

STATEMENT OF THE CANDLELIGHTERS  
ON THE "BIOMEDICAL RESEARCH AND RESEARCH TRAINING  
AMENDMENTS of 1978 (H.R. 10908)  
BEFORE THE  
SUBCOMMITTEE ON HEALTH AND ENVIRONMENT  
OF THE  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE  
OF THE  
UNITED STATES HOUSE OF REPRESENTATIVES

Mr. Chairman and Members of the Committee:

My name is Grace Powers Monaco; I am representing CANDLELIGHTERS, a national coalition of families of children affected by cancer in 40 states. We wish to bring to your attention those areas in which federal funding has had the most noticeable impact on our children's lives and those which we feel merit your further attention either through program re-direction, emphasis or increased funding levels or position allocation.

Let me first extend on behalf of all of us our deep gratitude and appreciation to you, Mr. Chairman, and the members of this Committee for your continuing efforts on behalf of all persons afflicted with cancer. Your unflagging interest in cancer research and the translation of this research into tangible programs for detection, treatment and rehabilitation of cancer victims throughout the country has widened the benefits of the whole cancer effort. We know that the lives of our children have been and are continually being extended, and in many cases preserved, through the cancer research efforts which this Committee has supported through the National Cancer Institute.

Our testimony on H.R. 10908 focuses upon: the establishment of Comprehensive Cancer Centers for the Research of Childhood and Adolescent Cancers; the establishment of a National Comprehensive Cancer Registry for Childhood and Adolescent cancers in support of the national research effort; cancer control, specifically the outreach programs for the demonstration of successful methods of treating childhood and adolescent cancers; nutrition and cancer and the information dissemination role of the National Cancer Institute. Attached as Appendix A hereto are drafts of the specific statutory language requested by CANDLELIGHTERS for the proposed revision of the authorization for the National Cancer Institute.

Further, Appendix B hereto contains CANDLELIGHTERS recommendations as to appropriations levels for the basic Institute program and for cancer control for fiscal 1979 through 1981. CANDLELIGHTERS believes that the authorization levels set in H.R. 10908 should be increased to provide the appropriations committees with flexibility in responding to the needs of the Institute as they evolve.

THE NEED FOR COMPREHENSIVE CANCER CENTERS FOR  
CHILDHOOD AND ADOLESCENT CANCERS AND FOR A  
NATIONAL COMPREHENSIVE CHILDHOOD AND ADOLESCENT  
CANCER REGISTRY IN SUPPORT OF THE RESEARCH EFFORT

CANDLELIGHTERS request for the specific establishment or designation of Comprehensive Cancer Centers for research into Childhood and Adolescent cancers and the clinical application of that research together with an expansion of outreach programs to the community based physician and a supporting National Registry has as its objectives:

- (1) To encourage a more effective advancement in the biomedical and behavioral sciences by focusing upon innovative, creative investigation in Childhood and Adolescent Cancer.
- (2) To develop through investigation, curative treatment for this patient population which would not include compromising either the quality of life or their individual basic human rights as research subjects and as minors.
- (3) To "extend survival with disease" by "curing" more children and adolescents more efficiently.

Through our unique vantage point as grass roots participants in the National Cancer Institute's clinical investigation efforts, we have observed and experienced both the rewards and the problems in the current research and demonstration programs which affect the cancer-stricken children and families. These observations, detailed below, provide the genesis of CANDLELIGHTERS proposal.

Childhood cancer research has proved to be the single most effective model for understanding and treating many forms of cancer. Developments in childhood cancer have been successfully applied to adult cancers. Pediatric cancers pioneered combined modality therapy utilizing surgery, radiotherapy and chemotherapy, various rescue factor approaches and adjuvant chemotherapy which have effectively arrested or retarded the development of many adult cancers. Dr. Emil J. Freireich of the University of Texas System Cancer Center in Houston has said that drug combinations pioneered in pediatric cancers are now producing remissions in a majority of adults with acute myelogenous leukemia and a "proportion of these patients are being cured. Five years ago if you asked me if we were producing cures, I could only say, 'rarely'." Additional specific examples include the development of and use of antifols in childhood leukemia which led to curative measures in adult cancers, specifically the use of antifols in women with choriocarcinoma; adjuvant chemotherapy in breast cancer to prevent metastases; and, the combination chemotherapy in acute lymphocytic leukemia which is now being used successfully in adult Hodgkins disease, finally the total therapy concept used for childhood ALL is now being used successfully in cooperative study clinical trials involving adult lung cancers.

These applications of the results of research in pediatric and adolescent cancers underscores the importance of preserving, expanding and building upon the research efforts committed to childhood and adolescent cancers.

Observations by parents in a variety of treatment settings suggest that this research effort can best be served by Comprehensive Cancer Research Centers for childhood and adolescent cancers.

Although the inclusion of a pediatric oncology center in an adult institution need not necessarily thwart development, our conversations with noted oncologists, -pediatric and otherwise-, confirm that the Comprehensive Cancer Centers authorized by this Committee are almost exclusively oriented toward the adult cancers.

Childhood and adolescent cancers present differently, may have different causes, also respond differently from the adult cancers. The research breakthroughs in pediatric cancer therapy have largely originated from centers specifically devoted to pediatric cancer. Further, the apparently prevailing view in these centers is that pediatric cancer is a small percentage of cancers, and thus shouldn't receive the attention or program status that adult cancers receive.

The need for a nationwide, coordinated approach to childhood and adolescent cancers arises from:

- (a) A need to insure that all children with cancer have access to effective diagnostic and treatment modalities.

CANDLELIGHTERS of Metropolitan Washington surveyed its members on the problems of diagnoses. The results, drawn from 54 case histories, showed that 61 percent of the cases, involving 13 types of cancer, were accurately diagnosed within 16 days. But diagnosis for the remaining 39 percent took anywhere from 16 days to a year.

The Chairman of the American Academy of Pediatrics Neoplastic Disease Committee, Dr. Frederic Silverman, confirms that "any given pediatrician in the course of his 30 or 35 years of practice is only going to see a few cases of actual cancer. Consequently, he's not in a position to deal with it unless he can get some real help and get to the experts in the field."

- (b) The need to develop less toxic therapies to avoid adverse complications in children with cancers which can now be successfully treated.

"For the longevity of life, we paid dearly. He lived for a long time (7years) but the results of his living with this disease caused extensive damage to

his lungs and cataracts in his eyes. The children are living longer, but the drugs are still as toxic as ever. It becomes a serious question of the deterioration in the quality of life" - Annandale, Va. mother of a 10 year old son recently deceased from acute leukemia.

- (c) A need for sufficient accrual of child cancer experience in certain cancer categories, which have been resistant to therapy, and require increasing research attention.
- (d) A need to follow meticulously the long term effects including tetragenic, carcinogenic, mutagenic, neurological and long and short term risks in pediatric and adolescent cancer treatment (survivors).

These latter needs arise from a welcome phenomenon. Children with leukemia, lymphoma or hodgkins disease may now be treated adequately in a community hospital setting. Demonstration outreach programs in community hospitals and pediatric oncologists treating children in a multi-center study funded by the NCI Division of Cancer Control and Rehabilitation (Children's Hospital, Los Angeles; Children's Hospital, Cincinnati; Children's Hospital, Denver; Dartmouth Medical School; University of Alabama; New York-Cornell; Mount Sinai School of Medicine) have clearly established, using a children's hospital as an evaluation and re-evaluation center, that in excess of 50% of these children will probably attain a five year survival.

However, since pediatric malignancies are much less common than adult cancers (1%) and since children treated in community hospitals are not generally included in research studies, the ability to follow and utilize them as research subjects in developing less toxic therapy and in following long term effects of childhood cancer is clearly diminished. This problem for research innovation and treatment will increase as more and more pediatric cancers, thru DCCR's demonstration programs, move into community hospitals for treatment. Since childhood cancer is the model for the study and understanding of all tumor types, these falling patient accrual rates pose a threat to the entire cancer research efforts.

For all these reasons, it is recommended that there be established or designated regional comprehensive cancer research centers for children and adolescents, including the clinical center at NIH. It is further recommended that the research effort at these designated centers be supported by the establishment, supervisor, and utilization of a nationwide Comprehensive Childhood Cancer Registry through the Division of Cancer Treatment at the National Cancer Institute.

This goal is realistic and workable: Almost 4800 of the anticipated 6400 new pediatric cancer cases each year in the U.S.A., are accessible to a data retrieval system through their inclusion in one of the childrens cancer study groups or existing pediatric comprehensive centers. Research programs and the community based or children's hospital based cancer

control programs may make the remainder accessible.

The Childhood and Adolescent Cancer Comprehensive Centers would serve as the focal point of a government financed effort in pediatric cancer research and its clinical application, i.e., these centers would serve as a diagnostic reference point and an available resource for re-evaluation and long term follow-up for all pediatric cancer patients. These centers, by management and use of this large and varied research data system, could more quickly pinpoint deadends or promising beginnings in research and clinical trials, and thus speed refinement, improvement and change in pediatric cancer management.

One model suggested for this National Registry is the "Delaware Valley Pediatric Oncology Program and Central Tumor Registry" which is a Division of Cancer Control and Rehabilitation program originating from Children's Hospital in Philadelphia under the direction of Dr. Audrey Evans.

The bottom line for this CANDLELIGHTERS proposal is finding the research and outreach climate that will not merely reverse the disease but will cure the child. This goal is not beyond our reach. At a National Conference on the Lymphomas and the Leukemias, in October of 1977, the term "cure" was used repeatedly by researchers. 30 years ago the average survival rate for children with acute lymphocytic leukemia (ALL) was only two months. Now for 50%, it is five years, with many living and well far longer.

When former childhood leukemia patients live long enough to have their own families and normal lives, "it is splitting hairs not to call them cured", said Dr. David J. Galton of the Royal Postgraduate Medical School, London, England. "We are possibly beginning to see the same upswing in other forms of cancer".

Dr. Joseph V. Simone of Stanford University and Dr. Donald Pinkel of Milwaukee Children's Hospital told of a group of more than 100 children with ALL who are in remissions, apparently well, three to ten years after drug treatment was stopped. "I think they are fairly safe now." Dr. Simone said.

Dr. Charles M. Huguley, Jr. of Emory University said, "you get different results if you treat in expectation of cure rather than palliation. Once we realized we were really curing Hodgkin's diseases, the cure rate zoomed up."

We are also seeing a similar pattern developing in several other cancers of children and young adults such as primary bone sarcoma. Not enough time has elapsed to be able

to give long-term survival figures, but the early pattern is so similar to the one we saw in ALL that I hope in a few years to be able to give equally good news about them, These recommendations by CANDLELIGHTERS hold the promise of more good news.

#### DIET AND NUTRITION IN CANCER

At the request of CANDLELIGHTERS, the Diet, Nutrition and Cancer Program (DNCP) of the National Cancer Institute was mandated by Congress in 1974. At that time amendments were introduced to Sec. 407 (b) (4) of the National Cancer Act of 1971 which now authorizes the National Cancer Program to:

"collect, analyze, and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) useful in the prevention, diagnosis and treatment of cancer..."

Up to the end of 1977, 31 projects have been initiated and a range of educational and informational documents has been developed. The program has established itself with the medical and scientific communities. This has been done with the funding and staffing that fall short of recommendations and requests, and that are very low in relation to the importance of nutrition in cancer prevention and treatment, and of the expected cost effectiveness of nutrition research.

The DNCP informally coordinates its research activities with NIH programs as well as other government agencies. During 1976 and 1977, the NIH Nutrition Coordinating Committee (NCC) emerged as a trans-NIH entity for overall coordination of nutrition activities. It is likely that the NCC will develop an operational coordinating function during the next few years. At that time, the activities of the Diet, Nutrition and Cancer Program will be integrated in an overall set of NIH priorities in nutrition.

Some of the projects completed are nutritional handbooks, for both adults and pediatric cancer patients; Review and Analysis of Categorical Citation Information relevant to the DNCP; Literature Study on Indicators of Health and Nutritional Status with Emphasis on Primitive populations; Literature Study to Evaluate Health parameters in various human populations in relation to diet.

Some ongoing projects include: Identification of Past, Ongoing, and future dietary and nutritional surveys and Cancer Epidemiology studies; Development of a guidebook for inclusion of Dietary and Anthropometric Parameters in cancer epidemiology studies; survey of Dietetic Practices and Procedures

used in feeding cancer patients; Evaluation of the role of Learned food aversion in the cancer patient; Gustatory (taste) evaluation of cancer patients; Anorexia in Adult and Pediatric cancer patients; Optimal Nutritional support as an adjunct to cancer therapy in the pediatric patient; studies of differential nutritional requirements by Host and tumor as the basis for dietary treatment of cancer (brain tumors); Optimal Nutritional support as an adjunct to cancer therapy in the adult; Environmental Stress and Tumorigenesis; Nutritive quality of dietary fiber for humans; dietary components and cancer development; effect of nutritional and environmental stress on carcinogenesis; effect on nutritional stress on carcinogenesis.

Some of the new programs include: Dietary patterns, nutritional assessment, and cancer incidence of American vegetarians; Quantification of changes in body composition in cancer patients and evaluation of pharmacologic agents for the treatment of anorexia in the cancer patient.

These programs speak from a scientific basis to the questions which American public asks on the relationship of diet and nutrition to the cause, prevention and treatment of cancer. We specifically request that authorization of this program be retained. Levels of appropriations which appear to be needed to support this program are 10 million in fiscal 1979, 12 million in fiscal 1980, 16 million in 1981.

#### INFORMATION DISSEMINATION

The Office of Cancer Communications has initiated a variety of programs including a Clearinghouse and Cancer Information Services through the Centers to implement the mandate of the 1974 Act to devise means to interpret and disseminate new and existing knowledge and information produced by the cancer program to researchers, practicing physicians and the general public. The demands on this office by the scientific and lay public are great. CANDLELIGHTERS can attest to the value of the information services provided and their usefulness to parents and front line physicians. They are indeed bridging the information gap. Due to the efforts of this office, all of the site specific pamphlets on pediatric cancer have been updated and new ones have been added. However, there is one omission in the current statutory language which should be remedied. The cancer "family" or patient also needs information on rehabilitation, the key, among other things -, to a successful re-entry into the community. For this reason CANDLELIGHTERS requests that the statute extend the Institute's information dissemination role to include and the rehabilitation of the cancer patient including in the latter term information relating to employability, insurability, education, physical therapy, psycho-social support, and the long term effects of cancer therapy in surviving cancer.

We also request that six additional positions be assigned to the dissemination effort.

Mr. Chairman, Members of the Committee, on behalf of all parents across the country, I should like to again commend you for your efforts and for your understanding of our problems. Your dedication to the cause, the cure and the prevention of cancer encourages us to face the future with a greater degree of hope and peace of mind. Those of us who have lost children are grateful that your efforts to authorize the cancer research that will be a memorial to them. And those of us whose children are under treatment are grateful for the hope which research gives in maintaining their well-being.

We gratefully acknowledge the part this Committee has played in the effort to conquer this dreaded disease. Thank you for permitting us to appear before you.



APPENDIX A

CHILDHOOD AND ADOLESCENT CANCER CENTERS;  
COMPREHENSIVE CHILDHOOD AND ADOLESCENT  
CANCER REGISTRY

SEC. 408 A. National Cancer Research and  
Demonstration Centers for Childhood  
and Adolescent Cancers;

National Comprehensive Childhood and  
Adolescent Cancer Registry

(a) Authorization; Support for Centers. The Director of the National Cancer Institute is authorized to provide for the establishment or designation of six centers (including the pediatric and adolescent oncology unit at The National Institutes of Health Clinical Center) for clinical research, training and demonstration of advanced preventive, diagnostic, treatment and rehabilitative methods relating to Childhood and Adolescent cancers. Such centers may be supported under subsection (c) of this section or under any other applicable provision of law.

(b) Authorization; Support for National Comprehensive Childhood and Adolescent Cancer Registry. The Director of the National Cancer Institute is authorized to provide for the establishment of a National Comprehensive Childhood and Adolescent Cancer Registry. Such registry will be established and managed by the Division of Cancer Treatment of the National Cancer Institute. Such registry may be supported under subsection (c) of this section or under any other applicable provision of law.

(c) Cooperative agreement with nonprofit agencies or institutions for federal payments of basic operating support; uses of federal funds; support limitations; periods and extensions of support. The Director of the National Cancer Institute, under policies established by the Director of the National Institutes of Health and after consultation with the National Cancer Advisory Board, is authorized to enter into cooperative agreements with public or private nonprofit agencies or institutions to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for existing or new centers (including, but not limited to, centers established under section (a) of this section) for clinical research, training and demonstration of advanced prevention, diagnostic, treatment and rehabilitation methods relating to childhood and adolescent cancers. Federal payments under this subsection in support of such cooperative agreements may be used for (1) construction (notwithstanding any limitation under section 285 of this title); (2) Staffing and other basic operating costs, including such patient care costs including

transportation and living expenses for a child or adolescent and family member as are required for research and also including the costs of entering and maintaining each child or adolescent with cancer nationally in the Comprehensive Registry under subsection (b) of this section; (3) Clinical training (including clinical training for allied professionals), and (4) demonstration purposes; but support under this subsection (other than support for construction) shall not exceed \$5,000,000 per year per center. Support of a center under this section may be for a period of not to exceed three years and may be extended by the Director of the National Cancer Institute for additional periods of not more than three years each, after review of the operations of such center by an appropriate scientific review group established by the Director of the National Cancer Institute.

#### Information

410 (G) (1) The Director of the National Cancer Institute shall provide and contract for a program to disseminate and interpret on a current basis, for practitioners and other health professionals, scientists, and the general public, scientific and other information respecting the cause, prevention, diagnosis and treatment of cancer, and the rehabilitation of the cancer patient including in the latter term information relating to employability, insurability, education, physical therapy, psycho-social support, and the long term effects of cancer therapy in surviving cancer patients.

#### Nutrition

407 (4) Collect, analyze; and disseminate information (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer) and expand, intensify and coordinate existing research programs within the National Cancer Institute relating to the role of diet and nutrition in the prevention, diagnosis and treatment of cancer...

APPENDIX B

Authorization for Appropriations

Section 409 (b) is amended by striking out "and" after "1977" and by inserting before the period the following: \$94,000,000 for the fiscal year ending September 30, 1979, \$96,000,000 for the fiscal year ending September 30, 1980, and \$99,000,000 for the fiscal year ending September 30, 1981.

Section 410 C is amended by striking out "and" after "1977"; and by inserting before the period the following: \$975,000,000 for the fiscal year ending September 30, 1979; \$1,075,000 for the fiscal year ending September 30, 1980; and \$1,175,000 for the fiscal year ending September 30, 1981."