DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
FORT SAM HOUSTON, TEXAS 78234-6100

REPLY TO ATTENTION OF

ARM1.941221.015

HSMC-GCI (40-38a) 15 March 1994

MEMORANDUM FOR RECORD

SUBJECT: Successes of Human Radiation Experimentation

1. The following accomplishments of military medicine can be cited in discussing the Army's role in exposure of human subjects to ionizing radiation. These accomplishments emphasize the hospitals of U.S. Army Health Services Command (HSC), but refer to other Army Medical Department (AMEDD) activities as well.

a. NUCLEAR MEDICINE & NUCLEAR PHARMACY:

(1) Over the last 40 years, Army hospitals participated in some 270 studies of the value of novel radio-pharmaceuticals. Research in Army hospitals contributed to the recognition of the safety and effectiveness of Gallium-67, Strontium-89, Technetium-99m, Indium-111, Iodine-131, Xenon-133, and other radioactive medications to diagnose or treat a variety of diseases, especially cancer. Each of these studies were conducted under the stringent requirements of the Food & Drug Administration (FDA) and the Nuclear Regulatory Commission (NRC), according to nationally recognized standards of informed consent and scientific peer review.

(2) Army scientists in medicine and pharmacy at Brooke Army Medical Center in San Antonio and Letterman Army Medical Center in San Francisco were among the first in the nation to attach radioactive Indium-111 to white blood cells and platelets and return them to a patient's blood stream. This intricate technique, now widely performed, aids the location of infections that might not otherwise be detected. Similar work involved labeling white cells with 99m-Technetium-Exametazine to evaluate localized infections and labeling red blood cells with 99m-Technetium to identify the location of gastric bleeding.

(3) Strontium-89 is now commonly accepted as a means of reducing the pain of certain bone cancers, recognized as safe and effective by FDA. This recognition would not have been possible without the cooperation of cancer patients at Army hospitals with Army investigators.

(4) Army hospitals were among the few sites that established the value of a compound called NP-59 as a method for obtaining images of the adrenal glands of the kidney. NP-59 includes Iodine-131, a well-studied isotope, as its source of radiation.

(5) In the late 1970s and early 1980s, Army researchers demonstrated the ability of radioactive Xenon-133 gas to detect disease in the lungs of burned patients. Performed at the U.S. Army Institute of Surgical Research (the famed "Army burn unit"), this research established that radioactive Xenon images detect changes in the lungs before conventional X-rays would have detected them. Other Xenon studies improved scientists' ability to study the right ventricle of the heart.

(6) Studies of the muscle function of the esophagus were improved by Army studies. Technetium-99m was linked to a chemical called sulfur colloid and mixed with scrambled eggs for these esophageal motility imaging projects.

(7) The Army Medical Department conducted the first Nuclear Pharmacy Residency Program in North America. For more than 10 years, it was the only program of its kind. The program is accredited by the American Society of Hospital Pharmacists (ASHP) and graduates one or two nuclear pharmacists per year.

(8) A variety of Army scientists are periodically selected by their civilian colleagues to serve in leadership roles of national professional associations, including the American College of Nuclear Physicians, the American Board of Pharmaceutical Specialties, and others.

(9) Researchers at Fitzsimons Army Medical Center, near Denver, are currently working on adopting a radioactive drug called 99m-Technetium-Sestamibi for a new use. The drug is currently used for measuring the amount of blood that flows through the heart, but is being investigated for value in detecting breast cancer.

(10) Current topics of interest to Army researchers include the use of monoclonal antibodies and other new technologies to better diagnose and treat cancers and many other diseases. For example, monoclonal antibodies can be selected that seek out the unique features of breast tumors or prostate tumors. These antibodies can then be attached to specific radioisotopes. Relatively weak radioisotopes are useful for detecting cancers with special cameras. High-energy radioisotopes attached to antibodies may eventually prove to be useful for attacking the tumor itself, and hopefully curing or reducing the severity of the disease.

b. RADIATION ONCOLOGY

(1) In the last 40 years, Army hospitals participated in more than 400 cooperative multisite oncology studies that evaluated the value and effects of radiation therapy. These cooperative studies involved Army physician investigators collaborating with their civilian colleagues from university and private teaching hospitals, in the search for the best means of diagnosing and treating a wide variety of cancers that afflict Army patients. About 15% of all cooperative oncology studies conducted at Army hospitals evaluate radiation therapy in the treat the disease (437 of 2,869 oncology group studies). More than half of all oncology patients receive radiation therapy to improve the quality of their life or to improve the cure rate of disease.

(2) A variety of Army scientists have been selected by their civilian colleagues to serve in leadership roles of national professional associations, including the American College of Radiation Oncology.

2. Sources for these comments include the following:

a. Citations in the Clinical Investigation Research System (CIRS) database maintained at Fort Detrick, accessed by the Clinical Investigation Regulatory Office (CIRO) at Fort Sam Houston and the Human Use Review & Regulatory Affairs Division (HURRAD) at Fort Detrick.

b. Telephone conversation with COL John Bauman, MC, Chief of Nuclear Medicine at Madigan Army Medical Center, Nuclear Medicine Consultant to The Surgeon General, DSN 782-1645.

c. Telephone conversation with LTC Richard Stotler, MS Pharm, BCNP, MS, Senior Nuclear Pharmacist at Fitzsimons Army Medical Center, director of the Nuclear Pharmacy Residency Program, DSN 943-3662.

d. Telephone conversation with LTC (Retired) Al Landry, BCNP, MS, widely recognized nuclear pharmacist at the University of Texas Health Science Center at San Antonio, 210-885-7726.

e. Telephone conversation with LTC Rahul M. Dewan, MC, Chief of Radiation Oncology at Madigan Army Medical Center, Radiation Oncology Consultant to The Surgeon General, DSN 782-2095.

3. Additional information may be obtained from our office by contacting MAJ John D. Grabenstein, Regulatory Affairs Pharmacist, at DSN 471-2511, commercial 210-221-2511, voice mail 471- or 210-221-9212, or fax 210-554-4756.

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