

STATEMENT OF

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Its time that Congress and the media got off the dime in terms of oversight of the cancer program and started concentrating on the really hard issues, the issues that will effect the potential for quality lives in cancer patients in the years to come. If the series of past Congressional hearings and media attention establishes anything, it is that the system set up to solve the cancer problem can and does police itself. The level of wrongdoing discovered is so minimal gauged against the size of the program that the attention paid to it is all out of proportion. The concern has been with the pebbles of the program, not boulders. Please look at the program, its directions, its frustrations from the point of view of the object of the program - the cancer patient. In this statement, that audience is the pediatric and adolescent cancer patient, the group that is only 1% of the cancer problem but which, because of its size and nature, has been the welcome testing ground for the approaches in cancer therapy that are now being used beneficially in the adult cancer population.

The child with cancer is in a unique position. Children constitute only one percent of the cancer cases in this country but cancer represents the most serious threat to childlife next to accidents. Ten years ago, no more that 10 to 20 percent of children treated with cancer were alive five years after diagnosis. Today the story is different. Childhood cancers are the category in which the greatest strides in long-term survival and "cure" have been made.

Dr. Vincent T. De Vita, Director of National Cancer Institute (NCI), in a report of the National Cancer Advisory Board in 1979, reported that in acute lymphocytic leukemia more than 90 percent of children with null cell variety of the disease are curable. In Wilms' Tumor in 1971 only 40 percent were curable with surgery and irradiation. Presently, 90

percent of children can be cured using drugs, irradiation and surgery together. In Rhabdomyosarcoma and Ewings Sarcoma a cure of 60-70 percent is now possible (compared with 10-20 percent in the pre 1972 era). These are the rates for specific cancers. There are other cancers in children which have lesser cure rates. However, according to the End Results Section of the Branch of the Division of Cancer Cause and Prevention at NIC, the overall nationwide survival rate in pediatric cancers for children is 33 percent and for five year life expectancies is 60-65 percent of childhood and adolescent cancer cases treated in centers adequately staffed and equipped.

The real issues confronting Congress are how to assure that children reach the best treatment; how to stimulate the development of new drugs and encourage the new approaches to cancer - which evolved from the Diet, Nutrition and Cancer Program and the support program and the new drug virology and immunology programs; how to properly induce the best and the brightest of our physicians and Ph.D.'s to commit themselves to cancer.

Children don't cause their own cancers. Childrens lifestyles, personal habits, nutrition cannot be pointed to as scapegoats for their cancers. Chemotherapy has been the "difference" in our childrens care or long term survival. The children cured today because of these advances, the better understanding of the way drugs work, the constant tailoring of treatment to meet new knowledge will add approximately \$101 million in taxes over the life span of each cohort of children cured by chemotherapy.

Candlelighters is intimately aware of the concerns of parents throughout the country whose children are being treated.

Candlelighters is an international organization of parents groups whose children have or have had cancer, with 135 groups throughout the country.

Parents of children with cancer regardless of their educational level become very informed consumers very fast. They make it their business to be aware of what is happening now that can benefit their child and share in the support for those things -- radiosensitizers, monoclonal antibodies, second generation drugs, specific immunology, - that will make a large difference in the treatment of our childrens' cancers in the future. The tenor of the recent congressional and media attention is not directed to making parents of children with cancer better informed consumers of services. In selective 20/20, 60 minutes reporting and the Washington Post articles, for example, it is not clear that the overwhelmingly large number of children with cancer are successfully treated with 40 drugs comprising the commercially available and category C drugs. These children do not usually reach the group A and B drugs category. Parents reading these articles, if frightened off by chemotherapy, will be signing their childrens death warrants.

Ten years ago, a parent's choice of cancer treatment had little effect on a child's chances for survival. Today, wrong choices can deprive a child of a good chance for survival, and deprive the parents of their child.

The avenue for wrong choices is particularly strongest for the poor and the minority cancer patient.

"A black, single, medicaid mother in a major metropolitan area with a wealth of pediatric specialists including hematology/oncology. A child with a lump on her jaw. A pediatrician referral to an adult head and neck specialist. No pediatric oncology or surgery consultations. Surgery. 'Mother, your child has a terminal cancer; nothing can be done.' The child had a type of rhabdomyosarcoma. Fortunately, a relative of this mother knew about Candlelighters. We told her that the NIH Clinical Center is studying her form of cancer.

The child has been accepted for treatment at NIH. Without the information and guidance Candlelighters provided, this child would be sitting at home waiting to die. Was the failure to involve pediatric specialist because the mother was poor and black? Was the failure due to ignorance on the part of the physicians involved? Was the failure an example of cronyism? How many of our children are falling within the cracks of the system. There may be no reason why most of a child's treatment cannot be kept in a community, but if the appropriate specialists-people and institutions - are not involved in the staging and treatment decisions, the child may be deprived of a chance at cure. Ignorance in these circumstances is a subtle form of murder."

Congress has looked at fraud and abuse in medicaid, medicare, welfare, long term care. Congress has not looked at the patterns of cancer care for pediatric and adolescent patients in this country and how these patterns can be changed or enhanced to provide an opportunity for cure or long term survival to all our children. They may be surprised to find that a streamlined care system will cost less and may permit the main elements of care to occur in the home community.

Congress is looking at the informed consent issues in cancer treatment, that has completely avoided the absence of informed consent criteria in the unproven methods of cancer treatment which assail our families eardrums through well intentioned neighbors, families and friends.

On the proven or clinically pursued therapies uner FDA license the information - good and bad - is right out there in black and white for consumers to see. The Physicians Desk Reference and related drug effect books are in every library, the summaries of NCI protocols are also available. The physicians treating our children, by and large, take time with the consent process. They tell, let it all sink in, then retell again helped by the nurse, social service and other patient support team. In some programs the consent is even videotaped and reviewed at a later time by parents and physicians together.

1. Candlelighters Foundation, Quarterly Newsletter, Fall issue

Contrast the unproven methods. The emotional scientific, legal and philosophic issues related to unproven methods of cancer management are tellingly stated by Senator Edward Kennedy in his introductory remarks to the Laetrile Hearing of 1977 (1,pg1):

"The role of the Food and Drug Administration... is to guarantee that the available drug therapies are the best and most effective that science can devise. Their role is to protect both the patient and his family from remedies that are neither safe nor effective. The elimination of useless treatments is a valid Federal role. It reduces the burden on cancer patients and their families and allows them to exercise their freedom of choice on the basis of informed judgments among viable alternatives."

A review of the literature put out by purveyors of one unproven method, laetrile, demonstrate that none of the informed consent criteria imposed upon and met by the proven drugs or those of clinical trial have been met. The misleading and contradictory claims of laetrile, whether relating to cure, control, nutrition, pain relief or appetite stimulation, have been well documented. The Laetrile publications present mixed messages to the physician about what amygdalin based products to use in treatment. There is no agreement among laetrile advocates on effectiveness of laetrile treatment upon the terminally ill.

The impact on families with children in treatment is frightening. It is the natural desire of parents to protect their children from needless suffering. The statements of the pro-laetrile groups advise avoidance of surgery and side effects involved in proven cancer treatments in favor of their non-toxic therapies. Their newsletters are replete with glowing anecdotal reports of cures. These representatives may seduce parents completely away from seeking proven treatment for their child or delay them from seeking treatment altogether, increasing the likelihood that a child will not be a long-term survivor. Let me call to the committee's attention one example in Senator Hawkins state.

"Articles dealing with the outcome of parental choice in pediatric cancer cases are few. One published case history involving delay in treatment and resultant death occurred in Florida and involved a child with acute lymphocytic leukemia under the interrupted care of Dr. Paulette Mehta.² The child had null cell acute lymphocytic leukemia. Her diagnostic features indicated a 90 percent chance of "cure". The mother initially refused all treatment for her child but transfusions. The child was started on laetrile, a "natural therapy", two weeks later she was hospitalized. At this time the parent agreed to proven therapy for three months. The child relapsed and was reinduced to remission by proven therapy. The parent again started laetrile therapy, the child again relapsed. The mother then left the country to obtain laetrile abroad. The child died within three months."

Our society has reached a stage of development in which the informational needs of consumers assume increased importance. Drug inserts, food ingredient and additive labeling, and washing instructions are some examples of attempts to facilitate consumer-reasoned decision making and eliminate expensive and dangerous guesswork from product choice. We have evolved an informational system for health protection information, beginning with the first steps toward federal drug regulation in 1906. That system uses a well-developed scientific approach to providing the practitioner and the public with information on drugs.

The legalization of laetrile use and prescription in some states, the National Cancer Institute tests of laetrile on concededly far less evidence of efficacy than they would customarily require, represent an accommodation by the drug approval system to practitioners who did not choose to play by the rules of scientific investigation and publication.

Will this series of congressional investigations and alleged media exposes result in a laissez faire attitude toward drug approval and erode the support for a structured process for drug approval, testing and marketing as well as erosion of the opportunity for families to have their

2. Mehta, Ineffectiveness of Laetrile in the Treatment of Acute Lymphocytic Leukemia, 19 Clinical Pediatrics 3641 (1980)

informational needs satisfied from a trustworthy and complete knowledge base. If so, we can reduce the Gross National Product base from our children being treated with cancer downward because we will lose the battle against cancer.