Opening Remarks

Mr Chairman and Members of the Subcommittee I am Gordon Soper and I represent the Department of Defense at this hearing. I'd like to introduce two colleagues sitting behind me who are prepared to provide additional information if appropriate. CAPT Robert Bumgarner, USN, MC is the Director of the Armed Forces Radiobiology Research Institute and an expert in military medicine. Also here is MAJ Dale Vander Hamm, US Army Medical Service Corps who is an expert on the Federal, Department of Defense and Army rules on human use.

I know you are aware of the extensive effort that this Administration is conducting to uncover the facts surrounding past government sponsored human radiation experiments. The DoD is a major partner in this effort and 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.

My purpose today is to provide you with a summary of the role that the Department of Defense played in the human radiation studies conducted at the University of Cincinnati from 1960-1972. My report to you is based on documents, reports and files that we have been able to locate from wide and varied sources--most of the official Department of Defense records were retired and then 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 extensively reported in the open literature; they were the subject of peer reviews at the University; 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 by the American College of Radiology in 1972 at the request of Senator Gravel; and they were--and continue to be--the subject of news articles in the press and other media reports.

These studies will be further reviewed by the Advisory Committee on Human Radiation Experiments which was 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. A major goal of DoD's records retrieval effort regarding the University of Cincinnati research is to provide a complete record for review by the Advisory Committee.

Let me give you a brief summary of the Department of Defense support of this research. A more detailed chronology is attached to my submitted testimony.

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 proposal to the Research and Development Division of the Army's Surgeon General's Office. The research 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 certain specific chemicals in humans would provide a reliable biological marker of radiation exposure--in other words, could we develop a simple urine or blood test to detect how much radiation an individual had received.

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 and recommend 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.

So, in early 1960, a contract was entered into between the Defense Atomic Support Agency 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. A follow-on contract carried the research until April 1969. The final contract, effective May 1969, funded the research until March 1972 when the University of Cincinnati refused DoD's offer for additional contract funding. Through 1971, the Department of Defense spent a little over $650,000 on this effort.

The search for a biological marker of radiation exposure was one steadfast aim of the University's research for the Department of Defense over the life of the three contracts. Also the results of the research contributed in a general way to a better understanding of the influence of radiation exposure on the combat effectiveness of military personnel and provided more suitable methods of diagnosis, prognosis, prophylaxis and treatment of radiation effects on a nuclear battlefield--a fearful possibility at that time. Department of Defense funds were used for laboratory studies and psychological and psychiatric tests of cancer patients that had received whole and partial body irradiation for the treatment of their disease. No Department of Defense funds were used for direct patient care nor did the Department of Defense play any part in patient selection or choice of treatment.

The University of Cincinnati 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.

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 DoD that only patients with non-radiosensitive tumors were selected for the research, which some see as an indication of a non-therapeutic purpose, and that symptoms and side effects were not described to the patients, which some see as reason to question the adequacy of the informed consent procedures. On the other hand, for example, the 1972 peer review of the American College of Radiology concluded that the research was validly conceived and carried out, 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 main focus regarding this task is to compile a complete record and make it available to the President's Advisory Committee and to the public.

Before concluding my statement, I want to briefly address the constraints which the Department of Defense imposes on human subject experiments today. Formal DoD policy for the protection of human subjects in research date back to at least 1953 when a then TOP SECRET Memorandum from the Secretary of Defense, titled "Use of Human Volunteers in Experimental Research", was sent to the Secretaries of the Military Services. 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 regulation for the protection of Human Subjects.

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 Regulations, 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.

Under these regulations, a proposal like that from the University of Cincinnati in 1958 would require more supporting documentation and justification to be considered for funding support by the Department of Defense. During the course of this hearing, perhaps I could have the opportunity to expand upon this point more thoroughly.

Mr. Chairman, I have tried to summarize for you what we know so far--we are continuing to track down further information and sincerely appreciate the openness of the University of Cincinnati in sharing with us the records that they have. This hearing will be a contribution to the knowledge gathering process. The Department of Defense fully supports the need to air, once again, all the issues

surrounding this early chapter in our government's human use research. Our goal is to pull together as complete a record as we can of our involvement and provide it to the President's Advisory Committee for their detailed study and ultimate release to the public.

This concludes my opening remarks. Thank you for your attention.