DEPARTMENT OF HEALTH & HUMAN SERVICES

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Testimony of

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Mr. Chairman and Members of the Committee:

I am Dr. D.A. Henderson, Deputy Assistant Secretary for Health-Science in the Department of Health and Human Services. With me today is Dr. Gary Ellis, Director of the Office for Protection from Research Risks. Today I will describe the activities currently underway to identify all experimentation between 1944 and 1974 which was conducted or supported by HHS and which involved human exposure to ionizing radiation. Before doing so, I believe it would be helpful for me to briefly reveiw the actions taken by HHS and its predecessor agency which, over the past 40 years, have evolved into a formal and well-codified administrative structure to assure that research involving human subjects fully takes into account both risks and benefits as well as consent which is voluntary, competent, and informed.

Today, all experiments involving human subjects whether conducted in PHS institutions or by grantees must be reveiwed, approved and regularly monitored by a formally constituted Institutional Review Board (IRB).

Protection of Human Subjects Today

The evolution of requirements for the protection of human subjects begins in 1953 at the National Institutes of Health (NIH). At that time, the NIH Clinical Center produced the first U.S. Federal policy for the protection of

human subjects. This policy and the committee that implemented it were an early step in the development of the research review mechanism, the institutional review board (IRB), that is now fundamental to the system of human subject protection throughout the United States. On February 9, 1966, the Public Health Service issued a policy that required prior review of research protocols involving human subjects in research supported by the PHS. It required several factors be carefully weighed; 1) the balance of benefits and risk to the individual; 2) methods used to obtain informed consent; and 3) the rights and welfare of the research subjects.

The Department of Health, Education, and Welfare (HEW), the predecessor to HHS, extended and formalized this policy as a regulation on May 30, 1974. The 1966 policy and the regulations that followed in 1974 were based on the concepts that freely given consent to participate in research is the cornerstone of ethical experimentation involving human subjects and that the risks of research need to be balanced against the benefits derived. The regulations established the Institutional Review Board (IRB) as the mechanism through which the adequacy of the informed consent process could be assessed and the rights and welfare of human subjects are otherwise protected.

In 1991, the core of the HHS regulations, further revised, was adopted as the Federal Policy for the Protection of Human Research Subjects. This Federal Policy (HHS, 45 CFR 46, Subpart A), or so-called "Common Rule," was promulgated by the sixteen Federal departments and agencies, including those represented here today, that conduct, support, or otherwise regulate human subjects research. The Policy is designed to make uniform the human protection system in all relevant Federal departments. This Policy is a framework in which investigators, institutional review board members, and others can ensure that serious efforts are being made to protect the rights and welfare of research subjects. The regulations also hold researchers and IRBs publicly accountable for their decisions and actions.

The Department of Health and Human Services's Office for Protection from Research Risks (OPRR) oversees implementation of the Policy in all HHS facilities as well as domestic and foreign institutions or sites receiving HHS funds. OPRR requires that each HHS agency and extramural research institution that conducts or supports research involving human subjects sets forth the procedures it will use to protect human subjects in a policy statement called an "assurance of compliance."

This is a formal, written commitment (i) to widely held ethical principles, (ii) to the HHS regulations for the Protection of Human Subjects, and (iii) to institutional procedures adequate to safeguard the rights and welfare of human subjects. The terms of the institution's assurance are negotiated with OPRR. OPRR has been in operation for over 20 years and is tasked with ensuring compliance with human subjects protections regulations. This office responds to allegations of noncompliance and actively pursues investigations.

It is now universally accepted that research investigators have a fundamental responsibility to safeguard the rights and welfare of the people participating in their research activities. In addition, it has been decided by law that an objective review of research activities involving human subjects by a diverse group of individuals is most likely to protect human subjects and promote ethically sound research. IRBs are generally composed of members with expertise in science, ethics and other nonscientific areas. This diversity fosters a comprehensive approach to safeguarding the rights and welfare of human subjects.

HHS Activities

Now I would like to briefly review the efforts we are currently undertaking as a part of the White House Human Radiation Interagency Working Group. HHS is actively participating in the Working Group as well as all of its subcommittees.

We are currently finalizing a memorandum for all HHS components which will:

- ask each Departmental division to identify an individual who will be responsible for activities related to the Working Group,

- direct each Departmental division to begin immediately to identify records related to human experimental exposure to ionizing radiation, and

- direct each Departmental division to retain and secure any and all records that may pertain to experimental exposure of humans to ionizing radiation.

It is anticipated that most of the experiments funded by HHS involving human exposure to ionizing radiation were funded by the Public Health Service (PHS). Therefore, a PHS Human Radiation Studies Working Group has been established with representatives from the Office of the Assistant Secretary for Health, the National Institutes of Health, the Centers for Disease Control and Prevention, the Indian Health Service, and the Food and Drug Administration. This group will provide detailed guidance and oversight to the staff investigating radiation research.

Preliminary projections indicate that PHS research records will be found in many locations. For those experiments conducted by PHS employees, the records that exist are likely to be found within agency files. However, as you know, much of the research supported by the PHS is by research scientists at institutions located throughout the United States. Problematic experimentation, for reasons I have noted, most likely could have occurred prior to the mid 1960's, i.e. more than 30 years ago.

Identifying and locating the records of these grantees and contractors will require additional effort as the overwhelming majority of the records of special interest -- research protocols, documents related to informed consent, and identities of research subjects -- will be located at awardee institutions. Thus,

while we are moving forward, the task is substantial and must be undertaken with considerable care. For example, we need to be concerned at every step of the way that we do not in anyway place the privacy interests of research subjects at risk.

We will be pursuing multiple leads in our efforts to identify human radiation experiments. First, we will be examining our own records of research and research grants and contracts. At the same time we will be working cooperatively with other agencies to conduct a comprehensive search of the scientific literature, follow up on calls coming in to the 800 number, and use all possible means to identify relevant experiments.

Finally, HHS is conducting an assessment of our expertise in providing follow-up to individuals who may have been exposed to radiation. NIH, in particular the National Cancer Institute, has conducted longitudinal studies on radiation exposure studies of Chernobyl victims, and follow-up studies of patients who have received radiation as a part of a treatment regimen. In addition, CDC has conducted studies of the human health effects of occupational and environmental exposure to radiation. Finally, since the early 1960s FDA has been monitoring the health effects of radiation exposure from fall out, occupational exposure and medical exposures.

Conclusion

Mr. Chairman, on February 9, this vigorous system of protecting human volunteers in research supported by HHS enters its 29th year of continuous oversight. In closing, we want to assure you that the projections in place are designed to preclude the very problems that we have gathered here today to discuss.