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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release March 29, 1996

REMARKS BY THE PRESIDENT
AT CEREMONY FOR ANTI-CANCER INITIATIVE

The East Room

3:06 P.M. EST

THE PRESIDENT: Mr. Vice President, Secretary Shalala, Dr. Kessler, Congressman Richardson, welcome. To all of you who are here, I welcome you and I thank you, each in your own way, for the power of your example.

I thank Stacy, too, especially for being here and telling us her story, and doing it in the way that she did. We know we can thank modern medicine, but you saw a little bit of her steel and grit when she was talking, and it's a great testimony to her faith and to her inner strength. I think that we ought to ask her parents to stand since she mentioned them.

Would you stand up, please, Mr. and Mrs. Oller? Thank you. (Applause.) Thank you very much.

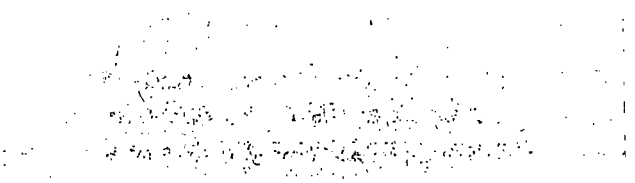
Perhaps more than any other health statistic in America, cancer touches virtually every family. My mother and my stepfather succumbed to cancer; the Vice President lost his sister. Just before coming here today I proclaimed April Cancer Control Month over in the Oval Office, and I was there with several cancer patients and their families. They're all over here, and I want to thank all of them for coming to visit with me, the children and the adults alike, the parents, the brothers, the sisters. As families, they are fighting for a way to win this battle, and the rest of us owe it to them to give them every chance they can to win. That's why we're here today; we want to have more people like Stacy.

More than ever before, we know from the sheer statistics that cancer is treatable and beatable. We know that early detection and prevention are critical. We have, therefore, put more resources in to mammograms for women over 50, and we have taken a very strong stand against the use of tobacco by young people, and against any attempt to induce them to use it.

When cancer does strike, we have an ever-growing arsenal of new drugs and cutting-edge therapies to fight it. But before any treatment can get to patients, we need to make sure it is safe and effective. The development and approval process can take years. When a member of a family gets cancer, the whole family bears the pain, and years are sometimes far, far too long. These families should not also suffer from the stress of knowing that there may be better remedies already out there, but they're somehow not quite

available.

So I'm happy today to say to those patients and to their families, the waiting is over. Today, we announce a major new initiative to speed new cancer therapies to our people. These changes will affect at least 100 drugs now being studied. Dozens of them will get to the market sooner, and that means they can help Americans suffering from cancers of the breast, lung, ovary, prostate



and colon, among others. For these Americans, we cannot guarantee miracles, but at least now new hope is on the way.

With our reforms, cancer patients won't have to leave the country to look for promising treatments. If a drug does demonstrate effectiveness, patients will have access to it here even while the drug continues to undergo tests for approval. Let me emphasize, these steps will speed cancer drugs to patients who need them when they need them. They will help to save lives. They will give cancer patients a better chance. They will do all this by cutting red tape, but they will not -- they will not -- cut corners on safety. We are doing this the right way and it is the right thing to do.

This initiative is part of our National Performance Review, popularly known as REGO, Reinventing Government. This remarkable effort has been chaired brilliantly by the Vice President, and it will, among other things, now cut the development time for drugs by as much as several years. At the same time, the FDA will cut is review time for these drugs from 12 months to six months.

The initiative contains four major proposals. First, we propose to accelerate approval for cancer drugs by allowing companies to apply to market a treatment that is still being tested. In other words, if a drug shows promise by shrinking tumors, for example, it can be considered for approval. That could cut several years off the time needed to get a drug to market.

Second, we propose to expand access to drugs that are already approved in other countries. The FDA will encourage the sponsors of these experimental drugs to apply for permission to distribute the drug to eligible cancer patients before final drug approval is granted here in the United States.

Third, we propose that cancer patients be better represented in FDA advisory meetings. These committees play a major role in policy and product decisions. And cancer patients who have valuable insights and the most at stake should be at the table when these decisions are made.

Fourth, we propose fewer applications for additional uses of approved cancer drugs. Often, these applications are for uses the drug maker does not even intend to market. By cutting out these unnecessary applications we will free investigators from paperwork and allow them to devote more time to cancer research.

These four steps are the results of listening to patients, to their families, to their advocates, to the pharmaceutical industry, the doctors, and the researchers. This initiative shows what we can do when we work together.

Since 1938, our nation has looked to the FDA to protect and improve the public health by making sure that medicines we take help us, not harm us. Our commitment to safety must never waver. Under Commissioner David Kessler, the FDA has reinforced that commitment while working to speed drug approval in the right way. In 1987 it took an average of 33 months to approve new drug applications. In 1994 96 percent of new drug applications were acted on within 12 months.

On AIDS drugs the United States was the first to approve

five of the six antiviral treatments for the disease. The most recent of these drugs was approved in 42 days -- a record. And the FDA has been the first to approve new drugs for ovarian cancer, for lymphocytic leukemia, for cystic fibrosis, for multiple sclerosis, for Lou Gehrig's Disease and Alzheimer's. Under Dr. Kessler, more than ever, the FDA is a place where advance science and common sense work together for the American people.

Now, using the principles of the National Performance Review, we have an opportunity to help more Americans conquer cancer. These four steps will make a big difference, and we are glad to give them to the American people today.

Now I'd like to ask the Vice President to come up here and talk just a few moments about the reinventing of these regulations -- how we did it, what we hope will happen. And let me say, again, how grateful I am to Secretary Shalala, to Dr. David Kessler and to the Vice President, and to all the other good people at FDA. We can keep our people safe and save more lives, and that's exactly what we're determined to do.

Thank you, God bless you all.

Mr. Vice President, please come up. (Applause.)

END 3:15 P.M. EST

October 20, 1997

MEMORANDUM FOR THE VICE PRESIDENT

THROUGH: Don Gips

FROM: Jerry Mande

CC: Ron Klain

SUBJECT: Cancer Initiative

I. SUMMARY

We are at a pivotal point in the fight against cancer. Your leadership would result in significant progress in this battle. Several factors have emerged to provide this opening. First, the current "war on cancer" has fallen short of public expectations. Second, the science has advanced to a point where additional investments in cancer research would likely result in important improvements in patient outcomes. Third, there is a renewed, visible, public interest in fighting cancer.

There is every reason to be confident of future success in the battle against cancer. Cancer is not one disease but many. Progress to date indicates we will eventually prevent or cure most cancers. We already have cures for childhood cancers, Hodgkin's lymphoma, and testicular cancers. But we have made only limited progress in the fight against most adult cancers, and we must take advantage of emerging science to do better.

To seize the opportunity, we need money. Specifically, we need $714 million more in FY99 than was in the President's last request ($2.442 billion for FY98) and a $3.5 billion increase over 3 years. As outlined below, this investment would: 1) protect millions of people at risk of developing cancer; 2) greatly improve early detection and diagnoses of cancer; 3) speed the discovery and development of new cancer drugs and devices; 4) dramatically increase adult participation in clinical trials; and 5) provide all cancer patients and their care givers with easy access to the latest information on treating their disease.

Given budget constraints, you would need to begin now establishing support for such a program. You could signal your interest by giving a major policy speech this fall, and advocating for an increase in the FY99 budget request. Comprehensive tobacco legislation may one day provide substantial new funds for cancer research. However, a cancer initiative funded through tobacco legislation rather than the FY99 budget would be poorly received by the cancer community. The tobacco bill's fate is just too uncertain.

II. BACKGROUND

The "war on cancer" began in 1971, when President Nixon and the Congress enacted the *National Cancer Act* (NCI was established by FDR in 1937). While significant advances have been made over the past 25 years, especially in treating cancer in children, many experts and much of the public are troubled by the lack of progress. Children's cure rates have approached 70-80%. Progress treating adult cancers, however, has been incremental and frustratingly slow. The science is thriving, but there is a sense that the nation does not have an effective national cancer program.

Each year, NCI publicly identifies key research opportunities and priority investments in its so-called "bypass budget." The 1971 Act authorizes NCI's director to submit an annual budget estimate directly to Congress after review "but without change" by the Secretary, the Director of NIH, and the National Cancer Advisory Board. The bypass budget is the holy grail of the cancer community.

III. PROPOSED VICE PRESIDENTIAL CANCER INITIATIVE

In his bypass budget for FY99, NCI Director Richard Klausner will request $750 million more than the President's FY98 request. I suggest you push for $714 million of this increase to achieve the five outcomes outlined below (with projected first year/three year cost of each outcome).

A. Enhance cancer prevention research, protecting millions of people at risk of developing cancer. ($121M/$559M)

Clinical trials for evaluating cancer preventive strategies (such as drugs, vaccines, better diet, more exercise, reduced environmental exposures) involve large numbers of subjects and take years to complete. There is currently a waiting list of interventions that merit testing. More resources would enable researchers to test promising interventions, leading to the prevention of millions of cases of cancer.

With the additional funds, NCI hopes to invest in the following new clinical trials:

- 22,000 women in a trial to test selective estrogen-response modulators to prevent breast cancer.
- 20,000 men in a trial to test vitamin E and selenium to prevent prostate cancer.
- 5,000 subjects in a trial to test cyclooxygenase Type 2 inhibitors, and 5,000 subjects in a trial to test aspirin, calcium, and selenium, to prevent colorectal cancer.

B. Improve early detection and diagnosis to make cancers more treatable. ($20M/$176M)

It is well known that early detection and effective screening can save lives because cancers caught early are more treatable. There are currently a number of innovative detection and screening technologies waiting to be explored. Added resources would provide the means to explore these technologies and ready more technologies for the field.

With the additional funds, we hope to:

- develop blood tests for detecting breast, lung, prostate, and colon cancer;
- develop new breast, lung, and bowel imaging technologies to detect cancers at more curable stages.

C. Speed the rate of discovery of new interventions related to all phases of the fight against cancer. ($220M/$1,376M)

We need to expand our understanding of the basic cellular pathways involved in making a cell cancerous, and apply this understanding to cancer interventions. NCI can currently fund only 25% of the grant applications it receives. This level of funding slows the engine of discovery and in turn slows progress against cancer. Funding 40% of grants would significantly speed the discovery of new interventions while maintaining competition for funding that drives excellence.

With the additional funds, we hope to:

- ensure that 20 additional drugs per year will enter the clinic for the initial phases of human testing;
- triple the number of clinical trials of new approaches to prevent, diagnose, and treat cancer.

D. Improve patient outcomes through increasing patient participation in clinical trials. ($335M/$1,221M)

We could make an immediate difference in patient outcomes by increasing patient participation in NCI experimental treatment protocols or clinical trials. Today, 90% of children are treated according to an NCI experimental protocol, 70% participate in an NCI sponsored clinical trial, and the cure rate is 70-80%. In contrast, only 2% of adult patients are enrolled in NCI sponsored clinical trials. By increasing the percent of adults enrolled in clinical trials from 2% to 10%, we could develop five times as many effective treatment, detection, and prevention strategies each year.

With the additional funds, we hope to:

- increase from 20,000 to 100,000 the number of new patients enrolled in NCI-sponsored trials;
- create new training programs in cancer clinical research in each of 10 NCI cancer centers.

E. Increase the access of the American people to state-of-the-art information about cancer and cancer interventions. ($18M/$116M)

Patients and doctors often do not have the most up-to-date information on treatment protocols. Many experts believe that if all adults were treated with the optimal protocol mortality would drop 10-20%. The extensive use of personal computers and the success of the World Wide Web provide a powerful new means to make the latest discoveries widely known. With additional resources we could place state-of-the-art information at the finger tips of cancer care providers and families, increasing the percentage of patients receiving optimal care and decreasing mortality.

With the additional funds, we hope to:

- create a Cancer Informatics Infrastructure;
- create patient-friendly clinical trials website for comprehensive information about state-of-the-art treatments and the availability of clinical trials;
- develop the next generation of informatics tools that will provide tailored messages to specific patients relevant to their own particular circumstances.

IV. SPENDING BREAKDOWN

We need to invest in six key, underlying and interdependent areas to build the needed infrastructure to achieve these five outcomes.

FY99 Spending	3yr. Spending	Description
$286 million	$1.218 billion	Enhance the clinical trials network including prevention initiatives. (Outcomes A, D)
$75 million	$200 million	Increase support of clinical investigators. (Outcomes A, D)
$20 million	$75 million	Improve the informatics associated with clinical trials and with dissemination of information about clinical trials. (Outcomes A, D, E)
$40 million	$195 million	Increase training and education of new clinical investigators including minority initiatives. (Outcomes A, D)
$93 million	$560 million	Increase the number of NCI-sponsored cancer centers. (Outcomes A-E)
$200 million	$1.2 billion	Increase funding of investigator-initiated research. (Outcome C)
$714 million	$3.448 billion	TOTAL

V. CONCLUSION

In this budget climate I had hoped to be able to recommend to you a cancer initiative that costs little or no money, but I am convinced such an approach would not be credible. Cancer control advocates have observed the tactics of the AIDS activists and are seeking to replicate their successes. Cancer advocates are now pursuing a "show me the money" strategy. The Administration has already acted on low-cost opportunities like speeding FDA approval of cancer drugs. The top priorities for the cancer advocacy community -- increasing biomedical research and assuring that research findings are rapidly translated into the clinic -- involve a significant investment of funds.

There are several paths you could take to author a credible Vice Presidential cancer initiative. Which path we take will be determined by the amount of money we can include in the FY99 budget.

Option 1-- You could advocate a comprehensive cancer initiative as part of the FY99 budget. The price tag is substantial -- $714 million or a 30 percent increase in NCI's budget over the President's FY98 request -- but these funds will buy significant progress in preventing, detecting, diagnosing, and treating cancer, and it will essentially implement the FY99 bypass budget which will guarantee widespread support from the cancer community.

Option 2 -- The second path is a more modest, "lite" version of the first path. You could seek a $425 million increase in NCI's budget. This would buy a credible but scaled down version of the outcomes described in this memo. It would pay for the "NCI Challenge" portion of the bypass budget, which focuses on translating scientific discovery into better patient care. This approach is a very credible initiative, will still generate widespread support, but Rick Klausner and prominent members of Congress will be calling for more.

Option 3 -- The third path is more modest still. You could seek less than $425 million but enough to have a credible initiative -- probably at least $250 million. A $250 million investment would increase NCI's budget 10%. A 10% increase should compare favorably to the Administration's FY98 request (a 2% increase) and Congress's expected FY98 appropriation (a 7% increase). Under this approach, we would fund one or more of the outcomes. In addition, we could shore up this approach by linking it to other initiatives the Administration is already pursuing. For example, if OMB approves, you could announce support for having Medicare cover the costs of its beneficiaries participating in clinical trials. This change, a priority of the cancer community, would substantially increase adult participation in NCI-sponsored clinical trials. You could also take ownership of the sharp increase in biomedical research that the President has said must be part of comprehensive tobacco legislation.

Finally, whichever path you choose the next step is the same. We must begin an immediate and public dialogue with the cancer community so that they have an opportunity to shape the final plan within the budget level you choose. Their participation and support will be critical to achieving our goals. You will have an important opportunity to begin building that support on October 27, when you are scheduled to meet with the Friends of Cancer Research, the leading cancer research advocacy group.

VI. DECISION

____ OPTION 1

Seek $714 million in the FY99 budget to fund all five outcomes of the cancer initiative outlined above, and NCI's FY99 bypass budget.

____ OPTION 2

Seek $425 million in the FY99 budget to fund a "lite" version of the five outcomes and the "NCI Challenge" portion of the bypass budget.

____ OPTION 3

Seek between $250 million and $425 million to fund a more modest cancer initiative, by championing one or more of the specific outcomes outlined above.

July 25, 1997

MEMORANDUM FOR THE VICE PRESIDENT

FROM: Jerry Mande

SUBJECT: Cancer Initiative

I. SUMMARY

We are at a pivotal point in the fight against cancer. Your leadership would result in significant progress in this battle. Several factors have emerged to provide this opening. First, the current "war on cancer" has fallen short of public expectations. Second, the science has advanced to a point where additional investments in cancer research would likely result in important improvements in patient outcomes. Third, there is a renewed, visible, public interest in fighting cancer.

There is every reason to be confident of future success in the battle against cancer. Cancer is not one disease but many. Progress to date indicates we will eventually prevent or cure most cancers. We already have cures for childhood cancers, lymphomas, and testicular cancers. But we have made only limited progress in the fight against most adult cancers, and we must take advantage of emerging science to do better.

To seize the opportunity, we need money. Specifically, we need $600 million more in FY99 than was in the President's FY98 request ($2.433 billion) and a $3.2 billion increase over 3 years. As outlined below, this investment would: 1) protect millions of people at risk of developing cancer; 2) greatly improve early detection and diagnoses of cancer; 3) speed the discovery and development of new cancer drugs and devices; 4) dramatically increase adult participation in clinical trials; and 5) provide all cancer patients and their care givers with easy access to the latest information on treating their disease.

Given budget constraints, you would need to begin now establishing support for such a program. You could signal your interest by participating in one or two cancer events this summer, give a major policy speech this fall, and advocate for an increase in the FY99 budget request.

II. BACKGROUND

The "war on cancer" began in 1971, when President Nixon and the Congress enacted the *National Cancer Act* (NCI was established by FDR in 1937). While significant advances have been made over the past 25 years, especially in treating cancer in children, many

experts and much of the public is troubled by the lack of progress. Children's cure rates have approached 70-80%. Progress treating adult cancers, however, has been incremental and frustratingly slow. The science is thriving, but there is a sense that the nation does not have an effective national cancer program.

Last year, NCI publicly identified key research opportunities and priority investments in its so-called "bypass budget." The 1971 Act authorizes NCI's director to submit an annual budget estimate directly to Congress after review "but without change" by the Secretary, the Director of NIH, and the National Cancer Advisory Board. In his bypass budget for FY99, NCI Director Richard Klausner is likely to request $900 million more than the President's FY98 request. I suggest you push for $600 million of this increase to achieve the five outcomes outlined below.

III. SPECIFIC OUTCOMES

Enhance cancer prevention research protecting millions of people at risk of developing cancer.

Clinical trials for evaluating cancer preventive strategies (such as drugs, vaccines, better diet, more exercise, reduced environmental exposures) involve large numbers of subjects and take years to complete. There is currently a waiting list of interventions that merit testing. More resources would enable researchers to test promising interventions, leading to the prevention of millions of cases of cancer.

Improve early detection and diagnosis to make cancers more treatable.

It is well known that early detection and effective screening can save lives because cancers caught early are more treatable. There are currently a number of innovative detection and screening technologies waiting to be explored. Added resources would provide the means to explore these technologies and ready more technologies for the field.

Speed the rate of discovery of new interventions related to all phases of the fight against cancer.

We need to expand our understanding of the basic cellular pathways involved in making a cell cancerous, and apply this understanding to cancer interventions. NCI can currently fund only 25% of the grant applications it receives. This level of funding slows the engine of discovery and in turn slows progress against cancer. Funding 40% of grants would significantly speed the discovery of new interventions while maintaining competition for funding that drives excellence.

Improve patient outcomes through increasing patient participation in clinical trials.

We could make an immediate difference in patient outcomes by increasing patient participation in NCI experimental treatment protocols or clinical trials. Today, 90% of children are treated according to an NCI experimental protocol, 70% participate in an NCI sponsored clinical trial, and the cure rate is 70-80%. In contrast, only 2% of adult patients are enrolled in NCI sponsored clinical trials. By increasing the percent of adults

enrolled in clinical trials from 2% to 10%, we could develop five times as many effective treatment, detection, and prevention strategies each year.

Increase the access of the American people to state-of-the-art information about cancer and cancer interventions.
Patients and doctors often do not have the most up-to-date information on treatment protocols. The extensive use of personal computers and the success of the World Wide Web provide a powerful new means to make the latest discoveries widely known. With additional resources we could place state-of-the-art information at the finger tips of cancer care providers and families, increasing the percentage of patients receiving optimal care and decreasing mortality. Many experts believe that if all adults were treated with the optimal protocol mortality would drop 10-20%.

IV. SPENDING BREAKDOWN

We need to invest in six key, underlying and interdependent areas to build the needed infrastructure to achieve these five outcomes.

FY99 Spending	3yr. Spending	Description
$160 million	$960 million	Enhance the clinical trials network including prevention initiatives.
$75 million	$200 million	Increase support of clinical investigators.
$20 million	$75 million	Improve the informatics associated with clinical trials and with dissemination of information about clinical trials.
$40 million	$195 million	Increase training and education of new clinical investigators including minority initiatives.
$93 million	$559 million	Increase the number of NCI-sponsored cancer centers.
$200 million	$1.2 billion	Increase funding of investigator-initiated research.
$588 million	$3.189 billion	TOTAL

V. CONCLUSION

In this budget climate I had hoped to be able to recommend to you a cancer initiative that costs little or no money, but I am convinced such an approach would not be credible. Cancer control advocates have observed the tactics of the AIDS activists and are seeking to replicate their successes. Cancer advocates are now pursuing a "show me the money" strategy. The Administration has already acted on low-cost opportunities like speeding FDA approval of cancer drugs. The top priorities for the cancer advocacy community -- increasing biomedical research and assuring that research findings are rapidly translated into the clinic -- involve a significant investment of funds.

September 1, 1997

MEMORANDUM FOR RON KLAIN

FROM: Jerry Mande

SUBJECT: Cancer Initiative

At our last meeting, you asked for a more detailed breakdown of the specific elements of the proposed cancer initiative. This memorandum provides those details.

At our meeting we discussed investments in six areas that would result in the following five specific outcomes: 1) protect millions of people at risk of developing cancer; 2) greatly improve early detection and diagnoses of cancer; 3) speed the discovery and development of new cancer drugs and devices; 4) dramatically increase adult participation in clinical trials; and 5) provide all cancer patients and their care givers with easy access to the latest information on treating their disease. You requested examples of concrete actions that would link the investments to the outcomes. We could commit to some or all of the actions set forth below.

CONCRETE ACTIONS (with projected cost for individual outcomes):

1. We will enhance cancer prevention research to prevent millions of cancer cases by conducting new clinical trials that focus on some of the most common and deadly cancers ($121M). NCI will enroll:

- 22,000 women in a trial to test selective estrogen-response modulators to prevent breast cancer.
- 20,000 men in a trial to test vitamin E and selenium to prevent prostate cancer.
- 5,000 subjects in a trial to test cyclooxygenase Type 2 inhibitors, and 5,000 subjects in a trial to test aspirin, calcium, and selenium, to prevent colorectal cancer.

2. To improve early detection and diagnosis to make cancers more treatable ($20M), we will:

- develop blood tests for detecting breast, lung, prostate, and colon cancer;
- develop new breast, lung, and bowel imaging technologies to detect cancers at more curable stages.

3. To speed the discovery and testing of new interventions ($220M) we will:

- ensure that 20 additional drugs per year will enter the clinic for the initial phases of human testing;

- triple the number of clinical trials of new approaches to prevent, diagnose, and treat cancer.

4. To improve patient outcomes through increasing participation in clinical research ($335M) we will:

- increase from 20,000 to 100,000 the number of new patients enrolled in NCI sponsored trials;

- create new training programs in cancer clinical research in each of 10 NCI cancer centers.

5. To increase access of the American people to information about cancer and state-of-the-art cancer interventions ($18M) we will:

- create a Cancer Informatics Infrastructure;

- create patient-friendly clinical trials website for comprehensive information about state-of-the-art treatments and the availability of clinical trials;

- develop the next generation of informatics tools that will provide tailored messages to specific patients relevant to their own particular circumstances.

EXECUTIVE OFFICE OF THE PRESIDENT

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

WASHINGTON, D.C. 20500

10-24-97

Sigal — 362-5592 :H — MARCH ADD[illegible]

Larry King last night - Ellen Stovall, Milken, Donaldson, Crawford

Ellen overview

Sherry - Hollywood - Sept mtg Brandon [illegible] / dved

Don Coffee - AACR President Amer Assoc of Ca Research 410 955-2517

14K members 215-440-9311 Margo

Hopkins - prostate Ca

Hone in on 3-4 key opportunities

Need to look at overall infrastructure, stop playing one Ca off against another

Ask - (1) supporting bypass budget FY99 an important start.

(2) 7.5% Senate position - spread $45M H/S

(3) Bigger picture - more than research

(4) Need stability yr to yr.

Toby Donenfeld @ OVP
10/23/97 04:39:35 PM

Record Type: Record

To: Jerold R. Mande/OSTP/EOP

cc:
Subject: Re: Cancer

The VP got your decision memo in his briefing book Tuesday and we just discovered today that he didn't decide anything. We resubmitted it to him today and his WW office said they'd get the VP to answer it today.

Attending the meeting on Monday: Sherry Lansing, Jack Valenti, Ellen Segal, Don Coffee, Tony Podesta, Jean Prewitt.

They said their agenda is: history of Friends, plans for the future, impact of cancer (particularly for baby boomers), disproportionate share of funding that goes to cancer, agenda for Hollywood, new Klausner by-pass budget and new ideas. I told them that of course the VP would want to hear what they have done and will do on tobacco. I asked Jean Prewitt for all the info on the topics above by noon tomorrow so that you and I could look at it.

Regarding a meeting, Don told me to check w/ Ron to see if we should request 15 minutes tomorrow or take 15 minutes out of the meeting on Monday.

The meeting is now scheduled for 12:40 -1:25.

I'll let you know what I hear from Ron and the WW office as soon as I hear.

Jerold R. Mande @ EOP

Jerold R. Mande @ EOP
10/23/97 03:20:25 PM

To: Toby Donenfeld/OVP
cc: Donald H. Gips/OVP
Subject: Cancer

Has the VP received the cancer memo? What are the plans for Monday's meeting? Who will be in attendance? Will we have time to discuss the memo with him before the meeting?

PRESIDENT CLINTON ANNOUNCES NEW CANCER INITIATIVES

Sunday, October 27, 1996

In honor of National Breast Cancer Awareness month and the 25th anniversary of the National Cancer Act, President Clinton today will announce three important new initiatives that will build on his Administration's efforts to fight breast cancer and to address the needs of cancer survivors.

The new initiatives being announced by the President are: (1) a $30 million increase in funding for new research into the genetic basis of breast cancer, through a collaborative initiative between the Departments of Defense and Health and Human Services; (2) the opening of a breast cancer web page site, a recommendation of the National Action Plan on Breast Cancer, a public-private partnership created under the Clinton Administration; and (3) the new Office of Cancer Survivorship in the National Cancer Institute, which will research issues relating to the physical, psychological, and economic well-being of the growing number of cancer survivors in this country.

Prior to his announcement in the Rose Garden, President Clinton will meet in the Oval Office with five cancer survivors and their families and sign a pink ribbon, the symbol of the nation's fight against breast cancer. They will be joined by Susan Blumenthal, Deputy Assistant Secretary in charge of the Office of Women's Health at the Department of Health and Human Services; Steven Joseph, Assistant Secretary for Defense for Health Affairs, Rick Klausner, Director of the National Cancer Institute, Ellen Stovall, Executive Director of the National Coalition for Cancer Survivorship; and Elizabeth Clark, Director of the National Coalition for Cancer Survivorship.

Biographies of the survivors are attached. The speaking program in the Rose Garden is as follows: Remarks by Susan Blumenthal, Deputy Assistant Secretary in charge of the Office of Women's Health at the Department of Health and Human Services; Remarks by Jane Reese-Coulbourne of Alexandria, Virginia, a cancer survivor; and Remarks by the President.

Over the past 25 years, the United States has made great strides in reducing cancer rates and increasing cancer survival. For example, 25 years ago, only one in 10 children survived childhood cancer and leukemia. Today, seven out of 10 children who get cancer are cured. Still, nearly 1.4 million people will be diagnosed with cancer this year, and over forty percent of Americans will have the disease over their lifetime. And, while the President will note today that death rates from breast cancer have fallen seven years in a row, studies estimate that the disease will be diagnosed in about 1.5 million American women and claim nearly half a million lives in this decade.

$30 MILLION IN FUNDING FOR BREAST CANCER GENETIC RESEARCH

President Clinton will announce a $30 million increase in funding for new research into the genetic basis of breast cancer, through a collaborative effort between the Departments of Defense and Health and Human Services. This represents a major increase in funding devoted to genetic breast cancer research over FY 1996. Of the $30 million, $20 million is being directed from within DOD's FY 1997 general breast cancer research funding to focus specifically on breast cancer genetic

research; $10 million is being directed from within NIH's biomedical research funds, also to focus on breast cancer genetic research.

The Clinton Administration has responded to the significant threat posed by breast cancer with increased efforts in research, prevention and treatment. Since the Administration has taken office, funding for these activities has increased more than 95 percent, from $276 million in FY 1993 to an estimated $541 million in FY 1997 at the Department of Health and Human Services alone. This investment has yielded promising results, including the recent identification of two genes, BRCA1 and BRCA2, which researchers say may account for five to 10 percent of the breast cancers diagnosed each year. Researchers estimate that more than half of the women who inherit these genes will be diagnosed with breast cancer by age 50, and more than 85 percent will have a diagnosis of breast cancer by age 70. This new research initiative, a collaboration between the Department of Defense and the National Institutes of Health, will focus on a broad range of investigations related to the role of genes in the development of breast cancer. The Administration's objective is to move rapidly toward the goal of identifying high-risk women and preventing breast cancer before it strikes.

NATIONAL ACTION PLAN ON BREAST CANCER GOES ON-LINE

President Clinton today announced that the National Action Plan on Breast Cancer (NAPBC) will take its resources on-line. The launch of the web site coincides with the three year anniversary of the creation of the National Action Plan on Breast Cancer, which catalyzes and supports innovative research and outreach projects on breast cancer, with a special emphasis on the development of public-private partnerships. The web site, coordinated by the Department of Health and Human Services in partnership with the private sector, provides answers to frequently asked questions about breast cancer and serves as a gateway to information on breast cancer clinical trials and research, breast cancer organizations and advocacy groups, educational conferences and meetings, publications, and other resources. The web site location: http://www.napbc.org

NEW EFFORTS PART OF A COMPREHENSIVE STRATEGY TO FIGHT BREAST CANCER

These new efforts are part of the Administration's comprehensive strategy to fight breast cancer in this country. For example, on October 1, 1996 the Administration announced the expansion of the National Breast and Cervical Cancer Early Detection program to all 50 states, with $102 million in federal funding for the upcoming year. The program, run by the Centers for Disease Control and Prevention, provides screening services for low income and medically underserved women. In March 1996, the FDA proposed regulations to implement the Mammography Quality Standards Act (MQSA), to ensure that mammography facilities meet high quality standards for equipment and personnel. First Lady Hillary Rodham Clinton also launched a campaign urging older women to get mammograms and promoting Medicare's coverage of mammography. In addition, the Department of Health and Human Services, the Central Intelligence Agency, and the Department of Defense have created a unique partnership to transfer defense and imaging technologies to improve early detection of breast cancer.

LAUNCHING OF THE OFFICE OF CANCER SURVIVORSHIP

President Clinton also today unveiled the new Office of Cancer Survivorship at the National Cancer Institute. Recent success of cancer prevention, early detection, and treatment efforts has created a new need: research into the physical, psychological, and economic well-being of the growing number of cancer survivors. The Office of Cancer Survivorship will support research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following cancer treatment; and their unique insurance and employment issues.

Today, more than 10 million Americans are cancer survivors. Seven million of these individuals are long-term survivors who were diagnosed with cancer more than five years ago. About 135,000 of these survivors are under the age of 15, and one in every 1,000 Americans between the ages of 20 and 40 is a survivor of childhood cancer. The number of breast cancer survivors is also growing, largely due to improved mammography screening and more effective treatment. The death rate from breast cancer has gone down seven years in a row. According to provisional statistics released earlier this month by the National Center for Health Statistics, there was a 7.7 percent reduction in age-adjusted breast cancer mortality from 1989 to 1995.

A fact sheet on the Clinton Administration's cancer-related initiatives is attached.

-30-30-30-

Cancer Survivors Attending the President's Announcement

Jane Reese-Coulbourne of Alexandria, VA

Jane Reese-Coulbourne, 42, is a breast cancer survivor for six years. She discovered a lump in her right breast during self-examination. Her cancer was in an advance stage and considered inoperable. She joined the FLAC clinical trial at the National Cancer Institute where she has received all of her treatments. She went through eight rounds of chemotherapy, eight weeks of radiation and four and a half years of tamoxifen treatments. A chemical engineer, Ms. Reese-Coulbourne is now a full-time breast cancer advocate, serving as executive vice president of the National Breast Cancer Coalition, representing over 350 member organizations involved with breast cancer. She has testified before Congress on such issues as the Department of Defense breast research program and health care reform. She is a member of the steering committee of the National Action Plan on Breast Cancer.

Dorothy Bankhead of Fort Washington, MD

Dorothy Bankhead, 72, retired U.S. Navy civilian worker and realtor, is a breast cancer survivor for 19 years. A lump was detected in her left breast during a regular checkup. Following the checkup, a biopsy was performed and her tumor was diagnosed as cancer. Her surgery was performed at the National Institutes of Health. She has been recovering very well through the years and is now a part-time student at the University of Maryland. She is the mother of one son and grandmother of four.

Patrick Garbe of Fairfield Connecticut

Patrick Garbe, 37, is a cancer survivor of 16 years. He is a legal assistant with the law firm of Shearman & Sterling. He was diagnosed in 1980 with a rare soft tissue tumor (paraganglioma-a tumor on the nerve system) which was removed successfully. Over the next few years, Mr. Garbe found tumors in different areas of his body -- the pelvis, cervical vertabra, and throat. All were slow growing tumors. Since 1993, he has been in remission and in good health. Mr. Garbe is an advocate for increasing funding for all cancers.

Olda Mondragon of Baltimore, MD

Olda Mondragon, 54, the mother of one daughter, is a breast cancer survivor of three years. She was treated at Johns Hopkins Hospital in Baltimore after a mammography detected a lump in her left breast. She had a mastectomy and has been recovering very well. Ms. Mondragon said that the cancer changed her life and now she is dedicated to teaching others about cancer. As a member of The Center of the Hispanic Community in Baltimore, Ms. Mondragon teaches others about the importance of early detection and mammograms.

Erin Schraibman of Rockville, MD

Erin Schraibman, 9, is a seven-year cancer survivor. She was diagnosed with acute lymphatic leukemia (known as childhood leukemia) at 2 and a half years old and has been in remission more than six and a half years. Erin is doing well and is very athletic. She is a fourth-grader at Ritchie Park Elementary School.

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Clinton Administration Cancer-Related Initiatives

Since taking office, the Clinton Administration has devoted increased resources to the prevention, detection, and treatment of cancer. The following are examples of new initiatives launched by the Administration to reduce cancer rates and increase cancer survival in this country:

- **Developed a National Action Plan on Breast Cancer.** The Clinton Administration has established a National Action Plan on Breast Cancer (NAPBC), which supports innovative research and outreach projects on breast cancer, with a special emphasis on the development of public-private partnerships. On October 27, 1996, President Clinton announced the new NAPBC web site, coordinated by the Department of Health and Human Services, in partnership with the private sector. The web site provides answers to frequently asked questions about breast cancer, information on breast cancer clinical trials and research, breast cancer organizations and advocacy groups, educational conferences and meetings, publications, and other resources.

- **Created the Office of Cancer Survivorship.** Recognizing the need for research into the physical, psychological, and economic well-being of the growing number of cancer survivors, on October 27, 1996, President Clinton unveiled the new Office of Cancer Survivorship at the National Cancer Institute. The Office of Cancer Survivorship will support research covering the range of issues facing survivors of cancer, including: long term medical and psychological effects; factors that predispose survivors to second malignancies; reproductive problems following cancer treatment; and their unique insurance and employment issues.

- **Increased spending on cancer by $400 million.** In FY 1997, the National Cancer Institute was funded at $2.38 billion, a $400 million increase over FY 1993. Since the Clinton Administration has taken office, funding for breast cancer research, prevention and treatment has increased by more than 95 percent in HHS alone, from about $276 million in FY 1993 to an estimated $541 million in FY 1997.

- **Accelerated approval of and expanded access to cancer drugs.** The Food and Drug Administration (FDA) has taken several steps to speed approval of cancer drugs and provide patients access to promising therapies not yet approved. For example, the FDA is using tumor shrinkage as a "surrogate marker" for effectiveness, cutting years off drug development time and months off of FDA review. This year the FDA approved *topotecan*, the first member of a promising new class of anti-tumor drugs that provides new hope to ovarian cancer patients and others. The FDA has given patients more of a voice in the drug review process by placing patient representatives on all cancer drug advisory committees. FDA is also working with other countries and manufacturers to make promising drugs approved in other countries available to patients in the United States.

- **Launched the Medicare mammography campaign.** The Clinton Administration has made it a priority to educate older women about the importance of detecting breast cancer early and to inform them about Medicare coverage of mammography services. Both the President and the First Lady have appeared in TV public service announcements encouraging older women to get mammography screenings.

- **Worked to ensure quality mammography facilities.** In March 1996, the FDA proposed regulations to implement the Mammography Quality Standards Act (MQSA). The rules will ensure that the roughly 10,000 mammography facilities nationwide accredited by the FDA meet high quality standards for equipment and personnel.

- **Proposed expanding Medicare coverage for mammograms.** In his balanced budget proposal, President Clinton proposes to expand Medicare coverage to include: annual mammograms for beneficiaries age 50 and over with no copayment or deductible requirement; and procedures for early detection of colorectal screening.

- **Launched National Breast and Cervical Cancer Early Detection Program.** The Centers for Disease Control's (CDC) National Breast and Cervical Cancer Early Detection Program offers free or low-cost mammography screening to uninsured, low-income, elderly, and minority women. The program, which has been operating in an increasing number of states over the past six years, has provided screening tests to almost one million medically underserved women. In October, 1996, the program went nationwide, with funding for all 50 states.

- **Adapted imaging technologies from the defense, space and intelligence communities to detect cancer and other diseases earlier and with greater accuracy.** The Department of Health and Human Services has been working with the Departments of Defense, the CIA, NASA, and other public and private entities to explore ways in which imaging technologies from other fields may be applied to the early detection of breast cancer.

- **Signed the Kassebaum-Kennedy legislation into law, ending pre-existing condition exclusions.** As a result of this legislation, no American will live in fear of losing their coverage just because they have a pre-existing condition. This legislation is particularly helpful for the millions of cancer victims who will no longer face the dilemma of hesitating to go to a new and better job for fear of losing their health insurance.

- **Protected children from tobacco.** President Clinton announced in August 1996, measures to eliminate easy access to tobacco products by children and to restrict advertising that makes tobacco appealing to kids. More Americans die every year from smoking related diseases than from AIDS, car accidents, murders, and suicides combined. Each day, almost 3,000 children start smoking and nearly 1,000 of them die earlier as a result. Tobacco use is responsible for over 30 percent of American cancer deaths and over 90 percent of lung cancer (NIH report: President's Cancer Panel, Report of the Chairman, Sept. 1996).

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THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release October 27, 1996

REMARKS BY THE PRESIDENT
ON ANNOUNCEMENT OF BREAST CANCER
RESEARCH AND CANCER SURVIVORS INITIATIVES

The Rose Garden

1:20 P.M. EST

THE PRESIDENT: Thank you so much. Thank you. First of all, thank you all for joining me on this beautiful, beautiful Sunday afternoon to discuss our common efforts to fight cancer.

I want to thank Secretary Shalala and Dr. Susan Blumenthal for their tireless service on behalf of women throughout America. I thank Dr. Harold Varmus, the Director of the National Institute of Health; Dr. Richard Klausner, the Director of the National Cancer Institute; and Dr. Steven Joseph, the Assistant Secretary of Defense for Health. They have all been instrumental in the efforts we are here to talk about today.

And thank you, Jane Reese-Coulbourne, for your courage, your dedication, your willingness to come up here and make a public statement today that represents the feelings, the convictions, the interests and the hopes of millions and millions of people throughout the United States.

Let me thank all the survivors and advocates who are here today, and who fight the battle against cancer every day for all the rest of us.

Our nation is only as strong as our families are healthy. I have devoted a lot of time and thought to the question of what we need to do to help strong families survive and thrive and increase as we move into the 21st century. We have to help more people succeed at home and at work. But, clearly, we have to help people live as long and as well as they can and then help families have the support they need when their family members are ill. That's why I was glad to sign the Kennedy-Kassebaum bill to preserve health insurance options for people when a family member has been sick; why I was proud to sign the bill that bans insurance companies from forcing mothers and their newborn babies out of the hospital after 24 hours; why in our new balanced budget there are funds for more regular mammograms for women on Medicare and funds to give respite care for families who are caring for members with Alzheimers.

We have an enormous opportunity as we stand on the brink of this new century to take advantage of scientific possibilities, to help people live as long as well as they can, and to build stronger families in the process. Nothing is more devastating to a family's strength than when someone is diagnosed with a life-threatening disease like cancer. As Jane said, I know about this from my own family's experience, and nearly every family does. This year alone nearly 1.4 million American men, women and children will be diagnosed with some kind of cancer. This is the 25th anniversary of the National Cancer Act, and in those 25 years we've come a long way in the fight.

This month is also breast cancer awareness month, a time to remember the terrible toll breast cancer has taken, to assess our progress, to redouble our efforts to find a cure. That's why I

wanted us to come together today, to talk about the new steps we are taking in the fight against cancer and breast cancer, in particular.

Since I took office we have mounted a comprehensive campaign to prevent and treat cancer. We are working to get tobacco out of our children's lives forever. We have accelerated FDA approval of cancer drugs and made it easier for patients to obtain promising therapies before they are formally approved. The Department of Health and Human Services, the Department of Defense, NASA and the CIA have all joined forces to develop cutting edge imaging technology for the early detection of cancer.

Most important of all, as has been said, we've increased spending on cancer research, treatment and prevention by some $400 million. In the battle against breast cancer we've increased funding for research and prevention by nearly 80 percent since 1993. We launched a public awareness campaign to encourage older women to use Medicare to have mammograms. And my balanced budget goes even further, as I said. It will guarantee free annual mammograms to Medicare beneficiaries, removing all financial barriers that prevent some women from obtaining this vitally important test.

We are making progress. The survival rate has gone up. Seven out of 10 children with cancer survive it. That's up from one out of 10 just 25 years ago. The death rate for breast cancer has gone down every year in the last seven, has dropped by nearly eight percent since 1990. Just last week, the NIH announced a milestone in the Human Genome Project, which is identifying the location and function of nearly every human gene. We've now mapped out 20 percent of all human genes, and anyone can use that map on the Internet. Soon we will know the genes that contribute to cancer and our genetic predisposition to inherit it -- and possibly then be able to prevent it before it strikes.

But as far as we have come, we still have far to go. We must continue to build on our progress and strengthen our efforts. Today, I announced three new steps to bring us closer to a cure and to improve the lives of those who do survive.

First, we know that genetic research may be the key to understanding and curing breast cancer. In the last two years, scientists have discovered two genes that indicate susceptibility to breast cancer. This remarkable discovery is giving hope to women everywhere. Last month, I signed a budget that reflects our values in devoting substantial resources to cancer research. Today, I'm announcing we are directing $30 million of that new budget to support and expand breast cancer genetic research at hospitals, universities and labs all across America. This step represents a major increase in breast cancer genetic research. It will ensure the development of this promising new research and bring us that much closer to a cure.

Second, we must all use the technology and we must use all the technology at our disposal to give women the information they need about breast cancer. We must unite the forces of the public and private sectors to achieve that goal. That's why I'm pleased to announce the launch of the new National Action Plan on Breast Cancer Web Site on the Internet. This is easily accessible. The web site address is right over there. It will answer the questions women have about early detection, clinical trials and much more.

And, finally, there's no greater proof of the progress we've made then the more than 10 million Americans who have survived cancer. Many have special psychological, physical and health care counseling needs that we are only beginning to understand. Some face recurrence of their illness. Some can't get health insurance. I'm proud to have passed landmark legislation to guarantee that cancer survivors will no longer live in fear of losing that health insurance just because they have a preexisting condition.

Today, I announced that this Friday, November 1st, the National Cancer Institute will open its new Office of Cancer Survivorship. The office will support much needed research that will help cancer survivors deal with the problems they face even after their cancer is cured. Dr. Anna Meadows will be the Director of the Office of Cancer Survivorship, and I thank her for her willingness to do this ground breaking service on behalf of people with cancer who have survived it all across America.

These steps help us to put science at the service of our families and say we will do whatever it takes to continue the fight until there is a cure for cancer. And we will do everything we can to improve the lives of those who do survive.

Just a few moments ago I signed a piece of the Ribbon of Hope. This yellow ribbon, which is already over 750 feet long in its entirety, has been signed by more than 10,000 cancer survivors around the world. The First Lady was the first person to sign the ribbon, and I was honored to place my own signature along side that of so many courageous people. The ribbon is a symbol of the hope that sustains people in their struggle with cancer. It is also a symbol of the progress we have made and the progress still to come in our common fight.

And now I'd like to present that piece of the Ribbon of Hope that I signed to Erin Schraibman, herself a cancer survivor, a very brave young girl whom I have very much enjoyed meeting today.

Thank you and God bless you all. (Applause.)

(The President presents Ribbon of Hope to Erin Schraibman.)

THE PRESIDENT: We're adjourned.

END 1:30 P.M. EST

The White House at Work

Friday, August 8, 1997
Balanced Budget -- Health

THE PRESIDENT'S BALANCED BUDGET:
REAL IMPROVEMENTS IN THE HEALTH OF MILLIONS OF AMERICANS

> ***The historic balanced budget legislation I signed on Tuesday is about more than balancing the books; it also honors our values, increases our chances of keeping the American Dream alive in the 21st century and improves the lives of every American. There are some little-known but very important provisions in this new balanced budget that will take us a tremendous step forward in our fight against diabetes.***
>
> **-- President Clinton, August 8, 1997**

Today President Clinton announced that the balanced budget he signed into law contains a package of investments to improve treatment, prevention and research for Americans with diabetes -- this package offers new hope to the 16 million Americans who suffer from diabetes. The President's package includes:

Expanded Coverage -- An important new preventive benefit which will help the millions of older Americans who suffer from diabetes better manage their treatment. The balanced budget invests over $2 billion to make testing strips and other methods of monitoring blood glucose levels, as well as instructions on how best to manage the complicated disease, available to all Medicare beneficiaries with diabetes. It will empower Medicare patients to take better care of themselves at home and to avoid complications that can lead to costly hospital stays and destroy health.

Investments in Research -- A new $150 million investment to find a cure for juvenile diabetes. Children who develop diabetes should not have to suffer the devastating consequences of this disease. The new diabetes initiative will increase our annual funding for diabetes research by nearly 10%.

Help For Those in Particular Need -- A $150 million investment to help prevent, treat and cure diabetes among Native Americans. Native Americans are three times as likely as white Americans to have diabetes and far less likely to find adequate treatment for their condition. This grant will bring public health services, schools, and nutrition programs together to reach families and children living on our reservations and provide them with information and tools they need to prevent and manage diabetes.

Protections for People with Diabetes -- A new, unprecedented public-private partnership that will bring our nation's leading health care providers, purchasers, and consumers together to develop uniform guidelines for diabetes care. Through these new guidelines, we can ensure that all doctors provide their patients with the thorough and vigilant care -- such as regular eye and foot exams -- to stay as healthy as possible.

The American Diabetes Association (ADA) has said: "Taken together, these new investments in diabetes, announced by President Clinton today, are as important for people

July 25, 1997

MEMORANDUM FOR THE VICE PRESIDENT

FROM: Jerry Mande

SUBJECT: Cancer Initiative

I. SUMMARY

We are at a pivotal point in the fight against cancer. Your leadership would result in significant progress in this battle. Several factors have emerged to provide this opening. First, the current "war on cancer" has fallen short of public expectations. Second, the science has advanced to a point where additional investments in cancer research would likely result in important improvements in patient outcomes. Third, there is a renewed, visible, public interest in fighting cancer.

There is every reason to be confident of future success in the battle against cancer. Cancer is not one disease but many. Progress to date indicates we will eventually prevent or cure most cancers. We already have cures for childhood cancers, lymphomas, and testicular cancers. But we have made only limited progress in the fight against most adult cancers, and we must take advantage of emerging science to do better.

To seize the opportunity, we need money. Specifically, we need $600 million more in FY99 than was in the President's FY98 request ($2.433 billion) and a $3.2 billion increase over 3 years. As outlined below, this investment would: 1) protect millions of people at risk of developing cancer; 2) greatly improve early detection and diagnoses of cancer; 3) speed the discovery and development of new cancer drugs and devices; 4) dramatically increase adult participation in clinical trials; and 5) provide all cancer patients and their care givers with easy access to the latest information on treating their disease.

Given budget constraints, you would need to begin now establishing support for such a program. You could signal your interest by participating in one or two cancer events this summer, give a major policy speech this fall, and advocate for an increase in the FY99 budget request.

II. BACKGROUND

The "war on cancer" began in 1971, when President Nixon and the Congress enacted the *National Cancer Act* (NCI was established by FDR in 1937). While significant advances have been made over the past 25 years, especially in treating cancer in children, many

experts and much of the public is troubled by the lack of progress. Children's cure rates have approached 70-80%. Progress treating adult cancers, however, has been incremental and frustratingly slow. The science is thriving, but there is a sense that the nation does not have an effective national cancer program.

Last year, NCI publicly identified key research opportunities and priority investments in its so-called "bypass budget." The 1971 Act authorizes NCI's director to submit an annual budget estimate directly to Congress after review "but without change" by the Secretary, the Director of NIH, and the National Cancer Advisory Board. In his bypass budget for FY99, NCI Director Richard Klausner is likely to request $900 million more than the President's FY98 request. I suggest you push for $600 million of this increase to achieve the five outcomes outlined below.

III. SPECIFIC OUTCOMES

Enhance cancer prevention research protecting millions of people at risk of developing cancer.

Clinical trials for evaluating cancer preventive strategies (such as drugs, vaccines, better diet, more exercise, reduced environmental exposures) involve large numbers of subjects and take years to complete. There is currently a waiting list of interventions that merit testing. More resources would enable researchers to test promising interventions, leading to the prevention of millions of cases of cancer.

Improve early detection and diagnosis to make cancers more treatable.

It is well known that early detection and effective screening can save lives because cancers caught early are more treatable. There are currently a number of innovative detection and screening technologies waiting to be explored. Added resources would provide the means to explore these technologies and ready more technologies for the field.

Speed the rate of discovery of new interventions related to all phases of the fight against cancer.

We need to expand our understanding of the basic cellular pathways involved in making a cell cancerous, and apply this understanding to cancer interventions. NCI can currently fund only 25% of the grant applications it receives. This level of funding slows the engine of discovery and in turn slows progress against cancer. Funding 40% of grants would significantly speed the discovery of new interventions while maintaining competition for funding that drives excellence.

Improve patient outcomes through increasing patient participation in clinical trials.

We could make an immediate difference in patient outcomes by increasing patient participation in NCI experimental treatment protocols or clinical trials. Today, 90% of children are treated according to an NCI experimental protocol, 70% participate in an NCI sponsored clinical trial, and the cure rate is 70-80%. In contrast, only 2% of adult patients are enrolled in NCI sponsored clinical trials. By increasing the percent of adults

enrolled in clinical trials from 2% to 10%, we could develop five times as many effective treatment, detection, and prevention strategies each year.

Increase the access of the American people to state-of-the-art information about cancer and cancer interventions.
Patients and doctors often do not have the most up-to-date information on treatment protocols. The extensive use of personal computers and the success of the World Wide Web provide a powerful new means to make the latest discoveries widely known. With additional resources we could place state-of-the-art information at the finger tips of cancer care providers and families, increasing the percentage of patients receiving optimal care and decreasing mortality. Many experts believe that if all adults were treated with the optimal protocol mortality would drop 10-20%.

IV. SPENDING BREAKDOWN

We need to invest in six key, underlying and interdependent areas to build the needed infrastructure to achieve these five outcomes.

FY99 Spending	3yr. Spending	Description
$160 million	$960 million	Enhance the clinical trials network including prevention initiatives.
$75 million	$200 million	Increase support of clinical investigators.
$20 million	$75 million	Improve the informatics associated with clinical trials and with dissemination of information about clinical trials.
$40 million	$195 million	Increase training and education of new clinical investigators including minority initiatives.
$93 million	$559 million	Increase the number of NCI-sponsored cancer centers.
$200 million	$1.2 billion	Increase funding of investigator-initiated research.
$588 million	$3.189 billion	TOTAL

V. CONCLUSION

In this budget climate I had hoped to be able to recommend to you a cancer initiative that costs little or no money, but I am convinced such an approach would not be credible. Cancer control advocates have observed the tactics of the AIDS activists and are seeking to replicate their successes. Cancer advocates are now pursuing a "show me the money" strategy. The Administration has already acted on low-cost opportunities like speeding FDA approval of cancer drugs. The top priorities for the cancer advocacy community -- increasing biomedical research and assuring that research findings are rapidly translated into the clinic -- involve a significant investment of funds.

Ron Klain @ OVP
07/24/97 04:35:03 PM

Record Type: Record

To: Jerold R. Mande/OSTP/EOP

cc:
Subject: Re: Cancer INitiative

I agree that we need to be careful about a specific promise of a cure by a date. Nothing like that. But, for example, the diabetes folks say that with $100 million they could get a "major breakthrough." Is there something like that here? Or put another way, with an additional quantum of funds, what QUALITATIVE CHANGE could we achieve?

Ron Klain @ OVP
07/22/97 02:06:48 PM

Record Type: Record

To: Jerold R. Mande/OSTP/EOP

cc: Donald H. Gips/OVP @ OVP, Toby Donenfeld/OVP @ OVP
Subject: Re: Cancer Initiative Memo

Jerry: This is a good start, but what we need is a two-pager that says: With $X more, we could buy Y, which would allow us to say Z. Not in detailed form, but just something like:

"A major new cancer initiative would cost $500 million over 3 years. This money would go to $100 million for research on brain cancer; $50 million for trials on lung cancer; etc., etc. If we did this, we could realistically set a goal of a 50% reduction in cancer deaths by the year 2010. "

We need this sort of plan QUICKLY so that the VP can sign off on it, and so that we can get it into the policy process here, and stake out our ground for the FY99 budget.

Reference #3

JOHN C. BAILAR III

Rethinking the War on Cancer

Our failure to lower the U.S. cancer death rate, despite an effort spanning 35 years, shows the need for a change of strategy.

How shall we evaluate progress in our attempts to control cancer? There have been some clear successes; perhaps greatest are the improvements in treating a broad range of cancers in children and young adults. There have been some clear failures, too; outstanding among them is the long-continuing rise in the incidence of lung cancer, stemming from our limited success in reducing tobacco smoking.

But if we want to evaluate progress across cancer as a whole, to balance the various ups and downs, how shall we do so? The three main measures are mortality rates, incidence rates, and case survival rates.

- The age-adjusted U.S. cancer *mortality rate* rose from 162.2 per 100,000 population in 1975 to 170.7 in 1984. (An "age-adjusted" rate is the weighted average of the rates that apply to different age groups; for consistency in cancer research, the weights generally are derived from the U.S. population distributions of 1970.) The preliminary cancer death rate for 1985 is nearly identical to the 1984 figure. I see no reason to omit lung cancer, but some people do; the death rate for nonlung cancer was 125.4 per 100,000 in 1975 and 125.1 in 1984. Not much progress there, even when lung cancer is excluded.
- The age-adjusted cancer *incidence rate* for the Surveillance, Epidemiology, and End-Result registry area, our closest thing to national cancer incidence data, was 330.5 per 100,000 in 1975 and 351.8 in 1984. There is again no reason to omit lung cancer, but if we do, the incidence rate for nonlung cancer rose from 285.3 per 100,000 in 1975 to 296.5 in 1984. No progress there, either.
- The 5-year relative *case survival rate* ("relative" means adjusted for mortality in the general population) was 48.6 percent in 1974–76 and 48.7 percent in 1977–83. Rates for single years of diagnosis are essentially unchanged since 1975.

John C. Bailar III, M.D., Ph.D., is a professor in the Department of Epidemiology and Biostatistics at McGill University and a statistical consultant to the *New England Journal of Medicine*. He is a former staff member of the National Cancer Institute, where he served, among other assignments, as acting director of the Cancer Control Program and editor of the *Journal of the National Cancer Institute*.

A basic, overall measure

Many alternative measures of where we stand, and where we are going, have been proposed. But in my view the most basic measure is age-adjusted mortality: It removes the effects of changes in the size and age composition of the population, prevents the selective reporting of data to support particular views, minimizes the effects of changes in diagnostic criteria related to recent advances in screening and detection, and directly measures the outcome of greatest concern—death. If we cannot reduce the age-adjusted rate of death for all cancers combined, we have failed in our primary purpose. Proponents of other measures, such as person-years of life lost, or quality-adjusted years of survival, have not made convincing cases.

No single measure, of course, can capture the rich variety of trends in incidence, mortality, and case survival for perhaps 100 kinds of cancer, or adequately express such other benefits as improved palliation (relief from symptoms), reduced side-effects of treatment, and the contributions of cancer research to other areas of research. Still, no broad cancer research program can be labeled successful unless it has an impact on the basic, overall death rate.

Table 1 provides some additional detail on trends across different age groups. The years 1950, 1975, and 1984 are appropriate because 1950 was just prior to the first major expansion of research efforts on cancer, 1975 was about the earliest anyone could expect any impact at all from the National Cancer Act of 1971, and 1984 is the most recent year for which comprehensive statistics are available for the whole set of data on cancer deaths.

It is apparent from Table 1 that cancer death rates have generally been going down in young people and up in older ones; the age-adjusted rate has risen because of the larger absolute change among older people. It is also apparent from Table 1 that there has been no overall acceleration in recent years in the average yearly declines in cancer deaths at young ages, and that the average year-to-year increases at older ages were actually larger for 1975–84 than they were for 1950–75. Although there may have been some improvement in the accuracy of death certificates over time, most of it likely occurred in the earlier period—the use of autopsies widened considerably during the 1950s, for example—than in the latter.

Table 2 shows what happened between 1975 and 1984 for some of the major forms of cancer. Mortality, incidence, and survival all moved up or down a bit for one or another form of cancer, but the figures for cancer as a whole are remarkably stable.

During these same years, countless technical reports, research papers, and general news stories have reported a rapid rise in knowledge about cancer and, presumably, progress in controlling its effects. How can this flood of new knowledge, with all its clinical implications, be reconciled with the rising death rate, rising incidence rate, and essentially unchanged survival chances of cancer victims?

TABLE 1

Age-Specific Death Rates for All Cancers Combined
Rates per 100,000 population per year

	Year			Average Annual Change	
Age	1950	1975	1984	1950–1975	1975–1984
Under 1 year	8.7	4.1	3.1	− 0.18	− 0.11
1–4	11.7	5.5	4.0	− 0.25	− 0.17
5–14	6.7	4.7	3.6	− 0.08	− 0.12
15–24	8.6	6.7	5.5	− 0.08	− 0.13
25–34	20.0	14.6	132.0	− 0.22	− 0.18
35–44	62.7	53.0	46.6	− 0.39	− 0.71
45–54	175.1	181.9	170.5	+ 0.27	− 1.27
55–64	392.9	424.9	448.4	+ 1.28	+ 2.61
65–74	692.5	773.2	835.1	+ 3.23	+ 6.63
75–84	1153.3	1168.0	1272.3	+ 0.59	+13.22
85 and older	1451.0	1452 1	1604.0	+ 0.04	+16.63
Age-adjusted*	156.1	162.2	170.7	+ 0.24	+ 0.93

* To U S 1970 standard

Source: National Center for Health Statistics

TABLE 2

Trends in All Cancers, and Cancers with Highest Age-Adjusted* Death Rates
Rates per 100,000 population per year

	Death Rate (U.S.)		Incidence (SEER)		5-Year Survival** (SEER)	
	1975	1984	1975	1984	1974–1976	1977–1983
All cancers	162.2	170.7	330.5	351.8	48.6	48.7
All except lung, bronchus	125.4	125.1	285.3	296.5	54.4	55.1
Lung, bronchus	36.8	45.6	45.2	55.3	12.1	12.8
Colon, rectum	21.7	21.0	47.3	50.3	48.9	51.6
Breast	14.6	15.3	47.7	51.8	73.7	73.8
Prostate	8.4	8.9	28.5	33.2	66.1	70.3
Pancreas	8.6	8.6	9.5	9.5	NA	2.6
Leukemias	6.6	6.5	10.3	9.3	32.7	32.5
Non-Hodgkin's lymphoma	4.7	5.4	9.3	12.0	46.6	48.3
Stomach	6.6	5.3	9.2	8.1	NA	16.6
Ovary	4.7	4.3	7.5	7.3	36.4	37.8
Brain, nervous system	3.8	4.0	5.4	5.4	NA	23.3

*To U.S. 1970 standard
**Survival Rates relative, rates for breast cancer for females only

SEER: Surveillance, Epidemiology, and End-Result registry area
NA: Not available from this source

Source: National Cancer Institute

Promises unfulfilled

The conclusion from these data is inescapable: We have had very little success in reducing overall cancer death rates or incidence rates, or in improving case survival rates. To the extent that these measures embody national targets or goals, we are losing the war against cancer.

This overall conclusion does not deny the real and welcome successes in some efforts to control cancer. Treatment of the disease in children and young adults has become markedly more effective in recent years, as shown in Table 3. For one form of cancer after another, death rates in the youngest age groups have been reduced. In addition, there have been marked improvements in palliation at all ages, which has made cancer victims more comfortable and extended their productive lives.

We have also learned a great deal about cancer as a biological phenomenon and as a clinical problem, and we have learned much about how to study the disease—that is, about research methods—at levels from molecules to whole populations. These new techniques have paid off in many ways, not all of them directly related to cancer—for example, in the diagnosis of AIDS and in the development of drugs that reduce its progression. My point, though, is that these have always been secondary goals, and that we have yet to make much of a dent in the three basic measures of overall success against cancer: incidence, mortality, and case survival.

Some experts argue that information already in hand—about chemotherapy, for example—could have a large impact if it were only applied more widely and more effectively. But that argument is far from new; it was in fact a driving force behind the National Cancer Act of 1971. We therefore must ask why 16 years of effort have accomplished so little in improving the application of knowledge available from the start, and whether the argument, updated to 1987, has any more merit now than it did in 1971. Was it based on false premises in 1971, now replaced by true premises in 1987?

Or is there something more fundamental at work? Perhaps it is a failure by program leaders to appreciate why patients and their physicians hesitate to embark on painful, debilitating, risky, and expensive courses of treatment for marginal increases in the probability of survival. Perhaps it is a failure to understand how medicine is really practiced—just as the military is rightfully criticized for developing weapons that the average soldier cannot use, so too can policymakers be faulted for sponsoring cancer treatment methods that can't be readily applied by the average physician or in the average hospital.

Another group of experts argues that our greatly increased understanding of cancer will surely have a large, beneficial impact in the future. This view basically accepts all the data presented here on trends up to the present, but concludes that there will be a major payoff at some future time. This view of the future is

also far from new, and there has been a long history of extravagant claims of research progress. Within recent decades these have included waves of enthusiasm over broad screening of thousands of chemical substances for antitumor activity, studies of virology related to cancer, immunologic approaches, the selection or "design" of drugs on metabolic or biological principles, and perhaps now molecular biology.

Yet, despite frequent public claims by leading cancer research organizations, cancer program leaders, and cancer investigators that major progress in cancer treatment was either at hand or within reach, great success still eludes us. If we take the beginning of the modern era of cancer research to be the early 1950s, we have had 35 years of unfulfilled promises. That is surely long enough to raise questions about the promises of today.

TABLE 3

Age-Adjusted Cancer Death Rates in U.S. Children
Rates per 100,000 population ages 0–14 years
White only, SEER area

	1975	1984	% Change
All sites	4.8	3.5	– 22.5
Acute lymphosytic leukemia	1.2	0.8	– 33.5
Brain, nervous system	1.0	0.9	– 10.4
Bone	0.2	0.2	– 13.6
Hodgkin's disease	0.0	0.0	– 50.0
Non-Hodgkin's lymphoma	0.4	0.2	– 35.3
Kidney, renal pelvis	0.2	0.1	– 34.3
Soft tissue	0.5	0.2	– 64.0

SEER Surveillance, Epidemiology and End-Result registry area

Source: National Cancer Institute

John Cairns of the Harvard School of Public Health has also discussed the results of the effort to develop cures for cancer. His approach is largely clinical and biological, whereas that given here is largely epidemiologic and statistical. Yet we come to similar conclusions about the poor rate of success to date and the need to reconsider present directions in research as well as applications.

The General Accounting Office, an agency of the U.S. Congress, also concluded in a report issued earlier this year that claims of progress against cancer have been substantially overstated. The director of GAO's Program Evaluation and Methodology Division summarized the report as showing that "the improvements in patient survival have been most dramatic for the rarer forms of cancer and least dramatic for the more prevalent ones. As a result, even though the absolute number of lives extended is considerable, this number remains small relative to all cancer patients. . . . From an absolute perspective, progress has been considerable. From a relative perspective, we must conclude that not much progress has been made."

Mid-course corrections

What then needs to be done, given the failures—or at best, the modest progress—cited above? First we must accelerate the shift of emphasis, in medical training and practice as well as in research, toward the *prevention* of cancer. Treatment must come to be seen as a second line of defense.

I do not say this out of any blind conviction that prevention is always better in principle than is treatment. Cancer prevention on a large scale is likely to require substantial changes in our personal habits, very expensive measures to clean up the environment and the workplace, abandonment of certain useful and pleasing consumer products, adoption of new ways to build houses and modify existing ones, and the like. Treatment, had it worked, would be better, but we must now ask quite seriously whether we can afford to continue putting most of our resources into efforts that may never solve some of the biggest problems of cancer.

The need for such a major shift in attitude and emphasis already seems to be better understood by the public than by the "cancer establishment." But the public needs substantial information and guidance if it is to avoid both the grave perils of faddism and a loss of faith in the well-established benefits of orthodox medical treatment at its best. [It is important to note that my comments about lack of progress are in no way an argument against the earliest possible diagnosis and the best possible treatment of cancer. Modern medicine already has much to offer to virtually every cancer patient, for palliation if not always for cure; the problem is the lack of any substantial recent *improvement* in treating the most common forms of cancer. There is no comfort here for the "medical countercul-

ture"; nonstandard (or "unorthodox") treatments are likely to be dangerous as well as utterly ineffective.]

A second critical need is for a thorough review of where we stand, how we got there, and where we are going. The National Cancer Institute (NCI) has argued forcefully that it has its own extensive mechanisms for this purpose, but such internal review, however technically competent it may be, cannot have the necessary degrees of independence and objectivity that are needed.

It will not be easy to find a sufficiently broad and technically competent group of experts who are not already committed to many of the unsuccessful efforts of the past. But this long background of disappointments must nevertheless be addressed; a straightforward and comprehensive analysis must be made before we go much further in pursuit of the cure that always seems just out of reach.

The third need is for a prompt revision of NCI's stated goal of cutting the age-adjusted cancer death rate by 50 percent by the year 2000. The figure above very nearly says it all: That goal is not only utterly unattainable, it is so far from reality as to cast doubt on the credibility of NCI in other matters. If we "start the clock" with the National Cancer Act of 1971, we are already past the half-way mark, with not even the beginnings of a downturn yet evident for overall cancer mortality. I am concerned about the loss of public support that such massive failure will provoke, even if there is some real reduction in mortality over the next 13 years. This goal surely was honest at the time it was formulated, but it must now be reconsidered—in full view of the public.

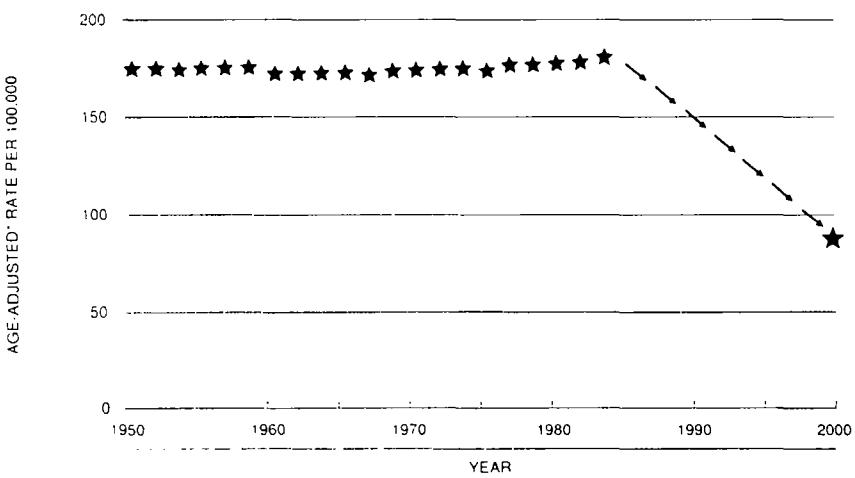
The fourth need is to reorient personnel and projects. There is enormous momentum in any program as large and as old as our national cancer effort. It is critical that the leadership of that effort be totally dedicated to making the needed changes rapidly, with careful attention to quality and scope of the science, but with minimal disruption to careers and institutions. Recent comments from the present leadership suggest that they are not up to it.

NCI's response to date has alternated between ignoring its own evident problem and "blaming the messengers." This seems particularly odd because most of the data cited here and elsewhere come from or through NCI, and because supporters of the present program orientation have not made any serious attack on the validity of these data.

Finally, there is a need—now alas evident throughout government—to encourage greater objectivity on the part of senior program managers as they report progress, or the lack of it, to their peers in science, to Congress, and to the public. This goes deeper than accuracy and honesty; I know of no deliberate misstatement or misrepresentation, ever, by any cancer program leader regarding any of the matters raised here. But some of them have consistently denied the implications of their own data. The result has been further delay in making needed changes, the misuse of funds to support unproductive research, and mounting damage to the credibility of science.

FIGURE

Mortality Rates for Cancer, All Types Combined, 1950–1984, with Year 2000 Goal of the National Cancer Institute



*To 1970 standard

Recommended reading

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A. Lippman

Cancer: So Close to Success

Make no mistake about it, cancer is a scary disease—and that reputation is well deserved. Forty-three percent of all Americans alive today will have a serious malignancy in their lifetime. With current treatments, about half of those diagnosed will eventually die of their disease. And this says nothing about the suffering that patients and their loved ones must endure. Nor does it speak to the economic impact of the premature loss of productive members of society.

Frightening as this information is, it is even more unacceptable because of the fact that the numbers do not need to be this bad. No, we obviously don't have cures for all patients. But the good news is that for the first time for many types of cancer, we actually know the specific causes. In an astounding series of discoveries in the past decade, the genes specifically causing many human cancers have been identified. In some cases, those altered genes are inherited, causing familial cancers, and in other cases sporadically mutated as we go through a life exposed to carcinogens.

A great deal is known about the exact function of many of these genes. It seems intuitive that knowing the exact causes of diseases ought to lead to very specific treatments that might reduce their impact or prevent their occurrence entirely. And now, over and over again in many laboratories, this intuition has been borne out. Amazing as it may seem, it is actually a students' experiment to cause a cancer in an otherwise normal human cell by transferring to it a single mutated cancer gene or to revert a cancer cell to normal by "knocking out" a single cancer gene or its protein product.

"Clearly, the federal government, which spends less than the cost of one Stealth bomber on all cancer research in the country, needs a wake-up call."

The cruel irony is that in many cases, these proven and successful preclinical research approaches are languishing badly. We are in an era in which what we now know about cancer and what we could almost certainly learn in the next five years with appropriate research efforts could dramatically change the way we diagnose, treat and control the disease. But a series of critical supports that would allow this to go forward have been removed from the enterprise. This is nothing short of a calamity.

First and foremost is the fact that numerous research initiatives are simply not being moved to human clinical settings because of the lack of money. These initiatives are based on fundamentally sound molecular and biochemical principles and have already demonstrated their ability to cure human cancers growing in experimental animals.

Funding by the federal government for cancer research has remained largely flat in real dollars for many years—ironically, at a time when we almost certainly know some things we could do better. The actual cost of doing this research has obviously increased. Tragically, while many of the right directions have been identified, these efforts are stuck short of the clinic.

There is an explanation. An incredibly large incremental expense is involved in moving experiments from test tubes and mice to human beings. In our own institution alone, I can identify at least a half-dozen strategies whose success in curing animals with human cancer would justify clinical trials. For each of these strategies, something in the range of $1 million to $2 million would be required to get them from the lab to a clinical trial for human beings. Other cancer centers could make similar claims. But the money just isn't there. And so discoveries of great potential languish, as do our patients.

The second critical development in the past few years is that in many cases the patients aren't there either. Every day, patients who have exhausted "standard therapies" (or for whom no standard therapies have ever existed in the first place) are refused coverage by their "managed care" organizations (increasingly an oxymoron) for new and exciting trials of experimental therapies. It is a sad reality that patients can receive reimbursement for care known to have response rates that are abysmally low but be refused access to some of the most new and exciting possibilities for treatment.

In less than five years, managed care (including Medicare) has taken over at least 75 percent of the Washington market. Thus, most Washingtonians have their health care controlled by groups that in many cases report to their stockholders and their excessively rewarded management rather than to patients and the institutions upon whose discoveries they depend. Thus, not only are there no money and no patients, but in many cases, it is rapidly becoming the case that there are no institutions or physicians to give this highly specialized experimental care either.

In the "good old days," academic hospitals were profitable enough to take care of the poor and put a great deal of their money into the development of research initiatives and the training of the next generation of physicians. That was then. In our own city, George Washington University Hospital is likely to become a for-profit institution in which it is hard to believe that research will be given a significant priority. My own institution, also beset by financial concerns, has been forced to divest itself of almost all responsibility for training of new faculty and research development, leaving this to often-generous but inadequate philanthropic funds.

It should be obvious, but it somehow isn't, that the academic health centers essential to any hope for the future are never going to compete perfectly with "for-profits," given the additional and appropriate burdens that they must carry: research and education, not to mention the poor.

So what can we do? Let me suggest several things that can help:

- Support the research activity that has brought us so close to success. Clearly, the federal government, which spends less than the cost of one Stealth bomber on all cancer research in the country, needs a wake-up call. Sen. Connie Mack, a cancer survivor himself (as is his wife), recently asked the Senate to express itself on whether the funding for NIH should be doubled. The Senate said yes, 98-0. Now we need to translate that sentiment into real money.
- Launch a grass-roots offensive drawing upon every American's concern with cancer deaths. There are tens of millions of cancer survivors out there who, together with their families and friends, need to demand support for cancer programs at every level.
- Become involved with your local comprehensive cancer center. Many of the programs they maintain that can prevent cancer, such as smoking cessation initiatives, dietary intervention, etc. are both non-reimbursable by insurers and managed care and unsupported to any significant extent by district, state or federal dollars.
- Learn what managed care is doing to American academic medicine. Whatever the need for cost containment, we must realize that we are gutting the institutions that are our total future for cancer research, and are actively and cruelly denying legitimate experimental treatments for cancer sufferers every day.

The bad news about cancer is that too many people are dying and suffering unnecessarily. The good news is that defeating the disease is a matter largely of will—personal will (chiefly, avoiding tobacco) and societal will—for cancer will surely yield to increased investment in research. With half a million Americans dying every year, now is the time to act.

The writer is director of the Lombardi Cancer Center at the Georgetown University Medical Center.

NCI's Vision for the Future

We have made significant advances in our war against cancer. Cures have been found for childhood cancers, lymphomas, testicular cancers; the overall cancer mortality rate has consistently decreased for the first time ever. In addition, patients with cancer are living longer and better. We have an unprecedented understanding of the molecular workings of a cancer cell with which we are now devising completely novel drugs for the future. However, the speed in achieving our goal of preventing and curing cancer has been and remains too slow.

The NCI, therefore, proposes an increase in our national investment to fuel the engine for discovery so that we may more quickly find ways to prevent and cure cancer. Our proposal to increase the investment in cancer research is intended to accelerate the rate of discovery in basic explorations, in clinical trials, and in application of our knowledge base with the ultimate goal of preventing and curing more cancers and doing so more quickly.

All the advances in cancer research are dependent on answering fundamental scientific and clinical questions. Though we cannot predict the exact time of discovery, we know that the more questions we can answer each year, the faster we will be in finding the solutions that will make a difference in the lives of millions of Americans. Currently, the limiting factor to our success is the speed with which these critical questions can be addressed. Simply put, our proposal to increase the investment in cancer research is aimed at accelerating the rate of discovery in cancer research. This acceleration will result in speeding the day when cancer is a thing of the past.

We propose to:

1 . Enhance cancer prevention research to stop millions of cancer cases from happening.

The trials associated with cancer preventative agents involve large numbers of subjects and take years to complete. There is currently a waiting list of interventions with basic scientific evidence sufficient to warrant testing. More resources would enable these tests to proceed ultimately leading to the prevention of millions of cases of cancer.

2. Improve early detection and diagnosis so as to make cancers more treatable.

It is very well known that early detection and effective screening can save lives because cancers caught early are more treatable. There are currently a number of innovative detection and screening technologies waiting to be explored. More resources would provide the means to do this critical exploration.

3. Speed the rate of discovery of new interventions related to all phases of the fight against cancer.

Discoveries of the basic cellular pathways involved in making a cancer cell what it is need to be sped. Once these discoveries are made, the new knowledge must be applied to cancer interventions. Currently, only about 2% of adult cancer patients are participating in the clinical trials that allow new interventions to be tested. With resources sufficient to increase this number 5-fold, five times as many questions could be answered each year.

4. Increase the access of the American people to state-of-the-art cancer care.

Cancer care is quite variable in different locations and among different groups of Americans. There are currently 55 NCI-sponsored cancer centers in the United States. With additional resources, all academic research centers having a critical mass of cancer researchers could become NCI-sponsored cancer centers. This would enable more clinical research to proceed more quickly but also provide access to millions of Americans

who might otherwise not be treated at a cancer center.

5. Increase the access of the American people to state-of-the-art information about cancer and cancer interventions.

A critical component of cancer prevention and cancer treatment is information. Additional resources would enable state-of-the-art information to placed in the hands of cancer care providers. In addition, all Americans could be provided with better information about ways to prevent cancer. Cancer patients and their families would have access to information about their treatment options.

The Costs

It should be obvious that these five proposals are heavily overlapping and that complex problems like these call for solutions that are complex. For example, access to quality cancer care cannot be divorced from the training of the next generation of care providers nor from the infrastructure that allows this care to occur. The costs involved in accomplishing these goals are by no means trivial.

Enhancement of the clinical trials network including prevention initiatives would require $160M in FY99 and $960M over three years; Increased support of new clinical investigators would require $75M in FY99 and $200M over three years; Improvement in the informatics associated with clinical trials and with dissemination of information about clinical trials would require $20M in FY99 and $75M over three years; Increased training and education of new clinical investigators including minority initiatives would require $40M in FY99 and $195M over three years; Increasing the number of NCI-sponsored cancer centers would require $93M in FY99 and $559M over three years; Increase funding of investigator-initiated research would require $200M in FY99 and $1.2B over three years.

NCI's VISION FOR THE FUTURE

There is every reason to be confident of future progress in the battle against cancer. Cancer is not one disease but many, and real progress has already been made against many cancers. Overall cancer mortality rates are dropping for the first time ever. If smoking-related lung cancers are omitted from the analysis of mortality data, the decrease in deaths from all other cancers is even more dramatic.

Progress in science and technology is inherently unpredictable, and historically, predictions by government officials about science and technology have proven to be more embarrassing than accurate. In 1899, the Commissioner of the US Patent Office stated, "Everything that can be invented has been invented." In the past, government officials have succumbed to the temptation to make predictions that a cure for cancer was "just around the corner" or would be obtained "in five years" or "in ten years." The benefit to the American people and to the scientific community of making such predictions has been nonexistent, and such predictions can certainly erode the credibility of the prophets if they do not come to fruition.

There will always be a temptation to make promises about the future of cancer, but NCI is committed to making only those promises that we know we can keep. We do promise that we will seek to exercise good stewardship of the resources provided us by the American people. We do promise to remain committed to excellence in research aimed at better prevention, earlier detection, more accurate diagnosis, and more effective treatment of cancer. Our firm belief that research will eventually cure cancers has been validated by the progress already made—progress that is firmly grounded in research. This validation strengthens our resolve to intensify our quest for answers and to apply these answers in ways that maximize their benefit to the American people. There is really no question about the direct connection between research and measurable progress against cancer. There is also really no question that more research will inevitably require more resources. The only real debate involves the level of resources that we, as a society, are willing to commit to this effort.

WHAT WILL ADDITIONAL FUNDING BUY FOR THE AMERICAN PEOPLE?

THE GOAL

Decreasing the burden of cancer through increased scientific discovery and the clinical application of specific discoveries for better prevention, earlier detection, more accurate diagnosis, and more effective treatments that together will ultimately lead to the eradication of cancer.

THE PLANS

1. Enhancing the NCI's program of clinical trials for new interventions. Completion of current clinical trials must be sped and a greater capacity for new trials must be achieved. Only with more speed and more capacity can the influx of new agents from the explosion of discovery be accommodated. The barrier to physician participation must be lowered by NCI support for more new clinical investigators who would be enabled to engage in clinical research. In addition, a new informatics system for clinical trials is needed that will take full advantage of the capabilities of modern computers and the World Wide Web. Such a system will allow efficient and secure handling of clinical data obtained in trials, and this increase in efficiency will also help to lower the barriers to participation by physicians in cancer clinical trials. The World Wide Web must also be used as a means of providing cancer patients and their families with user-friendly information about the options available to them in clinical trials. Computer terminals or kiosks in public places—libraries, stores, malls, airports—would provide people with tailored information relating directly to them in understandable language. Lowering the barriers to participation in clinical trials for both health care providers and patients would increase the numbers of Americans with access to state-of-the-art interventions available through clinical trials.

Measure of Success: Increase from the current 2% to ≥10% in the percentage of adult cancer patients participating in clinical trials.

2. Enhancing the NCI's emphasis on prevention. Large prevention trials involving tens of thousands of subjects can be completed within a few years. We must integrate emerging knowledge of what makes a cell cancerous with the discovery and testing of preventative strategies. Relevant animal models that will reliably predict the preventive action of drugs in people are needed. Creation of an ambitious new clinical trials capability that will feature close linkages between cancer prevention experts and the primary-care medical community will be essential to the success of this program. With the changing landscape of our Nation's health care system, managed care providers and health-maintenance organizations will be crucial participants.

Measure of Success: Development of relevant animal models to support prevention drug discovery and creation of a national prevention network linking cancer prevention experts with the primary care medical community.

3. Increasing the number of NCI-sponsored cancer centers. The NCI system of 55 cancer centers is the nation's principal engine of scientific discovery about cancer. Based on our evaluation of the Nation's academic health centers, we conclude that between 70 and 75 have the critical mass of cancer-relevant researchers to become NCI-sponsored cancer centers. Increasing the number of centers will have many beneficial effects and will ultimately increase the rate of discovery of improved cancer interventions. Cancer centers provide the training grounds for the cancer researchers that our Nation will need in the 21st century. 70-75 Centers would increase the diversity of research conducted within the centers program, including addressing the important problem of the cancer burden in disadvantaged and minority groups. By bringing clinical research excellence closer to all segments of the American population, an increase in the number of cancer centers will provide enhanced quality of care and greater access to state-of-the-art prevention, detection, diagnosis, and prevention.

Measure of Success: Increase in the number of NCI-sponsored cancer centers from 55 to 70-75.

4. Stimulating scientific discoveries that will lead to new drugs, devices, and behavioral interventions for better prevention, early detection, more accurate diagnosis, more effective treatment of cancer. The NCI supports cancer research in every state in the Union through its grants program but can only fund about one-forth of the applications it receives. This level of funding slows the engine of discovery and in turn slows progress against cancer. A funding rate of 40% would markedly speed scientific discovery while maintaining competition for funding that drives excellence. Scientific discovery would also be stimulated by creation of specialized consortia of individual investigators for discovery of new approaches to prevention, detection, diagnosis, and treatment.

Measure of Success: Increase in the percentage of funded grants from 25% to 40% and creation of new consortia for discovery in cancer prevention, detection, diagnosis, and treatment.

THE COSTS

Enhancement of the clinical trials network including prevention initiatives would require $160M in FY99 and $960M over three years; Increased support of new clinical investigators would require $75M in FY99 and $200M over three years; Improvement in the informatics associated with clinical trials and with dissemination of information about clinical trials would require $20M in FY99 and $75M over three years; Increased training and education of new clinical investigators including minority initiatives would require $40M in FY99 and $195M over three years; Increasing the number of NCI-sponsored cancer centers would require $93M in FY99 and $559M over three years; Increase funding of investigator-initiated research would require $200M in FY99 and $1.2B over three years.

Total cost estimates for these initiatives are $558M in FY99 and $3.2B over three years.

Date: July 21, 1997

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Message or comment:

At the request of Dr. Klausner, I am forwarding to you a copy of the "NCI Challenge" section of the FY99 Bypass Budget.

We are in the process of finalizing the budget numbers associated with this section. Our current estimate is that about an additional $500M in FY99 would be required if the goals/milestones set forth in this section are to be realized.

NCI's CHALLENGE

We cannot conquer what we will not fight. We have founded our fight against cancer in the power and process of science and have enlisted the best scientists and clinicians to create the knowledge and the tools we need to succeed. But will we?

Knowledge about the fundamental nature of cancer is exploding. Technology is giving us new instruments with which to see and understand cancer much as the Hubble telescope has given us a new eye on the universe itself. Investments made to achieve our accumulated knowledge and technical capacity are beginning to pay off--cancer mortality rates overall and for many individual cancers are finally falling, though slowly. Yet one thing is clear: these successes have resulted from the application of research--research on how lifestyle and environment affect cancer risk, on ways to detect cancers more readily, on how to treat cancers more effectively.

Without doubt, we are in a golden age of discovery, one unique in human history. The NCI has engaged the best minds from diverse disciplines to assess how best to further foster discovery, facilitate its application to the care of people with cancer and those at risk, and topple barriers to progress. Throughout these intense deliberations, all of us who are dedicated to the fight against cancer returned to this central question: "*What more must we do* to convert this golden age of discovery to the golden age in the prevention and cure of cancer we have so steadfastly sought?"

Research into the causes of cancer is our only route to effective prevention. Research into detection techniques is enhancing traditionally successful therapy. Research into the life and death of cancer cells is leading to incremental success in curative therapy. Our successes have shown us that no one approach will conquer the many different diseases we call cancer. We know progress

can be made, and we know it will have its roots in discovery. But it is now clear that the gap that still exists between discovery and application will not be closed unless we now set in place structures that will speed the engine of discovery, create bridges between all components of the cancer research enterprise, and encompass the care of those with cancer and those at risk into our national research system.

At the beginning of this budget document, we described three interconnected research settings: the laboratory, the clinic, and the community. While this budget is designed to assure that each thrives, we believe firmly that timely movement towards cancer cure and prevention will happen only when the current gap between discovery and application is spanned. To do this, we must create a system of bridges – among all aspects of research, between research and clinical practice, between research and industry, and between the cancer research enterprise and the American people. We must nurture and strengthen the ties among these diverse research areas, and between the research enterprise and those whose lives cancer touches, to ensure that the benefits reaped by our new ideas and new technologies flow directly into the reduction of suffering from cancer.

In this final section of NCI's budget, we present our plan to meet the challenge of building those bridges that will eventually conquer cancer.

THE CHALLENGE AND THE PLAN

The challenge before us is immense. How will we convert our knowledge of cancer into advances in prevention and care on the scale that is needed to conquer cancer? We must enter a new era– one in which scientific knowledge about cancer, rather than empiricism, directs our efforts in the fight against cancer. As laboratory, clinical, and population research reveals ever more about the

inner workings of cells and the ways in which cancers behave, the challenge before us is to convert this knowledge quickly into practical, affordable, and effective interventions that restore cancer patients to health and prevent the development of these diseases in all segments of our population.

To meet this challenge, we must have a clinical research base that can bring the best of our developing knowledge—the best ideas, technologies, and people—to the problems of cancer prevention and care. The dismaying fact that only about two percent of adult cancer patients participate in any type of clinical trial means that answers come slowly, and large numbers of patients do not have access to the latest developments. To accelerate our ability to find answers to crucial clinical questions, we must dramatically increase access to and participation in clinical trials. We must supply the structures and mechanisms that will not just span the gap between discovery and application but will transform the process by which we bring discoveries to the benefit of people and allow us to conquer all types of cancer.

The response to this challenge requires increased investment in eight key areas:

1. National Clinical Trials System
2. Investigator-Initiated Research
3. Support for Clinical Investigators
4. Cancer Centers--Restructuring and Expansion
5. National Repositories and Resources
6. Informatics and Information Flow
7. Studying Emerging Trends in Cancer

8. Training and Education

NATIONAL CLINICAL TRIALS PROGRAM

The importance of a strong clinical trials program -- and our urgent need to expand the Nation's current clinical trials infrastructure -- cannot be overstated. Clinical trials are the crucial final steps in the process of developing new cancer treatments, preventive measures, and detection and diagnostic techniques. As the place where promising new strategies from the laboratory bench are applied for the first time to real human problems at the bedside, clinical trials represent the best opportunity for patients to receive state-of-the-art care while adding greatly to our understanding of cancer and helping to create tomorrow's interventions.

Why, then, do so few people – only about two percent of cancer patients -- participate in clinical trials? There are barriers to participation, some of which are discussed below; these barriers are not insurmountable. But we need a robust clinical trials infrastructure to speed the way. **We need to ensure that *all people* who wish to participate in a clinical trial are able to do so. In short, we need to break down the barriers to clinical trial participation for patients, their families, at-risk individuals, and physicians.**

An expanded and strengthened clinical trials program will speed progress in:

Treatment. For most types of cancer, current treatments are inadequate. New and highly promising strategies for cancer treatment are emerging through our ever-increasing understanding of basic biology; we must speed their development by testing them in people as rapidly and efficiently as possible.

Prevention and early detection. As we are able to identify more individuals who are at risk, whether because of their genetic profile, their environment, or other factors, we need trials of drugs, dietary interventions, and new technologies to prevent their cancer, or to catch it early, before it has had time to spread.

Diagnosis. New, minimally invasive diagnostic techniques emerging from the work of the NCI's Cancer Genome Anatomy Project and elsewhere must also be tested in people.

A serious barrier to progress is the growing reluctance of health care payors and providers, particularly managed care organizations, to pay even the routine clinical care costs of patients participating in early clinical trials and to bar patients' access to research studies. But treatment and prevention advances must not be sacrificed to the cost consciousness now driving the health care industry. Therefore, the NCI is actively negotiating with representatives of the industry to arrive at a mutually agreeable solution. As part of any compromise, however, we envisage the need for funds to offset the costs of routine care in the context of certain early stage trials. NCI maintains that it is the legitimate responsibility of the insurance industry to reimburse the costs of routine medical care of cancer patients in all high-quality research trials. For certain innovative trials, however, in which patient care costs are significantly higher than routine care for the same condition, we recognize the need for cost sharing between the insurer and the research sponsor.

INVESTIGATOR-INITIATED RESEARCH

An enhanced level of support for investigator-initiated research at all levels remains a fundamental need. Research in the laboratory, clinic, and community provides the platform on which

translational research and clinical testing stand. In basic investigation, we now need to complete the picture of how the cell works and how its molecular circuits go astray in cancer. This is an enormous undertaking, but it is the foundation of future medicine--the pivotal base from which we will create the interventions that translate our knowledge into real improvement in cancer prevention and care.

We also need to make important additions to our research portfolios in areas that will support the crucial process of translation--the generation of clinical hypotheses from basic information and the testing of these hypotheses in applications for people.

NCI can only support approximately the top 25% of research grant applications. **To ensure that excellent ideas have the chance to be tested, and new investigators attracted to research on cancer, we need to fund the top 40 %.**

SUPPORT FOR CLINICAL INVESTIGATORS

In recent years, changes in the organization and financing of health care have resulted in significantly decreased revenues at many academic health centers. The resulting economic pressures have adversely affected clinical investigators – and, potentially, their research – in those centers; in particular, today's investigator frequently finds protected time for research to be an exceedingly hard commodity to secure. Unless clinical investigators receive the support they need to carry out research, many of the high-quality treatment, detection, diagnosis, and prevention studies that we desperately need will be delayed or even dropped.

Therefore, we must create and maintain an environment that supports and encourages health care professionals who are involved in clinical research. We propose to increase support for protected research time by providing partial salary support for health care professionals involved in clinical investigation. In addition, we must support training for health care professionals at any stage of their career who wish to become involved in clinical research. This is a difficult charge in a dynamic and rapidly changing health-care environment, but we cannot hope to succeed in meeting our challenge without a sufficient workforce of investigators appropriately trained to bring our discoveries to the benefit of patients.

CANCER CENTERS--RESTRUCTURING AND EXPANSION

NCI currently awards cancer center support grants to 55 institutions nationwide. **We believe that this program should grow over the next few years to include about 75 institutions.** In addition, it is our plan to broaden the cancer center concept to include smaller organizational units that can respond efficiently to highly specialized areas of opportunity. These consortia will bring together scientists from diverse disciplines to work in a multidisciplinary fashion on a broad range of problems such as the discovery of new preventives or treatments, genetic linkage studies, identification of gene-environment interactions, and more effective interventions for promoting health-seeking behaviors.

NATIONAL REPOSITORIES AND RESOURCES

The direct study of tumor tissue can give insights into cancer biology obtainable in no other way and provides a basis for understanding how cancers actually behave in people. NCI's Cancer Genome Anatomy Project and the further efforts in diagnostics development that will follow it

will greatly accelerate the need for tissue resources and appropriate clinical information with each specimen.

NCI has recently begun to supported collection and banking of human cancer specimens. These tissue resources are built and maintained by various investigator groups, and by organizations that collect specimens for the general use of the research community. NCI is also considering how tissues should be collected and organized in the years ahead to best serve the needs of patients and the research community while maintaining tissue donors' privacy and confidentiality. In addition, the NCI coordinates the dissemination of a broad spectrum of biological agents, including cytokines, antibodies, cells, and cell products, for use in laboratory research by the scientific community nationwide.

We are planning a substantial increase in our resources for drug and biologics development so that NIH-supported investigators around the country can be more adequately supported in their efforts to bring new discoveries to the clinic as cancer preventives or therapeutics. **It is our goal to make our repositories and resources readily accessible to every investigator that needs them.**

INFORMATICS AND INFORMATION FLOW

The power of computer-based communications and the capabilities of the World Wide Web will make possible new levels of research cooperation. Slow and cumbersome paper-based systems of data collection for multi-center studies will give way to electronic communication, facilitated by enhanced links between sites of care delivery (hospitals, offices, and clinics) and the research databases of investigators. In collaboration with other federal agencies, and with the participation

of many external scientists and clinicians, NCI is now planning a new architecture for the flow of information in its clinical trials programs -- a Cancer Informatics Infrastructure (CII) -- that will expedite the conduct of all types of interventional studies - prevention, diagnosis, and treatment. NCI is modernizing information links with its investigators in a manner that will be compatible with standards set by the international committee now studying this issue for North America, Europe, and Japan. We are also revising our criteria and standards for reporting adverse events. The result will be common terminology and reporting requirements that will greatly increase the speed, efficiency, and accuracy of results reporting.

The twin goals of the CII are to lower the barriers for patients, families, at-risk individuals, and physicians to learn about available clinical trials, and to create an infrastructure that facilitates information exchange among researchers, clinicians, and the public. The CII will greatly enhance NCI's current activities to provide the general public with up-to-date information about new research results, available clinical trials in diagnosis, treatment, and prevention, and contact points for additional information. For example, instructional modules on computers, tailored to individual needs, can supplement current standard techniques for teaching people about difficult concepts like the risk of getting a disease given a certain genetic predisposition. When housed in kiosks in public places like libraries or malls, computers can inform the public about research results or studies of personal interest and relevance. Such kiosks could also be an effective way to reach people in underserved areas. NCI is already exploring this possibility in collaboration with the library system in the state of Maryland. With the active participation of several patient advocate groups, NCI is engaged in an ambitious effort to create a "patient-friendly" PDQ database, containing information on cancer and on opportunities for participating

in investigational studies of new approaches to prevention, diagnosis, and treatment in non-technical language.

STUDYING EMERGING TRENDS

There is an important need to observe emerging trends in cancer death across broad populations. The NCI's primary means of studying such trends is the Surveillance, Epidemiology, and End Results (SEER) database, which tracks the impact of cancer on the general population. SEER has allowed us to identify environmental carcinogens, to track the effects of tobacco on men and women, and to identify geographic areas with higher than average rates of cancer. Confidentiality and privacy concerns are accorded the highest priority in the SEER database. **We want to ensure that, as much as possible, the SEER database not only tracks accurately changes in cancer incidence and survival, but also contains information that will enable researchers to generate hypotheses about the basis of observed changes in trends over time.**

Linking databases containing different kinds of health-related information on populations can provide a very powerful tool for certain kinds of analyses. For example, linkages between SEER and the comprehensive Medicare administrative database are already providing valuable information on relationships between health care resource utilization, costs, and medical outcome. Advances in information technology will enable linkages like these to be established much more easily than in the past and in time will facilitate the creation of databases through electronic transfer of information from electronic source documents.

TRAINING AND EDUCATION

We have been emphasizing the importance of new individuals who will be the leaders in accomplishing the complex tasks of translating discoveries into interventions. Where will they come from?

We must take steps now to ensure that some of the brightest, most creative young people from every segment of the American population enter the cancer field. We must convince some of them that the field of translational research offers tremendous challenges and rewards. Moreover, we need to persuade individuals from untapped segments of the research community to change direction and join us in these translational efforts. This kind of research is often conducted by physician-scientists and other investigators who possess a broad base of knowledge and expertise in basic science, epidemiology, clinical oncology, and clinical investigation. The training of such individuals takes many years. Despite the scientific and medical rewards of careers in this area, the contemporary health care scene also provides substantial disincentives.

It is time also to increase attention to the needs of minority students and young scientists and to make these needs a major thrust of NCI's training activities. Current NCI minority initiatives have shown some success in broadening training opportunities for minority scientists, but more are needed. We must find ways to attract more minority students into biomedical science and more minority biomedical trainees into cancer research. Successful efforts to do this will need to be ambitiously conceived and will need to start early in the educational process. A fully adequate enhancement of NCI's training programs for minority trainees would provide promising young scientists access to high-quality training opportunities in first-rate laboratories and clinics across the entire biomedical spectrum.

NCI's New Training Programs

The NCI is committed to creating training opportunities for junior scientists. The recently instituted Howard Temin Award, named for a Nobel laureate scientist who devoted his career to cancer and AIDS research, is intended to bridge the transition of the most promising M.D.s and Ph.D.s from a mentored research environment to an independent research career. Through ongoing financial support, this award encourages the "best and brightest" junior scientists in basic, clinical, and behavioral research to pursue a career relevant to cancer.

The NCI Scholars Program will assist promising young investigators in basic, clinical, or population research to launch independent research programs in the supportive environment of the NCI's Intramural Research Program. With access to the NCI's intramural research resources, including mentoring from senior scientists, NCI Scholars will independently design and carry out projects in their own laboratories for up to four years. After this period, NCI Scholars will move on to careers at extramural institutions. We expect this program to continually enhance and invigorate the intramural community by developing a cadre of creative young scientists who will expand collaborative research opportunities intramurally, while also strengthening our ties to the extramural community.

MILESTONES: WHERE WE NEED TO BE IN 5 YEARS

An ambitious set of goals will enable us to focus our efforts and permit an assessment of our success. The milestones that we propose for this initiative are near-term; as such, they concentrate heavily on easily measured criteria of success related to the structures and mechanisms we must now put in place or strengthen. Longer-range and more meaningful

measures of success will be the generation of new knowledge, new drugs, new devices, and improvements in diagnosis, treatment, and prevention strategies. This is the future we must secure.

At the five-year mark, we set our sights on the following measures of success:

- **Number of patients accrued to clinical trials.** Initially, we are aiming for a five-fold increase over the next five years in the NCI-supported cooperative treatment trials program. Ultimately, we believe that *every American* who wishes to participate in a clinical trial should be able to do so. This holds true not just for treatment trials but also for prevention, detection, and diagnosis studies. Increasing the number of individuals in clinical trials is the first step in speeding the timely completion of major trials of national importance and will facilitate patient access nationwide to the state-of-the-art therapy available on clinical trials.

- **Increased number of collaborations in diagnosis, prevention, and treatment facilitated by changes in informatics systems for clinical trials.** Presently, because of the many incompatible informatics systems in use in NCI's clinical trials program, the planning and execution of large-scale studies with multiple cooperative groups are labor-intensive and time-consuming. With the institution of state-of-the-art informatics systems for clinical trials that promote full compatibility among all participants in the program, the number of collaborative studies for clinical questions of national importance should increase.

- **Increased number of individual grant applications funded.** The current funding rate should be increased to 40% of grant applications submitted.

- **Increased number of NCI cancer centers.** An increase in the number of NCI cancer centers from the present 55 to about 75 will increase geographical distribution of centers and increase the versatility of the centers program as an agent of discovery.

- **Establishment of consortia for areas of particular scientific opportunity.** Measures of the consortia's success will be related to their scientific productivity and the number of successful new interventions developed as a result of their efforts.

- **Doubling of the number of agents brought forward for clinical testing through NCI's development pipeline.** The number of ideas worthy of early feasibility testing in the clinic currently exceeds our development capacity. We are aiming for a doubling of our development capability, which should enable an approximate doubling of the number of Investigational New Drug Applications filed with the FDA for agents that might prove useful as therapeutics.

- **Increase in the number of diagnostic devices under investigation for cancer indications and the proportion of the total effort whose development and clinical testing is aided significantly by NCI efforts.** NCI's impact on this area will be successful if we increase the overall flow of discovery from the laboratory to the clinic. We do *not* intend a mere shift in the source of support from the private to the public sector. The number of partnerships with the device industry for joint development projects will be an important ancillary measure.

- **Increase in the number of preventive agents brought forward for clinical testing.** We are currently only testing a handful of preventive agents. We need to substantially increase this number.

- **Increased access to and use of new biological and informational resources.** By giving scientists the tools they need to work efficiently and effectively, we will enable them to work more efficiently and more rapidly, thereby hastening the pace of discovery.

- **Increased number of multidisciplinary collaborations.** The establishment of new multidisciplinary collaborations supported by NCI and the productivity of such collaborations, particularly in terms of concrete products relevant to cancer prevention, diagnosis, and treatment, are obvious measures of success.

- **Increased number of clinical investigators whose time for research is partially protected by NCI support.** Currently, support grants to NCI cancer centers fund a portion of the work of selected senior staff investigators. We must extend this policy to include a broader spectrum of investigators, particularly promising young individuals starting out in the difficult area of translational research.

- **Increased number of new trainees entering cancer research; number of new minority trainees; success of new trainees' first-time grant applications as independent investigators.** These measures of success can all be assessed readily.

(16)

- **Expanded cancer surveillance.** Productive expansions of SEER and linkage of existing databases (including SEER) will allow us to observe more rapidly changes in the incidence of specific cancers and will give us insight into the causes of those changes, thus giving us targets for interventions.

- **Increased use of information, education, and communications resources by a greater diversity of users.** We will track increases in rates and patterns of use for NCI's information resources.

NCI Director Richard

In his bypass budget for FY98, Dr. Klausner requested $269.5 million more than the President's request. The amount increases to $397 million in FY99, and $518 million in FY00. ~~The additional money would fund 5 priority investments~~, Klausner believes this would modest but meaningful increase would significantly advance progress in 5 areas . . .

Cancer control advocates have observed the tactics of the AIDS activists and are seeking to replicate their successes. The fact is AIDS activists have rewritten the advocacy rules. Their take no prisoner tactics have rubbed many the wrong way, but they have also worked. As a result, cancer control advocates

July 20, 1997

MEMORANDUM FOR THE VICE PRESIDENT

FROM: Jerry Mande

SUBJECT: Cancer Initiative

I. SUMMARY

We are at a pivotal point in the fight against cancer. Your leadership would result in significant progress in this battle. Several factors have emerged to provide this opening. First, the current "war on cancer" has fallen short of public expectations. Second, the science has advanced to a point where additional investments in cancer research would likely result in important improvements in patient outcomes. Third, there is a renewed, visible, public interest in fighting cancer .

To seize the opportunity, we need money. Specifically, we need at least $400 million more (16%) in FY99 than was in the President's FY98 request ($2,433 million). Given budget constraints, you would need to begin now establishing support for such an increase. You could signal your interest as soon as possible by participating in one or two cancer events, give a major policy speech this fall, and advocate for an increase in the FY99 budget request.

The next two weeks provide two significant opportunities to demonstrate leadership on the issue. You could announce NCI's Cancer Genome Anatomy Project and meet with the Friends of Cancer Creative Task Force. You would quickly establish your role in a manner that might otherwise take months to achieve.

II. BACKGROUND

The "war on cancer" began in 1971, when President Nixon and the Congress enacted the *National Cancer Act.* While significant advances have been made over the past 25 years, especially in treating cancer in children, many experts and much of the public is troubled by the lack of progress (while children's cure rates have jumped from 5% to 70-80% over the last 35 years, adult survival rates have not made the same impressive gains). The science is thriving, but there is a sense that the nation does not have a national cancer program.

~~One provision in~~ The 1971 Act ~~is the~~ "~~bypass budget.~~ ~~Under this provision, the~~ director of NCI ~~is authorized~~ to submit directly to Congress an annual budget estimate for the National Cancer Program after review "but without change" by the Secretary, the Director of NIH, and the National Cancer Advisory Board. ~~The budget request has not been fully funded~~ bypass budget request has

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Last year, NCI publicly identified key research opportunities and needed investments in its so-called "bypass budget." The 1971 Act authorizes NCI's director to submit directly to Congress an annual budget estimate for the National Cancer Program after review "but without change" by the Secretary, the Director of NIH, and the National Cancer Advisory

Board. In his bypass budget for FY98, Dr. Klausner requested $269.5 million more than the President's request. The bypass budget is $397 million above the President's budget in FY99, and $518 million in FY00. The additional money would fund 5 priority investments designed to capitalize on gains in our understanding of the causes and nature of cancer, and to bridge the gap between basic discoveries and the development of new interventions to prevent, better detect, and more successfully treat cancer -- cancer genetics; preclinical models of cancer; molecular diagnostics; detection technologies; and the "NCI challenge," bridging the gap between discovery and patient care.

Klausner believes that we could make an immediate difference in patient outcomes by increasing patient participation in NCI experimental treatment protocols or clinical trials. Today, 90% of children are treated according to an NCI experimental protocol, and 70% participate in an NCI sponsored clinical trial. Along with this the cure rate has risen to 70-80%. In contrast, only 2% of adult patients are enrolled in NCI sponsored clinical trials. Experts believe that if all adults were treated with the optimal protocol mortality would drop 10-20%. This would require an additional investment of $160 million.

In this budget climate I would like to be able to provide you with a cancer initiative that costs little or no money. I am convinced such an approach would not be credible. Cancer control advocates have observed the tactics of the AIDS activists and are seeking to replicate their successes. Cancer advocates are now pursuing a "show me the money" strategy. The Administration has already acted on low-cost opportunities like speeding FDA approval of cancer drugs. The top priorities for the cancer advocacy community -- increasing biomedical research and assure that research findings are rapidly translated into the clinic and the community -- involve a significant investment of funds.

Ca - Friedman

Rick

- Klausner et al.

- Harold Nobel for oncology

- Specialty Organization
  - Amer Soc of Clinical Oncology
  -

- Decrease of smking - more enormous than any breakthrough treatment.

Bailor - some see him as a gadfly, some an importa voice

MAF - POTUS - AIDS vaccine

- There is something equally exciting about Ca vaccin

eg. Herpes - cervical Ca

- Easier problem than AIDS vaccine

Don't mind metaphor of war - but U.S. pop doesn't understand concept

Really hard wars take a very long time

Vietnamese - 40yrs

Europe - 100 yrs

- Not defending the status quo - over promised

Blur - The preventative steps are the same for good health.

Genetics - Envr