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ARGONNE NATIONAL LABORATORY

April 26, 1974

Dr. James L. Liverman, Director
Division of Biomedical and
Environmental Research
USAEC Headquarters
Washington, D. C. 20545

Dear Dr. Liverman:

In accordance with your TWX to Mr. Bauer of April 4, 1974, concerning patients injected with plutonium, our response to the Commission instructions contained in the TWX is as follows.

TWX item 1. ANL complies with and will comply with DHEW guidelines for the Protection of Human subjects with respect to patients injected with plutonium (and in all studies on human subjects). In accordance with Dr. Totter's letter to Dr. Duffield of May 1970, since late 1970 ANL has maintained an Institutional Review Committee for Research on Human Subjects.

This Committee reviews annually the activities of the Center for Human Radiobiology, which has been responsible for the studies on patients injected with plutonium. As part of its review for 1973, the Committee met on March 14, 1974, and the Committee Chairman issued, on April 8, 1974, an opinion to the Center for Human Radiobiology that it should not be involved in investigations of the body burden or excreta of plutonium patients "unless the patients have been informed that the examination is to establish the presence or absence of residual radioactivity stemming from the plutonium that they received many years ago."

The Committee felt that the protocol for obtaining informed consent from the Radium cases at the Center was applicable to the plutonium cases.

TWX item 2. Past, present and future studies by ANL on the plutonium cases have been referred to the Committee as part of its normal procedure. In order to comply with this item specifically, however, on April 10, Dr. Sinclair, on my behalf, requested a report on this subject from the Human Use Committee. The Committee Chairman, Dr. Fry, reported to me via memo on April 15, 1974. This report reviewed the Committees' awareness of ANL involvement in studies on patients containing residual plutonium since November 1973, presented copies of all documents and correspondence on the subject which had been supplied to the Committee, and included a copy of the Committee's memo of April 8 to the

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Center for Human Radiobiology. Copies of the report and all the documents associated with it were made available, informally, to Drs. Marks and Miazga during their visit here on April 10. Copies of the report have been available to me, as requested in the TWX, since April 15 and will be formally transmitted to you, if you so desire.

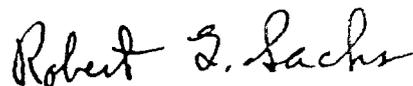
TWX item 3. Copies of all available information lacking however, patient identity by name in order to preserve the privacy of medical records, were made available to Drs. Brooks and Harvey upon their visit here on April 8 and 9, and to Drs. Marks and Miazga on April 15 and 16. We assume that these visits and the documents made available to them for copy, satisfied this item.

TWX item 4. This matter is still under discussion with Dr. Marks at AEC. ANL physicians stand ready to cooperate with AEC physicians in this matter as soon as AEC is ready to initiate action. In the meantime no action will be taken by ANL physicians.

TWX item 5. Dr. Marks has been in touch by telephone and by visit with ANL personnel, who are, of course, willing to cooperate fully in the objectives of this study with the single reservation concerning the privacy of medical records.

Please be assured of our interest and concern in this matter and do not hesitate to contact us if we can be of further assistance.

Sincerely,



Robert G. Sachs
Director

RGS/bls

CC: Robert H. Bauer
M. V. Nevitt
W. K. Sinclair

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