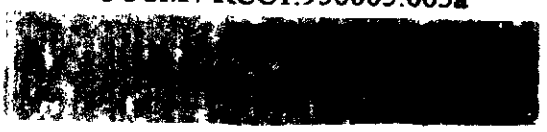

STATEMENT
OF
GORDON K. SOPER, PRINCIPAL DEPUTY
ASSISTANT TO THE SECRETARY OF DEFENSE
FOR ATOMIC ENERGY
BEFORE THE
SUBCOMMITTEE ON ADMINISTRATIVE LAW
AND GOVERNMENT RELATIONS
CINCINNATI, OHIO
APRIL 11, 1994

Mr. Chairman and Members of the Subcommittee, I am Gordon Soper the Principal Deputy in the Office of the Assistant to the Secretary of Defense for Atomic Energy. I am here to support your request of March 24th to conduct hearings on radiation experiments performed by the University of Cincinnati Medical School which were funded in part by the Department of Defense(DoD).

If I may, Mr. Chairman, I'd like to provide a prelude to my testimony in order to put our efforts into context. Since early January, when the White House called for the formation of a senior level Interagency Working Group to coordinate the government-wide effort to uncover the nature and extent of any government sponsored experiments on individuals involving intentional exposure to ionizing radiation, the Department of Defense has been engaged in an extensive effort to discover the facts surrounding DoD sponsored human radiation experiments.

It goes without saying that the Department takes this action seriously, that it has the complete support of Secretary Perry and that we pledge to you our unqualified commitment to a thorough and complete search of all available records and the full public release of the pertinent information in those records. As Dr. Harold Smith, the Assistant to the Secretary of Defense for Atomic Energy, and the DoD focal point for this action, testified to you at your February 2 hearing on this subject, the retrieval of records is a discovery process requiring time intensive "detective work"--we are well into that process now and beginning to make excellent headway. I would be glad to take any questions that you might have regarding the Interagency Working Group process and the results we have obtained so far.

With that as background, I'd like to provide you with as complete a report as I can on the role that the Department of Defense played in the human radiation experiments conducted at the University of Cincinnati College of Medicine from 1960-1972 which were led by the principal investigator, Dr. Eugene L. Saenger, MD. My report to you is based on documents, reports and files that we have thus far been able to locate from wide and

varied sources--some of the official Department of Defense records were destroyed long ago as part of the normal regulatory instructions for disposal of contract files.

What I am going to report to you is really not newly uncovered information. The entirely unclassified University of Cincinnati studies have been previously reported in ten technical reports, 17 publications, and 26 presentations at scientific meetings; they were the subject of peer reviews at the University of Cincinnati; discussion of this work appears in the Congressional Record in 1971 and 1972; they were the subject of a report by the Comptroller General of the United States in 1972 for Senator Edward Kennedy, Chairman of the Senate Health Subcommittee; they were the subject of a separate investigation in a report by the American College of Radiology in 1972, at the request of U.S. Senator Mike Gravel; and they were--and continue to be--the subject of news articles in the press and other media reports.

In addition, Mr. Chairman, these studies will be further reviewed by the Advisory Committee on Human Radiation Experiments which just recently established by President Clinton. This Committee is composed of eminent scientists, physicians, legal experts and medical ethicists. Its purpose is to advise and guide the government on the larger questions of ethical and scientific standards of any government sponsored experiments which involved the intentional exposure to ionizing radiation. Specifically, as stated in the Executive Order issued by President Clinton in January: "The Advisory Committee shall consider whether (A) there was a clear medical or scientific purpose for the experiments; (B) appropriate medical follow-up was conducted; and (C) the experiments' design and administration adequately met the ethical and scientific standards, including standards of informed consent, that prevailed at the time of the experiments and that exist today." A major goal of DoD's "detective work" regarding the University of Cincinnati research is to provide a complete record for review by the Advisory Committee.

Next I want to run through a brief chronology of this research, based on the record compiled to date, focusing on the Department of Defense sponsorship.

In September, 1958 Dr. Eugene L. Saenger of the Department of Radiology, University of Cincinnati College of Medicine, as the principal investigator, submitted an unsolicited research proposal to the Research and Development Division of the Army Surgeon General's Office. The research proposal was initiated by the University of Cincinnati and not solicited by the Department of Defense. The application proposed to research metabolic changes in humans following total body irradiation for the purpose of determining whether the presence of amino-aciduria in

humans after radiation would provide a reliable biological marker of radiation exposure. Restated less technically, the original goal was to try to develop a simple urine test to detect the amount of radiation exposure. The University of Cincinnati requested approximately $25,000 for the first year and $21,000 for two subsequent years. The proposal stated that Dr. Saenger was at that time also conducting pediatric cancer research funded by the National Institutes of Health, and preparing a Handbook on Medical Aspects of Radiation Accidents, under contract from the U.S. Atomic Energy Commission.

This unsolicited proposal was reviewed over the next year within the Department of Defense. Available documentation reveals that at least five Army Medical Corps officers reviewed the proposal. They recommended approval of the contract application. In October 1959 staff elements of the Defense Atomic Support Agency (DASA) recommended that DASA negotiate a contract with the University of Cincinnati for the study of the metabolic changes in humans following total body irradiation.

At that time a need existed within the Department of Defense to be able to determine the biological, statistical and clinical features of radiation injury. This was based on the requirements of our military commanders in the field to predict the outcome of human exposure to ionizing radiation, to predict the number of persons requiring hospitalization and to estimate the decrement in work capacity after radiation exposure on a nuclear battlefield. Remembering the context of the late 1950's, where fallout shelters were common in homes and schools and superpower tensions dominated public affairs, this was a real possibility of that time. Furthermore, such information would aid civil defense authorities in their efforts to combat the effects of nuclear explosions on the civilian population. I believe the fairly recent Chernobyl nuclear power reactor explosion underscores the importance of being able to ascertain radiation exposure effects and also understand its impact on a subject population.

So, in early 1960, a contract (DA-49-146-XZ-029, dated 1 January 1960) was signed between DASA and the University of Cincinnati Board of Directors. The contract provided $25,085 for the study. This contract, with supplements and modifications, funded the study through February, 1964. Another contract (DA-49-146-XZ-315) carried the research until April, 1969. The final contract (DASA-01-69-C-0131), effective May, 1969, funded the research until March, 1972 when the University of Cincinnati refused DASA's offer for additional contract funding. Through 1971, the DoD spent $651,482.79 on this research.

While the search for a biological marker of radiation exposure was one steadfast aim of the University's research effort over the life of the contract, the goals of the Department of Defense were to also understand better the influence of

radiation on the combat effectiveness of troops and to develop more suitable methods of diagnosis, prognosis, prophylaxis and treatment of radiation injuries. In order to obtain this information, the Department of Defense provided funds for laboratory, psychological and psychiatric tests to assess the effects of varying doses of whole and partial body irradiation for the treatment of cancer patients. No funds were paid to the University of Cincinnati for direct patient care nor did the Department of Defense play any part in patient selection or choice of treatment.

The University of Cincinnati College of Medicine submitted ten reports to the Department of Defense from 1961 through 1972 in accordance with the terms of the contract. I have provided the committee a copy of these ten reports as well as a number of other relevant documents that we have in our possession. Attachment 1 to my statement is a chronology summarizing major parts of the record compiled to date.

In reviewing these materials, we at DoD can understand the controversy that arose in the early 1970's, involving the University community, the press, and the Congress, and that which has reemerged this year, regarding this research. Some of the records, especially from the viewpoint of 30 years later, are troubling and raise very understandable concerns. Examples of these include statements in the University's early progress reports to the effect that only patients with non-radiosensitive tumors were selected for the research, which some see as evidence of a non-therapeutic purpose, and that symptoms and side effects were not described to the patients, which some see as evidence of the inadequacy of the informed consent procedures. On the other hand, for example, the 1972 peer review of the American College of Radiology, carried out at the request of Senator Mike Gravel, concluded that the research was validly conceived and executed, that the patient selection conformed with good medical practice, and that consent procedures complied with applicable standards. We at DoD do not at this point seek to resolve these apparent contradictions. Rather, our sole focus regarding this task is to compile a complete record and to make it available to the President's Advisory Committee and to the public.

Before concluding my statement, I want to address the constraints which the Department of Defense imposes on human subject experiments today and how we would respond to an unsolicited proposal, like the 1958 proposal from the University of Cincinnati College of Medicine, for experiments in which humans would participate.

Formal DoD policy for the protection of human subjects in research date back to at least 1953, when a then TOP SECRET Memorandum was sent to the Secretaries of the Services from Secretary of Defense C.E. Wilson, titled "Use of Human Volunteers

in Experimental Research". This memorandum authorized the voluntary participation of military personnel and civilian employees in DoD conducted research for atomic, biological and chemical warfare defense and established specific standards for informed consent, minimization of risk of harm to subjects, and other matters.

Over the years, more detailed procedures were established, including incorporation in 1991 of the 1974 Department of Health and Human Services regulations for the Protection of Human Subjects, 45 C.F.R. Part 46.

Today, DoD-supported research is governed by the so-called "Common Rule"--the Federal Policy for the Protection of Human Subjects--which is part of DoD regulations at Title 32, Code of Federal Regulation, Part 219. A copy of this regulation is attached to my statement. DoD is a full partner in the government's commitment to this standard and has further defined its human use regulation in DoD Directive 3216.2, "Protection of Human Subjects in DoD Supported Research," January 7, 1983 and Department of Defense Guidance for Assurance of Compliance with the Federal Policy for the Protection of Human Subjects, June 10, 1993.

Under these regulations, a proposal like that from the University of Cincinnati would require much more supporting documentation and justification to be considered for funding. This includes the following:

1. The therapy itself, separate from the research, would require more information on the possible benefits and the known side effects.

2. Several local committees (specifically, scientific, radiation and Institutional Review Boards, or IRBs), would have to review the proposed research protocol package, with proposed consent forms, before DoD would review the proposal for acceptance.

3. It would be required that the sponsor's Institutional Review Board be made up of people from diverse backgrounds, including non-scientific perspectives, who could objectively and fully assess the proposal.

4. The IRB record would have to document that the research design is sound, that risks to subjects are minimized, that the selection of subjects is equitable, and that, if applicable, special protections have been adopted for any vulnerable groups mentioned.

5. A written consent form signed by the patient/subject would be required for participation in the research. This

consent form would require an explanation of the proposed therapy, all procedures and studies to be performed, and all expected outcomes and side effects in laymen's terms. The consent form must also state that the patient has been counseled about all of the above, and space provided for the patient to sign stating this has occurred and that the patient understands it.

6. The protocol would be required to justify withholding radiation in the control group of patients if such radiation therapy were the standard of care for the cancer each patient had.

7. The investigator would be required to give a more in depth description of the known and suspected risks and the intended benefits of the research for the subject.

In other words, Mr. Chairman, we believe we have in place a set of guidelines for human use experimentation that will preclude 30 years from now, hearings like we are conducting today.

So in summary, Mr. Chairman, the DoD received from the University of Cincinnati College of Medicine in 1958 an unsolicited proposal, which resulted in a contract from 1960 to 1971 supporting a human radiation experiment. DoD played no role in the selection of subjects, decisions regarding treatments, or the day-to-day conduct of the research. DoD received a series of reports describing the research results, none of which were ever classified. Data that we obtained from the University of Cincinnati studies were used to enhance our knowledge about the biological response to nuclear warfare--knowledge that we all hope will never have to be put to use. We well understand the controversy regarding this research, but make no effort at this time to resolve apparent contradictions in the voluminous record compiled to date. Our goal is to compile a complete record for the use of the President's Advisory Committee and ultimate release to the public.

That concludes my prepared remarks. I would be happy to take your questions.