Dear Senator Lehman:

I am pleased to provide you with information on the procedure for the evaluation of proposed treatments of cancer, in reply to your letter of June 28 forwarding a letter from Dr. Robert Shiffman, Astoria, Long Island, New York.

The National Cancer Institute of the Public Health Service believes that anyone who thinks he has a treatment for cancer should have the opportunity of demonstrating the value of his therapy. The Institute believes also that to merit scientific investigation and evaluation by the Government, proposed methods of therapy should meet certain basic criteria which are designed to establish reasonable evidence of potential value. For this reason the Institute has adopted three requirements, all of which must be met in order to make a method of treatment eligible for investigation. These requirements are:

1. The method of treatment must be explained fully. There must be no secrecy whatsoever in regard to the composition or the nature of the treatment.

2. Complete clinical records must be submitted of a suitable number of cancer patients, treated with the remedy or method in question under competent medical supervision, and in each such case the diagnosis of cancer must rest on competent and verifiable microscopic examination.

3. The records must show that the patients survived at least 5 years following treatment.

When individuals request an evaluation of a cancer treatment based upon fulfillment of all three of the above requirements, the National Cancer Institute presents the matter to the Committee on Cancer Diagnosis and Therapy of the National Research Council. This Committee was appointed several years ago at the request of a number of national organizations concerned with cancer research, including the National Cancer Institute, the American Cancer Society, the Damon Runyon Memorial Fund for Cancer Research, and the American Medical Association. The Committee functions as an independent advisory body to investigate the numerous methods proposed for the diagnosis and treatment of cancer, and provides advice or opinion for guidance of its sponsoring agencies in deciding their courses in cancer research.
Dr. Shiffman mentioned three cancer treatments in particular.

At the request of the Public Health Service the Committee on Cancer Diagnosis and Therapy of the National Research Council undertook several years ago to evaluate the Lincoln therapy. Representatives of the Committee met twice with Dr. Lincoln but it was impossible to work out definite arrangements for clinical trials acceptable to both him and the Committee, and therefore the required data for an evaluation were not obtained before the death of Dr. Lincoln on January 30, 1954. In March 1952, the Massachusetts Medical Society issued a report of its Committee to Investigate the Lincoln Therapies which stated in part: "No scientifically valid evidence has been presented, nor has the Committee been able to obtain data which would substantiate claims of any definite organic changes in cancer which are attributable to Dr. Lincoln's bacteriophage therapy."

The Department of Health, Education, and Welfare has not evaluated the Gerson therapy for cancer, since Dr. Gerson has not submitted to the National Cancer Institute the data necessary for an investigation under the policy described herein, although he was invited to do so almost 10 years ago. If Dr. Gerson should request an investigation of a cancer cure based upon fulfilment of all three of the policy requirements, the National Cancer Institute would be pleased to institute such investigation.

The record on requests to the National Cancer Institute for investigation of the Hoxsey treatment is explained in the enclosed statement entitled "Hoxsey Treatment for Cancer."

In my opinion the procedure for investigations of cancer treatments described herein provides adequate and reasonable opportunity for any individual or group to establish the possible merit of proposed cancer treatment methods. The scientific evaluation of remedies for cancer is of vital importance in protecting cancer patients from unorthodox practices, and I am pleased to have had this opportunity to explain our evaluation procedure to you.

Sincerely yours,

[Signature]

Hon. Herbert H. Lehman
United States Senate

Enclosure