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May 24, 1994

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The Honorable William J. Perry
 Secretary of Defense
 Room 3E880, The Pentagon
 Washington, D.C. 20301

Dear Mr. Secretary:

As Chairman of the Subcommittee on Investigations and Oversight, I have followed closely the President's initiative to release information on the Federal Government's support for experiments involving the exposure of human beings to radioactive materials. I am writing to seek your assistance in learning more about certain tests described in the enclosed copy of an article published in the Baton Rouge *Sunday Advocate*. Originally published in the Boston *Globe*, it details the use of radioactive materials in patients at the Charity Hospital of New Orleans during the late 1940s and early 1950s.

With the assistance of the National Library of Medicine, the Subcommittee was able to locate a number of scientific publications from the doctors named in this article: Dr. George E. Burch, Dr. C. Thorpe Ray and Dr. Samuel Threefoot. These publications indicate that support for this work was provided in at least two instances by the War Department, predecessor to the Department of Defense. Copies of these publications are included for your information.

One group of publications, apparently published between 1949 and 1952, cites "War Department Grant No. W-49-007-MD-389" as partially supporting the work described. See, for example, the paper entitled, "Concentration-Time Course in the Plasma of Man of Radiomercury Introduced as a Mercurial Diuretic," Threefoot, *et al.*, *Journal of Clinical Investigation*, v. 28, July 1949, p. 661.

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A second group of publications issued between 1952 and 1954 indicates that partial support came from "War Department [grant] No. W-49-007-MD-182," which a later paper described as "Medical Research and Development Board, Office of the Surgeon General, Department of the Army, Contract No. DA-49-007-MD-182;" see "Chloride 'Space' and Total Exchanging Chloride in Man Measured With Long-Life Radiochloride, Cl³⁶," Threefoot, *et al.*, *Journal of Laboratory and Clinical Medicine*, v. 42, July 1953, p. 16.

I will hold a field hearing in New Orleans, Louisiana, on this episode on July 8, 1994. I believe the information cited above clearly shows that records of the work conducted at Tulane can be found in the files of your Department. Therefore, I invite you or your designee to attend and testify at this hearing. Should you be unable to attend, I request that you be represented by your primary assistant for this initiative, Dr. Gordon Soper, Principal Deputy Secretary for Atomic Energy.

Your testimony should discuss, and you should be prepared to respond to questions concerning, the following issues:

- o How is the Department of Defense participating in the Interagency Working Group on Human Radiation Experiments to fulfill the President's instructions to make available to the public all Government records pertaining to experiments funded by the Federal Government that exposed human subjects to radioactive materials?
- o How is the Department identifying and processing records in its files that relate to these experiments?
- o Using this case as an example, please describe how the Department responds to requests for information and assistance in finding information on particular cases where humans were exposed to radiation.
- o What process did the War Department or the military services use to determine which institutions received contract support?
- o What types of review did the Department or the military services conduct when deciding whether to provide contract support to researchers?
- o Did reviews conducted by the Department or the military services include consideration of the researcher's ability to obtain the "informed consent" of human subjects that might be exposed to radioactive materials in the course of fulfilling the contract?

- o Do the Department of Defense or the military services, in conducting research activities today, assure that researchers obtain the "informed consent" of those participating as subjects of experiments involving radioactive materials? Are these revised procedures adequate to address the problems noted in protecting the participants in earlier experiments using radioactive materials?
- o What responsibility falls on the Department and the military services to review ethical issues raised by the choice of participants in the research that it funds? How do the Department and the services ensure that selection of participants falls within ethical limits? How has the exercise of this responsibility changed over time?
- o How has the concern for the protection of human subjects been dealt with in the history of the Department of Defense, the military services and their predecessor organizations? Your response to this question should discuss implementation of the so-called "Nuremburg" and "Helsinki Codes" and the steps taken to implement relevant recommendations of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

In responding to this question, you should describe in detail the background of a particular document released on May 18, 1994, at the second meeting of the Advisory Council on Human Radiation Experiments. I refer to a memorandum from Secretary of Defense Charles Wilson to the service secretaries dated February 26, 1953, which apparently set out the policy to "govern the use of human volunteers by the Department of Defense in experimental research in the fields of atomic, biological and/or chemical warfare." What is fascinating about this memorandum is that it recapitulates the "Nuremburg Code," which had been publicly discussed and promulgated, yet the memorandum was classified TOP SECRET when issued. Discussion of the circumstances surrounding the evolution of this document and its subsequent history should be included in your testimony.

- o The Department participated in the interagency effort that led to promulgation of the so-called "Common Rule" on human subjects protection in 1991. Under these regulations, what responsibility falls upon Federal agencies funding research with human subjects to ensure that the requirements of current regulations for the protection of human subjects have been met? With these procedures, can the Department and the military services assure that human subjects will not be exposed to unwarranted doses of radiation?
- o What responsibility does the Federal Government now have for the patients that were exposed in these tests? Are the Department and the services assisting in efforts to identify and assist participants in this case? Are the steps to date undertaken by the Federal Government adequate to identify these patients and address their needs?

As part of the preparations for this hearing, the Subcommittee requires the Department's assistance in the following areas:

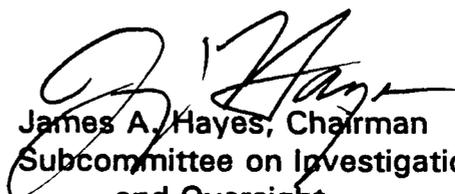
- o Obtaining all records related to the contracts issued by the War Department, its successor organizations and/or the military services to Dr. George E. Burch or his colleagues at Tulane University;
- o Obtaining all records of communications in any form between the Department, its successor organizations and/or the military services with Dr. Burch and his colleagues, particularly those progress reports filed in fulfillment of their contracts;
- o Obtaining records of the Department, its successor organizations and/or the military services that describe efforts to establish and enforce protections for human subjects in experiments funded by contracts, grants, or other financial or in-kind means of support provided by the Department, its successor organizations or the military services.

You should coordinate your activities with James Paul of the Subcommittee staff, who can be reached at (202) 226-3639. Attached for your information are the guidelines for witnesses testifying before the Subcommittee.

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I applaud the President's effort to close the gaps in the historical record and to raise important questions about the Government's relationship with its citizens. I trust the Department and the Subcommittee will cooperate closely in building a public record on this particular case.

Sincerely,



James A. Hayes, Chairman
Subcommittee on Investigations
and Oversight

Enclosures

INFORMATION ON HEARING PROCEDURES FOR WITNESSES
appearing before the
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

Your written statement may be of any length and will be made part of the printed record. To give Members and staff adequate time to review your testimony before the hearing, we request that you provide us with 50 copies of your prepared statement 72 hours before the hearing (July 5, 1994) to: Shirley Watson, Subcommittee on Investigations and Oversight, Room 822, O'Neill House Office Building, Washington, D.C. 20515. In addition, 75 copies of your written statement, for distribution to the public and media, should be provided at least 30 minutes before the hearing, at the hearing location: the Charity Hospital in New Orleans. Your statement may include supplemental materials for inclusion in the hearing record. Should you need audio-visual equipment for your presentation; please let the staff know in advance. We encourage you to transmit your testimony by electronic mail to the Committee address: HOUSESST@HR.HOUSE.GOV. Alternatively, you may provide your testimony on a 3.5" or 5.25" floppy disc in:

- o ASCII format.
- o A Word Perfect 5.2 (or earlier version) document using Courier 10 cpi font.

Key points of your written statement should be summarized in a five minute oral presentation; this will allow time for questions and answers following presentations by you and the other witnesses. It is customary for the Subcommittee on Investigations and Oversight to swear in all witnesses which appear before it in public hearings.

Under Committee rules, hearing proceedings are printed strictly in verbatim form, so that only typographical and transcriptional errors may be edited in the transcript. All other corrections -- insertions or deletions of words and phrases for clarity of meaning or for other purposes -- must be requested in writing (in letter form) by the witness, and these corrections may then only be included as an appendix to the verbatim proceedings. We will provide additional information on these matters when the hearing transcript is mailed to you for editing.

Use of Charity Hospital patients in 1940s radiation tests reported

Editor's note: Reports of radiation experimentation on human subjects have been in the news lately as federal officials have expressed concern about them. This report about Charity Hospital in New Orleans, now known as Medical Center of Louisiana, first appeared in the Boston Globe and was disseminated nationally through the Knight-Ridder news service.

BY SCOTT ALLEN
Boston Globe

NEW ORLEANS — People called it "The Big Free," the only hospital where many poor blacks could get medical care in the segregated Louisiana of the 1940s. They flocked to Charity Hospital by the thousands.

But all that free care left Charity Hospital chronically short of cash, and, in 1946, doctors found a way to make it up: radiation research.

Backed by grants from agencies including the U.S. War Department, a team from Tulane University's medical school undertook an ambitious series of human radiation experiments involving at least 300 Charity patients.

For more than a decade, mostly black female patients swallowed or were injected with the radiation equivalent of up to 100 chest X-rays in one experiment as researchers studied how quickly the human body could process radioactivity. The research could be unpleasant, sometimes requiring test subjects to endure 118-degree heat, intentional blisters or diarrhea.

The researchers recall that their test subjects voluntarily took part in the experiments after the doctors told them what was involved. For the patients, the researchers say, radiation experiments were a way out of Charity's overcrowded wards.

"The patients that we used for research really loved us. They really did," Dr. Sam Threefoot, who worked with the research team until 1953, said in an interview at his New Orleans home. "They got the most attention. We saw them several times a day. We cared about their diets."

Yet the voices of the test subjects have been lost. They are described obliquely in studies the Tulane team published: a 14-year-old boy who swallowed a toxic dose of radioactive mercury, a woman who remained hospitalized for 70 days so researchers could track a small amount of radioactive chlorine in her body, a "normal subject" who protested after sitting in stifling heat for half an hour so he would sweat before getting a radioactive injection.

Disclosure of the Charity research comes at a time of intense debate over the ethics of government-funded radiation experiments in the early days of nuclear medicine. A congressional subcommittee has focused on human radiation research at federal facilities, and En-

See **RADIATION**, Page 2B

INSIDE

4B EXERCISE, EDUCATION
Walk for Women's Health attracts more than 1,000 on Saturday.

5B

SPACE LAB
Students egg the school grounds; learn about space technology.

7B

FOR THE LATEST IN LOCAL AND STATE NEWS, READ THE ADVOCATE.

The Sunday Advocate Page 1B
March 6, 1994

Radiation

CONTINUED FROM 1B

erey Secretary Hazel O'Leary has suggested that some test subjects should be compensated.

The Charity experiments were part of a boom in radiation research that began when the Atomic Energy Commission made radioactive isotopes widely available to labs and hospitals. In a time when the rules governing human experiments were sketchy and informal, at least 1,800 of society's most vulnerable people — the sick, the insane, children and the imprisoned — were among the first to be chosen for experiments.

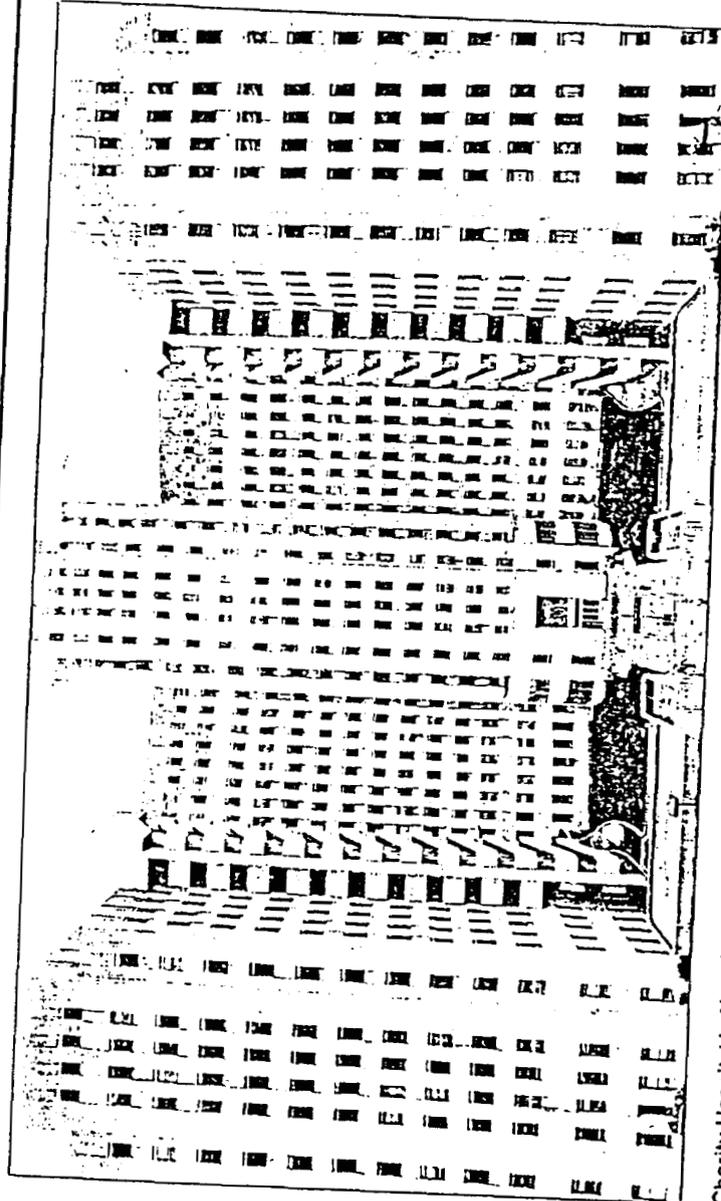
The Charity subjects were mainly poor blacks in an overtly racist society. It took a major lawsuit in the early 1960s to desegregate New Orleans hospitals, and Charity maintained segregated wards until 1965. "You're talking about a 19th-century society," said Ken Wing, one of the lawyers who brought the case integrating the hospitals.

The hospital, a faded downtown Art Deco tower, at least appears to have tried to meet the needs of the patients. But it was desperately underfunded. To survive, it relied on faculty and students at the Tulane and Louisiana State University medical schools, which used Charity as a teaching hospital.

The men who led the research were ambitious, but it appears that they were also devoted to the hospital's mission. Dr. C. Thorpe Ray, a senior researcher, worked six days a week without pay for years on his pay as a Tulane faculty member. He and Dr. George E. Burch, Tulane's chairman of medicine, drew their test subjects from the people they treated.

"This had nothing to do with color or sex. I did research on whites, too.... There was no mal intent," said Threefoot, 72.

But the researchers were working in a hospital where patients were routinely used in medical experiments unrelated to their conditions. The Sisters of Charity, the nuns who managed the hospital,



Charity Hospital in New Orleans was the site of radiation experiments in the 1940s involving at least 300 patients. File photo

larily in the area of biological half-life," said Ray, referring to the time it takes the concentration of a radioactive isotope in a human body to drop by 50 percent. In one of at least eight studies of the biological half-life of radioactive isotopes, the researchers say, their data could "throw light upon the problem of radiobiologic injury in both peacetime and military use of radioelements."

Knowledge of the biological half-life of radioactive elements would have important applications to medicine, as well.

Ray contends that the risks the test subjects faced was real but minuscule. He said researchers avoided isotopes that stayed in the body for long periods and kept exposure in general to a minimum. Much of the Tulane research involved isotopes that remain in the body only a few hours.

"We told (patients) it was radiation, like the equivalent of a chest X-ray," Ray said.

But at the time the researchers could not calculate the radiation exposure, largely because they had only a general idea of how long the radiation would stay in the body. Several of the isotopes had never been tested on people, and the point of the research was to find out how long the body would take to purge the radiation.

In addition, the researchers sometimes used radioactive materials, such as tritium, when they could have gotten the same results with non-radioactive alternatives. Ray said the alternative to using tritium was too cumbersome.

Today, it appears that most of the Charity experiments involved radiation exposure comparable to the amount people get each year from natural sources, around 300 millirems. However, one battery of tests gave four people the equivalent of 100 chest X-rays apiece, a full rem of exposure. Technically, researchers could expose test subjects to such levels of radiation today, but "it would have to be very good science," said Dr. Thomas Beck, a radiation authority at Johns Hopkins University in Baltimore.

By giving a radioactive form of mercury to Charity patients, Burch found that the diuretic could be hazardous if given orally. A 1950 research paper describes how four patients, including a 14-year-old boy, swallowed 10 radioactive mercury capsules apiece and three of them experienced a toxic reaction manifested by abdominal cramping and diarrhea.

The researchers also discovered the rate at which the mercury diuretic could penetrate human membranes, such as the ones around the heart. Ray applied a skin irritant to the forearms of patients to create blisters and cut off the top layers of skin. He then applied radioactive mercury to the

sores below, to see how fast the mercury penetrated. "We never had any patient cut out on us and say, 'I don't want to do that anymore,'" Ray, 78, said in an interview.

The research had medical goals, but it was a business, too, raising grant money for researchers to partly offset their low pay from the hospital. The doctors received funding from a variety of health organizations, but they also tailored their projects to appeal to the War (now Defense) Department. The military was very interested in the health effects of atmospheric atomic bomb tests.

"We applied for grants in areas they were interested in, particu-

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MSU mascot needed
LAKE CHARLES Applications

DR. GERALD B. WICKLINE

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