Gordon K. Soper
Principal Deputy
Assistant to the Secretary of Defense (Atomic Energy)
3E1074 (703) 697-5161

July 5, 1994

MEMO FOR: Mr Phil Caplan

SUBJECT: Advisory Committee Minutes

Phil:

As I promised, I'm sending you a copy of the minutes of the 13-14 June 1994 meeting of the Advisory Committee on Human Radiation Experiments. I hope this is useful. If you've got any questions or concerns, please give me a call.

Come see us. Are you still having fun? Say hello to Christine.

Warm Regards.

Gordon

EXECUTIVE SUMMARY
MEETING, ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS, 13-14 JUNE 1994

1.0 GENERAL

The Advisory Committee on Human Radiation Experiments conducted its third meeting on 13 and 14 June 1994. The 13 June session was held at the Ramada Plaza Hotel, 10 Thomas Circle, Washington, DC. Due to central air conditioning difficulties at the Ramada Plaza Hotel, the 14 June session was held at the Vista Hotel, 1400 M Street, N.W., Washington, DC. The meeting's agenda is at Tab A.

2.0 SUMMARY OF MEETING, 13 JUNE 1994

The 13 June session was called to order by Mr. Philip Caplan, Special Assistant to the President for Cabinet Affairs. The key agenda items accomplished were a briefing on remedies, conducted by Committee member Mr. Ken Feinberg; a briefing on risk communication, conducted by staff member Mr. Steve Klaidman; a series of staff reports on the status of the agency data collection efforts and a report on declassification efforts.

3.0 COMMITTEE MEMBER BRIEFING: REMEDIES

Committee member Mr. Feinberg conducted a half-hour briefing on the background information for the Committee that would help in any discussion on compensation.

3.0.1 Mr. Feinberg identified two classes of remedies that the committee would have to deal with: Particularized Remedy and Mass Exposure Remedy. Particularized Remedy is characterized by an action-consequence chain of events and is usually linked to an individual or small group. For example, an individual is hit by a car, and as a consequence that individual's leg is broken. There is a direct cause and effect from which to base a remedy.

3.0.2 Mass Exposure Remedy is characterized by an inability to demonstrate particularized injury. Examples would include the Nevada "Down-Winders", the Marshall Islanders, and the people living in proximity to the Hanford Nuclear Reservation. The positive causal link between exposure to radiation and subsequent development of cancer is not proven simply by proximity. Many times epidemiological studies are the only "proof" available in these cases.

3.0.3 The Committee would need to develop creative solutions to the Mass Exposure Remedy question. In the case of particularized injury, clear tort-based precedents are available. The Committee would simply have to collect the pertinent facts, establish a criteria to evaluate

injury, and develop a remedy. In the Mass Exposure cases, developing remedies would be more difficult.

3.0.4 One potential model Mr. Feinberg identified was the Disability/Workers Compensation Model. If individuals can satisfy the presumption of exposure, then they will not need to show causation.

4.0 STAFF BRIEFING: RISK COMMUNICATION

Mr. Steve Klaidman, the staff Director of Communication, presented a briefing on risk communication to the Committee.

4.0.1 He defined risk as the probability of any nontrivial negative outcome as a result of an experiment. Risk communication is intimately tied to informed consent because only after receiving a realistic portrayal of the possible risks can a subject give truly informed consent to participate in an experiment.

4.0.2 Risk communication has several major subcomponents, including risk perception and risk comparison. The investigator must convey to the subject the degree of risk to the individual. To accomplish this it is important to identify the target audience (based on a host of personal and cultural factors) and tailor the message appropriately. It is also important to frame the issue in such a way as to prevent any bias. Risk comparison is a valuable tool to communicate risk to a subject. It is often easier to assess the seriousness of an unfamiliar risk (ionizing radiation) if compared to a familiar risk.

5.0 REVIEW OF PROGRESS OF AGENCY DATA COLLECTION

Committee staffer Mr. Don Weightman briefed the Committee on the progress of data collection activities by the agencies. He is responsible for managing the flow of documentation and breaking the records down into useful categories.

5.0.1 Mr. Weightman stated that the Committee had received an enormous quantity of records including approximately 11,000 pages (The quantity was described variously as pages or records, pages seems the more likely correct description.) of DoE material, and several boxes of DoD records.

5.0.2 He indicated that the Committee staff had conducted meaningful discussions with five of the six agencies (The recalcitrant agency was not identified, but the CIA was alluded to.). It was indicated that the DoE was the farthest along and was seriously committed to providing the Committee with all necessary information. The DoD had problems because of the large numbers of players on the field ("no one-stop shopping"). The Department of Health and Human Services (DHHS) was also experiencing the same types of problems as the DoD,

because it was also a decentralized agency.

5.0.3 He characterized the overall Staff/Committee/Agency interaction as an efficient working relationship. There were several qualifications including the debate on who was going to perform archival record research and when this was going to occur.

5.0.4 Mr. Weightman identified three types of information that the staff was looking for: Line Items/Budget information, Program Areas, and Procurement Files. He did not define what these three types were.

5.0.5 Regarding the issue of classification, he indicated that the majority of the biomedical data was now or would soon be declassified. The classification of radiological warfare (RW) information was more problematic. Data on intentional releases was also problematic because (as indicated earlier) some DoD components had not looked for information on environmental releases.

5.0.6 Mr. Weightman indicated that a Committee outreach program was currently in progress to contact relevant groups with document collections that might be of interest to the Committee.

6.0 STAFF REPORTS ON STATUS OF AGENCY DATA COLLECTION: AN OVERVIEW

Mr. Dan Guttman, the Executive Staff Director, presented an overview of the status of the agency data collection efforts.

6.0.1 He reported that almost all agencies had completed Phase I research concerned with identifying participating organizations and developing basic information on experiments.

6.0.2 The Committee staff was involved in a series of exercises to map the information that had been forwarded to them into a usable format. This mapping is presently broken into three areas: Institutional (what agencies are connected by common research), Agency-Private Sector (what contractors worked for whom), and Ethics (the development of standardized ethical principles). The goal is to develop a comprehensive and usable scheme for evaluating the information that is forwarded to the Committee.

6.0.3 The staff had several high priority tasks, including identifying Governmental policy on human radiation experimentation for the purposes of revealing the intention of these experiments, the development of meaningful scientific categories for the experiments identified by the agencies, and developing more information on intentional environmental releases of radiation.

6.0.4 The Committee agreed that the staff should continue to pursue these lines of research.

6.1 UPDATE ON ETHICS DATA COLLECTION

Staffer Jonathan Moreno presented a brief update on the status of the ethics data collection effort.

6.1.1 He indicated that a steady stream of information from the agencies had been received. An effort was now being made to find data prior to the 1953 Wilson Memorandum with an emphasis on gathering information on the Armed Forces Medical Policy Council.

6.1.2 Dr. Gordon Soper, Principle Deputy to the Assistant Secretary of Defense (Atomic Energy) queried the Committee on what the time parameters for the record search were going to be. He noted that the Committee was now discussing researching policy development in the 1920's and 1930's, well prior to the 1944 start date identified by the Interagency Working Group and the White House.

6.1.3 Dr. Soper also asked the Committee to provide the agencies with advance warning if the timeframe the Committee decided to cover was expanded. This would help the agencies allocate their resources and obviate the need to retrace research the agencies thought was completed.

6.2 REVIEW OF DEPARTMENT OF DEFENSE DATA COLLECTION EFFORT

Mr. Guttman presented a review of the Department of Defense data collection effort.

6.2.1 He noted that the Committee staff had met with the DoD officials on 20 May and that the DoD had completed Phase I and was looking for guidance from the Committee on how to focus Phase II research.

6.2.2 Mr. Guttman stated that the DoD had not done Headquarters or OSD searches and these needed to be done.

6.2.3 He also stated that no archive research had been done. It was unclear if this comment was directed specifically at the OSD search or, erroneously, at the DoD effort in its entirety.

6.2.4 Mr. Guttman also indicated that the Defense Nuclear Agency (DNA) and the Department of the Army (DA) had not searched for information on intentional environmental releases of radiation and would need to do so.

6.2.5 Mr. Guttman stated that a lot of staff effort was allocated to looking into the evolution of Governmental policy on human use in experiments. This was being done because it is necessary to develop definable and workable categories for the large quantity of data that is being forwarded to the Committee from the agencies. Looking at the policy structure would enable the staff to begin to categorize the data into logical groups.

6.2.6 A tangential discussion on allocation of staff resources continued until the lunch break. Committee member Dr. Henry Royal stated that in order to properly prioritize staff work, it was necessary to look at what the Committee was striving to produce. In essence, this asked the question of what was the Committee's vision or mission. It was decided that discussion of the Committee's "vision" be put off until later.

6.3 REVIEW OF DEPARTMENT OF VETERANS AFFAIRS DATA COLLECTION EFFORT

Staffer Ms. Denise Holmes briefed the Committee on the status of the data collection effort at the Department of Veterans Affairs (DVA).

6.3.1 She indicated that the effort was primarily a field exercise at the 172 Veterans Administration (VA) hospitals. The Secretary of Veterans Affairs was committed to an open and thorough record search process to disclose as much information as possible regarding the Atomic Medicine Committee.

6.3.2 Several key staff observations were that the DVA had not identified any further historical documents related to the Atomic Medicine Committee. The DVA had not searched in depth for historic policy records nor begun to coordinate with other agencies regarding shared experiments.

6.3.3 The staff presented eight recommendations for approval of the Committee.

- DVA should continue to trace the history of the Atomic Medicine Committee.
- DVA should expand the scope of its search to focus on documents at a higher (i.e., national policy) level.
- DVA should begin to trace the history of its coordination of research with other agencies.
- Committee staff should interview key DVA personnel.
- DVA should trace the history of the VA/Omaha and other nuclear reactors.
- Committee staff should continue to interact with DVA personnel.
- Use the Committee staff to facilitate the transfer of information between the DVA and other agencies.

- Data collection should focus on :
  - -General fact finding
  - -Tracing DVA links with research schools
  - -Tracing DVA links with individual researchers at research schools.

6.4 UPDATE ON DEPARTMENT OF ENERGY DATA COLLECTION EFFORT

Mr. Guttman presented a brief update of DoE efforts to collect data.

6.4.1 He stated that the DoE was completed with Phase I sweep of its field offices.

6.4.2 The DoE is currently compiling an assessment of the quantity of records it holds related to human radiation experiments.

6.5 UPDATE ON DEPARTMENT OF HEALTH AND HUMAN SERVICES DATA COLLECTION EFFORT

Committee staffer Ms. Faith Bulger updated the Committee on the status of DHHS's data collection effort.

6.5.1 She stated the Committee staff had developed a close working relationship with DHHS personnel and that DHHS had been responsive to the staff's requests for information.

6.5.2 One key area to focus on was the interrelationship of the Public Health Service (PHS) and other agencies, notably the DoD and the Atomic Energy Commission (AEC). A subsidiary data source was the Committee on Medical Research (No agency identification was given, but this Committee was probably part of DHHS's predecessor.) which was closed in 1945 and had forty-five wartime programs transferred to the PHS.

7.0 REPORT ON DECLASSIFICATION

Mr. Guttman briefed the Committee on the status of agency declassification efforts.

7.1.1 Mr. Guttman introduced a letter sent to the agencies requesting that the agencies agree to review for declassification within three weeks of a request any documents requested by the Committee.

7.1.2 Four agencies were identified as having responded: the Central Intelligence Agency (CIA), the DoE, the DoD, and the National Aeronautic and Space Administration (NASA).

7.1.3 The CIA responded that it would work with the Committee on this issue.

7.1.4 The DoE indicated that it could declassify 3 linear feet per week of material and that at present it had identified 10 linear feet of classified material related to human radiation experiments.

7.1.5 The DoD responded that all reasonable requests could be done in the required timeframe, but that many documents were classified by more than one agency.

7.1.6 Mr. Guttman noted that it would be important to have all agencies working in parallel to declassify records that have multiple agency classification's.

7.1.7 The NASA response was vague, but affirmative.

8.0 PUBLIC COMMENTS SESSION

8.0.1 Representatives from three groups spoke to the Committee for five minutes each. The groups were the National Association of Radiation Survivors, the Survivors of Medical Radiation Experiments, and the Association of the Citizen-Soldier.

8.0.2 Their comments reflected the cynicism that veterans associated with atomic testing or related issues hold toward the Government. They encouraged the Committee to expand their brief to include all facets of American nuclear testing.

8.0.3 They also encouraged the Committee to be very inclusive when discussing what diseases to compensate as a result of radiation exposure.

8.0.4 The representatives indicated that veterans did not see the difference between participants in nuclear testing and participants in human radiation experiments.

9.0 SUMMARY OF MEETING, 14 JUNE 1994

The 14 June meeting had several key agenda points: a staff organization overview, and reports from the four subcommittees.

10.0 STAFF ORGANIZATION

The Advisory Committee staff is headed by a management team made up of five individuals, including the Committee Chair. A coordinating group comprised of the project leaders is responsible for project management. The project groups are structured along the lines of the Committee's Subcommittees (Ethics Data Collection, Scope and Priorities, Cold War Data Collection, and Public Outreach). Individual staffers are also tasked to focus on particular agencies.

11.0 SUBCOMMITTEES REPORTS

Each of the four Subcommittees presented a briefing on their progress.

11.1 ETHICS DATA COLLECTION SUBCOMMITTEE

Committee Chair, Dr. Faden, presented the Ethics Data Collection Subcommittee report on behalf of the Subcommittee chair Dr. Ruth Maklin.

11.1.1 She stated that the Subcommittee was tasked to identify the evolution of ethical standards related to medical research from 1944 to the present.

11.1.2 Data collection was divided into three parts. Part I data collection was on-going. Current activity was focused on finding policies, rules, guidelines, and procedures the agencies developed in relation to human radiation experimentation. Part II data collection focuses on understanding the roles, policies, guidelines, and procedures of universities and research organizations, including review boards and oversight groups, as it relates to human radiation experimentation. Part III data collection concerns the implementation and behavior of researchers in relation to those procedures laid out in Part II.

11.1.3 The Subcommittee wants to conduct interviews with researchers and experiment subjects to gather complete data on ethical standards used from 1944 to 1974.

11.1.4 The Committee discussed whether or not conducting interviews would produce information that was useful, and if Committee member's institutions should be exempt from the interview process. Subjects were to be included in the interview process to determine if researchers had been doing a good job with risk communication.

11.1.5 The overall goal of all three data collection parts and the interviews is to develop a picture of what the ethical standards were for the past 50 years and how research was conducted during this same time.

11.2 SCOPE AND PRIORITIES SUBCOMMITTEE

Committee member Dr. Duncan Thomas briefed the Committee on the status of the Scope and Priorities Subcommittee.

11.2.1 As part of defining the scope of the Committee, Dr. Thomas provided a working definition of medical experiments that would interest the Committee. The definition was, "intentional exposure by investigators of ionizing radiation that resulted in therapeutic or deleterious effects on subject."

11.2.2 Categorization/classification of experiments was also identified as an important task for the Scope and Priorities Subcommittee.

11.2.3 Dr. Thomas suggested one classification could be termed Secret Experiments. This could be split into two divisions, Military and Medical. Miliary Experiments could be further subdivided into Distribution Experiments and Acute Biological Effects (e.g., plutonium injections). Medical Experiments could be subdivided into Distribution Studies (e.g., tracers and tags), Diagnostic Studies, and Therapeutic Studies. Another category could be the Notorious Experiments (e.g., Saenger).

11.2.4 Dr. Thomas indicated that, because of the enormous quantity of data, it would be necessary to begin to categorize the information. A sampling (it was not indicated what statistical model was to be used as a base) could then be done. The inference was that this sampling could be used to determine if there was a problem with any one group or category of experiments.

11.2.5 The issue of sampling provoked several comments from members of the Committee. One member stated that, for sampling to be useful, categories need to be intelligently crafted. Another member indicated that the Committee would still need a description of what a reasonably informed scientific investigator should have known at any given time throughout the period of 1944 to 1974. This base of knowledge would impact the Committee's evaluation of many of the experiments (The question of whether or not whole body irradiation was an outdated therapeutic treatment prior to Dr. Saenger's experiments in the 1960's and early 1970's.)

11.2.6 Another Committee member warned that the Committee would not be in a position to pass judgement on any experiments for several months.

11.3 COLD WAR DATA COLLECTION

Committee member Dr. Mary Anne Stevenson briefed the Committee on the work of the Cold War Data Collection Subcommittee.

11.3.1 Dr. Stevenson told the Committee that a bottom-up approach to categorizing experiments was impossible because of the immense quantity of data that needs to be dealt with.

11.3.2 She proposed four categories for data:

- Biological Effects of Whole Body Irradiation
- Biological Effects of Atmospheric Releases
- Biological Effects of Radium, Uranium, Polonium, Plutonium (Biological Distribution Studies)
- Metabolic and Physiological Studies

11.3.3 There were several minutes of debate on specifically what was meant by each category, but the general consensus was that the categories seemed appropriate. Several Committee members commented that the "great unwashed mass of experiments" (a term coined by Mr. Guttman), those that are not secret or notorious would still have to be dealt with.

11.4 PUBLIC OUTREACH

Committee member Dr. Reed Tuckson briefed the Committee on the progress of the Public Outreach Subcommittee.

11.4.1 He stated that the Committee had three public outreach responsibilities: first, develop a relationship with stakeholders; second, develop a relationship with experts; third, work on the Committee's relationship with the media.

11.4.2 He disseminated a proposed draft letter to stakeholders asking them for information and their involvement in the Committee process. This letter would also request that other interested groups be identified. A similar letter could be drafted to experts to keep them updated on the Committee's progress.

11.4.3 Dr. Tuckson also discussed the location of proposed field hearings. San Francisco, Chicago, Nashville, and Atlanta were mentioned as possible locations. The Committee felt that cities that had "Notorious Experiments" should be avoided because it may seem the Committee is holding a field hearing solely to discuss that experiment. Another Committee member proposed that, instead of the entire Committee holding two or three field hearings, groups of two members could hold informational meetings in various cities. By this means more geographic locations could be covered and potentially generate greater public involvement in the Committee process. The Committee agreed to explore a combination of both of these approaches, but did not finalize a decision.

12.0 COMMITTEE DIRECTION TO STAFF

After the Cold War Data Collection briefing was completed, Committee Chair, Dr. Faden, proposed that the Committee look at what priorities it wanted to focus on.

12.0.1 She suggested that the Committee continue to tell the Cold War story, approaching it from the top down (i.e., looking at overall policy development first). The Committee should also continue to focus on Secret Experiments, especially radiological warfare and atmospheric releases. The Committee should also continue with the pursuit of developing data on ethical standards.

12.0.2 The Committee approved these pursuits.

12.0.3 This consensus resulted in four directions to the Committee staff:

- Continue top down policy data hunt
- Continue Cold War story data collection
- Look at publicly controversial case
  (The Scope and Priorities Subcommittee would develop a list of these experiments)
- Examine category four (Metabolic and Physiological studies) experiments and try to develop a workable sampling system.

12.0.4 Dr. Faden also pressed for closure on the proposal of the Ethics Data Collection Subcommittee to explore the feasibility of convening a panel of experts to decide if the interview project would be a value to the Committee.

13.0 VISION/PURPOSE OF COMMITTEE

The Committee had intended to complete its third meeting with a discussion of the purpose, mission, and vision of the Committee. However, it was proposed and approved that the Committee Chair draft a memorandum on the subject for discussion by the Committee. Any member that wanted to provide input to the Chair was welcome to do so. The memorandum is scheduled to be discussed during the second July meeting.

14.0 GENERAL OBSERVATIONS

General observations regarding the meetings include the following

14.0.1 The Committee is now debating how to best allocate its scarce resources. However, the essential element in this process (prioritizing its tasks) has not been adequately addressed. This is exemplified by the Committee delaying until the second July meeting (its fifth meeting overall) to debate the Committee's mission and vision. Without a universally accepted vision of the purpose and scope of the Committee's mandate, it will be very difficult to properly allocate staff and member resources.

14.0.2 During the Subcommittee reports, several diverse schemes for categorizing experiments were offered. None were exhaustively debated, however, the categorization methodology offered by the Cold War Data Collection Subcommittee seemed to have the most widespread approval among Committee members.

14.0.3 Many of the Committee decisions are delayed until the next meeting because of time constraints and lack of total consensus on the part of Committee members.

14.0.4 Some Committee members and staffers make negative judgmental comments related to specific experiments, as well as Governmental policy on human radiation experiments. All comments made during the Advisory Committee hearings become part of the public record and could cause problems later. These comments are often based on a little information.

14.0.5 The Committee and staff discussed two issues that impact the DoD data collection effort. First, the Committee is very interested in obtaining information on the radiological warfare program. Second, a substantial amount of discussion revolved around atmospheric releases of radiation.

Brian H. Thompson
DoD RECC

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A

Divider Title: _____

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
PUBLIC MEETING
JUNE 13-14, 1994

The Ramada Plaza Hotel--Washington Room--10 Thomas Circle, NW--Washington, D.C.

FINAL AGENDA

Monday, June 13

9:30 AM	Call to Order *Philip Caplan, Special Assistant to the President for Cabinet Affairs*
9:35	Welcome and Orientation to Meeting *Ruth Faden*
9:40	Introduction of New Staff *Jeffrey Kahn*
9:45	Review and Approval of Minutes of May 18-19, 1994 Meeting *Ruth Faden*
9:50	Briefing: Introduction to Remedies (Tab G) *Ken Feinberg*
(10:20)	Committee Question and Answer Period
10:35	Briefing: Risk Communication *Steve Klaidman*
(11:00)	Committee Question and Answer Period
11:10	Break
11:25	Overview of Staff Work *Dan Guttman*
11:35	Staff Report: Update on Ethics Data Collection Efforts (Tab H) *Jonathan Moreno*
11:50	Staff Report: Methodological Review of Agency Data Collection Efforts--Department of Defense (Tab J) *Jim David and Dan Guttman*
12:30 PM	Lunch

2:00 Staff Report: Methodological Review of Agency Data Collection Efforts--Department of Veterans Affairs (Tab I)
Denise Holmes and Dan Guttman

2:45 Staff Report: Update on Methodological Review of Agency Data Collection Efforts--Department of Energy (Tab K)
Jim David and Dan Guttman

3:00 Staff Report: Update on Methodological Review of Agency Data Collection Efforts--Department of Health and Human Services (Tab K)
Faith Bulger and Dan Guttman

3:15 Review of Progress of Agency Data Collection
Don Weightman

3:30 Report on Declassification
Dan Guttman

3:45 Break

4:00 Public Comments

5:00 Meeting Adjourned

Tuesday, June 14

9:00 AM Opening Remarks
Ruth Faden

9:05 Reports from Subcommittees:
Ethics Data Collection
Ruth Faden
Scope and Priorities
Duncan Thomas
Cold War Data Collection
Mary Ann Stevenson
Public Outreach
Reed Tuckson

12:00 PM Lunch

1:30 Meetings of Subcommittees

3:00 Meeting Adjourned

Gordon K. Soper
Principal Deputy
Assistant to the Secretary of Defense (Atomic Energy)
3E1074 (703) 697-5161

August 2, 1994

MEMO FOR: Phil Caplan

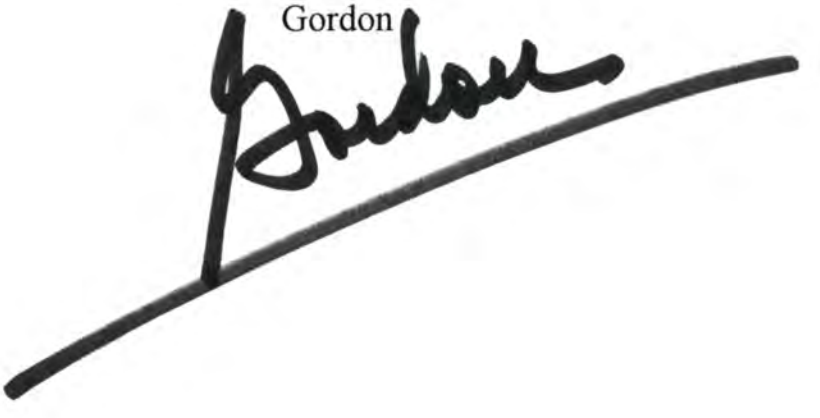
SUBJECT: Advisory Committee Minutes

Phil:

I've attached a copy of the last three Committee Meeting minutes--I don't remember which ones that I've sent you. If you are still missing any of these minutes, give me a call and I will get it to you *toute de suite.*

I talked with Dan Gutmann yesterday and told him of our plan to get the documents that they need from DNA and the Army. He seemed satisfied--but I'm not sure I understand what that means. I still think we took a cheap shot! Ultimately, it might be a good idea to sit down with Margaret Sullivan, Ruth Faden and Christine Varney to clear the air and make sure everyone has a comfortable feeling about the status of DoD's efforts.

Gordon



DOD RADIATION EXPERIMENTS COMMAND CENTER

FACSIMILE LEAD SHEET

6801 Telegraph Road
Alexandria, VA 22310-3398
(703) 739-9576 (Fax)
(703) 739-9572
(Verification and Main Number)

Date: 9 August 1994

To: The RECC Distribution List

From: Colonel Claud Bailey, Jr., USA

Subject: Relocation of the DoD RECC

Total Number Of Pages 1 Including This Cover Sheet.

Comments: Effective 12 August 1994 the Department of Defense Radiation Experiments Command Center will relocate to:

301-A S. West Street, Alexandria, VA

Please note the new telephone and facsimile numbers.

The mailing address remains the same as above.

Please call our office immediately if you did not receive this entire transmission or if you have any questions. Thank you.

Department of Defense
Radiation Experiments Command Center
6801 Telegraph Road
Alexandria, Virginia 22310-3398

JUL 2 8 1994

RECC

MEMORANDUM FOR DR. GORDON K. SOPER, PRINCIPAL DEPUTY, ASSISTANT TO THE SECRETARY OF DEFENSE (ATOMIC ENERGY)

SUBJECT: Advisory Committee on Human Radiation Experiments Meeting, 25-26 July 1994

Attached for your review is an Executive Summary (Attachment 1) of the Advisory Committee meeting, 25-26 July 1994. The summary was prepared by the DoD RECC personnel that attended the meeting.

FOR THE DIRECTOR:

CLAUD BAILEY, JR.
Colonel, AG, USA
Deputy Director,
Command Center

Attachment
as stated

EXECUTIVE SUMMARY
ADVISORY COMMITTEE ON
HUMAN RADIATION EXPERIMENTS
MEETING OF 25-26 JULY 1994

1.0 GENERAL

The Advisory Committee on Human Radiation Experiments conducted its fifth meeting on 25 and 26 July 1994, at the Stouffer Mayflower Hotel, 1127 Connecticut Avenue, N.W., Washington, DC. The meeting's agenda is at Tab A.

2.0 SUMMARY OF MEETING, 25 JULY 1994

The Advisory Committee was called to order by Mr. Philip Caplan, Special Assistant to the President for Cabinet Affairs. The Committee chair, Dr. Ruth Faden, stated that the Committee had four main objectives for the next two days: continue the on-going process of self-education; update the Committee on the work of the staff, including priority areas and any problems the staff was encountering; hear from the public; and advance the agenda of the Committee.

3.0 BRIEFING: REGULATION OF CONTEMPORARY RADIOACTIVE DRUG RESEARCH

An outside presenter, Dr. Barry Siegel, Professor of Radiology and Medicine and Director of the Division of Nuclear Medicine, Mallinckrondt Institute of Radiology, briefed the Committee on the regulation of contemporary radioactive drug research.

3.1 Dr. Siegel provided a historical background of regulation in the field of radioactive drug research, highlighting the linear development of a more structured regulatory environment.

3.1.1 He also stated that radioactive drugs were safe to use for several reasons: the radioactivity comes in trace quantities; radioactive drugs are not frequently used more than once in a life time; and with the proper dosimetry information, the effects on humans are predictable.

3.1.2 Dr. Siegel concluded his briefing by stating that, in his opinion, the field was already substantially regulated, and that there should be no need on the part of the Committee to propose new regulations.

4.0 STAFF BRIEFING: HISTORY OF RADIATION PROTECTION STANDARDS

Committee staff member Gil Whittemore briefed the Committee on the history of radiation protection standards.

4.1 Mr. Whittemore stated that organized radiation safety efforts began in the 1920's. However, the first organization, the *Advisory Committee on X-Ray and Radio Safety*, did not come about until later.

4.1.1 In the early 1930's recommended tolerance doses were publicized, but were based on what would cause permanent damage.

4.1.2 In 1941 the genetic hazards of radiation were recognized, and the tolerance level was decreased tenfold (to 3.6 rem). However, due to protestation from the radiography community the old limit of 36 rem per year was restored.

4.1.3 During the 1950's the tolerance crept down to 15 rem per year and then to 5 rem per year (1.5 rem for the general public).

4.1.4 Committee member Dr. Henry Royal pointed out that the present standard as given in the BIER V report states it is, "better to overestimate the risk [of radiation exposure] than underestimate the risk." He pointed out that this statement should be taken into consideration when using current tolerance standards to evaluate the levels of radiation subjects received during an experiment.

5.0 COMMITTEE MEMBER BRIEFING: EPIDEMIOLOGICAL PERSPECTIVE ON LOW-DOSE RADIATION RISKS

Committee member Dr. Duncan Thomas briefed the Committee on an epidemiological perspective on low-dose radiation.

5.1 Dr. Thomas stated that only recently had a basis for radiation risks from low dose radiation been established.

5.1.1 As an illustration, Dr. Thomas stated that the lifetime excess risk of cancer from a single 10 rem exposure was 0.8 percent. In comparison, the lifetime excess risk of cancer from lifetime background exposure was 18.0 percent.

5.1.2 Dr. Thomas offered several established benchmarks:

Occupational Standard	5 rem per year
General Population Standard	0.1 rem per year
Average Background Radiation	0.1 rem per year
Chest X-Ray	0.01 rem per exposure

5.1.3 Ten rem was chosen because it was approaching the upper end of low-dose radiation exposure.

5.1.4 In BIER V there was a generally unanimous agreement regarding the risks of low dose radiation with regard to cancer in humans.

5.1.5 In conclusion, Dr Thomas stated that there was considerable support for the principle of low dose linearity. However, low dose radiation studies were fraught with problems. It would also be important to evaluate each experiment on its own merits, and to keep an open mind when approaching this issue.

6.0 UPDATE ON AGENCY DATA COLLECTION EFFORTS

The Committee chair, Dr. Ruth Faden, summarized the agency's data collection efforts since the last Committee meeting.

6.1 Department of Health and Human Services (DHHS)

6.1.2 The Committee has been working with DHHS in three main areas:

- Fleshing out details of the historical research regulations governing the use of humans in experiments

- Fleshing out the Cold War Story, and continuing to try and link the efforts of the Public Health Service with the Department of Defense (DoD) and the Department of Energy (DoE)

- Reviewing projects related to the contemporary period, including assisting in developing the Protocol Review program.

6.2 National Aeronautics and Space Administration (NASA):

6.2.1 The Committee has been working with NASA in three main areas:

- The role of Oak Ridge National Laboratory in NASA's total body irradiation study

- The destruction of records related to radiation exposure in the mid-1980's (according to normal record disposal procedures)

- The evolution of NASA regulations and practices regarding human subject research

6.3 Central Intelligence Agency (CIA):

6.3.1 The Committee has been working with the CIA in two main areas:

- Establishing the CIA's own experience with radiation research

- Setting the context in which to view these experiments.

6.3.2 Dr. Faden also commented that the CIA had acted expeditiously to a request to declassify a requested record.

6.4 Department of Defense (DoD):

6.4.1 The Committee has been working with the DoD in several interesting areas:

- Questions related to the 1953 Wilson Memorandum
  - How was it implemented and for how long?
  - What level of compliance was reached and how was this monitored?

- Developing a "narrowly" constructed sense of military purpose. The Committee was interested in looking at experiments that were conducted because they had direct military application (e.g., the effects of radiation on humans) , not, for example, studies that were conducted to determine blood flow patterns.

- Ascertain if biomedical testing was regularly conducted in association with atomic weapons testing.

6.4.2 The Headquarters records were providing a wealth of information on the issue of implementation and compliance with policy.

6.4.3 The DoD continued to be behind in providing information to the Committee. The Defense Nuclear Agency (DNA) had not yet complied with the original DoD tasking to search for human radiation experimentation records, and the Department of the Army (DA) had not provided the Committee with information on the more than 900 plus experiments they had identified.

6.4.4 This issue of lack of responsiveness had been addressed with the highest levels of the Pentagon to resolve, and assurances had been received that additional information would be forthcoming.

6.5 Department of Energy (DOE):

6.5.1 The Committee has been working with the DOE in two main areas:

- How far has DOE's phase I plan been implemented?

- Was an important collection of Intelligence Division records destroyed, according to normal destruction procedures, in the mid-1980's?

6.6 Department of Veterans Affairs (VA)

6.6.1 The Committee has been working with the VA on two main issues:

- Continuation of the search for records related to the Atomic Medicine Division

- Completion of the search of Headquarters records.

6.6.2 The VA had only recently initiated its Headquarters records search, but had promised the Committee that it would complete its review of records at the National Archives and at the Federal Records Center within 90 days. The VA would also provide the Committee biweekly submissions of relevant information.

7.0 NEW STAFF INTRODUCTIONS, STAFF STRUCTURE AND CURRENT PROJECT ASSIGNMENTS

Committee staff member Jeffrey Kahn briefed the Committee on staff developments since the last Committee meeting.

7.1 Two new staff members were introduced to the Committee. Mr. Guttman indicated that the staff was very close to full complement.

7.2 Organizationally, the Coordinating Group had been eliminated and the staff was no longer split along the two themes of the "Cold War Story and "Ethics Policy."

8.0 STAFF REPORT: "FUNCTIONAL" HISTORY OF HUMAN RADIATION EXPERIMENTS

Committee staff member Greg Herken reported to the Committee on a "functional" history of human radiation experiments. Mr. Herken concentrated on the area of informed consent and commented that in the late 1940's the Atomic Energy Commission (AEC) was lacking oversight in this area.

9.0 STAFF REPORT: HISTORY OF ETHICS POLICIES RELATING TO HUMAN RADIATION EXPERIMENTS

Committee staff member Jonathan Moreno presented a report on the history of ethics policies related to human radiation experiments.

9.1 Mr. Moreno reported to the Committee that the idea of consent and voluntariness were around in the early years (1940's and 1950's) of human radiation experimentation.

9.1.1 By the 1950's experimentation on normal volunteers would require voluntary consent, and as early as 1948 voluntary consent would also be required for investigative studies (i.e., on terminal subjects).

9.1.2 Mr. Moreno commented that the position of Dr. Shields Warren on this important issue was occasionally contradictory, sometimes allowing human use studies and sometimes not allowing these studies.

10.0 STAFF REPORT: HISTORY OF GOVERNMENT REGULATION AND CONTROL OF HUMAN RADIATION EXPERIMENTS

Executive staff director Dan Guttman presented a report to the Committee on the history of government regulation and control of human radiation experiments.

10.1 Mr. Guttman focused on the differences between the AEC and the DoD in policy structure related to oversight of human use experiments.

10.1.1 The AEC had a limited policy structure in the early years, with loopholes that allowed researchers to conduct human radiation experiments.

10.1.2 The DoD had a more developed policy structure, exemplified by the 1953 Wilson Memorandum.

10.1.3 No evidence was yet available that any polices at the AEC or DoD were rigidly enforced.

10.1.4 The majority of the Committee discussion period was conducted after all reports were completed. The following major topics were discussed:

- Dr. Katz wanted the staff to focus on the idea of application and implementation rather than policy. The Committee and staff felt it was important to first know the policy background, although implementation and practice would also be closely examined.

- Dr. Royal pointed out that Dr. Warren's contradictions were not as severe as portrayed by the staff. Dr. Warren did not favor human radiation experiments when the effects of radiation on humans was the objective of the experiment, but was in favor of studying the medical applications of radioactivity.

- Mr. Guttman commented that he was surprised to discover that in the area of the ethics of human use experiments, the "military and the bureaucracy" were farther ahead of the civilians than he had expected.

- Dr. Stevenson commented that there was an interpretive bias on the part of the staff in looking at these records and that it was important to state whether AEC/DoD researchers were in the norm of scientific practices for that era or out of the norm.

11.0 STAFF REPORT: EXPERIMENTAL GROUPING -- TOTAL BODY IRRADIATION

Committee staff members Gary Stern, Ron Neumann, and Mr. Guttman presented a report to the Committee on the progress with the total body irradiation (TBI) grouping.

11.1 Early TBI research focused on the effect of radiation on the human body in excess of 0.1 R, the established daily safety standard.

11.1.1 Many research projects took advantage of "piggy-backing" of therapeutic exposures by conducting blood testing after the exposure. Many participants did consent but did not know they were contributing to the Manhattan Project (there were three Manhattan Project-related TBI studies).

11.1.2 By the early 1950's the DoD was continuing TBI research, with the Services acting independently. The Air Force conducted experiments at M.D. Anderson to gauge the effect of radiation on the human body. This project was driven by the plans for a nuclear-powered airplane (NEPA). The Defense Atomic Support Agency (DASA) approved and funded Dr. Saenger's research at the University of Cincinnati (85 subjects during 1960-1971).

11.1.3 Throughout the late 1950's and the 1960's Oak Ridge National Laboratory conducted TBI studies on 194 subjects. In 1964 NASA joined in the studies to determine the effects of radiation on astronauts passing through the Van Allen radiation belt.

11.1.4 The staff is attempting to reconstruct the history of TBI. By the 1950's the use of TBI on solid tumors was not felt to be terribly effective as a curative. However, it was noted that Dr. Saenger's exposures were designed to be palliative, not curative.

11.1.5 During the ensuing discussion period several Committee members commented on the staff reports:

- Dr. Royal stated that the science of TBI was very complicated.

- Dr. Royal also stated that he thought it was a startling omission that no mention was made during the briefing that three committees reviewed Dr. Saenger's work and only one, a junior faculty review, found fault. He further stated that the junior faculty review should be examined in the context of the time (the Vietnam War) and the prevalent antimilitary feeling of most junior faculty members at that time.

- Dr. Thomas asked the staff to try to put Dr. Saenger's work in perspective by looking for other contemporaneous bone marrow transplantation research projects. This could provide a useful yardstick by which to judge Saengers work.

- Dr. Glatstein commented that the advent of the Cobalt-60 X-ray machine (which was more powerful and could penetrate the body more deeply than previously available equipment) brought back into question the possibility that TBI could be therapeutic in the case of metastatic tumors. Dr. Glatstein stated that it did not work, but Dr. Saenger had a hypothesis and a solid plan for implementing his research. By the end of the 1960's TBI, as therapy, was discounted by most medical authorities because of the development of chemotherapy.

- The Committee also wanted the staff to get a sense of the standards of care for that era for comparison with Dr. Saenger's conduct.

12.0 STAFF REPORT: ABSTRACTION OF "MARKEY EXPERIMENTS" AND THE DEPARTMENT OF ENERGY

Staff members Mr. Gil Whittemore and Mr. Jonathan Engel presented a report to the Committee on the progress of the Markey experiments abstraction.

12.1 A computerized database system is being developed to contain the abstracts of experiments.

12.1.2 Five analysts had worked four full days abstracting 120 experiments. The system for abstraction worked fairly well, although the available data was very scant.

12.1.3 There were problems mating the information that was available with the themes the Committee had approved at the last meeting.

12.1.4 In addition, each experiment abstract would need a reference number so that it could be updated, as necessary.

13.0 PUBLIC COMMENT PERIOD

Six representatives addressed the Committee. The public comment period lasted one-hour longer than scheduled and went until 6 p.m.

13.1 Mr. Stuart Udall spoke to the Committee on the subject of uranium miners. He stated that the problem of the miners was ignored by the Government, even though it knew the risks.

13.2 Three representatives of Virginia Commonwealth University (the President, Vice President, and the Dean of the School of Medicine) responded to the recent *Washington Post* article on radiation experiments conducted at Virginia College of Medicine in the 1940's and 1950's by Dr. Evans. They refuted charges of secrecy and racial bias that were presented in the *Post* article and stated that they had spent an enormous amount of time since the appearance of the article reviewing their archives and defending their institution. They asked that in the future the Committee be cautious in their pursuit of the truth, in order not to distort events out of proportion to reality.

13.2.1 The main theme of the discussion was whether the Committee had precipitated a "media circus" and what the role of the Committee was in cases such as this. The general feeling among the Committee members that commented was that the Committee was not at fault in this case, and that investigating these types of experiments was definitely within the scope of the Committee's responsibility.

13.3 Mr. Zucker represented the group Disability Advocates, Inc. (an advocacy group for the mentally ill). The thrust of his statement was that regulations protecting the mentally ill were lax and uneven at the state level, and that no research on the mentally ill should be conducted when risk is involved and there is no chance of direct benefit for the mentally ill.

13.4 Ms. Pat Brody spoke to the Committee on behalf of those exposed to radiation as a result of being atomic veterans or as being "Downwinders." She believed that if the "victims" of the Green Run are within the Committee's responsibilitym then atomic veterans and "Downwinders" should also be included.

13.5 Mrs. Variano appeared before the Committee as a human radiation experiment victim. She had been exposed to radiation as an infant and was disfigured as a result. However, the exposure did not appear to be experimental in design, nor was it connected in any way with Government-sponsored research.

13.6 Mrs. Gordon's represented Citizens Call, an advocacy group for "Downwinders" in Southern Utah. Mrs. Gordon's main comment was that the lack of victim representation on the Committee would hurt the Committee's attempts to reach out to advocacy groups, and minimize the chances that the Committee would come to an unbiased conclusion.

14.0 SUMMARY OF MEETING, 26 JULY 1994

The 26 July 1994 meeting was scheduled to focus on a discussion of the goals and objectives of the Committee, experiment groupings, and restructuring of Committee members' work, however, the preponderance of time was spent discussing the reports from the subcommittees.

15.0 APPROVAL OF MINUTES OF 25-26 JULY MEETING

The minutes were approved without change or amendment.

16.0 INTERIM REPORT

Dr. Faden led a brief discussion on the topic of the Interim Report due 21 October 1994. The report will essentially be a progress report on the Committee's activities, identifying what tasks have been accomplished and what tasks are left to be accomplished. A timeline would also be included, both historical and projected, for these tasks.

17.0 OUTREACH SUBCOMMITTEE REPORT

The chair of the Outreach Subcommittee, Mr. Reed Tuckson, was not at the 26 July meeting. Committee staff member Steve Klaidman briefed the Committee on the status of the Subcommittee's work.

17.1.1 Mr. Klaidman stated that the Subcommittee had drafted boilerplate letters to stakeholder groups and to expert groups. The stakeholder letter had been approved by the Subcommittee, but the experts letter had not.

17.1.2 Planning for small panel field hearings was continuing, with four field hearings being considered.

17.1.3 One additional full Committee field meeting was also being considered (in addition to the 12-13 October meeting scheduled for San Francisco). The Subcommittee was waiting to see how the San Francisco meeting went before scheduling a second field meeting.

18.0 ETHICS SUBCOMMITTEE REPORT

The Ethics Subcommittee chair, Dr. Ruth Macklin, briefed the Committee on the status of the Subcommittee's work. Committee staff members Jeremy Sugarman and Nancy Kass also participated in the briefing and answered questions.

18.1 The Ethics Subcommittee has three ongoing projects that were discussed at the last Committee meeting: the Oral History project, led by Dr. Susan Lederer; the Protocol Review project led by Dr. Katz; and the Subject Interview project that had been tabled for more discussion at the last meeting.

18.2 Committee member Dr. Lederer briefed the Committee on the status of the Oral History project. She indicated that the project was proceeding and that the expert oversight panel was assembled and had received the Committee's proposal for work. The panel would review this proposal and contact the Committee.

18.2.1 The next step was to compile a list of individuals to interview. The Committee and the staff would have input into the finalization of that list. Interviews would focus on individuals who conducted research during the Cold War era.

18.2.2 Committee member Dr. Thomas asked if people involved in the intentional environmental releases of radiation were going to be included. The Committee agreed that it would be important to do so.

18.3 Dr. Macklin briefed the Subcommittee on the status of the Protocol Review project.

18.3.1 She stated that only FY 93 Protocols would be reviewed.

18.3.2 The total number of protocols to be reviewed would be approximately 100, concentrating first on National Institutes of Health (NIH) extramural protocols.

18.3.3 Dr. Macklin indicated that the sampling task would be monumental. Apparently nothing like this has ever been done previously.

18.3.4 The Committee staff was working with DHHS on developing a plan to accomplish the Protocol Review project.

18.3.5 At this point, the most important steps were to devise a sampling scheme for choosing which Protocols to review and to flesh out the section related to Institutional Review Board (IRBs).

18.4 Dr. Macklin briefed the Committee on the possible options that the Ethics Subcommittee had developed for conducting the Subject Interview project.

18.4.1 Option One involved conducting a short survey of approximately 1,000 research subjects in research institution waiting rooms. Participation would be purely voluntary and

would focus on how informed the subjects are about the research they are participating in. Permission to review the interviewee's medical file would also be requested. This was viewed as a minimal first step in the process of completing this project, not as fulfillment of the goals of the project.

18.4.2 Option Two involved the short survey and a follow-up focus group meeting.

18.4.3 Option Three involved the short survey and a follow-up personal interview with each participant.

18.4.4 The ensueing Committee member discussion covered a range of topics:

- Dr. Philip Russell questioned the ability of the staff to successfully accomplish this task. He was informed that an outside contractor would be hired to handle most of this task, with Committee staff oversight. He also stated that, if the Committee was going to do this project, it should be done fully, so that it would be of real value.

- Dr. Stevenson questioned whether it would be possible to organize focus groups, because of scheduling problems, and because patients change treatment schedules frequently.

- Dr. Thomas offered a revised Option Three that would include a small number of early focus groups for the purpose of helping to develop the structure and questions of the personal interview to be followed by interviewers.

18.4.5 Dr. Thomas' suggested revised Option Three was approved by the Committee.

18.5 Dr. Thomas briefed the Committee on the work of the Scope and Priorities Subcommittee.

18.5.1 The Subcommittee is still fine-tuning experiment classifications.

18.5.2 The Subcommittee proposed that two new subcommittees be established; one to cover medical experiments, and one to cover environmental releases.

18.5.3 The Subcommittee also proposed a trial scheme for handling experiment data:

- Develop a database in which to store experiment data.
  (Dr. Thomas commented that this was already being done.)

- Have the two new proposed subcommittees review the data after its compilation.

- After some preliminary trial runs, the system could be implemented on a broader scale and sampling could begin.

- The Committee should then request additional data from the agencies on pertinent experiments.

18.5.4 Dr. Faden made two comments at this point; first, that the DoD had promised to increase the staff effort by the DA in order to accomplish the requests for supplemental data; and second, that DHHS had been requested by the Committee to hold off on identifying experiments until it was clearer what information on what types of experiments the Committee wanted to look at.

18.5.5 The Committee had a lengthy discussion concerning how it was going to handle the problem of sampling the large number of identified human radiation experiments. The most important issues raised were

- The Committee could not look at all the experiments, so sampling was necessary

- The Committee's options were limited, and sampling allowed the Committee to look at the big picture first, before getting into the details

- Dr. Faden believed that the Committee needed to pursue the "notorious" experiments in enough detail to draw solid conclusions, because that was expected of them.

18.5.6 No final decision was reached during the meeting on how sampling was to be conducted.

19.0 COMMITTEE RESTRUCTURING

Dr. Faden moderated a discussion on the creation of new subcommittees and the reassignment of Committee members. These new subcommittees would take the place of the old subcommittees.

19.1 The new subcommittees are:

Intentional Releases
Nancy Oleinick, Co-Chair
Duncan Thomas, Co-Chair
Jay Katz
Ruth Macklin
Ken Feinberg (possible)

Biomedical
Henry Royal, Co-Chair
Mary Anne Stevenson, Co-Chair
Eli Glatstein
Nancy Oleinick
Phil Russell

Subject Interview
Ruth Faden, Chair

Protocol Review
Jay Katz, Co-Chair
Ruth Macklin, Co-Chair
Eli Glatstein
Lois Norris
Henry Royal

Outreach
Reed Tuckson, Chair
Ruth Macklin
Lois Norris
Henry Royal

Oral History
Susan Lederer, Chair
Ruth Macklin
Phil Russell

Remedies
Ken Feinberg, Chair
Duncan Thomas

19.1.1 Ms. Patricia King was not present during the 26 July 1994 meeting and would chose her assignments later.

Brian H. Thompson
DoD RECC

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ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
1726 M STREET, N.W., SUITE 600
WASHINGTON, D.C. 20036

PUBLIC MEETING
JULY 25-26, 1994

Stouffer Mayflower Hotel✣1127 Connecticut Avenue, N.W.✣Washington, D.C. 20036

FINAL AGENDA

Monday July 25 (Colonial Room)

9:00 am	Call to Order
9:05 am	Welcome and Orientation to Meeting *Ruth Faden, Chair*
9:10 am	Briefing: Regulation of Contemporary Radioactive Drug Research (Tab L) *Barry Siegel, Professor of Radiology and Medicine and Director of the Division of Nuclear Medicine, Mallinckrodt Institute of Radiology*
(9:30 am)	Committee Question and Answer Period
9:45 am	Briefing: History of Radiation Protection Standards (Tab M) *Gil Whittemore*
(10:00 am)	Committee Question and Answer Period
10:10 am	Briefing: An Epidemiologic Perspective on Low-Dose Radiation Risks (Tab N) *Duncan Thomas*
(10:40 am)	Committee Question and Answer Period
10:50 am	Break
11:05	Update on Agency Data Collection Efforts *Ruth Faden*

11:20 am	Staff Reports: Early History (1940s and 1950s) (Tab F) Overview *Ruth Faden, Dan Guttman*
(11:25 am)	History of Ethics Policies relating to Human Radiation Experiments *Jonathan Moreno*
(11:30 am)	"Functional" History of Human Radiation Experiments *Gregg Herken*
(11:35 am)	History of Government Regulation and Control of Human Radiation Experiments *Dan Guttman*
(11:40 am)	Committee Question and Answer Period
12:30 pm	Lunch
1:45 pm	New Staff Introductions, Staff Structure and Current Project Assignments (Tab C) *Jeffrey Kahn*
1:55 pm	Staff Report: Experimental Grouping -- Total Body Irradiation (Tab H) *Gary Stern, Ron Neumann, Dan Guttman*
(2:05 pm)	Committee Question and Answer Period
2:30 pm	Staff Report: Abstraction of "Markey Experiments" and Department of Energy Experiments (Tab I) *Gil Whittemore, Jonathan Engel, Dan Guttman*
(2:40 pm)	Committee Question and Answer Period
3:10 pm	Break
3:30 pm	Public Comment Period (Tab P)
5:00 pm	Meeting Adjourned

Tuesday, July 26 (State Room)

9:00 am	Opening Remarks *Ruth Faden*
9:05 am	Approval of Minutes of July 5-6 Meeting *Ruth Faden*
9:10 am	Interim Report *Ruth Faden*
9:20 am	Reports from Subcommittees (Tab E)
10:45 am	Break
11:00 am	Committee Discussion of Goals and Objectives of the Advisory Committee, Experiment Groupings, and Restructuring of Committee Members' Work *Moderator: Ruth Faden*
12:30 pm	Lunch
1:45 pm	Discussion of Goals and Objectives of the Advisory Committee, Experiment Groupings, and Restructuring of Committee Members' Work (continued) *Moderator: Ruth Faden*
3:00 pm	Meeting Adjourned

Department of Defense
Radiation Experiments Command Center
6801 Telegraph Road
Alexandria, Virginia 22310-3398

JUL 0 8 1994

RECC

MEMORANDUM FOR DR. GORDON K. SOPER, PRINCIPAL DEPUTY, ASSISTANT TO THE SECRETARY OF DEFENSE (ATOMIC ENERGY)

SUBJECT: Advisory Committee on Human Radiation Experiments Meeting, 5-6 July 1994

Attached for your review is an Executive Summary (Attachment 1)) of the Advisory Committee meeting, 5-6 July 1994. The summary was prepared by the DoD RECC personnel that attended the meeting.

FOR THE DIRECTOR:

CLAUD BAILEY, JR.
Colonel, AG, USA
Deputy Director,
Command Center

Attachment
as stated

EXECUTIVE SUMMARY
ADVISORY COMMITTEE ON
HUMAN RADIATION EXPERIMENTS
MEETING OF 5-6 JULY 1994

1.0 GENERAL

The Advisory Committee on Human Radiation Experiments conducted its fourth meeting on 5 and 6 July 1994, at the Vista Hotel, 1400 M Street, N.W., Washington, DC. The meeting's agenda is at Tab A.

2.0 SUMMARY OF MEETING, 5 JULY 1994

The Advisory Committee was called to order by Mr. Philip Caplan, Special Assistant to the President for Cabinet Affairs. The Committee chair, Dr. Ruth Faden, stated that the Committee had four main objectives for the next two days: Reviewing staff efforts to date and providing guidance on how best to allocate staff effort in the future; briefing staff and committee members on areas of importance; listening to public comment during the public comments period; and moving the work of the Committee forward.

3.0 STAFF BRIEFING: UPDATE ON ETHICS DATA COLLECTION EFFORTS

Committee staff member Jonathan Moreno provided an update on the status of the agency's ethics data collection effort.

3.1 Mr. Moreno concentrated on the Department of Defense (DoD) and the Department of Energy (DOE)/Atomic Energy Commission (AEC).

3.1.1 The focus of the DoD search revolved around the 1953 Secretary of Defense Wilson Memorandum and seemed to indicate that prior to 1953 there was a regulatory vacuum regarding use of humans in radiation experimentation.

3.1.2 There also were indications that the tenets set down in the 1953 Wilson Memorandum were not excepted by all DoD components and that there was a great degree of concern about Soviet progress in the areas of radiological warfare (RW), biological warfare (BW) and chemical warfare (CW).

3.1.3 One area of DOE research centered on the debate and disagreement concerning the level of and necessity for fully informed consent on the part of human experiment subjects.

3.1.4 Another area of DOE research centered on statements made by AEC officials in the early 1950's that the Commission was not participating in human use experimentation, when in fact this was not true.

4.0 SUBCOMMITTEE REPORT: ETHICS DATA COLLECTION

The Committee chair, Dr. Faden, provided a briefing on the progress of the Ethics Data Collection Subcommittee on behalf of that Subcommittee's chair, Dr. Ruth Macklin, who was not present at this series of meetings.

4.1 Dr. Faden stated that the Subcommittee has focused on continuing the ethics data collection.

4.1.1 Dr. Faden indicated that there was an immediate need for information on the practice of using humans in biomedical and ionizing radiation research.

4.1.2 Information on the historical practice of research and its relationship to historical policy for conducting research was also needed.

4.1.3 The Subcommittee proposed conducting an oral history project with the intent of elucidating actual practices (as compared to the policy guidelines) of investigators. The project would entail identifying 15 to 20 investigators, approximately 10 in the field of ionizing radiation and 10 from another field, focusing on practices in the 1940's and 1950's. The project would be conducted by experienced oral historians and guided by an expert panel consisting of oral historians, biomedical ethicists, and other experts from pertinent fields.

4.1.4 The Subcommittee was also concerned with the portion of the Advisory Committee's mandate that called for an evaluation of the current state of ethical policies and practices related to human experimentation.

4.1.5 The Subcommittee proposed that, in light of the absence of information on current practices, a second project be initiated to review a sample of protocols currently being implemented that involved ionizing radiation and another nonradiation related field. Funding agencies would be asked to provide lists of grant proposals to the Committee for review by Committee members and staff. The purpose of the project was to answer questions such as the following

- To what extent are humans exposed to more than minimal risk during research?
- Is there an offsetting benefit for the subject to compensate for the risks incurred?
- Is there any evidence that current informed consent procedures are adequate?
- Are 'vulnerable' groups being especially singled out for use in experimentation?

Dr. Faden proposed this Project be led by Dr. Katz.

4.1.6 The Subcommittee proposed a third project that would entail interviewing patients that may be involved in experiments. The plan is to identify 10 institutions (five academic

institutions and five Government agencies) that received the highest volume of Federal funds for research involving humans and inviting these institutions to participate in this project. The focus of the project would be on medical/radiological oncology and would involve interviewing patients in waiting rooms that may or may not currently be subjects in research projects. The project would involve getting permission to review patient/subject medical files and verifying any information collected during the interview with the patient/subject primary care giver (at that institution).

4.1.7 The Subcommittee called for these proposals to be approved. The oral history project was approved if a panel of experts believed it could be validly conducted. The proposal to review a sampling of current protocols was also approved. The majority of the Committee discussion period focused on the feasibility and practicability of the third proposal – to interview possible patients that may be involved in research. The discussion focused on problems of patient confidentiality, the degree of likelihood that an adequate sample of subjects could be found by interviewing patients in waiting rooms; and whether or not this proposal could be later seen as violating the standards of ethics that the Committee was created to review.

4.1.8 The Committee decided to send this proposal back to Subcommittee for more preliminary review.

5.0 SUBCOMMITTEE REPORT: SCOPE AND PRIORITIES SUBCOMMITTEE

Committee member Dr. Duncan Thomas briefed the Committee on the status of the Scope and Priorities Subcommittee.

5.1 The Subcommittee focused on the issue of intentional releases, especially attempting to draw the limits of what was in the scope of the Committee and what was not.

5.1.1 The first priority was the intentional releases identified in the Executive Order that established the Committee. These were definitely within the scope of the Committee.

5.1.2 There were, however, a large number of 'borderline' incidences that were not clearly within the scope of the Committee.

5.1.3 The main issue the Subcommittee focused on when evaluating these 'borderline' incidents were

- Whether harm was done
- Whether there were secret aspects to any of these incidents
- What type of information was provided to the subjects
- To what extent the experiment was conducted for the purpose of researching human health effects of radiation.

5.1.4 The first group examined was Marshall Islanders. The question to be answered by the Committee was whether testing done there constituted a human radiation experiment.

5.1.5 The second group examined was atomic veterans. This group was divided into two sub-categories. First, those involved in clean up activities (i.e., ship and aircraft decontamination). It was thought by the Subcommittee that this category fell under occupational exposure, not under the scope of the Committee's mandate. Second, any experimentation involving human performance measurements after exposure to radiation. The feeling of the Subcommittee was that some of these exposures were very experimental in nature and may well fall under the scope of the Committee.

5.1.6 The third group examined was Uranium miners. The Subcommittee believed that it was difficult to see any experimental aspects related to this group, although deep ethical questions are raised in this area.

5.1.7 The fourth group examined was the 'Down-Winders'. The feeling of the Subcommittee was that this group was not an experimental category, but questions were raised about the quality of information provided to the public and the possible misrepresentation of data.

5.1.8 The last group examined was the Department of Energy (DOE) nuclear facility workers. The feeling of the Subcommittee was that this group was clearly occupational, and not within the Committee's scope.

5.1.9 The ensuing discussion focused on the desire of Committee members to fully review all available information before eliminating groups, the need to determine what other information and other groups were still "undiscovered" and the need for the Subcommittee to begin to focus on the area of Committee priorities.

6.0 SUBCOMMITTEE REPORT: COLD WAR SUBCOMMITTEE

Committee member Dr. Maryanne Stevenson briefed the Committee on the progress of the Cold War Subcommittee.

6.1 The Subcommittee had focused on developing methodological aids through which the large quantity of information the Committee was receiving could be examined.

6.1.1 The first methodological aid was the development of a form. The purpose of the form was to sharpen and define the criteria that are of interest in respect to each experiment.

6.1.2 Dr. Faden stated that the Committee was free to critique the form after the next days briefing on the Pilot Project which used the form as a tool for digesting information.

6.1.3 The second methodological aid was the development of 'groupings' of experiments. The idea was to develop groups of experiments that could be examined together because they shared common features. These groupings were, effectively, a working classification scheme.

7.0 SUBCOMMITTEE REPORT: OUTREACH SUBCOMMITTEE

The chair of the Outreach Subcommittee, Dr. Reed Tuckson, was unable to make the Committee meetings because of overseas travel complications. Committee staff member Mr. Steve Klaidman briefed the Committee on Dr. Tuckson's behalf.

7.1 Mr. Klaidman stated that the issues before the Outreach Subcommittee were of a very time-sensitive nature.

7.1.1 The major issue before the Subcommittee was how many field meetings were needed and where these meetings were to take place.

7.1.2 The Subcommittee evaluated this issue with three criteria in mind

- Making the Committee available to a concerned public
- Making information and perspectives of interested groups available to the Committee
- Help to publicize the Committee's work.

7.1.3 The Subcommittee proposed that three full-scale Advisory Committee field meetings be held, plus four field meetings with panels of approximately three Committee members each.

7.1.4 The cities proposed for the full-scale meetings were San Francisco, Atlanta, and Chicago. These cities were chosen because of geographic spread and because no large-scale human radiation experimentation took place in close proximity to these locations.

7.1.5 During the following Committee discussion period a counterproposal was offered calling for having only panel field meetings, possibly linked into a full-scale Committee meeting by video-conferencing.

7.1.6 The issue was returned to the Subcommittee for review with direction to at least reduce the number of proposed full-scale field hearings and an examination of the idea of only field panel meetings, augmented by video-conferencing.

8.0 NEW STAFF INTRODUCTIONS, STAFF STRUCTURE AND CURRENT PROJECT ASSIGNMENTS

Committee staff member Mr. Jeffrey Kahn introduced three new staff additions to the Committee.

8.1 Because of time constraints, staff structure and current project assignments were only briefly discussed.

9.0 COMMITTEE DISCUSSION OF GOALS AND OBJECTIVES OF THE ADVISORY COMMITTEE

Committee chair Dr. Faden and Executive Staff Director Mr. Dan Guttman briefed the Committee on the development of a draft document examining the goals and objectives of the Committee.

9.1 This document was an outgrowth of the assignment to Dr. Faden and Mr. Guttman to produce a vision document that could be used to solidify the Committee's sense of what they were doing.

9.1.1 The goal of Tuesday's briefing was to present an outline, for the Committee's benefit, so that an in-depth discussion could take place on Wednesday. In effect, this document would be the working outline for the Committee's interim and final reports.

9.1.2 The document was arranged in three sections: *Foundation, Focal Point, Experiments and Intentional Releases*, and *Looking to the Future*.

9.1.3 In the *Foundations* section, a subsection titled *Ethical Principles and Practices Related to Human Use in Experimentation* was envisioned. This section would focus on what the policies related to ethical procedures were, as well as what the actual practices were.

9.1.4 In the *Focal Point* section, the intent was to put various pieces together using groupings and themes. The groupings were scheduled to be discussed on Wednesday so they were not examined, however, three basic themes were identified:

- Exploitation and power differential — basically the use or misuse of vulnerable populations
- The idea of openness and full disclosure — this theme is intended to convey to the public the idea that this issue was exhaustively examined
- The level of risk that subjects involved in these experiments were exposed to.

9.1.5 In the *Looking to the Future* section, the issue of remedy was to be examined, as well as the aspect of the changing needs of national security.

9.1.6 Dr. Faden stated that the desire was to shape staff structure along the lines of the final (or near final) version of this document, because it would embody all of the issues the Committee wanted examined. It was also made clear that this document would not be finalized for quite some time, and she envisioned a lot of restructuring along the way.

10.0 PUBLIC COMMENT PERIOD

Three groups participated in the public comment period, a representative of the Government of the Marshall Islands, a representative of the people of Bikini, and a representative of the National Committee for Radiation Victims.

11.0 SUMMARY OF MEETING, 6 JULY 1994

The 6 July 1994 meeting had several key agenda points: a briefing by a Committee member, two reports on agency data collection efforts, a discussion of the possible experiment groupings, and a discussion of the draft document on goals and objectives.

12.0 COMMITTEE MEMBER BRIEFING: HISTORY OF HUMAN EXPERIMENTATION

Committee member Dr. Jay Katz conducted a one hour briefing on the history of human experimentation, as part of the Committee's continuing effort to cross-educate each other.

12.1 Dr. Katz provided the Committee with a series of steps that medical ethics have taken since the beginning of the nineteenth century. The general trend was toward increased need for informed consent from the subject of experiments, as well as increased responsibility for researchers to insure that adequate steps have been taken to obtain truly informed consent. Several key steps in this process have been: the 1900 Prussian Ministry of Medical Affairs directive on human experiments, which demanded unequivocal consent of the subject; the 1947 Nurenberg Code which calls for the consent of the experiment subject; and the 1969 World Medical Association's Declaration of Helsinki, which contained less strident informed consent language than that embodied in the Nurenberg Code.

13.0 STAFF REPORT: METHODOLOGICAL REVIEW OF AGENCY DATA COLLECTION EFFORTS -- CENTRAL INTELLIGENCE AGENCY (CIA)

Committee staff member Mr. Gary Stern briefed the Committee on the progress of the CIA's record search.

13.1 Mr. Stern stated that the CIA had uncovered no records of any involvement in human radiation experimentation, even in conjunction with the MKULTRA project that focused on manipulation of people by chemical and other means.

13.1.1 Several documents led the staff to believe that there was at least a possibility that the CIA was involved in human radiation experimentation. A 1963 CIA Inspector General report referred to radiological materials (along with a number of other substances) as a possible material to be used in MKULTRA. Additionally, in a 1977 report it was apparent that all possible materials, with the exception of radiological material, had been covered.

13.1.2 To date, the CIA had conducted a computer search of over 34 million records, had hand searched 480,000 records, and had conducted 50 interviews with personnel associated with the MKULTRA program, and it found no indication that the CIA had participated in any human radiation experiments.

13.1.3 The Committee staff met with CIA officials on 16 June 1994.

13.1.4 The CIA has not focused on some issues of concern to the Advisory Committee, including information on intentional releases and records on the development of ethics policies related to human use experimentation.

13.1.5 The staff requested the Committee request the CIA to:

- Provide information on contemporaneous intelligence on Soviet experimentation that could have influenced the United States' experimentation program. A special emphasis should be placed on intentional releases of radiological material
- Provide documents that highlight the level of perceived threat from the Soviet Union that could have also influenced the United States' conduct of these tests
- Initiate a search for historical information on ethics and ethical standards
- Continue to search for records on CIA involvement in human radiation experimentation.

13.1.6 The Committee authorized the staff to continue to work toward the goals indicated above.

14.0 STAFF REPORT: METHODOLOGICAL REVIEW OF AGENCY DATA COLLECTION EFFORT--NATIONAL AERONAUTICS AND SPACE ADMINISTRATION (NASA)

Committee staff member Mr. Mark Goodman briefed the Committee on the NASA's record search.

14.1 NASA was set up along a functional, programmatic field center structure so that only a limited number of records repositories needed to be checked. However, the headquarters structure had changed several times since NASA's inception in 1958, so headquarters searches were more complicated.

14.1.1 NASA had completed a database search and identified 189 publications related to several dozen experiments. Of these, NASA believed four studies indicated deliberate radiation exposure to humans, including at least one study of total body irradiation. A series of interviews of cognizant officials had also taken place.

14.1.2 NASA would like to work with the Committee on establishing the parameters of the record search, for example whether incidental exposure to radiation is included in the Committee's purview.

14.1.3 Staff requested guidance from the Committee. The staff recommended conducting interviews with NASA officials if no ethics documents could be located for NASA. The staff requested guidance from the Committee on what to do if no documentation related to the experiments could be located.

14.1.4 The Committee advised the staff to continue working along the same plan.

15.0 UPDATE ON AGENCY DATA COLLECTION EFFORTS: OTHER AGENCIES

Dr. Faden briefed the Committee on the status of other agency data collection efforts.

15.1 The Department of Veterans Affairs (DVA) had agreed to search for records related to its Atomic Medicine Division (AMD), but to date no records had been forwarded to the Committee.

15.1.1 The Committee staff had identified some DVA-related policy records, but to date no records had been received by the Committee.

15.1.2 Not much information had been forwarded to the Committee from Veterans Administration (VA) field offices.

15.1.3 Dr. Faden commented that DVA was at a "pretty preliminary stage" in the record search process.

15.1.4 The Committee staff was working with the Department of Health and Human Services (DHHS) to try to find an efficient and effective means to locate policy documents and experiment information that correspond to the Committee's priorities.

15.1.5 The Committee staff had told DHHS to temporarily suspend its search for information on the large number of studies that were not linked to national security or military purpose issues.

15.1.6 DHHS was instructed to focus on searching for information that linked DHHS and its predecessors to the DoD and the DOE.

15.1.7 The DOE was continuing to actively participate in identifying records related to human radiation experiments, including working on headquarters policy records.

15.1.8 One group of DOE that the Committee staff had identified in its search was the Division of Intelligence, but no records had been located there at this time. Apparently, most of the pertinent records were destroyed in the late 1970's, however, that is not yet known for certain.

15.1.9 The Committee had requested numerous records be declassified, and in at least two instances, the DoD had responded within the Committee established timeframe of three weeks.

15.1.10 Dr. Faden characterized the Committees feelings on this issue by stating, "Today [the Committee] is not unhappy" with the progress of the agencies.

16.0 OVERVIEW OF INFORMATION SYSTEMS MANAGEMENT AND EXPERIMENTAL GROUPINGS

Mr. Guttman introduced the discussion of Information Systems Management by stating that the present plan and staff structure was designed as a means to organize information and develop means to examine information on experiments. He then introduced Committee staffer, Mr. David Saumweber who briefed the Committee on the Information Systems Management.

16.1 To date the Committee had received to date 15,000 to 20,000 pages of records from various agencies.

16.1.1 The on-line system, Lotus Notes, was being used as a records management system and to provide Committee members and staff access to the records.

16.1.2 When records are received at the Committee, a quick review is done to determine their significance and to identify "hot docs." The criteria used to review these records were established by Committee members and senior Committee staff.

17.0 PILOT PROJECT: ABSTRACTION OF MARKEY REPORT EXPERIMENTS

Committee staff members Mr. Gil Whittemore and Mr. Jonathan Engel made this presentation to the Committee.

17.1 The pilot project entailed taking the form developed by the Cold War Subcommittee and using it as a tool to examine real life experiment records. In its final version, the form would assist in the development of the experiment database and could be used as a finding aid to the records.

17.1.1 Mr. Engel used the form in evaluating the information the Committee had on the 61 experiments identified in the Markey report. One crucial problem experienced when conducting the pilot project was economy of time. Even when using fact sheets on each experiment provided by Rep. Markey's office and filling out the form in an abbreviated way, it took one and a half days to review 61 experiments. If original documents were used instead of fact sheets (as would be necessary in most cases) the time to complete each form would be quite lengthy.

18.0 POSSIBLE GROUPINGS

Various Committee staff presented briefings on four possible groupings of experiments: *Government Purpose*, *Total Body Irradiation*, *Radiological Warfare*, and *Intentional Releases*.

18.1 The objective of the briefings was to justify the proposal for the experiments being grouped in this way.

18.1.1 The experiments were to be grouped in this way more as a means of "covering the waterfront" than of developing categories that put every experiment in one and only one group.

18.1.2 While no formal consensus was reached on the validity of these groupings, the Committee members did not seem to object to these classifications.

19.0 COMMITTEE DISCUSSION: DRAFT OUTLINE OF GOALS/OBJECTIVES DOCUMENTS

Dr. Faden moderated a Committee discussion on the goals/objectives document. She indicated that the desire was to develop a consensus among Committee members on the basic structure of the interim and final reports so that the Committee staff can be realigned to reflect the goals of the Committee.

19.1 This one and a hour discussion period focused on what should be included in the report, not necessarily the structure. It was felt that this would allow the Committee staff to most efficiently structure itself, while allowing the Committee the flexibility to continue to work on the organization of the report.

19.1.1 The two main areas of discussion were in what groupings to use and what themes should predominate. Those groupings and themes proposed in the draft document developed by Dr. Faden and Mr. Guttman remained the backbone of the Committee report.

Brian H. Thompson
DoD RECC

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ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
PUBLIC MEETING
JULY 5-6, 1994

Washington Vista Hotel ❖ Ballrooms A and B❖1400 M Street, NW ❖ Washington, DC

AGENDA

Tuesday, July 5

11:00 AM	Call to Order
11:05	Welcome and Orientation to Meeting *Ruth Faden, Chair*
11:10	Staff Report: Update on Ethics Data Collection Efforts (TAB L) *Jonathan Moreno*
11:20	Reports from Subcommittees (TAB I) *Moderator: Ruth Faden*
12:30 PM	Lunch
1:45	Reports from Subcommittees (Continued) *Moderator: Ruth Faden*
2:45	New Staff Introductions, Staff Structure and Current Project Assignments (TAB C) *Jeffrey Kahn*
2:50	Committee Discussion of Goals and Objectives of the Advisory Committee *Moderator: Ruth Faden*
3:45	Break
4:00	Public Comment
5:30	Meeting Adjourned

Wednesday, July 6

9:00 AM	Opening Remarks *Ruth Faden*
9:05	Approval of Minutes of June 13-14 Meeting *Ruth Faden*
9:10	Briefing: History of Human Experimentation (TAB F) *Jay Katz*

(9:50)	Committee Question and Answer Period
10:15	Staff Report: Methodological Review of Agency Data Collection Efforts--Central Intelligence Agency (TAB J) *Dan Guttman and Gary Stern*
10:35	Staff Report: Methodological Review of Agency Data Collection Efforts--National Aeronautics and Space Administration (TAB K) *Dan Guttman and Mark Goodman*
10:55	Update on Agency Data Collection Efforts: Other Agencies *Ruth Faden*
11:00	Break
11:15	Overview of Information System Management and Experimental Groupings (TAB O) *Dan Guttman*
(11:20)	Information System Management *David Saumweber*
(11:25)	Pilot Project: Abstraction of Markey Report Experiments *Gil Whittemore and Jonathan Engel*
(11:35)	Possible Grouping: Total Body Irradiation *Dan Guttman, Gary Stern, Mark Goodman and Ron Neumann*
(11:40)	Possible Grouping: Radiological Warfare *Dan Guttman and Gregg Herken*
(11:45)	Possible Grouping: Intentional Releases *Dan Guttman and Gregg Herken*
(11:50)	Possible Grouping: Government Purpose *Dan Guttman and Jim David*
(11:55)	Committee Discussion *Moderator: Ruth Faden*
12:15 PM	Lunch
1:30	Revisit Discussion of Goals and Objectives *Moderator: Ruth Faden*
2:55	Closing Remarks *Ruth Faden*
3:00	Meeting Adjournment

EXECUTIVE SUMMARY
MEETING, ADVISORY COMMITTEE ON
HUMAN RADIATION EXPERIMENTS,
13-14 JUNE 1994

1.0 GENERAL

The Advisory Committee on Human Radiation Experiments conducted its third meeting on 13 and 14 June 1994. The 13 June session was held at the Ramada Plaza Hotel, 10 Thomas Circle, Washington, DC. Due to central air conditioning difficulties at the Ramada Plaza Hotel, the 14 June session was held at the Vista Hotel, 1400 M Street, N.W., Washington, DC. The meeting's agenda is at Tab A.

2.0 SUMMARY OF MEETING, 13 JUNE 1994

The 13 June session was called to order by Mr. Philip Caplan, Special Assistant to the President for Cabinet Affairs. The key agenda items accomplished were a briefing on remedies, conducted by Committee member Mr. Ken Feinberg; a briefing on risk communication, conducted by staff member Mr. Steve Klaidman; a series of staff reports on the status of the agency data collection efforts and a report on declassification efforts.

3.0 COMMITTEE MEMBER BRIEFING: REMEDIES

Committee member Mr. Feinberg conducted a half-hour briefing on the background information for the Committee that would help in any discussion on compensation.

3.0.1 Mr. Feinberg identified two classes of remedies that the committee would have to deal with: Particularized Remedy and Mass Exposure Remedy. Particularized Remedy is characterized by an action-consequence chain of events and is usually linked to an individual or small group. For example, an individual is hit by a car, and as a consequence that individual's leg is broken. There is a direct cause and effect from which to base a remedy.

3.0.2 Mass Exposure Remedy is characterized by an inability to demonstrate particularized injury. Examples would include the Nevada "Down-Winders", the Marshall Islanders, and the people living in proximity to the Hanford Nuclear Reservation. The positive causal link between exposure to radiation and subsequent development of cancer is not proven simply by proximity. Many times epidemiological studies are the only "proof" available in these cases.

3.0.3 The Committee would need to develop creative solutions to the Mass Exposure Remedy question. In the case of particularized injury, clear tort-based precedents are available. The Committee would simply have to collect the pertinent facts, establish a criteria to evaluate

injury, and develop a remedy. In the Mass Exposure cases, developing remedies would be more difficult.

3.0.4 One potential model Mr. Feinberg identified was the Disability/Workers Compensation Model. If individuals can satisfy the presumption of exposure, then they will not need to show causation.

4.0 STAFF BRIEFING: RISK COMMUNICATION

Mr. Steve Klaidman, the staff Director of Communication, presented a briefing on risk communication to the Committee.

4.0.1 He defined risk as the probability of any nontrivial negative outcome as a result of an experiment. Risk communication is intimately tied to informed consent because only after receiving a realistic portrayal of the possible risks can a subject give truly informed consent to participate in an experiment.

4.0.2 Risk communication has several major subcomponents, including risk perception and risk comparison. The investigator must convey to the subject the degree of risk to the individual. To accomplish this it is important to identify the target audience (based on a host of personal and cultural factors) and tailor the message appropriately. It is also important to frame the issue in such a way as to prevent any bias. Risk comparison is a valuable tool to communicate risk to a subject. It is often easier to assess the seriousness of an unfamiliar risk (ionizing radiation) if compared to a familiar risk.

5.0 REVIEW OF PROGRESS OF AGENCY DATA COLLECTION

Committee staffer Mr. Don Weightman briefed the Committee on the progress of data collection activities by the agencies. He is responsible for managing the flow of documentation and breaking the records down into useful categories.

5.0.1 Mr. Weightman stated that the Committee had received an enormous quantity of records including approximately 11,000 pages (The quantity was described variously as pages or records, pages seems the more likely correct description.) of DoE material, and several boxes of DoD records.

5.0.2 He indicated that the Committee staff had conducted meaningful discussions with five of the six agencies (The recalcitrant agency was not identified, but the CIA was alluded to.). It was indicated that the DoE was the farthest along and was seriously committed to providing the Committee with all necessary information. The DoD had problems because of the large numbers of players on the field ("no one-stop shopping"). The Department of Health and Human Services (DHHS) was also experiencing the same types of problems as the DoD,

because it was also a decentralized agency.

5.0.3 He characterized the overall Staff/Committee/Agency interaction as an efficient working relationship. There were several qualifications including the debate on who was going to perform archival record research and when this was going to occur.

5.0.4 Mr. Weightman identified three types of information that the staff was looking for: Line Items/Budget information, Program Areas, and Procurement Files. He did not define what these three types were.

5.0.5 Regarding the issue of classification, he indicated that the majority of the biomedical data was now or would soon be declassified. The classification of radiological warfare (RW) information was more problematic. Data on intentional releases was also problematic because (as indicated earlier) some DoD components had not looked for information on environmental releases.

5.0.6 Mr. Weightman indicated that a Committee outreach program was currently in progress to contact relevant groups with document collections that might be of interest to the Committee.

6.0 STAFF REPORTS ON STATUS OF AGENCY DATA COLLECTION: AN OVERVIEW

Mr. Dan Guttman, the Executive Staff Director, presented an overview of the status of the agency data collection efforts.

6.0.1 He reported that almost all agencies had completed Phase I research concerned with identifying participating organizations and developing basic information on experiments.

6.0.2 The Committee staff was involved in a series of exercises to map the information that had been forwarded to them into a usable format. This mapping is presently broken into three areas: Institutional (what agencies are connected by common research), Agency-Private Sector (what contractors worked for whom), and Ethics (the development of standardized ethical principles). The goal is to develop a comprehensive and usable scheme for evaluating the information that is forwarded to the Committee.

6.0.3 The staff had several high priority tasks, including identifying Governmental policy on human radiation experimentation for the purposes of revealing the intention of these experiments, the development of meaningful scientific categories for the experiments identified by the agencies, and developing more information on intentional environmental releases of radiation.

6.0.4 The Committee agreed that the staff should continue to pursue these lines of research.

6.1 UPDATE ON ETHICS DATA COLLECTION

Staffer Jonathan Moreno presented a brief update on the status of the ethics data collection effort.

6.1.1 He indicated that a steady stream of information from the agencies had been received. An effort was now being made to find data prior to the 1953 Wilson Memorandum with an emphasis on gathering information on the Armed Forces Medical Policy Council.

6.1.2 Dr. Gordon Soper, Principle Deputy to the Assistant Secretary of Defense (Atomic Energy) queried the Committee on what the time parameters for the record search were going to be. He noted that the Committee was now discussing researching policy development in the 1920's and 1930's, well prior to the 1944 start date identified by the Interagency Working Group and the White House.

6.1.3 Dr. Soper also asked the Committee to provide the agencies with advance warning if the timeframe the Committee decided to cover was expanded. This would help the agencies allocate their resources and obviate the need to retrace research the agencies thought was completed.

6.2 REVIEW OF DEPARTMENT OF DEFENSE DATA COLLECTION EFFORT

Mr. Guttman presented a review of the Department of Defense data collection effort.

6.2.1 He noted that the Committee staff had met with the DoD officials on 20 May and that the DoD had completed Phase I and was looking for guidance from the Committee on how to focus Phase II research.

6.2.2 Mr. Guttman stated that the DoD had not done Headquarters or OSD searches and these needed to be done. other than the Navy

6.2.3 He also stated that no archive research had been done. It was unclear if this comment was directed specifically at the OSD search or, erroneously, at the DoD effort in its entirety.

6.2.4 Mr. Guttman also indicated that the Defense Nuclear Agency (DNA) and the Department of the Army (DA) had not searched for information on intentional environmental releases of radiation and would need to do so.

6.2.5 Mr. Guttman stated that a lot of staff effort was allocated to looking into the evolution of Governmental policy on human use in experiments. This was being done because it is necessary to develop definable and workable categories for the large quantity of data that is being forwarded to the Committee from the agencies. Looking at the policy structure would enable the staff to begin to categorize the data into logical groups.

6.2.6 A tangential discussion on allocation of staff resources continued until the lunch break. Committee member Dr. Henry Royal stated that in order to properly prioritize staff work, it was necessary to look at what the Committee was striving to produce. In essence, this asked the question of what was the Committee's vision or mission. It was decided that discussion of the Committee's "vision" be put off until later.

6.3 REVIEW OF DEPARTMENT OF VETERANS AFFAIRS DATA COLLECTION EFFORT

Staffer Ms. Denise Holmes briefed the Committee on the status of the data collection effort at the Department of Veterans Affairs (DVA).

6.3.1 She indicated that the effort was primarily a field exercise at the 172 Veterans Administration (VA) hospitals. The Secretary of Veterans Affairs was committed to an open and thorough record search process to disclose as much information as possible regarding the Atomic Medicine Committee.

6.3.2 Several key staff observations were that the DVA had not identified any further historical documents related to the Atomic Medicine Committee. The DVA had not searched in depth for historic policy records nor begun to coordinate with other agencies regarding shared experiments.

6.3.3 The staff presented eight recommendations for approval of the Committee.

- DVA should continue to trace the history of the Atomic Medicine Committee.
- DVA should expand the scope of its search to focus on documents at a higher (i.e., national policy) level.
- DVA should begin to trace the history of its coordination of research with other agencies.
- Committee staff should interview key DVA personnel.
- DVA should trace the history of the VA/Omaha and other nuclear reactors.
- Committee staff should continue to interact with DVA personnel.
- Use the Committee staff to facilitate the transfer of information between the DVA and other agencies.

- Data collection should focus on :
  - -General fact finding
  - -Tracing DVA links with research schools
  - -Tracing DVA links with individual researchers at research schools.

6.4 UPDATE ON DEPARTMENT OF ENERGY DATA COLLECTION EFFORT

Mr. Guttman presented a brief update of DoE efforts to collect data.

6.4.1 He stated that the DoE was completed with Phase I sweep of its field offices.

6.4.2 The DoE is currently compiling an assessment of the quantity of records it holds related to human radiation experiments.

6.5 UPDATE ON DEPARTMENT OF HEALTH AND HUMAN SERVICES DATA COLLECTION EFFORT

Committee staffer Ms. Faith Bulger updated the Committee on the status of DHHS's data collection effort.

6.5.1 She stated the Committee staff had developed a close working relationship with DHHS personnel and that DHHS had been responsive to the staff's requests for information.

6.5.2 One key area to focus on was the interrelationship of the Public Health Service (PHS) and other agencies, notably the DoD and the Atomic Energy Commission (AEC). A subsidiary data source was the Committee on Medical Research (No agency identification was given, but this Committee was probably part of DHHS's predecessor.) which was closed in 1945 and had forty-five wartime programs transferred to the PHS.

7.0 REPORT ON DECLASSIFICATION

Mr. Guttman briefed the Committee on the status of agency declassification efforts.

7.1.1 Mr. Guttman introduced a letter sent to the agencies requesting that the agencies agree to review for declassification within three weeks of a request any documents requested by the Committee.

7.1.2 Four agencies were identified as having responded: the Central Intelligence Agency (CIA), the DoE, the DoD, and the National Aeronautic and Space Administration (NASA).

7.1.3 The CIA responded that it would work with the Committee on this issue.

7.1.4 The DoE indicated that it could declassify 3 linear feet per week of material and that at present it had identified 10 linear feet of classified material related to human radiation experiments.

7.1.5 The DoD responded that all reasonable requests could be done in the required timeframe, but that many documents were classified by more than one agency.

7.1.6 Mr. Guttman noted that it would be important to have all agencies working in parallel to declassify records that have multiple agency classification's.

7.1.7 The NASA response was vague, but affirmative.

8.0 PUBLIC COMMENTS SESSION

8.0.1 Representatives from three groups spoke to the Committee for five minutes each. The groups were the National Association of Radiation Survivors, the Survivors of Medical Radiation Experiments, and the Association of the Citizen-Soldier.

8.0.2 Their comments reflected the cynicism that veterans associated with atomic testing or related issues hold toward the Government. They encouraged the Committee to expand their brief to include all facets of American nuclear testing.

8.0.3 They also encouraged the Committee to be very inclusive when discussing what diseases to compensate as a result of radiation exposure.

8.0.4 The representatives indicated that veterans did not see the difference between participants in nuclear testing and participants in human radiation experiments.

9.0 SUMMARY OF MEETING, 14 JUNE 1994

The 14 June meeting had several key agenda points: a staff organization overview, and reports from the four subcommittees.

10.0 STAFF ORGANIZATION

The Advisory Committee staff is headed by a management team made up of five individuals, including the Committee Chair. A coordinating group comprised of the project leaders is responsible for project management. The project groups are structured along the lines of the Committee's Subcommittees (Ethics Data Collection, Scope and Priorities, Cold War Data Collection, and Public Outreach). Individual staffers are also tasked to focus on particular agencies.

11.0 SUBCOMMITTEES REPORTS

Each of the four Subcommittees presented a briefing on their progress.

11.1 ETHICS DATA COLLECTION SUBCOMMITTEE

Committee Chair, Dr. Faden, presented the Ethics Data Collection Subcommittee report on behalf of the Subcommittee chair Dr. Ruth Maklin.

11.1.1 She stated that the Subcommittee was tasked to identify the evolution of ethical standards related to medical research from 1944 to the present.

11.1.2 Data collection was divided into three parts. Part I data collection was on-going. Current activity was focused on finding policies, rules, guidelines, and procedures the agencies developed in relation to human radiation experimentation. Part II data collection focuses on understanding the roles, policies, guidelines, and procedures of universities and research organizations, including review boards and oversight groups, as it relates to human radiation experimentation. Part III data collection concerns the implementation and behavior of researchers in relation to those procedures laid out in Part II.

11.1.3 The Subcommittee wants to conduct interviews with researchers and experiment subjects to gather complete data on ethical standards used from 1944 to 1974.

11.1.4 The Committee discussed whether or not conducting interviews would produce information that was useful, and if Committee member's institutions should be exempt from the interview process. Subjects were to be included in the interview process to determine if researchers had been doing a good job with risk communication.

11.1.5 The overall goal of all three data collection parts and the interviews is to develop a picture of what the ethical standards were for the past 50 years and how research was conducted during this same time.

11.2 SCOPE AND PRIORITIES SUBCOMMITTEE

Committee member Dr. Duncan Thomas briefed the Committee on the status of the Scope and Priorities Subcommittee.

11.2.1 As part of defining the scope of the Committee, Dr. Thomas provided a working definition of medical experiments that would interest the Committee. The definition was, "intentional exposure by investigators of ionizing radiation that resulted in therapeutic or deleterious effects on subject."

11.2.2 Categorization/classification of experiments was also identified as an important task for the Scope and Priorities Subcommittee.

11.2.3 Dr. Thomas suggested one classification could be termed Secret Experiments. This could be split into two divisions, Military and Medical. Miliary Experiments could be further subdivided into Distribution Experiments and Acute Biological Effects (e.g., plutonium injections). Medical Experiments could be subdivided into Distribution Studies (e.g., tracers and tags), Diagnostic Studies, and Therapeutic Studies. Another category could be the Notorious Experiments (e.g., Saenger).

11.2.4 Dr. Thomas indicated that, because of the enormous quantity of data, it would be necessary to begin to categorize the information. A sampling (it was not indicated what statistical model was to be used as a base) could then be done. The inference was that this sampling could be used to determine if there was a problem with any one group or category of experiments.

11.2.5 The issue of sampling provoked several comments from members of the Committee. One member stated that, for sampling to be useful, categories need to be intelligently crafted. Another member indicated that the Committee would still need a description of what a reasonably informed scientific investigator should have known at any given time throughout the period of 1944 to 1974. This base of knowledge would impact the Committee's evaluation of many of the experiments (The question of whether or not whole body irradiation was an outdated therapeutic treatment prior to Dr. Saenger's experiments in the 1960's and early 1970's.)

11.2.6 Another Committee member warned that the Committee would not be in a position to pass judgement on any experiments for several months.

11.3 COLD WAR DATA COLLECTION

Committee member Dr. Mary Anne Stevenson briefed the Committee on the work of the Cold War Data Collection Subcommittee.

11.3.1 Dr. Stevenson told the Committee that a bottom-up approach to categorizing experiments was impossible because of the immense quantity of data that needs to be dealt with.

11.3.2 She proposed four categories for data:

- Biological Effects of Whole Body Irradiation
- Biological Effects of Atmospheric Releases
- Biological Effects of Radium, Uranium, Polonium, Plutonium (Biological Distribution Studies)
- Metabolic and Physiological Studies

11.3.3 There were several minutes of debate on specifically what was meant by each category, but the general consensus was that the categories seemed appropriate. Several Committee members commented that the "great unwashed mass of experiments" (a term coined by Mr. Guttman), those that are not secret or notorious would still have to be dealt with.

11.4 PUBLIC OUTREACH

Committee member Dr. Reed Tuckson briefed the Committee on the progress of the Public Outreach Subcommittee.

11.4.1 He stated that the Committee had three public outreach responsibilities: first, develop a relationship with stakeholders; second, develop a relationship with experts; third, work on the Committee's relationship with the media.

11.4.2 He disseminated a proposed draft letter to stakeholders asking them for information and their involvement in the Committee process. This letter would also request that other interested groups be identified. A similar letter could be drafted to experts to keep them updated on the Committee's progress.

11.4.3 Dr. Tuckson also discussed the location of proposed field hearings. San Francisco, Chicago, Nashville, and Atlanta were mentioned as possible locations. The Committee felt that cities that had "Notorious Experiments" should be avoided because it may seem the Committee is holding a field hearing solely to discuss that experiment. Another Committee member proposed that, instead of the entire Committee holding two or three field hearings, groups of two members could hold informational meetings in various cities. By this means more geographic locations could be covered and potentially generate greater public involvement in the Committee process. The Committee agreed to explore a combination of both of these approaches, but did not finalize a decision.

12.0 COMMITTEE DIRECTION TO STAFF

After the Cold War Data Collection briefing was completed, Committee Chair, Dr. Faden, proposed that the Committee look at what priorities it wanted to focus on.

12.0.1 She suggested that the Committee continue to tell the Cold War story, approaching it from the top down (i.e., looking at overall policy development first). The Committee should also continue to focus on Secret Experiments, especially radiological warfare and atmospheric releases. The Committee should also continue with the pursuit of developing data on ethical standards.

12.0.2 The Committee approved these pursuits.

12.0.3 This consensus resulted in four directions to the Committee staff:

- Continue top down policy data hunt
- Continue Cold War story data collection
- Look at publicly controversial case
  (The Scope and Priorities Subcommittee would develop a list of these experiments)
- Examine category four (Metabolic and Physiological studies) experiments and try to develop a workable sampling system.

12.0.4 Dr. Faden also pressed for closure on the proposal of the Ethics Data Collection Subcommittee to explore the feasibility of convening a panel of experts to decide if the interview project would be a value to the Committee.

13.0 VISION/PURPOSE OF COMMITTEE

The Committee had intended to complete its third meeting with a discussion of the purpose, mission, and vision of the Committee. However, it was proposed and approved that the Committee Chair draft a memorandum on the subject for discussion by the Committee. Any member that wanted to provide input to the Chair was welcome to do so. The memorandum is scheduled to be discussed during the second July meeting.

14.0 GENERAL OBSERVATIONS

General observations regarding the meetings include the following

14.0.1 The Committee is now debating how to best allocate its scarce resources. However, the essential element in this process (prioritizing its tasks) has not been adequately addressed. This is exemplified by the Committee delaying until the second July meeting (its fifth meeting overall) to debate the Committee's mission and vision. Without a universally accepted vision of the purpose and scope of the Committee's mandate, it will be very difficult to properly allocate staff and member resources.

14.0.2 During the Subcommittee reports, several diverse schemes for categorizing experiments were offered. None were exhaustively debated, however, the categorization methodology offered by the Cold War Data Collection Subcommittee seemed to have the most widespread approval among Committee members.

14.0.3 Many of the Committee decisions are delayed until the next meeting because of time constraints and lack of total consensus on the part of Committee members.

14.0.4 Some Committee members and staffers make negative judgmental comments related to specific experiments, as well as Governmental policy on human radiation experiments. All comments made during the Advisory Committee hearings become part of the public record and could cause problems later. These comments are often based on a little information.

14.0.5 The Committee and staff discussed two issues that impact the DoD data collection effort. First, the Committee is very interested in obtaining information on the radiological warfare program. Second, a substantial amount of discussion revolved around atmospheric releases of radiation.

Brian H. Thompson
DoD RECC

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ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
PUBLIC MEETING
JUNE 13-14, 1994

The Ramada Plaza Hotel--Washington Room--10 Thomas Circle, NW--Washington, D.C.

FINAL AGENDA

Monday, June 13

9:30 AM	Call to Order *Philip Caplan, Special Assistant to the President for Cabinet Affairs*
9:35	Welcome and Orientation to Meeting *Ruth Faden*
9:40	Introduction of New Staff *Jeffrey Kahn*
9:45	Review and Approval of Minutes of May 18-19, 1994 Meeting *Ruth Faden*
9:50	Briefing: Introduction to Remedies (Tab G) *Ken Feinberg*
(10:20)	Committee Question and Answer Period
10:35	Briefing: Risk Communication *Steve Klaidman*
(11:00)	Committee Question and Answer Period
11:10	Break
11:25	Overview of Staff Work *Dan Guttman*
11:35	Staff Report: Update on Ethics Data Collection Efforts (Tab H) *Jonathan Moreno*
11:50	Staff Report: Methodological Review of Agency Data Collection Efforts--Department of Defense (Tab J) *Jim David and Dan Guttman*
12:30 PM	Lunch

2:00	Staff Report: Methodological Review of Agency Data Collection Efforts--Department of Veterans Affairs (Tab I) *Denise Holmes and Dan Guttman*
2:45	Staff Report: Update on Methodological Review of Agency Data Collection Efforts--Department of Energy (Tab K) *Jim David and Dan Guttman*
3:00	Staff Report: Update on Methodological Review of Agency Data Collection Efforts--Department of Health and Human Services (Tab K) *Faith Bulger and Dan Guttman*
3:15	Review of Progress of Agency Data Collection *Don Weightman*
3:30	Report on Declassification *Dan Guttman*
3:45	Break
4:00	Public Comments
5:00	Meeting Adjourned

Tuesday, June 14

9:00 AM	Opening Remarks *Ruth Faden*	
9:05	Reports from Subcommittees:	Ethics Data Collection *Ruth Faden* Scope and Priorities *Duncan Thomas* Cold War Data Collection *Mary Ann Stevenson* Public Outreach *Reed Tuckson*
12:00 PM	Lunch	
1:30	Meetings of Subcommittees	
3:00	Meeting Adjourned	