means the medical assistance in the State plan of a participating State, as determined under subsection (c), furnished to an individual, as determined under subsection (b), who is a worker with a potentially severe disability.

(b) Worker with a Potentially Severe Disability Defined.—In this title, the term “worker with a potentially severe disability” means an individual ages 16 though 64 who—

(1) meets the State definition, as approved by the Secretary under subsection (c), of having a specific physical or mental impairment that, but for medical assistance, will result in eligibility under section 1614(3); and

(2) is employed, as defined in 1902(v)(1)(ii).

(c) Criteria for Approval of Participating States.—The Secretary shall approve a limited number of State plan amendments under this section using the following criteria:

(1) the State definition under (b)(1) is determined by the Secretary to be clearly specified and developed with public consultation, so as to reduce the likelihood of litigation over the limits of such definition;

(2) the State provides medical assistance to individuals described in 1902(a)(10)(A)(ii)(XV) and applies the same premiums and cost-sharing charges applied to individuals eligible under 1902(a)(10)(A)(ii)(XV) to individuals eligible under this subsection; and

(3) the number of participating States shall be limited to 5; and

(d) Maintenance of Effort.—Federal funds paid to a State for medical assistance under this section must be used to supplement but not supplant the level of State funds expended for workers with potentially severe disabilities under programs in effect for such individuals at the time the State plan under this section is submitted for approval. A State plan under this section is approvable on condition that the Governor certifies that the plan satisfies this requirement.”

(e) Limitation on Federal Financial Participation.—If the sum of all participating States' cumulative Federal financial participation, beginning with the effective date, exceeds [\$300,000,000], Federal financial participation shall end.

(f) Effective Date, Evaluation, and Sunset.—This section shall apply on and after October 1, 1998 and expires on September 30, 2003. The Secretary shall assure that an independent evaluation of this option is completed prior to its sunset.

DRAFT

September 2x, 1998

TO:

FROM:

RE: **HEALTH INSURANCE NUMBERS FOR 1997**

On Tuesday, September 29, the Census Bureau will release its estimates of health insurance coverage for 1997. Its main findings include:

- **Number of uninsured has increased by 1.7 million:** About 43.4 million people had no health insurance coverage in 1997, up from 41.7 million in 1996 and 38.6 in 1992.
- **Number of uninsured children remained constant at 10.7 million.** The same holds true for poor children: about 3.2 million were uninsured in both 1996 and 1997. This is a big difference from the change between 1995 and 1996, when 800,000 of the 1.1 million increase in the uninsured were children.
- **Number of uninsured poor also did not increase.** About 11.2 million poor Americans were uninsured, virtually unchanged from the 1996 estimate of 11.3 million. The Census press release notes that about half (49.2 percent) of poor full-time workers were uninsured, down from 52.2 percent in 1996. The proportion of all uninsured who are poor continues to fall -- showing that this is an increasingly middle-class problem.
- **The increase in the uninsured occurred among non-poor adults.** It appears that all of the increase in the uninsured was for adults with income above the poverty line.
- **The rate of lack of insurance increased most in young adults (18 to 24), people in families earning between \$25,000 and 50,000, and working in firms with 25 to 500 employees.** People considered "near poor" -- in mid-size firms, often in first jobs that earn them a decent income -- are increasingly lacking insurance.

REASONS FOR THE CHANGES

Since the number of people covered by Medicaid has decreased at the same time as the increase in the uninsured, we expect that most advocates will blame welfare reform for this effect. Critics of welfare reform have been watching the poverty and health coverage trends closely, looking for validation for their predictions of negative effects. There is evidence that some states use "diversion" programs which discourage people from applying for TANF and thus learning about Medicaid. A more important issue is that many low-income people assume that they are not eligible for Medicaid because their work.

However, a close look at the trends suggests that what is happening is not closely related to welfare reform. The general trend toward fewer people in poverty and a greater proportion of low-income people working suggests that adults are moving out of Medicaid eligibility and into jobs that may not offer affordable health insurance. States have to offer Medicaid only to adults who would have been eligible for AFDC under its pre-reform rules and those transitioning to work. States have the option to expand to higher income parents -- an option expanded through the "100 hour rule" released this summer -- but generally do not even cover all parents below poverty, thus leaving out most workers.

This leads to the question of trends in employer-based insurance. There continues to be a strong relationship between health insurance coverage and the type of work and firm size. Coupled with an increase in the number of people who work part-time (check), a growing proportion of part-time workers are uninsured (24 percent). Also, the proportion of firms with 25 to 500 employees that offer employer-based insurance continues to decline, although their rates of offering coverage are still not as low as employers with few than 25 workers (only 28 percent of such workers have employer-based coverage). However, on the whole, the proportion of the U.S. workers receiving employer-based insurance has remained relatively constant.

Recently, the Health and Human Services Actuaries released their projections of national health spending that include an interesting assumption about employer-based health coverage. They suggest that employment-based insurance may begin to increase in the future as unemployment remains low, since it will serve as a way to attract workers. This could mitigate the increasing number of uninsured.

RESPONSE

We believe that we should express strong concern about this trend. Health insurance coverage has always been one of the President's major concerns, and, given the gains made in employment, income and the reduction of poverty, this news is particularly distressing.

To ensure that this problem does not get worse, we should emphasize our work with Children's Health Insurance Program (CHIP). The rapid decline in coverage for children stopped in 1997, as the nation debated expanding coverage to children and states began expanding coverage. Now, we must work with states to implement CHIP as rapidly as possible and work with Federal agencies, the private sector, providers, community-based groups and others to make sure that all children eligible for CHIP and Medicaid are enrolled.

It also might be helpful to suggest that we will consider new policies that will help adults as well as children in working families. In the same way that CHIP was built on state and Medicaid programs for children, we should examine models for coverage low-income, working adults, including simplifying Medicaid or seeing if CHIP can be extended.

Recent Trends in Health Insurance: Embargoed Until 9/29/98

	1994	1995	1996	1997
OVERALL				
Uninsured (millions)	39.7 m	40.6 m *	41.7 m **	43.4 m **
Uninsured	15.2%	15.4% *	15.6% *	16.1% **
Private coverage	70.3%	70.3%	70.2%	70.1%
Medicaid	12.1%	12.1%	11.8%	10.8%
POOR				
Uninsured (millions)	11.1 m	11.0 m *	11.3 m	11.2 m
Uninsured	29.1%	30.2%*	30.8% *	31.6%
Proportion of uninsured who are poor	27.8%	27.1%	27.0%	25.9%
Medicaid	46.2%	46.4%	45.5%	43.3%
UNINSURED BY AGE				
0 to 17 years	14.2%	13.8%	14.8%	15.0%
18 to 24 years	26.7%	28.2%	28.9%	30.1%
25 to 34 years	22.0%	22.9%	22.3%	23.3%
35 to 44 years	16.0%	16.6%	16.3%	17.3%
45 to 64 years	13.3%	13.3%	13.7%	14.1%
65 + years	0.9%	0.9%	1.1%	1.0%
UNINSURED BY INCOME				
< \$25,000	23.2%	23.9%	24.3%	25.4%
\$25,000 - 49,999	15.4%	16.2%	16.6%	18.1%
\$50,000-74,999	8.7%	9.3%	10.0%	10.1%
\$75,000 +	7.0%	6.7%	7.6%	8.1%
WORKERS WITH EMPLOYER-SPONSORED INSURANCE				
All firms	53.3%	53.2%	53.1%	53.0%
< 25 workers	27.9%	28.3%	28.2%	28.4%
25-99 workers	52.6%	53.7%	53.9%	52.4%
100-499 workers	63.2%	63.5%	63.1%	61.8%
500-999 workers	67.4%	65.1%	66.1%	66.7%
1000 + workers	67.9%	67.7%	67.1%	66.6%

* Insignificant change; ** Significant change; if no asterisk, no test available.

Uninsured Children Less than 18 Years Old

	1995	1996	1997
OVERALL UNINSURED			
Total (number)	9.8	10.7 **	10.7 *
Total	13.8%	14.8% **	15.0%
Private	66.1%	66.3%	66.9%
Medicaid	23.2%	21.8%	20.5%
POVERTY AND THE UNINSURED			
Poor uninsured (number)	3.1 m	3.4 m *	3.4 m *
Poor uninsured	21.4%	23.3% *	23.8%
UNINSURED BY AGE			
< 6 years	13.3%	13.8%	14.4%
6 to 11 years	13.5%	14.6%	13.9%
12 to 17 years	14.5%	16.1%	16.7%
UNINSURED BY RACE			
White	13.4%	13.9%	14.1%
Black	15.3%	18.6%	18.9%
Hispanic	26.8%	28.9%	28.6%

* Insignificant change; ** Significant change; if no asterisk, no test available.

To Dizeus -
Please call/
come BY.

TALKING POINTS ON THE NEW HEALTH INSURANCE NUMBERS

BACKGROUND. On Tuesday, the Census Bureau will release its estimates of the health insurance coverage of Americans for 1997. Highlights include:

- **Number of uninsured has increased by 1.7 million:** About 43.4 million people had no health insurance coverage in 1997, up from 41.7 million in 1996 and 38.6 in 1992.
- **Number of uninsured children remained constant at 10.7 million.**
- **Number of uninsured poor also did not increase.** About 11.2 million poor Americans were uninsured, virtually unchanged from the 1996 estimate of 11.3 million. The proportion of all uninsured who are poor continues to fall -- showing that this is an increasingly middle-class problem.

RESPONSE

- The increase in the number of uninsured Americans is of great concern to the President. Since the day he took office, the President has recognized the problems that come from lacking insurance: parents not being able to buy needed medication for their children; people letting chronic conditions go uncared for and ending up in the emergency room; families losing their savings due to a catastrophic illness.
- We remain concerned that some of this increase in the number of uninsured may be an unintended consequence of welfare reform. One of the President's highest priorities in welfare reform was maintaining Medicaid eligibility for people who have had such eligibility before reform. He also recently released a regulation, called the "100 hour rule," that essentially allows states to cover working parents who earn too much to be eligible for Medicaid. We hope that states take advantage of this option.

However, many low-wage workers may think that, because they are not eligible for work assistance, they are not eligible for Medicaid — which is not always true. Additionally, not all of the jobs employing former welfare recipients offer affordable insurance.

To address these problems, the President has directed his staff to review policies that can better ensure that workers eligible for Medicaid are enrolled and that those who are not eligible for Medicaid have affordable options.

- The good news is that the number of uninsured children, which had been climbing, did not increase in 1997. This may have resulted because of the President's, Governors' and Congress's focus on this problem. The Children's Health Insurance Program (CHIP), created in the Balanced Budget Act, is the largest single expansion of coverage for children in 30 years. Passed in August, it became effective in October 1997 and some states began enrolling children at that point. We hope that, next year, we will begin to see the number of children decline as a result.

"We now have a new weapon in our fight against breast cancer," said HHS Secretary Donna E. Shalala. "For certain women with advanced disease, this ~~new~~ ^{can mean new} product ~~brings~~ hope."

"As an oncologist myself, I know nothing is more important than giving patients and their doctors new ways to fight serious and life-threatening illnesses," said Dr. Michael A. Friedman, FDA Acting Commissioner. "The increasing use of biological products such as HERCEPTIN to treat the underlying causes of diseases is an exciting development in medicine. FDA will continue to make the review of products for serious and life-threatening diseases one of our highest agency priorities."

The benefits of HERCEPTIN was shown in two clinical trials. In a randomized, controlled clinical trial, 469 patients with metastatic disease who over-expressed HER2 were assigned to receive chemotherapy alone or chemotherapy in combination with HERCEPTIN. As a group, the women who received chemotherapy plus HERCEPTIN had less rapid tumor growth, more tumors were reduced 50% or more in size, and one-year survival rates were higher.

Specifically, the median time to disease progression was 7.2 months for those receiving HERCEPTIN and chemotherapy and 4.5 months for patients receiving chemotherapy alone. The overall tumor response was 44% in the HERCEPTIN group and 29% in the chemotherapy alone group. The one-year survival rate for the HERCEPTIN combination treatment was 79% versus 68% for chemotherapy alone.

In a second clinical trial with 222 patients, HERCEPTIN was found effective when used alone for a group of breast cancer.

patients who had relapsed following previous chemotherapy for metastatic disease. The tumor response rate was 14% overall, with 3% of patients having their tumors completely disappear. Tumor responses lasted in a range of 6 weeks to 18 months, with a median of 9 months.

In both clinical trials, the patients who responded best to HERCEPTIN had the highest levels of HER2 protein.

Testing of tumors from women with metastatic breast cancer is critical for the identification of the 25-30% of patients who overexpress HER2 and who can potentially benefit from treatment with HERCEPTIN. A new test to measure HER2 protein in tumors was approved today (DATE) and is called the DAKO HercepTest, manufactured by Dako, a Denmark-based company.

Selection of patients who are most likely to benefit is important because along with the benefit for certain patients also comes possible serious risks. The use of HERCEPTIN either alone or in combination with chemotherapy can result in a weakening of the heart muscle which can lead to congestive heart failure. This potentially life-threatening side-effect was most common in patients who received HERCEPTIN in combination with chemotherapy consisting of anthracyclines and cyclophosphamide (AC). Because the benefit is not great enough to overcome this serious risk, HERCEPTIN is not approved to be used with AC.

All patients treated with HERCEPTIN should have their heart function assessed before starting treatment and closely monitored during treatment. If patients have heart problems, physicians must be extremely cautious in deciding whether the potential

benefit is worth this risk.

Other side-effects which were more frequent with HERCEPTIN plus chemotherapy as compared to chemotherapy alone include a reduction of white blood cells (leukopenia), anemia, diarrhea, abdominal pain and infections. Side-effects that occur in about half of the patients during the first infusion with HERCEPTIN include chills, fever, pain, weakness, nausea, vomiting and headache. These were treatable and were much less likely to occur with subsequent infusions.

HERCEPTIN is administered as an intravenous infusion given weekly, according to the package insert. The treatment can be administered in an outpatient setting.

HERCEPTIN is the second monoclonal antibody approved to treat cancer. The first, Rituxan (trade-name), was approved in Nov., 1997, for patients with one type of non-Hodgkin's lymphoma, a cancer of the immune system.

HERCEPTIN is manufactured by Genentech, Inc., San Francisco California. FDA's Center for Biologics Evaluation and Review (CBER) granted fast track and priority review status to Genentech's application for HERCEPTIN and reviewed and approved it in approximately 4.5 months. For further information about the availability of HERCEPTIN, physicians or patients can call the company at 650-225-.....

###

New, Innovative Programs of the National Cancer Institute

Here are fleshed out descriptions of several of the innovative new National Cancer Institute initiatives discussed at the Monday meeting. Also included is a timetable for the further integration of consumer in the operations of the NCI and its review processes. The final item is a press release about the new survivorship grants, written as though the Vice President will make the announcement September 26.

Table of Contents

Cancer Genome Anatomy Project, Page 2

Unconventional Innovations Program, Page 5

Clinical Trials and Informatics, Page 8

New Drug Development: Chemistry/Biology Centers and Drugs from Nature, Page 11

Integration of Patients and Advocates in NCI Programs, Page 13

Draft Press Release on Survivorship Grants, Page 15

Cancer Genome Anatomy Project

A year ago, I unveiled a powerful new tool in the fight against cancer, the Cancer Genome Anatomy Project. This project may prove to be the dawn of a new era in harnessing genes for the good of people.

CGAP uses interdisciplinary research teams at the National Cancer Institute (NCI), at academic centers, and within the private industrial sector. The overall goal is to determine the complete profile of the genes expressed in normal, precancerous, and cancer cells, with the aim of making it possible to recognize all major steps of cancer development. This genetic information can guide future efforts to develop diagnostic indicators and to identify targets for early detection or drug discovery. The progress made by CGAP in just one year is staggering:

- The project is now the leading source for discovery of new genes associated with cancer. Despite the complexity of the task, the NCI predicts that it will complete the index of genes expressed in cancer in the year 2000, well ahead of the original schedule. When complete, this information and the technologies needed to test these findings will be provided to doctors to improve our ability to diagnose cancer by the molecules fueling cancer growth. A significant problem now for doctors is that they are unable to identify the organ of origin in a significant number of cancers. CGAP information will make this a problem of the past, because the genes expressed in all cancers will be known, and cancers previously recorded as "of unknown origin" will be identifiable based on their genetic profiles.
- To date, the project has uncovered more than 300,000 DNA sequences and more than 12,000 new genes. In five major cancers (breast, colon, ovary, prostate and lung), CGAP has discovered 1,500 new genes that can now be studied for their

possible role in cancer development.

- CGAP research has led to improved methods for preparing and examining DNA for study. Under the microscope, tissues are complicated structures with many different types of cells. To be able to analyze the genetics of a particular type of cell, scientists must first be able to dissect those cells from the tissue sample. A new technology originated at the NIH, laser capture microdissection, is being commercially developed by the NCI in collaboration with a private sector company. This research technology procures pure cells from microscopic samples of tissue, enabling the genetic analysis of normal and cancerous tissues by a broad spectrum of scientists worldwide.
- CGAP research has led to the discovery of a gene that is strongly expressed in the epithelial cells of the male and female reproductive systems. Because epithelial cells are the source for most of the cancers of these organs, the new gene is a possible target for the development of new diagnostic antibody tests and new treatment vaccines.
- Researchers working with CGAP information have discovered a gene for the enzyme telomerase, a key to the genetic processes that control cell aging and death. Scientists are actively looking at telomerase as an early indicator of a wide variety of cancers.

Background

Of the approximately 100,000 genes found in human cells, scientists believe that the altered activities of a relatively small number of them are responsible for transforming a normal, well-behaved cell into a cancer cell. Identifying these cancer genes and their patterns of expression

defines the central scientific hunt in cancer biology and opens an unprecedented window into the nature of cancer.

No one genetic alteration is enough to make a normal, healthy cell a cancer cell. Rather, an accumulation of changes in a relatively small number of genes during the lifetime of a cell is required. This understanding has allowed scientists to begin describing the evolution of specific cancers from normal to pre-cancer to cancer.

Each cancer is ultimately defined by its pattern of gene activity. This unique pattern determines the cancer's rate of growth, its tendency to spread, and whether it will be responsive to hormones and drug treatments. The genetic activity is also responsible for the ability of a person's immune system to recognize and respond to the cancer.

To do this work, scientists are extracting RNA from tumor tissue. When a gene becomes activated, RNA instructs a cell to manufacture a particular protein. By reading the RNA, scientists can identify the genes that are expressed in a cancer cell. By making copies of the RNA, making complementary DNA (cDNA), they can decipher the code of the gene. As scientists find the genes, they organize them into a library. Each library includes information on the number of genes discovered so far for a specific cancer, codes for each gene, the gene's location, and information on how prominently it is expressed. Many laboratories around the world are working to decipher the genetic code of various cancers. It is a laborious, time-consuming and expensive process. The Tumor Gene Index will help scientists in this work by enabling them to compare genetic information from cancer cells with the genetic information from normal cells of the same body site.

Unconventional Innovations Program

Imagine that your doctor can scan your body for alterations in the molecules within your cells and identify changes leading to cancer. Imagine also that the doctor can correct the changes with minimally invasive procedures instead of the current use of biopsies, surgery, chemotherapy and radiotherapy.

Star Wars medicine? Perhaps, but the National Cancer Institute's forward-thinking vision for cancer medicine in the 21st century is based on stimulating the development of brand new technologies, such as remote sensing (from a monitor outside of the body) to detect body cells that are beginning to express genes typical of the profiles seen in cancer cells. The long-term goal is the development of noninvasive detection, diagnosis and intervention in cancer at its earliest stages of development.

The problem with current approaches to cancer tests and treatments is that, while often effective, they can be uncomfortable, painful, or require surgery. Even then, the doctor often must recommend treatment approaches based on incomplete information. By building on the growing index of genetic information expressed by normal and cancer cells, scientists at the NCI are putting together the Unconventional Innovations Program to take what is being rapidly learned about the genetic profile of cancer cells and create highly specific, noninvasive applications for cancer care.

This past summer, the NCI began to plant the seeds for the development of these new approaches. The NCI is reaching out to communities of scientists outside of cancer research to find out about technologies developed for other purposes, such as interplanetary probes and military defense, to find technologies that might be useful for the highly specific molecular recognition and signaling capability needed for this new generation of diagnostic and treatment tools. Once this information is acquired and sifted, the NCI will solicit proposals for the first

investments in these new technologies, year 1999 contracts to develop new technologies and build a community of scientists working synergistically in this new field of cancer research.

The vision of the Unconventional Innovations Program is to couple detection and diagnostic approaches, based on remote sensing of the genetic profile and location of cancer cells, to treatments that are less invasive. The ultimate goal of the program is medical care for cancer patients using diagnostic approaches to detect very early cellular changes typical of cancer and to suggest treatments that stop the precise molecular alterations occurring in individual patient's cells.

Cancer results from changes in the genes and changes in how our genes are at work within our cells. As scientists learn more and more about gene changes that lead to cancer, they are conceiving new ways to apply that knowledge to cancer medicine, including prevention.

How would the new cancer medicine work? Imagine that you are visiting your physician for a routine yearly checkup. You are given a cocktail with synthetic molecules that together can spotlight hundreds of genetic changes that are specific for cancer. You then receive a whole body scan. It detects a small focus of cells in your liver that are related to cancer development.

You are then sent to another room, where a laser focuses on the exact location of the abnormal cells in your liver. A short burst of the laser destroys the cells that were marked during the diagnostic procedures, avoiding any damage to normal cells. You then return to work with the recommendation that you return to your doctor in six months for another checkup.

Or, say that you go to your doctor for your yearly medical examination. Samples of your urine, blood, sputum, and saliva are tested by a handheld device that detects hundreds of cellular changes associated with cancer. The device detects at low levels the presence of alterations indicating that your bladder harbors cells that may become a cancer. Your doctor then administers fluids that go to your bladder and wash it with molecules carrying a drug and a marker for the

cancer cells, so that the drugs only enter the cancer cells. A week later, you receive from the doctor a kit of indicator sticks to test your urine weekly for reappearance of the altered cells.

Sounds amazing, doesn't it? Yet, scientists at the NCI believe that, by imagining what is currently impossible, scientists will be able to visualize radically new approaches to cancer diagnosis and treatment, such as injectable tumor-killing nano-robots or smart polymers that both detect cancer and deliver drugs. NCI is creating a creative and ambitious new research environment for technology innovation and, within a year or two, will begin to fund the first new projects that will some day make their vision of better cancer care a reality for all of us.

Clinical Trials and Informatics

The National Cancer Institute is reforming its national clinical trials program through the power of computer-based communications and the capabilities of the World Wide Web. This new effort, called the Cancer Informatics Infrastructure (CII), will transform the current system over the next two years. After the transformation, patients and their physicians will be able to obtain cancer information faster and easier, and it will be easier to take part in clinical trials. CII will greatly speed the application of today's amazing discoveries to the daily practice of medicine.

NCI is developing the CII to simplify and accelerate all intervention studies--prevention, diagnosis, and treatment. The result will be revolutionary. For the first time, all cancer clinical trials will have common terminology and reporting requirements, greatly increasing the speed and efficiency of conducting a trial and the accuracy of their results. For example, by making trials simpler, with common data sets, doctors and patients will have one form to fill out rather than 50, and will have the privacy of their personal cancer information protected by the best technology available.

NCI is modernizing information links and establishing standards that will allow collaboration and sharing of results among North America, Europe, Japan, and indeed the whole world. Already, the U.S. Office of Protection from Research Risks has formed an agreement with the European Organization for Research and Treatment of Cancer that will improve and speed up trans-Atlantic cancer clinical research. It will make accrual of patients to trials faster, help harmonize cancer treatment worldwide, and speed transfer of knowledge from research to clinical practice. In addition, the U.S. Food and Drug Administration recently took action that further set the stage for a joint trans-Atlantic cancer clinical trials network.

Industry and the academic sector will play the principal role in building the CII. NCI will

promote communications among participating organizations, help develop appropriate standards, and fund initial projects.

But it will be the private sector that will ultimately make it happen. Over the next two years, the infrastructure will expand significantly as cancer centers, groups managing clinical trials, physicians in private practice, managed care organizations, large self-insured employers, pharmaceutical companies, patient advocates, and consumers join in an unprecedented partnership to make the CII a reality. NCI has requested \$20 million for this effort for 1999.

Another CII goal is to make it easier for patients, families, at-risk individuals, and physicians who wish to learn about available clinical trials. Slow and cumbersome paper-based systems of collecting data for multi-center studies will give way to electronic communication, linking sites of care delivery (hospitals, doctors' offices and clinics) and secure, research databases of investigators.

For example, by using their a computer, patients and their oncologists can find, for a patient's specific cancer, the best treatments and clinical trials. The physician can fill in a simple form, submit it, and — if the physician and patient meet certain standards and criteria — the patient will be entered into the clinical trial, receive the therapy, and remain in the care of his or her physician. This will remove many of the barriers patients and physicians face in entering clinical trials. At the same time, by accruing patients to trials faster than before, answers to key scientific questions will come much faster.

In addition, the CII will provide instant access to information on best cancer management practices, new research results, and on the availability of clinical trials in the areas of diagnosis, treatment, and prevention. As a key part of this initiative, NCI has begun a comprehensive overhaul of its Physicians Data Query (PDQ) a clinical trials database, and has developed the new

cancerTrials web site (cancertrials.nci.nih.gov), a comprehensive resource designed to help the public find clinical trials information quickly and easily.

Not only will the public, patients, and physicians have easy access to the latest information, they will be able to be able to tailor the information to fit their individual needs.

The CII is a superb example of how NCI will use the information superhighways to test more rapidly the explosion of new ideas in cancer research and reach more Americans with vital cancer information. NCI realizes, however, that not everyone has access, or will have access, to the information superhighways. The CII is designed to bring information to people in all ways possible--the Web, the telephone, through an HMO, through print and electronics. NCI is exploring the use of public kiosks in libraries and malls to enable the public to have online access to cancer information.

This is but another in a series of bold new approaches at the NCI to create specialized cancer science infrastructures so that all Americans have ready access to the best, newest cancer information. These programs will be developing new diagnostics, new interventions, and new treatments by applying the discoveries of scientists in molecular biology to the practice of medicine. Using the information superhighways to best effect, these programs integrate the worlds of laboratory science, informatics, the World Wide Web, and clinical research to speed the application of scientific discoveries to the real world of cancer that is faced by doctors and patients.

Drug Development

Recent developments in chemistry and biology suggest possibilities for an entirely new vision for cancer drug discovery. Using compounds developed in the laboratory or found in nature, scientists can now use the principles of genetics, chemistry, and engineering to develop new anti-cancer drugs.

Chemistry-Biology Centers Program

Scientists' use of genetic chemistry is making it possible to develop millions of new molecular compounds within only a few months and then screen them for potential use against cancer. In the past, scientists relied on molecules found only in nature. Today, thousands of compounds can be developed and tested instantly, using high tech machinery, to determine if they may have an anti-cancer effect.

New cancer treatments must come from the discovery of new molecules. To speed the discovery of these new molecules, the National Cancer Institute began the "Chemistry-Biology Centers Program," to create multidisciplinary teams for drug discovery. These teams feature close collaboration between chemists and biologists to take full advantage of the opportunities presented by scientific advances in genetics, biology, and engineering. This year, NCI awarded \$5.5 million in grants to create Chemistry-Biology Centers at four institutions: Harvard University (co-funded by Merck), the University of Pittsburgh, Torrey Pines Institute for Molecular Studies in San Diego, and the Scripps Research Institute in La Jolla, CA. NCI has set aside an additional \$3 million for the first year of funding for a new round of grants that will create more centers in 1999.

The program brings together the best scientists in chemistry and biology to focus their efforts on cancer drug discovery. By enabling chemists and biologists to work together on

research projects, these Centers promise to help discover truly novel ways to prevent and treat cancer that were previously unimaginable.

New Drugs from Nature

Recent developments in biology, chemistry, and genetics are enabling scientists to take full advantage of the rich, untapped world of microbes in ways that were previously impossible.

The National Cancer Institute has been researching natural products for the last 40 years, and a number of anti-cancer agents have been discovered. Until recently, however, scientists have been greatly limited in their ability to study them. It is estimated that less than 1% of bacterial species and less than 5% of fungal species are currently known, and recent evidence indicates that millions of microbial species remain undiscovered. New cultivation technologies and genetic engineering are opening the door to this vast and valuable resource. Extreme environments, such as hot springs and sulfur pools, deep-sea reefs, terrestrial ice fields, and Arctic and Antarctic waters are now being studied to find anti-cancer compounds.

Beyond finding compounds in nature, scientists are now using genetic engineering to create "biosynthetic" or "unnatural natural" products that may produce novel drugs for the treatment of cancer. Scientists now can change the genes in an organism that is producing one type of chemical so it produces another type of chemical altogether. The new chemical may be a more effective anti-cancer agent, or cause fewer side-effects, than the original.

NCI is supporting research in these areas aimed at finding new molecules and enhancing the potential for the discovery of novel drugs to fight cancer.

Integrating Patients and Advocates in NCI Programs

The role of patients and advocates in decision-making at the National Cancer Institute (NCI) has grown in recent years as NCI's mechanisms for obtaining and utilizing their input have expanded. In 1996 NCI established the Office of Liaison Activities (OLA) to serve as a central point of contact and link to cancer advocacy organizations, and to strengthen NCI's relationships and cooperation with these groups. With the help of that office, the NCI Director, Dr. Richard Klausner, established the Director's Consumer Liaison Group (DCLG), the first all-consumer advocate advisory committee at NCI and the National Institutes of Health (NIH). The DCLG is a landmark initiative that brings together a diverse group of consumer advocates and scientists on a regular basis to address key issues in cancer research. It is a model for other NIH institutes.

By virtue of its own work, and by facilitating the broader participation of other consumer advocates in various NCI activities, the DCLG 1) ensures that cancer patients help to shape the course of NCI's efforts to eradicate this disease; 2) provides a rich source of ideas and viewpoints for NCI; 3) gives the cancer advocacy community an opportunity to provide input in the planning of NCI programs and future directions; 4) is a channel for consumers to voice their opinions and concerns; and 5) provides NCI with advice and feedback from the consumer community on a broad array of issues.

Cancer consumer advocates also:

- Provide a cancer patient's view on a wide range of issues including those of special concern to medically under-served populations.
- Serve on a variety of NCI advisory committees, including the National Cancer Advisory Board (NCAB), and review groups to help NCI determine the current state of research in the most prevalent cancers affecting men and women, such as prostate and breast cancers.

- For several years, consumer advocates have served on NCI peer review groups evaluating special competitions for contracts and grants.
- In 1998, for example, consumers served as full voting members of a peer review panel evaluating grant applications received in response to NCI's request to develop research projects in cancer survivorship. (These are scheduled to be announced by the Vice President on September 26 – see following press release draft).
- This year, NCI expanded its use of consumers in review panels for grants to cancer centers and for grants supporting Specialized Programs of Research Excellence on specific cancers. They also participate in the review of grant and contract applications for clinical studies and population-based (epidemiological) research.
- In 1999, NCI will expand its current database of consumer advocates available for service on its committees. It will do this by soliciting nominations for people to be included in that database, with a special attempt to find advocates for diseases now under-represented, such as lung and colorectal cancers.
- In 1999, NCI will formally evaluate its experience in using consumers in grant and contract review; then, if feasible, plan a pilot test for use of consumers on panels reviewing more basic and translational science grant proposals.
- By 2000, consumers will be participating in the review of all large, multi-project (program project) grant applications that deal with clinical or population-based research. If the earlier evaluation is favorable, NCI will begin its pilot test using consumers on panel reviewing basic research applications.

DRAFT Press Release on Survivorship Grants

For Response to Inquiries

National Institutes of Health

EMBARGOED FOR RELEASE

p.m. EDT

Saturday, September 26, 1998

NCI Press Office

(301) 496-6641

NCI Awards \$15 Million to Study Cancer Survivors

Vice President Al Gore today announced that the National Cancer Institute (NCI) has earmarked \$15 million over five years for new research into the physical and emotional well-being of cancer survivors who are alive five or more years after diagnosis. This is in addition to the approximately \$18 million already earmarked by NCI for survivorship-related studies.

Advances in prevention, early detection, and treatment — the payoff from decades of research — all contribute to improved survival rates for most major cancers. As a result, eight million Americans are living with a history of cancer. Recent survivorship milestones:

- The five-year survival rate for children with cancer improved from 65 percent in the early 1980s to 74 percent in the early 1990s.
- The five-year survival rate for all cancers improved from 51 percent in the early 1980s to almost 62 percent in the early 1990s.
- Two million women with breast cancer are alive today.
- One million men are survivors of prostate cancer.

The grants will be made by NCI's Office of Cancer Survivorship (OCS), headed by Anna T. Meadows, M.D. OCS was formed in 1996 to identify important areas of research on survivorship. Workshops in 1996 and 1997 shaped OCS priorities, and in November 1997 the office supplemented existing NCI survivorship research with an additional \$4 million over two years. (Co-funding came from the Komen Foundation and the Public Health Service Office of Women's Health.) A request for applications for new grants on long-term cancer survivor

research went out during the summer of 1997.

NCI is funding 13 new survivorship grants; the National Institute on Aging is funding an additional two. The 15 grants listed below were chosen from a pool of 80 applications.

University of California-Berkeley, Berkeley, Calif.

Title: Young breast cancer survivors: a population based cohort

Principal investigator: Joan Bloom, Ph.D.

Term: Sept. 30, 1998 - Sept. 29, 2002; First-year amount: \$404,000

This study focuses on the social, emotional, and physical changes experienced by young breast cancer survivors — those diagnosed at age 50 or younger. By using information from a cohort of San Francisco-area survivors, the researchers will also assess the usefulness of workshops offering the latest breast cancer information.

University of California - Los Angeles, Los Angeles, Calif.

Title: Psychological well-being in long-term cancer survivors

Principal investigator: Beth Leedham, Ph.D.

Term: July 1, 1998 - June 30, 2000; First-year amount: \$42,000

Mental health consequences of cancer include depression and anxiety. But no one knows if these problems tend to linger 5 years or longer after diagnosis. This study will start answering these questions by developing new ways to measure the psychological well-being of cancer survivors.

AMC Cancer Research Center, Denver, Col.

Title: Quality of life in gynecologic cancer survivors

Principal investigator: Lari Wenzel, Ph.D.

Term: July 1, 1998 - June 30, 2000; First-year amount: \$169,000

Women suffering ovarian and uterine cancer often experience quality-of-life disruptions -- like infertility. By looking for ways to improve care for these cancer survivors, this study will hopefully point to strategies for reducing long-term problems caused by these cancers and their treatment.

University of Miami, Miami, Fla.

Title: Quality of life in adult cancer survivors

Principal investigator: Charles Carver, Ph.D.

Term: July 1, 1998 - June 30, 2003; First-year amount: \$324,000

After developing a method to measure quality of life for cancer survivors, researchers will assess Hispanic, White, and African-American survivors of breast, prostate, and colorectal cancers and Hodgkin's disease. Another branch of the study will look for psychological or social factors that may predict breast cancer recurrence.

***Cancer Research Center of Hawaii, Honolulu, Hawaii**

Title: Well-being in long-term multiethnic cancer survivors

Principal investigator: Carolyn Gotay, Ph.D.

Term: July 1, 1998 - June 30, 2003; First-year amount: \$256,000

This study will track 2,100 Filipino, Hawaiian, Japanese, and White prostate cancer survivors and their partners. Data on overall quality of life and satisfaction with treatment received and its side effects will help the researchers identify what interventions may be needed.

Sloan-Kettering Institute for Cancer Research, New York, N.Y.

Title: Premature menopause in survivors of childhood cancer

Principal investigator: Charles Sklar, M.D.

Term: July 1, 1998 - June 30, 2001; First-year amount: \$200,000

Girls who survive childhood cancers may experience early menopause and other reproductive problems. Studying a cohort of 5,500 adult female survivors of childhood cancer will help researchers determine what risk factors -- such as treatment received and age at treatment -- leads to reproductive problems. Understanding these risk factors will help patients and their doctors decide which treatments to pursue.

University of Rochester School of Medicine, Rochester, N.Y.

Title: Cardiac risk factors in pediatric cancer survivors

Principal investigator: Steven Lipschultz, M.D.

Term: July 1, 1998 - June 30, 2003; First-year amount: \$308,000

Children who survive leukemia and other cancers may have an increased risk of heart disease as a side effect of their treatments. By studying childhood cancer survivors from upstate New York, the researchers hope to find out which treatments cause such long-term heart problems and then look for ways to mitigate those risks.

***Wake Forest University School of Medicine, Winston-Salem, N.C.**

Title: Issues of survivorship among breast cancer survivors

Principal investigator: Electra Paskett, Ph.D.

Term: July 1, 1998 - June 30, 2001; First-year amount: \$122,000

Two million American women are breast cancer survivors, yet little is known about their physical, emotional, social, and economic well-being. After interviewing 400 long-term survivors about their quality of life, the researchers will develop a telephone counseling service.

Case Western Reserve University, Cleveland, Ohio

Title: Quality of life of older long-term cancer survivors

Principal investigator: Gary Deimling, Ph.D.

Term: July 1, 1998 - June 30, 2003; First-year amount: \$234,000

This study will look at a host of factors contributing to the quality of life of cancer survivors age 60 and older -- including physical and emotional well-being -- and will point to possible interventions -- such as support groups -- to improve the overall well-being of these survivors.

Oregon Health Sciences University, Portland, Ore.

Title: Quality of life following successful therapy for acute myelogenous leukemia

Principal investigator: Henry Nicholson, M.D., M.P.H.

Term: July 1, 1998 - June 30, 2002; First-year amount: \$213,000

This study will measure health problems that may stem from bone marrow transplants in children who survive leukemia. Intervention strategies aimed at improving the quality of life for future transplant recipients will also be developed.

American College of Radiology, Philadelphia, Pa.

Title: Quality of life in survivors of head and neck and prostate cancer

Principal investigator: Charles Scott, Ph.D.

Term: July 1, 1998 - June 30, 2001; First-year amount: \$187,000

More than 4,500 prostate cancer survivors and 2,700 head and neck cancer survivors will contribute to this survey of overall health and functioning. Among other topics, the study will explore survivors' physical, social, emotional, and spiritual well-being.

University of Texas M. D. Anderson Cancer Center, Houston, Texas

Title: Mutations induced in human sperm by cancer therapy

Principal investigator: Marvin Meistrich, Ph.D.

Term: Sept. 15, 1998 - Sept. 14, 2000; First-year amount \$57,000

Radiation and chemotherapy often damage sperm cells, perhaps even to the point of causing permanent mutations. By using longitudinal data from men with a variety of cancers, this study will help determine the risk of birth defects the children of men with cancer may face.

Fred Hutchinson Cancer Research Center, Seattle, Wash.

Title: Enhancing long-term survival after bone marrow transplant

Principal investigator: Karen Syrjala, Ph.D.

Term: July 1, 1998 - June 30, 2003; First-year amount: \$231,000

Although leukemia patients often receive bone marrow transplants, the long-term effects of such transplants are largely unknown. This study will compare two cohorts: the first received transplants 10 or more years ago; the second transplant group participated in clinical trials aimed at easing transplant recovery. After comparing the groups, the researchers will have better understanding of physical and psychological side effects of bone marrow transplants.

University of Wisconsin Comprehensive Cancer Center, Madison, Wisc.

Title: Quality of life in female colorectal cancer survivors

Principal investigator: Patrick Remington, M.D.

Term: July 1, 1998 - June 30, 1999; First-year amount: \$72,000

Do women who survive colorectal cancer benefit from support groups? A survey of several

hundred survivors will help answer this question while also providing data for further research on colorectal survivors' quality of life.

Medical College of Wisconsin, Milwaukee, Wisc.

Title: Measurable effects in head and neck cancer survivors

Principal investigator: Bruce Campbell, M.D.

Term: June 1, 1998 - May 31, 2001; First-year amount: \$230,000

Head and neck cancer survivors often have difficulty talking, swallowing, and performing other day-to-day tasks. Pilot data shows survivors who report these symptoms and continued pain also report a fear of recurrence; the researchers would like to look for ways to mitigate this fear.

* Grant funded by National Institute on Aging.

###

PROSTATE
CANCER
~~INFO~~ File

Gregory G. Henry

08/12/98 06:11:29 PM

Record Type: Record

To: Sarah A. Bianchi/OPD/EOP
cc: David H. Morrison/OMB/EOP, Bryan R. Smith/OMB/EOP, Robert L. Nabors/OMB/EOP
Subject: Materials for Response to Dean Ornish letter

Here is info you requested.

House appropriators have included the following in their report accompanying HR 4103 (they have said nothing specific in the bill):

"The bill includes \$10,000,000 only to continue the Department's nationally-recognized program to conduct basic and clinical research studies to combat diseases of the prostate. The goal of this program is to develop more effective, more specific and less toxic forms of therapy for patients in all stages of prostate disease. The Center for Prostate Disease Research established under this program uses the large net work of military hospitals around the country as a resource for information on the improved detection and treatment of prostate disease. The Department [of Defense] should continue to give the highest priority to funding research that is multi-institutional, multi-disciplinary and regionally focused. The Committee directs that of these funds, not more than \$2,500,000 shall be available only for a non-invasive prostate and coronary disease reversal program."

The Senate made the following statement in its report (also no mention in the bill):

"The Committee provides a total of \$250,000,000 for medical research activities conducted by the Department [of Defense]. Of this amount, the Committee directs that not less than \$135,000,000 be available for peer review breast cancer research and not less than \$40,000,000 be available for peer review prostate cancer research...."

You should be aware that 10 USC 2361 requires that DoD grants or contracts to colleges or universities be awarded on a competitive basis (except under very strict and difficult to meet circumstances). Thus, in all likelihood, even if Congress appropriates some funding, Ornish would have to submit to the competitive, peer-reviewed grants application and award process.

The following is a summary of DoD-Funded Prostate Cancer Research since 1992 (\$ in millions). Note that all funding was the result of earmarks. No President's Budget has ever requested funding in DoD for prostate cancer research, although significant funds are requested for NIH.

\$ in millions	1992	1993	1994	1995	1996
DoD Funded Prostate Research	2.0	2.0	2.0	14.3	7.5

KETCHUM PUBLIC RELATIONS
W O R L D W I D E

Fax: 202-835-~~7288~~ 8891

Date: 10/2/96

Time: 5:35

TO: CHRIS TENNING

FROM: JEFF KEPNER

FAX: 456 5542

TOTAL # OF PAGES INCLUDING COVER SHEET: 3

IF FAX TRANSMITTAL IS INCOMPLETE, PLEASE CONTACT ME AT: 835 8811

MESSAGE

PER OUR CONVERSATION

Note: The information contained in this facsimile is confidential and is intended only for the use of the individual or entity to whom it is addressed. If you are not the intended recipient or the person responsible for delivering it to the intended recipient, do not use or disclose this facsimile. If you have received this facsimile in error, please notify us immediately by telephone (202) 835-8800 and return the original via the U.S. Postal Service to 1201 Connecticut Avenue, Suite 500, Washington, D.C. 20036. Thank you.

BACKGROUND

Academic medical centers, the training ground for our nation's future health care professionals and the centers for world class, breakthrough, medical advances, are facing significant financial challenges as new efforts at cost containment force radical transformations in the health care marketplace. The Administration has shown its commitment to academic health centers by supporting increases in NIH funding for extramural research and, in health care reform by ensuring that they would be a cornerstone of managed care networks.

As recognized in the 1996 Democratic National Platform, investments in science and technology drive economic growth, generate new knowledge, create new high-wage jobs, build new industries, and improve our quality of life. The Platform states, "[w]e recognize that our system of research colleges and universities is the bedrock of American leadership in science and technology... We recognize the enormous contribution of our teaching hospitals and medical schools - they lay the foundation for the best medical care in the world, and we will continue to promote policies that strengthen them." However, recent reports make clear that the increased prominence of managed care has placed serious stresses on university hospital systems, which, unlike community hospitals, have the added missions of medical education and medical research. Greater attention to cost has decreased the ability of university-based hospitals to simultaneously compete for patients with institutions with no research and teaching capacity.

The erosion of support for biomedical research will endanger our effort to discover and develop new therapies for serious disease conditions and threaten America's world leadership in medicine. Plainly put, research is the cornerstone of creation in science and technology. To take but one example, our ability to exploit the achievements of basic science earlier this century led to the discovery of antibiotics and to the treatment of bacterial diseases. This was an unprecedented cooperative effort on the part of science, industry, and government that is rightly called "a miracle" and introduced an era marked by extraordinary advances to treat a broad range of heretofore intractable diseases. Yet today, more and more bacterial strains no longer respond to the same drugs that once killed them. Without a new partnership between academic medicine, the pharmaceutical and biotechnology industries, and government, such medical miracles may become relics of the past. If our commitment to biomedical research wavers, then it is possible that our children, and our children's children, will not achieve the same level of health that we have long taken for granted. This bridge to, and for, the future must be part of our legacy.

In more worldly terms, generous funding of biomedical research stimulates the creation of high-paying jobs, fosters the success of prosperous industries, and helps fuel a vibrant economy, all of which are essential if America is to continue to work for all Americans. **The Clinton Administration has a good story to tell and should take advantage of it during the remaining few weeks of the campaign.**

POLITICAL MESSAGE

A public event by the President at the campus of an academic medical center can accomplish several important objectives:

- Showcase the Administration's commitment to encouraging biomedical research and advancements in breast and prostate cancer (or other familiar diseases) as a result of research conducted at academic medical centers.
- Underscore the President's commitment to investments in research and development and improving the quality of life of all Americans.
- Highlight the preeminence of our nation's research institutions.
- Encourage private sector investments in university-based research activities (public-private partnership has been an important theme of the Administration).
- Emphasize continued NIH funding for university-based research.
- Stress the importance of the survival of academic medical centers as the training ground for future scientists and physicians.

Senate Subcommittee on Aging
September 23, 1997

E. David Crawford, M.D.
Chairman, National Prostate Cancer Education Council
Associate Director, University of Colorado Cancer Center

Prostate cancer represents a male epidemic. During 1997, it is projected that over 200,000 men will be diagnosed with prostate cancer --- and 41,000 will die as a direct result of the disease. In the past 15 years, the number of new cases of prostate cancer diagnosed has increased by three-fold. Less than seven years ago, greater than 80% of the cases of prostate cancer diagnosed were advanced, and therefore incurable. During this presentation, I will explain why testing for prostate cancer is important as well as discuss the urgent need for research support.

Faced with these previously mentioned grim statistics regarding the rising incidence and mortality from prostate cancer, there are a number of possible strategies to pursue. One can bury his head in the sand and ignore the problem, citing the fact that prostate cancer is usually a disease of older men, and you "have to die of something". Others might rationalize that our healthcare system cannot afford to deal with this disease because there are so many other pressing issues such as AIDS, childhood immunizations, smoking cessation, etc. In fact, during a trip to Europe just two weeks ago, I found that many countries subscribe to the latter way of thinking.

A *second strategy* is to try to prevent the disease. Ideally, this would be the optimal solution. In the past decade, we have learned a lot about what causes prostate cancer. This knowledge leads to strategies to alter its initiation. If we

examine the worldwide incidence of the disease, we see that it is extremely low in Japan, China, and other Oriental cultures. Yet when you examine the US incidence, it is dramatically increased -- especially in African-American males -- why?

A Western diet which is high in fat plays a major role in the development of prostate cancer, since when men from countries with a low incidence move to the United States and partake of our diet, their incidence of prostate cancer dramatically increases.

Table 1

**Worldwide Age-Adjusted
Prostate Cancer Death Rates
per 100,000 Population**

<i>Country</i>	<i>Mortality Rate</i>
Sweden	21.1
Demark	19.5
United States	17.5
United Kingdom	17.1
Spain	13.2
Singapore	4.4
Japan	4.0

Recently, there have been reports of a reduced incidence of prostate cancer in men consuming tomato products, soy, vitamin E, selenium, and other items in our food chain. These findings offer exciting leads to see if adding one or more of these substances to our natural diet will decrease the risk of prostate cancer. I believe there exists a lot of exciting potential in preventing prostate cancer -- but unfortunately, even if we knew how to prevent prostate

cancer today, it would be many years before a positive impact would occur on either the incidence or mortality rates. And why do African-Americans have such an alarmingly high rate of prostate cancer and increased mortality? In some cases it is due to the lack of access to healthcare, but many other factors are emerging through research in the area. It is critical that we understand these factors if we are to change the high incidence and death rate from prostate cancer experienced by African-Americans.

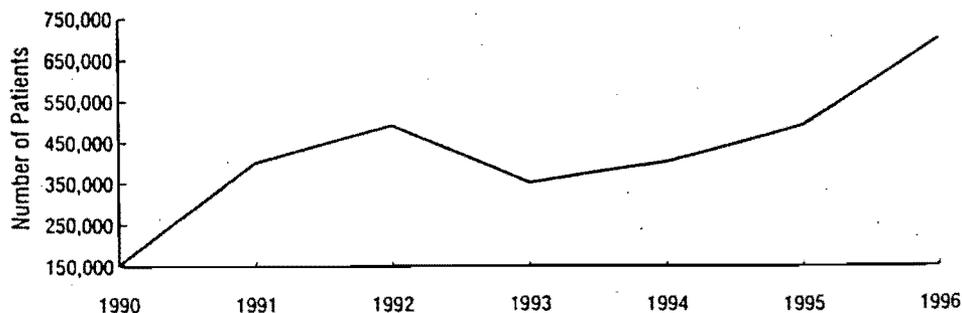
A *third strategy* would be to develop some a cure for advanced prostate cancer. Progress has been made in this area during the last decade, but the "magic bullet" has yet to be discovered. Doctor David McLeod from Walter Reed Army Medical Center will talk about a large, randomized clinical trial that we performed in advanced prostate cancer, where the simple addition of a well-tolerated oral antiandrogen (Eulexin) improved survival in this fatal disease by 26%. Recently it has also been reported that a well-tolerated chemotherapy drug called Mitozantrone can improve the quality of life in men dying of prostate cancer. Neither one of these treatments represents a cure; however, as I travel around the world to visit research centers, it is apparent that significant potential exists. I have become very optimistic that progress is being made which will either cure many patients with advanced prostate cancer, or at least slow its growth.

The *fourth strategy*, and one with the most immediate benefit, is to find it early, treat it, and to cure it. In 1988, we did a survey of several hundred men over the age of 40 -- asking questions about whether or not they had a regular physical exam, and what they talked about with their physician. Surprisingly, less than 50% of men had a physical exam within the last two years, and -- of greater concern -- of those who did, less than half of their physicians had performed a rectal exam to attempt to detect prostate cancer.

In 1989, prostate cancer became the most common cancer diagnosed in American males, surpassing lung cancer in incidence. That same year, we formed the Prostate Cancer Education Council to try to inform men about how common prostate cancer was and to try to encourage early diagnosis. One of the first challenges was to try to find a national spokesperson. We couldn't find a prominent male with prostate cancer who was willing to help us. However, former Pittsburgh Steeler running back, Rocky Bleyer, agreed to help that year -- primarily because his grandfather had prostate cancer. We utilized Mr. Bleyer to generate national media coverage and launch Prostate Cancer Awareness Week the last week of September, 1989. During that Prostate Cancer Awareness Week, nearly 10,000 men visited sites around the country to find out about prostate cancer, as well as to undergo early detection with a rectal examination. We did attract a lot of media attention, and it appeared that men were starving for information about prostate cancer.

The growth of Prostate Cancer Awareness Week has been phenomenal. We have been able to secure the help of a number of prominent spokespersons, including Norman Schwarzkopf and (for this year) Harry Belafonte. In the past seven years, over three million men have been screened during Prostate Cancer Awareness Week. Millions of others have requested examination because of the publicity generated. The American Urological Association, the American Foundation for Urological Diseases, and the American Cancer Society have all contributed to prostate cancer awareness.

Table 2
Prostate Cancer Awareness Week



Vital information has been accumulated since our initial Awareness Week in 1989. We found that a simple blood test known as PSA (prostate specific antigen) was capable of detecting cancers and at an early curable stage. We discovered that the combination of an abnormal PSA blood test and abnormal rectal exam (DRE) had a 50% predictive value for the presence of prostate cancer.

See Table 3

This compares very favorably to an accepted screening modality, mammography for breast cancer detection. The predictive value for mammography is only 20%. Through careful analysis of our data, as well as that of others, we have improved the sensitivity of testing to detect the disease while reducing false negative results. Recently, different forms of the PSA blood test have been discovered which has further refined our diagnostic accuracy. We've learned to screen for prostate cancer beginning at age 40 in higher-risk groups such as African-Americans and those individuals with a family history of the disease. Finally, we have virtually eliminated advanced incurable prostate cancer in men who participate in annual screening. Screening for prostate cancer has been shown to be cost-effective compared to the financial outlays to detect breast and a number of other cancers.

See Table 4

In spite of all this good news, there is controversy about the value of screening. A number of prestigious organizations do not endorse screening, yet they do not deny that it might be beneficial.

Table 3

Positive Biopsy Detection, by Year

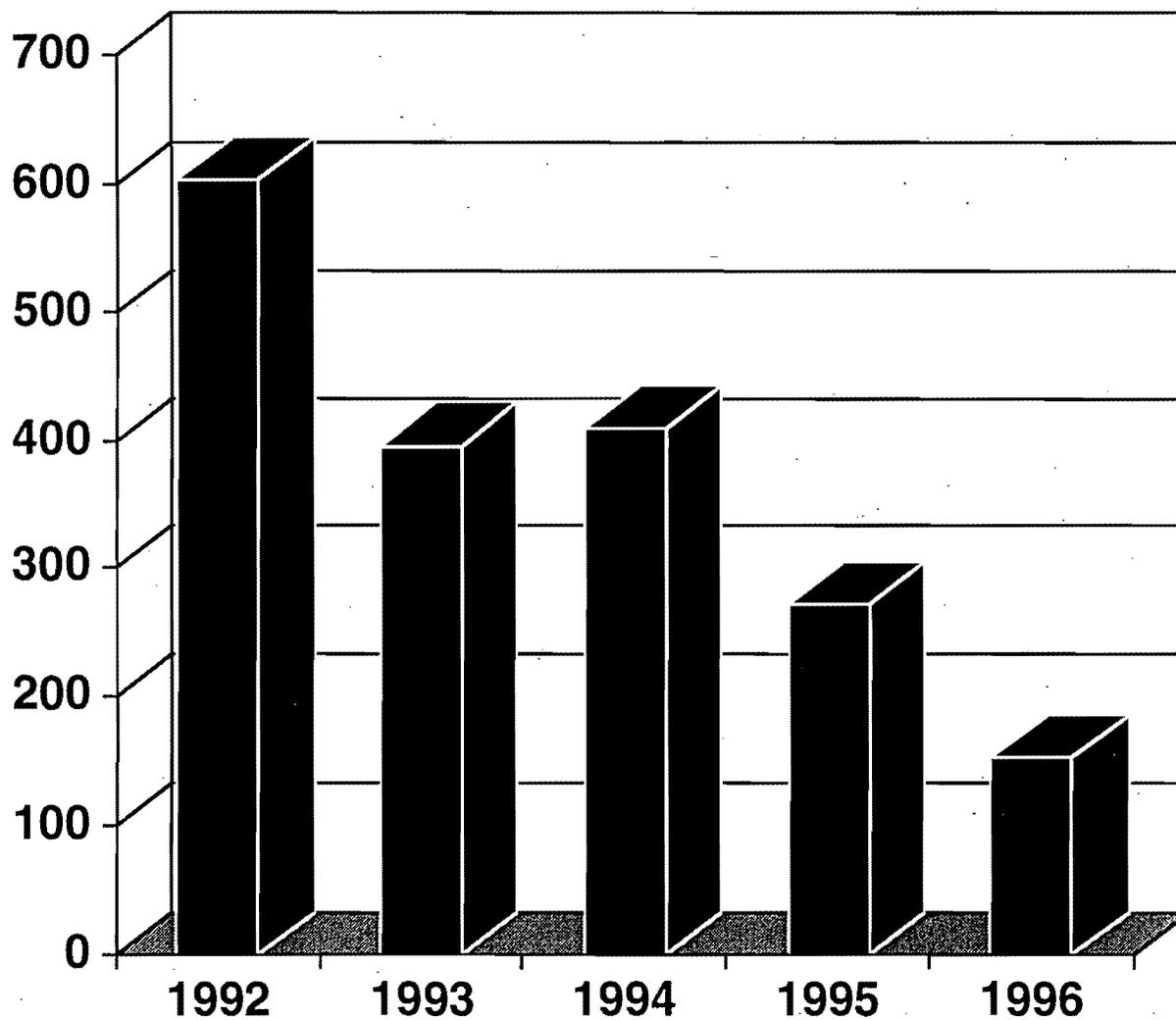
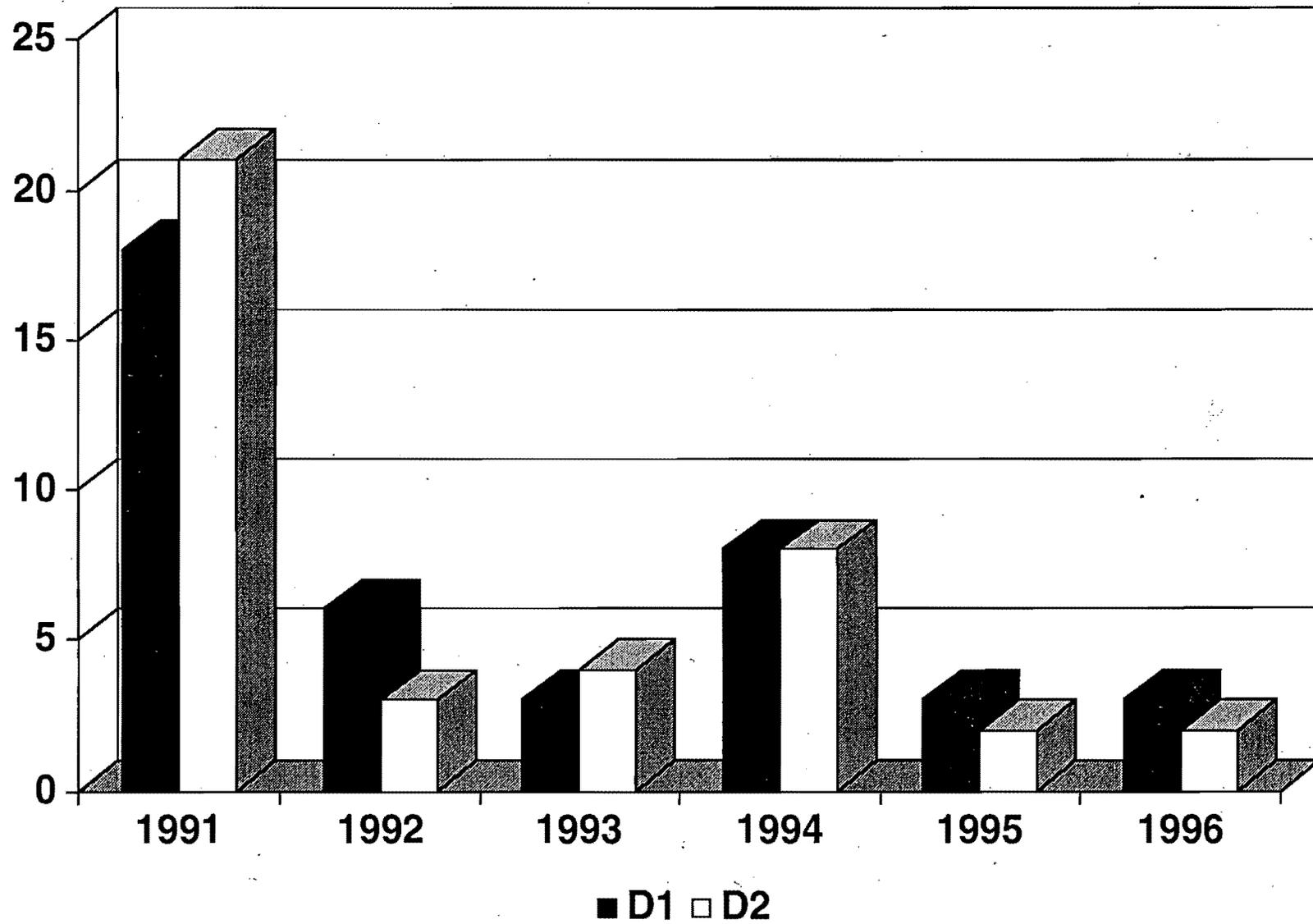


Table 4

Stage of Cancer, by Year with Serial Screenings



I believe that in order to comprehend their position, it is necessary to separate the components of concern. No one can deny that early detection detects early and potentially curable cases of prostate cancer. Early detection is associated with some financial implications, but it is not prohibitive, and falls within cost parameters to detect other cancers, including breast cancer. Through early detection we have reduced or eliminated the presence of advanced, incurable prostate cancer.

The real area of controversy is in the value and side effects of treatment. I believe that if you find and treat an early prostate cancer in a man with a ten-year life expectancy, you can extend his life. Unfortunately, we do not have a randomized clinical trial which proves my conviction. Unlike breast cancer, where research support existed in the early 1960s for studies which ultimately showed a survival benefit, we don't have these in prostate cancer. At the University of Colorado, we are participating in a large and important National Institutes of Health-sponsored trial called the PLCO (prostate, lung, colorectal, ovarian) Cancer Screening Trial. The purpose of this study is to establish the value of early detection. It will be many years (perhaps 10-15) before we know the results of this pivotal study. Because we do not know the value of early detection on ultimate mortality, we have established a motto for Prostate Cancer Awareness Week which states that "men should be able to *choose to know* in order to *know to choose* their treatment". Once they have the reassurance of knowing whether or not they have prostate cancer, they can make an informed decision. If a diagnosis of prostate cancer is made, options from simple watchful waiting to surgery or radiation can be considered. It is discouraging to see many men who are refused the opportunity to have a PSA test and rectal exam. In order to deal with this challenge, three and a half years ago, legislation was enacted in the state of Colorado which mandates the PSA test be covered by health insurance carriers. We need this coverage on a nationwide basis, and

your efforts to provide this coverage through Medicare is important.

We need significant research support to evaluate and improve our results, as well as the side effects from treatment.

In summary, there is a good and bad news about prostate cancer. The good news is that there has been an intense public focus concerning the disease. At least for those men who undergo early detection, we have drastically changed the grim statistics regarding their chance of developing an incurable cancer. Because prostate cancer is so common, more researchers are interested in finding a cure, prolonging survival, and eliminating the pain and suffering that accompanies the disease.

The bad news is that men are still reluctant to declare war on prostate cancer. We haven't been able to get significant numbers of African-Americans to participate in early detection when compared to Caucasians. Men still die seven years earlier than women, and make one-quarter as many doctor visits. We don't have enough research dollars to effectively combat this disease. Increased research moneys will result in a rapid development of a cure. These moneys are necessary in the arena of prevention, early detection, cure of advanced disease. In 1989, when we first began to talk about this lack of research support, less than \$10 million were allocated for prostate cancer research. During 1990 to 1997, \$376 million have been directed toward prostate cancer research -- and over \$1.8 billion for breast cancer.

See Tables 5 and 6

I believe that every dollar (and even more!) allocated for breast cancer research is deserved -- but I also believe that what is currently happening relative to prostate cancer research borders on insult to American males, especially

Table 5

National Cancer Institute, 1990-1997.

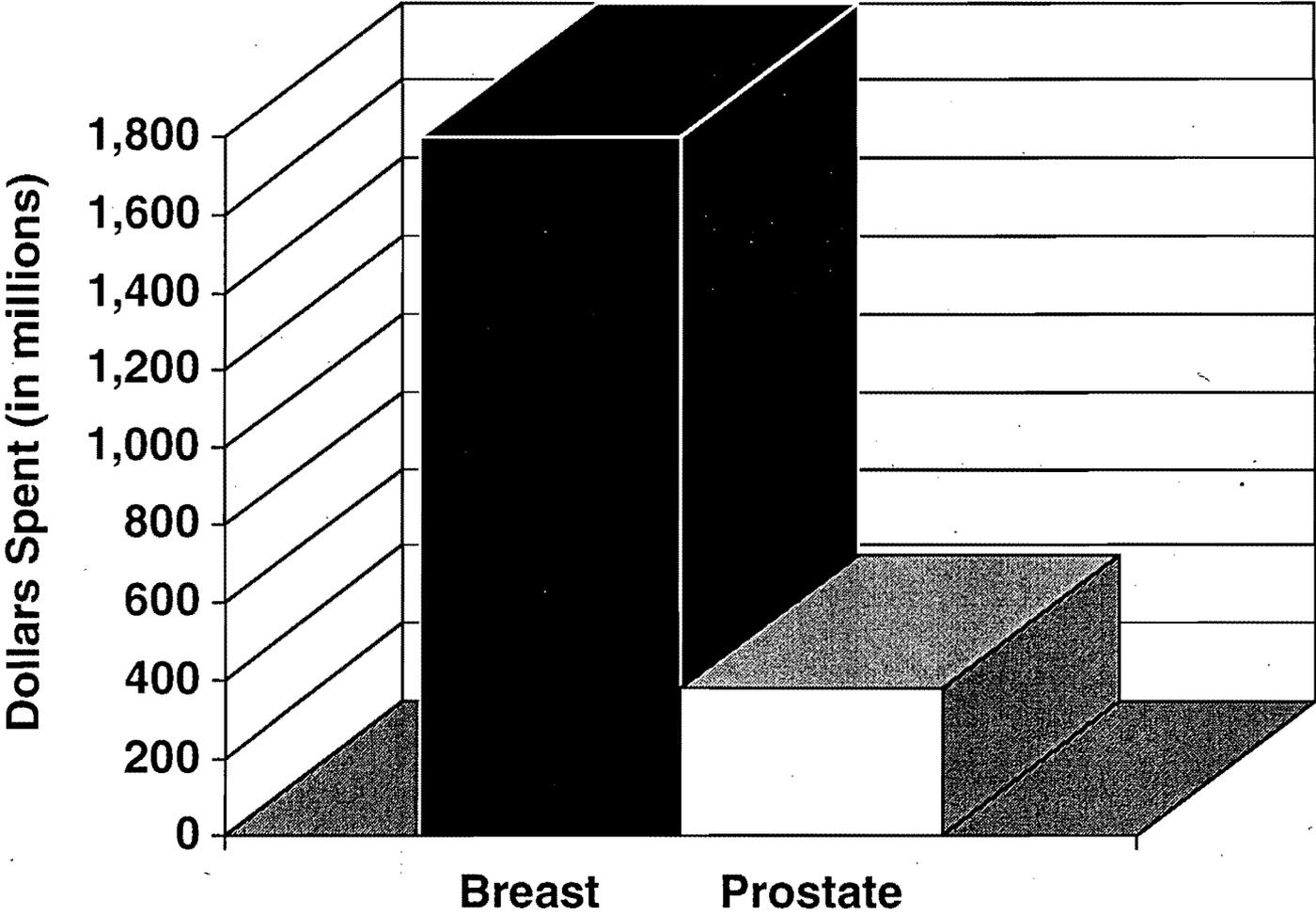
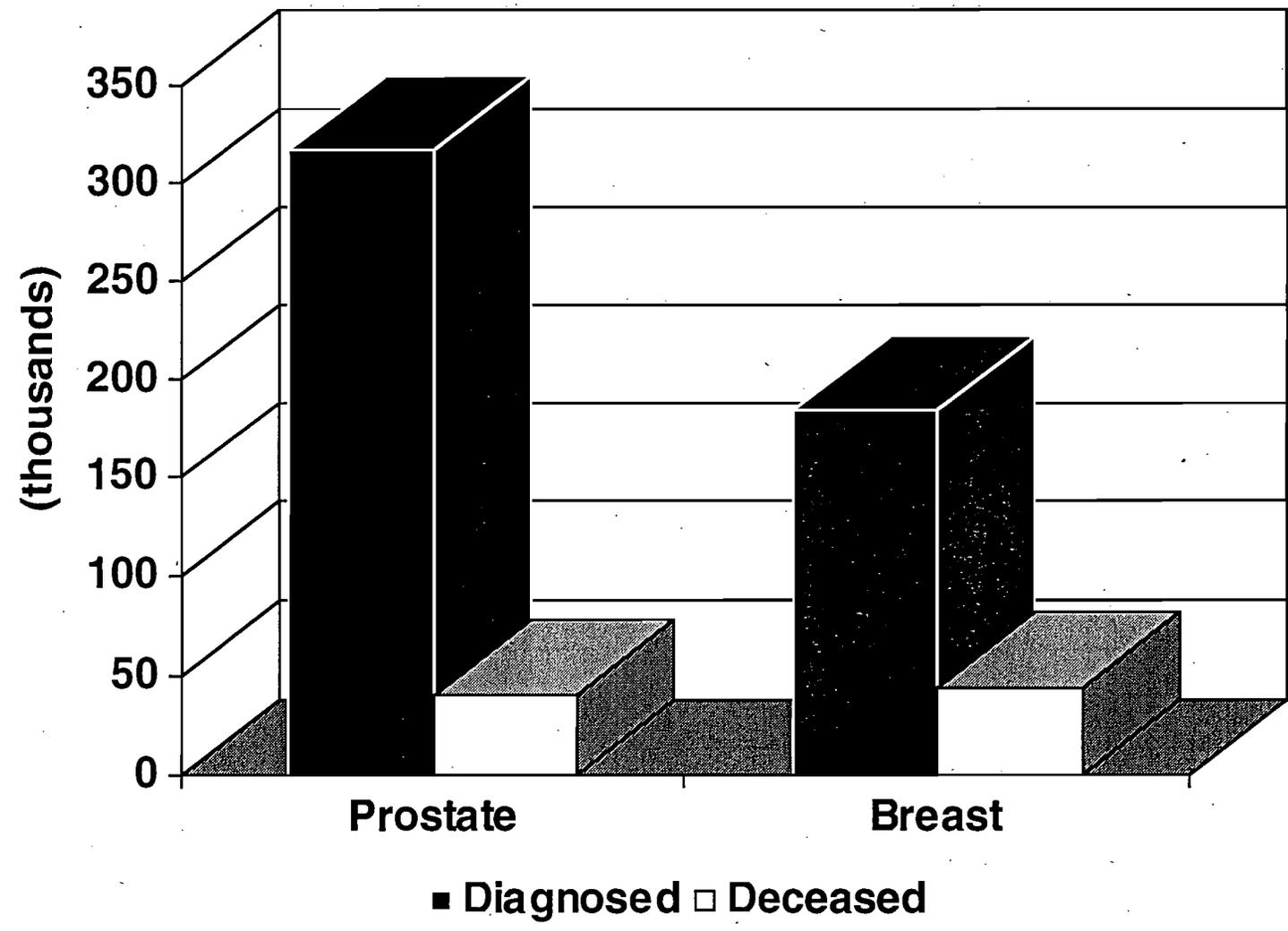


Table 6

American Cancer Society, 1996



those of African-American descent. We need support for programs like Prostate Cancer Awareness Week. It currently costs less than \$200,000 a year to support the awareness week, which is minuscule when one examines its overall impact. We need at least \$500,000 per year to continue this Prostate Cancer Awareness Week under the auspices of the Prostate Cancer Education Council. These moneys will permit us to expand successful promotional efforts, and to analyze and add to our tremendous database.

Researchers become frustrated when great ideas in science exist, when months are spent writing grant applications, and then learn there is less than a 20% chance of any funding. A great deal of what occurs with this disease in the next decade is dependent on the research dollars that are available for education, detection, and treatment. I sincerely request your assistance on behalf of the American male.

Thank you.

Prostate Cancer RAs

Steven Insinger, Thomas Murtha PA

Alvin CA

Leach DA

PRESIDENT ANNOUNCES HISTORIC PROSTATE CANCER RESEARCH GRANTS AT THE DEPARTMENT OF DEFENSE AND HIGHLIGHTS THE ADMINISTRATION'S AMBITIOUS AGENDA TO FIGHT PROSTATE CANCER

June 19, 1998

Today, in his Father's day radio address, the President announced the release of nearly \$60 million at the Department of Defense for prostate cancer research. These largest-ever prostate cancer grants will be awarded by DoD to promising researchers making important contributions to the diagnosis and treatment of prostate cancer. These efforts will complement exciting developments in prostate cancer research at the National Institutes of Health (NIH). This year nearly 200,000 men are expected to be diagnosed with prostate cancer, accounting for 30 percent of cancer in men, and nearly 40,000 men are projected to die from this disease (virtually the same number of women who die from breast cancer). The President also renewed his call on Congress to pass his budget proposals for historic, multi-year increases in cancer research at NIH and coverage of cancer clinical trials for Medicare beneficiaries. These proposals complement the President's strong record in the war against cancer. Highlights of the President's ambitious prostate cancer agenda include:

- ◆ **Releasing the Largest-Ever Grants at the Department of Defense (DoD) for Prostate Cancer Research.** The President announced that approximately \$25 million for prostate cancer research is being awarded today and another \$34 million will be announced in the next month. Over 600 grant applications were submitted for the prostate cancer research program. The DoD conducted a comprehensive two-tiered scientific review process involving prostate cancer experts, patients, and advocates to identify the most promising proposals. This new prostate cancer research program builds on the widely-acclaimed peer-review breast cancer research program at DoD. DoD will also be posting the recipients of these new grants on the Internet.
- ◆ **Proposing Unprecedented Multi-year Increases in Cancer Research at the National Institutes of Health.** The President's budget includes a historic 65 percent increase in cancer research at NIH over the next five years. Since the President took office, research in prostate cancer at the NIH has increased by 100 percent to \$122 million in FY1998. This year alone there are 450 research projects at the National Cancer Institute (NCI) on prostate cancer, including prevention research studying the environmental, dietary and other influences on this disease; and research to develop more effective interventions and design more effective screening techniques. There is also new genetic research in this area, as scientists recently located the first gene that predisposes men to prostate cancer. Also, prostate cancer was the first cancer studied as part of NCI's recently launched Cancer Genome Anatomy Project, which resulted in the discovery of dozens of new genes that may be associated with the development of prostate cancer.

\$433 m Breast Cancer > NIH dollars (almost 4x more)
\$1.6 b AIDS (over 10x more)

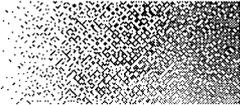
* NCI ↑ 65% from \$22 billion to \$48 billion = \$4.7 billion over 5

* cancer clinical trials ↑ 750 million over 3 years

- ◆ **Supporting Coverage for Cancer Clinical Trials for Medicare Beneficiaries.** The President's budget includes a three-year, \$750 million demonstration to cover Medicare beneficiaries' patient care costs associated with certain Federally-sponsored cancer clinical trials. Medicare currently does not cover cancer clinical trials. This proposal is particularly important for prostate cancer patients because: most of men with prostate cancer are Medicare beneficiaries, as fully 80 percent of those diagnosed with this disease are over age 65; the lack of participation of elderly men in trials has undermined clinical research for the treatment, prevention, and screening for this disease; and given promising new findings in research, NCI expects there may be an increase in clinical trials for prostate cancer, creating a need for even more participants.
- ◆ **Proposing \$25 Million to Raise Awareness About Prostate Cancer Prevention, Treatment, and Screening for Minorities.** African-American men have an incidence rate over 30 percent ^{higher} than white men and a mortality rate over 50 percent for prostate cancer. The President's race and health initiative includes \$25 million over the next five years at the Center for Disease Control to promote awareness about who is at risk for prostate cancer, current screening options, and the best treatment options for those who are diagnosed with this disease. This investment, in addition to clinical trials underway at the NIH, will also help determine why there is such variation in the prevalence and mortality of prostate cancer.

These Proposals Build on the President's Strong Record in the War Against Cancer Including:

- ^{Supporting} **Advocating for a Federally-Enforceable Patients' Bill of Rights.** The President has called on Congress to pass Federally enforceable consumer health care protections before it adjourns this fall. This patients' bill of rights contain a range of protections that are particularly important to people with cancer, including guaranteed access to needed health care specialists, continuity of care if a health provider is dropped in the middle of treatment, and access to a meaningful internal and external appeals process for consumers to resolve their differences with their health plans and health care providers. The nation's health care system has changed dramatically, with 160 million Americans now in managed care plans. This legislation will ensure that whether Americans have traditional health insurance or managed care, they are assured quality care.
- **Pushing for Legislation Preventing Health Insurers and Employers from Discriminating on the Basis of Genetic Discrimination.** Scientists recently discovered the first gene related to prostate cancer and more progress in understanding the genetic basis of this disease is expected in the near future. However, progress in genetics has the potential to be undermined by fear of genetic discrimination. One study showed that 63 percent of Americans would not take a genetic test if their health insurers or employers could get access to the results. To ensure that new advances in genetics are used to improve health rather than to discriminate against individuals, the President has called for legislation prohibiting the use of genetic screening to discriminate in health insurance and employment.
- **Enacted New Prostate Cancer Screening Benefit for Medicare Beneficiaries.** As part of the historic Medicare reforms in the Balanced Budget Act of 1997, the President signed into law a series of new preventive benefits for Medicare beneficiaries, including coverage of prostate cancer screening. Starting in 2000, Medicare will cover prostate cancer screening.



David Rowe

06/19/98 11:15:10 AM

Jeff Serhel

Record Type: Record

To: Sarah A. Bianchi/OPD/EOP
cc: See the distribution list at the bottom of this message
bcc:
Subject: Re: please advise asap

Sarah,

Please note that the numbers I gave you in my voice mail for NIH breast cancer and AIDS research are estimates, which may turn out to be high (after the HHS 1% transfer authority, the CBW transfer, etc.). Again, for breast cancer, I have \$433 million in FY98, and \$458 million in FY99. For AIDS, I have \$1,607 million in FY98, and \$1,731 million in FY99 (these are NIH numbers only... they do not include AIDS/breast cancer research in other areas of HHS, in DoD, etc.).

What's the context in which you're asking for these numbers? Is the press release/radio address also going to deal with breast cancer and AIDS?? I'm confused.

I'm going to be in a staff meeting until noon. If you have any questions between now and then, just leave a voice mail or an email. If it's really urgent, call the Health Division line (5-4925).

Thanks.

192

Sarah A. Bianchi

*Can you further clarify for
your describe the
changes that
these population have
I have looked
we could address them*



Sarah A. Bianchi

06/19/98 10:46:31 AM

Record Type: Record

To: David Rowe/OMB/EOP@EOP
cc:
Subject: Re: please advise asap

One more question.... Do we have the NIH breast cancer ## \$625 million? and the AIDs number???

pls advise.

sb

INFORMATION PAPERMRMC-PLF
May 21, 1998**SUBJECT: PROSTATE CANCER RESEARCH PROGRAM****U.S. ARMY POSITION:**

The U.S. Army began managing Congressionally Directed Medical Research Programs in Fiscal Year 1992 with a breast cancer research program focused on short-term, high-technology research aimed at early detection and novel interventions. In Fiscal Year 1997, the Joint Appropriations Bill 104-863 provided \$38 million for both basic and clinical research in prostate cancer. In Fiscal Year 1998, the Joint Appropriations Bill 105-265 provided \$38 million to conduct basic and clinical research studies aimed at combatting diseases of the prostate. The U.S. Army was designated as the Department of Defense executive agent to administer a Prostate Cancer Research Program in accordance with the intent of the Fiscal Year 1997 and 1998 Appropriations Acts, using the same highly focused, goal-directed strategy that is applied to all of its medical research efforts. The Prostate Cancer Research Program follows an execution strategy recommended by the Institute of Medicine, Congressional language, and a panel composed of advocates and scientists/clinicians who are experts in prostate cancer research.

TALKING POINTS:

- Congress directed the U.S. Army's involvement in the current Prostate Cancer Research Program.
- \$45 million was appropriated in Fiscal Year 1997 for peer reviewed research in prostate cancer that is multi-institutional, multidisciplinary, and regionally focused.
- A stakeholders meeting was held in April 1997 to solicit opinions from the prostate cancer scientific and advocacy/support communities about direction for the Program.
- An Integration Panel was recruited and a meeting was held in June 1997.
- A Broad Agency Announcement was released on July 28, 1997, which solicited proposals across all areas of basic, clinical, behavioral, and epidemiological research.
- \$40 million was appropriated in Fiscal Year 1998 for peer reviewed research in prostate diseases to develop more effective therapies.
- Due to the high scientific quality of the proposals received and the desire to increase the efficiency of getting the funds to the scientists, the appropriations for Fiscal Year 1997 and 1998 were used to fund proposals received in response to the July 28, 1997 Announcement.
- Award negotiations of Fiscal Year 1997 and 1998 funds began in April 1998.
- The time between receipt of the Fiscal Year 1997 appropriation and distribution of the research funds to scientists was 15 months. A proposal has been submitted to Congress to further decrease the time between appropriation and distribution of research funds to scientists to 6-7 months.

BACKGROUND:*a. Disease Background*

Cancer of the prostate is the most commonly diagnosed cancer in men accounting for 29 percent of all cancers in men. An estimated 184,500 men will be diagnosed with and approximately 39,200 will die from prostate cancer. Prostate cancer is second only to lung cancer as a leading cause of cancer deaths in men. The incidence rates are 66 percent higher for and mortality rates are more than two times higher in African-American men than Caucasian men. Currently, there is no cure for locally advanced or metastatic prostate cancer.

I

Good Morning. Tomorrow is Father's Day, a day to celebrate the role our fathers have played in our lives.

Today, I'd like to talk about how the Federal government is working to find ways to protect men from a disease that, only a few years ago, people rarely discussed -- prostate cancer. But now, there is a great awareness of this disease and there is a strong commitment to do something about it. Research to overcome prostate cancer is a high national priority, because only through research can we conquer this disease and remove the fear we still have of it. The National Cancer Institute's budget for prostate cancer alone has risen over 1,300 percent from 1981 to 1998 -- from \$6.4 million in fiscal 1981 to an estimate of \$90 million in fiscal 1998. (From the beginning of my Administration in 1993, NCI support for prostate cancer research increased 200 percent, from \$31 million to \$96 million.) This year alone, the National Cancer Institute will fund more than 450 research projects on prostate cancer.

This high level of effort is necessary because prostate cancer is a serious and a complex problem in this country. Serious because it affects so many men and complex because it has such a variable behavior. It is the most common cancer in men. About 184,500 American men will be diagnosed with prostate cancer this year. Nearly 40,000 will die of it. But in many cases, the tumors are very slow growing and may not require treatment. Research is under way to help us decide which men could benefit from treatment.

Federally sponsored research is taking a broad, comprehensive approach to conquering this disease. First, and very important, is basic research. The recent upsurge in research on prostate cancer includes several notable breakthroughs in our basic understanding of the disease:

- The presence of the first gene whose alteration predisposes men to prostate cancer

MRMC-PLF

SUBJECT: Prostate Cancer Research Program

b. Origin of the Program

The Prostate Cancer Research Program was established in Fiscal Year 1997 by public law (P.L. 104-863, *The National Defense Authorization Act for Fiscal Year 1997*) to address "the need for both basic and clinical research in prostate cancer in order to reduce the incidence of this life-threatening disease and to develop more specific and less toxic forms of therapy for patients in all stages of the disease." One hundred million dollars was authorized and \$45 million appropriated in the U.S. Army Medical Advanced Technology program element for the establishment of a prostate cancer research study. Congress urged that the Department of Defense give highest priority to funding research that is multi-institutional, multidisciplinary, and regionally focused. An additional \$40 million was appropriated in the U.S. Army Medical Advanced Technology program element in Fiscal Year 1998 for the continuation of the Prostate Cancer Research Program to address "basic and clinical research to combat diseases of the prostate."

c. Fiscal Year 1997 and 1998 Operation Plan and Timeline

Congressionally Directed Medical Research Programs, such as the Prostate Cancer Research Program, historically have a lifetime of approximately six years, spanning from Congressional appropriation of funds to completion of research projects. The U.S. Army Medical Research and Materiel Command received funds for prostate cancer research on January 8, 1997. During this first program year, Congressional language was analyzed, a stakeholders meeting was held (April 1-2, 1997), and an Integration Panel representing a wide range of scientific perspectives and ethnic diversity was recruited and convened (June 2-3, 1997). The Integration Panel is composed of prestigious scientists and clinicians, some of whom are associated with the Department of Defense, as well as representatives of the patient advocacy/support community. With the assistance of the Integration Panel, an investment strategy was developed and a solicitation for research proposals (Broad Agency Announcement) was crafted and released on July 28, 1997. On October 29, 1997, 606 prostate cancer research proposals were received; and peer reviewed in January 1998. Due to the high scientific quality of proposals received for the Fiscal Year 1997 Prostate Cancer Research Program, and the enthusiasm of both the scientific and advocacy communities to distribute funds quickly to scientists; the funds appropriated in Fiscal Year 1998 for the Prostate Cancer Research Program were combined with the Fiscal Year 1997 appropriation to fund investigators with highly meritorious proposals submitted to the Fiscal Year 1997 program. Proposals were programmatically reviewed in March 1998. Negotiation of awards began in April 1998, and all funds will be obligated no later than September 30, 1998.

d. Fiscal Year 1997 and 1998 Program Objectives and Goals

The intent of the Program is to promote innovative ideas and technology through both clinical and basic science to conquer prostate cancer. The mission of the Program is to promote innovative, multi-institutional, multidisciplinary, and regionally focused research directed toward eliminating prostate cancer. The Program was designed after consultation with other national prostate cancer research funding agencies (specifically, the National Institutes of Health—National Cancer Institute, the American Cancer Society, CaP CURE, and the American Foundation for Urological Disease) to avoid overlap of programs and to target under-represented avenues of research and novel applications of existing technologies. Coordination with the U.S. Army Center for Prostate Disease Research at Walter Reed Army Medical Center is also on-going.

The five primary goals of the program are to:

- (1) pursue new directions and breakthrough ideas and approaches in prostate cancer;

MRMC-PLF

SUBJECT: Prostate Cancer Research Program

- (2) prepare new scientists and encourage established investigators to join in the battle against prostate cancer;
- (3) embrace prostate cancer public awareness and education;
- (4) promote a unique dual-phase funding strategy; and
- (5) fund a balanced attack across broad disciplines of prostate cancer.

The programmatic strategy is being implemented by a solicitation for proposals in two subcategories: New Investigator Awards and Idea Development Awards. The intent of the New Investigator Award category is to promote and reward innovative projects that lack pilot data and encourage new investigators to enter the prostate cancer research field. The Idea Development Awards are intended to support established investigators with highly innovative projects.

The programmatic strategy embodies the continuing evolution and flexibility of the U.S. Army Medical Research and Materiel Command in managing the Department of Defense Congressionally Directed Medical Research Programs. In particular, a unique dual-phase funding strategy has been implemented as part of the Prostate Cancer Research Program. Approximately 140 Phase I awards will be made across five broad disciplines of prostate cancer research to both young and established investigators. After two years of research, the U.S. Army Medical Research and Materiel Command will challenge investigators to compete for two additional years of support, pending appropriations in Fiscal Year 2000. This unique dual-phase strategy was designed to encourage the rapid development of ideas in Phase I and to provide transition support to position investigators for competition in traditional funding mechanisms in Phase II.

e. Fiscal Year 1998 Minority Training Initiative

Acknowledging the disparity in morbidity and mortality rates of patients with prostate cancer among some ethnic groups, the Integration Panel proposed a new award category, Minority Population Focused Training Awards. These awards are designed to enable investigators to develop a prostate cancer research concept that focuses on the disparity in prostate cancer incidence and mortality. One of the goals of these awards is to establish collaborations between applicant and established investigators.

f. Fiscal Year 1999 Prostate Cancer Research Program Timeline

Contingent upon Congressional funding for the Fiscal Year 1999 Prostate Cancer Research Program, the U.S. Army Medical Research and Materiel Command will issue an Announcement to solicit prostate cancer research proposals.

The following award categories could be included in the Fiscal Year 1999 Prostate Cancer Research Program Announcement contingent upon the level of funding appropriated by Congress:

- **Idea Development Awards:** The intent of Idea Development Awards is to stimulate and reward speculative but especially promising and creative ideas that may yield a high payoff.
- **New Investigator Idea Awards:** The intent of the New Investigator Idea Awards is similar to that of Idea Development Awards but is targeted toward funding investigators in the early phases of their careers, specifically independent investigators (Assistant Professor or equivalent) within six years of post-doctoral, residency, or equivalent training. In accordance with the challenge to be innovative, proposals are accepted even if they lack preliminary or pilot data. These proposals should none-the-

MRMC-PLF

SUBJECT: Prostate Cancer Research Program

less be based on sound scientific rationale established through a critical review and analysis of the literature and/or logical reasoning.

- **Clinical Trial Awards:** The intent of Clinical Trial Awards is to encourage and support pre-clinical studies and clinical trials that offer the opportunity to improve the survival and quality of life of patients with prostate cancer.
- **Training/Recruitment Awards:** The intent of the Training/Recruitment Awards is to encourage junior scientists who have completed post-doctoral training, but are not yet established investigators, to pursue a prostate cancer-related research career, as well as to encourage senior scientists who are currently working in areas other than prostate cancer to shift their focus to prostate cancer research. Institutional Training Program Awards also may be offered as a Training/Recruitment Award.
- **Infrastructure Awards:** The intent of Infrastructure Awards is to support the development of cell lines, tissue banks, animal models, informatics, and the like specific to the study of prostate cancer.
- **Center Grant Awards:** The intent of the Center Grant Awards is to establish national centers for the study and treatment of prostate cancer. A proven track record of scientific research and scholarship, an institutional commitment of resources and space, and strong leadership in the field of prostate cancer are required for successful competition in this category.

g. Fiscal Year 1999 Prostate Cancer Research Program Timeline

In response to admonitions from scientists, advocates, and Congress members to increase the pace of distributing appropriations for scientific research, the Prostate Cancer Research Program has submitted a plan to Congress to decrease the time between appropriation of funds and distribution to scientists. Pending Congressional action on this proposal, the Fiscal Year 1999 Prostate Cancer Research Program Announcement could be released mid-Summer 1998 with a submission deadline 90 days after Announcement publication. Potentially, the time between receipt of appropriation and distribution to scientists could decrease from 15 months to 6-7 months.

CONGRESSIONAL INTEREST:

Congress has directed the Department of Defense to undertake a prostate cancer research program. Strong supporters of the Prostate Cancer Research Program include Senators Stevens (R-AK), Inouye (D-HI), and Thurmond (R-SC) and Representatives Murtha (D-PA), Horn (R-CA), Leach (R-IA), and Bateman (R-VA).

BUDGET DATA:

	<u>Fiscal Year</u> <u>1997</u>	<u>Fiscal Year</u> <u>1998</u>	<u>Total</u>
Congressional Supplement	\$45 million	\$40 million	\$85 million

PROGRAM ACCOMPLISHMENTS:

To date, 142 proposals have been recommended for funding. It is anticipated that approximately 250 awards will be made with the Fiscal Year 1997 and 1998 Congressional appropriations.

For more information on Congressionally Directed Medical Research Programs

**Copies of
Research Program Announcements***
are available by request via the following:

fax: (301) 619-7796

e-mail: radvi_baa@ftdetrick-ccmail.army.mil

phone: (301) 619-7079

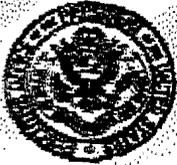
website: <http://mrmc-rad6.army.mil>

**Please indicate specific program*

Log onto the website at:
<http://mrmc-rad6.army.mil>

The Website contains:

- Background information on Congressionally Directed Medical Research Programs
- Current and past research programs
- Program award lists for fiscal years 1993 through 1996
- Abstracts from previously funded proposals
- Release dates for Research Program Announcements
- Copies of Research Program Announcements
- Information on the Era of Hope Conference



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

FACSIMILE COVER SHEET

NUMBER OF PAGES: 1 (excluding cover sheet) DATE: 16 June 98

TO: Sarah Branch

ORGANIZATION: OPD/DFC

OFFICE NO.: 465585

TELEFAX NO.: 2127431

FROM: Gregory G. Henry AGENCY/OFFICE: OMB/NSD/FSIB

OFFICE NO.: 202-395-6945 E-MAIL: henry_g@a1.eop.gov

TELEFAX NO.: 202-395-6167

SPECIAL INSTRUCTIONS:

I SUGGEST YOU USE THE FORMULATION ON THE ATTACHED FOR PARAGRAPHS REFERRING TO DOD IN YOUR PRESS RELEASE. THIS FORMULATION WAS THE RESULT OF A PHONE CONVERSATION WITH COL. RICH. NOTE THAT \$9M OF THE AT LEAST \$59M TOTAL AWARDS IS NOT FOR GRANTS, SO THE WORDING WAS CHANGED FROM THE PREVIOUS SOMEWHAT INACCURATE DRAFT.

IF YOU HAVE ANY QUESTIONS, PLEASE CALL.

2

has been localized. The gene explains why some men inherit a predisposition to develop prostate cancer and may be particularly important for African American men.

- Recently, the NCI launched the Cancer Genome Anatomy Project aimed at providing scientists with the first comprehensive analysis of the molecular fingerprints that distinguish normal cells from cancer cells. The first cancer studied in this project has been prostate cancer. This research has resulted in the discovery of dozens of new genes that may provide molecular markers associated with the development of prostate cancer. These markers might also allow scientists to begin to predict the behavior of the different types of prostate cancer.

As they learn more, scientists hope to develop approaches to diagnosis and treatment that will enable doctors to select treatment strategies that are specially designed for each patient's cancer, and help tell whether a particular patient has an aggressive cancer or not.

Perhaps even more important is prevention research. Dozens of studies are looking at the environmental, occupational, dietary and hormonal influences on the likelihood of developing prostate cancer. Particular attention has focused on the role of dietary fat in increasing the risk of prostate cancer and the role of naturally occurring components such as vitamin E. A recent study suggested that Vitamin E may reduce prostate cancer cases and deaths in men who smoke.

One of the major goals of our research program is to understand the development of prostate cancer so that we may design interventions that reduce the risk of developing this cancer. Furthest along is a large study involving 18,000 men over the age of 55 to establish whether the drug finasteride can prevent prostate cancer, much like tamoxifen has just been shown to prevent

3

breast cancer in women in NCI's large Breast Cancer Prevention Trial. The Prostate Cancer Prevention Trial is based on the knowledge that normal male hormones can serve as growth factors for prostate cancer, so that specifically blocking their effect on the prostate could possibly decrease the risk of getting prostate cancer.

The third approach is research on screening. Scientists are learning that prostate cancers produce many different markers, including the well-known prostate specific antigen (PSA). Knowing about these markers and what they mean will some day help detect prostate cancer more accurately than is possible today. A major study is looking at PSA testing and digital exams to see if these tests reduce the chances of dying of prostate cancer.

A fourth approach is research to improve prostate cancer treatment, and to decrease the side effects associated with treatment. For the nearly 200,000 American men who are predicted to be diagnosed with prostate cancer this year, we must have optimal treatment choices. New treatments are needed and current treatments need to be improved. The only way to establish new, more effective treatments with fewer side effects is through clinical trials.

NCI currently is sponsoring 62 clinical trials for the treatment of prostate cancer. This year, one such trial has provided the first evidence that a particular hormonal treatment coupled with radiation therapy may improve the survival of patients who have localized prostate cancer but a poor prognosis.

Novel therapies including the development of a vaccine aimed at mobilizing the immune system to destroy prostate cancer are, for the first time, being tested in men. In a major study "watchful waiting" is being compared to surgical removal of the prostate.

In another approach to research, both radiation therapy and surgery are being improved by



4

computer modeling that helps doctors accurately focus these treatments on cancerous tissues while sparing normal tissues. Another goal is to develop ways to treat serious side effects of treatment such as impotence and incontinence.

African American men have the highest rate of developing prostate cancer of any group of people in the world. Their rate of developing prostate cancer is 30 percent higher than that for white Americans and their mortality is 50 percent higher. Numerous studies are under way to understand why both incidence and mortality rates are different.

An important study by NCI and the Department of Defense (DoD) showed that when black and white men with prostate cancer at similar stages are treated in the same or comparable medical system, their outcomes are the same - suggesting that at least some of the difference in mortality rates between white and black Americans is likely due to differences in access to quality medical care.

I'd like to personally thank every American man who has participated in clinical research on prostate cancer. They are helping America find answers to this much feared disease. Our country has the best health care system in the world. With medical research providing the knowledge, I'm confident we can continue to improve our health and look forward to a stronger and healthier future than ever before.

06/18/98 23:02 ID: JUN 11 '98 11:03 AM CO-17 0017

DoD funding of Breast Cancer and Prostate Cancer Research, 1992-1998

(\$ in millions)

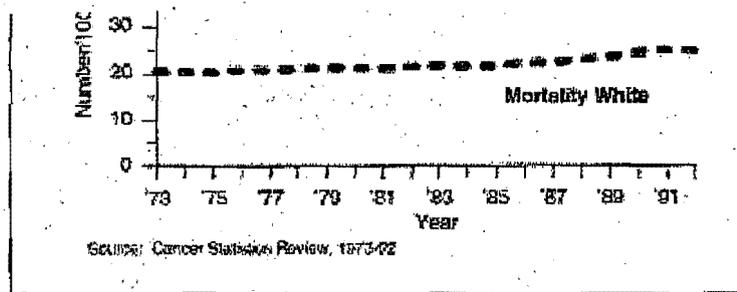
All amounts were added by Congress--no Executive Branch requests

	<u>1992</u>	<u>1993</u>	<u>1994</u>	<u>1995</u>	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>Total</u>
Breast Cancer Research								
Total*	25.0 ***	206.9	29.5	135.7	71.1	112.5	135.0	715.7
Prostate Cancer Research								
Total**	2.0	2.0	2.0	14.3	7.5	45.0	45.0	115.8

* Amounts in 1997-1998 do not reflect undistributed reductions, which lower the amounts by about 4-8%

** Amounts in 1992-1998 do not reflect undistributed reductions, which lower the amounts by various amounts ranging up to about 8%

*** Breast Cancer in '92 -- 2-4% undistributed reduction.



Although our screening
tests are

Early Detection

Preventable risk factors for prostate cancer are unknown, and effective measures to prevent the occurrence of this disease do not currently exist. Although one proposed method to reduce the risk of death from prostate cancer is through screening and early detection, health professionals have not come to a consensus on early detection guidelines. To date, the scientific evidence has been insufficient to determine if screening for prostate cancer reduces mortality or if treatment of early disease is more effective than no treatment in prolonging a patient's life. Currently, health practitioners cannot accurately determine which cancers will progress to become clinically significant and which will not. Thus, widespread screening and testing for early detection of prostate cancer are not scientifically justified at this time.

Professional medical organizations are divided on the issue of screening for prostate cancer. The U.S. Preventive Services Task Force (USPSTF) recommends against routine screening, and the Centers for Disease Control and Prevention (CDC) supports the USPSTF recommendations. The ACS and the American Urological Association (AUA) recommend an annual DRE examination and PSA measurement beginning at age 50 years. They also recommend that screening start at a younger age for men of African descent and for men with a family history of prostate cancer. The AUA suggests that these high risk groups begin testing at age 40 years.

Two methods for detecting prostate cancer are currently available to clinicians:

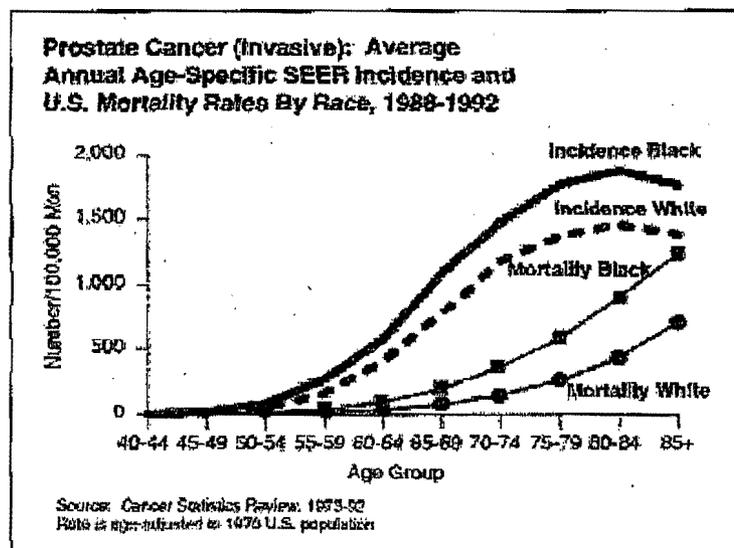
Digital rectal exam (DRE) has been used for years as a screening test for prostate cancer. However, its ability to detect prostate cancer when it is present is limited. Small tumors often form in portions of the prostate that cannot be reached on a DRE. Clinicians may also have difficulty distinguishing between benign abnormalities and prostate cancer, and the interpretation and results of the examination may vary with the experience of the examiner.

The **prostate-specific antigen (PSA)** is a blood test that is popular with many clinicians, but medical consensus on its use and interpretation has not been reached. PSA is an enzyme measured in the blood that rises in the presence of prostate abnormalities and naturally as men age. Thus, it is difficult to differentiate between prostate cancer, benign growth of the prostate—a condition referred to as benign prostatic hypertrophy (BPH)—and other conditions of the prostate, such as prostatitis. About 50 percent of men with BPH have elevated PSA levels and may receive additional diagnostic tests for cancer, such as a biopsy and transrectal ultrasound. Many of the men who receive these additional diagnostic tests are not diagnosed with prostate cancer. PSA also fails to detect some prostate cancers—about 20

percent of patients with biopsy-proven prostate cancer have PSA levels that are within normal range.

Who Is at Risk?

Prostate cancer is most common among men aged 65 years and older. Men in this age group account for about 80 percent of clinically diagnosed prostate cancers. From 1973 to 1992, the death rate for African-American men, who already have one of the highest incidences of prostate cancer in the world, rose by 41 percent. At all ages, African-American men tend to be diagnosed with the disease at later stages, and they die from prostate cancer more often than do white men. The reasons for the greater incidence and mortality among African-American men are unknown.



Treatment Options

Decisions regarding appropriate treatment options for men with prostate cancer are based on the stage of the cancer at the time of diagnosis. Patients with early stage cancer that is confined to the prostate have several treatment options. Three treatments are currently in use for cancers thought to be confined to the prostate:

Radical prostatectomy, or complete surgical removal of the prostate, is frequently used for patients less than 70 years old who are otherwise in good health. Physicians rarely suggest radical prostatectomy if cancer has spread to pelvic lymph nodes or a distant site. Complications of radical prostatectomy may be short- or long-term; these complications can include impotence and urinary incontinence. The risk for these complications increases with age and also depends on the amount of damage to nerve and blood supplies that occurs during the surgical procedure. Between 5 and 19 percent of men become incontinent, and from 24 to 62 percent may become sexually impotent. Most men who undergo a radical prostatectomy experience at least a partial decrease or decline in potency. Currently, data

from randomized clinical trials are not available to provide definitive evidence that this surgical procedure decreases mortality or prolongs life.

Radiation therapy, or treatment of the tumor site with low levels of radiation, is usually used only for men with cancer that is confined to the prostate or to the surrounding tissue. Some side effects of radiation therapy, which can include acute inflammation of the bladder, rectum, and intestines, are generally reversible. However, chronic inflammation can result in strictures that require surgical intervention in 0.5 to 2 percent of men treated with radiation therapy. Following radiation therapy, from 25 to 44 percent of men experience some degree of sexual impotence. Incontinence also occurs in 0.5 to 7 percent of men treated with radiation.

Men with prostate cancer may also choose to have no treatment initially. This option is referred to as **watchful waiting**. When this option is chosen, the tumor is evaluated periodically for changes that suggest rapid growth. Recent studies have found that watchful waiting may be an acceptable alternative management option for some men, particularly for older men with small low-grade tumors that are unlikely to spread.

Patients with cancer that has spread beyond the prostate gland may receive radiation and hormonal therapies to inhibit further progression of the cancer, but most metastatic tumors eventually become resistant to hormonal therapy. Some patients with advanced metastatic disease may be considered for participation in clinical trials of experimental therapies.

Because of limitations in current medical technology, accurate determination of prostate cancer is difficult. As a result, about 50% of men thought to have early stage cancer have more extensive disease. Patient outcomes and the quality of life after treatment are influenced by the patient's age, coexisting medical conditions, and the aggressiveness of the tumor.

State Partnerships

In 1993, Congress authorized the CDC to work with existing cancer control efforts in state health departments to develop state-based demonstration projects for prostate cancer. Fiscal year 1996 funding for CDC prostate cancer initiatives was \$4.6 million. Currently established in central Harlem in New York City and in rural northwest Louisiana, the demonstration projects have obtained information on knowledge, attitudes, and practices of men and their physicians that is crucial for designing early detection programs. Both projects have focused on the highest risk group-African-American men. Results from these projects will be available in 1997.

Two other projects are ongoing in Massachusetts and Missouri to further refine and validate methods and instruments for assessing knowledge, attitudes, beliefs, and practices related to prostate cancer screening.

In the absence of scientific consensus of the effectiveness of prostate cancer screening in reducing mortality, a significant challenge facing state public health agencies is to determine how best to balance the public's need for and interest in prostate cancer programs with useful prostate cancer health communication messages and activities. In October 1996, CDC



cosponsored the State Issues Workshop on Prostate Cancer in which state and territorial chronic disease directors addressed the complex issues related to prostate cancer control. During the workshop, participants shared experiences, identified roles and strategies for public health agencies, and identified capacity building needs of public health agencies. In response to the challenges identified at the workshop, CDC established a multidisciplinary work group that will use health communications strategies and methods to craft health messages for men and their families about prostate cancer screening and early detection.

Prevention Center Activities

CDC currently supports two programs at Prevention Centers, one at the University of California at Berkeley and a second at the Harlem Center for Health Promotion and Disease Prevention in conjunction with the New York State Department of Health and Columbia University. These projects are designed to assess the relationship between coexisting health conditions and to determine how these conditions may affect the risk of death among men diagnosed with prostate cancer. An important component of these projects is to determine how many men die of prostate cancer and how many die with the disease.

International Conference

In September 1995, CDC held an International Conference on Prostate Cancer Screening, Early Detection, and Control. The conference provided a forum for national and international prostate cancer experts to review current information about early detection and disease management. A broad range of health professionals and specialists from the fields of urology, internal medicine, oncology, radiology, family medicine, health administration, biostatistics, and epidemiology participated in the conference.