Dept NIH (Cancer Institute)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC HEALTH SERVICE BETHESDA 14, MD.

NATIONAL INSTITUTES OF HEALTH

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Dear Mr. Fogarty:

This is in reply to your letter of December 30 forwarding a copy of a letter from John M. Davis, Committee for a Fair Test of Krebiozen, Incorporated, and requesting my comments.

We are aware of the activities of Mr. Davis' committee, and his letter presents the arguments which have been freely circulated and publicized by the proponents of Krebiozen, particularly during the past few months. I should like to summarize for you the principal developments in this matter since the first public announcement of Krebiozen was made by Dr. Andrew C. Ivy in 1951.

The National Cancer Institute has not participated in any testing of Krebiozen and therefore has no direct knowledge of its possible usefulness in treating cancer. Two disinterested studies of clinical data on the agent have been published. Studies of 100 case histories of cancer patients treated with Krebiozen, from seven sources in four widely separated regions of the country, were reported in the Journal of the American Medical Association on October 27, 1951, by a subcommittee of the Committee on Research, Council on Pharmacy and Chemistry, of the American Medical Association. The subcommittee concluded that the patients failed to show objective evidence of improvement. The Committee on Cancer Diagnosis and Therapy of the National Research Council reached a similar conclusion on the basis of 63 case summaries received from six investigators or groups who had evaluated Krebiozen and also on the basis of data in the American Medical Association report. This committee reported in the November 24, 1951 issue of the Journal of the American Medical Association that no evidence had been found of any curative effect of Krebiozen nor any proof of palliative effect attributable to the agent itself.

As you are no doubt aware, Senator Douglas, in a speech on the Senate floor on August 22, 1958, requested that the Public Health Service investigate the possible anti-tumor properties of Krebiozen as a treatment for human cancer. The National Cancer Institute has responded by participating in conferences and communications with the interested parties. These have been for the purpose of establishing 1) whether available information about the agent itself, and data on

its use in treating cancer merit further evaluation of the therapy, and 2) the procedure for carrying out such an evaluation.

The first step taken by the Institute after Senator Douglas made his request was to ask Dr. Ivy, medical consultant to the Krebiozen Research Foundation of Chicago, to supply information about the nature of the substance and its use in treating cancer. This was done by Dr. Ivy. The Institute then undertook to select a panel of medical scientists mutually acceptable to the Institute and Dr. Ivy, to study this information and advise whether further evaluation of the treatment should be made and how it should proceed.

It has been agreed by all parties involved in these preliminary discussions that if further evaluation is undertaken, it should be done in a scientifically acceptable manner. This agreement was reached at a meeting on September 24 attended by Dr. Ivy and Dr. Stevan Durovic of the Krebiozen Foundation, Mr. Frank McCulloch of Senator Douglas's staff, myself and other members of the National Cancer Institute staff. The following statement was made public at the conclusion of the meeting: "It is generally agreed that the evaluation of Krebiozen should be explored further and we are seeking to develop an agreed procedure that will be acceptable to the scientific community."

Dr. Ivy and the Krebiozen Foundation have not been willing to accept the findings of the American Medical Association and the National Research Council groups. Agreements by Dr. Ivy and the Institute have now been reached on the composition of an evaluating panel which will be unbiased. Dr. Ivy at a meeting with Senator Douglas and representatives of the National Cancer Institute on December 5, expressed his desire to spell out in writing his understanding of his role in relation to the evaluating panel. Neither Senator Douglas nor the National Cancer Institute has heard from Dr. Ivy since the December 5 meeting.

It should be pointed out that many cancer patients can receive some benefit from chemical agents already available and that several new ones are currently in clinical trials on the basis of promise as determined by a group of outstanding consulting experts skilled in evaluation of treatments for cancer. It is necessary, therefore, that the scientific evidence indicate the likelihood of a new material showing benefit to cancer patients which is at least equal to that already available; otherwise, there is no valid reason for denying to cancer subjects the use of current agents, for raising the hopes and expectations of these unfortunate victims only to have them fall at a later date, or for pre-empting the services of those

few highly skilled investigators who can critically evaluate by objective criteria the result of cancer therapy. The manner in which these evaluations are to be made must ensure that objective criteria of benefit to the patient are the basis of determination, for it has been shown repeatedly in medical research that subjective improvement is not a valid criterion for evaluation of a therapeutic agent.

Several books and a number of articles have been published on the subject of Krebiozen since the first announcement about the product by the sponsors. A selected bibliography is enclosed, and if you would like to have additional copies we shall be glad to provide them.

I am very glad to supply this information and trust that it will meet your needs.

Sincerely yours,

J. R. Heller, M. D.
Director
National Cancer Institute

Hon. John E. Fogarty
House of Representatives
Washington 25, D.C.

Enclosure