

*Field Hearing-- Statement submitted for the
hearing record*

STATEMENT

BY

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SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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Mr. Chairman and Members of the Committee:

I welcome this opportunity to appear before you today to discuss the Kaposi's sarcoma/opportunistic infections/acquired immunodeficiency syndrome.

It is our understanding that more than 250 cases of this new, complex and very serious illness have been reported within the past fifteen months in the United States, and that almost half of these patients have developed Kaposi's sarcoma, a form of cancer which has hitherto been extremely rare in this country. The remainder of these patients have had life-threatening infections, and some patients have had both the infections and the cancer either concurrently or sequentially. Furthermore, it has become evident that both the infections and the cancer are probably preceded by a failure of certain elements of the immune system. In fact, this acquired immunological deficiency may be very widespread among certain groups of American people; the sarcomas and serious infections may be only one facet of what has become a public health problem of great magnitude. The National Cancer Institute is extremely concerned about this problem with respect to its epidemic dimensions and the seriousness, and even lethality, of the illness in individual patients. It is our intention to do all possible to learn how to prevent the syndrome, to devise new treatments not only for Kaposi's sarcoma but for the underlying condition which may give rise to this rare tumor, and to develop strategies by which recurrence of the cancer can be prevented.

This new syndrome was first widely reported by the Centers for Disease Control in July of 1981. While the illness seems to be concentrated among young homosexual men in the United States, bisexual and heterosexual

men, as well as women, are involved as well. This is, therefore, an occurrence of cancer and infection of concern to all Americans. As has already been discussed, the underlying state of immune deficiency is characterized by a profound and prolonged suppression of at least one component of the immune system, the "helper" type of lymphocyte which circulates in the blood. Epidemiologic studies by the CDC and other institutions have yet to reveal the precise cause of this immunity failure, although the use of certain drugs (especially nitrite inhalants), and previous or concomitant infection with a variety of viral and other communicable agents, have been common.

Kaposi's sarcoma itself is not a new disease. Since cancer incidence data on Kaposi's sarcoma have been recorded, there have been at least 100 cases reported each year in this country, mostly occurring among elderly men and having a rather slow course. More recently, the tumor has also been diagnosed in a small number of kidney transplant patients given drugs which suppress the immune system. In certain areas of Africa, however, the tumor is 100 times more prevalent than in this country and younger patients, with a more acute course, are involved as well. Moreover, Kaposi's sarcoma is not the only type of cancer which is being diagnosed in this new syndrome. Other tumors, for example Burkitt's lymphoma, are also being reported. This tumor too is common in certain areas of Africa, but rare in this country. Both Kaposi's sarcoma and Burkitt's lymphoma (in Africa) are strongly associated with herpes viruses, but we do not yet know if the viruses cause these tumors or are merely passengers within the tumor cells.

Whatever the cause of this illness, it is clear that the earlier we can detect its symptoms and signs, the greater is the likelihood that we can prevent the infectious complications and possibly the cancer. While we have already had some positive results not only in treating the infections but in the treatment of the sarcoma over the short term, it is clear that real solutions depend on further research. There is a particular problem in treating the cancer because conventional cancer therapy, consisting of chemotherapy or radiotherapy, may itself suppress the normal functions of the bone marrow and the immune system. Therefore, many patients with this syndrome will be unable to tolerate doses of therapy which would be acceptable in other cancer patients.

I would like now to describe the steps taken by the NCI since we learned of this illness ten months ago. The NCI's Division of Cancer Treatment and Division of Cancer Cause and Prevention and the CDC sponsored a workshop at the National Institutes of Health on September 15, 1981. Fifty-four medical scientists from many institutions met at this workshop, representing all areas of biology which seemed to be germane to our understanding of the problem. The expertise, observations and intuition of all of these investigators were shared, and plans were developed to initiate concentrated research on the cause, prevention and treatment of the syndrome. The workshop served to heighten interest in, and familiarity with, the new disease, and a number of investigators began to divert their established NIH grant funds into Kaposi's sarcoma research. Some NCI grants and contracts were specifically supplemented for this purpose, and other researchers began to submit new grant requests for the support of laboratory and clinical studies.

In addition to this ongoing support, the NCI now plans to make new, targeted awards for research on the Kaposi's sarcoma/opportunistic infection syndrome. We are coordinating our plans with those of the CDC, the National Institute of Allergy and Infectious Diseases, and other NIH divisions. We are in the process of announcing the availability of our targeted funds to institutions possessing an interest in this problem, as well as a population of affected patients and/or appropriate laboratory resources. Moreover, our own intramural scientists in Maryland are already intensively involved in studies on this illness and will expand their involvement. The NCI funds will support innovative approaches to studies on genetic factors, designed to identify those people who may be at a particular risk of developing the Kaposi's sarcoma syndrome. Secondly, NCI funds will support basic research projects on cause and pathophysiology. These projects will be closely coordinated with the CDC and will include studies in such areas as immunology, virology and toxicology. Most importantly, we plan to support innovative clinical treatment and prevention research projects involving patients with any manifestations of this illness. It is our hope that institutions responding to our announcement of the availability of research funds will propose treatment studies linked to their notions as to the cause of the illness. Along these lines, we are encouraging the development of new cancer therapy strategies altogether for these patients, and will be very interested in exploring the possibilities of treatment with interferon, anti-tumor antibodies, bone marrow transplantation, and other biological approaches which may not produce further immunological deficiency and which may have a more specific and selective effect on the tumor than conventional cancer treatments.

We hope to be able to award our funds to successfully competing institutions by October 1 of this year, and we believe that it will be possible to make awards to a number of research and treatment centers in various parts of the country. The NCI plans to hold biennial workshops on this subject for the purpose of updating the scientific and medical communities and encouraging the maximum amount of research collaboration.

Finally, many of the most important clues now available to us, in regard to the cause and course of this illness, have been provided by our patients and their friends. I therefore encourage and urge all people who have observations and suggestions on any aspect of this very serious illness to report their thoughts to any of the physicians here today or to other interested physicians and scientists. I should like to take special note of the fact that in all clinical studies to be sponsored by the NCI, we shall continue to insist on the patient's right and obligation to provide his/her informed consent to any research. Furthermore, we shall always support the patient's right to privacy and confidentiality, and guarantee this right at all appropriate institutional and governmental levels. Specifically, no patient's name will be included on any records to be transmitted outside of the institution providing treatment.

Thank you for the opportunity to comment, and I will be happy to answer any questions that you may have.

Mr. Chairman, this concludes my statement.