

Irradiation Study

February 7, 1972

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REPORT OF CONFERENCE WITH MESSR. MYRTON TOM ~~REPORT AND~~

ROBERT MURPHY OF THE GENERAL ACCOUNTING OFFICE (GAO)

FRIDAY FEBRUARY 4, 1972, 11:00-11:45 A.M.

The GAO is an agency of the legislative branch of the Federal Government. These men are in the Cincinnati Office, 8112 Federal Building, phone 684-2107. At present they have space in Mr. Modene's office, phone 475-2343.

Although they have some accounting background, they are here as investigators.

Also attending were Miss Ruth Lindsey and Mr. Vern Rolf.

The following questions were asked:

1. Q. On what date did the project begin?
  - A. The work began in February 1960. The protocol was developed by Dr. Saenger beginning in 1955 and an application was submitted to the R & D Command of the Surgeon General of the Army in 1958. No patients at General Hospital were treated under this protocol prior to February 1960.
2. Q. Did DOD approach U.C. or did U.C. approach DOD?
  - A. Dr. Saenger submitted a contract proposal to DOD as described in Q 1 above in 1958.
3. Q. What are NIH and DOD requirements for informed consent? What are the requirements of U.C.? When was Faculty Research Committee set up?

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A. Dr. Saenger indicated that this material would be prepared in writing (it will be taken from the report of the Suskind Committee in large part).

4. Q. Which patients were given care in the GCRC? Were not Federal funds thus used for direct patient care in these cases? Determine the amount of Federal funds provided to the program.

A. This question will be answered in writing. Dr. Saenger discussed briefly the use of the GCRC in that patients were hospitalized there from time to time since facilities for specimen collection and ease of supervision for completion of complicated tests was superior. Since these goals were some of the ones for which the GCRC was supported and since these protocols were approved by the GCRC, when available these special facilities were employed. The majority of our patients were not hospitalized in the GCRC. There was no discussion of the three children at the GCRC at Children's Hospital but they should be included in our reply.

No DOD funds under these contracts were at any time used for payment of patient days in any hospital. DOD funds were used for technical help, support of a biochemist, physicians, physicists and for psychological and psychiatric studies.

5. Q. How was patient care financed? How could the GAO investigators check the records of patient payment without having patient names?

A. Dr. Saenger was unable to answer this question because of lack of knowledge of methods for patient bookkeeping. The GAO investigators have been referred to Mr. Mendenhall.

6. Q. Were the treatments given for the benefit of the patients or DOD?

A. Dr. Saenger stated that in all cases the treatment was given for the palliation of cancer of the patients and information for the DOD was a byproduct. The nature of therapeutic research (the U.C. program) in which the patient stands to benefit directly was contrasted with non-therapeutic research (not applicable to the U.C. program) where the patient derives no benefit but society may benefit.

7. Q. How did patients enter the study? Were these routine patients?

A. The patients were referred from various clinics, chiefly Tumor Clinic. Some were sent from the hospital wards. Some patients were sent from private physicians.

8. Q. Is there any connection between the Whole Body Counter and the Whole Body Radiation project?

A. No. Dr. Saenger explained that the Whole Body Counter is an instrument for measuring radioactivity at very low levels and has nothing to do with the therapy of cancer patients and study of radiation effects in the Whole Body Radiation project. The investigators were shown the whole body counter.

9. Q. What other Federal grants or contracts were associated with the DASA project and contributed financial support?

A. Dr. Saenger mentioned that some physics trainees did dosimetric work associated with the project. None of us could recall at the moment other work. A written answer will be made to this question.

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In summary these investigators are concerned solely with identifying all sources of support for this project and identifying the total cost borne by the Federal Government and that which is not Federal. For the patients, costs of diagnosis, treatment and other care are included. Medicare and Medicaid funds would have to be included in the category of Federal funds. They stated that best estimates would be satisfactory. They are not concerned as to whether funds were spent appropriately.

Our chief task is to identify the fact that no funds under DASA contracts were given to General Hospital for patient care, i.e. charges for patient days and for direct care. This is a key issue since if it could be shown that patients were treated only so that we could collect the DOD funds, we should be in difficulty. It was for this reason among many others that no such budget item was ever requested.

Some consideration should be given to estimates for cost of patient care based on the total cancer illness or just that period when the patient was receiving the whole or partial body radiation. By including the total illness, all hospitalizations, clinic visits and other special services, the relative contribution of DHEW to the GCRC stays of the several patients would be minimized.

cc: Dr. Gall  
Dr. Barrett  
Dr. Grulee ✓  
Dr. Silberstein  
Mr. Beirne  
Mr. Mendenhall  
Mr. Rolf