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NATIONAL COALITION FOR CANCER SURVIVORSHIP

September 24, 1997

Jerry Mande
Toby Donenfeld
Office of the Vice President
286 Old Executive Office Bldg.
Washington, D.C. 20501

Dear Mr. Mande & Ms. Donenfeld:

Thank you for our recent meeting in which we discussed items of interest to the cancer community. Specifically, I wanted to bring to your attention the campaign for cancer awareness known as "The March" and one of the issues that will be highlighted in that effort. For several years, the cancer community -- consisting of patient advocates, physicians and other providers, and both basic and clinical researchers -- have banded together to support coverage of patient care costs for persons enrolled in high quality clinical cancer trials. We believe this issue represents an area in which all interests, whether related to patient care or to research, converge.

A major undertaking in support of this issue is the legislation sponsored by Senators Rockefeller and Mack (S. 381) that would establish a Medicare demonstration project under which all beneficiaries with cancer could enroll in an approved clinical trial. This initiative would enhance the quality of cancer care for Medicare beneficiaries while at the same time advancing the research agenda. We have been dismayed that the Health Care Financing

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Administration (HCFA) has steadfastly opposed this demonstration project and has persuaded the Congressional Budget Office (CBO) that its cost would be exorbitant. In fact, cancer experts believe enrolling Medicare beneficiaries in high quality clinical trials would reduce costs in both the short and the long term.

With a new HCFA Administrator, we would hope that the Vice President would lend his offices to encourage a new perspective on this question. Certainly, all of the cancer groups involved in The March take the issue of clinical trials coverage as a high priority. We want to do everything we can to work with the Administration on enhancing the quality of cancer care for all its citizens -- and surely the elderly should be among the forefront of those enjoying such quality.

However, to date we have been somewhat frustrated by the refusal of HCFA to think about these very important matters in other than a wooden, reflexive manner. Your suggestion of a meeting with Nancy-Ann DeParle to discuss these issues in greater detail is a welcome one, and we would appreciate your help in facilitating this discussion of the issues.

We are grateful for your personal interest, and that of the Vice President. Please call me if you think we can work together on this issue of critical concern to 8 million cancer survivors and the many million more who will be diagnosed with cancer in the future.

Sincerely,

Ellen L. Stovall

Ellen L. Stovall
Executive Director

3299 K Street, NW, Washington, DC 20007
(202) 944-6710 Fax (202) 333-7840

FRIENDS OF CANCER RESEARCH

Fax

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To:	Mr. Jerry Mande	**From:**	Ellen Sigal
Fax:	202-456-6027	**Pages:**	15
Phone:	202-456-6018	**Date:**	November 24, 1997
Re:	The March -- Setting the Future Cancer Research Agenda		

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• **Comments:**

If any problems with this transmission please call (202) 944 6710. Thank you.

Please deliver to Mr. Jerry Mande, he is expecting this fax per our conversation just a few moments ago.

Thank you.

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Friends of CANCER RESEARCH

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Sandra Millon Underwood, Ph.D.
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Robert C. Young, M.D.
Fox Chase Cancer Center

Legal Council
Latham & Watkins

November 24, 1997

Mr. Jerry Mande
Senior Advisor to the Director OSPT
Old Executive Office Building
Room 436
Washington, D.C. 20502

Dear Jerry,

I am enclosing a copy of the summary draft recommendations from our first task force meeting. **Please keep in mind that this was a very preliminary first draft from the working task force.**

It became clear from our first meeting that we needed to define mechanisms and charge each working group with a clear mission. I am sending you a copy of the charge to our 13 subcommittees starting from cancer causation and etiology through public-private partnerships.

We have assembled the best minds in the country to work on this and feel confident that we will have innovative and thoughtful conclusions that will eradicate these diseases if the resources are available.

It is important for you to realize that this is still very early in the process and the recommendations from the first meetings have not been accepted or rejected. It is simply a process that requires more time and thought.

Please feel free to call me with any questions you may have.

Sincerely,

Ellen V. Sigal Ph.D.
Friends of Cancer Research, Chairman

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THE MARCH: SETTING THE FUTURE CANCER RESEARCH AGENDA
(September 8, 1997 Meeting – Georgetown University Medical Center)
SUMMARY

Overview

In September of 1998 there will be a landmark gathering ("The March") in Washington to awaken our citizens and the federal government to the fact that we must move with urgency to harness the resources required to eradicate cancer. An unprecedented meeting of cancer survivors, families of cancer survivors, cancer consumer advocates, basic and clinical scientists from professional cancer societies, academic institutions and treatment centers, representatives from the pharmaceutical and biotechnology industries, and other interested individuals from the cancer community met on September 8, 1997 to begin a process of defining the future cancer research agenda, and funding levels required, to wage an all-out war on cancer. Following "The March" the proposed research agenda and plans for dealing with issues such as quality cancer care and cancer in minority and underserved populations will serve as the beginning for the development of a substantive plan for the United States to move decisively forward to cure and ultimately prevent cancer for our citizens and the world.

Waging a full-scale "War" to Eradicate Cancer

The scope and complexity of how to develop a national research-based plan to conquer cancer, what should be included in such a plan, as well as implementation strategies were captured in a series of brief perspectives offered by several individuals speaking on behalf of the diverse cancer community represented at the meeting. Groups, convened to discuss specific aspects of the problem, identified a range of barriers that must be addressed to achieve our goal to develop and implement a unified, fully funded national plan to conquer cancer. These groups also suggested some major changes and initiatives that would be required to develop and implement a real "war" to conquer cancer, and offered examples of specific research opportunities to make significant progress in the detection, treatment and prevention of cancer.

Overall, barriers identified were grouped into the following seven major areas:

- The status-quo phenomenon. (Scientists have come to accept cancer statistics as "normal", current funding as appropriate and progress as sufficient, while the public has become more apathetic and less trusting that cancer will be conquered. The cancer "bureaucracy" has grown and become less able to develop and implement strategy and measure progress. This was described as being unable to 'think outside the box".
- Government policy making, bureaucracy and regulatory environment related to cancer.
- Healthcare delivery and transition to managed care.
- Loss of current research talent and failure to attract and/or train new scientists and clinicians.
- Lack of adequate participation by the private sector in cancer research, development and commercialization of new products.
- Fragmentation of the cancer community.
- Lack of unified vision, leadership, strategy, plan and resources to launch and win an all-out (Manhattan Project – Like) assault against cancer.

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The group(s) also focused on "the system" by which the agenda for cancer research is currently developed and implemented and what needs to change in order to overcome the barriers cited and achieve our ultimate goal to eradicate cancer. Several key issues were discussed as being basic to the development and implementation of an overall strategy and plan to eradicate cancer, as well as to the development of the research agenda for such a "war". These key issues fall generally into the following categories: communication; leadership; planning and strategy; systems and program development/redevelopment; incentives; and organization and management. A summary of specific actions were discussed to address some, but not all of these issues, highlights included:

- An unprecedented public education campaign to change the status-quo and enlist public support to mount a real "war" on cancer – with a sense of urgency.
- A campaign to "educate" all branches of the federal government as to the current and impending cancer crisis - with a focus on the development of legislative advocates.
- A focused effort to investigate and understand how managed care strategies will impact our vision to eradicate cancer – with a goal of constructively integrating this significant portion of the "system" into any final plan.
- An inclusive plan (government, academia, and the private sector) and implementation programs to improve the treatment and care of individuals who have (or will have) cancer, including appropriate clinical trials.
- An integrated fully inclusive plan (government, academia and the private sector) and implementation strategies and programs to prevent cancer.
- A fully integrated effort to understand, define and eradicate cancer in underserved and minority populations.
- An incentive-based plan to insure the active participation of the pharmaceutical and biotechnology industries in a real "war" to eradicate cancer.
- Visionary leadership that would build trust, reduce fragmentation, create a sense of urgency and focus the power of the various segments of the cancer community on waging and winning the "war".
- A responsive approach to manage the implementation of a national plan to eradicate cancer that reflects the magnitude of the current and future problem, sense of urgency and mandate of our citizens.

Specifics Relative to the Future Cancer Research Agenda

As summarized above, the future cancer research agenda was discussed in the context of a sense of urgency to develop and implement an aggressive national program to eradicate cancer. Two groups considered the basic needs and opportunities in basic and clinical research and a third group examined alternate research models and issues affecting the entire research agenda. A series of specific suggestions were presented by each of these groups that ranged from very specific recommendations for research programs to major "overarching" issues that will affect all aspects of the research, development and commercialization processes.

What was most prominent in all of these deliberations was the vast array of opportunities to advance in all areas of research, re-enforcing that our investments in cancer research to date have paid off and now is the time to wage a full-scale research-based "war" to eradicate cancer. The research and development process was also considered relative to the value of basic science in generating knowledge that can be used to develop technology for translation into new products for detecting, treating and preventing all forms of cancer. In this regard, it was noted that we must find new mechanisms for government and academic laboratories and pharmaceutical and

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biotechnology companies to work synergistically at all phases of this process for the benefit of all stakeholders in the cancer community.

It is clear that each phase of the cancer research and development process requires careful analysis and prioritization by groups of individuals that reflect the diversity of the cancer community, especially cancer consumer advocates. This step may well require a paradigm shift in terms of the way we think things must be done vs how other stakeholders perceive the same issues. The following represents some specific examples of critical needs and/or opportunities in basic, translational and clinical research developed by the participants:

Basic Research	**Translational Research**	**Clinical Research**	**Overall Needs**
Create and fund "star" teams of top investigators involving up to 200 scientists nationwide.	Supplemental, "translational core" grants to cancer centers and cooperative groups ($500,000 each/year).	Fund Phase I, II and III clinical trials at required levels.	Fund RO1 grants at a 45-50% level.
Create new antitumor drugs focused on the chemical biology of cancer – emphasize organic synthesis, signaling molecules, combinatoral chemistry, design of inhibitors of growth regulatory pathways.	Consortium to invest $1-2M/program (in cancer centers) to move 5-10 new agents (demonstrated anti-tumor response) per year into phase I/II	Require insurance coverage for cancer patients on clinical trials.	Increase RFPs and RFAs to attract the Private Sector.
Create new research programs for early detection of pre-malignant lesions.	Fund translational programs to develop immunotherapeutic approaches to treat cancer.	Provide cancer centers support for two young clinical scientists for seven years ($100-150,000/student/year).	Invest to significantly update infrastructure, including informatics systems.
Develop and test new chemopreventive agents.	Significantly increase funding for SPORE and program project grants.	Increase training grants for clinical biostatisticians.	Provide sufficient training support at all levels for basic and translational scientists.
Integrate functional genomics and functional cell biology of cancer cells.		Increase funding for research in cancer pain control and management.	Develop required training programs for clinical scientists.
Fund population studies and intervention strategies in minorities and underserved		Fund specific clinical trials for specific cancer problems in minorities and underserved	Invest to attract students to scientific careers early.
		Fund academic-private partnerships to perform clinical trials	Fund innovative, non-mainstream research.

A third group focused on alternative issues and research models. Much of the output from this group dealt with issues related to what is required for the government, academic and private sectors to work together in the development of a full-scale "war" to eradicate cancer. Feedback from this group, focused on current barriers, systems problems, communication and private sector involvement, is incorporated in the earlier sections of this summary.

Finally, a great deal of discussion centered on the importance of enlisting the private sector, especially the pharmaceutical and biotechnology industries, to participate in the planning and implementation of programs to achieve our goal to conquer cancer. There are currently very few incentives for pharmaceutical and biotechnology companies to fund cancer research and develop products to diagnose, treat and prevent cancer. Several suggestions were made to remove current roadblocks and encourage biotechnology and pharmaceutical companies to pursue serious research, development and commercialization programs in cancer, including:

- Investment tax credits.
- Cancer bonds.
- Extending patent life for anti-cancer intellectual property.
- Limiting corporate liability.
- Private public partnerships with less bureaucracy.
- Increasing SBIR grants.
- Increased reimbursement for clinical trials.
- Matching funds for cancer programs.
- Removing regulatory roadblocks for approval of anti-tumor agents.
- Support for cancer prevention trials.

Defining the Problem

The time is at hand to wage an all-out "war" to eradicate cancer. The magnitude of the current cancer burden is overwhelming, but by the time we reach 2010-2015, the cost of cancer in terms of lives lost and health care dollars required will become staggering. "The March" will provide the opportunity to focus the country on the urgent need for a research-based, comprehensive real "war" to conquer cancer. If we attempt to initially tackle this almost overwhelming task, our response may be that the problem is too complex and big as others have determined in the past. We must and will develop a plan to wage a full-scale "war", but for now our charge is to develop the future agenda for cancer research as a follow-up to "The March". While this is not a small, bite-sized problem, it can be done. We have made a good beginning and identified several important issues, opportunities and barriers related to the research agenda. Our next action in this process will be to identify specific goals/opportunities for major research areas and/or mechanisms (within selected categories) rank them in terms of their relative impact and identify barriers to realizing these opportunities. This will give us a basis for prioritization and developing funding requirements.

Thank-you for the individual reports and we look forward to your continued participation and contributions.

Anna D. Barker, Ph.D, Facilitator for Sept. 8 Meeting

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URGENT RESPONSE REQUESTED

November 21, 1997

Dear Colleagues and Friends:

As you may be aware, a landmark event in our mutual goal to eradicate cancer will take place in September of 1998. Cancer survivors, cancer consumer advocates, basic and clinical scientists and concerned citizens will come together in a major demonstration ("The March"), that will make clear to the federal government that the time is at hand to wage a full-scale "war" to eradicate cancer for all of our citizens.

We are writing to invite you to join us in developing a proposed "cancer research agenda" for The March. This document will provide support for the estimated level of federal resource commitment(s) required to wage a real "war" to eradicate cancer with a sense of real urgency.

The dialogue to develop a proposed research plan to support "The March" began at a meeting of cancer survivors, family members, cancer consumer advocates, basic and clinical scientists, representatives from academic centers and the pharmaceutical and biotechnology industries, and other interested individuals that was held on September 8, 1997. Many of you were part of that meeting and we appreciate your participation. At this meeting we heard that, in addition to calling for an unprecedented increase in funding for cancer research, issues such as access to quality cancer care and cancer in minority and underserved populations will be developed by additional committees in support of "The March".

The scope and complexity of how to develop a national research-based plan to conquer cancer and possible implementation strategies were discussed during the September meeting. The group identified a range of issues and barriers that much be addressed to achieve our goal to develop and implement a unified, fully funded national plan to conquer cancer.

It became obvious during this first meeting that the next step in this process was to bring together experts in the fields of basic, translational and clinical research to identify needs, opportunities, barriers, actions and supportive budget estimates for each of these areas. Working subcommittees were developed to deal with specific aspects of the research agenda and to make specific recommendations. The intent of these subcommittees is not to design specific research programs, or give specific instructions to the cancer research community, but rather to develop a consolidated (several point) cancer research agenda and supportive budget estimate in support of "The March".

This is a major task and we need your help. If "The March" is to succeed, it must be supported by a comprehensive, realistic research proposal to Congress on behalf of our citizens. It is the task of the scientific community to propose the actions and priorities for a research-based full-scale war to eradicate cancer. We believe that with a united front of

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THE MARCH: SETTING THE FUTURE CANCER RESEARCH AGENDA

RESEARCH TASK FORCE WORKING SUBCOMITTEES

Instructions to Working Subcommittee Chairpersons

Thank you for agreeing to serve as a Chairperson for one of the Working Subcommittees. The following represents a summary of the specific tasks required of the Chairpersons:

Call the members of your Working Subcommittee to invite them to participate. Explain the process and final product.

Meet with your working group through conference calls as needed to accomplish the tasks defined.

Participate in "kick-off" conference call meeting with other Chairpersons and attend one meeting in January or February 1998 to complete final product.

Process – Each Working Subcommittee member will receive a roster of all Subcommittees and the overall plan for the process and final product. Although the specific process may vary somewhat for each group, the recommended approach is as follows:

- Define the scope of your area and "brainstorm" with your group to determine what advances/goals would be most important in your area (s) to make significant progress in our goal to wage a real "war" to eradicate cancer. Be bold. It may range from accelerating something as large as the sequencing of the human genome to the establishment of specific national resource databases to new areas of training. As part of your process, rank the potential impact of the advances and/or goals from 1-10 (e.g., "10" being the highest to "1" being the lowest impact).

- Determine what barriers currently exist to reaching the particular goals or making the specific advances. Determine the level of difficulty associated with overcoming a specific barrier and rank with the same scale 1-10 (low, moderate or high of difficulty), with "1" being low level of difficult and "10" being extremely difficult. Barriers might range from lack of appropriate tumor models to inadequate numbers of trained physicians to support significant increases in clinical trials for anti-tumor agents, etc.

- Select and prioritize those advances/goals that you determine from your analysis should be part of a significantly expanded "war" to eradicate cancer. From your barrier analysis, list the actions/changes that must occur to reach the important advances/goals developed from your Working Subcommittees. Develop an estimate of the cost (with assumptions) of each recommended action (develop, increase, build,

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etc.) required to achieve this advancement/goal. Summarize the cost of each required action in order to develop an overall cost associated with achieving the advance/goal defined. Each Working Subcommittee will report a series of specific advances/goals, required actions and the estimated costs/resources required to achieve major progress in their respective areas of cancer research. The specific actions will be important support for inclusion of the specific advances/goals in the final document. (Cost estimates can be developed as you feel is most appropriate, but if you use assumptions, please include them as support for your final estimates.)

Once we are well into the process, the Chairpersons will conference on a regular basis to determine where overlaps exist and who needs help.

We would expect your Working Group to finalize its product by mid February 1998. The Working Group Chairpersons will meet in early mid-March to develop the draft final document.

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Summary of Suggestions from First Research Task Force Meeting

Basic Research	Translational Research	Clinical Research	Overall Needs
Create and fund "star" teams of top investigators involving up to 200 scientists nationwide.	Supplemental, "translational core" grants to cancer centers and cooperative groups ($500,000 each/year).	Fund Phase I, II and III clinical trials at required levels.	Fund RO1 grants at a 45-50% level.
Create new antitumor drugs focused on the chemical biology of cancer – emphasize organic synthesis, signaling molecules, combinatorial chemistry, and design of inhibitors of growth regulatory pathways.	Consortium to invest $1-2M/program (in cancer centers) to move 5-10 new agents (demonstrated anti-tumor response) per year into Phase I/II	Require insurance coverage for cancer patients on clinical trials.	Increase RFPs and RFAs to attract the Private Sector.
Create new research programs for early detection of pre-malignant lesions.	Fund translational programs to develop immunotherapeutic approaches to treat cancer.	Provide cancer centers support for two young clinical scientists for seven years ($100-150,000/student/year).	Invest to significantly update infrastructure, including informatics/ information systems.
Develop and test new chemopreventive agents.	Significantly increase funding of SPORE and program project grants.	Increase training grants for clinical biostatisticians.	Provide sufficient training support at all levels for basic and translational scientists.
Integrate functional genomics and functional cell biology of cancer cells.		Increase funding for research in cancer pain control and management.	Develop required training programs for clinical scientists.
Fund population studies and intervention strategies in minorities and medically underserved		Fund Clinical trials for specific cancer problems in minorities and medically underserved.	Invest to attract students early in their scientific careers.
		Fund academic-private partnerships to perform clinical trials	Fund innovative, non-mainstream research.

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VIA FACISIMILE

THE MARCH: SETTING THE FUTURE CANCER RESEARCH AGENDA
(RESEARCH TASK FORCE)

FOLLOW-UP STRATEGIC PLANNING PROCESS

Overall Planning Strategy

During the first meeting of the "Research Task Force", we agreed that the time has come to wage a full-scale "war to eradicate cancer. Our prior investments in medical and cancer research have resulted in significant advances in the diagnosis, treatment and prevention of cancer and produced a wealth of opportunities for future progress. It is time to escalate our current efforts to cure and prevent cancer to a full-scale "war". This will require that we unite as a Nation to think differently about how to wage a real "war" to eradicate this tragic disease and commit the additional resources required – now. Our goal is to think differently about what is possible and to create a research plan to support a real "war" to eradicate cancer.

In our discussions we identified several overall barriers to obtaining the necessary public support for this aggressive attack on cancer. We also focused on a series of actions that must be undertaken if we are to launch an expanded, research-based national plan to eradicate cancer. Finally, we began the difficult process of determining some of the critical issues and questions that must be addressed through basic, translational and clinical research to achieve our overall goal. It is this process that we must now undertake systematically and thoroughly to establish an estimate of the additional resources required to wage this full-scale "war"against cancer. It is not our intent to design specific research projects, or to give instructions to the scientific community concerning what research should be performed. Rather it is to focus on the identification of the:

-critical advances or goals that must be achieved;

- research problems that must be solved;
- new and existing research areas that need to be initiated or reinforced;
- barriers that currently stand in our way of achieving these advances/goals;
- mechanisms, new approaches and/or changes required to remove these barriers and achieve the required advances and/or goals;
- estimated costs of the resources required.

We are now ready to more completely define the major barriers to achieving the critical research advances and goals identified, determine what it will take to overcome these

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barriers and estimate the resources required for each of the major areas of cancer research.

This is a major task, but for The March to be successful in raising public awareness about the critical value and needs of cancer research, it must be accompanied by a comprehensive, carefully conceived research proposal to offer to Congress on behalf of our citizens and the scientific community. A real "war" to eradicate cancer will require new and different thinking and approaches on the part of everyone involved, and it will require a united front of the people, the government and the scientific community. With this solidarity and resolve we feel strongly that a real "war" against cancer can be fought and that the resources required to win will be made available.

The following Research Task Force Working Subcommittees will work individually to address the key points cited above, and collectively come together to develop a final product. The final product will represent our collective thinking on the advances/goals that are critical across all areas of cancer research, and the actions and the resources required to wage an all-out "war " to eradicate cancer.

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We realize that this list of Working Subcommittees could have been organized in several ways. Our goal was not to make each group comprehensive, but rather to gain a reasonable cross-section of each of the areas selected for analysis. We need to develop key actions, priorities and funding estimates for each of these major areas. The output from the Working Subcommittees will be consolidated to develop an overall estimate of what will be required to wage a real "war" to eradicate cancer. It is critical to obtain sufficient detail on the key advances and/or goals and the required actions to support budget projections from each Working Group.

Working Subcommittee Process and Timelines

Each of the Working Subcommittees will have a designated chairperson and a relatively small number of members. There are several approaches that could be used to arrive at priorities and funding estimates for each Working Group. The following process (barrier analysis) is suggested as an approach that each group should undertake to reach its goal.

The emphasis in this approach is on the identification of required advances or specific goals and an analysis of what barriers must be overcome to realize these advances or goals. Once the relative value of the advance or goal is compared with the difficulty of overcoming/removing the barrier, it becomes possible to prioritize. **In your analysis of what is required (the actions) to remove the barrier(s) and realize advances/goals, pay particular attention to barriers associated with the need for infrastructure, training, equipment, models, informatics, new information systems, changes in government regulations, etc.** Scientific barriers are obviously more difficult to analyze, but it may be possible to make estimates of what is required in terms of staff, support structures, etc. The output from each of the Working Subcommittees should be a set of actions that must be taken to remove barriers and achieve advances/goals. This should be tied to an estimated cost for the major actions proposed. You will likely need to make assumptions to arrive at estimated resource needs; if you use assumptions, please state them as part of your final approach. The suggested process is as follows:

- "Brainstorm the research area assigned to each working group and develop a list of key advances and/or goals that, if reached, could move the area forward, provide pivotal information, or may be a breakthrough.

- Rank these in order of priority (determined by group). It will be up to each Working Subcommittee to prioritize within its respective areas of cancer research. Assign a numerical value from 1-10 (low, average, high impact), with number "10" being the highest value or impact.

- Identify the barriers for each of the key advances/goals identified and assign a level of difficulty. Assign a numerical value (1-10) to the level of difficulty (easy, moderate or extremely difficult to remove), with number "10" being the most difficult to remove. The more difficult the barrier is to remove, the more consideration that your group will have to give to the actions and/or changes that will be required to overcome it.

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- Insofar as possible, prioritize the required advances/actions in their order of importance to waging an all-out "war" to eradicate cancer.

- Identify actions (**research areas, new mechanisms to support research, increases in current mechanisms such as RO1s and SPORES, infrastructure needs, national resource bases, informatics, etc.**) that can be taken to overcome the barriers and to make progress to achieve the advances cited. Where possible, make assumptions to estimate costs of each action, change, etc. (e.g., increasing numbers of patients on clinical trials to X%, based on current costs). If costs cannot be estimated, project the magnitude of effort and we will work, as a group, to determine a method for estimating the resources required.

We will bring the results from our respective Working Subcommittees together to achieve a final document. Our goal is to develop a working draft by the end of January 1998 and a final product by mid-March 1998. This is a large undertaking, but if we work closely together on this task, we can develop a detailed presentation of what we believe will be required to launch an all-out "war" to eradicate cancer. Thank you for your help.

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THE MARCH: SETTING THE FUTURE CANCER RESEARCH AGENDA

RESEARCH TASK FORCE WORKING SUBCOMITTEES

Instructions to Working Subcommittee Chairpersons

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- Determine what barriers currently exist to reaching the particular goals or making the specific advances. Determine the level of difficulty associated with overcoming a specific barrier and rank with the same scale 1-10 (low, moderate or high of difficulty), with "1" being low level of difficult and "10" being extremely difficult. Barriers might range from lack of appropriate tumor models to inadequate numbers of trained physicians to support significant increases in clinical trials for anti-tumor agents, etc.

- Select and prioritize those advances/goals that you determine from your analysis should be part of a significantly expanded "war" to eradicate cancer. From your barrier analysis, list the actions/changes that must occur to reach the important advances/goals developed from your Working Subcommittees. Develop an estimate of the cost (with assumptions) of each recommended action (develop, increase, build,

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etc.) required to achieve this advancement/goal. Summarize the cost of each required action in order to develop an overall cost associated with achieving the advance/goal defined. Each Working Subcommittee will report a series of specific advances/goals, required actions and the estimated costs/resources required to achieve major progress in their respective areas of cancer research. The specific actions will be important support for inclusion of the specific advances/goals in the final document. (Cost estimates can be developed as you feel is most appropriate, but if you use assumptions, please include them as support for your final estimates.)

Once we are well into the process, the Chairpersons will conference on a regular basis to determine where overlaps exist and who needs help.

We would expect your Working Group to finalize its product by mid February 1998. The Working Group Chairpersons will meet in early mid-March to develop the draft final document.

THE MARCH

Coming Together To Conquer Cancer℠
September 25 & 26, 1998

1730 K Street NW, 4th Floor, Washington, DC 20006
1-877-THE-MARCH / fax: 202.861.4794
web site: www.themarch.org

"President Nixon declared war on cancer in 1971. Twenty-seven years is a long time to fight a war—too long. I challenge you to be a hero in the war on cancer."
~ Gen. H. Norman Schwarzkopf (U.S. Army, Ret.)
cancer survivor and honorary chair, *THE MARCH*

Presenting Sponsor
THE SIDNEY KIMMEL FOUNDATION *for* CANCER RESEARCH

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SURVIVOR (noun) any person diagnosed with cancer from the time of discovery through the balance of life **MARCH** (verb) to move forward, advance or proceed with a steady rhythm **WAR** (verb) to struggle, contend or fight **HOPE** (noun) the feeling that what is desired is also possible **CON QUER** (verb) to be victorious

THE MARCH

Coming Together To Conquer Cancer℠

THE MARCH...Coming Together To Conquer Cancer is a momentous event in Washington, D.C., on September 25 & 26, 1998, and a continuing national campaign to win the war against cancer.

OUR MISSION

- To call on all Americans to make the cure and prevention of cancer the nation's top research priority.
- To demand greater government investment in the public and private sectors for all cancer research, treatment, education and prevention.
- To ensure access to clinical trials and quality care for everyone.

Cancer is a heartless killer that does not discriminate. It randomly attacks people of all ages, faiths, races, ethnic groups and economic backgrounds. We at THE MARCH believe everyone is physically, emotionally, spiritually and financially affected by cancer, whether it's the person diagnosed, their spouse, parent, child or other family and friends. And, that is why members of labor, business, environmental, religious, senior citizen, civil rights, minority, youth and women's organizations throughout the country are joining THE MARCH.

The weekend in Washington, D.C., begins the evening of Friday, September 25, 1998 with a candlelight vigil and interfaith service. The morning of September 26 will feature educational displays and other activities, followed at noon by the centerpiece of our campaign: a rally on The Mall.

"Thirty years ago, my cancer was life threatening. Today it's life challenging. I know with the right amount of research and medical help, we can beat this. I will see you at THE MARCH in September."

~ Scott Hamilton,
cancer survivor

ACROSS THE NATION

We hope to see you in Washington, D.C., on September 25 & 26, 1998, but, if not, you can join one of the hundreds of marches, rallies, candlelight vigils, town halls and other events being planned this summer and fall across the nation. Cancer survivors, caregivers, the medical and research communities and concerned citizens like YOU, will be coming together to demand an end to cancer.

Our grassroots organizing staff in Washington can direct you to an event in your area. And if there is not yet a MARCH-related event near you, they can give you ideas for starting one.

WHY JOIN THE MARCH?

- Because 1 in 2 men and 1 in 3 women will develop cancer in their lifetimes.
- Because 1.5 million Americans will be diagnosed with cancer *this year.*
- Because more than 535,000 Americans will die from cancer *this year.*
- Because cancer costs us ***more than $107 billion a year*** in direct medical costs and in lost productivity. That's about 50 times the federal investment in cancer research.
- Because for every $10 the government collects of your taxes, it spends only *one penny* on cancer research.

"I invite every member of every minority throughout the U.S. Join hands. Join hearts. THE MARCH to conquer cancer is the beginning of a bridge that I pray will span the world."

~ Annie Mary Johnson
cancer survivor

HOW YOU CAN HELP

- Bring or join a delegation from your community to THE MARCH in Washington, D.C., via buses, trains or planes.
- Add your name to the National Register of Americans who demand an end to cancer.
- Organize or join an activity in your community.
- Volunteer at THE MARCH headquarters.
- Call THE MARCH headquarters for more ideas and information about specific events.

ON SEPTEMBER 27, 1998, HOPE IS TURNED INTO ACTION

THE MARCH is only the beginning. On September 27, a successor organization needs to become a unified advocacy voice for all the constituencies dedicated to fighting cancer. Until cures are found, the organization will lead the crusade for a greater investment in cancer research and quality care.

WHERE YOU CAN REACH US

THE MARCH
Coming Together To Conquer Cancer
National Headquarters
1730 K Street NW, 4th Floor
Washington, DC 20006
toll-free phone: 1-877-THE-MARCH
e-mail: info@themarch.org
fax: 202.861.4794

Visit our web site at www.themarch.org

To make hotel reservations in the D.C. area call Corniche Travel at 1.877.267.6424 or DC Accommodations at 1.800.554.2220.

"September 25, 1998 is the beginning of the end of cancer."

~ Ellen Stovall, cancer survivor and *president of THE MARCH*

THE MARCH
Coming Together To Conquer Cancer™
September 25 & 26, 1998

- ❑ Enlist me in the war on cancer!
  Add my name to the National Register of Americans who demand an end to cancer.
- ❑ Yes, I'm interested in coming to Washington, D.C.
- ❑ Yes, I'm interested in planning an event in my community. *Please send me information.*

_____
Name
_____
Address
_____
City, State, Zip
_____
Day phone
_____
Eve phone
_____
Fax

Please print information and return to:
THE MARCH, 1730 K Street NW, 4th Floor
Washington, DC 20006

Presenting Underwriters
Bristol-Myers Squibb Oncology
CaP CURE/Milken Family Foundation
GlaxoWellcome
Pharmacia & Upjohn

Lovell Jones <lovell_jones @ gynonc.mdacc.tmc.edu>
09/17/98 01:20:38 AM

Record Type: Record

To: Jerold R. Mande/OSTP/EOP

cc:
Subject: March Information

9/16/98 7:47 PM
March Information

Jerry,

Here is the information I promised to sent to you. As I stated, I don't want this to become a public pissing contest, but I will not allow minorities and the medically underserved be used for an agenda that will not lead to a positive effect on the health of all Americans.

As I said to the ICC membership, you be the judge of this dialog!!!

TO: THE MARCH RESEARCH TASKFORCE CHAIRS

FROM: Lovell A. Jones, Ph.D.
Professor & Director
Experimental Gynecology/Endocrinology
Head, Breast Cancer Nutrition Research Group

SUBJ: Research Taskforce Report

After the conference call on Wednesday, I decided to read the draft again. This time reading it as someone who was not part of the cancer establishment; trying to see what impact this would truly have on the populations with whom the Intercultural Cancer Council's membership is most concerned. In reviewing it the last time, I looked at it with my cancer hat. This time I wanted to look at it in a holistic manner; trying to determine what would be its impact on minority and medically underserved communities. To be honest, given the past history of the NCI and NIH in general, I don't see it having the impact the we all would like to see. I have attached a copy of the Philadelphia inquirer article which basically says it all. When the news reporters began the investigation for their story I purposely stayed away from it. I did not talk to them until after the story was written and published. Please read it carefully and then ask yourself, will this have the impact we would like. I am not saying that the report is not outstanding, it is for the cancer establishment. I think that we all need to commend Anna for taking the time to put this together. I don't think that any of us realize the amount time and effort it has taken on her part to do this. As a scientist I have very little to add. However, stepping back from the report and looking at it as someone who has dealt with a variety of communities, I wonder if we have the real sensitivity to the issues; and I did say we. For instance as stated recently

in a Philadelphia Inquirer article "medical research has always been a white man's world. Until the early 1990s, more than 90 percent of the subjects of clinical trials -the studies that determine breakthroughs in preventing and treating diseases--were married white men. Although much has changed -- Congress passed a law in 1993 mandating that women and minorities be included in research -- much has not. One reason no one knows why blacks and some other ethnic groups suffer more of some diseases than whites is that no one has really looked." Nine reporters spent three months research this story and came up with that statement without any input from me!! The former director of the American Public Health Association, Dr. Fernando Trevino was stated as saying "The National Institutes of Health (NIH) spends a fraction of its $14 billion annual budget on studies to get at the heart of the problem. I've never seen an institution more reticent at looking at ethnicity and race than NIH. They've done relatively little to understand disparities. They want to pretend good science doesn't look at that." As I stated in one conference call, Dr. Louis Sullivan, president of Morehouse College in Atlanta and former secretary of Health and Human Services in the Bush administration, calls NIH officials "tone deaf" when it comes to research on minority health.

Last July a young Assistant Professor from the University of Texas wrote an editorial on white privilege. In it he defined in his mind what white privilege means. For instance "most importantly, when I (Robert Jensen) seek admission to a university, apply for a job, or hunt for an apartment, I don't look threatening. Almost all of the people evaluating me look like me - they are white. They see in me a reflection of themselves - and in a racist world, that is an advantage. I smile. I am white. I am one of them. I am not dangerous. Even when I voice critical opinions, I am cut some slack. After all, I'm white."

It is that last point that I want to stress because I don't want this to end in a discussion of race, but what we can do to make the document have a better chance of being effective. Remember that Anna did not take into account the changing demographics when she calculated her numbers. If we do not take into account this change, will we really have the necessary impact we are hoping for? I am concerned that we will not with the present document. For instance, will a change from 30% back to 10% have the impact we would like to see, I respectfully disagree with Dave's point of view. Even though I am not a physician, I do have some experience with clinical trials. Yes, as Dave Albert's said, to go from 2% to 10% is increasing such by 5 times. But again the question to be answered is whether or not 10% will accomplish our goals. Joe Simon's editorial makes a very strong case for the 30% or more. When we decided to go to the moon, we did not set limits on what we needed to accomplish because we did not have the infrastructure to do so. We built the necessary infrastructure because we had a vision of where we would like to be before the end of the 1960's. We need to have this vision regarding cancer research and it does not mean just more dollars. To accomplish what is needed should be a team effort; not just focused on one agency. Research has many components to it. In my opinion, one of the failures of the previous war on cancer was the lack of partnerships both within and outside of the federal health establishment. To formulate a document without any real reference to the Centers for Disease Control and Prevention and the other institutes at NIH, i.e. the National Institute of Environmental Health Sciences, is to repeat the errors of the past. And yes, I know that this is a research document, but research has many components to it.

Dr Gilbert Freidell and I spent a great deal of time formulating and trying to blend in statements which we felt would give this document that favor without changing the essence of it. I know that it late, but I do hope that such can be incorporated along with the changes suggested with regard to the private/public partnership portion.

Thank about Joe's editorial, a major impact on the cancer without any other major discoveries. A major impact on cancer in minority and underserved children, that is the most amazing part. Let me say that I am not arguing against the need for more research. I have and have had research grants from NCI and would love to see its budget increased. But not at the price of seeing no real change in the cancer rates in the communities which experience the greatest suffering and impact of cancer. Putting more money into a system that is "tone deaf" may lead us to a disaster none of us wishes to experience or have our children experience.

> ----------
> > Date: 9/9/98 10:44 AM
> > To: Lovell Jones
> > From: ELLEN STOVALL
> > Hi Lovell:
> >
> > I had a chance yesterday to read through your recommended changes to the
> > Research Task Force Report and would like to suggest you consider
> > incorporating your and Gil's thoughtful observations into a stand-alone
> > document that addresses "Applying Research Across All Populations."
> >
> > The more I read the report (with a frustrated editor's eye as well as an
> > advocate's eye), the more I realized how valuable your suggestion's are
> > and how much they need their own forum. This is where my angst has been
> > with regard to writing about how we get research to people. I think
> > what you are really trying to convey is how important all the
> > governmental and nongovernmental agencies and organizations outside of
> > NCI are to the process of Applied and Behavioral Research. The Quality
> > Care document doesn't address this head-on either, and I feel ICC could
> > craft this into a position statement about the kind of research that
> > would most benefit minority and underserved populations.
> >
> > What do you think?
> >
> > Hope all's well. With best regards,
> > Ellen

> > Hi Ellen:
> >
> > Thanks for your email. It is not too late for addressing the research and
> > quality of care needs of minorities and medically underserved to be
> > incorporated into the other two Task Force Reports. We stand ready to help
>the

> > leadership of the March to make this happen.
> >
> > Bottom-line, if the March is going to truly benefit all people the message
> > needs to be uniform and inclusive.
> >
> > Right now another generation of my wife's family is facing breast
cancer, 36
> > years old and a fourteen month old son. Following her mother, they thought
> it
> > would be another sister and not a niece!!! They were prepared for the
latter
> > and not this!!!
> >
> > Otherwise,things are going as well as can be expected!!!
> >
> > Lovell
> >
>
>
>Lovell:
>
>It's always difficult to hear about yet another young woman with a
>diagnosis of breast cancer. And especially when it strikes a family
>already burdened unfairly by this disease. I hope the long-term
>prognosis is good.
>
>Regarding your note, I am concerned that the only document that is ready
>for prime time from the three task forces is the Quality Care Document.
>The March has been asked to put together a hearing on the task force
>reports by Senators Mack and Feinstein which is slated for Friday,
>September 25th--two weeks from today. I know that Anna is still working
>on the Research Task Force report. I believe I understood Elin Greenburg
>to say on Wednesday that the report T.J. gave us in May was officially
>ICC's report. Is that your understanding?
>
>It would be, at the least, embarrassing, for our three task forces to
>not have our act together for the Senate hearing, regardless of whatever
>else we cannot agree to. At worst, our credibility will be shot and I
>am not willing to risk that, nor do I believe are you, Anna or Ellen.
>
>In any case, we are, for all purpose, out of time. I suggest we have a
>conference call among you, Anna, Ellen Sigal and me to reconcile this
>issue later today. I am free after 4:30 p.m. Eastern Time. Please let
>me know.
>
>Thanks, Lovell.
>
>Best, Ellen
>

>Hi Ellen,
>
>Unfortunately, I did not get your email until Saturday morning. I was at the
>White Thursday afternoon and at a White House event on racial health

>disparities out in Potomac, Maryland all day Friday. Yes, Elin was correct
>about the ICC Task Force Report. However, our report was one of messages as
>originally charted by the Board of the March. It was not meant to be a
public
>document. It was my impression that all three reports were to be combined
and
>presented to the Board; not before a congressional hearing prior to this
>happening. Yes, such was discussed regarding the research taskforce report,
>but it was my impression that the Board would have to sign off on these
reports
>and not just the respective members of the task forces. As it stands now, I
>can not support either document in their present form as addressing the needs
>of minority and medically underserved communities. If I did, I would be a
>hypocrite when I feel that they will not help the communities the ICC
>represents.
>
>As was stated in a memo to Rick Atkins, the ICC is presently working on a
>public document and will share it when it is completed.
>
>Ellen, it is already embarassing with regard to these documents!!! To
have two
>reports as we both seem to agree, not truly addressing the needs of
minorities
>and the medically underserved, gives the impression that these groups are
being
>used. Gil and I put considerable time in trying to address the research
>taskforce report to give it more of what we felt was needed. As both the
>research task force report and quality of life task force report now
stands, I
>know that the majority of the membership of the ICC will not support these
>reports. This is not a knock on either Anna or yourself, but that is the
truth
>of the matter.
>
>Again, I say that it is not too late to incorporate what has been
suggested!!!
>
>Lovell
>
>Here is the memo:
>
>To: Richard N. Atkins, M.D.
> Chair, The March Board of Directors
>
>From: Lovell A. Jones, Ph.D.
> Member, The March Board of Director
>
>Subj: Your Memo of September 8, 1998
>
>Rick, I found your memo interesting. Let me clearly address the several
points
>that erroneously indicate failures on my part as well as the Incultural
Cancer
>Council (ICC) staff.

>
>1. The accounting for the $36,000 grant to the ICC to help underwrite a special
>workshop to develop March messages from the perspectives of minority and
>medically uderserved communities has been sent to Peggy Harrison under separate
>cover.
>
>2. Members and advisors of the ICC (approximately 36 individuals) who were able
>to participate in the workshop held on April 2 - 4, 1998 constitute the ICC
>Task Force. Furthermore, ICC members made it clear to Ellen Stovall at its
>meeting in February that the term "outreach" was inappropriate. Therefore, in
>subsequent communications to Betsy Clark and Ellen Stovall, it was stressed
>that the term "outreach" should no longer be used in reference to the ICC Task
>Force efforts. Since that time, in all correspondence to the March, the ICC
>ceased use of the term "outreach" and has referred to this effort as the ICC
>Task Force.
>
>3. The ICC Task Force draft message report was delivered to The March
>leadership and Board Members on May 22, 1998. This document not only
>highlighted the ICC members' messages and priorities, but articulated very
>clearly charges to The March leadership. At the May 22nd meeting, you
>acknowledged receipt of the report and that it was in the hands of the members
>of the Board as well as some members of The March staff. (I should also state
>for the record that the report was not discussed at that meeting or any
>subsequent meeting)
>
>4. T.J. is correct. The Task Force report, although not written in a final
>edited form, represents the essence of The MARCH messages and priorities from
>the perspective of the Council and the communities it represents.
>
>5. Let me point out that the ICC Task Force was the first to produce a report
>for consideration by the entire March Board. At the meeting attended by ICC
>representatives and members of the March Board and staff in early July, it was
>clear that this document had not been read or taken into consideration by those
>of you truly making decisions in terms of developing the March messages. Let
>me also state for the record that our Task Force report, although in your
>possession for over three months, has never been brought before the full Board
>for review or discussion.
>
>6. Proof of this was your request for a summary of priorities. Had you read
>the report and given it careful consideration, you would have realized that
>such a request was redundant. However, in our attempt to try and meet needs of
>you and The March staff, the ICC staff agreed to provide yet another document
>summarizing the priorities. It should be noted that such was granted with

the
>clear understanding that this would occur after we had a chance to review the
>other Task Force reports. As you are aware, we did not receive other draft
>reports until late August.
>
>7. Having received those Task Force reports, it is clear that the heartfelt
>messages contained in the ICC Task Force report have not been taken into
>consideration. Furthermore, having reviewed the other reports, it is also
>clear that no standard guidance was provided for the development and
>presentation of the reports, and therefore they lack cohesiveness.
>8. Most importantly and in my opinion, neither the Research Task Force report
>nor the Quality of Care Task Force report as currently drafted would be
>supported by the majority of the ICC members. This poses a particular
problem
>in that it puts the ICC in the position of having to address these issues in
>its public document which may run counter to the recommendations of the other
>Task Force reports. Frankly, Rick, on repeated occasions I have attempted
>without success to convey this message to other Task Force leaders.
>
>9. As you know, we are formulating our Task Force report into a public
>document. I am aware that the Research Task Force report is also following
>this course. As T.J. indicated to you in her communications last week, we
will
>forward our public document upon completion.
>
>10. I would also like to state for the record that the Research Task Force
>report is the result of an extensive process which began over a year ago.
This
>Task Force report was supported by a March budget of at least $100,000, as
well
>as cash and in-kind contributions from other organizations, amounts yet to be
>determined. More over, it is evident that all three Task Force reports were
>generated virtually without a common theme. Yes, I am aware of "the
cause, the
>care, the cure" theme. But remember, this theme emerged in recent weeks.
>Furthermore, this theme is not evident in the other Task Force reports. As a
>result, taken together these reports lack synergy, focus and cohesiveness
which
>may limit their value.
>
>
>Bottom line Rick, the ICC Task Force report has been in your possession since
>May. Had you or anyone on your staff read it we would not be having this
>exchange of memos. In addition, to our report, at the meeting in July, Dr.
>LaMar McGinnis clearly summarized and articulated the four overriding
concerns
>of the ICC. Following the July meeting, Dr. McGinnis and T.J sent
>correspondence to you and Isabelle summarizing these points again.
Therefore,
>I don't feel that it is necessary, once again, to summarize them.
>
>As I stated at the outset, I found your memo curious at best. This memo is
>intended to clarify these important issues for the record.
>

> Furthermore, for the record, I will be participating in the Board meeting via
>conference call.
>

Lovell, I have substantial issues with your characterization of the research task force report. I believe that Ann went out of her way to incorporate any issues with minority populations that pertain to a research task force agenda. Frankly she accommodated your wishes more than other's that had legitimate concerns about their sections. They all compromised and are willing to have a consensus document.

I'm sorry that you are not happy, however this is a consensus document and there is no task force member that unilaterally can have all there wishes and opinions addressed. Many on this committee made substantial compromises to get a consenses document. I believe you have the ability to withdraw your name from this report if that is what you would like. Please call later in the day so we can decide on how to proceed. Ellen
>
That is it!!!

Lovell

BWGraphics

SURVIVOR (noun) any person diagnosed with cancer from the time of diagnosis through the balance of life

MARCH (verb) to move forward, advance or proceed with a steady rhythm

WAR (verb) to struggle, contend or fight

HOPE (noun) the feeling that what is desired is also possible

CONQUER (verb) to be victorious

THE MARCH

Coming Together To Conquer Cancer™

REPORT FROM THE MARCH RESEARCH TASK FORCE

PREPRESS COPY

REPORT FROM THE MARCH RESEARCH TASK FORCE

Commissioned by

THE MARCH—Coming Together to Conquer Cancer

September 25–26, 1998

October 1998

"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 RESEARCH TASK FORCE

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.

Research Task Force Chairpersons

ELLEN V. SIGAL, PH.D., CO-CHAIRPERSON
Vice Chairperson, THE MARCH—Coming Together to Conquer Cancer
Chairperson, Friends of Cancer Research

ANNA D. BARKER, PH.D., CO-CHAIRPERSON
Vice Chairperson, THE MARCH—Coming Together to Conquer Cancer
President and CEO, BIO-NOVA, Inc.

Research Task Force Board of Directors

JOHN R. DURANT, M.D.
Executive Vice President, American Society of Clinical Oncology

MARGARET FOTI, PH.D.
Executive Director, American Association for Cancer Research, Inc.

PHILLIP A. SHARP, PH.D.
Salvador E. Luria Professor and Head, Department of Biology Center for Cancer Research, Massachusetts Institute of Technology

ELLEN L. STOVALL
President, THE MARCH—Coming Together to Conquer Cancer
Executive Director, National Coalition for Cancer Survivorship

Research Task Force Subcommittees and Chairpersons

SUBCOMMITTEE 1
CANCER CAUSATION & ETIOLOGY RESEARCH
WEBSTER K. CAVENEE, PH.D.
Director, Laboratory of Tumor Biology,
Ludwig Institute for Cancer Research

SUBCOMMITTEE 2
CELL AND MOLECULAR BIOLOGY RESEARCH
STEPHEN B. BAYLIN, M.D.
Professor of Oncology and Medicine,
John Hopkins Cancer Center

SUBCOMMITTEE 3
CANCER THERAPEUTICS RESEARCH
PHILLIP A. SCHEIN, M.D.
Adjunct Professor of Medicine and Pharmacology,
University of Pennsylvania School of Medicine

SUBCOMMITTEE 4
TRANSLATIONAL RESEARCH I—THERAPEUTICS
MARC E. LIPPMAN, M.D.
Director, Lombardi Cancer Center,
Georgetown Medical Center

SUBCOMMITTEE 5
TRANSLATIONAL RESEARCH II—EARLY DETECTION
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SUBCOMMITTEE 7
CLINICAL RESEARCH & TRAINING
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SUBCOMMITTEE 8
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SUBCOMMITTEE 11
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SUBCOMMITTEE 13
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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 29% 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 now have unprecedented opportunities to achieve essential progress against cancer, but only if we move with real urgency to provide the necessary resources.

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-

search Task Force to define what is essential and possible in all areas of cancer research.

The Research Task Force Report includes a large number of specific recommendations aimed at expediting cancer prevention and treatment research and advancing the prospect for conquering cancer. These recommendations address issues ranging from funding to information sharing and streamlining to the creation of public-private partnerships and quality of life improvements. The recommendations appear in the following major sections of the Report:

- Recommendations I: Unprecedented Opportunities For Essential Progress in Cancer Research
- Recommendations II: Necessary Actions to Realize Essential Progress Against Cancer
- Recommendations III: Expected Return From our Increased Investment.

The recommendations presented herein are fully supportive of the NCI's Bypass Budget that delineates the needs and opportunities of the Nation's National Cancer Program. The Research Task Force recommendations represent broad research initiatives and actions needed to fully support an accelerated "war" to address the looming cancer crisis and ultimately to cure and prevent cancer for all Americans. The projected costs of these initiatives are estimates based on the status of current areas of cancer research and recommended levels of effort required.

Opportunities for Essential Progress

Basic Research. Most of our past investments in cancer research were utilized to build an incredibly powerful discovery resource, and the experts agree that we must accelerate our efforts to achieve the additional necessary breakthroughs required in basic research. For 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.*

> *. . . we must accelerate our efforts to achieve the additional necessary breakthroughs required in basic research.*

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 profiles 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.*

. . . support the research required to understand why cancer occurs in disproportionate rates in certain minority populations . . .

. . . ensure that the technologies and new medicines that derive from the discoveries and advances in clinical research detailed in these opportunities are applied to all populations . . .

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 mi-*

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.

There is a real and immediate need to establish highly effective relationships and partnerships among. . .government, academic and the private sectors. . .to conquer cancer.

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.*

It is specifically recommended that we increase our annual investment in cancer research to $10 billion over the next 5 years.

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

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.*

. . . if the required resources are dedicated now. . . required reductions in cancer incidents and mortality can be achieved.

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.

. . . our fundamental understanding of the basic molecular biology and genetics of cancer cells has virtually exploded.

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.

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.

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.

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.

Redouble Our Efforts in Basic Research and Discovery

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 know that cancer cells 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.

. . .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.

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..."

—*U.S. Senator Connie Mack, September 4, 1998*

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 unprecedented opportunities to develop new medicines and approaches to prevent, detect and treat cancer for all Americans. Hundreds of new compounds are under active study in academic and private pharmaceutical laboratories for application to the treatment and prevention of cancer. Discoveries from molecular biology and genetics are providing entirely new approaches to detect cancer and profile the risk of cancer in high-risk and normal individuals. Findings from basic behavioral and psychosocial research could save thousands of lives and reduce suffering in cancer patients now. The fact is that we do not have nearly enough trained scientists and physicians, nor the infrastructure and systems required to "translate" these discoveries into clinical applications.

Never have we understood the cancer cell and its myriad pathways as well as we do now.

We must act now to leverage our past investments and create specific national initiatives to accelerate the development of new cancer treatments; pursue novel strategies to detect cancer early; establish a national cancer prevention program; and fully support behavioral and psychosocial research to improve the quality of life of cancer patients. To create an environment in the academic sector where translational and clinical research will flourish requires that we bring basic and clinical scientists together from across key disciplines and diverse areas into "centers of excellence." *These centers should logically be located in our current cancer centers, and represent a new "translational research" culture that could focus on specific cancer sites and/or research areas such as drug development.*

To realize our goal of accelerated progress to conquer cancer, *it is critical that we act now to create a new overall national system for the "translation" of new discoveries that optimizes and maximizes collaboration and cooperation among academia, government and industry.* Building this new system also requires that we improve access to approved clinical trials and train the required clinical personnel. Lastly we must fully empower the NCI to spearhead these efforts on behalf of the Nation.

Capitalize on Exceptional Opportunities in Cancer Therapeutics

Never have we understood the cancer cell and its myriad pathways as well as we do now. Although there is still a lot to do, through basic research we have developed a working understanding of areas such as the cell cycle, signaling pathways by which the cancer cell transmits information and how tumors make their own blood supply (angiogenesis). Every day we learn more about specific genetic changes in cancer cells, ways that we can detect them and how immune cells respond to these tumor cells. This knowledge has allowed us to develop vaccines and new agents to boost the immune system. Evidence is accumulating that many of the abnormal communication pathways in tumor cells provide

We need to fully leverage the strengths of the pharmaceutical and biotechnology industries as essential partners in the development of new anti-cancer drugs.

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

Improve 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.

Early detection of cancer is our best hope for increased survival and cure of patients with cancer.

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 semi-conductor 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.

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

Defeat 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.

Our dream is the prevention of cancer for all Americans.

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 facilitate cessation 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.

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

ADDRESS EXCEPTIONAL NEEDS IN BEHAVIOR AND PSYCHOSOCIAL RESEARCH.

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.

. . . it is important to remember that cancer occurs in people; it is the individual, not just the cancer, who must be treated.

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 Schwartzkopf, cancer survivor and Honorary Chair of* THE MARCH

Recommendations II: Necessary Actions to Realize Essential Progress Against Cancer

Create a New "System" of Public/Private Partnerships to Implement and Accelerate the National Cancer Program

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

Develop a Comprehensive and Responsive National Cancer Clinical Trials System

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.

An aggressive increase in support of cancer clinical trials now will yield significant results in lives saved in years to come.

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 CaP CURE*

Train a Cadre of Critically Needed Clinician Scientists

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.

Investment is urgently needed to support a new training and research program for clinical research investigators, ideally at the Nation's cancer centers.

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*

Empower the National Cancer Institute and Free It of Bureaucracy

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.

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. . .

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.

Recommendations III: Expected Return From Our Increased Investment

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.

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.

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.

APPENDIX

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