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OA/ID Number: 13033
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Cancer Budget Fiscal Year 1999

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Andrea Martin • 415-543-2979

The Breast Ca Fund #: 331-5477

Breast Ca Action

Community Ca Project MA

Silent Spring Inst.

War on Ca too complicated for NCI only
Every agency will set aside \$x.

- Work safety

- labeling

- schools

the Oak Ridge Forum

Harold Freeman - President's Ca Panel

Dr. Lisc Butler ACS CA
surgeon

510-883-1095

Debra Axelrod

212-844-8212

Michel Gagner

212-410-3824

(Paul Hill)

Upper Cumberland open meetings. As a result, in a world where most public health advocates viewed tobacco manufacturers and farmers as indistinguishable parts of a monolithic evil empire, you were among the first to understand that tobacco farmers and their communities had not caused the tobacco problem and that there was value of driving a wedge between the growers and the industry.

In 1983 Congress started ^{the} working in earnest on a tobacco labeling bill

In October 1983, ~~movement toward a tobacco labeling bill had~~ stalled. The Senate Labor Committee, under Hatch's leadership, had passed a tough, single warning label: "WARNING: Cigarette Smoking causes Cancer, Emphysema, and Heart Disease; may complicate pregnancy; and is addictive." ^{Cong. Waxman is} Henry ^{had passed} had passed out of his subcommittee an even tougher set of rotating warning labels. But the legislation was stalled at the full Commerce Committee and there was a need for an honest broker, trusted by Dingell and Waxman, to dislodge it.

^{Your role in} ~~The events~~ ^{that follow have been reported in 2 books. (excerpts attached).} According to Mike Pertschuk in ^{his} ~~his~~ book *Giant Killers* (see ^{that} attached), he secretly approached you at a Friday breakfast chaired by him and Ben Palumbo and sounded you out on the labeling issue. Pertschuk wrote that you offered to be as helpful as possible without alienating the 10,000 tobacco farmers in your congressional district. Pertschuk then arranged for a meeting with you and Matt Myers.

^{the Myers with Myers} Following ~~that~~ ^{both} meeting, and again according to ^{is} ~~written accounts by~~ Pertschuk, and Richard Kluger in ^{his} ~~his~~ book *Ashes to Ashes*, you contacted Howard Liebengood, a former chief aide of Senator Howard Baker who was ~~new~~ with the Tobacco Institute, and began work on a compromise. What followed was a pattern of lies and treachery by the tobacco industry, which eventually so angered John Dingell and Charlie Rose, that not only did they help enact your labeling compromise, but it marked a turning point in the tobacco industry's relationship with Congress. As you will recall the industry did not bargain in good faith

You should be aware that while both Pertschuk and Kluger credit you as the author of the final labeling language, you are portrayed as an honest broker -- a friend of both tobacco and the public health. It is a very different image than the current image of you as a fierce foe of the tobacco industry that has emerged with your convention speech and advocacy of FDA's rule. It is possible in reading Pertschuk's and Kuger's accounts to conclude that while the labeling bill was a significant political victory because it was a defeat for the previously unbeatable tobacco lobby and marked a turning point, it was not a policy victory because of the compromises you forced on the public health community. ^{These books report that you supported} You are presented as being responsible for trading limits on industry liability for the warning labels and for eliminating the label on addiction.

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January 3, 1998

Government Ready to Boost Spending for Biomedicine

By ROBERT PEAR

WASHINGTON -- In his new budget, President Clinton plans to seek a substantial increase in federal spending on biomedical research, and members of Congress from both parties say they are virtually certain to approve an even bigger increase.

Science and politics point to the same conclusion. When Congress reconvenes this month, lawmakers will be seeking more money for the National Institutes of Health because they believe that researchers can exploit promising scientific opportunities like new advances in cancer treatment. They also believe that such investments will be popular with voters in an election year.

"We are in a golden age of discovery, one unique in human history," said Dr. Richard Klausner, director of the National Cancer Institute, expressing the view of many scientists and lawmakers.

Even before Clinton formally sends his budget request to Capitol Hill early next month, NIH officials have told Congress that the federal government must increase its support of biomedical research because managed-care companies, with their emphasis on the bottom line, have reduced the amount of money available to conduct clinical trials of promising treatments. In the past, academic health centers used surplus revenues from patient care to supplement the money they received from the government, but such surpluses are drying up.

The budget of the health institutes has doubled in the last decade, to \$13.6 billion this year. Nonetheless, lawmakers of both parties say they intend to accelerate the increases, and they talk seriously about trying to double the budget of the NIH in five years. That would require annual increases averaging 15 percent, far more than the latest increase of 7.1 percent, from 1997 to 1998.

Anne Thomas, a spokeswoman for the National Institutes of Health, said NIH officials had begun internal discussions so they could answer questions from Congress about how they would use a big infusion of federal money. In setting priorities, Ms. Thomas said, the agency's director, Dr. Harold Varmus, is asking, "Where are the scientific opportunities, and what are the public health needs?"

"Where are the scientific opportunities, and what are the public health needs?"

The Senate voted 98-0 last year to endorse the goal of doubling the agency's budget in five years, but did not say where the money should come from.

Two influential Republicans, Rep. John Edward Porter of Illinois and Sen. Arlen Specter of Pennsylvania, said they were determined to find the money. They are chairmen of the Appropriations subcommittees responsible for health care spending.

In an interview, Porter said that he had discussed the question at length with Speaker Newt Gingrich, and that Gingrich "supports doubling the NIH budget in five years, within the overall context of a balanced budget." At a forum on health issues in Smyrna, Ga., in November, Gingrich said he wanted to double spending on biological research.

Porter said Clinton had sought rather modest increases for the health institutes in recent years, knowing that Congress would provide more money than he requested. "That is not honest budgeting," Porter said.

Republican senators, including Connie Mack of Florida and Alfonse D'Amato of New York, said they would join Democratic senators like Tom Harkin of Iowa and Edward M. Kennedy of Massachusetts in seeking big budget increases for the health institutes. Some Republicans were skeptical about such spending after they took control of Congress in 1995, but they have since been persuaded that biomedical research is an engine of economic growth, with many commercial uses for biotechnology, agriculture and the drug industry.

Kennedy has proposed using money from new tobacco taxes to finance medical research, an idea that seems to be gaining favor on Capitol Hill.

In a recent interview with The New York Times, Clinton sounded a theme that White House officials said would show up in his State of the Union Message late this month. "I do believe that in scientific terms, the last 50 years will be seen as an age of physics and an age of space exploration," Clinton said. "I think the next 50 years will very likely be characterized predominantly as an age of biology and the exploration of the human organism, especially with the completion of the human genome project, which I think will literally explode what we know about how to deal with health issues."

A major goal of the genome project is to understand and decipher the human genetic code, identifying genes responsible for particular diseases.

Within the administration, Vice President Al Gore has been a strong supporter of high-technology projects at the health institutes. He has joined Donna Shalala, the secretary of health and human services, in seeking an increase of more than \$1 billion for the agency in the fiscal year that begins on Oct. 1.

Patients' groups concerned about specific diseases, doctors and medical schools are forming a coalition to lobby for a 100 percent increase in the institutes' budget over the next five years. Terry Lierman, president of Capitol Associates, a lobbying concern, said Friday: "We plan a grass-roots campaign inside and

a lobbying concern, said Friday: "We plan a grass-roots campaign inside and outside the Beltway. It will be run the same way Northrop Grumman lobbies for the B-2 bomber."

Members of Congress said they would look to NIH officials, rather than to the White House, for guidance as they decide this year on the appropriate level of spending for biomedical research. Klausner, the director of the National Cancer Institute, recently sent Congress a blueprint for spending \$3.19 billion in the next fiscal year, up from the \$2.55 billion provided to the cancer institute this year.

"Knowledge about the fundamental nature of cancer is exploding," Klausner said.

The budget request, reflecting the professional judgment of government scientists, includes these proposals:

- The number of cancer research and treatment centers around the country should be increased to 70, from the current 57.
- The government should authorize "a fivefold increase over the next five years in the number of people participating" in clinical trials of new techniques for the prevention and treatment of cancer. At present, 300,000 people participate in such studies. The goal is "to insure that all people who wish to participate in a clinical trial are able to do so," Klausner said.
- Congress should provide an additional sum of \$40 million next year so the Government can finance the top 40 percent of applications for research. The cancer institute says it now awards grants to the top 25 percent. (Applications are evaluated by panels of experts, through a competitive process of peer review.)

In appealing to Congress for more money, Klausner said the growth of managed care and other changes in the health care industry posed "a very real danger for the continuation of cancer research and our continued progress against cancer." Health maintenance organizations and other insurers are increasingly reluctant to pay even the costs of routine care for patients in early clinical trials, he said.

The cancer institute is seeking \$60 million next year to subsidize the salaries of 600 scientists at the 57 cancer centers, so they will have more time for research.

Members of Congress said they would seriously consider such requests. "What we are doing today, making scavengers and beggars of the best in biomedical research, is just simply wrong," D'Amato said.

Harkin, who wants to establish a special government trust fund for medical research, said: "Of the \$1 trillion spent on health care in America every year, a paltry 2 percent is spent on research. The United States has spent more on Pentagon research and development in the last four years than we have on

medical research since the turn of the century."



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TELEFAX TRANSMITTAL

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Fax No. (301) 402-2700
Confirmation Phone No. (301) 496-2433

DATE: January 6, 1998TO: Josh GorhamFAX NUMBER: 202 395-4993PHONE NUMBER: 202 395-9188NUMBER OF PAGES (INCLUDING COVER PAGE): 12☒ PLEASE CALL TO CONFIRM RECEIPT. THANK YOU.

REMARKS:

Bunny C

Cop: T12
12T(2)
MG

January 5, 1998 11AM

To: Josh Gotbaum

From: Harold Varmus



Thanks for your very constructive contributions to yesterday's conversation.

I am sending you three things:

- Draft language from the NIH FY1999 Budget Justification, indicating the approach and emphasis we would like to provide for the President's initiatives on cancer and diabetes.
- A list of the new or expanded projects that are completely or partially devoted to cancer research and supported by Institutes and Centers other than the NCI. I have tried to be conservative in developing this list; even so, as you can see, the assigned dollars are significantly above the \$33 million that separates OMB guidance and the NIH proposal for the NCI. I believe that a demonstration of the breadth of Institute involvement in cancer research displays both the depth of NIH's commitment to cancer and the multi-disciplinary way in which we do our best work.
- A list of new or expanded projects that address diabetes mellitus. None of these are to be paid for by the \$30 million from the Balanced Budget Agreement (as you know, there is no annual dollar increase prescribed by the amendment, and I am counting only increases). The net effect is clearly a strong commitment to significant expansion of the diabetes portfolio in several Institutes, including NIDDK. Note that I have not included here several infrastructural projects (training, equipment, etc.) that will also benefit diabetes research.

Note that the dollars for projects on these lists are additions to the general (quasi-inflationary) increase of nearly 3% provided to all Institutes.

I believe that the approach we are taking will allow all of us to realize our objectives, and I very much appreciate your patience in this final phase of the budget process. Please give me a call when you have reviewed these items and I will be glad to provide you with anything else you need.

From the Congressional Justification (DRAFT)

In the ensuing paragraphs, we describe some of our specific research targets for FY1999. It is part of the genius of the NIH that each of our goals can be approached by multiple Institutes and Centers, all making unique contributions to complex problems to human disease, through disciplines ranging from chemistry to behavioral science.

A Multi-dimensional Attack on Cancer. We are rapidly learning about the molecular changes that are fundamentally responsible for the abnormal properties of cancer cells. In response to such progress, the President's budget request includes a major expansion of our cancer research portfolio, reflecting our conviction that these advances can lead to better means to prevent and treat the many forms of this common disorder. The cancer initiative will be supported largely through the work of the National Cancer Institute, but will also involve new and enhanced activities in more than a dozen other Institutes and Centers. These many programs will enhance our knowledge of the genetic basis of both rare and common forms of cancer; increase the number of targets for intervention through work with animal models and biochemistry; explore new ways to identify, modify, deliver, and test candidate drugs and other novel therapies; develop better imaging methods for detecting cancers and for monitoring them during therapy; establish information networks that expedite clinical trials and communicate findings to the public; foster the training of cancer investigators; recruit patients into clinical trials; address behavioral issues related to the prevention of cancer, the detection of predisposing mutations, and the treatment of cancer patients; and seek new means to alleviate symptoms of cancer, including pain.

A continuing emphasis on diabetes. In view of the still increasing toll that diabetes takes on our citizens, the President's budget request contains \$30 million in new projects that will explore the genetic and biochemical basis of the several types of diabetes; advance our knowledge of the cardiac, ocular, and large vessel damage that occurs in diabetic patients; offer new understanding of nutrition and obesity and their roles in diabetes; expand prevention and treatment trials; and investigate the potential for regeneration of insulin-producing cells. Other new projects have the potential to identify molecular targets for intervention and to advance drug development and delivery. These projects very significantly extend the new diabetes research initiated last year as a result of the substantial increase appropriated to the NIDDK and the \$150 million provided over five years through the Balanced Budget Act.

NATIONAL INSTITUTES OF HEALTH
FY 1999 New and Expanded Cancer Projects Outside NCI

Institute	Project	Cost	Notes
NIHHS	Development of Alternative Models for Carcinogenicity and Toxicity Testing	1,000	
	Modulation of Cellular Redox Status and Cancer	500	
	Role of Signal Transduction in Environmentally Induced Diseases	500	
	Environmental Genome Project	4,724	To identify genes that determine environmental risks to cancer
NIA	Telomerase and Chromosomes	1,500	Genome maintenance in cancer cells
NIDCD	Pathogenesis of squamous cell carcinoma	1,000	
NIDA	Neurobiology of Addiction	1,000	All projects address nicotine (tobacco) addiction
	Prevention of Drug Use Among Children and Adolescents	1,000	"
	Continuation and Expansion of Medications Development and Behavioral Therapies Program	1,500	"

**NATIONAL INSTITUTES OF HEALTH
FY 1999 New and Expanded Cancer Projects Outside NCI**

Institute	Project	Cost	Notes
NINDS	Brain Molecular Anatomy Project	1,000	Part of project relevant to brain cancers
	Pain Research Initiative	1,500	Part of project attributed to cancer pain
	Initiative in CNS Stem Cell Biology	500	
	New Approaches in Neuroradiology for Diagnosis and Treatment	2,000	Addressed to brain cancers
	Brain Tumor Genome Anatomy Project Joint Effort with NCI C-GAP	1,500	
NICHD	Tissue Repair and Bioengineering	1,000	Rehabilitation after cancer treatment
NLM	Genetics Medicine	1,500	Cancer related components of large projects
	Computers in Medicine and Research	1,000	"
	Health Information	2,000	"
NIDDK	Hepatitis C Initiative	2,000	HBV is major cause of liver cancer; only half of costs listed

NATIONAL INSTITUTES OF HEALTH FY 1999 New and Expanded Cancer Projects Outside NCI			
Institute	Project	Cost	Notes
NIAAA	Alcohol and Hepatitis C	300	
NIAID	Hepatitis Animal Model Study Groups	2,000	
NIDR	Genetic Mechanisms in Oral Cancer	2,000	
NHLBI	Hematopoiesis: The Ideal Tissue Model for Bioengineering	2,000	Relevant to leukemia and recovery from chemotherapy

NATIONAL INSTITUTES OF HEALTH
FY 1999 New and Expanded Cancer Projects Outside NCI

Institute	Project	Cost	Notes
NIGMS	Therapeutics Development: * Structure of Membrane Proteins * Discovery of Novel Ligands as Drugs and Biological Probes * Understanding Individual Variability in Drug Responses * When, Where and How Should Drugs be Delivered? * From Gene Sequence to Protein Function	6,000	Part of multi-phase approaches to drug development attributable to cancer drugs
NIH	End-of-Life Care	1,000	Portion relevant to cancer patients
TOTAL		84,024	

NATIONAL INSTITUTES OF HEALTH

FY 1999 New Diabetes Projects

Institute	Project	Cost	Notes
NIDDK	Neuroendocrine Influences on Energy Balance and Obesity	5,000	
	Intracellular Transport and Signal Transduction	1,000	
	Pathogenesis of Diabetes	1,000	
	Diabetes Prevention and Treatment Initiative	10,000	
	Developmental Biology and Organ Regeneration	2,000	
	Genetics	2,000	Part of a larger project
NHGRI	Genetics of non-insulin dependent diabetes	1,500	Part of a larger project
NIHLEI	Diabetic Cardiomyopathy	1,500	
	Medical and Revascularization Investigation in Diabetes (MARID) Trial	2,500	
	Genetic Factors Affecting Response to Drug Therapy and Nutrition	1,000	Part of a larger project
NEI	Neovascularization in the Retina	2,000	

NATIONAL INSTITUTES OF HEALTH FY 1989 New Diabetes Projects			
Institute	Project	Cost	Notes
NIGMS	Therapeutics Development		Part of a \$18 million multi-component program
	* Structure of Membrane Proteins * Discovery of Novel Ligands as Drugs and Biological Probes * Understanding Individual Variability in Drug Responses * When, Where and How Should Drugs be Delivered? * From Gene Sequence to Protein Function	2,000	
TOTAL		31,500	



NATIONAL GOVERNMENT RELATIONS OFFICE

April 16, 1998

Mr. Jerry Mande
436 Old Executive Office Building
Washington, D.C.

Dear Jerry:

Attached is the draft overview of the National Cancer Plan. There is a work group meeting to review this here in D.C. on the 20th of April. Please use this with discretion as we are in the support building phase. As per the issues we discussed, can we talk this week and review?

Hope you're well. We are working hard here striving to meet our mission. Thanks as always.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Hay Crawford".

Linda Hay Crawford
National Vice President
Federal and State Government Relations

cc: Harmon Eyre
encl: Confidential



December 22, 1997

Jerry Mande, JD
Special Assistant
Office of The Vice President
Room 436, OEOB
Washington, DC 20501

Dear Mr. Mande:

As you are aware, more than 1 million Americans face a diagnosis of cancer, and almost 500,000 people will lose their battle to this disease this year alone. The news is not all bad; 25 years after the signing of the National Cancer Act, we have witnessed the first ever sustained decrease in death rates from cancer, and in 1998, we will mark a decrease in actual deaths. More important, we know why we are seeing this downturn - through the continued application of all that we have learned about how to prevent, screen, diagnose cancer over the years.

That good news is most emphatically not a signal for complacency. Breaking down the statistics we find that poor, minority and other underserved Americans still bear a disproportionate share of the burden, suffering and death from cancer - and most of that is unnecessary. The simultaneous aging of American along with increasing ethnic and cultural diversity of our communities underscores the challenges facing us in translating and equitably applying the miracles of research. A renewed War on Cancer - the final chapter - must be fought in the trenches, a partnership between the public, private and independent sectors, and with increased coordination and focus.

As the nation's largest community-based army fighting to eliminate cancer and its burden, the American Cancer Society has taken a careful look at its own cancer control agenda - identifying new opportunities in research, education, service and advocacy which match the unique strengths and capabilities of our organization's greatest resource - our volunteers. We have enclosed copies of two critical internal reports which summarize our findings and provide you with a blueprint of what we bring to the table, so that we better coordinate our efforts with other cancer fighting agencies and organizations.

The American Cancer Society's research program is unparalleled - we're proud to have funded 27 Nobel Laureates early in their careers. But in keeping with new opportunities and challenges, we have retooled this \$90 million annual program so that it best complements the research being funded through NIH, DOD and other public sector agencies, as well as the private-based efforts

Mr. Jerry Mande
Page Two

of pharmaceutical companies. We will continue to invest in young scientists - bringing new, fresh ideas to the cancer research marketplace, while providing the training and support for those early in their careers which ensure that science remains a viable field of work for them.

Translating state of the art into state of the practice is an even tougher challenge and no one group can do it alone. Our report on "Cancer Control" identifies those areas, based on science and organizational experience, which can have the greatest impact on cancer in the near and long terms. You are familiar with our declared goal to work with this Administration and Congress to enact a comprehensive national tobacco control policy that will save the lives of more than 1 million children living today by preventing them from ever starting to smoke, or helping them to quit. In addition, we will work this year to ensure that poor and underserved women facing cancer have access to the proven screening regimens and quality medical care that will boost their cancer survivor rates to the equivalent of educated, insured women who have so benefited, or that those elderly Americans living with cancer have access to cancer specialists and clinical trials that can mean the difference between quality and longevity of their lives.

The American Cancer Society has the expertise, network and access to take our 86 years of programs and science and now actualize that knowledge into an effective national cancer plan for prevention and control of this disease. The Society has the commitment to cut the mortality rate of cancer by 50% by the year 2015. Certainly tobacco use prevention is a major part of that effort, but is joined with other important initiatives in breast, colorectal, prostate cancer and reaching underserved Americans.

We look forward to the opportunity to explore our recommendations with The Vice President, and commend the interest and leadership that has been shown to date. If you have any immediate questions, please contact either one of us at 202-661-5700. We look forward to discussing these ideas with you shortly.

Sincerely,



Linda Hay Crawford
Strategic Business Manager, Advocacy
National Vice President for Federal
and State Government Relations



Kerrie B. Wilson
National Vice President, Policy Advocacy

Enclosure:
Blue Ribbon Committee Report on Cancer Control
Blue Ribbon Committee Report on Research

BLUE RIBBON ADVISORY COMMITTEE REPORT

OCTOBER, 1995



THERE'S NOTHING MIGHTIER THAN THE SWORD

Blue Ribbon Advisory Committee Report

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I. EXECUTIVE SUMMARY

In 1994, the American Cancer Society appointed a Blue Ribbon Committee (BRC) to examine its research and professional training functions and offer recommendations to ensure that those programs achieve their potential in cancer prevention and control. This Executive Summary contains, in a succinct manner, the BRC's recommendations. The next section, the Report of the Blue Ribbon Advisory Committee, offers further background and explanation for these recommendations.

Besides strengthening the American Cancer Society's research and professional training programs, these recommendations serve the American Cancer Society's vision for the future which calls for the development of a highly focused, high-impact cancer research program. These recommendations attempt to fulfill that vision by suggesting changes to the current programs so that they complement, but do not duplicate unnecessarily, other organizations' cancer research and training programs by focusing on beginning scientists; initiating a program of targeted research; and further strengthening the Society's commitment to epidemiologic research, psychosocial, behavioral and policy research, and cancer prevention. The BRC recognizes that the American Cancer Society's research and health care professional training programs have been successful in the past; these recommendations intend to strengthen already strong programs.

Following are the BRC's recommendations:

BLUE RIBBON ADVISORY COMMITTEE REPORT

A. GENERAL PRINCIPLES GOVERNING ALL RESEARCH AND TRAINING

1. The American Cancer Society should strengthen and refine its research and training programs.

American Cancer Society-sponsored research and health care professional training should continue to receive high priority because they meet societal needs of critical and growing importance and are central to the mission of the American Cancer Society. The BRC is concerned by the threats of absolute reductions in research funding and the current real reductions in the rate of growth of research funding by the federal government, industry, and non-profit organizations. The BRC therefore urges the American Cancer Society to restore its research commitment to the highest levels of support possible.

2. Investigator-initiated, peer-reviewed research should remain the basis of the American Cancer Society's extramural research program.

Historically, offering individual researchers the resources to pursue novel ideas (investigator-initiated research) has been the most successful method of generating new scientific knowledge. Combined with high-quality peer review, investigator-initiated research represents an optimal method of performing worthwhile research. While embracing new forms of distributing research funds, the American Cancer Society should maintain its solid foundation in peer-reviewed basic, preclinical, clinical, behavioral and epidemiologic investigator-initiated research.

3. Cancer control grants should be subjected to rigorous review and assessment in terms of the American Cancer Society's goals.

The BRC recognizes the need to fund specific cancer control activities that are neither basic nor clinical research under a category called "cancer control grants." Such grants should be reviewed by the Council. Some exceptions to this review mechanism would be allowed under certain circumstances. Some cancer control programs should be encouraged to become self-sufficient through the attainment of independent funding

4. All research and training applications should undergo appropriate pre-award peer review and post-award evaluation of their accomplishments, progress, priorities, and relevance to the American Cancer Society goals.

The research grants program of the American Cancer Society has one of the most highly regarded peer-review systems in the world. This system should be expanded to cover all aspects of the American Cancer Society's research and training programs. All recipients of American Cancer Society awards and grants should be tracked so that their impact can be measured against the American Cancer Society's priorities and overall progress in cancer control. Priorities and programs should be periodically reviewed, with regular adjustments to reflect changing needs and goals.

BLUE RIBBON ADVISORY COMMITTEE REPORT

B. RECOMMENDATIONS TO FOCUS THE RESEARCH AND PROFESSIONAL TRAINING PROGRAMS IN ACCORDANCE WITH THE AMERICAN CANCER SOCIETY'S MISSION AND MEET IDENTIFIED NEEDS.

1. The American Cancer Society's research and training grant programs should emphasize support for investigators and health care professionals at the beginning of their careers.

The future of cancer control lies with the next generation of researchers and teachers, the very people most at risk of reduced support by other agencies. In order to continue the momentum of discoveries of past decades, and to provide the launching pad for future advances, the BRC believes that it is vital to support beginning investigators and teachers (within their first eight years after training) to develop the necessary skills to continue exploring frontiers in cancer control. This is a gap the American Cancer Society can fill -- particularly since the National Institutes of Health and other funding sources do not specifically support this category of cancer researchers and teachers.

2. The American Cancer Society should promote targeted research in areas of high priority and opportunity.

The concept of funding targeted areas of research represents a new direction for the American Cancer Society. The BRC notes that targeting areas of research provides the flexibility to focus on areas of prime interest to the organization and to the public that may not have yet attracted adequate applications by scientists. The BRC therefore recommends that up to 10% of extramural research funding be initially placed in specifically targeted

research areas. All research applications, including targeted research, should be peer reviewed.

3. The American Cancer Society should increase its emphasis on psychosocial, behavioral, and policy research to fulfill unmet needs, especially in cancer prevention and technology transfer over a range of cancer issues.

The American Cancer Society was among the first organizations to recognize the importance of psychosocial and behavioral research and to develop a specific program for funding research in this area. In addition to its external funding in this area, the American Cancer Society recently inaugurated a new intramural research program to examine behavioral factors in cancer prevention and treatment. Research in these areas, which include some of the more complex health questions of our time, will enable the American Cancer Society to enhance prevention and early detection programs and to improve patient care. The BRC therefore recommends that at least 5% of extramural research funding initially be placed in psychosocial, behavioral, and policy research.

4. The American Cancer Society should maintain the Institutional Research Grants program.

The Institutional Research Grants program, which awards funds to institutions that in turn make awards to young investigators, is an important vehicle for achieving many of the American Cancer Society's goals in research funding. While encouraging continued support for the Institutional Research Grants program, the BRC recommends that review and tracking of recipients' successes be enhanced and that the association between

BLUE RIBBON ADVISORY COMMITTEE REPORT

American Cancer Society Divisions and the recipient institution be strengthened so that the American Cancer Society can be better acknowledged as the source of these awards.

5. The Research Development Program should be maintained.

The BRC recommends that some flexible discretionary funds, up to 1% of the overall research budget, should be available for the National Vice President for Research to fund projects that are promising, but risky. The Research Development Program should be renamed as the Research Opportunity Fund to better reflect the goal of this program. However, the new Research Opportunity Fund should retain the Research Development Program's ability to rapidly fund grants through a simplified application process which has been unique to the American Cancer Society. In these times of rapid change and great opportunity in biomedical research, the ability to quickly fund potentially important, new projects may create opportunities and rapid progress in new research areas.

6. Intramural American Cancer Society research should be strongly supported.

Due to the foresight of previous policies and investigators, the American Cancer Society's Epidemiology and Surveillance Research program has at its disposal extraordinarily comprehensive data from Cancer Prevention Studies I and II (CPS I and II). CPS II data need to be further exploited to understand the complex relationships between personal behavior (e.g., tobacco use), environmental exposures, genetic predisposition, and cancer risks. The new Behavioral Research Unit is another important area for future intramural research that should provide insights for understanding the cancer problem in the United States. The BRC believes that intramural research is an

important part of the overall American Cancer Society research program. In order to maintain long-term effectiveness and high-quality, intramural research should undergo the same rigorous level of peer review as applicants for extramural research.

7. Personnel awards should be consolidated and focused on beginning investigators.

The personnel awards of American Cancer Society have served the vital purpose of offering scientific and health care professionals opportunities for specific training in the field of oncology. Currently, a variety of awards are offered to researchers, physician scientists, nurses, social workers, and other health care professionals at various stages in their careers. The BRC believes that supporting the training and development of careers in health care education should be an integral part of the American Cancer Society's priorities but the current wide array of awards should be simplified and rationalized. Some programs have accomplished their goals and should be discontinued.

8. Extramural collaborative activities should be encouraged.

As a way of maximizing its impact, the American Cancer Society should consider, in a systematic way, participation in outside collaborations. Examples of successful past collaborations include the ASSIST trial with the National Cancer Institute for tobacco control and the breast and cervical cancer detection programs with the Centers for Disease Control and Prevention. Additional opportunities exist in areas of vital interest, such as tobacco control policy research, that would be subject to political pressures aimed at federal funding. The American Cancer Society has the option of contributing money, professional cooperation, strategic direction, and other components critical to cooperative

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efforts to achieve cancer control. The benefits of such collaborations need to be weighed in relation to the American Cancer Society's mission. The strengths and weaknesses of individual collaborative projects should be clearly defined.

C. PROPOSED POLICY CHANGES

1. The Division Research Grants programs should be discontinued.

Historically, a few of the American Cancer Society's 57 Divisions have funded their own research grant programs. The BRC believes that even though it has been useful in the past to devote funds at the Division level to extramural research, it is not equitable or efficient for a few Divisions to create individual infrastructures to perform peer review and to sequester funds restricted to local research. The BRC therefore recommends that all Division Research Grant programs be discontinued during a three-year phase-out period. Divisions are encouraged to use unrestricted donations to fund those local research projects that have been approved through the National peer-review process

D. ADMINISTRATIVE RECOMMENDATIONS

1. The BRC should reconvene in approximately three years to evaluate progress toward fulfilling the recommendations in this report.

To ensure that the recommendations in this report which are approved by the Board of Directors are initiated and carried out and to evaluate the early outcomes of the

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recommendations, the BRC suggests that it should reconvene in approximately three years.

The BRC believes these recommendations offer the American Cancer Society the best opportunity to develop balanced programs in research, health care professional training, and cancer control to ensure that the American Cancer Society will continue to make significant contributions in the understanding of the biology of cancer, the prevention of cancer, and the early detection and treatment of cancer. The evolution of these programs should be considered an ongoing process -- one that routinely uses objective evaluation to guarantee that these programs remain vital to the organization's mission and that they reflect and contribute to the environment in which they exist.

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Illustration 1: Summary of recommendations in BRC Report

SUMMARY OF RECOMMENDATIONS IN BRC REPORT	
A. GENERAL PRINCIPLES GOVERNING ALL RESEARCH AND TRAINING	
1. The American Cancer Society should strengthen and refine its research and training programs. 2. Investigator-initiated, peer-reviewed research should remain the basis of the American Cancer Society's extramural research program. 3. Cancer control grants should be subjected to rigorous review and assessment in terms of the American Cancer Society's goals. 4. All research and training applications should undergo appropriate pre-award peer review and post-award evaluation of their accomplishments, progress, priorities, and relevance to the American Cancer Society goals.	
B. RECOMMENDATIONS TO FOCUS THE RESEARCH AND PROFESSIONAL TRAINING PROGRAMS IN ACCORDANCE WITH THE AMERICAN CANCER SOCIETY'S MISSION AND MEET IDENTIFIED NEEDS.	
1. The American Cancer Society's research and training grant programs should emphasize support for investigators and health care professionals at the beginning of their careers. 2. The American Cancer Society should promote targeted research in areas of high priority and opportunity. 3. The American Cancer Society should increase its emphasis on psychosocial, behavioral, and policy research to fulfill unmet needs, especially in cancer prevention and technology transfer over a range of cancer issues. 4. The American Cancer Society should maintain the Institutional Research Grants program. 5. The Research Development Program should be maintained. 6. Intramural American Cancer Society research should be strongly supported. 7. Personnel awards should be consolidated and focused on beginning investigators. 8. Extramural collaborative activities should be encouraged.	
C. PROPOSED POLICY CHANGES	
1. The Division Research Grants programs should be discontinued.	
D. ADMINISTRATIVE RECOMMENDATIONS	
1. The BRC should reconvene in approximately three years to evaluate progress toward fulfilling the recommendations in this report.	

BLUE RIBBON ADVISORY COMMITTEE REPORT

Illustration 2: Recommendations of the Blue Ribbon Advisory Committee regarding current programs

Recommendations of the Advisory Committee on Research and Medical Grants regarding <u>current</u> programs	
CURRENT	PROPOSED
I. New or Changed	
Project Grant	Limit to Junior Investigators
Physician Research Training Award Junior Clinical Research Award Clinical Oncology Career Development Award	Combine into a single "Clinical Research Training Award for Junior Faculty"
Research Professorship Clinical Research Professorship	Limit to 5 years plus one 5 year renewal
II. Continue	
Postdoctoral Fellowship	Continue
Institutional Research Grant	Continue
Research Development Program	Continue, but simplify and rename: Research Opportunity Fund
Intramural Research Program	Continue
Cancer Control Programs	Continue
Collaborative Activities	Continue
Cancer Control Career Development Award Physician Training Award in Preventive Medicine Clinical Oncology Social Work Traineeship Scholarship in Cancer Nursing	Continue, pending evaluation
III. On Hold/Discontinue	
Professor of Clinical Oncology Professor of Oncology Nursing	On hold, pending evaluation
Clinical Oncology Fellowship International Fellowship (UICC) Scholar Award Junior Faculty Research Award Cytotechnology Training Grant	Discontinue
Division Research Program	Discontinue

II. REPORT OF THE BLUE RIBBON ADVISORY COMMITTEE

*The American Cancer Society is the Nationwide Community-Based Voluntary Health Organization
Dedicated to Eliminating Cancer as a Major Health Problem by Preventing Cancer, Saving Lives and
Diminishing Suffering from Cancer through Research, Advocacy, Education, and Service.*

Mission statement, American Cancer Society

As this report is written, two disturbing trends have imbued a new sense of urgency to the mission of the American Cancer Society.

At the turn of the century, five short years from now, the continuing decline in heart disease and a rapidly aging population will combine to make cancer the leading cause of death in the US.

The other trend that has major implications for the future is the planned reduction of federal and industrial funding for all biomedical research, including cancer, and concerns about the serious adverse impact of managed care on clinical research.

The combination of these two trends creates a call to action for those concerned with the control of cancer. In response to these pressing external circumstances and a recommendation by American Cancer Society staff and volunteers, a comprehensive analysis of the American Cancer Society's activities in intramural and extramural research support, personnel and training awards, and cancer control activities was initiated. A Blue Ribbon Committee (BRC), consisting of non-medical and medical American Cancer Society volunteers with broad knowledge of both the organization and cancer, together with scientists and clinicians outside the American Cancer Society who have expertise in cancer research, was charged with conducting the review. The charge to the BRC

included evaluating current programs and advising the American Cancer Society on how those programs can help the organization meet its priorities and mission. Additionally, the BRC was to look outward and examine the state of cancer research and health care professional training nationwide and identify gaps and opportunities that the American Cancer Society can fill.¹

Therefore, this report presents the BRC's evaluation and suggested restructuring of the American Cancer Society's research, health care professional training, and cancer control grants programs. These critical areas of the American Cancer Society were measured against the parameters set by the BRC -- that the programs must efficiently contribute to the development of a balanced approach to better understand the biology of cancer, to discover better ways to treat cancer, and to implement proven means to prevent and detect cancer at its earliest possible stage.

History

The American Cancer Society has supported research and training programs since the mid-1940s. Over the past 50 years it has expended approximately \$2 billion for research and \$100 million for training support for health care professionals in fields pertinent to the American Cancer Society's mission. The BRC recognizes the significance and impact of the American Cancer Society's programs.² Some noteworthy examples of these successes are:

- The American Cancer Society's research program has supported some of the most fundamental advances in understanding the biology of cancer -- from contributing to

¹ See Appendix A for full committee charge.

² See Appendix C for an expanded list of accomplishments of these programs.

discoveries such as the structure of the DNA double helix by James Watson and Francis Crick and the hormonal responsiveness of breast and prostate cancers, to the development of interferons and recombinant DNA technology and the support of hundreds of notable scientists, including 28 Nobel laureates.

- Development of the peer-review system for research grants was pioneered by the American Cancer Society. This system ensures that funds are expended for the most meritorious research, disregarding political, personal, or geographic preferences. Outstanding stewardship and integrity have always been the hallmark of the American Cancer Society's peer-review system. In turn, this system has gained the American Cancer Society the respect and support of the scientific community.
- The American Cancer Society's epidemiology-based intramural research program has been highly successful in shaping the directions of the American Cancer Society and of cancer control around the world. Discovery of the health-related effects of tobacco use has provided the knowledge to prevent at least 30% of deaths from cancer. This knowledge drives the American Cancer Society's prevention and advocacy programs aimed at eliminating tobacco-related deaths in this country.
- The health care professional training programs of the American Cancer Society have made great contributions to cancer control. In the 1940s, when the first American Cancer Society clinical oncology fellowships were initiated, few oncologic specialists existed. Today, there is an ample supply of physicians and nurses trained to apply their specific skills to the field of oncology. The American Cancer Society's professional training programs through the years have represented the first and often

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the only support for individuals committed to clinical oncology. These programs have remained flexible and reflected the changing needs of oncology training.

While recognizing the importance of these contributions, the BRC believes the proposed restructuring of the American Cancer Society research and professional training programs offers the best approach to take advantage of the enormous opportunities and solve some of the critical needs of the future. For example, the ability to cure up to two-thirds of children with cancer and to achieve a five-year relative survival of over 50% for adults with cancer is due to the application of research findings from the 1950s, 1960s, and 1970s. Current groundbreaking research in molecular biology and genetics leads the BRC to predict that the next decades of advances will be more striking for cancer prevention, detection, and treatment than any in history. Unfortunately, these great opportunities come at a time when the cancer research community faces a crisis in available funding. The federal government's budgetary constraints point to an even greater need for the American Cancer Society to continue -- to even increase -- its funding of promising scientists and health care educators in order to reach the full potential of the fundamental knowledge being developed today.

The BRC believes that the American Cancer Society will be an important force in the increased control of cancer in the world, in part because of its research and training programs. The BRC therefore offers the following recommendations for enhancing the American Cancer Society's intramural research, extramural research grants, and health care professional training programs. The recommendations are divided into four sections based on their orientation:

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- A. General Principles Governing All Research and Training
- B. Recommendations to Focus the Research and Professional Training Programs
- C. Proposed Policy Changes
- D. Administrative Recommendations

A. GENERAL PRINCIPLES GOVERNING ALL RESEARCH AND TRAINING

1. The American Cancer Society should strengthen and refine its research and training programs.
2. Investigator-initiated, peer-reviewed research should remain the basis of the American Cancer Society's extramural research program.
3. Cancer Control Grants should be subjected to rigorous review and assessment in terms of the American Cancer Society's goals.
4. All research and training applications should undergo appropriate and consistent pre-award peer review and post-award evaluation of their accomplishments, progress, priorities, and relevance to the American Cancer Society's goals.

1. The American Cancer Society should strengthen and refine its research and training programs.

When the American Cancer Society started its research and professional training programs in the mid-1940s, it was a major source of cancer research funds.³ With the growth of the National Cancer Institute's research budget, particularly after the passage of the National Cancer Act in 1971, and the advent of research programs from other private organizations and the biomedical industry, the American Cancer Society's role is not as dominant in cancer research funding -- currently supplying 3% to 5% of the total national funding for cancer research. However, this investment represents a large portion of the American Cancer Society's budget and enables the organization to continue to play a critical role in funding research and education because of its flexibility, high quality, ability to act rapidly, and freedom from political pressure.

The American Cancer Society's research and professional training programs also benefit the organization. For example, these programs enhance:

- Organizational effectiveness. Research into various aspects of cancer and the training of health care educators can help advance the objectives of all American Cancer Society programs, its mission, and its goals. Additionally research and training awardees reside in the American Cancer Society's Divisions and represent a link with leading research institutions.

³ Refer to Appendix B for the chronology of American Cancer Society research and training programs

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- Volunteer recruitment. Recipients of the American Cancer Society's research and training awards often volunteer their time or expertise to the organization. Lay volunteers are also motivated by a strong research mission.
- Fundraising efforts. Marketing research shows that the primary reason donors give to a cancer-fighting organization is because of the need for more research.
- The Foundation. Often, individuals or corporations making large donations want their money to go to a specific area of research. A flexible research program maximizes the possibility of matching donor wishes to programs.
- The American Cancer Society's image. The American Cancer Society's research program separates it from look-alike organizations.

Having noted that the American Cancer Society's research and training programs are important to cancer prevention and control and that they are central to the organization itself, it should be emphasized that the American Cancer Society faces intense competition for the public dollar from other groups that are also interested in cancer prevention and control. In order to fulfill its mission and to attract and maintain donors, it is vital to ensure that a sizable portion of the American Cancer Society's budget is devoted to research and training. The BRC therefore urges the American Cancer Society to restore its research commitment to the highest levels of support possible, especially since these programs fill critical unmet needs such as funding beginning investigators and the expanding of the field of psychosocial, behavioral, and policy research.

2. Investigator-initiated, peer-reviewed research should remain the basis of the American Cancer Society's extramural research program.

Investigator-initiated research, the process of encouraging researchers to originate ideas and questions, create methods of answering those questions, and apply the resulting knowledge to the next level of questions, has resulted in most of the major advances in understanding cancer today. Peer review, the process of having applications reviewed by impartial professionals in the same field as the applicant, ensures that the proposed project is of high quality and that the investigator has the expertise and resources necessary to successfully complete the project. Indeed, utilizing an investigator-initiated, peer-reviewed approach, the American Cancer Society has been successful in identifying and funding the best science. Therefore, the BRC recommends:

- a) The foundation of American Cancer Society's extramural research program continue to be investigator-initiated research.
- b) All research applications, including targeted research, must be evaluated through the peer-review mechanism.
- c) The American Cancer Society should annually review the membership and organization of its peer-review committees to ensure they contain expertise in the areas of the research grants submitted.

3. Cancer Control Grants should be subjected to rigorous review and assessment in terms of the American Cancer Society's goals.

After reviewing the history and spectrum of allocations awarded under the category of Cancer Control Grants, the BRC recognizes that the American Cancer Society needs a mechanism to continue funding activities that support the organization's overall mission but are not defined as research or personnel awards. These activities, in the past, have been subject to uneven review and evaluation in terms of American Cancer Society goals.

The BRC recommends that all cancer control programs be subjected to uniform review under standard mechanisms which apply to all grant activity. Therefore, requests for funding would be routed through the appropriate standing or ad hoc peer-review committee and reviewed by the council prior to recommendation to the Medical Affairs Committee and the Executive Committee for funding.

Some exceptions to this review mechanism would be allowed for projects that are deemed eligible by the Board of Directors for continued support, such as lectureships at specialty society meetings, e.g., the American Association for Cancer Research. These exceptions would be reported to the Council so that a total review of this activity would be available. Opportunities for those programs to become self-sufficient through the attainment of independent funding should be encouraged.

4. All research and training applications should undergo appropriate and consistent pre-award peer review and post-award evaluation of their accomplishments, progress, priorities, and relevance to the American Cancer Society's goals.

Both the peer-review process by which grants are awarded and the post-award evaluation necessary to judge the success of a given program toward the mission of the American Cancer Society are essential for all components of the organization's research and health care professional training programs. Several departments oversee the awarding of extramural research and professional training grants, none of which have a comprehensive and ongoing evaluation system. While these departments manage peer review processes, there are differences in the structures of the review and in the procedures for nominating and rotating committee members. Additionally, the intramural research program does not undergo a true peer review; instead, it receives annual guidance from an outside advisory committee.

The BRC recommends:

a) All American Cancer Society's entire research, professional training, and cancer control programs should be periodically evaluated for their accomplishments, progress, and relevance to the organization and to the greater research and health care communities.

To achieve this, recipients of all awards, research, training, and cancer control programs, should be tracked in order to assess their outcome and impact of the award. This will ensure that progress toward the American Cancer Society's mission can be evaluated, communicated and promoted where appropriate. The implementation of full

evaluation of these programs will ensure that the budgets for those programs are distributed by need rather than by a fixed formula.

b) A uniform standard of peer review should be applied to the pre-award evaluation of all intramural and extramural research, health care professional training, and to cancer control projects. All proposals for research, training, or cancer control grants should be reviewed by standing or ad hoc peer-review committees of experts from outside of the American Cancer Society.

c) Mechanisms should be created to allow the ongoing evaluation of research and training programs and their productivity and effectiveness. Once these mechanisms are established, they should be applied to the evaluation of intramural research programs and post-award evaluation of extramural research and health care professional training outcomes should be initiated.

The BRC recognizes the difficulty in classification of research and suggests that a volunteer/staff group should be convened to guide the creation of such a mechanism.

Both intramural and extramural research and training programs should be evaluated on a regular basis to determine whether they continue to advance the goals of the American Cancer Society. Analysis of the careers and the research supported by American Cancer Society grants and awards should be performed, if necessary, by outside contractors. This information will be essential for the activities of the Research Evaluation and Targeting Committee as described in section B2.

**B. RECOMMENDATIONS TO FOCUS THE RESEARCH AND
PROFESSIONAL TRAINING PROGRAMS**

1. The American Cancer Society's research and training grant programs should emphasize support for investigators and health care professionals at the beginning of their careers.
2. The American Cancer Society should promote targeted research in areas of high priority and opportunity.
3. The American Cancer Society should increase its emphasis on psychosocial, behavioral, and policy research to fulfill unmet needs, especially in cancer prevention and technology transfer over a range of cancer issues.
4. The American Cancer Society should maintain the Institutional Research Grants program.
5. The current Research Development Program should be maintained.
6. Intramural American Cancer Society research should be strongly supported.
7. Personnel Awards should be consolidated and focus on beginning investigators.
8. Extramural collaborative collaborative activities should be encouraged.

1. The American Cancer Society's research and training grant programs should emphasize support for investigators and health care professionals at the beginning of their careers.

Currently, it is very difficult for beginning researchers and health care professionals to establish their own research programs and careers because of limited resources at research institutes, universities, and the federal government. Indeed, a recent report shows that the number of young investigators (< 36 years of age) applying to the NIH, and the number of grants awarded to them, have dropped by 54% and 70%, respectively, in recent years.⁴ Therefore, supporting the development of beginning investigators is a gap that the American Cancer Society's extramural research program can help to fill. Directing funding to those at the beginning of their careers not only facilitates the building of cancer research programs but also provides crucial support to young scientists at the stage when their maximal time, energy, and innovation can be applied to research. This strategy will also help to maintain research capability in the face of high attrition of researchers and educators. The major risk of committing research support to the youngest investigators is their short track record on which to assess the probability of success in achieving their stated goals. However, the most competitive young investigators have had extensive predoctoral and postdoctoral periods of research training and are likely to develop innovative ideas in cancer research. Experience has shown that the American Cancer

⁴ National Research Council. The Funding of Young Investigators in the Biological and Biomedical Sciences. National Academy Press, Washington DC. 1995.

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Society's peer-review system has been highly effective in identifying promising research by young investigators. Additionally, young investigators benefiting from an American Cancer Society grant may identify with the organization and become future volunteers.

The BRC therefore recommends that the principal mechanism for research funding should be a redefined Research Project Grant, designed to support beginning investigators proposing projects across the broad spectrum of cancer research. These grants will enable a young investigator to collect the preliminary data necessary to successfully compete for larger foundation and federal grants. Following are the specific recommendations for this redefined Research Project Grant:

- a) Individuals seeking project-related research support may apply for funding from the American Cancer Society at any time within eight years of their first independent research or faculty appointment.
- b) Initial grants will be for up to three years (unless exceptional needs require up to five years) and may be competitively renewed twice, for a maximum of two consecutive two-year periods. In no case may an investigator be funded past the 14th year of his/her first independent research or faculty appointment.
- c) The currently funded grantees not qualifying as "beginning" would continue eligibility to apply for a maximum of two competitive renewals of two years each.

d) The current option of extending support for one year at up to 50% of the annual budget if an application for the second or subsequent competitive renewal of a grant does not achieve a rating high enough for funding should be continued. This aspect of the American Cancer Society's research program is unique among funding organizations and permits qualified researchers time to continue their work, refine their proposals, and reapply for support.

e) Individuals cannot be principal investigator on more than one American Cancer Society grant simultaneously. Investigators currently holding more than one grant will be able to apply for a maximum of two competitive renewals of two years each for each grant. This recommendation is made in order to equitably distribute research dollars and encourage the support of as many beginning investigators as possible.

f) Budgets for the redefined project grants may be larger than the current informal ceiling of \$100,000 per year. Applicants should be able to request salary support up to a maximum that equals the NIH salary cap, prorated according to the percentage of effort devoted to the project, plus additional funds sufficient to carry out the proposed work. This recommendation recognizes the increasing cost of performing research, increasing sophistication of projects, inflation, and the need of junior researchers to have protected time allocated to their research project.

g) The American Cancer Society's current indirect cost rate cap of 25% should be maintained. This allocation pays for general institution costs, such as library and laboratory maintenance, and other research-related expenses not covered by the direct grant award.

Applications covering a wide spectrum of cancer-related research should be encouraged. However, given the limitations of funds available, unsolicited expensive phase II and phase III clinical trials should be excluded. The BRC endorses support for less costly studies that may be piggybacked onto large trials, such as basic mechanistic or behavioral studies in the context of a phase II or phase III clinical trial funded by other sources.

2. The American Cancer Society should promote targeted research in areas of high priority and opportunity.

Historically, the American Cancer Society's research program has been investigator-initiated. While investigator-initiated research has been highly successful in the past, the BRC believes the time has come to reconsider how the American Cancer Society, in an era of rapidly expanding insights into the nature of cancer, can best use its research funds to facilitate progress in cancer control. The BRC recommends that investigator-initiated grants for beginning scientists continue to form the base of the American Cancer Society's research program but that the American Cancer Society set aside a percentage of research money for targeted research. These funds, while maintaining the overall research program's emphasis on beginning investigators, should not exclude more senior investigators.

The BRC recognizes that the idea of targeted research may represent the most significant change recommended in this document. Targeted research is recommended because:

- Targeting a portion of research funds could be the most efficient way to respond rapidly to a changing environment and to explore areas of prime interest in which the American Cancer Society feels opportunities or deficits exist. An example would be the areas of psychosocial, behavioral, and policy research related to cancer prevention or the transfer of research findings in molecular biology or genetics to clinical applications. Many areas of interest to the American Cancer Society could fall under

the category of targeted research, ranging from understanding the steps of change necessary for adopting cancer-preventive behaviors to exploring the management of genetic knowledge about the predisposition to cancer;

- By choosing appropriate targets, the American Cancer Society could generate a record of achievement that could complement its current broadly distributed efforts.

Targeting might enhance the efforts of the Foundation, which could solicit contributions for exciting new developments in specific areas;

- Its inability to rapidly change direction has been a major criticism of American Cancer Society. Targeted research will allow the organization to expeditiously act on new needs or opportunities.

The American Cancer Society has two very important resources with which to pursue targeting: (1) an excellent peer-review system with a demonstrated track record in identifying high-quality, productive research; and (2) large numbers of volunteers who can provide expertise into defining areas of targeting. The involvement of these resources in a cooperative effort could go far in ensuring the success of a targeted approach.

Therefore, the BRC recommends:

- a) Up to 10% of the total extramural research budget should be devoted to targeted research. Initially, the BRC recommends the targeted areas include psychosocial, behavioral, policy, prevention, and/or translational research. To ensure continuity of programs, specific goals and timelines should be developed for each research target. The initial 10% ceiling and all aspects of the targeting process should be regularly evaluated.

b) A Research Evaluation and Targeting Committee should be appointed to solicit and review recommendations for targeted research areas.⁵ The Committee should be composed of members of the Research Council, the Research and Clinical Investigation Committee, the Medical Affairs Committee, American Cancer Society Research and Clinical Research Professors, and volunteers knowledgeable in marketing, fundraising, administration, and other program areas. This committee should also make use of ad hoc scientific consultants for specific evaluations. This recommendation is based on the concept that choosing the research area to be targeted is a multi-faceted decision -- one that considers the knowledge base emanating from science fields, the wishes of the public, the interests and capabilities of the American Cancer Society, and the objective identification of the problem to be addressed. Accordingly, the decision process requires input from diverse segments of the American Cancer Society to properly blend science, value judgments, and practicality in designing useful targets. It is proposed that the Research Evaluation and Targeting Committee consist of 12 members: a non-voting chairperson, who is the Vice Chair of the Research and Clinical Investigation Committee, and 11 voting members. As a guiding rule, at least a majority of the voting members of the Research Evaluation and Targeting Committee members should have demonstrated broad scientific perspectives and notable scientific achievements. The Research Evaluation and Targeting Committee should submit an annual written report through the Research and

⁵ See illustration 5 p70.

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Clinical Investigation Committee and the Medical Affairs Committee to the Executive Committee of the Board of Directors.

c) The Research Evaluation and Targeting Committee should evaluate the total research and training portfolio of the American Cancer Society annually in order to define areas of strength, underemphasis, and special opportunities for funding. Due to the complex nature of this task, it is further recommended that a group of volunteers be convened to work with staff to devise a method of assessing the portfolio. Part of the target selection process should be the identification of the long-term research goals of the American Cancer Society and the role of targeting within this research plan.

d) In addition to the areas being considered for targeting, the Research Evaluation and Targeting Committee can receive suggestions for other areas from the Medical Affairs Committee, the Research and Clinical Investigations Committee, the Board of Directors, various advisory committees, Divisions, and outside sources.

e) Recommendations for targeted areas other than those with the initial emphasis on behavioral and preventive research will be sent from the Research Evaluation and Targeting Committee through the appropriate standing committee to the Board of Directors for consideration.

f) The Research Evaluation and Targeting Committee should direct staff, with outside consultants if needed, to develop Requests for Applications in the area of targeting.

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g) The proposals resulting from the request for applications, including any intramural proposals, should be reviewed for relevance and merit by the appropriate standing or ad hoc Peer Review Committee.

3. The American Cancer Society should increase its emphasis on psychosocial, behavioral, and policy research to fulfill unmet needs, especially in cancer prevention and technology transfer over a range of cancer issues.

This recommendation is based on the belief that psychosocial, behavioral, and policy research⁶ is central to the rapid transfer of research findings to meeting the needs of the public and cancer patients. These areas represent important opportunities for the American Cancer Society since psychosocial and behavioral research now receives little support from all sources of funding relative to other types of basic and clinical research. These areas of research also provide the scientific underpinnings for cancer prevention and control programs.

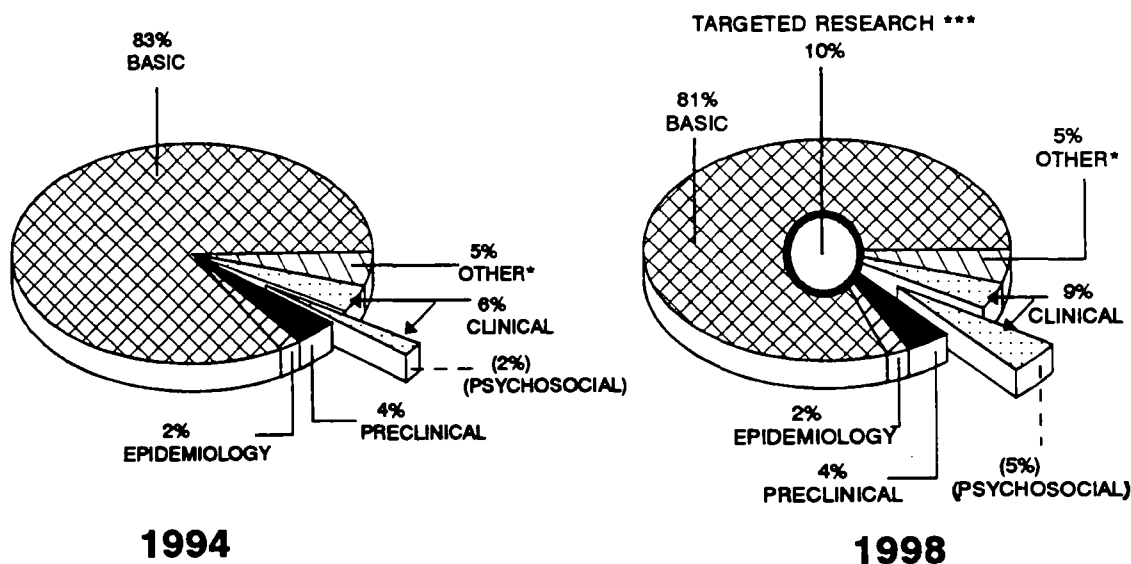
Recently, the American Cancer Society developed an intramural Behavioral Research Unit to pursue research into areas of particular interest to the American Cancer Society. Although the areas of psychosocial and behavioral research have benefited greatly from the American Cancer Society's focus, the organization currently devotes relatively few of its research dollars to this area. Extramural funding in this area accounted for only 2% of American Cancer Society grants and awards research budget in fiscal year 1994 and these are areas of health care professional training which are not well represented in past personnel awards (*see illustration 3*).

⁶ See Appendix D for definitions of psychosocial and behavioral cancer research.

Illustration 3: Percent of funds awarded by type of research

PERCENT OF FUNDS AWARDED BY TYPE OF RESEARCH FY 1994 AND FY 1998(projected)**

TOTAL AWARDS FOR FY 1994 = \$94,517,198



* Includes Institutional, Special and Research Development Grants

** An increase from 2% in 1994 to 5% by 1998 is planned for Psychosocial and Behavioral research

*** Targeted research can be any type of research

The BRC recommends:

a) The American Cancer Society actively promote psychosocial and behavioral research in cancer prevention and control and link this research with existing basic and clinical activities in a translational manner. These areas of research will enable the American Cancer Society to respond to:

- Effective prevention and early detection. Some researchers estimate that if everything known about the prevention of cancer were applied, up to two-thirds of cancers would not occur and far fewer would die from cancer. But to

achieve those potentials, many questions must be answered, including those that relate to barriers that are cultural, emotional, and institutional;

- Emerging ethical concerns. The revolution in understanding the genetic aspects of cancer is spawning new ethical challenges which can only be responsibly managed through careful research into these issues;
- Emotional needs of cancer patients and their families. Societal changes are resulting in more health care being managed at home and by primary physicians. Mental, emotional, and behavioral aspects of social and therapeutic interventions (which are intended to improve the quality of life, reduce suffering, and facilitate decision-making and informed consent) are important research areas;
- Attitudes of leaders. Research is needed on how to reach the people most likely to create change in society, such as teachers, health educators, business and community leaders, politicians, and government officials, to institute effective programs most rapidly. As American Cancer Society advocates for public policy initiatives related to cancer, more empirically based knowledge is needed to understand how these policies are formulated, adopted, and implemented to translate research findings into action.

b) The American Cancer Society should develop more effective strategies for soliciting targeted psychosocial and behavioral proposals. Funding should be increased for research on psychosocial, behavioral, and policy aspects of cancer control. A series of directed

requests for applications and other mechanisms, including intramural research, targeted to areas of high interest to American Cancer Society should be developed.

Some issues are important to current Society priorities or may provide special opportunities for targeting such as:

- Understanding the sequential psychological steps in behavior change, especially in minority, socioeconomically disadvantaged, and underserved populations.
- Designing interventions and creating strategies in cancer prevention. How volunteers and the public can effectively deliver complex cancer prevention and control programs may require extensive research.
- Examining the needs of patients and families in relation to the changing face of health care financing and organization.
- Researching physiologic and environmental influences on behavior.

It is recognized that the fields of psychosocial, behavioral, and policy research represent relatively new areas of endeavor; therefore, there are proportionally fewer investigators working in them. Given the historic examples of research into cancer after the 1971 National Cancer Act and more recently, research into the acquired immunodeficiency syndrome (AIDS), where the fields expanded enormously after an infusion of funds, the BRC deems it appropriate to recommend the expansion of grants in this broad research area to a minimum of 5% of the total research portfolio in the near future. Additionally, the BRC suggests that psychosocial, behavioral, and policy research, especially in cancer prevention and the transfer of findings from these areas to clinical settings, be considered among the first areas to receive targeted funds.

c) The staff of the new Behavioral Research Unit should develop a request for applications on selected areas of psychosocial, behavioral, and policy research and present it to the Research and Clinical Investigation Committee as soon as possible.

4. The American Cancer Society should maintain the Institutional Research Grants program.

The Institutional Research Grants can achieve many of the American Cancer Society's goals in research funding. These awards support young investigators, encourage research into psychosocial and behavioral research, may be amenable to targeting opportunities, and should build institutional awareness of the American Cancer Society's role in research.

The process by which these funds are distributed is unique within the American Cancer Society's research portfolio since they are awarded in the form of block grants (average size \$60,000) to institutions. Beginning investigators then apply directly to their institution, rather than to the American Cancer Society (average grant to the researcher is approximately \$10,000). Additionally, these awards may offer a good vehicle to start careers in psychosocial and behavioral research since additional funds are available to investigators in these areas. The grants are reviewed as to their productivity by a report that is filled out by the institution.

In FY 1994, 65 institutions from 36 Divisions participated in this program for about \$3 million grants-in-effect. The Institutional Research Grants program is authorized to award up to 5%⁷ of the Grants and Awards allocation each year.

⁷ Exceptions may be made during these transitional years of funding the Triple 5 program.

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The problems associated with this program relate primarily to image. Since the grants are administered locally by institutions, recipients may perceive that their institution is the source of funds rather than the American Cancer Society. Additionally, Divisions may not be highly involved in this program, thus missing opportunities to support income development, Division image, and marketing.

The BRC strongly supports the Institutional Research Grants program and recommends:

- a) The Institutional Research Grants program be continued. This program is an excellent way to attract and support beginning investigators at a time in their career when their recognition by the American Cancer Society will have the greatest impact. Additionally, these grants provide funds to support just their research, rather than their stipend. A preliminary evaluation of the program, based on subsequent competitive funding and publications, indicates that these individuals continue in research careers. In addition, their research topics seem to have relevance to cancer and relate to areas of programmatic importance to the American Cancer Society.
- b) The association between the Division and the recipient institution should be strengthened to support the American Cancer Society's overall goals and priorities and identify the American Cancer Society as the source of these grants. Several Divisions use this program to effectively promote the image of the American Cancer Society and their success in this regard should be shared with other Divisions.

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c) The mechanism for evaluating and tracking recipients' success should be strengthened.

A strengthened evaluation and reporting mechanism would enable the American Cancer Society to better determine the merits of this program in the future.

d) The cap on individual grant awards should be increased to \$20,000 from the current \$15,000. This proposed increase represents a recognition by the BRC of the increasing costs of conducting research. No increase on the duration of the award is recommended.

e) The program should continue to comprise up to 5% of the Grants and Awards budget allocation.

5. The current Research Development Program should be maintained.

The current Research Development Program, designed to rapidly provide small grants to fund special opportunities in high-priority research, has many strengths. However, the BRC feels that the current name does not adequately describe its function and some modifications to the program should be implemented. Therefore, the BRC recommends:

- a) The Research Development Program should be renamed the Research Opportunity Fund.
- b) Up to 1% of the research budget should be made available, at the discretion of the National Vice President for Research, to support potentially outstanding projects for which a need for urgent funding can be demonstrated.
- c) A simplified process should be developed for applying for these awards, which includes support by an ad hoc peer review process to assist the National Vice President for Research in the granting decisions.
- d) A grant limit of \$75,000 for one year should be set and a final report of results and analysis of the project should be required.

6. Intramural American Cancer Society research should be strongly supported.

The intramural research component of the American Cancer Society's research program consists of the Epidemiology and Surveillance Research department and the newly formed Behavioral Research Unit. In addition to conducting research, both of these groups have a large service component which provides the rest of the American Cancer Society with statistics, assessments, and recommendations based upon their data.

The BRC strongly supports the continued funding of intramural research but recommends:

a) Each intramural program develop a five-year plan, with annual revisions, that includes both the research and service components of the programs.

For the recently established Behavioral Research Unit, such a plan should be developed during the first year of its operation. Such five-year plans should include development of program-based budgets. The Epidemiology and Surveillance Research Department, should also consider:

- Future volunteer-assisted data collection, similar to Cancer Prevention Study I and Cancer Prevention Study II;
- Utilization of data from outside the American Cancer Society;
- Involvement of multiple scientific disciplines;
- Collaborative research with outside organizations;
- Maintenance of a visiting research scholar program;

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- Applying for funds from sources outside of the American Cancer Society, when appropriate.

While these two intramural groups have aspects of targeted research, the BRC felt that further targeting opportunities exist within them. Areas of particular interest to the American Cancer Society could be explored using the resources available to the intramural research groups.

Outside funding obtained should be considered additive rather than substitutive to the budgets of these programs.

b) To maintain the high quality of the Epidemiology and Surveillance Research and Behavioral Research programs, these programs should be reviewed every five years by an ad hoc committee of outside experts.

This committee should evaluate the departments' basic programs, their core research objectives and activities, their personnel/administrative structures, and their program-based budgets. The evaluation and recommendations of the committee should be reported to the Council for review, and then to the Board of Directors. Assessment of specific research projects undertaken within the overall program of such a department should be the subject of ongoing review and discussion by a separate advisory group of outside experts meeting with department staff on an annual basis. Such advisory groups would be separate and distinct from the formal peer-review committee described above.

It is recognized that support for specific intramural research projects might be requested from funding sources outside the American Cancer Society, such as the NIH. Such grant requests would receive peer review from the outside funding agency and hence

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would not require separate peer review by the American Cancer Society. These externally supported research grants would be reported to the Council and the Board for information and program coordination.

c) All new intramural research projects with an estimated total cost greater than \$75,000 should receive individual review by an appropriate standing or ad hoc peer review committee, which would then report its decision to the Council for review and then to the Board of Directors.

This recommendation applies to any research project fitting the definitions of research already established by the American Cancer Society.⁸ Review of smaller research projects, initiated by departments in which intramural research is not a principal function, can be arranged within the American Cancer Society but independent of the involved department. To maintain the strong scientific base of the American Cancer Society, the research department should offer an internal consultation service to other departments.

⁸ See Appendix D for research definitions.

7. Personnel Awards should be consolidated and focus on beginning investigators.

Helping researchers and health care professionals develop the skills necessary to make successful contributions to cancer research, academic medicine, and cancer care has been a focus of the American Cancer Society since the mid-1940s. The American Cancer Society currently funds 17 different research personnel and clinical awards, administered by different departments. The BRC examined all of the awards to see if they still meet the goals of the American Cancer Society and the needs of the professions and if there were any new areas in which the organization should be sponsoring training awards. The BRC also examined the mechanism and quality of peer review for each award and offered recommendations to streamline and unify the entire process of funding personnel awards. The BRC was interested in ensuring a continuum of awards for young scientists and opportunities in clinical and translational research.

Four **general** recommendations for the personnel awards of the American Cancer Society are made. These general recommendations will serve to simplify the personnel award portfolio, reduce confusion among applicants, and make the administration of the awards more efficient.

a) Personnel awards should be continued, but with consolidation of awards that overlap. Research personnel and health care professional training awards are vital to the fulfillment of the American Cancer Society's mission. These awards should support the development of teachers and researchers and therefore fulfill the goals of education, research, and improvement in cancer prevention and management. When reviewing the portfolio of

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personnel awards as a whole, without regard for department of origin, it became apparent that some awards were duplicitous, a situation which should be remedied.

b) All personnel awards should be subject to identical peer review standards and post-award evaluation. Appropriate and consistent peer review procedures must be established and applied to all types of research personnel and health care professional training awards to ensure truly competitive selection. Objective post-award evaluation procedures must be part of each of these awards. In the future, every award should have stated goals and measurable outcomes, so that data can be collected and outcomes determined. Periodic evaluation, based on objective data, will maintain useful programs and phase out those programs that no longer fulfill their purpose.

c) Personnel awards should be time-limited and focus primarily on early but to some extent also on mid-career activities. The main emphasis of future American Cancer Society awards in the personnel area should be early teaching, academic, and research career development among junior faculty and young teachers and investigators. These levels of career development are where the largest reduction in funded positions and research money has occurred from other funding sources.

d) All health care professional training programs currently under evaluation will be reviewed by the BRC when it reconvenes. Decisions about the programs' continuation will be made at that time.

Following are **specific** recommendations by the BRC regarding personnel awards :

- a)** Postdoctoral fellowships should be continued in the present number.

These awards are intended to help young investigators qualify for an independent career in cancer research. The American Cancer Society's postdoctoral fellowships should concentrate on fields with a clearly defined relationship to cancer and with a preference for areas that are linked to the overall organizational mission and goals.

- b)** Clinical Oncology Career Development Awards (intended to support academic oncologists in the early stages of their careers), Junior Clinical Research Awards (intended to provide salary support for clinical investigators just beginning their scientific career), and Physician Research Training Awards (intended to improve physicians' research competence) should be combined into a single award emphasizing clinical research activities by investigators in the first four years of their academic career.

The rationale for this recommendation is that these awards have similar goals of emphasizing clinical research or training just physician scientists, but differ in their review mechanisms and stipends. These awards might be called "Clinical Research Training Awards for Junior Faculty." They would also be open to applicants with doctoral degrees and be available for all areas of clinical oncology investigation, including epidemiologic, psychosocial, behavioral, and policy research. Eligible grant applications must meet the American Cancer Society's definitions of clinical or epidemiological research. The awards should be for three years with a possible single competitive two-year renewal.

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Applications will be judged based on the strength of the research project, the applicant, the mentor(s), and the institutional environment.

These awards are for investigators who are not yet fully independent and will be mentored during the project. The awards recognize the need for development of clinical research careers which are not adequately supported at present by funding organizations. The goal is to develop independent clinical investigators who would then be eligible to apply for research project grants as beginning investigators under Section B, item 1 of this report.

An applicant for this project grant may request his/her salary up to the NIH salary cap and additional funds sufficient to carry out the research work proposed. The salary support should be prorated according to the percentage of effort devoted to the project and adequate to justify a minimum of 30% effort, but preferably greater commitment, by the principal investigator.

- c) Research Professorship Awards and Clinical Research Professorship Awards should be limited to outstanding mid-career scientists for an initial five year-period with a single competitive five-year renewal.

These programs offer long-term salary support for established investigators or outstanding clinical scientists who have made significant contributions to cancer research or who will bring together basic science and clinical approaches. This recommendation departs from the current practice of awarding the Professorships for the duration of the professor's research career subject to five-year scientific renewals. Current funding is \$50,000 for salary and \$10,000 per year in flexible research development funds. It is

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recommended that the \$60,000 yearly funding be apportioned to salary and/or research project support at the discretion of the awardee. Funding would cease at the end of the 10- year period, but the title of American Cancer Society Research Professor or Clinical Research Professor would be acknowledged throughout the remainder of the scientist's career. The current holders of these awards would continue to be funded under their original contractual agreement with the American Cancer Society.

d) Cancer Control Career Development Awards for Primary Care Physicians should be continued for the present but undergo careful evaluation. The evaluation of this program will be reported to the BRC when it reconvenes.

This award supports primary care physicians pursuing an academic career with an emphasis on cancer control. The BRC recommends that the first 15 awardees should be evaluated in the near future to provide data on which to base decisions about continued funding for this program.

e) Physician Training Award in Preventive Medicine should be continued for the present but undergo careful evaluation. The evaluation of this program will be reported to the BRC when it reconvenes.

This award was created in 1994 to support academically oriented physicians obtaining training in preventive medicine with an emphasis on cancer epidemiology, prevention, and early detection. It should be noted that the general purposes of this award and the Cancer Control Career Development Award for Primary Care Physicians are similar, even though the Physician Training Award in Preventive Medicine targets

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residents while the Cancer Control Career Development Award is for primary care physicians. Therefore, after appropriate evaluation, consideration should be given to combining them.

f) Professorships in Clinical Oncology should be evaluated while continuing those previously awarded. No new nationally co-funded awards should be made during the evaluation. The evaluation of this program will be reported to the BRC when it reconvenes.

These awards are to improve teaching of cancer control and management in medical schools and other appropriate institutions and to increase cooperation of medical and scientific disciplines in cancer patient management. Evaluation of these recipients is currently underway; therefore, decisions regarding the future of the program should await results of that review.

The main goal for Professorships of Clinical Oncology Awards is the development of a comprehensive oncology curriculum in medical schools to best teach multidisciplinary integrated cancer management. The American Cancer Society needs to consider developing and disseminating innovative and contemporary oncology teaching methods, such as interactive video teaching tools, rather than relying on this award to achieve these goals in oncology education.

g) Professorships of Oncology Nursing should be evaluated while continuing those previously awarded. No new nationally co-funded awards should be made during the

evaluation. The evaluation of this program will be reported to the BRC when it reconvenes.

These awards were to enhance the care of cancer patients and their families and those at risk for cancer by strengthening the cancer curriculum in graduate and undergraduate nursing programs. The BRC recommends that the professorships be devoted to developing new, innovative teaching methods for use by all nursing schools in the country.

h) Scholarships in Nursing

i) Doctoral scholarships in oncology nursing should be continued with an emphasis on subsequent education and research career paths. This program supports doctoral preparation of nurses in oncology-related fields. Ongoing short- and long-term evaluation of this program should be completed and utilized for decisions about continuation.

ii) Master's level scholarships in oncology nursing should be continued pending an assessment of current nursing personnel needs in cancer control to determine appropriate program emphasis. This program was originally created to prepare nurses for advanced roles in clinical practice, education, and administration in oncology. An assessment of the needs for nursing personnel and the funding available from other agencies will allow the American Cancer Society to re-focus the goals of this program, if necessary.

i) Traineeships in Oncology Social Work

i) Master's level traineeships in oncology social work should be continued pending evaluation. This program was created to support the training of oncology social workers

to provide psychosocial services to cancer patients and their families. An evaluation of personnel needs in this field should be conducted.

ii) Post-master's traineeships in oncology social work should be evaluated with an emphasis on subsequent education and research career paths. This program was created to support the preparation of oncology social workers for advanced clinical practice and research. These awards should support teaching and research. An assessment of the need to continue this emphasis in light of current personnel needs in this field should be conducted and reported to the BRC when it reconvenes.

j) The current UICC fellowships should be discontinued at the completion of current funding obligations. A new international program should be considered for young investigators in the context of the American Cancer Society's international programs.

Funds from the current program are awarded through the International Union Against Cancer (UICC) headquarters in Geneva, Switzerland. These fellowships enable highly qualified investigators from any country in the world to work in collaboration with outstanding scientists in another country. However, the BRC feels that the UICC fellowships should be discontinued because:

- These awards have traditionally been given to mid- to late-career scientists.

The American Cancer Society should focus its research support on investigators at the beginning of their careers.

- Since the inception of the program in 1961, the economies of many of the recipients' countries has changed dramatically and many should now support their own fellowships.

- Almost 25% of the awards are given to scientists who have no relationship with the United States; that is, the scientists travel between two other countries and have no exposure to the US research environment.

If the American Cancer Society believes it is important to support international research, the BRC recommends that staff submit ideas on how this should be achieved keeping the following parameters in mind:

- The new program must be consistent with the goals and objectives of other research programs, e.g., focusing on beginning investigators;
- The new program should increase the number of researchers coming to the United States from other countries;
- The new program should maintain American Cancer Society standards of research.

k) Scholar awards should be discontinued at the completion of current funding obligations.

This recommendation is based on the fact that this award program provides funding for a sabbatical leave, and there are many institutions and foundations currently offering resources for this purpose.

l) Clinical Oncology Fellowships should be discontinued at the completion of current funding obligations. This recommendation is based on the following reasoning:

- The awards, formerly \$10,000 for one year, were reduced to \$5,000 last year due to budgetary constraints, thus minimizing their effectiveness.

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- When the predecessor to this award (Clinical Fellowship) was developed in 1948, there were few clinical practitioners specializing in oncology. The US now has sufficient staffing in all the current oncologic specialties. This program can be phased out due to its success. Funds could be distributed to other areas of higher priority.

m) Cytotechnology Training Grants should be discontinued at the completion of current funding obligations.

This program was initiated to help increase the number of cytotechnologists by awarding grants to existing programs to expand their student capacity and to new programs seeking accreditation. The need that led to the development of this program no longer exists.

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Illustration 4: Summary of current personnel programs and recommended actions

CURRENT PROGRAMS	RECOMMENDATIONS
1. Postdoctoral Fellowships	Continued
2. Clinical Oncology Development Award	Combined into Clinical Research Training Awards for Junior Faculty
3. Junior Clinical Research Award	
4. Physician Research Training Award	
5. Junior Faculty Research Award	Renamed, combined with project grant
6. Research Professorships	Continued, limited to 5 yrs plus 1 renewal
7. Clinical Research Professorships	Continued, limited to 5 yrs plus 1 renewal
8. Cancer Control Career Development Award	Continued, pending evaluation
9. Physician Training Award in Preventive Medicine	Continued, pending evaluation
10. Professorships of Clinical Oncology	On hold, pending evaluation
11. Professorships of Oncology Nursing	On hold, pending evaluation
12. Scholarships in Cancer Nursing	Continued, pending evaluation
13. Clinical Oncology Social Work Traineeships	Continued, pending evaluation
14. UICC Fellowships	Discontinued
15. Scholar Awards	Discontinued
16. Clinical Oncology Fellowships	Discontinued
17. Cytotechnology Training Awards	Discontinued

8. Extramural collaborative activities should be encouraged.

One of the ways to enhance productivity from increasingly scarce dollars is to foster collaborations in which organizations contribute specific components to create a whole that is greater than the sum of its parts. Collaborative research has always been a focus of the American Cancer Society since it has many resources to share with other organizations. Historically, the American Cancer Society has generated a lengthy list of collaborations with other organizations, with mixed outcomes. The BRC examined the potential for collaboration with government, universities, industry, and individuals with the resulting recommendations:

- a) Any collaborative research program undertaken by the American Cancer Society should be evaluated according to the same peer-review standards as all other American Cancer Society research.

The committee recommends that research, training, and cancer control collaborations, whether with the National Cancer Institute, Centers for Disease Control and Prevention, industry, foundations, or other organizations, should be conducted as co-sponsorship projects with the details pertinent to budget, peer review, use of volunteers, publications, ownership of intellectual property, etc., arranged for each program and the whole project subject to peer review.

b) Collaborative projects which do not have a research focus should result from a planned process of determining how they enhance the American Cancer Society's mission and priorities how they should be managed and evaluated.

A planned process would allow the originating departments and the Board of Directors to judge if the projects are meeting their objectives. Additionally, the American Cancer Society should maintain enough control over collaborative projects to ensure that those projects remain consistent with the organization's mission and priorities.

c) Collaborative research with outside investigators who wish to use the American Cancer Society's databases should be encouraged after appropriate evaluation.

The American Cancer Society houses unique epidemiologic data from Cancer Prevention Studies I and II. Knowledge generated from these data may be expanded by allowing their use by qualified outside investigators.

d) The American Cancer Society should promote outside collaboration in high-priority areas.

Well-planned research, professional training, and cancer control collaborative projects may bring about progress more quickly in those areas which the American Cancer Society has designated as priorities.

e) The Epidemiology and Surveillance Research department and appropriate advisory committees should evaluate the goals and objectives of the National Cancer Data Base

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and review how the data base can complement the mission and priorities of the American Cancer Society.

While the motive for support of the National Cancer Data Base is well meaning, it is not clear to the BRC what its objectives are, how those objectives complement existing registries, what use is made of the data to improve patient care, what evaluation exists, or what the anticipated outcomes are. Funding for the National Cancer Data Base represents a large expenditure. The American Cancer Society should review and assess the continued need for this program to be satisfied that the program is designed and operated in a fashion which will provide data necessary to achieve the goals for the program and to complement the mission and priorities of the American Cancer Society. This evaluation should be reported to the BRC when it reconvenes.

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C. PROPOSED POLICY CHANGE RECOMMENDATION

1. The Division Research Grants Program should be discontinued.

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1. The Division Research Grants Program should be discontinued.

The Division Research Grants program is funded from contributions restricted to research performed in the local area, with a budget of \$4 million. The following nine Divisions are currently authorized to have their own research programs: California, Florida, Illinois, Maryland, Massachusetts, New York City, Ohio, Oregon, and Vermont. The Research and Clinical Investigation Committee of the National Board of Directors has oversight responsibilities for this program. The quality of the review process and the grants that are awarded are periodically reviewed to see if they meet the American Cancer Society's standards for peer-reviewed research.

However, there are problems with the Division Research Grants program as it currently functions. For example:

- Only nine of the American Cancer Society's 57 Divisions currently can participate in the Division Research Grant program, creating an unfair situation for other Divisions which would like to participate in the program;
- The Division Research Grants program overlaps with the Nationally managed Institutional Research Grants program and personnel programs, which means that Divisions with research programs fund the same pool of investigators as the National program. In seven of the nine Divisions, starter grants are being given to junior faculty in medical schools that also have Institutional Research Grants;
- The program detracts from the pool of money that would be available for the National Research program to fund a larger percentage of highly rated grant applications

identified by the National peer-review system. In essence, Divisions operating research programs sequester funds that would be available to all Divisions through the National research program;

- The reporting, follow-up and evaluation of the outcomes of grants that are funded are not uniform across Divisions;
- The administrative costs of Divisional Research programs are higher relative to amount of funds administered, compared to the National research program.

In light of these problems, the BRC recommends that:

a) The Division Research Grants Program be discontinued during a three-year phase-out period. The BRC recognizes the primary positive aspect of the Division Research Program is enhancement of the local Division's image. However, the negative aspects of the Division Research Program, including the fact that peer review at the Division level is expensive and duplicative and that it is unfair to allow only nine Divisions to participate in the program, represented the stronger consideration. Since the Division Research program is funded with contributions restricted to research, those funds previously retained in the Divisions would be added to the National research budget and would help to fund new initiatives described in this report.

b) Divisions should be encouraged to use unrestricted donations to fund research and training grants that are approved through the National peer-review process. The BRC encourages Divisions to raise money for research not limited to any geographic area. This will ensure that the American Cancer Society continues to support the best science

available to prevent, diagnose, and treat cancer. The National research grants and awards staff will assist Divisions wishing to fund nationally ranked research grant applications with the selection of grants that are both meritorious and appealing to the Division.

c) The National Research Department should develop a system to manage contributions that are restricted to research within a given Division or geographic area. The resulting system should neither compromise the American Cancer Society's high standard of research nor the donor's wishes.

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D. ADMINISTRATIVE RECOMMENDATIONS

1. The BRC should reconvene in approximately three years to evaluate progress toward fulfilling the recommendations in this report.
2. Proposed administration
3. Resource allocation

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1. The BRC should reconvene in approximately three years to evaluate progress toward fulfilling the recommendations in this report.

As part of its overall recommendation of evaluation of all programs, the BRC feels strongly that it should reconvene in approximately three years to measure the progress made in fulfilling the approved recommendations in this report. The BRC recognizes that some recommendations, such as targeting, involve new processes and may take time to initiate; they should be evaluated accordingly. However, follow-up of this report is an important element in ensuring the successful completion of its recommendations.

2. Proposed Administration

a) The BRC proposes a new way of structuring the oversight of the grants and awards program that is based on the functional distribution of awards. The proposed administration would:

- Centralize functions while respecting the needs of the volunteer committees that originate the programs;
- Allow ideas to originate from any source;
- Create a defined method through which research and training proposals are reviewed and funded;
- Provide for merit-based, need-driven funding.

The proposed administration of the research and professional training programs would originate from two functional pools of money: 1) research and 2) professional programs. It is important to emphasize that these are not departmental designations, but rather, functional allocations of funds. The proposed administration might be managed by two committees, the Research and Clinical Investigation Committee and the Medical Affairs Committee, both of which report to the Executive Committee of the Board of Directors.

Following is a schema that an application would undergo as it is being reviewed for funding:

- i) Applications enter the review process, either through the research grants application or training or professional programs arms. Applications that require

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peer review would be sent to an appropriate Peer-Review Committee, formerly called Scientific Advisory Committee. These Peer-Review Committees will review all research projects, personnel grants, and professional training awards (roughly analogous to the Division of Research Grants at the National Institutes of Health) and will be administered under the auspices of the Research department. The creation of a number of Peer-Review Committees specific for the proposed types of grants, awards, and training programs, should ensure a uniform standard of peer review.

ii) Applications for funds that do not require peer review would be sent directly to the Research and Clinical Investigation Committee or the Medical Affairs Committee for review, evaluation, and funding consideration. Examples of this group may include applications from Candlelighters Childhood Cancer Foundation, the American Society for Clinical Oncology and the American Association of Cancer Research lectureships, and dues for various organizations.

iii) After review by the appropriate Peer-Review Committee, the application would be forwarded to the reconstituted Council. The new Council should be more broadly based than the current one to provide appropriate knowledge for review of the wider spectrum of awards for which it will be responsible. Making the Council more broadly based does not necessarily require a net increase in membership, but will require an increase the range of expertise represented. This new Council

would be somewhat analogous to the National Cancer Institute's National Cancer Advisory Board.

iv) After review by the Council, the application would be forwarded to either the Research and Clinical Investigation Committee or the Medical Affairs Committee, depending upon its origination, for approval.

v) The Research and Clinical Investigation Committee and the Medical Affairs Committee, after their approval, will forward the application to the Executive Committee of the Board of Directors for final approval.

There would be two additional subcommittees in this schema:

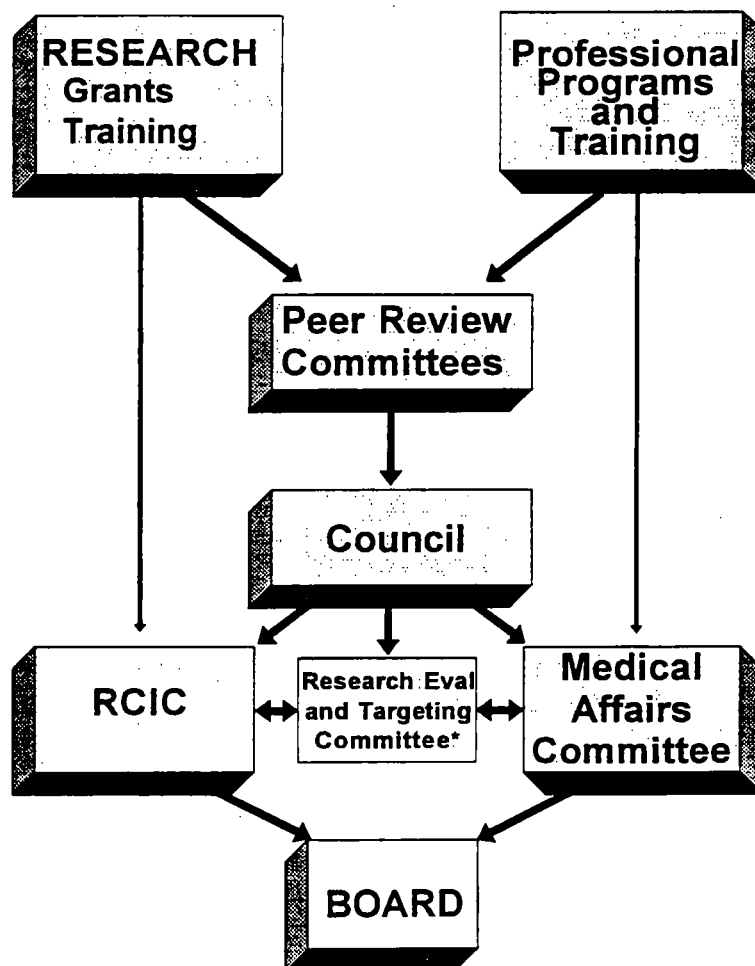
- a Subcommittee to Nominate Members of the Peer-Review Committees and the Council, charged with generating names to fill the positions in the Peer Review Committees. This subcommittee would consist of appropriate members of the Research and Clinical Investigation Committee and Medical Affairs Committee and the incumbent Council chair.
- a Research Evaluation and Target Selection Subcommittee, charged with reviewing the American Cancer Society's research portfolio and defining targeted research areas in which the American Cancer Society should invest.
(Please see section B.2.b. for the composition of this committee.)

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b) Further, the BRC strongly recommends that the time between Council recommendation and approval by the appropriate volunteer governance body be shortened so that the awardee can be notified in a timely fashion.

Under the current system of application review and approval, it is possible for a grant recipient to be notified only a few weeks or even days before the initiation of the grant. This situation is unacceptable and the staff and the Board of Directors should work together to devise a method to provide the awardee with more lead time to prepare for the initiation of the grant, adjust career decisions, and allow their institutions more rational planning.

Illustration 5: Proposed administration of Research and Professional Programs



3. Resource Allocation

Historically, research program support has received a minimum of 25% of the contributions to the American Cancer Society and programs related to medical grants and training of health care professionals have received 3% of the National Crusade income. The BRC discussed, at length, the support for American Cancer Society research and professional programs and ultimately recognized that it was not authorized to determine the priorities for funding for the overall organization. Acknowledging the importance of research to cancer control and the public's interest and demand for continuing support for research to understand and control cancer, the BRC feels strongly that the American Cancer Society should allocate the maximum possible amount of its income to research and professional programs.

Under the developing budgeting mechanism of the American Cancer Society, decisions should be made annually which recommend appropriate levels of support for research and professional programs. Justification for support of these proposed levels will be reviewed by the Board of Directors, or an appropriate committee designated by the Board of Directors, staff, and Divisions to ensure appropriate funding of recommendations. As this mechanism for National budgeting is implemented and more experience occurs, the BRC recommends an evaluation be performed of the percentages devoted to research grants and training when the BRC reconvenes.

Conclusion

The American Cancer Society's research and professional training programs offer a vital way of addressing the cancer needs of this country. The BRC feels that its recommendations strengthen already solid programs and provide avenues for their growth into the 21st century. However, the BRC does not have the ability to see into the future. Therefore, it tried to create flexible mechanisms so the American Cancer Society can adapt to newly identified needs and priorities that fit with its mission. The philosopher Heraclitus said, "There is nothing permanent except change." These recommendations position the American Cancer Society for that inevitability.

III. APPENDICES

APPENDIX A:

- 1. Charge to the Blue Ribbon Advisory Committee**
- 2. Members of the Blue Ribbon Advisory Committee**
- 3. Process of fulfilling charge to Committee**

1. Charge to Committee

The Committee is charged with conducting a broad review of the intramural and extramural research and medical grants programs; discussing and evaluating the future potential of these programs for the Society to accomplish its mission; and to advise the Society on which course to take to achieve the greatest impact.

This review should include discussion relating to the following points:

- What are we doing and why are we doing it? This includes consideration of intra and extramural programs, divisional research, and priorities for the Society.
- What have we contributed to the field of cancer research and training of specialized researchers, oncologists, nurses, and other shortage areas, and what national shortages currently exist?
- What is the Society's proper future role in contributing to cancer research and why should we do it?
- What proportion of the Society's resources should be invested in the intramural and extramural research and medical grants programs?
- Should research, cancer control, and career development awards be centralized at NHO and reviewed by a single standard of peer review?
- Review the matter of indirect costs of research -- how much is required and on which grants?

This committee will, in part, work with the Society Futuring efforts to assist in developing a vision for the future, keeping in mind some important points:

1. What are our distinctive and unique competencies as a cancer fighting organization?
2. What voids in research and cancer control do we need to fill?
3. What can we do for the fight against cancer that no one else can or will do?
4. What do we want the American Cancer Society to be like in the next century?
5. How can grantees and research and demonstration projects have the optimal impact on cancer control, image of the Society, and fundraising?

The Committee will prepare final reports to be given to the Medical Affairs Committee and the Research and Clinical Investigations Committee for review and subsequent approval by the Executive Committee and the Board of Directors.

BLUE RIBBON ADVISORY COMMITTEE REPORT

2. Members of the Blue Ribbon Advisory Committee

Thomas G. Burish, PhD (Chair)
Provost
Vanderbilt University

Blake Cady, MD (Vice Chair)
Professor of Surgery
Harvard Medical School
Director, Surgical Oncology
Deaconess Hospital

Archie Bleyer, MD
Head, Division of Pediatrics
Professor of Pediatrics
University of Texas
MD Anderson Cancer Center

Helen Brown
Jonsson Comprehensive Cancer Center
University of California, Los Angeles

Tim Byers, MD, MPH
Professor
Department of Preventive Medicine and Biometrics
University of Colorado School of Medicine

George Dessart
Chair-elect
American Cancer Society

John Durant, MD
Executive Vice President
American Society of Clinical Oncology

James Fordyce
Prince Ventures

Barbara Given, RN, PhD, FAAN
Director of Research
Michigan State University College of Nursing

Raymond Greenberg, MD, PhD
Vice President for Academic Affairs
University of South Carolina

Peter Greenwald, MD
Director
Cancer Prevention and Control
National Cancer Institute

Gordon R. Klatt, MD
Surgeon
Tacoma, WA

Raymond Lenhard, Jr. MD
Professor of Oncology and Medicine
Johns Hopkins Oncology Center

Gerald Mueller, MD
McArdle Laboratory
University of Wisconsin

John E. Niederhuber, MD
Professor of Surgery
Professor of Immunology and Microbiology
Stanford University Medical Center

David Rosenthal, MD
Director
Harvard University Health Services
Harvard University

William A. Semmes, Jr.
International Executive
Chase Manhattan Vista Funds

Hamilton O. Smith, MD
Professor of Molecular Biology and Genetics
Johns Hopkins University

Patricia G. Spear, PhD
Chair
Department of Microbiology and Immunology
Northwestern University Medical and Dental Schools

Robert Weinberg, PhD
Professor of Biology
Massachusetts Institute of Technology
Member, Whitehead Institute for Biomedical Research

Robert Young, MD
President
Fox Chase Cancer Center

Ex-Officio Members:

Irvin Fleming, MD
Immediate Past President
American Cancer Society

Larry Fuller
Chair, Board of Directors, 1993-1995
American Cancer Society

LaMar McGinnis, MD
President, 1994-1995
American Cancer Society

John Seffrin, PhD
Executive Vice President
Chief Staff Officer
American Cancer Society

3. Process of fulfilling charge to Committee

May 1994: Staff Research Design Team recommends that the American Cancer Society undertake a comprehensive review of the research and cancer control grants, oncology fellowships, and clinical career development programs.

September 1994: Blue Ribbon Advisory Committee on Research and Medical Grants is appointed.

October 1994: First meeting of BRC. Seven subcommittees were formed:

- Peer Review
- Division Research
- Outside Organization Research
- Behavior and Policy Research
- Targeted Research
- Collaborative Research
- Evaluation of Research Programs

All members of the Board of Directors were invited to submit their suggestions to the BRC.

November 1994: Subcommittees meet by conference call.

Synthesis of research ideas collected during the Society's Futures Project prepared for the BRC.

December 1994. Second meeting of the BRC.

December 1994-February 1995: Subcommittees meet by conference call.

February 1995: Third meeting of BRC.

February 1995-June 1995: Subcommittees meet by conference call.

June 1995: Fourth meeting of the BRC.

September 1995: BRC meets by conference call. Draft report presented to Executive Committee.

November 1995: Report presented to Research and Clinical Investigation Committee and Medical Affairs Committee.

APPENDIX B: CHRONOLOGY OF RESEARCH AND TRAINING PROGRAMS**1. Extramural Grants and Awards**

The American Cancer Society began its extramural research program in the mid-1940s, at the insistence of prominent volunteers, including Mary and Alfred Lasker, with the purpose of determining, as quickly as possible, the causes, prevention, early detection, and cure of cancer. Close to \$2 billion has been spent since the inception of the research program. During the 50 years of its operation, the program has evolved steadily, with new awards being created and others phased out in accordance with changing scientific and training needs and opportunities. Each programmatic change has been approved by the volunteer committee which has responsibility for the program, the Research and Clinical Investigation Committee, generally with advice from the scientific community. Stewardship to the public has always included outstanding peer review as the best means to ensure the scientific and fiscal integrity of the research grants program. Indeed, the American Cancer Society used peer review before the NCI or any of the voluntary health agencies. A brief research program chronology follows.

1945: Research is added to the Society's mission of education and service. Reports to Research Committee of the Board. Twenty-five percent of funds contributed to the Society earmarked for Research Program.

1946: First extramural research grants awarded.

1946-56: Peer review of grant applications done under contract by the Committee on growth of the National Research Council of the National Academy of Sciences.

1955-56: Review of the Research Grants program by the Ad Hoc Research Policy Survey Committee.

- Peer review transferred from National Research Council to National Office
- Four Scientific Advisory Committees established to peer review grant applications.
- Postdoctoral Fellowships, Scholar Grants, Institutional Research Grants, Additional Faculty Level Positions created. The latter is the predecessor of the current Research and Clinical Research Professorship program.
- Scientific Advisory Council established (predecessor of current Council for Research and Clinical Awards).

1966-69: Council on Projection and Analysis created to identify under-funded areas of investigation.

Clinical Investigations Grants Program created. Reports to Clinical Investigation Review Committee of the Board.

1969-70: McKinsey and Company review the management of the Research and Clinical Investigation Grants Programs and many of the resulting recommendations are

BLUE RIBBON ADVISORY COMMITTEE REPORT

implemented. Structure, management, and volunteer oversight of the peer-review system as it exists today is established:

- Clinical Investigation Program combined with general Research Program.
- Research Committee and Clinical Investigation Review Committee combined into Research and Clinical Investigation Committee of the Board.
- Council for Research and Clinical Investigation Awards created to serve as an oversight body for the Scientific Advisory Committees and to recommend paylines to the Research and Clinical Investigation Committee.

1971: Joint meeting of the Council for Analysis and Projection, Council for Research and Clinical Investigation Awards, and Chairs of the Scientific Advisory Committees:

- Scientific Advisory Committees should rank applications based only on scientific merit.
- Increase funds for Personnel Program.
- Council for Research and Clinical Investigation Awards should allocate funds among the Scientific Advisory Committees based on relative merit.

1983: Establishment of the extramural grants program on psychosocial and behavioral oncology research.

1984: Ad Hoc Committee to Review the Allocation of Funds Among the Programs:

- Strengthen the advisory role of the Council for Research and Clinical Investigation Awards in research policy and strategy decisions.
- Increase the number of three-year new grants and two-year renewals; previously most new grants were awarded for two years and renewals for one year.
- Award three-year fellowships to top candidates; previously all fellowships were awarded for two years.
- Earliest possible notification of applicants of review outcome.

1985-Present: Periodic realignment of the Scientific Advisory Committees to accommodate evolving research trends and training needs, resulting in the current 14 Scientific Advisory Committees, two of which review clinical and cancer control research grant applications exclusively.

Peer review of approximately 3,500 investigator-initiated project, personnel and institutional grant applications annually on a broad variety of topics in basic, preclinical, clinical and epidemiologic research.

Current types of grants and awards are: Research and Clinical Investigation (Project) Grants, Research Development Grants, Institutional Research Grants, Postdoctoral Fellowships, Physician Research Training Awards, Junior Clinical Research Awards, Junior Faculty Research Awards, International Cancer Research Fellowships, Scholar Grants, Research Professorships, and Clinical Research Professorships.

2. Intramural Epidemiology and Surveillance Research

When the Society was founded in 1913, it established a Statistical Committee to address the epidemiologic and statistical aspects of cancer. In 1946, after the Society's national reorganization, a Statistical Research Section was created, focused largely on evaluating cancer incidence and mortality trends, and on promoting the development of cancer registries in different parts of the US. Surveillance of cancer incidence and mortality patterns, together with projections of future trends as published annually in *Cancer Facts and Figures*, continues to be a major function of the present Department of Epidemiology and Surveillance Research.

1952: The Statistical Research Section expanded its work by undertaking a large scale prospective cohort study (the Hammond-Horn Smoking Study) which by the late 1950s, demonstrated decisively the effect of cigarette smoking on death rates from cancer and other diseases.

Mid-1950s-Present: Collaboration with Dr. Oscar Auerbach, a pathologist at the Veterans Medical Center in East Orange, NJ. The object of this work was to relate preclinical tissue changes in hospital autopsy material to environmental exposures as determined through next-of-kin interviews. Pathologic specimens have been saved from this collaborative work to form an archive at the National Home Office of 2,500 tissue specimens (paraffin blocks) from over 1,700 cases with accompanying data on smoking and occupational histories. Many important findings have resulted from this research, such as causative effects of smoking on bladder cancer. Collaborative studies have recently been undertaken using molecular epidemiologic approaches, correlated with smoking histories, with respect to specimens of the tracheobronchial tree and pancreas drawn from this tissue collection.

1954-1972: Cancer Prevention Study I (CPS I) involving about one million subjects recruited by 68,000 Society volunteers in 25 states, focusing on a wide range of potential oncogenic factors (diet, occupation, etc.) in addition to tobacco use.

1963-1987: Collaborative epidemiologic studies with Dr. Irving Selikoff, Division of Environmental and Occupational Medicine, Mt. Sinai Medical Center in New York City, concerning occupational causes of cancer, with special attention being given to interactions between asbestos exposure and cigarette smoking.

1982-Present: CPS II encompassing 1.2 million subjects recruited by 77,000 volunteers in 50 states; like CPS I, this study also addresses a variety of potential oncogenic factors. New relationships continue to be discovered about tobacco, diet, hormones, and exercise and certain medications (e.g., aspirin).

1988-present: The present Department of Epidemiology and Surveillance Research was formed after the Society moved its national headquarters from New York to Atlanta in 1988. The overall goals of the department are largely unchanged:

- to conduct ongoing surveillance and analysis of trends and patterns both of cancer occurrence (incidence, mortality, and survival) and cancer risk factors (behavioral and community-based) and
- to carry out analytic epidemiologic research concerning potential cancer risk factors, using different epidemiologic data bases (principally CPS I and CPS II).

3: Intramural Behavioral Research

Achievement of the Society's Mission 2000 goals rests on developing a better understanding of individual and population behavior. Therefore, the Society established an intramural Behavioral Research Unit to speed efforts in this area. The background leading to formation of this unit includes a Society Working Conference on Unmet Research Needs in Human Behavior and Cancer Risk Reduction (Bloomington, IN, 1989), the Society's Second Workshop on Methodology in Behavioral and Psychosocial Cancer Research (Santa Monica, CA, 1989), followed by a smaller joint planning meeting of Research, Public Education, and volunteer leaders. The unit also draws on the ideas of a model unit of the Victoria Anti-Cancer Council in Melbourne, Australia. The Victoria Unit works very closely with its own Epidemiology and Statistics staff as well as with education programs; its findings are published in scientific journals and publicized through its communication program.

The new Behavioral Research Unit will:

- Evaluate extramural behavioral research being conducted in cancer prevention and detection, and other priority areas, with the intent of facilitating and integrating relevant research accomplishments into existing American Cancer Society programs (technology transfer) via its committees and departments.
- Conceive original behavioral research with the purpose of helping to develop practical new program opportunities for the Society, some of which might best be conducted by volunteers (similar to CPS II) with population-based studies.
- Coordinate its activities with the extramural Psychosocial and Behavioral Research Units now being supported (via competing grants) at three cancer centers with Special Institutional Grants, and with the Psychosocial and Behavioral Research Scientific Advisory Committee.
- Provide, on request, the availability of expert impartial and systematic guidance in program design and voluntary consultation for new initiatives of the National office, including assisting with evaluating outcomes.
- Provide consultation to Divisions as resources permit.

4. Clinical Awards Program

The American Cancer Society has long recognized that one effective method of cancer control is to provide the means for physicians and dentists to obtain clinical training so that they may become future leaders and teachers in the fight against cancer. The Society has had a Clinical Awards program since 1948 and approximately \$103,000,000 has been invested in this effort. In the 46 years since its inception, the Clinical Awards program has been modified under constant volunteer guidance to respond to changing needs in oncology training. A brief chronology follows:

1948: Establishment of the National Regular Clinical Fellowships program to increase the number and improve the competency of physicians and dentists in the diagnosis and treatment of cancer. Whenever there has appeared a need for training in special skill, the program has been expanded accordingly.

1954: Adoption of a resolution by the Board of Directors to ensure ongoing funding of the Clinical Fellowships program by earmarking 3% of the total funds raised by the Society for medical grants and fellowships.

Development of Advanced Clinical Fellowships in Radiotherapy.

1957-1958: Evaluation of the Clinical Fellowship program results in expansion of the Advanced Clinical Fellowships in Radiotherapy program to include the other medical and dental specialties in the diagnosis and treatment of cancer. (Name changed to Junior Faculty Clinical Fellowship in 1972.)

1971: Adoption of the Professorships of Clinical Oncology as a National grants program based on successful piloting by a small number of Divisions between 1967 and 1969.

1985: Establishment of the Clinical Oncology Career Development Awards and elimination of the Junior Faculty Clinical Fellowship.

1988: Expansion of the Professorships of Clinical Oncology as a result of favorable evaluation by the Acadia Institute.

Creation of the current Clinical Oncology Fellowship program and abolition of the Regular Clinical Fellowship program based on the results of a 1987 survey of Fellows and Fellowship program directors.

Establishment of Clinical Oncology Social Work Training grants to increase the number of oncology social workers in clinical practice and to support psychosocial oncology research. The first awards are made in 1989.

1989: The Clinical Fellowships Committee recommends creation of a Cancer Control Career Development Award for Primary Care Physicians. The first are funded in 1990.

BLUE RIBBON ADVISORY COMMITTEE REPORT

1993: Based on recommendations of an Ad Hoc Task Force, the first Cytotechnology Training grants are awarded to institutions with training programs accredited by the American Society of Cytology.

Approval of the recommendation of a special task force to create a Physician Training Award in Preventive Medicine. The first awards were made in 1994.

5: Nursing Awards

The American Cancer Society's Scholarships and Professorships in Oncology Nursing program was established to enhance the care of persons with cancer and their families and those at risk for cancer by strengthening nursing practice. This is accomplished by providing assistance for advanced preparation in research, education, administration, and clinical practice in cancer nursing and by strengthening the oncology content in curricula of undergraduate and graduate programs of oncology nursing. A brief history follows:

1978: The Society Workshop on Role Definition and Curriculum Construction in Oncology Nursing concluded that oncology clinical nurse specialists should be prepared at the master's degree level. This conclusion was endorsed by the Oncology Nursing Society.

1980: Approval of the recommendation of the National Nursing Advisory Committee that a Scholarship program for nurses studying for a Master's degree in oncology nursing be established. The first scholarships are awarded in 1981.

Establishment of the Professorship in Oncology Nursing program modeled along the lines of the Professorship in Clinical Oncology program.

1986: Approval of the Scholarship program for doctoral study in oncology nursing and awarding of the first Scholarships.

1990: External evaluation of the Professorship in Oncology Nursing Program.

1994: Publication in Oncology Nursing Forum of the results of the long-term evaluation of the Scholarship program initiated in 1984, and initiation of evaluation of the doctoral degree program.

**APPENDIX C: CONTRIBUTIONS OF THE AMERICAN CANCER SOCIETY TO
CANCER RESEARCH AND THE TRAINING OF HEALTH CARE
PROFESSIONALS**

1. Research

Since the American Cancer Society awarded its first research grants in 1946, the Society has been a major contributor to progress in these areas:

- **Biologic basis of cancer.** An enormous achievement, which depended upon the research results of many investigators studying many different cancers, has been the basis of our current understanding that (i) cancer is not a single disease, but many diseases; (ii) each cancer is genetically determined and occurs as a result of a distinct set of mutations in genes that control cell growth and division; (iii) each cancer therefore has a somewhat different biologic basis and presents different challenges for prevention and treatment; (iv) the best hope for designing treatments effective against a spectrum of cancers is to understand more fully the mechanisms by which cell division is controlled and by which blood vessels are able to grow into solid tumors.
- **Causes of cancer.** Another very important achievement, again based on the research results of many investigators studying many different cancers, has been our current understanding that (i) nearly every cancer has multiple causes; (ii) environmental factors, including tobacco smoke and extracts, can be important causes of cancer and these environmental actors have their effect by causing mutations in genes that control cell growth and division; (iii) certain viruses can also be causes of cancer, by introducing into cells viral genes that alter the control of cell growth and division (iv) inherited mutations can also be causes of cancer; (v) there may be other causes of cancer that have not yet been identified. The epidemiologic research conducted by the Society over the past 40 years (especially Cancer Prevention Studies I and II) has contributed greatly to our understanding of the relation of tobacco use and other environmental factors to human cancer risk. These continuing epidemiologic analyses have provided data essential to public programs of cancer prevention and control.
- **Control of cancer.** Given the multiple causes of cancer, it has become clear that prevention of cancer must involve a multipronged approach including public policy efforts to limit exposure to environmental carcinogens, public health efforts to improve access to diagnosis and treatment and to prevent infections with carcinogenic viruses, and public education efforts to change behaviors that put persons at risk of cancer or that impede effective diagnosis and treatment. because of past progress in defining the genetic basis of cancer, it can be predicted that genetic profiles of individuals (their inherited genes) and their tissues (subject to genetic mutations caused by environmental or infectious assaults) will be used in the future to determine the types of screening and diagnostic tests that should be performed for any individual. The need for genetic counseling to guide medical and reproductive decisions will undoubtedly increase. Cancer control continues to require a wide range of research efforts including

projects to identify new environmental carcinogens and define their mechanisms of action, to develop effective approaches to the prevention of certain viral disease, to fill in the gaps in our understanding of the genetic basis of cancer, and to understand how to influence the behavior of individuals and institutions.

- **Cancer treatment:** There has been considerable progress in the development of treatments that are more effective against the cancer itself and less toxic to the individual. For the most part, these past improvements in cancer treatment have been empirical rather than rational, because key information about the biologic and genetic basis of cancer was not available or could not be exploited. The accumulated knowledge about the biologic basis of cancer and new developments in molecular biology only now provide the means to develop new cancer treatments that correct the underlying genetic defects or selectively control the multiplication and metastases of cancer cells. Now, more than ever, a continued investment in basic and applied research can be expected to yield a quantum leap in the development of new and more effective cancer treatments.

Specific areas in which the Society has made contributions include:

- establishing the link between use of tobacco products and increased risk for cancer;
- recognizing the need for fundamental research to define the biologic and genetic basis of cancer;
- initiating some of the first research programs directed toward changing human behaviors;
- understanding the structure of DNA;
- identifying the presence and function of oncogenes and suppressor genes;
- understanding the hormonal basis of many cancer;
- discovering that viruses can cause cancer;
- developing some of the basic tools used in molecular genetics;
- defining the recombination of the body's immune system;
- exploring the use of bone marrow transplants;
- developing the Pap test;
- elucidating the role of tobacco in cancer and heart disease;
- developing tamoxifen as the first candidate drug to prevent breast cancer;
- discovering the progressive genetic alterations in colon polyps and their progression to cancer;
- showing that lumpectomy and adjuvant chemotherapy together are as effective as mastectomy;
- increasing the importance of supportive care through advances in control of nausea and vomiting, pain, and stress;
- developing early knowledge of gene therapy;
- showing that oral contraceptives decrease uterine and ovarian cancer by 50%.

2. Health Care Professional Training

Education is identified in the American Cancer Society mission statement as one of three methods for achieving our primary goal of eliminating cancer as a major health problem. The potential for accomplishing this through support for health care professional training was formally recognized by the American Cancer Society with the creation the National Clinical Fellowships Program. About 40 years ago, and concurrent with the institution of the American Cancer Society's Research Grants Program, the first support for the training of physicians and dentists in the diagnosis and treatment of cancer began. Between 1948 and 1995, 8,587 physicians and dentists were supported by these fellowships. As a result, the American Cancer Society has had a significant impact on the conduct and content of oncology training. This has been accomplished by direct funding of medical and dental fellows and less directly, but no less importantly, by the development of criteria for the approval and funding of training programs. By 1981, when the number of institutions requesting support for fellowship training exceeded the available funding, a priority rating system was developed to choose the recipients of the awards. The strong implication is that the Society played a significant role in the development and standardization of specialty training in oncology.

The Society has been similarly involved in the field of oncology nursing. In 1978, 10 years after the first master's degree program in oncology nursing was initiated, the American Cancer Society convened a workshop that had two significant outcomes. The first was a recommendation, ultimately supported by the Oncology Nursing Society, resolved that in order to use the title "Oncology Clinical Nurse Specialist," an individual must hold a master's degree in oncology nursing. Second, a document entitles "A Master's Degree with a Specialty in Oncology Nursing: Curriculum Guide and Role Definition" was produced. These guidelines are used for the development of oncology content in graduate nursing school education programs as well as by students when making decisions about oncology programs. Subsequently, in 1980, the Board of Directors approved funding to initiate a program of master's level scholarships for nurses seeking advanced preparation in oncology. Six years later, the need for support for advanced preparation for specialists in oncology nursing in the areas of research, education, administration, and clinical practice was recognized with the addition of doctoral-level Scholarships in Cancer Nursing (1986). To date, a total of 368 scholarships have been awarded, and other agencies and organizations have formulated their own programs of training support.

The approach and philosophy of the Society's Clinical Awards programs have therefore evolved to explicitly include the intent to exert a positive influence on a profession as a whole while also attempting to increase the number of personnel in these fields. With this as the case and based on the advice of experts in the specific field, the policies and program requirements are developed with the purpose of encouraging the development of programs and individuals in concert with not only the American Cancer Society's mission, but also the ideal professional practices for the oncology field. This is achieved by identifying very specifically the minimum resources and staff, e.g., an approved multidisciplinary cancer program and individuals with recognized specialty

training, that must be available for a program to be considered for funding; by defining the activities that must occur during the course of an award, e.g., relevant research or teaching; and by precisely communicating the outcomes expected from the funding; e.g., commitment to a career in academic oncology. So, beyond realizing quantitative results by increasing the number of health care professionals engaged in various clinical cancer control activities, the Clinical Awards programs have the potential to qualitatively affect the overall profession to which funding is offered. In addition, the significance of this activity has been acknowledged by other agencies and organizations, which have formulated their own programs of training support.

Currently, there are nine Clinical Awards programs. Support continues to be offered to medical and nursing specialists in oncology, but there has been considerable expansion and evolution of this area to include many other professions within oncology. Newer programs include, in chronological order, the Professorship of Clinical Oncology (1971) and the Professorship of Oncology Nursing (1980). These programs support medical and nursing school faculty involved in teaching, patient care and research, and have as a primary goal to increase curricular oncology content. In 1985, the longstanding advanced fellowship program for oncologists was revised to become the Clinical Oncology Career Development Award. This grant was intended to encourage beginning faculty committed to academic careers by supporting their development as expert clinicians and as independent oncology researchers. Three years later (1988), the Clinical Oncology Social Work Traineeship was created to increase the number of social workers trained to deal with the psychosocial needs of cancer patients and their families and to encourage more biopsychosocial cancer research. The following year, with the goal of improving cancer control in primary care, the Board of Directors approved the Cancer Control Career Development Award for Primary Care Physicians. Individuals funded through this program would exert leadership in this field through involvement in primary care practice, education, and research activities related to cancer control. In order to alleviate a manpower crisis among cytopathology technologists, who are instrumental in the process of screening for cervical cancer, Cytotechnology Training Grants were first funded in 1993 for accredited programs and new programs seeking accreditation. Lastly, during the same year, the Physician Training Award in Preventive Medicine was started to provide support to physicians to become trained in preventive medicine with expertise in cancer epidemiology, prevention, and early detection. In each instance, the Society has initiated a process to increase the number of individuals or programs engaged in particular activities relevant to cancer control and to exert a positive influence on the conduct of these activities. It is hoped that these programs for health care professional training will continue to build on these accomplishments.

APPENDIX D: RESEARCH DEFINITIONS

Basic research: Research which seeks to answer fundamental questions about the development and the nature of cancer. Most of these studies involve non-human materials, though some involve human materials. Any of these studies may eventually lead to major improvements in the prevention and/or cure of cancer but at this stage are more than one step away from clinical application. Some basic studies have to be done in humans because there are not adequate animal models; for example, to study mechanisms of pain or nausea.

Behavioral Aspects of Cancer Prevention and Control Research: Investigation into the means to reduce exposure to carcinogens by altering lifestyle to reduce cancer risk, to improve early detection and utilization of effective treatment. The latter refers to options which cure or significantly improve survivorship and enhance the quality of life. The intent of cancer prevention and control research is to find methods for reducing the cancer burden in defined populations and systematic strategies for translating them into practice. (Cancer at a Crossroads: A Report to Congress for the Nation, September, 1994)

Change Agents. Those individuals who are integral to promoting and influencing behavior change in others, such as teachers, public health professionals, health educators, and administrators.

Clinical research: Research which utilizes human subjects or materials and has direct application to the prevention, diagnosis, or treatment of cancer in the individual or group of individuals under study, or the rehabilitation (including quality of life issues) of the patient. Clinical research includes a broad variety of activities and there are many ways to subcategorize those areas of study. The American Cancer Society divides clinical research into the functional subcategories of clinical trials, psychosocial and behavioral research, and cancer control research.

Epidemiologic research: Research which investigates the circumstances under which cancer occurs in populations. It seeks factors which cause cancer (environmental exposures, personal habits, genes, viruses, etc.) or which promotes prevention or control of cancer in populations. Epidemiologic studies both describe the distribution of cancer in populations (rates of time and between places) and analyze cancer risk determinants. Such research is the source of many of our ideas about the causes of cancer, factors that determine high risk for development of cancer and methods for the control of cancer

Ethics Research: Value judgments and decision-making in regard to cancer control. This may include behaviors related to cancer prevention (i.e., what kind of education is most effective for various populations), detection (i.e., what screening tests are appropriate to recommend to people in genetically determined high-risk groups) or treatment (i.e., access to experimental therapy, attitudes towards physician-assisted suicide).

Health Services Research. Also called research on access to care, this research deals with the ways by which people interface with health care delivery systems. It investigates the barriers to health care and the differing, and often changing, needs of patients due to changes in the health care system, such as managed health care, high-tech day hospitals, and reduction in social services. This area of research includes the study of attitudes and sensitivities of professionals who provide cancer care, a very important issue in times of rapid change within the health care system

Policy Research: Investigation or experimentation which deals with the creation and effects of laws and public policies which affect people who are making health decisions related to cancer control. Such research would include issues of patient confidentiality, smoking regulations, health insurance, and accessibility of health care.

Preclinical (clinically relevant) research: Research which has the primary aim of providing results which are intended to be applicable to the prevention, diagnosis or treatment of human cancer or to the rehabilitation of the cancer patient but are not yet ready for use in humans. Such studies will frequently utilize materials but do not directly lead to the improved management of patients with cancer. Some examples are: the chemical synthesis of anti-cancer drugs based on models of clinically effective substances; studies of human growth factors leading to diagnostic or therapeutic application; the production of monoclonal antibodies for potential use in the diagnosis or treatment of human cancer.

Psychosocial and Behavioral Cancer Research: Research directed at understanding and improving the motivational factors in cancer prevention and screening, and the social and emotional impact of cancer and its treatment on individuals, their families, and their caregivers. It includes studies for improving quality of life, and also the development of instruments (questionnaires, tests) that will generate new knowledge.

Research: The trained inquiry or experimentation to discover facts, their interpretation, and practical application. It is by continuing biomedical research that the nature, causes, prevention, and cures of diseases are discovered. There are four major categories of cancer-related research: Basic research, epidemiologic research, preclinical (clinically relevant) research, and clinical research. These are intended to be mutually exclusive.

Translational research. Investigates methods for rapidly applying research findings to clinical practice or public health interventions. It also serves to bring scientific questions from the field back for laboratory or clinical research study.



Marc Garufi

01/28/98 05:25:58 PM



Record Type: Record

To: Jerold R. Mande/OSTP/EOP, Joshua Gotbaum/OMB/EOP
cc: Barry T. Clendenin/OMB/EOP, Richard J. Turman/OMB/EOP
Subject: Per Your Request: NIH Cancer Information

As you requested, attached (as a Freelance Graphics document) is a chart displaying the 5-year NIH Cancer Research funding levels for use in tomorrow's briefing. The chart highlights the largest increase in cancer research at NIH in history.

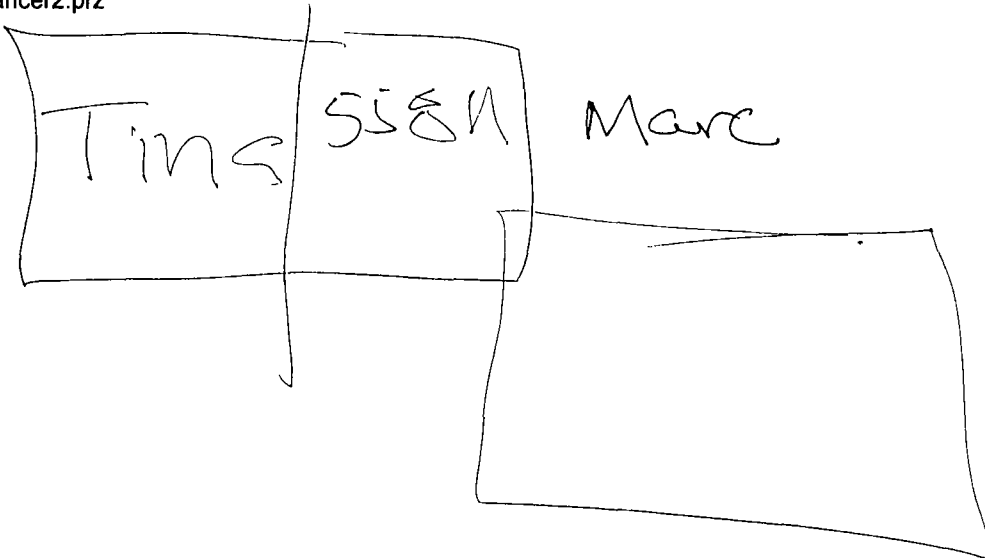
FYI: We did some follow-up on the question of whether the FY 1999 Budget provided the largest increase for NCI and/or Cancer Funding:

- From 1938 to 1998, the largest single year funding increase for NCI was \$248 million in FY 1992; the FY 1999 increase for NCI is \$229 million.
- The FY 1999 funding increase for Cancer Research at NIH of \$291 million is the largest single year increase since 1987, the first year NIH began keeping record of cancer research funding levels.

Please let us know if you have questions.



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NewsFlash
WHAT'S HAPPENING NOW

WASHINGTON
THE FULL STORY

Clinton budget offers salvo in war on cancer

By **LAURA MECKLER**
The Associated Press
01/29/98 5:00 PM Eastern

WASHINGTON (AP) -- Saying scientists are "right on the verge" of a breakthrough in cancer research, Vice President Al Gore said Thursday the administration wants to increase federal funding by 65 percent over the next five years.

The budget plan, which must be approved by Congress, would also allow Medicare patients access to clinical trials for the first time.

"We want to be the first generation that finally wins the war against cancer," Gore said Thursday. "For the first time, the enemy is outmatched."

Later, Gore flew to California's Silicon Valley to announce plans to extend a corporate research and development tax credit.

In his budget, President Clinton is proposing considerably more money for all federal research at the National Institutes of Health, but cancer research would get the biggest boost.

Clinton is counting on revenue from a national tobacco settlement to fund the plan, despite its shaky prospects on Capitol Hill. Still, his call for more biomedical research funding should be welcomed in Congress, where members usually propose spending more than the president requests.

"We are united in our effort to get the resources into the hands of the researchers," Sen. Connie Mack, R-Fla., said Thursday. But he cautioned that it's not a sure thing. "Where are we going to find this money?" he asked.

Last year, Clinton proposed only a 2.6 percent increase in funding for NIH. But for next year he is asking Congress for \$1.15 billion more for NIH, an 8 percent jump, including 10 percent more for cancer research. Over five years, Clinton wants a 50 percent increase overall, including a 65 percent jump for cancer research to \$4.8 billion.

In singling out cancer research for more money, Gore noted that cancer touches nearly every family, afflicting 40 percent of Americans and killing

half of them. Advances in research, he said, hold promise for better prevention, detection, treatment and, ultimately, a cure.

"We're right on the verge of a whole new phase in this war," he said.

So far, most of the research has focused on understanding cancer and its genetic links, said Dr. Joseph Pagano, founder of the Lineberger Comprehensive Cancer Center at the University of North Carolina. Now, he said, researchers are ready to apply that knowledge to treatments for actual patients.

"In the next decade we're going to be actually putting it to the test," Pagano said.

At the same time, administration officials said, the long-term budget plan should allow researchers to plan for the future while giving frustrated young scientists hope that money will be there. Health and Human Services Secretary Donna Shalala said the new money should allow NIH to fund about one-third of the approved research applications it receives.

The administration is also proposing \$750 million to allow Medicare patients to participate in clinical cancer trials for the first time. Like many other health insurance plans, Medicare will not pay for treatments unless they are established treatments.

A three-year demonstration project will determine how much it actually costs to participate in a trial and will develop guidelines for what constitutes a "high-quality" experiment, said Richard Klausner, director of the National Cancer Institute. The data could then be used to persuade private insurers to cover clinical trials for their patients.

There should be enough money to pay for all Medicare patients who qualify for cancer trials and want to participate in the project, he said.

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