



DEPARTMENT OF THE ARMY  
FITZSIMONS ARMY MEDICAL CENTER  
AURORA, COLORADO 80045-5001



REPLY TO  
ATTENTION OF

HSBG-CI

ARM1.941221.005a

1 March 1994

MEMORANDUM THRU Chief, Department of Clinical Investigation,  
Fitzsimons Army Medical Center *[Signature]* 2/25/94

FOR Chief, Clinical Investigation Regulatory Office, ATTN: HSMC-  
GCI, 1608 Stanley Road, AMEDD Center & School, Fort Sam Houston, TX  
78234-6125

SUBJECT: Human Radiation Research Report

1. This report is considered to be an interim report due to the fact that all the information requested regarding the subject is not yet available. However, additional information will be forthcoming and will be submitted to the Clinical Investigation Regulatory Office in an addendum to this report.

2. At this time the information listed below has been obtained and is submitted as directed in the memo dated 26 January 1994 from your office. The information was obtained from the following sources:

(a) All Clinical Investigation Service annual progress reports from 1965 (the first report issued) until 1975. (See attached statement from the medical librarian regarding the 1969 annual progress report.)

(b) All available progress reports from the Army Medical Research and Nutrition Laboratory (AMRNL) from the late 1940's until 1974. (Those reports not available in the FAMC medical library were requested from the Defense Technical Information Center.)

(c) All available journal publications and abstracts cited in the above progress reports relating to human radiation research.

The following list of research protocols/projects is divided into two categories: Category 1 - those protocols/projects in which commonly accepted diagnostic or therapeutic procedures were used or tested as part of the research; this category corresponds to those protocols involving the use of radiopharmaceuticals or radiation therapy deemed safe and effective (and thus should be

HSHG-CI

SUBJECT: Human Radiation Research Report

considered as marked with the symbols "SE" or "RT"). Category 2 - those protocols/projects in which radioisotopes or radiopharmaceuticals were used to answer specific research questions and would not have been considered as "commonly accepted" procedures or standard of practice. However, even in research protocols or projects placed in category 2 (based on the criterion stated above), as well as in category 1 protocols, the amounts of radioisotopes administered to the research subjects were well below acceptable (approved) therapeutic doses. This determination was made by LTC Mike McBiles, MC, Chief, Nuclear Medicine Service, FAMC, as indicated in his statement attached to this report.

#### CATEGORY 1

- (1)
  - a. The value of rose bengal  $^{131}\text{I}$  in evaluating jaundiced patients
  - b. 1967-1968
  - c. US Army Medical Research & Nutrition Laboratory (USAMRNL)
  - d. Robert Pastore, MAJ, MC, David Preston, MAJ, MC
  - e. USAMRDC
  - f. Unknown number of subjects
  - g. Unknown quantity of  $^{131}\text{I}$  administered
  
- (2)
  - a. Scintigraphic evaluation of thyroid disorders - clinical evaluation of oral  $^{123}\text{I}$ -sodium iodide
  - b. 1973
  - c. Thomas A. Verdon, Jr., LTC, MC
  - d. Fitzsimons Army Medical Center
  - e. USAMRDC
  - f. 36 subject
  - g. 100 to 400 microcuries ( $\mu\text{C}$ ) of  $^{123}\text{I}$ -sodium iodide administered
  
- (3)
  - a. Ultrasound in placental localization
  - b. 1967-1968
  - c. Keith Deubler, LTC, MC, D. Preston, MAJ, MC
  - d. Fitzsimons General Hospital
  - e. USAMRDC
  - f. 25 subjects
  - g. "Standard radioisotope" was administered (unspecified)
  
- (4)
  - a. Effects of selective coronary arteriography on myocardial blood flow in man
  - b. 1968
  - c. Richard P. Carson, CPT, MC, Charles Peterson, CPT, MC, Robert C. Jones, COL, MC
  - d. Fitzsimons General Hospital

HSHG-CI

SUBJECT: Human Radiation Research Report

- e. USAMRDC
  - f. 6 subjects
  - g. 0.5 millicuries (mc) of <sup>133</sup>Xenon was administered
- (5)
- a. Evaluation of technical factors of the brain scan and their relationship to diagnostic accuracy
  - b. Joseph L. Marcarelli, LTC, MC
  - c. 1967
  - d. Fitzsimons General Hospital
  - e. USAMRDC
  - f. 300 subjects
  - g. Isotope type and quantity unknown
- (6)
- a. An evaluation of renal function utilizing radioiodine labeled diodrast
  - b. Richard R. Taylor, LTC, MC, Irvin C. Plough, LTC, MC
  - c. 1959
  - d. USAMRNL
  - e. USAMRDC
  - f. 55 subjects
  - g. 10-20  $\mu$ c of Diodrast-<sup>131</sup>I was administered
- (7)
- a. Renal function and <sup>131</sup>I clearance in hyperthyroidism and myxedema
  - b. Charles J. Hlad, Jr., MS, Neal S. Bricker, 1st LT, MC
  - c. 1954
  - d. Fitzsimons Army Hospital
  - e. USAMRDC
  - f. 11 subjects
  - g. <sup>131</sup>I did not exceed 125  $\mu$ c in any experiment
- (8)
- a. Observations on the mechanism of the renal clearance of <sup>131</sup>I
  - b. Neal S. Bricker, Charles J. Hlad, Jr.
  - c. 1954
  - d. Fitzsimons Army Hospital
  - e. USAMRDC
  - f. 47 subjects
  - g. <sup>131</sup>I was administered, quantity unspecified
- (9)
- a. Regional ventilation perfusion relationships of the lung, it's measurement of <sup>133</sup>Xenon and a linear scanner
  - b. David Preston, MAJ, MC, Paul J. Leach, CPT, MS, Edward Mays, MAJ, MC, Joseph Hawkins, LTC, MC

SHG-CI

SUBJECT: Human Radiation Research Report

- c. 1967
  - d. USMRNL
  - e. USMRDC
  - f. 10 subjects
  - g. <sup>133</sup>Xenon in "appropriate doses" was administered
- (10)
- a. Detection of pulmonary emboli using <sup>133</sup>Xenon and macroaggregated human serum albumin (MAAG) <sup>131</sup>I
  - b. David F. Preston, MAJ, MC, Maurice E. Gilbert, SSGT
  - c. 1967
  - d. USMRNL
  - e. USMRDC
  - f. 13 subjects
  - g. <sup>133</sup>Xenon inhalation and, macroaggregated human serum albumin tagged with <sup>131</sup>I (MAAG) was administered, quantity unspecified
- (11)
- a. Evaluation of technical factors of the brain scan and their relationship to diagnostic accuracy
  - b. David F. Preston, MAJ, MC, Robert H. Caplan, CPT, MC
  - c. 1967
  - d. USMRNL
  - e. USMRDC
  - f. 20 subjects
  - g. Isotope dose and type unknown
- (12)
- a. Radioisotopes in pulmonary physiology and pathology
  - b. Murray Spotnitz, MAJ, MC, Joseph A. Hawkins, LTC, MC
  - c. 1962-1965
  - d. USMRNL
  - e. USMRDC
  - f. 14 subjects
  - g. <sup>133</sup>Xenon and MAAG <sup>131</sup>I was administered, quantity unspecified
- (13)
- a. Radioisotopes in pulmonary physiology and pathology
  - b. Murray Spotnitz, LTC, MC, Joseph A. Hawkins, LTC, MC
  - c. 1965-1966
  - d. USMRNL

HSHG-CI

SUBJECT: Human Radiation Research Report

- e. USMRDC
  - f. 36 subjects
  - g. <sup>133</sup>Xenon and MAAG <sup>131</sup>I was administered, quantity unspecified
- (14)
- a. Scintigraphic evaluation of thyroid disorders - clinical evaluation of oral <sup>123</sup>I sodium iodide
  - b. Nasser Ghaed, LTC, MC
  - c. 1973
  - d. FAMC
  - e. HSC
  - f. Number of subjects unknown
  - g. 100 to 400 µc of <sup>123</sup>I-sodium iodide was to have been used. Did not use, due to technical problems. Study was to be resumed in the future
- (15)
- a. Bone marrow scintigraphy and scintigraphic localization of soft tissue tumors by use of <sup>111</sup>Indium chloride
  - b. Nasser Ghaed, LTC, MC
  - c. 1974
  - d. FAMC
  - e. HSC
  - f. Number of subjects unknown
  - g. 2 mc of <sup>111</sup>Indium chloride was to be administered when subjects became available
- (16)
- a. Use of <sup>67</sup>gallium citrate in evaluation of patients with known or suspected tumors and pyogenic abscesses
  - b. Nasser Ghaed, LTC, MC
  - c. 1974
  - d. FAMC
  - e. HSC
  - f. 39 subjects
  - g. <sup>67</sup>Gallium Citrate was administered, quantity unspecified
- (17)
- a. The use of <sup>111</sup>indium DTPA for the study of cerebrospinal fluid pathways
  - b. Nasser Ghaed, LTC, MC
  - c. 1974-1975
  - d. FAMC
  - e. HSC
  - f. 7 subjects
  - g. <sup>111</sup>Indium DTPA was administered, quantity unspecified

HSHG-CI

SUBJECT: Human Radiation Research Report

- (18) a. Bone marrow scintigraphy and scintigraphic localization of soft tissue tumors by use of <sup>111</sup>indium chloride
  - b. Nasser Ghaed, LTC, MC
  - c. 1974
  - d. FAMC
  - e. HSC
  - f. Number of subjects unknown
  - g. 2 mc of <sup>111</sup>Indium Chloride was to be administered
  
- (19) a. Use of <sup>67</sup>gallium citrate in evaluation of patients with known or suspected tumors and pyogenic abscesses
  - b. Nasser Ghaed, LTC, MC
  - c. 1974
  - d. FAMC
  - e. HSC
  - f. 6 subjects
  - g. <sup>67</sup>Gallium Citrate was administered, quantity unspecified
  
- (20) a. Sequential lung scanning of tuberculosis patients under treatment
  - b. E.T. Morita
  - c. 1971 - 1972
  - d. USMRNL
  - e. USMRDC
  - f. Number of subjects unknown
  - g. MAAG <sup>131</sup>I and <sup>133</sup>Xenon was administered, quantity unspecified
  
- (21) a. The diagnosis of functioning metastasis from thyroid carcinoma with <sup>131</sup>I and scintillation camera
  - b. E.T. Morita
  - c. 1971-1972
  - d. USMRNL
  - e. USMRDC
  - f. Number of subjects unknown
  - g. 1000  $\mu$ c of <sup>131</sup>I was administered
  
- (22) a. Placental imaging with <sup>99m</sup>technetium pertechnetate
  - b. E.T. Morita
  - c. 1971-1972
  - d. USMRNL

HSHG-CI

SUBJECT: Human Radiation Research Report

- e. USMRDC
  - f. Number of subjects unknown
  - g. Tc <sup>99m</sup>pertechnetate was administered, quantity unspecified
- (23)
- a. Sequential lung scanning of tuberculosis patients under treatment
  - b. E.T. Morita
  - c. 1971-1972
  - d. USMRNL
  - e. USMRDC
  - f. Number of subjects unknown
  - g. MAAG <sup>131</sup>I and <sup>133</sup>Xenon was administered, quantity unspecified
- (24)
- a. Placental imaging with <sup>99m</sup>Tc technetium pertechnetate
  - b. E.T. Morita
  - c. 1971-1972
  - d. USMRNL
  - e. USMRDC
  - f. 8 placentograms were done
  - g. Tc <sup>99m</sup>pertechnetate was administered, quantity unspecified
- (25)
- a. Joint imaging with <sup>99m</sup>Tc technetium pertechnetate
  - b. E.T. Morita
  - c. 1971-1972
  - d. USMRNL
  - e. USMRDC
  - f. 1 subject
  - g. Tc <sup>99m</sup>, 3 mc dose was administered
- (26)
- a. Ultrasound in placental localization
  - b. K. Deubler
  - c. 1969-1970
  - d. USMRNL
  - e. USMRDC
  - f. 12 subjects
  - g. "Standard radioisotope" scan was used (unspecified)
- (27)
- a. Quantitative lung scanning in pulmonary tuberculosis, tuberculous pleural effusion and lung surgery for tuberculosis
  - b. D.R. Hazlett
  - c. 1969-1970
  - d. USMRNL

HSHG-CI

SUBJECT: Human Radiation Research Report

- e. USMRDC
  - f. 33 subjects
  - g.  $^{133}\text{Xenon}$  in "appropriate" doses was administered, (dose unspecified)
- (28)
- a. The value of rose bengal  $^{131}\text{I}$  in evaluating jaundiced patients
  - b. Robert Pastore, CPT, MC, David Preston, MAJ, MC
  - c. 1967
  - d. USMRNL
  - e. USMRDC
  - f. 6 subjects
  - g.  $^{131}\text{I}$  Rose Bengal was administered, quantity unspecified
- (29)
- a. Regional ventilation perfusion relationships of the lung, it's measurement of  $^{133}\text{Xenon}$  and linear scanner
  - b. David Preston, MAJ, MC, Paul J. Leach, CPT, MSC, Edward Mays, MAJ, MC, Joseph Hawkins, LTC, MC
  - c. 1967
  - d. USMRNL
  - e. USMRDC
  - f. 10 subjects
  - g. "Appropriate" size dose of  $^{133}\text{Xenon}$  was administered
- (30)
- a. Detection of pulmonary emboli using  $^{133}\text{Xenon}$  and macroaggregated human serum albumin  $^{131}\text{I}$
  - b. David F. Preston, MAJ, MC, Maurice E. Gilbert, SSGT
  - c. 1967
  - d. USMRNL
  - e. USMRDC
  - f. 13 subjects
  - g. Macroaggregated human serum albumin tagged with  $^{131}\text{I}$  (MAAG) was administered, quantity unspecified
- (31)
- a. Evaluation of technical factors of the brain scan and their relationship to diagnostic accuracy
  - b. Norman Hellman, CPT, MC, Charles A. Sutton, MAJ, MC
  - c. 1967-1968
  - d. USMRNL
  - e. USMRDC
  - f. 20 subjects
  - g. Type and quantity of isotope unspecified

HSHG-CI

SUBJECT: Human Radiation Research Report

- (32) a. Effects of selective coronary arteriography on myocardial blood flow in man
- b. Richard P. Carson, CPT, MC, Charles Peterson, CPT, MC, Robert C. Jones, COL, MC
- c. 1968
- d. USMRNL
- e. USMRDC
- f. 6 subjects
- g. <sup>133</sup>Xenon, 50-100  $\mu$ c per dose, total amount administered to each subject being less than 500  $\mu$ c

**CATEGORY 2**

- (1) a. Blood volume parameters at 5200 feet altitude
- b. Dec 65 - June 67
- c. Fitzsimons General Hospital
- d. CPT Jerry Ballard, MC; MAJ David Preston, MC
- e. USAMRDC
- f. 31 subjects
- g. <sup>51</sup>Cr labeled RBC and <sup>125</sup>I labeled serum albumin administered, quantity unknown
  
- (2) a. Studies in phosphorus metabolism in man III. The distribution, exchange and excretion of phosphorus in man in vivo using radioactive phosphorus (<sup>32</sup>P) as a tracer
- b. 1952
- c. Army Medical Nutrition Lab, Chicago, IL
- d. Stanley M. Levenson, MD, Margaret A. Adams, A.B., Hyman Rosen, 2nd LT, MSC, F.H. Lasky Taylor, Ph.D.
- e. Medical R&D Project
- f. At least 6 subjects
- g. 100-200  $\mu$ c of <sup>32</sup>P administered (as inorganic phosphate)
  
- (3) a. Metabolism of ascorbic-1-<sup>14</sup>C acid in experimental human scurvy
- b. 1967 -1971
- c. US Army Medical Research and Nutrition Lab, (USAMRNL) Fitzsimons General Hospital
- d. Eugene M. Baker, Ph.D., Robert E. Hodges, MD, James Hood, MD, Howerde E. Sauberlich, Ph.D. Steven C. March, BA.
- e. USAMRDC, OTSG
- f. At least 6 subjects
- g. Up to 200  $\mu$ c of <sup>14</sup>C and <sup>3</sup>H was administered

HSHG-CI

SUBJECT: Human Radiation Research Report

- (4)
  - a. Metabolism of  $^{14}\text{C}$  thiazole labeled thiamine in man
  - b. 1965
  - c. USAMRNL
  - d. E.M. Baker, M. Balaghi, R.S. Pardini, H.E. Sauberlich.
  - e. USAMRDC
  - f. 1 subject
  - g. 46.9  $\mu\text{c}$  of  $^{14}\text{C}$  was administered
  
- (5)
  - a. Respiratory catabolism in man of the degradative intermediates of L-ascorbic-1- $^{14}\text{C}$  acid
  - b. 1963
  - c. USAMRNL
  - d. Eugene M. Baker, Nicholas G. Levandoski. Howerde E. Sauberlich.
  - e. USAMRDC
  - f. 3 subjects
  - g. 20  $\mu\text{c}$  of  $^{14}\text{C}$  was administered
  
- (6)
  - a. Tracer studies of vitamin C utilization in men: Metabolism of D-glucuronolactone-6- $^{14}\text{C}$  D-glucuronic-6- $^{14}\text{C}$  acid and L-ascorbic-1- $^{14}\text{C}$  acid
  - b. 1962
  - c. USAMRNL
  - d. E.M. Baker, H.E. Sauberlich, S.J. Wolfskill, W.T. Wallace, E.E. Dean.
  - e. USAMRDC
  - f. At least 5 subjects
  - g. 20  $\mu\text{c}$  of  $^{14}\text{C}$  was administered
  
- (7)
  - a. Clinical manifestations of experimental scurvy
  - b. James Hood, Robert E. Hodges, John E. Canham, Steven C. March, Raymond I. Davenport and Eugene M. Baker
  - c. 1970
  - d. USAMRNL
  - e. USAMRDC
  - f. 9 subjects
  - g. L-ascorbic-1- $^{14}\text{C}$  was administered, quantity unknown

HSHG-CI

SUBJECT: Human Radiation Research Report

- (8) a. Excretion and body load of ascorbic-1-<sup>14</sup>C acid in clinical human scurvy
- b. S.C. March, R.E. Hodges, J. Hood, H.E. Sauberlich, E.M. Baker
- c. 1970
- d. USAMRNL
- e. USAMRDC
- f. 5 subjects
- g. Ascorbic-1-<sup>14</sup>C acid was administered, quantity unknown
  
- (9) a. The metabolism of <sup>14</sup>C-labeled mono-dehydroascorbic acid complex in man
- b. J.C. Saari, E.M. Baker, H.E. Sauberlich
- c. 1965
- d. USAMRNL
- e. USAMRDC
- f. 2 subjects
- g. 24.7  $\mu$ c of <sup>14</sup>C was administered
  
- (10) a. Metabolism of <sup>14</sup>C-6 D-glucuronolactone and <sup>14</sup>C-6-D-glucuronic acid in man
- b. E.M. Baker, H.E. Sauberlich, S.J. Wolfskill
- c. 1961
- d. USAMRNL
- e. USAMRDC
- f. Number of subjects unknown
- g. 20  $\mu$ c each of the labeled carbohydrates

3. Attached to this report are statements from LTC McBiles regarding the categorization of the protocols, Ms. Helen Littlejohn, Public Affairs Officer, Historian, FAMC, Ms. Sue Caldron, Medical Librarian, Ms. Bernice Kohut, Tumor Registry, Medical Record Supervisor, and COL Verdon, MC, concerning his experience here and at Letterman in regard to conducting research during the 1960s and 1970s. Also attached are copies of category 2 papers/protocol summaries. More information concerning the purpose and description of the studies than is evident from the titles listed above can be obtained from these papers. However, in most cases there is little or no information regarding medical or research follow-up of the study participants.



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Department of Clinical Investigation