United States General Accounting Office

GAO

Testimony

Before the Committee on Governmental Affairs,
U.S. Senate

For Release on Delivery
Expected at
9:30 a.m. EST
December 1, 1994

HEALTH AND SAFETY

Status of Federal Efforts to Disclose Cold War Radiation Experiments Involving Humans

Statement of Victor S. Rezendes, Director, Energy and Science Issues, Resources, Community, and Economic Development Division

GAO/T-RCED-95-40

Mr. Chairman and Members of the Committee:

We are pleased to be here today to discuss the ongoing federal effort to locate, analyze, and disclose the details of U.S. government activities that exposed humans to radiation between 1944 and 1974. Many of these activities took place in the early years of the "Cold War" and are being referred to as Cold War radiation experiments in this testimony. You asked us to monitor and report the status of the federal effort to disclose the details of government activities that included "biomedical" radiation experiments involving humans and tests that released radiation to the environment. As you are aware, although much of this radiation research led to advances in nuclear medicine, concern has been recently expressed that some of the subjects of this research may not have been fully informed of the dangers of being exposed to radiation.

In January of this year, the President established a Human Radiation Interagency Working Group (Interagency Working Group) composed of the heads of pertinent agencies to oversee federal efforts to locate historical records describing radiation experiments on humans and radiation releases to the environment. The President also established an independent Advisory Committee on Human Radiation Experiments (Advisory Committee) that reports to the Interagency Working Group and is chartered to analyze and determine whether "appropriate" ethical and scientific standards were used to conduct the experiments and radiation releases. The Advisory Committee issued an interim progress report on October 21, 1994,[1] and is scheduled to make its final report on this issue in April 1995. Consequently, we believe that this hearing provides a timely opportunity to discuss the progress of this federal effort.

In summary, the federal agencies and the independent Advisory Committee have been working diligently to develop the story of Cold War government activities that exposed humans to radiation. However, the final results of this ongoing federal effort may not be complete for a number of reasons:

-- Although the federal effort is still evolving and thousands of experiments have been identified, it now appears that the full extent of Cold War radiation experiments involving humans may never be known because of the difficulties of locating and analyzing all pertinent documents describing experiments that occurred 20 to 50 years ago. Furthermore, agencies have used inconsistent definitions for their searches and, for the most part, have not verified the accuracy of these searches. As a result, federal agencies are finding it difficult to identify persons involved in the Cold War radiation experiments. Thus,

---

[1]Interim Report of the Advisory Committee on Human Radiation Experiments, Washington, D.C., October 21, 1994.

it may not be possible to complete one of the major objectives of this work--to contact the subjects of radiation experiments (or their relatives).

-- Although the Advisory Committee and its staff are working diligently, concern is growing that the committee will not be able to adequately complete its work within the current 1-year time frame. The committee is having difficulties satisfying its original charter and, as of November 1994, has done little of the ethical and scientific analysis of Cold War experiments called for in its charter. Despite these difficulties, the committee has chosen to expand the overall scope of its work.

Before I proceed further, Mr. Chairman, it may be helpful to provide some brief background information.

BACKGROUND

Between 1944 and May 1974,[2] the U.S. government exposed humans to radiation in a variety of biomedical experiments, under a variety of circumstances and for a variety of reasons. During this same period, the government performed a number of tests that released radiation to the environment and may have exposed the public to radiation. The details, or in some cases even the existence, of these experiments and releases were not widely publicized. Even the subjects, some of whom were from vulnerable populations, such as children and the elderly, may not have been aware of the purposes and risk of being exposed to radiation.

In December 1993, the Secretary of Energy acknowledged the existence of these Cold War radiation experiments involving humans and pledged full disclosure of the details. In January 1994, at the direction of the White House, the administration organized an Interagency Working Group on Human Radiation, composed of the heads of pertinent agencies. The administration instructed federal agencies to search for all records of radiation experiments involving humans and environmental releases that occurred between 1944 and May 1974. The agencies were instructed to use the following definition as the scope for their search:

---

[2]Since 1974, federal regulations have become more protective of research subjects and, in general, require (1) the formation of institutional review boards and procedures and (2) researchers to obtain informed consent from human subjects and ensure that their participation is voluntary and based on the potential risks and benefits.

Experiments on individuals involving intentional exposure to ionizing radiation[3] (excluding routine clinical procedures) and experiments involving intentional environmental releases of radiation that were designed to test human health effects of ionizing radiation or were designed to test the extent of human exposure to ionizing radiation.

The agencies were also instructed to investigate four specific sets of government tests that released radiation to the environment.[4] We reported on these four sets of radiation releases in November 1993.[5] Our report disclosed that during the Cold War the Atomic Energy Commission and DOD had intentionally released radiation into the atmosphere at federal facilities to, among other things, measure the dispersion of radioactive materials.

The independent Advisory Committee on Human Radiation Experiments, consisting of one citizen representative and 13 nongovernment experts in ethics, medicine, science, and law, reports to and provides expert advice to the Interagency Working Group. The committee's charter directs it to evaluate experiments conducted from 1944 to May 1974 using criteria based on ethics and science standards determined to be appropriate by the committee. Specifically, the charter directs the committee to consider whether (1) there was a clear medical purpose for the experiments, (2) appropriate medical follow-up was conducted, and (3) the experiments' design and administration adequately met ethical and scientific standards, including standards of informed consent. The Advisory Committee is also directed to evaluate and provide advice concerning government tests that released radiation to the environment. Finally, the charter gives the committee the option to evaluate current radiation experimentation on a sample basis, if it wishes and the Interagency Working Group approves.

To prepare for this testimony, we reviewed the status of federal agencies' efforts to locate historical records detailing radiation experiments involving humans and releases to the environment. We also reviewed the status of the committee's effort

---

[3]Ionizing radiation can damage skin and tissue or cause genetic effects.

[4]These four sets of radiation releases involved 13 tests that the government conducted in the 1940s and 1950s at the Atomic Energy Commission's Hanford Reservation, Oak Ridge National Laboratory, and Los Alamos National Laboratory; and the Army's Dugway, Utah, site. It is suspected that radiation from some of these tests may have reached inhabited areas and affected an unknown number of people.

[5]Nuclear Health and Safety: Examples of Post World War II Radiation Releases at U.S. Nuclear Sites (GAO/RCED-94-51FS).

to analyze the records. The five agencies that we reviewed include the Departments of Energy (DOE), Defense (DOD), Health and Human Services (HHS), and Veterans Affairs (VA), and the National Aeronautics and Space Administration (NASA).

THE FULL EXTENT OF RADIATION EXPERIMENTATION MAY NEVER BE KNOWN

The direction of the federal effort to locate and analyze Cold War era radiation activities has been evolving as more knowledge is gained concerning the nature and difficulties of this task. For example, agencies, while working earnestly to do so, now realize that it may be impossible to identify and retrieve all radiation records that were created 20 to 50 years ago. As of November 1994, hundreds of thousands of documents have been located, representing thousands of radiation experiments and hundreds of intentional radiation releases, all of which may have involved tens of thousands of potential human subjects. However, many other documents, and presumably experiments, will not be located mainly because of historically poor record keeping and records management practices, records destruction policies, or the enormous volume of a variety of records that would have to be manually searched, many of which are not in the possession of the government.

Some agencies may never be able to locate all pertinent records of radiation experiments and releases. They have encountered logistical difficulties, including the need for searches of massive volumes of data, historically poor records management practices, the destruction of some records, declassification difficulties, and lack of access to some records. For example, HHS officials encountered severe difficulties when they attempted to carry out the broad search called for in the President's January 1994 directive and subsequent instructions. They pointed out that a general search of the National Institutes of Health records, the main sponsor of medical experiments, would cost millions of dollars, involve hundreds of millions of documents, and require access to and review of the records of 27,000 grantees. HHS officials consider such a general search not cost beneficial and the Advisory Committee has since directed HHS toward narrower searches for specific Cold War documents identified by the Advisory Committee.[6] Also, all the agencies have noted the difficulties of searching for records that are 20 to 50 years old. Some agencies' poor records management systems make this task particularly difficult. In addition, some agencies have destroyed old records on a regular cycle in accordance with federal records retention and destruction regulations. Thus, many pertinent records may have been destroyed years ago, and the full extent of radiation experiments involving humans may never be known.

---

[6]HHS is also helping the Advisory Committee to review current radiation experiments involving human subjects.

The Advisory Committee now realizes the difficulty of trying to analyze the thousands of experiments in the limited time set for this work. The committee and its staff came to this conclusion after initially receiving tens of thousands of documents from the federal agencies, with more to come. The committee stated in late October that the number of documents is over 250 thousand and still growing. Consequently, the committee has sought to develop an alternative analytical approach that would ensure the administration, the Congress, and the public that the committee has done its best to evaluate Cold War radiation activities.

The Advisory Committee has concluded that all radiation experiments do not have to be analyzed in order to report on Cold War radiation experimentation. The committee believes that it can give an account of these government radiation activities by reviewing historical policy documents and other memoranda describing the context and circumstances in which selected experiments might have been performed. According to the committee's October interim report, it will reinforce and support the results of this document review with selected case studies. For example, the committee plans to study certain types of biomedical radiation experiments, including those that exposed (1) a human's entire body to radiation, (2) children, and (3) healthy adults. The committee will also study other biomedical radiation experiments, including some recently publicized experiments, such as the injection of 18 humans with plutonium in the 1940s. Other case studies are expected to include a study of institutional involvement in Cold War radiation experimentation. The committee has selected the Oak Ridge National Laboratory complex and components of the University of California as sites for its institutional case study. Finally, it appears that the committee is still determining to what extent it will analyze government tests that released radiation into the environment. The committee, however, feels obligated to at least comment on the 13 releases that are specifically mentioned in its charter. Some information related to some releases may not be fully declassified by federal agencies because of national security concerns. However, committee members and staff with security clearances will be able to review this classified data to determine what, if any, of this information may be pertinent to the Advisory Committee's study.

Records Searches May Be Incomplete, Inconsistent, and Inaccurate

Compounding the search for records, some agencies have used inconsistent definitions for the scope of their records searches and have not ensured the accuracy of search results. Agency officials claim that the scope defined in the January instructions is vague, confusing, and does not necessarily apply to the agency's situation. For example, agencies are struggling with the meaning of "experiment" versus treatment and diagnosis in the definition and have questioned where an experiment leaves off and diagnostic

procedures and treatment begin. Some agencies are also struggling with the use of the word "intentional" in the definition, which would be open to interpretation. Consequently, search teams within and among agencies have used inconsistent definitions in their searches.

We visited several search sites and found that their search teams either used the established definition or broadened it to include everything even remotely connected to radiation and humans, or they used their own definition. To illustrate, one laboratory had conducted tests involving the dispersion of plutonium into the environment through use of non-nuclear explosives. We found that one of these tests may have contaminated a group of individuals not connected with the test. However, since these tests were not conducted to measure human effects, the laboratory excluded these tests from its reported search results. In contrast, another laboratory, which used a broader definition for radiation releases, included radiation dispersion tests in its search results.

Agencies also may not have adequately ensured "the quality, comprehensiveness, and integrity" of the search process, as directed by the Interagency Working Group. For example, agencies have done little checking of the accuracy of search results, but instead are depending mainly on the ability and integrity of searchers. In some instances, a group within an agency may have checked the accuracy of search results. For example, we observed Defense Nuclear Agency personnel following written procedures for physically checking the accuracy of the searches of boxes containing pertinent records. In addition, NASA and DOE told us that they plan to check the accuracy of searches and NASA has established an independent group to do this. However, for the most part, we found little evidence that agencies have thus far independently checked the accuracy of search results.

Most Subjects of Cold War Radiation Activities May Never Be Identified

It has also become increasingly evident that identifying and contacting all of the individuals, or their relatives, which were the subjects of Cold War radiation activities will be a formidable task. One of the objectives of the federal effort is to find and disclose the details of experiments to those who were the subjects of experiments or their living relatives. However, agencies are finding it difficult to identify many of the subjects of biomedical experiments. These difficulties arise out of the vagueness and incompleteness of old records or the lack of access to information that may be in records at nongovernment institutions. In addition, I am sure that you can appreciate the great difficulties involved in identifying those individuals who may have, unknowingly, been affected by releases of radiation, either intentionally or not.

As the federal effort further evolves, federal agencies may feel obligated to concentrate more of their time on strategies for identifying and contacting the subjects of both the biomedical experiments and radiation releases. For example, DOD and VA officials told us that even though the Advisory Committee probably will not analyze most of the records that their agency has located, they feel obligated to review all of these records in an attempt to identify radiation subjects that may need their help. These officials told us that they are already following up on thousands of hot-line call-in inquiries on this matter. However, agency personnel and Advisory Committee staff told us that the government may have to establish a formal mechanism--more formal than the current telephone call-in help lines--to allow potential subjects or their relatives to come forward and identify themselves.

ADVISORY COMMITTEE HAS INCREASED THE SCOPE AND WORKLOAD FOR THIS FEDERAL EFFORT

The Advisory Committee has expanded its workload and the overall scope of its charter. This expansion may take time away from the committee's ethical and scientific analysis of Cold War experiments that is required by its charter. However, the committee believes that this expansion is necessary in order to provide an accurate assessment of not only Cold War radiation activities but also current experiments involving humans.

The Advisory Committee has added items that were either not emphasized or not included in its charter, such as (1) current experiments involving humans, (2) nuclear bomb testing, and (3) proposing remedies for the subjects of Cold War radiation activities. For example, the committee is now planning to expend significant time and resources to determine the conditions under which biomedical radiation experiments are currently conducted in the United States. This would include, among other things, interviewing researchers and human subjects. While the charter allows the committee the option to sample current experiments involving humans, with the concurrence of the Interagency Working Group, this was not emphasized in the charter.

In addition, the committee is spending significant time studying nuclear bomb testing and its effect on veterans and others. This area, which has been previously addressed by the government, was not included in the committee's charter. The committee also plans to recommend criteria for determining remedies for human subjects that the committee concludes were wronged or harmed through government Cold War radiation experiments. The committee's recommendation will be based on its analysis of the experiments and its consideration of alternative forms of remedy, including "governmental acknowledgement of the wrong done, medical monitoring and followup, access to personal information,

compensation, or other potentially appropriate responses." This responsibility was not included in the committee's charter. The Interagency Working Group has, however, established an interagency subcommittee on legal issues to determine possible remedies if the Advisory Committee determines that the government used unethical or improper scientific standards in its experiments. The subcommittee's work is on hold until the Advisory Committee completes its analysis.

We understand and agree with the committee's desire to obtain a thorough picture of what historically occurred and is happening in the United States as far as the use of humans in radiation experiments. However, we note that the committee has done little analysis to determine, as directed by its charter, whether appropriate ethical and scientific standards were used to conduct Cold War experiments. In its October interim report, the committee stated that it will address this part of its charter during the next 6 months of its task. None-the-less, we are concerned that the expanding workload and the limited time frame for completing the work may conflict and as a result, it seems unlikely that the committee will be able to adequately complete its work within the current 1-year time frame.

- - - - -

Mr. Chairman, this concludes my prepared statement. I will be pleased to answer any questions from the Committee at this time.

(302113)

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 6015
Gaithersburg, MD 20884-6015

or visit:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000
or by using fax number (301) 258-4066, or TDD (301) 413-0006.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (301) 258-4097 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

United States
General Accounting Office
Washington, D.C. 20548-0001

Bulk Mail
Postage & Fees Paid
GAO
Permit No. G100

Official Business
Penalty for Private Use $300

Address Correction Requested