

## **INFORMATION PAPER**

**SUBJECT:** Department of Defense Human Subjects Radiation Experiments Review

**PURPOSE:** To provide an update about DoD human radiation experiments research initiatives and the possible outcome of findings of the Advisory Committee on Human Radiation Experiments.

### **BACKGROUND:**

- 7 December 1993, Energy Secretary O'Leary announced openness initiatives about DOE involvement in human radiation experiments.
- 24 December 1993, a National Helpline was initiated at DOE to respond to public concern and collect preliminary data regarding reported exposure.
- 3 January 1994, an Interagency Working Group, chaired by the Secretary to the Cabinet and composed of DOE, DoD, CIA, HAS, OMB, DOJ, DVA, and NASA, was established to ensure a coordinated effort.
- 15 January 1994, the Advisory Committee, comprised of 14 respected professionals of law, ethics, and health, was established by Executive Order 12891. The Advisory Committee is chartered to:
  - Review experiments conducted from 1944 to 1974 (later extended to include the present).
  - Evaluate ethical and scientific standards and criteria on human radiation experiments conducted or sponsored by the U.S. Government.
  - Prepare a Final Report to the Interagency Working Group and to the President.

### **DoD MISSION AND SCOPE:**

- To achieve a full accounting of the DoD involvement in radiation research and experimentation on human subjects during the last 50 years.
- Includes experiments on individuals involving intentional exposure to ionizing radiation, not including common and routine clinical practices such as established diagnosis and treatments involving incidental exposures to ionizing radiation.
- Includes experiments involving intentional environmental releases of radiation that were designed to test effects of ionizing radiation on human health, or the extent of human exposure to ionizing radiation, and several other specific military research projects.

### **DoD INITIATIVES, JANUARY 1994 TO PRESENT:**

- SECDEF memo, 7 January 1994, from then SECDEF Les Aspin, affirmed DoD's commitment to openness and appointed Dr. Harold P. Smith, ATSD(AE), as DoD focal point.

- Radiation Experiments Command Center (RECC) established as DoD central repository on 2 February 1994, under ATSD(AE), initially headed by a Flag Officer, now headed by an SES civilian. The RECC has:
  - Coordinated DoD human radiation experiment research in conjunction with the Services and Agencies.
  - Conducted extensive examination and review of relevant documents at National Archives and National Records Centers throughout the U.S.
  - Coordinated the declassification of more than 1,200 documents.
  - Identified approximately 2,600 possible DoD-sponsored human radiation experiments. Numbers are high because of DoD policy to err on the side of inclusion for fairness and openness.
  - Processed more than 7,000 inquiries from the Congress and public.
  - Collected and forwarded copies of approximately 10,000 human radiation experiment-related records (200,000 pages) to the Advisory Committee.
  - Coordinated DoD's extensive review of drafts of the Advisory Committee's Final Report.
- Participated in five Congressional hearings and briefings on controversial activities such as total body irradiation (TBI) and atmospheric releases of radiation.
- Total expenditure by DoD is \$7.36 million; 149,000 person hours of research

**ADVISORY COMMITTEE ACTIVITIES:**

- Starting in April 1994, conducted document research and held 20 public meetings/hearings in six locations, including Washington, DC.
- Initially focused on the identification of specific human radiation experiments for case study review. However, in June 1994, began an intensive review of the Government's policies concerning human use research protocols from 1942 to the present.
- Scheduled to conclude with release of the Final Report on 3 October 1995. Advisory Committee Chair, Dr. Ruth Faden, will formally present Final Report to the President.

**ADVISORY COMMITTEE FINDINGS -- RELATED TO DoD:**

- From 1944 through 1974 (extended to present), the Government sponsored several thousand human radiation experiments. Of this number, DoD conducted several hundred experiments.
- The DoD did not have comprehensive policies requiring the consent of all research subjects, including both healthy subjects and patient subjects, until 1974.
- Agencies did not consistently comply with their requirements and policies on human subjects

consent to research.

- Problematic experiments cited in the Advisory Committee Final Report include:
  - Total body irradiations (TBI) such as those conducted at the University of Cincinnati, on which litigation is pending. In conjunction with these experiments, research was funded by DoD on patients exposed to TBI in clinical settings. Key points:
    - DoD funds were used solely for laboratory studies and psychological and psychiatric tests of cancer patients who received whole and partial body irradiation.
    - No DoD funds were used for direct patient care, nor did the DoD play any part in patient selection or choice of treatment.
  - Biomedical research in connection with selected atmospheric nuclear weapons tests, e.g., Desert Rock exercises and Operation REDWING.
    - More than 200,000 service personnel participated in nuclear weapons tests from 1945 to the early 1960s; most of these personnel were engaged in test management, training maneuvers, or data gathering activities.
    - About 1,000-2,000 were research subjects.
  - Air Force research in the 1950s on Native Alaskans and military personnel using iodine-131 as a radioisotopic tracer to determine the role of human thyroid activity in acclimatization to extreme cold weather (expected litigation involves 70 participants).

#### **ADVISORY COMMITTEE RECOMMENDATIONS:**

- Public apology and compensation to certain human radiation experiment participants under particular factual circumstances, including excessive secrecy; injury to healthy subjects in non-therapeutic research projects; and misrepresentation regarding unconventional therapeutic investigations.
- Independent oversight of classified research involving human subjects to create an atmosphere of openness.
- Increased public access to research information. DoD has worked closely with the Advisory Committee and the National Record Centers to increase public access.
- Better oversight for all Government sponsored or conducted human subject research. Although effective oversight mechanisms are in place, further refinements are required.

#### **EFFECTS ON DoD:**

- Positive public perception of DoD openness in providing public access to human radiation experiment information. Over the long term, such access should help in reducing public cynicism.

- Anticipate Advisory Committee Final Report to raise public expectations about possible compensation, at least in several cases.
- Increase in media, public, and Congressional interest.
- Congress, the media and interest groups will likely refocus on other human subject experiments, i.e., chemical and biological (out of the scope of the Advisory Committee's Charter).

**DoD FOLLOW-UP (ON-GOING):**

- Review human radiation experiment oversight policy and make appropriate revisions based on Advisory Committee recommendations.
- Continue initiatives to increase public access to human radiation experiment information.
  - Enter DoD data into INTERNET/World Wide Web (complete in early spring 1996).
  - Publish DoD report/book about human subject radiation experiment research (early 1996).
  - Transfer human radiation experiment records to National Records Centers.
  - Continue declassification of relevant documents.
- Attempt to resolve pending injury claims under Advisory Committee's recommendations.
- Continue responsiveness to Congressional and public inquiry.

**ACTION:** Continued close coordination with OSD General Counsel, ASD (Public Affairs) and other interested agencies.

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