REPORT
FROM
THE MARCH
RESEARCH TASK FORCE

Commissioned by

THE MARCH—Coming Together to Conquer Cancer

September 25–26, 1998

THE MARCH
Coming Together To Conquer Cancer

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October 1998

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"I shall be telling this with a sigh
Somewhere ages and ages hence;
Two roads diverged in a wood, and I—
I took the one less traveled by,
And that has made all the difference."

—from “The Road Not Taken” by Robert Frost

The cancer community came together on this project with the knowledge that while research surely will lead us to the prevention and cure of cancer that is somewhere down this less traveled road, millions of lives have been and will be lost as we make the journey. We believe that with no less than a national commitment to conquer cancer and the resources required to do it, we will speak of the success of this journey in our lifetime. Our greatest regret is the lives of those lost, both dear to us and unknown, who with their valiant families have paid the ultimate price that the length of our journey has demanded. It is to those who have lost their battle and the millions who fight every day to defeat this tragic disease that we dedicate this report from THE MARCH Research Task Force.

Ellen V. Sigal and Anna D. Barker
Co-Chairpersons, THE MARCH Research Task Force
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THE MARCH—Coming Together to Conquer Cancer, hereafter THE MARCH, is an unprecedented grass-roots movement and historical national event dedicated to the conquest of cancer. THE MARCH unites cancer survivors, families, scientists and the public in an urgent campaign to place the prevention, treatment and cure of cancer at the top of research and health care priorities for every government official and American citizen.

The Research Task Force came together in support of THE MARCH to consider the wide range of diverse and related areas that comprise cancer research today. Their "charge" was to distinguish the exceptional opportunities and needs in basic and clinical research that are critical to addressing the current and looming crisis of cancer incidence, mortality and health care costs. The group also focused on the identification of key barriers that must be removed if we are to realize these opportunities and accelerate progress against cancer now. Finally, each subcommittee gave serious consideration to particular research issues in minority and medically underserved populations and to underfunded areas of cancer research.

The Research Task Force consisted of 164 leading scientists from the academic and private sectors and cancer survivors and advocates working together in 13 subcommittees. The focus of all of the groups was the same—determine what it would take to expedite the conquest of cancer through research, if we were limited only by creative ideas and solutions—and if adequate resources were made available.

The following report details exceptional opportunities and initiatives that clearly justify a significant, immediate increase in our national investment in cancer research. The Research Task Force recommendations capture an overall estimate of the breadth and depth of research and the additional resources required to fully support an accelerated "war" to cure and prevent cancer for all Americans. These recommendations complement programs of the National Cancer Institute (NCI), specifically the annual Bypass Budget, which delineates the needs of the National Cancer Program and recommends extraordinary opportunities for progress as a basis for its annual budget request. The Research Task Force fully endorses the NCI Bypass Budget.
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Chairperson, Friends of Cancer Research

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Vice Chairperson, THE MARCH—Coming Together to Conquer Cancer
President and CEO, BIO-NOVA, Inc.

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A complete list of Research Task Force members appears in the Appendix.
**EXECUTIVE SUMMARY**

**BACKGROUND**

Cancer is one of the most complex and tragic diseases that humankind has faced. It is also in a very real sense a dark shadow on our lives and those of our children, with most of the future devastation from the disease neither fully envisioned, appreciated, nor understood. Cancer has reached epidemic proportions in the United States, with an estimated 1,228,600 new cases and over 560,000 Americans lost in 1997 at an annual economic cost of over $104 billion. If current rates continue, one quarter of our population will die from cancer.

The effect of the changing demographics in America and our aging population will cause cancer rates to reach staggering proportions as early as 2010, with the incidence of cancer conservatively estimated to increase by 25% and deaths by 25% at an annual cost of over $200 billion. It is even more sobering to realize that these statistics do not reflect the pain, suffering, emotional desolation and economic devastation that cancer inflicts on its victims, especially minorities and medically underserved populations, such as the poor and elderly. Although defeating cancer remains, in every sense, a daunting task, we can change the future. We now have unprecedented opportunities to achieve essential progress against cancer, but only if we move with real urgency to provide the necessary resources.

...changing demographics in America and our aging population will cause cancer rates to reach staggering proportions as early as 2010...

President Richard M. Nixon recognized that cancer would take an ever-increasing number of American lives, when in 1971 he signed into law the National Cancer Act and declared a "war"—to eradicate cancer. This was a bold first step, but unfortunately a "war" was never fully launched or funded in relation to the complexity, size and cost of the problem. We currently invest approximately $2.5 billion per year in cancer research, primarily through the National Cancer Institute (NCI), which represents approximately 2% of the economic burden of the disease and translates to about 1 cent invested in research for each $10.00 paid in taxes.

The Administration and Congress have begun to respond to this challenge during the past few years by making the cure and prevention of cancer a major priority on America's healthcare agenda. This growing bipartisan support for increased investments in cancer research and quality cancer care has made many of the proposed initiatives in this report possible. The members of the Research Task Force recognize and appreciate the leadership of the Administration and Congress and look forward to their partnership in undertaking the initiatives required to launch a final assault to defeat cancer for all Americans.

We could not have predicted in 1971 that solving the mystery of cancer would require that we literally "unravel" the basic secrets of normal life processes. Our past investments in cancer research have produced an ever-increasing understanding of the fundamental differences between normal and cancerous cells, especially in the past few years. We finally have many of the weapons needed to conquer cancer and many other diseases. It is an optimistic and hopeful time in cancer research.

This hope provided the energy for individuals from all walks of life to unite in a movement called THE MARCH—Coming Together to Conquer Cancer (hereafter THE MARCH). As part of THE MARCH, a group of experts that included basic and clinical scientists, behavioral and psychosocial researchers, cancer survivors and executives from academia, government, industry, cancer research organizations and professional societies came together as THE MARCH Re-
we must accelerate our efforts to achieve the additional necessary breakthroughs required in basic research.

example, genetic changes in cancer, mechanisms by which cancer cells become immortal, pathways by which they signal and communicate and the process by which tumor cells spread all represent high potential pay-off areas that require increased support. The foundation of our unparalleled capability in basic biomedical and behavioral cancer research is built on ideas that come from individual scientists. Unfortunately, only 25% of approved grants are currently funded and many excellent ideas and investigators with great potential are lost. We must increase this level to a minimum of 45% and fund more investigators in nearly all areas of cancer research, especially historically underfunded areas such as cancer prevention, behavior and psychosocial research. It is also critical that we attract young and minority investigators to cancer research and fund the most innovative ideas. The complexity of cancer and convergence of disciplines required to address the research problems mean that the future belongs to teams of scientists working together to make discoveries and translate them into clinical applications. Therefore, current mechanisms to fund multidisciplinary research teams and “centers of excellence” (focused around the strengths of the Nation’s cancer centers) to accelerate translational/clinical research must be expanded and new mechanisms developed as required.

Cancer Therapeutics. Basic research has provided us with a wealth of exceptional opportunities to develop new and better drugs to treat cancer successfully. Drugs can now be more rationally designed and the process accelerated through the use of new technologies such as “combinatorial chemistry”, computer modeling and “high-throughput screening”. A new concept of chemical-cellular biology holds the promise of allowing us to convert our knowledge of biological molecules into cancer drugs that will be more effective in humans. There are hundreds of new compounds being studied in academic and private laboratories for application to the treatment of can-
cer, but new resources must be provided to realize these benefits for cancer patients. There is currently an unprecedented necessity and real opportunity to link discovery to commercialization of new cancer therapeutics by forming a public-private consortium that can validate cancer targets and accelerate new cancer drugs through preclinical and early clinical development. We must provide incentives, such as periods of exclusivity and tax credits, to fully leverage the strengths of the private sector, especially for the development of new cancer therapeutics. To fully implement this concept, we must also empower and fund the NCI and other federal agencies as well as the academic sector so they can participate fully in this partnership.

Early Detection of Cancer. Imagine visiting your physician in the future and having your cancer risk determined from a single drop of blood. Our increased understanding of the genetic and other changes that occur in cancer cells has provided us with “signposts” or markers that will facilitate the development of risk pro-

files and screening tests to determine cancer risk. Once risk is determined, intervention strategies can rationally be used to prevent cancer. Funding a national initiative to accelerate the development of these early detection technologies and developing public-private partnerships to make these tests widely available to all populations will save hundreds of thousands of lives each year.

Cancer Prevention. Cancer is a preventable disease. Furthermore, cancer prevented is cancer we do not need to treat. Cancer prevention is multifaceted, ranging from research on behavior modification and diet control to chemoprevention and environmental exposures. For example, the potential causative role of the environment in many forms of cancer must be thoroughly studied. Overall, funding for cancer prevention research should be doubled and “centers of excellence” established to accelerate a proactive approach. Chemoprevention research can be performed using the same public-private model that we will employ for developing cancer therapeutics, but we must be prepared to pay for the large, expensive clinical trials required to engage the private sector in developing chemopreventive agents for cancer.

Success in cancer prevention depends, in large measure, on the extent to which research can help people change destructive behaviors such as smoking and choosing poor diets. To reduce cancer incidence and mortality from all tobacco-related cancers, we must develop and implement a major new nationwide tobacco research and control initiative.

Improved Quality of Life. We can never forget the suffering that individuals face because of cancer, and through research, we can control the pain, fatigue, depression and nausea that so often destroy the quality of the lives of cancer patients. With the necessary additional resources, we can understand and control the physical symptoms of cancer and the side effects of cancer therapies. Psychosocial and behavior research related to cancer has not received adequate research attention in the past, but we have the opportunity to change this picture by supporting important grants in these areas, training more scientists and addressing critical research issues such as controlling pain and symptoms at the end of life.

Minority and Medically Underserved Populations. To truly understand and impact the current and looming cancer epidemic, we must realize that the complexity of cancer goes beyond the multi-factorial nature of the disease and the mystery of the cancer cell. We must support the research required to understand why cancer occurs in disproportionate rates in certain minority populations...
nority and medically underserved populations. We must apply what we already know from previous research, such as breast, cervical and colorectal cancer screening technologies, to detect and treat cancer earlier in these populations. In addition, we must ensure that the technologies and new medicines that derive from the discoveries and advances in clinical cancer research described herein are applied to all populations, so that rates of cancer incidence and mortality cannot only be reduced, but also equalized across all populations. Finally, we must support high quality registries to provide a basis for cancer control and assessment of our progress.

NECESSARY ACTIONS

Results from our past investments in cancer research have produced a wealth of new opportunities to develop new medicines and technologies for translation to cancer patients, but to realize these gains we must take immediate actions to remove a few key barriers. In short, we must develop novel public-private partnerships, increase the participation of cancer patients in clinical trials, train the required cadre of clinical investigators and empower the NCI to spearhead a full-scale national effort to cure and prevent cancer.

Establish a New Culture and a New “System”. We need to establish a new culture where “translational” research can flourish—through “centers of excellence” that leverage the basic and clinical research strengths of our National cancer centers. It is also urgent that we develop a new system to translate laboratory discoveries into products and technologies to cure and prevent cancer. This will require new models that optimize and speed this process. The current system is too slow and significantly underfunded to expedite the translation of laboratory discoveries into new drugs and technologies that will reduce the incidence and mortality of cancer. There is a real and immediate need to establish highly effective relationships and partnerships among the three sectors involved (government, academic and the private sectors), with a special focus on leveraging the strengths of the private sector in our national effort to conquer cancer. To do this, we need to offer incentives such as increased periods of product exclusivity and federal tax credits, and take specific actions such as support for large, expensive cancer prevention clinical trials.

Reform and Expand Cancer Clinical Trials. Our clinical system for translating discoveries has not grown in accordance with need, and in fact, the National Cooperative Groups that perform cancer clinical trials require a great deal more support. An unacceptably low 2% of cancer patients are enrolled in these clinical trials to test new agents. This number needs to be increased to 10% through better public education, a simplified enrollment process and incentives for clinical cancer researchers to enroll cancer patients in clinical trials. Brilliant young clinical investigators are pursuing careers elsewhere because of the lack of funds to ensure training, research, and ongoing career support. A renewed national effort on an unprecedented scale must be made to attract and train these new clinician researchers and provide them the necessary resources to do their work.

Empower the NCI. Finally, the implementation of the recommendations of the Research Task Force requires that the National Cancer Institute

It is specifically recommended that we increase our annual investment in cancer research to $10 billion over the next 5 years.
will have the increased resources, flexibility and authority required to plan, coordinate and implement the unified national initiative to cure and prevent cancer envisioned by the National Cancer Act. The NCI must be able to make rapid decisions, provide expeditious support for critical research as well as our Nation’s cancer centers and build the partnerships required to leverage discoveries into the clinic, and subsequently, into new products to cure and prevent cancer. This required level of “readiness” means that the NCI must be freed of burdensome policy constraints and empowered in all respects. In fact, it could be considered as a potential national “reinvention laboratory” and/or empowered through the use of other models employed to meet the needs of similar critical national programs.

RETURN ON INVESTMENT

Our investments in cancer research have provided us with unprecedented opportunities to accelerate progress against cancer.

We must immediately address the increasing burden of cancer that will hit America the hardest in the next 10-25 years as the population ages and the demographics of the country change. The Research Task Force recommends that we initiate a National strategy to incrementally increase our investment in all areas of cancer research. It is specifically recommended that we increase our annual investment in cancer research to $10 billion over the next 5 years. Implementation would begin in 1999 by doubling the current NCI budget to $5.0 billion and increasing the budget by approximately 20% per year for the ensuing five years.

The Research Task Force believes that if its recommendations (and those detailed in the Bypass Budget of the NCI) are implemented and if the required resources are dedicated now, that required reductions in cancer incidence and mortality can be achieved. At current levels, it is anticipated that cancer incidence could be reduced 20% in 10 years and as much as 30% annually in 20 years. This translates into 246,000 and 369,000 fewer cases of cancer annually in 10 years and in 20 years, respectively. The Research Task Force also projects that deaths from cancer could be reduced from 25-40% over this same 20 year period, saving 150,000-225,000 lives each year in the United States and countless lives around the world, from the recommended application of research discoveries and research-based initiatives such as cancer prevention.

Everyone working in cancer research feels the excitement and understands the possibilities offered by the vast number of extraordinary opportunities to make essential progress against cancer in all populations now. Through research we have cured several cancers such as testicular cancer, Hodgkin’s disease, and certain types of leukemias, and we are hopeful that many more cancers can be cured in the next few years. The clear message from the members of the Research Task Force is—don’t let this moment pass; seize this opportunity to launch an inclusive, national, full-scale “war” to eradicate cancer for all Americans NOW.

As a Nation, we know what this challenge means and how to meet it. We have done it before and we can do it again—to defeat cancer. We have supported the level of commitment it took to win World War II, put a man on the moon and triumph in the Gulf War. These campaigns required decisive commitment by our government and the American public; full engagement of our best research minds in the academic, government and private sectors; freedom to act by the federal sector; full participation and support from the private sector; and dedication of the required resources. A full-scale, coordinated national effort to cure and prevent cancer will require no less.
INTRODUCTION

Cancer is a feared and deadly enemy. The current and future burden of cancer is staggering, both in terms of its human toll and economic impact. The American Cancer Society (ACS) estimates that in 1997 alone, 1,228,600 new cases of cancer were diagnosed and 564,800 Americans (1,500/day) died from their disease. To put cancer deaths in perspective, the number of our citizens that die each year from cancer exceeds the total number of Americans lost to all of the wars that we have fought in this century. The current economic burden of cancer is estimated at over $104 billion per year, including medical costs, lost productivity and death.

As we look forward into the next century, at current rates, it is projected that one-half of men and one-third of women in America today will be diagnosed with cancer at sometime in their lifetime and one-quarter of our population will die from cancer. These statistics are extremely daunting in terms of increased health care costs, especially given the current managed care environment, and an estimated 40 million Americans under the age of 65 who have no health insurance.

THE MARCH is about ending the fatalism and the apathy that cancer cannot be conquered. It is also about coming together as a Nation to create a turning point in our long struggle to defeat cancer. THE MARCH Research Task Force believes that cancer can be cured and ultimately prevented, and the time to wage a real “war” to achieve these goals is NOW. Based on past success and current research opportunities, we can envision that patients with cancer will eventually be cured, or their disease will be treated as a chronic illness with good survival rates and quality of life. Eventually many cancers will be prevented. Progress through cancer research will provide the weapons we need to realize this vision and win the numerous battles that must be fought to achieve the unified goal of THE MARCH—“No More Cancer.”

Thus, the Research Task Force turned its attention primarily to the extraordinary research opportunities to accelerate progress against cancer that have come directly from our past investments in cancer research—and they are numerous. The Task Force focused on: extraordinary basic and clinical research opportunities to expedite progress against cancer in all populations; improving the quality of life of cancer patients through psychosocial and behavioral research; building novel partnerships and engaging the private sector in all aspects of cancer research; and developing a “state-of-the-art” clinical trials system. The recommendations also highlight the real need to empower the major federal institution charged with leading our national effort to conquer cancer, the National Cancer Institute.

VISION OF A “WAR” TO CONQUER CANCER (1971–1998)

Recognizing the terrible specter and ever-increasing burden of cancer, President Richard M. Nixon declared a “war” against cancer in 1971, when he signed into law the National Cancer Act. This Act strengthened the National Cancer Institute (NCI), made the Director of the NCI a presidential appointee to be confirmed by the Senate, and created a budget process called the “Bypass Budget” that goes directly to the President for transmittal to Congress. The Bypass Budget was created to provide a mechanism whereby the NCI Director could define the annual funding level needed to wage a full-scale “war” on cancer.

The National Cancer Act was a bold step, but unfortunately a “war” was never fully launched or funded in relation to the complexity, size and cost of the cancer epidemic. We currently invest approximately $2.5 billion per year in cancer research through the NCI. This investment represents only 2% of the current economic bur-
den of the disease and translates to about 1 cent invested in research for each $10.00 paid in taxes.

In recent years, the Administration and Congress have begun to respond to this challenge by making the cure and prevention of cancer a priority on America’s healthcare agenda. This increasing bipartisan support for cancer research and quality cancer care has made many of the initiatives proposed in this Report possible.

Although our national commitment and resource allocations to create and sustain a “war” on cancer have only recently begun to reflect the magnitude and complexity of the problem, astounding advances in cancer research have occurred as a result of programs funded through the NCI. During the past 25 years, and especially since we have begun to increase our investment in cancer research, our fundamental understanding of the basic molecular biology and genetics of cancer cells has virtually exploded. These advances have given rise to an age of biology that will surely provide new opportunities to conquer cancer and many other diseases.

We have successfully cured some cancers, such as selected types of leukemia and testicular cancer in young people, and for the first time, the NCI reported in 1997 that cancer death rates had fallen slightly between 1991 and 1995. This progress is further reflected in recent editions of the NCI Bypass Budget which highlight discoveries from basic research and unprecedented numbers of opportunities to develop new technologies and medicines to detect, treat and prevent cancer.

CANCER DEFINED

Research is unraveling the cloak of mystery and complexity around cancer. We now know that normal cells are programmed much like a computer through their genetic makeup (genes) to carry out specific functions, including when to divide. Normal cells become cancerous, or transformed, when abnormal changes occur in the genes to the extent that they no longer respond to normal control mechanisms and divide in an uncontrolled fashion. The genetic changes that lead ultimately to cancer can accumulate over a period of 10 years or more.

Cancer is not a single disease but a complex group of more than 100 different diseases. To add to this complexity, there are differences even within a specific type of cancer. For example, one type of breast cancer might have a set of three altered genes, while another type might have a different combination. Understanding all of the genes that can cause cancer, and how to type specific cancers to determine which genes are altered, is critical to designing new approaches to treatment and prevention.

Normal cells become cancerous, or transformed, when abnormal changes occur in the genes to the extent that they no longer respond to normal control mechanisms and divide in an uncontrolled fashion.

One of the most devastating aspects of cancer cells is their capacity to spread to other organs and tissues within the body. This process of moving from the original site into other organs is called metastasis. While normal cells are programmed to remain fixed to perform their functions, changes in cancer cells allow them to move into organs and grow at the expense of normal cells. This ability to metastasize makes cancer extremely dangerous, as normal organs can be damaged to the point of being unable to perform normal functions and lead to the death of the patient. During the past few years we have made significant strides in understanding the basic biology of the metastatic process, and there are currently opportunities to design and develop new rational approaches to slow or stop the spread of cancer and eventually prevent it completely.
**FUTURE BURDEN OF CANCER**

Despite our increasing understanding of cancer, unless we act with urgency now, at current rates, the human and economic cost to the United States is likely to become unmanageable within our health care system in the next 10-20 years. For example, if current rates are used to calculate the incidence rate (number of people per 100,000 who develop cancer during a year) of cancer in 2010, the number of estimated new cases is expected to increase by 29% and the number of expected cancer deaths will increase by 25%. These projections are extremely conservative, as they do not account for changes in demographics and the increasing age of our population in 2010 and beyond. Using these conservative values, the projected economic burden due to the direct cost of medical treatment will increase to approximately $65 billion per year and the “productivity” cost (lost economic productivity due to disability and death) will grow to over $135 billion for a total expected economic burden of over $200 billion annually in 10 years.

Looking beyond 2010, cancer incidence and mortality in our aging U.S. population become even more staggering. Unless we act now to dramatically change current cancer incidence and death rates, we can expect over 2.0 million new cancer cases and 1.0 million deaths per year by 2025. These estimates represent individuals that will suffer and die from cancer unless we do a great deal more now. Moreover, the brunt of these statistics will be borne disproportionately by those least able to bear it—minority and medically underserved populations. Launching a full-scale national effort to accelerate all of our efforts to cure and prevent cancer requires that we commit to a level of federal funding for cancer research that is several-fold higher than we are currently spending. Unless we make this commitment now, we will be unable to significantly alter the inevitable increase in new cancer cases and deaths that will surely become a health care crisis of unimagined proportions in the next century.

“We want to be the generation that wins the war against cancer and ends that war in victory. We will not rest until we have a cure for cancer.”

—Vice President Al Gore
September 26, 1998
RECOMMENDATIONS I: 
UNPRECEDENTED OPPORTUNITIES FOR
ESSENTIAL PROGRESS IN CANCER RESEARCH

STATUS OF CANCER RESEARCH
Fortunately, this is a remarkable time for biomedical research and our national effort to eradicate cancer. Every day newspapers and television report new, exciting treatments and prevention approaches for cancer. Clearly it is a time for optimism. The NCI has spearheaded and supported new groundbreaking programs in many areas of cancer research, especially those related to "unraveling" the intricate genetics and molecular biology of cancer cells. As a result of these past investments, there are exceptional opportunities to make essential progress in basic and clinical cancer research. We can improve the survival of cancer patients and provide a better quality of life than experienced with earlier treatments. With an increased understanding of the process by which normal cells are transformed into cancer cells, we are truly on the brink of being able to prevent cancer, and our knowledge of the "signature" of cancer cells gives us enormous capability to detect cancer early.

The Research Task Force strongly endorses the four extraordinary investment opportunities delineated in the NCI Bypass Budget for FY 2000. These include broad, national programs to: identify and study all of the genes involved in human cancer, including the development of support systems and infrastructure to exploit these discoveries for all of our citizens; develop preclinical models of cancer so that cancer development can be studied and new prevention, detection and treatment strategies can be tested; pursue groundbreaking research in the imaging of tumors to significantly increase progress in early detection; and to utilize the molecular "signature" of cancer cells to detect tumors at their very earliest stages.

Research is a process, beginning with basic research, which produces discoveries that must be developed, "translated" and ultimately commercialized through the private sector for application in humans. This process requires the active participation of the government (especially the NCI), academic and private sectors to move these discoveries into clinical applications. In the past, the preponderance of cancer research has focused by necessity on very basic questions aimed at understanding cancer at the molecular level—and we have been successful.

These past investments have produced a wealth of new opportunities to develop new medicines and technologies for cancer patients, but to realize these gains it is urgent that we develop a new culture to translate discoveries into clinical applications. There is an urgent need to establish novel relationships and partnerships among the three sectors involved, with a special focus on significantly increasing the participation of the private sector in our national effort to conquer cancer. The NCI must be free to participate easily in these new partnerships, so we must do everything possible to relieve the Institute of bureaucratic constraints.

The following recommendations of the Research Task Force are focused on real and immediate opportunities to accelerate progress against cancer; as well as the key barriers that must be removed to fully exploit these opportunities for the benefit of current cancer patients, families and the staggering number of our citizens who will yet fall victim to cancer in their lifetime.
We must accelerate progress in basic cancer research (discovery). Although we have achieved a significant basic understanding of cancer cells, there is a great deal left to do. Cancer remains, in every respect, an extremely complex disease—in fact, it is more than 100 different diseases.

Curing established cancer requires the killing of tumor cells but not normal cells. We need to learn why and how cells decide to die, and specifically, how to induce the preferential death of tumor cells. We have recently discovered that both normal and tumor cells have access to a mechanism called programmed cell death, and finding signals which preferentially induce switches to this program in different types of cancer cells is key to designing new therapies. We have recently discovered that tumors are more genetically unstable than normal cells, and it is this quality that allows tumor cells to rapidly evade the normal growth control mechanisms and resist response to drug treatment. We have only very recently begun to understand the cellular processes which underlie this ability to evade therapy. Clearly, more basic research is also required to utilize this knowledge to discover new approaches to detect and prevent cancer.

Each cancer initially develops at a specific site in the body and from a specific cell. For example, this cell could be either a lung or colon cell and thus has a cell identity created through a developmental process as the adult body is formed from the fertilized egg. We know very little about this developmental process, which must be important in generating the character of tumors. Surprisingly, we also know very little about how the immune system restricts the generation of either very small early tumors or late-stage cancers. Cancers, like other parts of the body, must be perfused with blood to survive. The growth of the small blood vessels supplying such blood is called angiogenesis, and recent evidence suggests that blocking angiogenesis can block tumor growth. Hopefully this insight can be used to treat cancers. However, more basic science is needed to understand why the angiogenesis process of a tumor is different than that of a normal organ in the body such as a liver. It is this difference that must be exploited in cancer treatment.

Many tumors are restricted to one site in the body and can usually be successfully treated. However, cancer cells commonly acquire the ability to migrate throughout the body and metastasize to other sites rendering local treatment ineffective. We are only now beginning to understand the cellular processes responsible for cell migration and cell targeting to particular sites in the body. Obviously, further basic research is important in designing new treatments.

Modern chemistry has discovered powerful methods to generate and select specific inhibitors of cellular reactions. Such inhibitors can become "guides" to determine the role of a reaction in the biology of the cell. These inhibitors can also be important as pioneer drugs to test the role of the specific cellular reaction in the treatment of cancer. For example, does the pioneer drug preferentially induce the death of cancer cells? If the results were sufficiently positive, sophisticated chemotherapeutic and preventive drugs might be generated from the pioneer-lead drug. Thus, the future interaction of chemistry and the physical sciences with the basic science of cancer research is critical for rapid progress to better therapies and new preventive agents for cancer. This interface among chemistry, physics and molecular biology has given rise to a promising new concept and area of research called chemical-cellular biology.
RECOMMENDATIONS

- The “bedrock” of the unparalleled biomedical research capability of the United States is built on the ideas that come from individual scientists. The peer review system identifies the best of those ideas for support. Unfortunately, at current levels we are funding only 25% of the approved grants from these investigators who want to work in cancer research. Young investigators stand little chance of entering this system because of funding constraints, and there is a dearth of minority scientists across the spectrum of cancer research. The Research Task Force recommends that we appropriate the money to fund a minimum of 45% of these approved grants.

- The cure and prevention of cancer will require that scientists from all research disciplines work together in multi-disciplinary teams. It is recommended that a minimum of 50% of program project grants be funded—especially in support of cancer prevention, the new emerging area of chemical-cellular biology, translational/clinical, psychosocial and behavioral research, molecular epidemiology, environmental carcinogenesis and increased cancer rates in specific populations.

- Increased funding for cancer centers, especially to support “centers of excellence” in translational research and infrastructure needs.

- We cannot predict where breakthroughs in science will come from, so we need to be able to move quickly, fund innovative ideas and attract scientists from areas such as physics, chemistry and the computer sciences to work on cancer. We should double current support for research and training mechanisms that encourage innovation and recruitment of scientists from other disciplines and utilize public-private partnerships to bring additional investments into these and other areas of basic cancer research.

Annual Investment Target in Five Years—
$3.0 Billion

Researchers are on the verge of discovery in so many different areas of disease—it is crucial that we provide them with the tools necessary to continue the tremendous advances made in biomedical research…”

ACCELERATE THE “TRANSLATION” OF IMPORTANT NEW LABORATORY DISCOVERIES

We must leverage current exceptional opportunities in clinical (also called translational or applied) cancer research. Advances in discovery research have brought us to the most promising and exciting point in the 26-year history of what is commonly referred to as the National Cancer Program. We have unprec-
rational targets for cancer treatment and prevention. In addition, there are new, exciting ways to rapidly make drugs that are based on our increased understanding of the fundamental biology of cancer cells. For example, computer modeling of specific molecular targets can aid drug discovery. Large numbers of new molecules can now be prepared through a process called "combinatorial chemistry." We also can rapidly screen large numbers of molecules for activity using a process called "high-throughput screening."

We need new cancer drugs that specifically kill tumor cells and spare normal cells to maximize the therapeutic effects and reduce damaging side effects. We can improve the scale, speed and effectiveness of the cancer drug discovery and development process through the creation of new partnerships—partnerships between chemists, biologists, clinicians and patients, and among academia, government and industry. We need to fully leverage the strengths of the pharmaceutical and biotechnology industries as essential partners in the development of new anti-cancer drugs. They have extraordinary expertise and capabilities in all phases of drug discovery and development, especially the preclinical and clinical phases. We can thereby connect cancer drug discovery to preclinical and clinical development on a national basis and accelerate the process of getting new drugs to cancer patients.

**RECOMMENDATIONS**

- Develop a public-private consortium (academia, NCI and pharmaceutical and biotechnology companies) to review molecules developed in the academic sector and/or proposed by the private sector as potential cancer therapeutics. The Consortium would prioritize and expedite the progress of the most promising candidates through the preclinical and clinical proof-of-concept developmental stages.

- Provide incentives for pharmaceutical and biotechnology companies to engage in discovery of "lead" molecules for target validation and to perform Phase I and II clinical trials to test new cancer therapies. Incentives to perform Phase III trials for cancer therapeutics that qualify as "orphan drugs" should be provided. Overall, incentives could include tax credits, patent extensions and/or market exclusivity.

- Provide additional federal funding for drug discovery and development through mechanisms such as the National Cooperative Drug Discovery Groups and the new Rapid Access to Interventional Development programs of the NCI.

- Develop novel partnerships and new federal funding mechanisms to provide significant targeted support for key areas of therapeutics research, especially the promising new area of chemical-cellular biology that will facilitate the conversion of knowledge about biological molecules into drugs that can be effectively used in humans.

**Annual Investment Target in Five Years—$1.2 Billion**
Improving Early Detection of Cancer to Save Lives

Early detection of cancer is our best hope for increased survival and cure of patients with cancer. Imagine in the future visiting your physician for an assessment of your risk for cancer determined from a single drop of blood. This is no longer a dream—we now recognize many molecular "signposts" or markers that have evolved from our increased understanding of the genetics and abnormal functions of cancer cells. These markers have the power to predict who is at risk for cancer early enough to intervene, so cancer can be treated before it is out of control. These "signposts" will also allow us to follow the progression of cancer in patients to predict the recurrence of disease.

We have sensitive tools available to develop these screening tests and implement intervention strategies to prevent cancer and/or reduce disease severity. We have opportunities to test for specific changes in genes that are altered in cancer; genes that affect an individual's ability to break down cancer-causing chemicals; genetic markers of damage related to smoking and environmental exposure; and biochemical markers of deficiencies in key nutrients. As a result of the marriage of genetics and semiconductor technology, "chips" are being developed that will eventually allow testing for changes in a single gene, or hundreds of genes, and this field is progressing rapidly.

To fully exploit these promising leads in early detection and risk profiling, we must test these markers in patients to determine which are most valuable in terms of their specificity, sensitivity and practicality of use. We also need to bring together scientists, clinicians and epidemiologists to test these markers in large clinical populations, especially by conducting large observational studies to identify gene-environment interactions.

To fully exploit this technology will require repositories of samples and data to support and accelerate progress in early detection. We must proceed with haste to implement a national program to realize the enormous value of early detection in cancer prevention and determine precisely when to initiate and terminate therapy. Every effort should be made to apply these new screening approaches to minority and medically underserved populations that bear such a disproportionate share of the burden of cancer. To proceed with early detection and risk profiling, we must insure through legislative action that this type of information is kept confidential and not used to deny insurance or otherwise discriminate. Lastly, realization of the promise of these powerful new tools for early detection of cancer requires that industry be engaged to commercialize the tests and make them widely available to everyone.

The NCI has proposed a program to expedite progress in this important area as one of its extraordinary opportunities (Signature of Cancer Cells) in the Bypass Budget for FY2000. The Research Task Force supports this initiative and recommends that we commit significant resources beyond this request to accelerate the development of these early detection technologies.
THE MARCH RESEARCH TASK FORCE REPORT

RECOMMENDATIONS

- In keeping with the NCI Bypass Budget, develop a major national initiative to accelerate progress in the translation of discoveries from basic research into new technologies for the early detection of cancer. As part of this initiative, develop panels of markers to assess cancer risk, and facilitate early detection.

- Determine the required research, resources, regulatory issues and partnerships required to achieve a national program in risk-profiling and early detection in individuals at high risk for cancer and in the overall population, and develop a system for implementation.

- Provide incentives for the private sector to commercialize technologies for marker development and risk profiling.

- Perform small mechanistic studies and larger confirmatory trials that focus on the development of exposure markers and the underlying biological mechanisms to identify environmental agents that damage DNA and design protective agents based on these studies.

- In cooperation with the Centers for Disease Control (CDC) and other private and public organizations, implement a comprehensive national public education program on the value of screening and risk profiling in the early detection of cancer, with special emphasis on high risk and minority and medically underserved populations.

Annual Investment Target in Five Years—$1.3 billion

"...Mr. President, Mr. Vice President... Senators and members of Congress [make this your legacy]...you must recognize this epidemic...you must take charge of this chaos called cancer...on behalf of those 8 million cancer survivors, on behalf of all of us—I say to you, Good God—what the hell are you waiting for?"

—Mr. Sidney Kimmel, Chairman, THE MARCH
Chairman, Jones Apparel Group
Founder, Sidney Kimmel Foundation for Cancer Research

RECOMMENDATIONS I: UNEQUALED OPPORTUNITIES FOR PROGRESS IN CANCER RESEARCH
DEFEND CANCER THROUGH PREVENTION

Our dream is the prevention of cancer for all Americans. Cancer prevention is multi-faceted, and a wide array of approaches must be undertaken now to reduce the cancer burden in both the short and long term. The major areas of prevention research that promise to have a significant impact on cancer incidence, and in certain instances mortality, include behavior modifications in tobacco use, nutrition and diet, and chemoprevention. It is likely to be several years before we can fully understand and control all genetic and/or environmentally-induced genetic changes that cause cancer. In the meantime, many lives can be saved by dedicating significant additional resources to the needed basic and clinical prevention research in each of these areas.

The Research Task Force supports the need for a major national, comprehensive tobacco research and control initiative to reduce morbidity and mortality from all tobacco-related cancers. Although prevention of smoking in children and interventions designed to reduce the impact of tobacco use in adults should be a major focus of this national program, studies on the impact of passive smoking, fetal effects and interactions of nicotine with other carcinogens should also be undertaken. Major emphasis in this research-based tobacco control initiative should be on reducing tobacco-related cancers in minority and medically underserved populations.

It is estimated that one-third of cancer is related to poor nutrition and diet. Knowledge of the behavior of cancer cells at the molecular level offers significant opportunities to specifically study and monitor the effects of diet in the prevention of cancer. Specific nutrition research should be pursued in multi-disciplinary teams to develop testable, rationally-designed nutrition approaches in clinical trials. In addition, we should apply what we know from prior research on the role of diet in cancer prevention to all populations.

Basic research has provided an encouraging picture for cancer prevention in the future. Knowledge of the changes in cellular pathways and specific genes that occur as cells progress from normal to cancerous states provide targets to develop new chemical agents for cancer prevention. As an example, in a recent study, intervention in women at high risk for breast cancer with a drug called tamoxifen resulted in a 45% reduction in breast cancer in treated patients.

Discoveries from basic research have shown that it is possible to protect DNA from damage by substances called free radicals and reactive oxygen species. Studies with agents such as vitamin E, selenium, certain vitamin A compounds and active substances from natural products such as green tea support the testing of these types of agents in clinical trials. The clinical trials required to test cancer prevention strategies and agents will be large and expensive, but we must allocate the funds to support these trials. Otherwise, years of research that have established a sound basis for cancer prevention will be lost.

Finally, there are unprecedented opportunities to apply the principles of therapeutic drug development to cancer prevention. All of the tools of chemistry and biology can be used for the rational design of new chemopreventive agents for intervention, initially in high-risk populations of patients and eventually in the general population. Pharmaceutical and biotechnology companies must be engaged in the development of new chemopreventive agents. The NCI must be empowered and funded to take the lead in designing and conducting these types of trials—and building the partnerships required to significantly engage the private sector in cancer prevention.
THE MARCH RESEARCH TASK FORCE REPORT

RECOMMENDATIONS

As part of a national research and education initiative that addresses all aspects of cancer prevention, develop and implement a major new tobacco-control initiative to reduce the incidence of all tobacco-related cancers and educate the American public on sound prevention approaches. Ensure a focus in these efforts that targets minority and medically underserved populations (see also behavior research).

- Double current funding for basic, clinical and behavioral cancer prevention research and training. Support review processes and support mechanisms such as program project grants that reflect its multi-disciplinary nature.

- Create several "cancer prevention centers of excellence," primarily through the Nation's cancer centers, to bring scientists and clinicians together in an environment focused on cancer prevention in areas such as nutrition, behavior and/or chemoprevention.

- Utilize a consortia approach similar to that proposed for cancer therapeutics to facilitate the discovery and preclinical and clinical development of new chemopreventive agents for cancer, providing incentives for pharmaceutical and biotechnology companies to enter the cancer chemoprevention field.

- Support and/or co-support with industry the large and expensive clinical trials required to test the efficacy and safety of new chemoprevention agents.

Annual Investment Target in Five Years — $1.5 billion

"We can now say with certainty, we know the road to take. The only question is the speed to which we proceed along the way."

—Richard D. Klausner, M.D., Director, National Cancer Institute
In an era of unparalleled advances from prior investments in basic and clinical research, it is important to remember that cancer occurs in people; it is the individual, not just the cancer, who must be treated. We should also realize that, in order to effectively eradicate cancer, we must understand much more about human behavior. For example, research into understanding how to influence behavior relative to lifestyle choices is critical to reducing the incidence and death from lung and other cancers caused by smoking and poor diets.

In a period when we have, by necessity, focused a substantial proportion of our resources on understanding the biology and genetics of cancer, behavior and psychosocial research have not been well supported historically. We must now increase support for research directly related to the psychosocial aspects of cancer, to improve the quality of life for the millions of Americans who must undergo treatment and ultimately live with cancer. By targeting more resources to support high-quality research in these areas, we can learn to deal with the major problems of pain, fatigue, depression, nausea, and other side effects of cancer therapy that make cancer so horrific for its victims.

Research in basic behavior is needed to realize the potential of new strategies to treat and prevent cancer. Moreover, if we are to prevent cancer, we must convince people to adopt healthy lifestyles that include making changes in long-standing eating, smoking, and alcohol consumption habits as well as other destructive behaviors. To develop effective techniques that will enable people to make these changes, we need an increased understanding of some basic principles of human behavior. We must learn what motivates people, what maintains behavioral change over time, what factors lead to addictive behaviors, and how learning affects the immune and nervous systems.

There is currently a great need and opportunity to conduct research on the decision-making process by which patients and their physicians choose among cancer treatment alternatives. Each treatment has its own associated probability of success and effect on the quality of life of the patient. Research on the decision-making process by minority populations in areas such as treatment options is especially in need of increased emphasis. Members of these populations often seek medical attention late in the disease process. Research to determine the effects of cultural differences and economic factors in minority and medically underserved populations, on access, screening and cancer treatment must be conducted. Findings from this research must be implemented to reduce the toll of cancer in these groups, where incidence and mortality rates of cancer are disproportionately high.

Tools are now available to understand and control the causes of the physical symptoms of cancer and its treatments, including clinical trials research. These symptoms include pain, fatigue, nausea, depression and difficulty breathing, many of which are especially pervasive at the end of life. Pain and fatigue, in particular, merit additional attention, since most cancer patients experience these debilitating side effects, yet few patients have them adequately controlled. Partnerships among the academic, government and pharmaceutical and biotechnology sectors must be established to pursue the development of new, rationally designed pain control agents, and a similar initiative is needed for fatigue. Significant new resources must also be invested in research to improve treatment and provide relief from these symptoms to cancer patients at the end of life. In order to make progress in these areas, investment in both basic and clinical biobehavioral research is needed, especially through multidisciplinary teams of investigators working together to reduce the suffering and distress caused by cancer and its treatment.
RECOMMENDATIONS

- Support the behavioral research required to reduce cancer incidence and death caused by tobacco use in children and adults.

- Increase support for basic behavioral and psychosocial research to individual investigators through the current individual investigator grant mechanisms and allocate a minimum of $75 million per year to these critically important areas.

- As part of the recommended therapeutics initiative, provide the additional resources and incentives needed to develop partnerships among the government, academic and private sectors to engage in pain research and develop new agents to address the problem of pain in cancer patients.

- Use current grant mechanisms, such as program project grants, to support national multidisciplinary research initiatives to specifically understand and manage end-of-life symptoms and care in cancer patients.

- Study behavioral and psychosocial interventions in patients through approved clinical trials. Create a clinical trials program to study these interventions, or perform these studies as part of the current National Cancer Cooperative Groups Program, to collect data from large groups of patients.

- Create training programs in psychosocial and behavioral oncology research and practice to address the increased demand for expertise in these areas and provide funding for five-year periods.

Annual Investment Target in Five Years—
$750 million

When the American public sees how woefully under-funded cancer research is, they will be mad as hell.”

—General H. Norman Schwarzkopf, cancer survivor and Honorary Chair of THE MARCH
Academic institutions, government agencies and private industry all play critical yet distinct roles in cancer research. Together these sectors create a "system" of research that ranges from fundamental insight into the mechanisms that cause cancer to the translation of that knowledge into new products for the prevention, treatment and diagnosis of cancer. This tripartite system of cancer research has evolved over many years, resulting in large, highly complex and separate sectors that operate somewhat independently and are driven by different strategies. We now have a major opportunity and need to leverage the strengths of these sectors to accelerate our national goal to conquer cancer.

A fully responsive partnership, combining all of the strengths of academia, government and industry, is perhaps our greatest opportunity to leverage all of our national expertise to cure and prevent cancer. Unfortunately, the existing tripartite system has a number of weaknesses. Among them is the duplication of research, resulting from a system that is less than maximally efficient. Communication gaps and cultural differences also hinder the development of the truly optimum partnerships that are so desperately needed to accelerate progress against cancer.

Individually, none of the three sectors can provide the breadth and depth of research, development and commercialization required to adequately advance discoveries from basic cancer research to the introduction of new safe and effective medicines.

A national strategy based on the full participation and expertise of all three sectors in a full-scale effort to conquer cancer is required now. To create a new system of partnerships, we must identify and eliminate any existing barriers that stand in the way of achieving the synergy needed to achieve our goal.

The novel partnership model must become a major focus for everyone with the capabilities to accelerate progress against cancer—academia, the NCI, the Nation's cancer centers, and industry. These novel relationships should be designed to use the strengths of the three sectors in the various stages of the research process. These partnerships must also focus on increasing the efficiency and effectiveness of discovery, development and commercialization, while preserving intellectual property rights. The stated goal of these new high-performing partnerships will be to accelerate the application of the best discoveries into new strategies for the early detection, treatment and prevention of cancer.

**Recommendations**

Private industry allocates its resources based on a risk-reward analysis to maximize value to its shareholders. To fully engage the private sector, we must be able to mitigate these risks. It is recommended that the following incentives be provided to engage private companies in a unified national partnership to eradicate cancer:

- Grant extended periods of increased product exclusivity.
- Make government tax credits available to participating companies.
- Provide government funding and/or co-funding for the large prevention trials that must be performed to develop new strategies for cancer prevention.

Annual Investment Target in Five Years—$1.5 billion
Realization of nearly all of the extraordinary opportunities to “translate” previous discoveries into safe and effective treatments depends on a highly effective and efficient national system of clinical trials. A clinical trial is the process by which a new anticancer drug, preventive agent or behavior or psychosocial intervention is tested for safety and effectiveness in patients. Drugs and chemopreventive agents proceed through preclinical development and, initially, into a Phase I clinical trial that primarily tests safety. If an agent is safe, and there is evidence that it is likely to be effective in treating cancer in humans, it is tested in Phase II and III clinical trials for efficacy and to optimize issues such as dosage and regimens of treatment. Studies may also be performed in Phase IV trials to address additional questions about the drug. If new drugs are shown to be an improvement over current therapy, they become the new standard of care.

Clinical trials to test new agents and approaches to treat and prevent cancer are performed primarily through an NCI-funded program called the National Cancer Cooperative Groups. These NCI-sponsored groups place approximately 20,000 cancer patients on clinical trials each year, which represents only 2% of patients diagnosed with cancer. These groups currently receive only 50-60% of the funds recommended by experts as needed to perform these studies.

It is currently extremely cumbersome to place cancer patients on clinical trials through the Cooperative Groups. Each group has its own set of forms and definitions, creating barriers for physicians to place patients on studies in more than a single group. Moreover, it costs physicians approximately $3,000-4,000 per patient, out of pocket, to enroll patients in clinical trials, and they are reimbursed between $750 and $1,500 per patient for this work. Contrast this to industry-sponsored clinical trials research, where per-patient payments average in the range of $5,000. The Cooperative Groups are simply not efficient or cost-competitive with industry in conducting cancer clinical trials. The NCI is currently attempting to improve this situation, but a major increase in funding is required to enroll enough cancer patients to develop new, more effective agents to treat cancer.

We must fund the Cooperative Groups at a level that will allow them to deal with issues of research modernization, administrative efficiency, information exchange and reimbursement to physicians. In addition, we need to also focus on the development of partnerships with industry to perform clinical trials to test new cancer prevention and treatment agents. Building a “state-of-the-art” national clinical trials system will allow studies to be completed much faster and enough patients can be enrolled to identify small but important differences in therapeutic effects.

“What can be done to speed the pace of progress in cancer research?” This single activity—substantially increasing funding to the Cooperative Groups and building partnerships with the private sector to increase the enrollment of cancer patients in clinical trials—is an immediate answer. An aggressive increase in support of cancer clinical trials now will yield significant results in terms of lives saved in years to come.
RECOMMENDATIONS

• Accelerate the “translation” of new discoveries, including behavior and psychosocial findings, into possible treatments for cancer patients and improve the statistical validity of trials. Increase the number of patients enrolled in approved clinical trials each year, from 2% to 10%.

• Remove economic barriers to participation in clinical trials by requiring third party payers to cover routine patient care costs for those enrolled in clinical trials. Coverage should be provided for routine patient care costs for patients in trials that are approved by government agencies, including the National Institutes of Health, the Food and Drug Administration, the Department of Defense, and the Veterans Administration, or private organizations, such as the American Cancer Society, with adequate peer review mechanisms.

• Develop a national campaign to improve public awareness of the importance of clinical trials, provide high-quality, up-to-date information to consumers and simplify the process for enrolling patients.

• Double current funding to the Cooperative Groups just to meet present workloads. Equalize case reimbursement to attract adequate research physician resources to implement this urgent national agenda to test potentially more effective treatments and preventive agents in cancer patients.

• Optimize the infrastructure of the clinical trials cooperative groups to reflect the modern approaches to information handling and analysis.

Annual Investment Target in Five Years—
$600 million

“. . .accelerating the cure of cancer by a generation will save 100 million lives worldwide. 100 million. I think that ought to be enough incentive to a country where we grew up to believe how precious just one life is.”

—Michael Milken, cancer survivor and founder of CapCURE
The number of clinical researchers in oncology is diminishing, and fewer young people are entering this field at a critical time when there are literally hundreds of new compounds and strategies that must be evaluated. The current environment of managed care places tremendous pressure on clinical investigators to generate clinical income, and senior clinical researchers face the same pressure. Few formal training programs are available to clinical investigators, and clinical trials often take several years to perform and analyze—raising the question of stable support for this long process. All of these forces have reduced the number of clinical investigators available to perform high-quality cancer research. The NCI recently proposed a training program to respond to this critical need, but funds are not available to support this new effort.

We must act now or we will not have enough trained investigators to perform the needed clinical cancer research. Investment is urgently needed to support a new training and research program for clinical research investigators, ideally at the Nation’s cancer centers. There may also be opportunities through public-private partnership to partially underwrite the costs of this program.

**RECOMMENDATIONS**

- Fund the new NCI clinical training program and/or create a new program for young clinical investigators to provide competitive support for 5-year renewable terms ($45 million) and provide approximately $20 million to fund the mentors and infrastructure required for this program. (Support for a minimum of 15 investigators at each of 30 cancer centers is recommended.)

- Academic clinical investigators are promoted through the academic ranks, in part through the performance of peer-reviewed, investigator-initiated research. Although approximately 30% of investigator initiated research grants supported by the NCI have a clinical component, less than 1% of these grants are allocated for the support of clinical scientists to perform clinical trials research in patients. It is recommended that a minimum of $40 million of additional grant funds be allocated to specifically support clinical investigators to perform clinical trials research in cancer patients.

**Annual Investment Target in Five Years—$105 million**

*The time has come for all professional societies, coalitions, and advocacy groups to join forces to stop this carnage.*

—Donald S. Coffey, Ph.D., Past President of the American Association for Cancer Research
The implementation of the recommendations of the Research Task Force requires that the National Cancer Institute has the increased resources, flexibility and authority required to plan, coordinate and implement a unified national initiative to cure and prevent cancer. It is unlikely that the NCI will be able to respond as required under the current burdensome policy constraints. The NCI needs to be able to make rapid decisions, provide expeditious support for critical research and build the partnerships required to leverage discoveries into the clinic, and subsequently, into new products to cure and prevent cancer. This required level of “readiness” means that the NCI must be empowered to re-program funds and carry over funds between fiscal years.

The NCI needs to be free to both allocate and accept funds to build novel partnerships and develop consortia with industry and academia. In this regard, the NCI could fund some of its requirements for infrastructure improvements if it were allowed to use revenues from sources such as royalties from licensed patents for these purposes. The NCI also needs flexibility and freedom to develop and fund contracts efficiently and purchase services and materials to support the recommended national initiatives in clinical and translational research and especially to provide needed resources and flexibility to the cancer centers. Building the infrastructure and approaches to implement translational and clinical research and cancer control will require new models such as those employed by NASA and other agencies to accomplish specific national goals.

Finally, spearheading the efforts required for an urgent national push to accelerate progress toward our national goal to conquer cancer requires that the NCI must be in a position to attract and keep top management and scientific talent. This means that the NCI must be able to be competitive in all respects with the academic, and, in selective areas, with the private sector for personnel.

Empowering the NCI to move rapidly and efficiently, without a number of the constraints that currently limit its ability to act, is critical to winning a national “war” to conquer cancer. There are other federal models that could serve as guideposts for these changes. In fact, it would be prudent to utilize the NCI as a “reinvention laboratory,” as has been done with other government agencies.

RECOMMENDATIONS

- Remove burdensome policy constraints that represent significant barriers to achieving the authority, flexibility, efficiency and effectiveness required to optimize the efforts of all sectors and accelerate progress toward our national goal of curing and preventing cancer.

- Empower the NCI and provide additional resources to facilitate the development of and participation in the novel system partnerships required to optimize and leverage discoveries into new cancer detection treatment and preventive strategies and products, and provide flexibility and needed resources to the cancer centers.

- Use the NCI as a “reinvention laboratory” as one approach to relieve bureaucracy and achieve these aggressive goals for the Nation.

RECOM MENDATIONS II: NECESSARY ACTIONS TO REALIZE ESSENTIAL PROGRESS AGAINST CANCER
It is critical that we address the increasing burden of cancer that will certainly become an unprecedented health care crisis in the next 10-20 years, unless we take steps to change it now. We have shown that cancer incidence and mortality can be reduced through basic, clinical and population-based behavioral research. We have cured some cancers, but much of the job remains in front of us.

THE MARCH Research Task Force recommends that we initiate a National strategy—to significantly increase our federal investment in cancer research. Our goal is to achieve a federal funding level of $10 billion per year in five years to support the basic and clinical research required to accelerate progress in a National campaign to cure and prevent cancer. It is recommended that we launch this strategy in 1999 by doubling the current budget ($2.5 billion in 1998) for cancer research to a level of $5.0 billion and increase the budget by approximately 20% per year for the ensuing four years until we reach the $10 billion goal. This would mean an increase from the current 1-cent for every $10.00 paid in taxes that is dedicated to cancer research to approximately 4 cents in the next 5 years. A thorough analysis should be undertaken annually and in five years to assess progress, develop our goals for the subsequent five-year periods and determine the required investment. Reassessment of our strategy, investment levels and priorities should be undertaken at regular intervals to insure the success of our unified national strategy to address this cancer health care crisis that will hit America the hardest in the next 10-25 years.

If the plan of THE MARCH Research Task Force is implemented and the budget is increased as recommended, we believe that the annual incidence of cancer can be reduced 20% in 10 years and as much as 30% in 20 years. Using today's incidence levels as a baseline, we would expect 246,000 fewer cases in 10 years and 369,000 fewer cases annually in 20 years. We also believe that death from cancer can be reduced from 25-40% over this same time period. At current mortality rates, we could save 150,000—225,000 lives each year in the United States and countless lives around the world from the application of research discoveries. The impact of these reductions in cancer incidence and mortality will be staggering in lives saved and pain averted, not to mention the gains in productivity and long-term reductions in healthcare costs.

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Not only will lives be saved, medical costs avoided and productivity maintained, but a significant reduction in fear of the disease can be accomplished and the lives of those who do get the disease will be of much higher quality. While it is not possible to predict how long it will take to cure and prevent all cancer, we surely will significantly improve the quality of life of cancer patients so that it is regarded as a chronic and manageable condition—not a death sentence.

Imagine the change in outlook for every American when physicians can say, “Yes, you have cancer, but after a few weeks of therapy and some periodic maintenance you should live a pain-free, productive and normal life.” And because the root causes of cancer will be better defined and prevention begun early in life, these prevention strategies will have positive effects beyond cancer—leading to healthier and longer lives for all Americans.

Cancer is perhaps the most difficult problem that we have tried to solve to improve the health of our Nation. Although cancer remains a fearsome enemy, there is optimism in all areas of cancer research that we can turn the tide against cancer. The message, from cancer survivors, families, scientists, physicians and citizens, is NO MORE—no more cancer and no more waiting. We have cured several other types of cancers, and we are confident that this dream can be achieved, but only if we redeclare a “war” to conquer cancer and we stand together as a Nation to do it NOW.
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September 25–26, 1998

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