



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

December 27, 1994

Philip Caplan
Special Assistant to the President
for Cabinet Affairs
The White House
111 1/2 Old Executive Office Building
Washington, DC 20500

Dear Phil:

Pursuant to your request, we are sending minutes from the Advisory Committee's second through eighth public meetings (May through November). In the future, copies of the minutes of our public meetings will be forwarded to you. If I may be of further assistance, please contact me at 202-254-9795.

Sincerely,

A handwritten signature in dark ink, appearing to read "J. Kahn".

Jeffrey Kahn, PhD, MPH
Associate Director





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

Minutes: Meeting of May 18-19.

Attending: Ruth Faden, Duncan Thomas, Mary Ann Stevenson, Patricia King, Eli Glatstein, Lois Norris, Kenneth Feinberg, Susan Lederer, Henry Royal, Ruth Macklin, Nancy Oleinick, Reed Tuckson, Jay Katz.

Mr. Philip Caplan, special assistant to the President for Cabinet Affairs, opened the meeting at 9 a.m., May 18, 1994, at the Ramada Plaza, 10 Thomas Circle, Washington, D.C.

Dr. Faden in the chair announced that Frank Press resigned because of his concern that he could not devote sufficient time to the Committee's efforts. Dr. Faden will consult with the Administration to see if the Committee can or should fill the vacant slot.

Dr. Philip Russell apologized through the chair for his absence, and she reported that he will attend the third meeting of the Committee. He has worked with staff between Committee meetings.

Dr. Faden briefed members on the general goals of the May meeting: to hear presentations from staff about its progress, provide direction for the staff's work over the coming four weeks, hear presentations about case studies which will guide methodology for later searches, begin a process of mutual education among the specialists on the Committee, and hear public comment from concerned parties.

The chair and Executive Director Dan Guttman introduced the staff and noted that the science staff is to be fleshed out in coming weeks. A number of staffers are coming on board after other assignments but have already begun working part-time.

Briefing: Ethical Principles of Human Experimentation. *Dr. Macklin*

Dr. Macklin traced the origins and implications of underlying ethical principles, particularly on informed consent. Members questioned the speaker on issues that included whether it is possible to do ethical experimentation on populations housed in institutions where some coercive element is implicit; the nature of severity of infringement of voluntary participation and what objective tests might elicit a standard; how precise were criteria for disclosure of risk and benefits to patients.

Dr. Katz emphasized that he did not believe the Belmont Report clarified many of these issues.

Briefing: Health Effects of Radiation. *Dr. Royal.*

Dr. Royal briefed the Committee on the nature of radioactivity with particular emphasis on



the types of emissions which damage human tissue, and the dose levels that constitute life-threatening exposure. Members questioned Dr. Royal on the difficulty of measuring dosage long after exposure; patient reactions to risks of biological diseases and to radiation; problems of measuring fatal dosages or carcinogenic or teratogenic effects from data derived from Hiroshima and Nagasaki.

Dr. Thomas disagreed with Dr. Royal's use of the phrase "middle of the road" to describe the point of view of an article by Rosalind Yalow provided to members.

Briefing: History of Human Experimentation in the United States. *Dr. Lederer.*

Dr. Lederer's brief included background on human experimentation, with special emphasis on what Dr. Lederer described as a vast increase in human research experimentation in 1910-1940, rather than World War II, which is often described as the point of acceleration in the number of these experiments. Dr. Lederer also traced a significant public discussion, focused in large part around efforts of Anti-Vivisectionist societies, about the merits and ethical dimensions of human subject experimentation. Written consent forms date from yellow fever research ca. 1900, but debate about perceived abuses of human subjects resurfaced on a regular basis well before the 1932-72 Tuskegee studies and the 1974 revision of government standards.

Members questioned Dr. Lederer on the legislative history of efforts to curb human subject experimentation at the turn of the century, and the opposition of professional societies to the proposed legislation; the circumstances in which practitioners used human subjects rather than animals.

Staff Report: Review of Agency Ethical Standards. *Jeffrey Kahn, Jeremy Sugarman.*

Drs. Kahn and Sugarman briefed members on the report listing documentation generated by initial searches by federal agencies. Beyond the agencies initially believed to be focuses of Committee efforts -- Departments of Energy, Health and Human Services, Defense, Veterans Affairs, and CIA and the National Aeronautics and Space Administration -- relevant documents appear also to be in possession of the Federal Emergency Management Agency. In 1991, federal agencies adopted "common rule" policies embodied in 45CFR46, Subpart A.

Drs. Kahn and Sugarman summarized responses from various agencies, including those subsumed by newer departments:

- ▶ HHS. A chronology of human research policies. A research report on HHS documents was to be presented later in the May meeting.
- ▶ Department of Energy: An overview report found that human research policies existed as early as 1947, when Atomic Energy Commission contractors were asked to provide certification from doctors that patients consented to experimentation. A more detailed DOE report was to be presented later in the May meeting.
- ▶ Department of Defense: Secretary of Defense Wilson and Secretary Stevens of the Army approved policies embodying the Nuremberg Code in memoranda of 1953 and 1954. The Army policies were mentioned in a secondary source, the 1975 Inspector General's report

regarding chemical experiments involving human subjects.

- ▶ Department of Veterans Affairs: The agency is working on document outlining what papers it has in its possession or that are retrievable.
- ▶ Central Intelligence Agency: Staff will meet with CIA. Initial contact suggested documents to 1977 will be reviewed as part of the work with the agency.
- ▶ NASA: Materials are being assembled.

Committee staff noted that many documents appeared in different places than might be expected, e.g. a letter to another agency that contained new material not obtained by the authoring agency. While questions are raised about the utility of policies that were classified and thus limited in distribution, notably the 1953 memo from Secretary Wilson, policies tended to exist. An early example: Interagency communications by the Committee on Medical Research, which funded projects during World War II, indicated that the agency required in 1942 that informed volunteers be used and that consent forms be obtained.

Dr. Katz noted that the 1975 Inspector General's report concluded that consent policies were not followed in chemical experiments. Dr. Macklin noted that the 1942 regulations of the Committee on Medical Research included an explicit waiver of future claims against the government. Mr. Guttman said the disclosures of high-level policies in the Defense Department, based on the 1953 memo and the 1975 report, required vigorous exploration of several issues: the level of debate in the agency said to have been necessary to produce the 1953-54 Army policies; the level of implementation of the policy; the discovery of relevant additional documents.

Dr. Royal suggested that staff also include in the search for ethical codes a survey of those issued by medical societies at the time. Dr. Macklin added that the Committee's need for documentation included the penumbra of both official and nongovernmental rules affecting researchers.

Methodological Case Study: Cincinnati Experiments. *Ron Neumann.*

Dr. Neumann reported that additional documents beyond those already known in the extensive files on the Cincinnati experiments are needed to assess consent issues. Additional reviews of publications by Dr. Saenger are needed, and patient records so far available do not make clear how patients came into the study. Issues: NIH funding of patient wards in the hospital for the experiments; the cost of the total-body radiation program; documentation of AEC and other government consultancies and whether Dr. Saenger held security clearances.

Members questioned Dr. Neumann about the existence of any records that would help assess the usefulness of the Saenger experiments; why and how psychological testing expanded as part of the program; the apparent absence of comprehensive listing of patients.

Dr. Neumann and members discussed the study and its implications for additional work. The Cincinnati experiments have been extensively studied, so there were a large number of documents and sources available, but that litigation over the experiments is likely to inhibit further cooperation from litigants in possession of documents. It is not clear how much documentation, if any, is today classified. A fruitful line of investigation involves making connections across agency lines by following documents related to funding, administration and follow-up to the experiments.

Dr. Herken added that the degree of military interest was a striking point about the experiments.

Members discussed both an assessment of the experiments, and the methodological questions. Dr. Glatstein noted that the statistics on mortality from the experiments are difficult to assess as death rates were very high from leukemia in the period, and that the first-phase of such research typically attempted to derive toxicity of dosages, and thus control groups were not used.

Dr. Katz and Ms. King noted that it is important to be able to establish what different treatments were used and how research was designed, and Dr. Macklin added that it is important to know what was considered appropriate research methodology at the time. Dr. Neumann said that current documents would not make those issues clearer.

Dr. Faden said the primary information may no longer be available to allow the assessment, in context of the times, of the appropriateness of treatment and the likelihood of constructive results from the Cincinnati research program.

Dr. Stevenson said that the documents may be found to demonstrate the incentive to conduct the experiments, especially the question of whether government funding was the driving force in doing experiments that may have had no therapeutic value.

Statement by Dr. Oleinick.

Dr. Oleinick stated for the record that she had a prior association with one individual connected with the plutonium injection experiments, Dr. Hymer Friedell, who was head of the Department of Radiology at Case Western Reserve University and had previously had a role as deputy to Stafford Warren. Dr. Oleinick was unaware of the connection until the staff reports arrived, and Dr. Friedell has since retired, but Dr. Oleinick said that she wished her colleagues to know of the former association before consideration of the presentation on the plutonium injection experiments.

Dr. Faden expressed appreciation for Dr. Oleinick's candor in bringing the matter before the Committee. Dr. Faden said in her judgment the association did not represent a conflict of interest, and without objection the Committee moved to consideration of the case study.

Methodological Case Study: Plutonium Injection Experiments. *Dr. Herken.*

Dr. Herken reported on the 18 known plutonium injection experiments and said that documents found as part of the search suggested that the 1943-47 experiments were part of a larger scheme, probably not carried forward because public controversy over the experiments surfaced in 1946. There is no record to determine if any further experiments were performed, although it is probable that the larger program planned by the AEC Interim Medical Advisory Committee was not carried out.

While the AEC originally proposed that signed consent forms be obtained from subjects of experiments, the documents indicate that this proposal was successfully resisted by contractors. In a compromise that was in effect for at least one set of experiments, in July 1947, two attending physicians were required to certify that patients understood and consented to the experiments. It was not clear from the documents available why AEC officials did not insist on signed consent forms.

Members questioned Dr. Herken about informed consent issues; whether animals had been tried as subjects prior to the human experimentation; potential sources of information. Dr. Herken said that while a 1974 investigation did a creditable job, the current file includes only references to the primary files and an inventory. Some records are to be found in repositories of different agencies, suggesting some primary material may be found through a wider search.

Public Comment Period.

The following persons addressed the Committee during its public comment period:

E. Cooper Brown, National Committee for Radiation Victims. Mr. Brown urged the Committee to investigate the exposure of Marshall Island inhabitants and Navajo uranium miners as part of its work.

Wallace H. Cummins, Radiation Health Effects Public Law Group (RADLAW). Mr. Cummins urged the Committee to ensure the full cooperation of agencies with its document searches and asked that the Committee hear regularly from the community of persons affected by radiation exposure.

Fred Allingham, National Association of Radiation Survivors. Mr. Allingham urged the Committee to interpret broadly its definition of what kind of radiation exposure constituted experimentation, and to include a representative of the survivor community on the Committee.

Daryl Kimball, Physicians for Social Responsibility. Mr. Kimball said the Committee's investigations should be an open process with the widest possible outreach for interested parties. He urged the Committee to hold some of its meetings in cities outside Washington.

Dr. Tuckson expressed the view of the Committee that its efforts are aimed at responsibility and accountability on the part of the government of the United States. Survivor groups in particular were urged to provide information to the Committee.

Statement by Dr. Thomas.

Dr. Thomas stated for the record that he had consulted with the Centers for Disease Control on the Hanford studies. The work was limited to review of a few draft protocols, and the White House counsel's office did not view that role as a conflict of interest.

Dr. Faden expressed appreciation for Dr. Thomas' candor and said the consensus of the Committee is that his role does not constitute a conflict of interest.

Methodological Case Studies: Green Run. Dr. Whittemore.

Dr. Whittemore noted that the "green run," the release of a radioisotope of iodine at Hanford, Washington, in December 1949 was not a clinical experiment, but radiation released into the environment to aid in the government's long-range detection program. At the highest levels, it may have been a reaction to the first atomic bomb explosion in the Soviet Union; at the most basic level it is difficult to re-create what physically happened at the site. Apparently, the magnitude of radiation released could not be regulated because instruments in the smokestack did not work; the biological impact is even more difficult to measure after the passage of more than 40 years.

Members questioned Dr. Whittemore about the extensive gathering of animal and plant specimens by officials, and an apparent lack of inquiries about the impact of the Green Run on persons; the reasons that the experiments were discontinued; whether sufficient documents have been declassified to adequately understand the experiments.

Dr. Stevenson stated that it is imperative that the Committee gain access to classified documents if it is to fulfill its mandate. Members asked if subpoena power were available to the Committee. Dr. Faden and Mr. Guttman said that if the Committee finds it needs additional authority to carry out its mission, then it would seek that authority from the Administration.

Members discussed whether environmental releases are within the scope of the Committee's mandate. Dr. Royal questioned whether the Committee has time or resources to deal with environmental releases. Dr. Faden said the issue of Green Run was specifically included in the Committee's charge by Executive Order. Dr. Whittemore noted that ethical issues raised by the scope of planning for Green Run may be a subject for consideration, rather than the event, but Mr. Feinberg noted that it is difficult to separate the ethical and technical issues.

Thursday, May 20

Kathleen Whalen and Drew Poole of the White House counsel's office spoke to members about conflict of interest rules. At the request of members, Ms. Whalen said the counsel's office would research concerns about fees for future expert witness testimony.

Staff Report: Review of Agency Data Collection Efforts, Department of Energy.

Mr. Guttman reported on what he characterized as a strong effort from archivists and historians in federal agencies to gain access to the many documents, some still classified, pertaining to human experimentation. He said that of the immense volume of documents, many of the potentially interesting ones already declassified, there are many that are missing or have not yet been targeted for search by agencies. Agencies have reported on the difficulties caused by quality of recordkeeping in the past, and identified the Committee's research as an opportunity to improve that situation. Resource issues include secrecy classifications, and pockets of resistance in some agencies to searches; the latter are most likely for budgetary reasons. Staff recommends continuation of effort despite large volume of boxes, and continuation of effort to work with agencies on behalf of openness of both government records and those of contractors, as ordered by DOE.

Members questioned staff on how records would be disseminated to the public; on the critical importance of Committee staff targeting its searches; on the importance of cross-checking to ensure that appropriate documents are being made available; and on potential alternative sources, such as the materials compiled by advocates of Navajo uranium miners.

Mr. Guttman entered into the record a memorandum from Glenn Podonsky of DOE expanding upon the Staff Report. DOE suggested changes in the data collection Staff Report to reflect the department's views about the status of the document search.

The Committee discussed the advisability of obtaining security clearances for two or more members to gain access to classified documents, but several members expressed concern about

inhibiting the Committee's discussion. Dr. Faden said that obtaining security clearances would be strictly voluntary, as security clearances were not required as a condition of joining the Committee.

Members and staff historians expressed concern that declassification would be a slow process, and Dr. Faden said the Committee would send a memorandum to agencies urging that declassification of documents relevant to the Committee's work be expedited. Mr. Podonsky told the Committee that DOE is committed to aggressive declassification of documents. He added that obtaining security clearances across many agency jurisdictions may be timeconsuming, although officials are working on procedures to allow reciprocation of clearances.

Staff Report: Review of Agency Data Collection Efforts, Health and Human Services.

Mr. Guttman discussed HHS organizational structures and search operations. He noted that early extramural grant records from HHS research agencies are the most difficult to get; HHS records for that period constitute tens of thousands of noncomputerized capsule descriptions of grants. In many cases it is impossible to tell whether these records refer to human experimentation, although some may be identified through a parallel search of published studies.

Radiation Section studies from the 1940s to 1960s indicate that human experimentation involved anywhere from 15 to 400 grants a year, but some records also may appear in other section files. Cross-references with radioisotope licensing records may identify many of these, and the staff proposes to work with X-ray research subsections through HHS officials.

Joint sponsorship of research also complicates matters, as do projects that involved both classified and unclassified components, some of which might not be in published literature.

Wendy Baldwin of the department told the Committee that grantees were told to preserve their records. She said Option One proposed by the staff would be to re-orient the department's search to policymaking documents, but that would be done as directed by the Committee.

Members discussed focusing HHS searches on the policy level; additional resources such as universities; additional searches by cross-referencing pools of reviewers of experiments, who were allocated by areas of expertise.

Without objection, members approved most options proposed in the HHS staff recommendations. Deferred to later in the afternoon were:

Option Five: Interview knowledgeable individuals.

Option Six: Written documentation from Helpline callers.

Committee Discussion: Committee/Staff Working Relationships and Formation of Subcommittees.

Dr. Faden summarized the directions to staff: That the Committee endorsed and wished to continue all three methodological case studies, with some special emphases. Cincinnati questions included whether there was an original medical protocol; how patients were selected; what was the incentive or driving force behind the experiments; and whether Dr. Saenger held security clearances.

For the plutonium injection studies, agencies should be directed to contact the Universities

of Chicago and Rochester for additional information. Other data may also be sought from other universities. Staff should follow leads for linkages with other experiments than those currently known, and should try to determine the scope of other planned studies in that area.

For the Green Run studies, the staff should pursue policy-level documents to determine where Green Run experiment originated. Questions include whether anyone challenged the propriety of the experiment, who started and designed the project in the context of research, how was it viewed from an ethical standpoint and why was it suspended.

AEC Memorandum

Ms. King introduced into the record a 1947 Atomic Energy Commission memorandum in which an AEC official ordered that information on human experimentation be classified as secret because of potentially adverse public comment. *The memorandum is Appendix B.*

Discussion of Subcommittees

Members discussed in detail the responsibilities of standing and ad-hoc subcommittees that would meet regularly in person or by phone and direct activities of staff. Members had some difference of opinion about the focus of an initial list of subcommittees proposed by the chair. Several members noted that there would have to be considerable communication across the subcommittee lines.

Dr. Katz emphasized the view that one subcommittee must be largely focused on recommendations for future ethical behavior, and argued that proposals placed too much emphasis on the 1974 adoption of IRB rules as a clear guiding line. Ms. King expressed concern that the subcommittee structure might inhibit consideration of subjects across subcommittee lines. Other members felt the subcommittees should first proceed to the descriptive task, as the chair phrased it, or to discovery, as Mr. Feinberg described it.

Members agreed to establish several subcommittees:

Outreach. Outreach to the radiation survivors, professional communities and the public. Drs. Tuckson, Macklin, Lederer, Royal and Ms. Norris.

Scope. Examining the charter of the Committee and determining if other cases (the Navajo, Micronesia) should be taken up by the group. Drs. Thomas and Royal and Mr. Feinberg.

Data/Cold War. Overseeing searches for government-sponsored research in the Cold War. Drs. Glatstein, Oleinick, Stevenson and Ms. King.

Data/Ethics. Drs. Macklin, Glatstein, Lederer and Faden.

Staff Report: Department of Energy.

Members revisited the specific directions to staff contained in the Staff Report on the DOE document searches. All eight specific Options proposed were approved, as summarized in the following:

Option 1. DOE should proceed with the strategy of developing, in the near future, a comprehensive guide which will identify pertinent collections of records at various sites.

Option 2. DOE should immediately focus on collections of high-level documents which can be immediately retrieved and made available.

Option 3. DOE should focus on defining categories of classified documents not previously addressed that may contain relevant documents.

Option 4. Focus on documentation of AEC radioisotope licensing process.

Option 5. Provide the Committee with "work for others" study performed for Secretary Watkins.

Option 6. Provide documents supporting the 1974 Inspector General's report on plutonium injection experiments.

Option 7. Provide the Hotline database to the Committee.

Option 8. Identify the most efficient means of accessing data from the National Archives.

Staff were also directed to seek information from other universities that may have been involved in human experimentation other than the universities of Rochester and Chicago. Members said that secondary sources, such as libraries or grant offices, might yield additional information beyond the information tracked through funding sources and government documents.

Staff Report: Health and Human Services.

Members revisited options five and six proposed in the IIIS Staff Report regarding interviews. Ms. King emphasized the need for Committee direction to staff about who should be interviewed by agencies, and what information should be sought by what questions.

Security Clearances

Members discussed whether clearances needed to be required of all members or of none, and whether clearances could be obtained but not acted upon. The questions were to be referred to the subcommittees for discussion.

Members agreed to meet in subcommittees briefly before the close of the regular meeting. Mr. Caplan of the White House adjourned the meeting at 2:54 p.m.

APPENDIX A

The following persons signed in to attend all or part of the Committee's meeting: Karen MacPherson, Scripps Howard News Service; Marina Volkov, Federation of Behavioral, Psychological and Cognitive Science; John W. Billett, Health Physics Society; Sharon Brown, Battelle/PNL; Ellyn Weiss, DOE; Amy McClair, University of Cincinnati; Virginia Johnson, Gene Yount, Vince Morantis, Hal Halpern, DOE; Susan Crandall, OASIL; David George, Katy Hawkins, U.S. Navy; Peter Stewart-Harry, NIH; Traci Watson, U.S. News and World Report; Herb Perrone, ABC News; Sid Shaw, VA; Stephanie Niemier, Fred Bonkovsky, NIH; Lynn Zanski; Rebecca Kupper, American College of Radiology; Charles Sherrill, Bonneville Broadcasting; Bob Hohler, Boston Globe; Paul Barton, Gannett News Service; Craig Cobdell,

DOE; Philip Hilts, New York Times; Gary Sanders, Ken Groves, Los Alamos National Laboratory; Earl Lane, Newsday; A.K. Tylin, E.R. Johnson Assoc.; Sarah Comley, International Observers; Tom Popa, DOD (RECC); Gary Lee, Washington Post; Dan Glick, Newsweek; Marty Hamed, OUSD (P&R); William L. Freeman, IHS; Fred Allingham, National Association of Radiation Survivors; Lantz Miller, Society of Nuclear Medicine; H.W. Cummins, RADLAW; Daryl Kimball, Physicians for Social Responsibility; Stacey Cunningham, American Psychology Association; Eliot Marshall, Science; Stan Cimmons, AAMC; Colin Macilwain, Nature; Gerald J. Merritt, USAF; Wendy J. Fibison, NIH; Stephanie Shenier, DOD (ROCC).

Attending from the Committee staff were Faith Bulger, Kristin Crotty, James David, Jerry Garcia, Dan Guttman, Gregg Herken, Deborah Holland, Jeffrey Kahn, Lanny Keller, Jeanne Kepper, Stephen Klaidman, Anna Mastroianni, Ron Neumann, David Saumweber, Jeremy Sugarman, Gary Stern, Donald Weightman and Gilbert Whittemore.



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Minutes: Meeting of June 13-14.

Monday, June 13

Attending: Ruth Faden, Susan Lederer, Jay Katz, Philip Russell, Lois Norris, Kenneth Feinberg, Henry Royal, Duncan Thomas, Nancy Oleinick.

Dr. Faden, chair. Philip Caplan, Special Assistant to the President for Cabinet Affairs, opened the meeting of the Advisory Committee on Human Radiation Experiments at 9:30 a.m. at the Ramada Plaza Hotel, 10 Thomas Circle, Washington, D.C.

Patricia King and Eli Glatstein were unable to attend the meeting and Reed Tuckson and Mary Ann Stevenson joined the Committee on the following day.

Dr. Faden outlined the objectives of the meeting: continuing the series of presentations by Committee members about their specialties relevant to the Committee's work; updates from staff of document searches; public comment on issues before the Committee; and hearing reports from subcommittees appointed at the May meeting.

Staff Director Jeffrey Kahn introduced new staff members: Sara Chandros, Gwen Davis, Patrick Fitzgerald, Mark Goodman, Gary Stern, and Kathy Taylor. Dr. Kahn also introduced Ted Webster of Harvard University, who will be a consultant to the Committee on radiation dosimetry.

Draft minutes of the May 18-19 meeting were distributed, and the Committee authorized Dr. Faden to approve the minutes after review of Committee comments.

Briefing: Introduction to Remedies. *Mr. Feinberg.*

Mr. Feinberg discussed how harms alleged from mass exposures to potentially harmful substances, including pesticides, breast implants or defective medical devices, as well as ionizing radiation, pose challenges to traditional notions of tort remedies in the judicial system. He noted the difficulty in devising methods of compensating groups exposed to hazardous substances, and the heavy burdens of proof for plaintiffs alleging government wrongdoing. Mr. Feinberg referred members to the report of the Presidential Commission on Catastrophic Nuclear Accidents as a potential aid to the work of the Committee.

Committee members questioned Mr. Feinberg about compensation for increased risk of illness or injury; the mitigating effect of benefits from drugs or pesticides, and the aggravating



effect of fears of potential harm; payments to estates of survivors; whether statutes of limitations apply to latent diseases; and the influence of epidemiological evidence.

Briefing: Risk Communication. *Stephen Klaidman.*

Mr. Klaidman briefed the members on the problems of risk communication. He discussed conservative biases of federal risk assessment methods and policies and how the public as well as experts evaluate risk information, including the public's difficulty in evaluating risk assessments because of its resistance to uncertainty and probabilistic thinking, and other cognitive and emotional challenges.

Staff Report: Overview of Staff Work. *Daniel Guttman.*

Mr. Guttman briefed the Committee on the records search being conducted by Federal agencies that might have sponsored or conducted radiation experiments on human subjects. He reported that the focus on policymaking organizations that authorized and directed experiments, a priority in the Committee's May instructions to staff, is producing a more targeted agenda for staff follow-ups with agencies. Federal agencies, having completed or nearing completion of their initial searches, are seeking direction from the Committee about how to proceed.

Mr. Guttman discussed the operating logic of the Committee staff in mapping the experiments currently known, identifying additional experiments, and categorizing experiments by the goals of sponsoring agencies or of researchers. Three major lines of work are indicated:

Institutions. Work with agencies to identify the funding and management authorities overseeing human experimentation. This process allows the staff to fill gaps in knowledge about where and by whom experiments were conducted, and takes advantage of new document searches to lead to further experiments.

Accomplishments have included the recent declassification of minutes of meetings of the Medical Advisory Committee to the Secretary of Defense. Significant challenges to a comprehensive understanding of the experiments include tracking the complex series of changes in the management of the government's radiation research program, including changes in agencies, and the complex nature of government collaboration with private institutions.

Ethics. Develop a timeline of ethical policies and procedures. Mr. Guttman noted that informed consent policies were discussed in the armed services as early as 1932, according to recent research by the Navy.

Experiments. Group experiments by the nature of the study (e.g., whole body irradiation) and the purpose of the experiments. In some cases, Mr. Guttman said, it is unclear whether the most important impetus for experimentation was government purposes such as protecting arms workers, or biomedical research that was funded by the government.

Potential categories to group experiments include scientific objective, intentional releases apparently designed to satisfy the need for knowledge about exposure to radiation, and radiation warfare studies.

Mr. Guttman said staff work to date suggests several new lines of inquiry, including indications that whole-body irradiation and excretion studies were more widespread than

previously known.

The last category, radiological warfare, involves substantial amounts of classified material, Mr. Guttman said, but he reported that the Committee had received assurances that biomedical research files would be speedily declassified if they were not already in the public domain.

Difficult issues for the staff are likely to include grouping of experiments in meaningful fashion; keeping documents flowing from the variety of Federal agencies; dealing with the large volume of tracer isotope studies; and working with agencies on classification issues.

Mr. Guttman said the staff particularly seeks guidance from the Committee about the appropriate grouping of experiments by scientific purpose.

Members of the Committee questioned Mr. Guttman about different ways to map information about ethics policies and exposure standards, and about allocation of staff time to Cold War experiments in the early phases of the inquiry.

Staff Report: Update on Ethics Data Collection. *Jonathan Moreno.*

Dr. Moreno briefed the Committee on the ethics search, particularly noting the prevalence of formal ethics policies earlier than previously known and reporting on efforts to develop more information about the 1953 promulgation of the Nuremberg Code by the Department of Defense.

Dr. Russell noted that ethics researchers may find that eminent nongovernmental institutions were assumed to have adequate policies for protection of volunteers, and that in particular the armed services may have not had the knowledgeable staff to look into those issues.

Dr. Gordon Soper, Deputy Assistant Secretary of Defense, told the Committee that the Department will be aided in its efforts if the Committee staff provides the earliest possible guidance on the time frame in which to search for documents. Dr. Moreno and members of the Committee noted that Federal agencies have a substantial task but that there are major finds in the 1930s and 1940s because of internal debates about ethical standards in experiments involving nonradioactive substances.

Dr. Royal said that the Committee staff's work should be tightly focused because of the large task. Dr. Faden noted that there are few histories or summaries that would help to focus the inquiry, requiring the initial document searches sought by the Committee.

Staff Report: Methodological Review of Agency Data Collection Efforts, Department of Defense.

Mr. Guttman reported on the document searches by Department of Defense agencies, including the armed services and the Defense Nuclear Agency. He said much work remains to be done to identify headquarters policy records and to gain access to some records dispersed through organizational changes in the 1950s and 1960s.

Members discussed the targeting of research on funding sources in DOD and other Federal agencies, and suggested that the Committee and staff better define their goals through a discussion of alternative objectives in the current meeting.

The Committee agreed to begin initial discussions in Tuesday's meeting of a vision statement that could be agreed upon by the July meetings of the Committee, in order to help focus

work through the summer. The staff was instructed to prepare reports that would give members a better understanding of priorities in the period before the September meeting. In the interim, staff members were given approval to use their judgment in directing the DOD searches in preparation for the July meetings.

Staff Report: Review of Progress of Agency Data Collection. *Don Weightman.*

Mr. Weightman briefed the Committee on the difficulties of collecting and assessing data from different agencies, which even within departments do not lend themselves to "one-stop shopping." He stressed that staff members are keenly aware of the amount of archival material that must be accessed as efficiently as possible, and noted steps taken to pinpoint searches in relevant batches of materials.

Mr. Weightman noted that policy documents provide a context and background that may aid in the targeting process, but that secrecy classifications may be a barrier to efficiency, as researchers may not know what questions to ask of agencies.

Computerization of the document classification system will make the work of the Committee staff much easier, he said. Coordination of the work of staff groups and identification of long-range milestones in their work are top priorities.

Staff Report: Methodological Review of Agency Data Collection Efforts. Department of Veterans Affairs. *Denise Holmes.*

Ms. Holmes briefed the Committee on the data collection in Veterans Affairs, particularly about the previously secret Atomic Medicine Division. The division was apparently created in response to concern about service-related disability claims. She traced VA participation in use of isotopes for research and therapeutic purposes.

The Committee endorsed staff-proposed options for further research within the context of the strategic plan to be defined at the July meeting.

Staff Report: Update on Review of Agency Data Collection Efforts, Department of Energy. *Jim David and Dan Guttman.*

Mr. Guttman said the staff is following up on data collection based on the staff options approved in May. The staff sought Committee direction on a second phase of research, and reported on the assessment of the large volume of materials received from DOE.

The Committee approved the staff plan to follow up on document searches with the Department.

Staff Report: Update on Agency Data Collections, Health and Human Services. *Faith Bulger.*

Ms. Bulger reported on the follow-up to research in HHS, particularly efforts to identify potentially relevant experiments and compile lists of documents. She discussed the significant links among the Public Health Service, the Atomic Energy Commission and the Department of

Defense on radiation research work.

The Committee endorsed options for follow-up within the context of general targeting priorities to be discussed later.

Dr. Katz added that staff should be mindful of experience from the Tuskegee studies that showed that the Surgeon-General knew relatively little first-hand about those experiments. The staff's work should assess whether there was active participation in management of experiments by high-level officials.

Staff Report: Declassification. *Dan Guttman.*

Dr. Faden wrote on behalf of the Committee urging agencies to quickly declassify documents sought by the Committee. The Committee discussed responses received from three of the six agencies, DOE, CIA and NASA, and asked Dr. Faden to write again to the CIA as the CIA's letter did not speak specifically to a three-week time limit for declassification suggested by Dr. Faden.

Public Comment Period

Mr. Klaidman read into the record two letters from the National Association of Radiation Survivors.

Dr. John J. McCarthy of Sacramento Radiation Survivors Group urged the Committee to examine nasal radiation treatments.

Ms. Cherie Anderson of the group wrote that such treatments, while widespread in the 1950s, are more accurately characterized as experiments.

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Thomas Smith, regional vice president, National Association of Radiation Survivors, addressed the Committee as a veteran of witnessing atomic blasts at Eniwetok atoll. He said a complete report of the Committee should cover a wide range of radiation illnesses suffered by veterans, and urged the appointment of a victim representative to the Committee.

Mrs. Pat Broudy, national legislative director, National Association of Atomic Veterans, seconded Mr. Smith's statement and said that the government has not dealt fairly with the atomic veterans.

Dr. Faden directed that staff work with Mrs. Broudy to make the Atomic Veterans group's records available to the Committee.

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Tuesday, June 14.

Drs. Stevenson and Tuckson joined the Committee. Dr. Faden called the meeting to order at the Washington Vista Hotel ballroom at 10 a.m. Dr. Faden reported that the meeting had to be moved because of air-conditioning failure at the original meeting place, and that the new location of the meeting had been posted.

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Dr. Kahn briefed the Committee on staff organization, including time lines and current staff assignments for existing projects. Dr. Kahn noted that members are welcome to visit the M Street office and participate in staff meetings.

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Reporting for Dr. Macklin, Dr. Faden stated that the subcommittee has outlined an extensive program of work in the ethics area. The Ethics Subcommittee report outlined a program of surveying selected institutions to determine the conduct of clinical science to the present day, and to discuss how research in radiation studies has differed from other research.

Members discussed the report and raised issues of its scope and mission, including whether to survey pharmaceutical companies' clinical trials, which institutions will participate in the study, and the value of the study.

The Committee agreed to seek the counsel of the White House as to whether institutions with which Committee members are affiliated can participate in the study. Dr. Faden suggested that it may be advisable to seek the counsel of university presidents in designing the study.

Dr. Moreno told the Committee that the ethics working group expects to gather a panel of experts to develop the plan in June and submit it to the Committee in July meetings. The prospective timetable is to identify local research groups by late August and hear their reports by late January, with the presentation of the results by the February meeting of the Committee. Dr. Faden said the work must be parallel with the Committee's other work in order to have findings available in time for consideration of the final report.

The Committee accepted the Ethics Subcommittee report and asked that the subcommittee report at the next meeting on the feasibility of the proposal. The subcommittee will also consider whether there are in other fields, such as DNA research, useful parallels to study implementation of ethical standards in human subject research.

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Dr. Thomas reported that there was within the Scope Subcommittee an emerging consensus that intentional exposures must appear in the Committee's report, as part of the overall Cold War radiation story. Where earlier studies have detailed the history of intentional releases the Committee has considerable discretion in how much time to devote to specific experiments, and may decide to focus on particular aspects of the experiments that have received inadequate attention in the past.

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The subcommittee recommended that the Committee hold at least two of its full meetings in cities around the country, with San Francisco being suggested for the West Coast, and Chicago, Atlanta or another Southern/Midwestern venue for another meeting. Smaller groups of Committee members might take testimony in other cities around the country. Issues include ease of access for the public, although members expressed caution about venues that might be dominated by discussion of particular cases. At each off-site meeting, members may also gain the opportunity to view uses of nuclear medicine procedures in today's research institutions or

hospitals.

Committee Discussion

The Committee asked Dr. Faden and Mr. Guttman to draft a memorandum as a basis for a discussion of the vision of the Committee's work and report. Members were asked to submit draft goals, report agendas or mission statements to work with in the draft statement. Dr. Faden said that members should indicate if they wished the vision statement suggestions to be circulated to all the Advisory Committee members. The statement will be discussed in the first or second meeting in July.

Dr. Faden announced that the subcommittees would meet briefly at the close of the meeting. She said the meeting of July 5-6 will be held at 11 a.m. at the Vista Hotel.

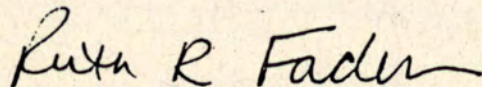
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APPENDIX A

The following persons signed in to attend all or part of the Committee's meeting: Troy Jenkins, Potomac TV; John Kruger, Group for Public Integrity; Tod Ensign, Citizen Soldier; Dan Brown, U.S. Air Force; Stacey Cunningham, APA; Hal Halpern, Elly Mewmen, Ellyn Weiss, G. Yount, V. Johnson, DOE; Neil Otchin, VA; Amy Hall, NIH; Karen MacPherson, Scripps Howard; Jonathan Weisgall, Bikini Atoll; Janis Stoklosa, John Howell, John Lyver, NASA; Paul Barton, Gannett News Service; Michael S. Yesley, Los Alamos; Craig Cobdell, DOE; Stephanie Niemier, NIH; Darren R. Fisher, Battelle; Arthur Simon; Robert Allen Jr., GAO; Les Blumenthal, McClatchy Newspapers; Pat Broudy, NAAV; Oscar Rosen, NAAV; Tom Smith, NARS; Kitty Tucker, Health and Energy Institute; Gwendon Plair, Ohio CROSP.

CERTIFICATION

The above minutes represent an accurate summary of the June meeting of the Advisory Committee on Human Radiation Experiments, held in Washington, D.C., June 13-14, 1994.



RUTH R. FADEN, Ph.D., M.P.H.



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

Minutes: Meeting of June 13-14.

Monday, June 13

Attending: Ruth Faden, Susan Lederer, Jay Katz, Philip Russell, Lois Norris, Kenneth Feinberg, Henry Royal, Duncan Thomas, Nancy Oleinick.

Dr. Faden, chair. Philip Caplan, Special Assistant to the President for Cabinet Affairs, opened the meeting of the Advisory Committee on Human Radiation Experiments at 9:30 a.m. at the Ramada Plaza Hotel, 10 Thomas Circle, Washington, D.C.

Patricia King and Eli Glatstein were unable to attend the meeting and Reed Tuckson and Mary Ann Stevenson joined the Committee on the following day.

Dr. Faden outlined the objectives of the meeting: continuing the series of presentations by Committee members about their specialties relevant to the Committee's work; updates from staff of document searches; public comment on issues before the Committee; and hearing reports from subcommittees appointed at the May meeting.

Staff Director Jeffrey Kahn introduced new staff members: Sara Chandros, Gwen Davis, Patrick Fitzgerald, Mark Goodman, Gary Stern, and Kathy Taylor. Dr. Kahn also introduced Ted Webster of Harvard University, who will be a consultant to the Committee on radiation dosimetry.

Draft minutes of the May 18-19 meeting were distributed, and the Committee authorized Dr. Faden to approve the minutes after review of Committee comments.

Briefing: Introduction to Remedies. *Mr. Feinberg.*

Mr. Feinberg discussed how harms alleged from mass exposures to potentially harmful substances, including pesticides, breast implants or defective medical devices, as well as ionizing radiation, pose challenges to traditional notions of tort remedies in the judicial system. He noted the difficulty in devising methods of compensating groups exposed to hazardous substances, and the heavy burdens of proof for plaintiffs alleging government wrongdoing. Mr. Feinberg referred members to the report of the Presidential Commission on Catastrophic Nuclear Accidents as a potential aid to the work of the Committee.

Committee members questioned Mr. Feinberg about compensation for increased risk of illness or injury; the mitigating effect of benefits from drugs or pesticides, and the aggravating



effect of fears of potential harm; payments to estates of survivors; whether statutes of limitations apply to latent diseases; and the influence of epidemiological evidence.

Briefing: Risk Communication. *Stephen Klaidman.*

Mr. Klaidman briefed the members on the problems of risk communication. He discussed conservative biases of federal risk assessment methods and policies and how the public as well as experts evaluate risk information, including the public's difficulty in evaluating risk assessments because of its resistance to uncertainty and probabilistic thinking, and other cognitive and emotional challenges.

Staff Report: Overview of Staff Work. *Daniel Guttman.*

Mr. Guttman briefed the Committee on the records search being conducted by Federal agencies that might have sponsored or conducted radiation experiments on human subjects. He reported that the focus on policymaking organizations that authorized and directed experiments, a priority in the Committee's May instructions to staff, is producing a more targeted agenda for staff follow-ups with agencies. Federal agencies, having completed or nearing completion of their initial searches, are seeking direction from the Committee about how to proceed.

Mr. Guttman discussed the operating logic of the Committee staff in mapping the experiments currently known, identifying additional experiments, and categorizing experiments by the goals of sponsoring agencies or of researchers. Three major lines of work are indicated:

Institutions. Work with agencies to identify the funding and management authorities overseeing human experimentation. This process allows the staff to fill gaps in knowledge about where and by whom experiments were conducted, and takes advantage of new document searches to lead to further experiments.

Accomplishments have included the recent declassification of minutes of meetings of the Medical Advisory Committee to the Secretary of Defense. Significant challenges to a comprehensive understanding of the experiments include tracking the complex series of changes in the management of the government's radiation research program, including changes in agencies, and the complex nature of government collaboration with private institutions.

Ethics. Develop a timeline of ethical policies and procedures. Mr. Guttman noted that informed consent policies were discussed in the armed services as early as 1932, according to recent research by the Navy.

Experiments. Group experiments by the nature of the study (e.g., whole body irradiation) and the purpose of the experiments. In some cases, Mr. Guttman said, it is unclear whether the most important impetus for experimentation was government purposes such as protecting arms workers, or biomedical research that was funded by the government.

Potential categories to group experiments include scientific objective, intentional releases apparently designed to satisfy the need for knowledge about exposure to radiation, and radiation warfare studies.

Mr. Guttman said staff work to date suggests several new lines of inquiry, including indications that whole-body irradiation and excretion studies were more widespread than

previously known.

The last category, radiological warfare, involves substantial amounts of classified material, Mr. Guttman said, but he reported that the Committee had received assurances that biomedical research files would be speedily declassified if they were not already in the public domain.

Difficult issues for the staff are likely to include grouping of experiments in meaningful fashion; keeping documents flowing from the variety of Federal agencies; dealing with the large volume of tracer isotope studies; and working with agencies on classification issues.

Mr. Guttman said the staff particularly seeks guidance from the Committee about the appropriate grouping of experiments by scientific purpose.

Members of the Committee questioned Mr. Guttman about different ways to map information about ethics policies and exposure standards, and about allocation of staff time to Cold War experiments in the early phases of the inquiry.

Staff Report: Update on Ethics Data Collection. *Jonathan Moreno.*

Dr. Moreno briefed the Committee on the ethics search, particularly noting the prevalence of formal ethics policies earlier than previously known and reporting on efforts to develop more information about the 1953 promulgation of the Nuremberg Code by the Department of Defense.

Dr. Russell noted that ethics researchers may find that eminent nongovernmental institutions were assumed to have adequate policies for protection of volunteers, and that in particular the armed services may have not had the knowledgeable staff to look into those issues.

Dr. Gordon Soper, Deputy Assistant Secretary of Defense, told the Committee that the Department will be aided in its efforts if the Committee staff provides the earliest possible guidance on the time frame in which to search for documents. Dr. Moreno and members of the Committee noted that Federal agencies have a substantial task but that there are major finds in the 1930s and 1940s because of internal debates about ethical standards in experiments involving nonradioactive substances.

Dr. Royal said that the Committee staff's work should be tightly focused because of the large task. Dr. Faden noted that there are few histories or summaries that would help to focus the inquiry, requiring the initial document searches sought by the Committee.

Staff Report: Methodological Review of Agency Data Collection Efforts, Department of Defense.

Mr. Guttman reported on the document searches by Department of Defense agencies, including the armed services and the Defense Nuclear Agency. He said much work remains to be done to identify headquarters policy records and to gain access to some records dispersed through organizational changes in the 1950s and 1960s.

Members discussed the targeting of research on funding sources in DOD and other Federal agencies, and suggested that the Committee and staff better define their goals through a discussion of alternative objectives in the current meeting.

The Committee agreed to begin initial discussions in Tuesday's meeting of a vision statement that could be agreed upon by the July meetings of the Committee, in order to help focus

work through the summer. The staff was instructed to prepare reports that would give members a better understanding of priorities in the period before the September meeting. In the interim, staff members were given approval to use their judgment in directing the DOD searches in preparation for the July meetings.

Staff Report: Review of Progress of Agency Data Collection. *Don Weightman.*

Mr. Weightman briefed the Committee on the difficulties of collecting and assessing data from different agencies, which even within departments do not lend themselves to "one-stop shopping." He stressed that staff members are keenly aware of the amount of archival material that must be accessed as efficiently as possible, and noted steps taken to pinpoint searches in relevant batches of materials.

Mr. Weightman noted that policy documents provide a context and background that may aid in the targeting process, but that secrecy classifications may be a barrier to efficiency, as researchers may not know what questions to ask of agencies.

Computerization of the document classification system will make the work of the Committee staff much easier, he said. Coordination of the work of staff groups and identification of long-range milestones in their work are top priorities.

Staff Report: Methodological Review of Agency Data Collection Efforts. Department of Veterans Affairs. *Denise Holmes.*

Ms. Holmes briefed the Committee on the data collection in Veterans Affairs, particularly about the previously secret Atomic Medicine Division. The division was apparently created in response to concern about service-related disability claims. She traced VA participation in use of isotopes for research and therapeutic purposes.

The Committee endorsed staff-proposed options for further research within the context of the strategic plan to be defined at the July meeting.

Staff Report: Update on Review of Agency Data Collection Efforts, Department of Energy. *Jim David and Dan Guttman.*

Mr. Guttman said the staff is following up on data collection based on the staff options approved in May. The staff sought Committee direction on a second phase of research, and reported on the assessment of the large volume of materials received from DOE.

The Committee approved the staff plan to follow up on document searches with the Department.

Staff Report: Update on Agency Data Collections, Health and Human Services. *Faith Bulger.*

Ms. Bulger reported on the follow-up to research in HHS, particularly efforts to identify potentially relevant experiments and compile lists of documents. She discussed the significant links among the Public Health Service, the Atomic Energy Commission and the Department of

Defense on radiation research work.

The Committee endorsed options for follow-up within the context of general targeting priorities to be discussed later.

Dr. Katz added that staff should be mindful of experience from the Tuskegee studies that showed that the Surgeon-General knew relatively little first-hand about those experiments. The staff's work should assess whether there was active participation in management of experiments by high-level officials.

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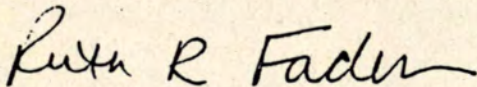
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RUTH R. FADEN, Ph.D., M.P.H.



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

Minutes: Meeting of July 5-6

July 5, 1994

Attending: Ruth Faden, Eli Glatstein, Jay Katz, Patricia King, Susan Lederer, Lois Norris, Nancy Oleinick, Henry Royal, Philip Russell, Mary Ann Stevenson, Duncan Thomas.

The meeting was called to order by Philip Caplan, Special Assistant to the President for Cabinet Affairs, at 11 a.m. at the Vista Hotel, 1400 M Street NW, Washington, D.C. Dr. Faden noted that Ruth Macklin was out of the country and Ken Feinberg would join members later in the day. She briefed members on the agenda and called upon Jonathan Moreno for the first report.

Staff Report: Update on Ethics Data Collection Efforts. *Dr. Moreno.*

Dr. Moreno briefed the Committee on ethics data collection, including Department of Defense follow-up research on the 1953 Wilson memorandum regarding the Nuremberg Code. Policy documents from the time show stress on ethics practices because of a perceived lack of U.S. capability in biochemical and radiological warfare. The documentary evidence suggests that proposed ethics policies provoked debate and disagreement in both Defense and the Atomic Energy Commission, with the AEC denying to the press (1950) that it sponsored any human experimentation at all.

Subcommittee Report: Ethics Data Collection. *Dr. Faden.*

Dr. Faden briefed the Committee on the subcommittee proposals:

An oral history project to elucidate actual research ethics practices, with an emphasis on the earlier years of research, through interviews with practitioners.

A sampling of the current portfolio of human-subject experiments, reviewing agency and researcher documentation to answer key questions about the present status of human experimentation and whether recommendations for change are needed. Questions to be answered by the sample study would include the extent to which experimental subjects are being put at risk, and whether consent procedures appear to be adequate.

Interviews with patients involved in research at hospitals and federal laboratories with substantial research commitments.

Members agreed to the first and second proposals, with the amendment that the oral history project encompass current investigators to give a wider view of practices from the viewpoint of practitioners. Members of the Committee questioned whether a representative



sample of subjects or patients could be obtained, and decided to defer the proposal to the July 25-26 meeting.

Subcommittee Report: Scope and Priorities. *Dr. Thomas.*

The Scope subcommittee report noted the wide range of exposures that may or may not be construed as experiments on the basis of available evidence, but also observed that evidence has come to light suggesting that a human experimentation component might have existed in planning of weapons tests. Dr. Thomas said human-subject experiments clearly were necessary to achieve the type of data envisioned by the as-yet incomplete records of the Joint Panel on the Medical Aspects of Atomic Warfare.

To tell the entire story of human-subject experimentation during the Cold War era, a variety of exposures must be dealt with in the report, Dr. Thomas said, but the Committee retains latitude in assessing which areas need extensive investigation beyond what is already in the public record. He noted that the Green Run, included in the Committee's charge, is only one of a wide variety of intentional releases, but is the subject of a major dose reconstruction study already.

Key questions raised by the variety of exposures include whether an experimental purpose motivated the exposures, and whether serious ethical improprieties need to be assessed and referred to in the Committee's report.

Dr. Thomas said a National Academy of Sciences research group is reviewing studies of the dose measurement of atomic veterans' exposures.

For two of the relevant areas, uranium miners and downwinders, Dr. Thomas noted that he was involved in analysis of the miner data, and was deeply involved as a senior researcher in downwinder exposures.

Mr. Feinberg said the Scope report basically concludes that the Committee should not draw early conclusions about which categories of exposures are within or without the Committee's ambit. He said the Committee will need to seek further information from interested parties over the coming months, and should not preclude discussion of activities not clearly included under the charter if they are relevant to the comprehensive story.

Mr. Feinberg also observed that discussion of remedies is premature until more specific information is developed by the Committee's inquiries.

Members questioned Scope subcommittee members on the impact of their report on priorities of the staff; the definition of what exposures and subsequent medical follow-up constitute "experiments of opportunity" on the part of government officials; and the range of definitions of experimentation that may be necessary to classify the many experiments before the Committee. Executive Director Dan Guttman noted that the Joint Panel documents specifically use the word experiment in reference to planning a biomedical component at weapons tests.

The Committee accepted the Scope report and directed staff to take care not to duplicate efforts in the case of experiments/exposures which have been extensively studied by Congress or other panels.

Subcommittee Report: Cold War Data Collection. *Dr. Stevenson.*

Efforts to group experiments in categories have begun and the staff will report Wednesday afternoon on the pilot project of sorting through the 61 experiments in the Markey document collection, Dr. Stevenson reported.

Committee members discussed the problems of mapping experiments with limited evidence from fragmented records collections, and the use of groupings in the preparation of a Committee report.

Subcommittee Report: Outreach. *Stephen Klaidman.*

In the absence of Dr. Tuckson, who was abroad, Communications Director Stephen Klaidman reported that the subcommittee recommended that three full-scale committee meetings be held outside Washington, and four other panels be dispatched to hear testimony in or near cities that are loci of experiments, e.g. Spokane, Albuquerque, Nashville, etc.

Cities proposed for full Committee meetings were San Francisco, Atlanta and Chicago, based on geographic criteria suggested by Committee in June. The meetings would provide extended opportunities to hear from citizens. Panels to hear testimony would be focused on loci of experiments, e.g. Spokane, Albuquerque, Nashville.

Members of the Committee questioned whether staff work would be disrupted by out-of-town meetings, and directed the Outreach subcommittee to cut back its proposal for full Committee meetings outside of Washington.

Staff Report: Structure and Current Project Assignments. *Jeffrey Kahn.*

Staff Director Jeffrey Kahn introduced Barbara Birney, Noel Theodosiou, Sandra Thomas, John Harbert. Dr. Kahn briefed members on staff assignments.

Committee Discussion: Goals and Objectives. *Dr. Faden.*

Committee members were given a preliminary draft of ideas for an outline of the Committee's reports. Members were asked to review the ideas for discussion next day, with the goal of providing guidelines the staff can use to help organize its work in coming months.

Public Comment Period.

The Ambassador of the Republic of the Marshall Islands, Wilfred Kendall, and Tony deBrume, a senator in the Marshalls parliament, presented the Committee with documents it has discovered concerning exposures in the Marshalls. They asked the Committee for its help in identifying documents hitherto unavailable about exposures in the Marshalls.

Jonathan Weisgall, author of a book on the Bikini tests and an attorney representing the Bikini islanders, briefed the Committee on evidence which he said indicated foreknowledge of radiation effects and clear evidence of official misrepresentation, both suggesting an official plan

to derive data on human experimentation from the weapons tests.

Members questioned Mr. Weisgall about the extent of exposure and standards set by the government; the effectiveness of dosimetry at the sites; and potential remedies, which he suggested included a formal apology and potential memorial for atomic veterans.

Cooper Brown, president of the National Committee for Radiation Victims, urged the Advisory Committee to address issues of remedies in its final report.

July 6, 1994

Briefing: History of Human Experimentation. *Dr. Katz.*

Dr. Katz briefed members on key dates in human experimentation, including instances of promulgation of codes of ethics which were often disregarded in practice. He noted that at the same time that NIH/PHS were debating increased protection for subjects, the PHS did not re-evaluate its notorious syphilis study at Tuskegee until it became a *cause celebre*.

Issues: latitude extended to physicians on issues of disclosure and consent, a license which is extended to research situations; blurring of lines between therapy and research as the new specialty of physician/researchers developed in the wake of the scientific method; the military concerns that drove research in both the United States and Nazi Germany, and Nazi experiments driven by a policy of genocide; the impact of secrecy in government, and the relative secrecy of local decisionmaking by IRBs.

Members questioned Dr. Katz about distinctions among particular cases of controversial experiments; about how questions of exploitation and fairness in the selection of research subjects also need to be considered; about the impact of litigation and insurance liability; about the regulatory structure which might enforce appropriate policies; and about the preparation of IRB members to deal with ethical issues.

Staff Report: Methodological Review of Agency Data Collection, Central Intelligence Agency. *Gary Stern.*

Mr. Stern said CIA reported no radiation experiments, although some agency documents suggested official concern about radiological warfare issues. CIA may have more information of interest to the Committee about Green Run and other intentional releases, as well as intelligence background which can lend context to the Committee's inquiries, and information about research conducted by other agencies. CIA has indicated its willingness to focus its search on the basis of direction by the Committee.

Members questioned Mr. Stern about classification issues and the ethical and policy framework for experiments. Members authorized the staff to proceed along lines of the staff memorandum to the Committee.

Staff Report: Methodological Review of Agency Data Collection, NASA. *Mark Goodman.*

Dr. Goodman said the staff continues to seek human research records, particularly

involving total-body irradiation. A primary concern of the agency was radiation exposure of astronauts, either because of environmental radiation or propulsion studies. No formal ethical policies have been found before 1969, although the agency continues to search for records of formal or informal policies in effect at field laboratories. A 1981 Congressional study found that many records were destroyed. Some bedrest studies may have involved vulnerable populations, e.g. inmates in California prisons.

Members questioned Dr. Goodman about the nature of NASA exposures; and about recent ethical procedures and conferences. The Committee authorized staff to proceed along the lines of the staff memorandum.

Update: Other Agency Data Collection Efforts. *Dr. Faden.*

Dr. Faden and Mr. Guttman briefed members on status of efforts to follow up on initial data collection by agencies. A new data collection effort will be required of all agencies to denominate the current portfolio of human subject experiments for sampling on ethics issues.

Members questioned Mr. Guttman about declassification issues and about Department of Energy criteria for its recent release of experiment information.

Staff Report: Overview of Information System Management and Experimental Groupings. *Mr. Guttman.*

Mr. Guttman briefed members on potential groupings of experiments for purposes of the Committee's report. David Saumweber outlined how information will be processed for the Committee's work and Gil Whittemore and Jonathan Engel reported on the pilot project characterizing the Markey Report experiments using the Committee's classification scheme.

Members discussed what publication citations might be included on the experiment form, the speed with which primary documents can be assessed, targeting of staff efforts and the ability of the Committee to gain access to information not readily available in the public record, e.g. selection of vulnerable populations.

Staff members briefed members on possible groupings of experiments, as follows: Government purpose, Jim David. Total body irradiation, Ron Neumann. Radiological warfare, Gregg Herken. Intentional releases, Mr. Guttman.

Committee Discussion: Goals and Objectives. *Dr. Faden.*

Members discussed draft outlines of the groups of experiments to be covered in the Committee's interim and final reports. Issues included the structure of the report and whether the groupings represented meaningful differences among experiments. Dr. Royal suggested that staff pay particular attention to use of sealed sources of radiation in some environmental releases.

Drs. Oleinick and Stevenson suggested that the history of radiation experimentation clearly outline both the positive and negative outcomes, including the benefits for therapeutic medicine.

Dr. Katz suggested that the history of the doctor-patient relationship be outlined to

illuminate how research was conducted, and the report also delve into the influence of the medical profession on policymaking.

Dr. Lederer suggested that statements from patients be included, and also a thorough section on the tensions between scientific and national security motivations of experimentation. Ms. King said the report needs an additional theme about openness in government.

Dr. Royal suggested that narratives should encompass those who have seen benefits from participation in experimentation.

Dr. Russell said an important factor is the management of experiments by the various agencies and the official structures that oversaw, and oversee, experimentation. Dr. Oleinick said that theme includes issues of the funding of science.

Dr. Glatstein suggested a theme exploring the attitude of investigators, e.g., that the ends justified the means.

Dr. Royal said a relevant question is how research with radiation differed from other human subject experimentation.

Dr. Russell noted that all Defense Department grants were by definition for military purposes, and that significant basic research was funded by broad-brush grantmaking.

Drs. Glatstein and Faden noted that experiments of opportunity may be a problematical grouping, in part because of the nature of cases not explicitly covered by the Committee's charter.

The Committee asked the staff to make themes identified by the Committee part of the database of experiment identification forms.

Adjournment.

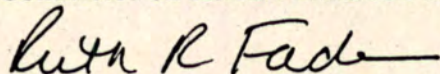
Mr. Caplan of the White House adjourned the meeting at 3 p.m.

APPENDIX A

Persons signing in to attend all or part of the meeting were: Trang Emmer, Oil, Chemical and Atomic Workers International Union; Jennifer Schiller, Physicians for Social Responsibility; Darell Bevis, BAI; Karen MacPherson, Scripps Howard; Melissa Robinson, AP; Larry Shuster, UPI; Jason Vest, The Washington Post; Kevin Foley, Stars and Stripes; Paul Barton, Nadine Slimak, Gannett News Service; Barry Serafin, ABC News; Vicki Allen, Reuters; Tony Sargent, ABC Radio; Albert Lubkan; Brian Thompson, Conus; B. Novak, GAO; Ellyn Weiss, DOE; James H. Stohlon, John Howell, NASA.

APPROVAL

The above minutes represent an accurate record of the July 5-6 meeting of the Advisory Committee on Human Radiation experiments.



Ruth R. Faden, Ph.D., M.P.H.



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

Minutes: July 25-26.

July 25, 1994

Attending: Ruth Faden, Eli Glatstein, Jay Katz, Pat King, Susan Lederer, Ruth Macklin, Lois Norris, Nancy Oleinick, Henry Royal, Philip Russell, Mary Ann Stevenson, Reed Tuckson.

Philip Caplan, Special Assistant to the President for Cabinet Affairs, opened the meeting in the Council Room of the Mayflower Hotel, 1127 Connecticut Avenue, NW, Washington, D.C. Dr. Faden briefed members on the plans for the meeting and noted that there would be a more extensive than usual public comment session at the end of the first day, because of the number of public comment requests received.

Briefing: Regulation of Contemporary Radioactive Drug Research. *Barry Siegel.*

Dr. Siegel, director of the Division of Nuclear Medicine at Mallinckrodt Institute of Radiology and chairman of the Advisory Committee on Medical Uses of Isotopes of the Nuclear Regulatory Commission, briefed members on the regulatory regime for isotope research ushered in by the Atomic Energy Act of 1946 and amended over the following decades. He traced how Atomic Energy Commission/Department of Energy regulations were over time entwined with Food and Drug Administration regulations, and that many institutional committees oversee uses of radioactive drugs. Radioactive drugs are adequately regulated, he said.

Members questioned Dr. Siegel about Institutional Review Boards and Radioactive Drug Research Committee processes and his experience with oversight of human subject research at Washington University.

Briefing: History of Radiation Protection Standards. *Gil Whittemore.*

Dr. Whittemore briefed members on the history of radiation standards, beginning with medical effects of x-rays and radium. The difficulties multiplied in the post World War II-era of vastly greater use of radioisotopes.

Members discussed with Dr. Whittemore the great difficulty of demonstrating genetic effects of radiation exposure; difficulties of determining risks of increased illness in statistical terms; and the early concern with the safety of medical workers.



Briefing: An Epidemiologic Perspective on Low-Dose Radiation Risks. *Duncan Thomas.*

Dr. Thomas briefed members on BEIR V risk estimates, many derived from epidemiological studies following the bombing of Hiroshima and Nagasaki. He briefed members on thyroid and leukemia studies from Nevada Test Site fallout, radon studies of lung cancer in uranium miners, and studies of leukemia risk from diagnostic x-rays. Dr. Thomas characterized BEIR V as accepting carcinogenic effects of low-dose exposures, and he discussed the implications for compensation of data published since passage of the Radiation Exposure Compensation Act.

Members questioned Dr. Thomas about dose reconstruction problems and inherent statistical uncertainties in fallout studies.

Update: Agency Data Collection Efforts. *Ruth Faden.*

Dr. Faden briefed members on the status of data collection efforts in government departments and agencies: Health and Human Services, National Aeronautics and Space Administration, Central Intelligence Agency, Defense, Energy, Veterans Affairs.

Dr. Faden said the Committee has received assurances from the highest levels at the Pentagon that any delays in pursuing searches will be resolved. The Department of Veterans Affairs pledged that searches of National Archives records will be completed in 90 days.

The Committee is assessing the progress of DoE searches and working with the department to increase the flow of documentation.

Executive Director Dan Guttman said it is clear that promising trails exist and can be pursued..

Staff Report: Functional History of Human Radiation Experiments. *Gregg Herken.*

Dr. Herken briefed members on the AEC program of human subject proposals and its program of regulatory committees. Dr. Herken said it is becoming clear that AEC oversight was fitful and that parts of the AEC bureaucracy, as well as AEC contractors, actively promoted human subject experiments at the same time that officials at the Division of Biology and Medicine were discouraging the same.

Staff Report: History of Ethical Policies. *Jonathan Moreno.*

Dr. Moreno outlined documentation indicating that concepts of informed consent existed from the earliest days of human radiation experiments sponsored by the government. What is not clear, is the reach of consent policy and practice; for example, whether they were limited to healthy volunteers, whether they covered subjects given tracer amounts of radioisotopes within what were considered safe limits, and whether they covered activities with therapeutic intent.

Official ambivalence about human subject rules was represented by debates among armed service representatives even the day after Secretary of Defense Wilson's 1953 memorandum on the Nuremberg Code rules.

Staff Report: History of Government Regulation and Control. *Dan Guttman.*

Mr. Guttman briefed members on findings that suggest several significant questions about the behavior of the government bureaucracy, including why the Nuremberg Code rules did not percolate through the chain of command, what role was played by insurance/legal liability concerns, and what policies or restraints accounted for varying degrees of debate on human subject experimentation in different services or government agencies.

Members questioned Mr. Guttman on differing conceptions of voluntariness over time; whether patients correctly appreciated risks of procedures; differing roles of medical agencies in terms of priorities, as in the preventive medicine focus of armed services doctors. In response to questions, Mr. Guttman said the full role of Shields Warren in preventing or supporting human subject work by agencies remains to be fully fleshed out. Dr. Stevenson noted that total-body irradiation work in the 1940s and 1950s may have been driven by limited knowledge of immune system suppression and the lack of therapeutic alternatives to many related diseases.

Staff Report: Staff Structure and Current Project Assignments. *Jeffrey Kahn.*

Dr. Kahn introduced new staff member John Harbert and consultant Nancy Kass. He noted that the Committee staff is basically at a full complement for the project.

He briefed members on the reorganization of staff assignments to reflect priorities and experiment groups approved by the Committee July 5-6.

Staff Report: Experimental Grouping of Total-Body Irradiation. *Gary Stern, Ron Neumann, Dan Guttman.*

Mr. Stern briefed members on the total-body irradiation that began prior to the 1940s. Mr. Stern outlined the group of experiments pursued by researchers with funding participation by the military and other government agencies. Questions raised included concerns about secrecy and sponsorship of experimentation, the level of control exercised by authorities which had formal ethics policies in place, and design of experiments to reflect both government purpose and the motivation of investigators.

Dr. Neumann told the Committee about the changing rationales offered by Dr. Saenger in reports on his work during the 1960s, with varying emphasis on military/government purpose.

Members asked the staff to include more scientific/medical detail to allow members to assess the experiments, particularly Dr. Saenger's experiments, in light of a dearth of other treatment options at the time and the more common use of TBI therapies in recent years.

Dr. Royal noted that many government-sponsored projects were suspect during the Vietnam War era. Dr. Neumann said that critical judgments by the junior faculty committee at the University of Cincinnati appear to have been unrelated to that motivation.

Staff Report: Abstraction of "Markey" Experiments. *Gil Whittemore, Jonathan Engel, Dan Guttman.*

Dr. Engel reported that the categorization of experiments is proceeding but that files,

including those developed by other investigations, often are not complete enough to provide the depth of subject categories sought by the Committee.

Mr. Guttman said that the Committee staff needs to dig for documentation to fill out files to provide members with adequate data.

Public Comment Period

Stewart Udall, attorney and former U.S. Secretary of the Interior. Mr. Udall urged the Committee to address the case of more than 3,000 uranium miners studied by the U.S. Public Health Service. He said the case should fall within the purview of the Advisory Committee because of the Public Health Service study and urged members to address compensation issues in their report.

Members questioned Mr. Udall about the effectiveness of the Radiation Exposure Compensation Act and about details of disclosures or withholding of information about risks to the miners.

Eugene Trani, Hermes Kontos, John E. Jones, respectively president, dean of the School of Medicine, and vice president, Virginia Commonwealth University. Dr. Trani related the experience of his university with what he described as press sensationalism about burn studies at the Medical College of Virginia, 1949-59. The experiments were neither secret nor dangerous, and led to significant medical advances, he said, urging the Committee to make objectivity and balance a keynote in its report on experiments.

Dr. Lederer said that her review of some MCV documents during a visit to Richmond found no evidence to support interpretations suggested in the June 19 article in *The Washington Post* to which Dr. Trani referred. Members of the Committee briefed Dr. Trani on the work of the Committee and questioned him about the conduct of the experiments and the extent of records available at the university; Dr. Russell noted the extensive benefits of burn studies to trauma victims.

The Committee asked for additional information about MCV experiments, including protocols regarding selection of experiment subjects.

Chris Zucker, Disability Advocates of New York Inc., Albany, N.Y. Mr. Zucker urged the Committee to look into ways to improve protection to those subjects of experimentation not funded by the federal government, and to subjects incapable of informed consent because of disabilities.

Pat Broudy, legislative director, and Oscar Rosen, National Association of Atomic Veterans. Mrs. Broudy urged the Committee to include weapons test exposures in its scope for its final report. She presented documents relating to the exposure of soldiers at atomic tests.

Mrs. Catherine Variano of South Bend, Ind. Mrs. Variano described her extensive medical problems which she ascribed to radiation treatments as a child. She said the federal government provided materials for her treatments and should be responsible for treatment of survivors.

Members questioned Mrs. Variano about evidence of the experimental intent of the exposures and whether other persons were involved.

Mrs. Janet Gordon of Citizens Call Utah. Mrs. Gordon presented a statement from a newly formed Task Force on Radiation and Human Rights. She urged the Committee to take up

the cases of downwinders from weapons tests, which occasioned experiments of opportunity in exposed populations, such as the Marshall Islanders and residents of Washington and Oregon exposed by the Green Run. She also urged the Committee to add a "victim" representative to its membership.

July 26, 1994

Dr. Faden called the meeting to order at 9 a.m. in the State Room of the Mayflower Hotel. The Committee approved the minutes of the July 5-6 meeting.

Committee Discussion: Interim Report. *Dr. Faden.*

Dr. Faden said the Committee's interim report is due to the Interagency Working Group on Oct. 21. The report is intended to be a progress report.

Subcommittee Report: Outreach. *Stephen Klaidman.*

Dr. Tuckson, chair of the Outreach subcommittee, designated Mr. Klaidman to speak on his behalf. Mr. Klaidman briefed members on letters being sent to stakeholder groups to solicit their input into the Committee's deliberations. The Outreach subcommittee also met July 25 with leaders of stakeholder organizations to solicit their help in gathering information and providing testimony at meetings outside the Washington, D.C., area.

Mr. Klaidman said that the subcommittee is working on organizing the meeting of the full Committee in San Francisco in October and up to four panel hearings in cities around the country.

Members were asked to provide guidance on the stakeholder letters drafted by the subcommittee.

Subcommittee Report: Ethics. *Dr. Macklin.*

Dr. Lederer briefed members on the oral history segment of the Ethics subcommittee proposal. A panel of ethicists and historians is being gathered to advise the Committee on the project and Committee members were asked to provide names of potential interviewees.

Members discussed the criteria for choosing interviewees.

Drs. Thomas and Oleinick raised the issue of ethical problems surrounding environmental releases, and the need to focus on ethical issues, e.g. the role of PHS doctors in the uranium miners case. Dr. Faden said the Ethics oral history project is intended to focus narrowly on practices of investigators. The staff will generate a separate list of interviews that focus on fact-finding relative to the Cold War story. Dr. Oleinick noted that environmental releases might be handled in a very different manner in today's ethical environment.

Dr. Faden asked the staff to begin inquiries into today's ethical attitudes and policy constraints regarding environmental releases. These inquiries would not necessarily include interviews.

Dr. Royal noted that the investigator interviews may result in very different answers to

questions because the interviews are conducted for a federal commission looking into a highly controversial topic.

Dr. Lederer said many interviewees will be eager to see their firsthand observations in the public record of the Committee.

Dr. Macklin asked members to provide ideas and feedback to Dr. Lederer.

Ms. Norris expressed concern that subjects' views would not be solicited in oral histories, which will focus on investigators. Dr. Faden noted that the Outreach program is designed to solicit those views and Mr. Guttman reported that the Committee staff is seeking access to Helpline callers to provide direct access to persons who contacted the Department of Energy regarding human radiation experiments.

Protocol sampling. Drs. Sugarman and Kass made proposals on the sampling of National Institutes of Health extramural protocols from fiscal year 1993. Committee members and staff will determine an appropriate method of sampling. About 100 protocols will be investigated. Dr. Macklin said that the study appears to be unprecedented. The Committee will coordinate its efforts to avoid conflicts with the General Accounting Office and the National Institutes of Health, which have also expressed interest in these issues.

Members discussed the difficulties of getting representative examples of the most common types of protocols, e.g. radiation oncology at Health and Human Services, biodistribution at the Department of Energy. Dr. Faden said that HHS officials are collaborating closely with the protocol sampling project and will meet with the staff this week to determine how efficiently the list can be accessed.

Dr. Royal noted that an important variable will be the quality of the work done by Institutional Review Boards at different institutions. Dr. Macklin noted that the IRB minutes and consent forms are likely to be gathered in the protocol study, but Dr. Sugarman said that it will be difficult to assess how well the IRB process works from the protocol sampling project. Dr. Faden said that the protocol sampling may suggest how to approach issues of IRB participation in the process of approving human experimentation.

Subject interviews. The Ethics subcommittee presented three options for interviews with subjects of contemporary research. Responding to Committee members' concerns at the July 5-6 meeting, Dr. Sugarman said each option is designed to increase the number of active participants interviewed. Dr. Sugarman said the projects would require contracting out some of the functions of the study.

Members discussed use of focus groups rather than subject interviews; the number and type of institutions to be surveyed; logistical difficulties of the study.

Subcommittee Report: Scope and Priorities. *Dr. Thomas.*

Dr. Thomas briefed members on the Scope subcommittee report and the continuing process of experiment classification, enumerating cases the subcommittee believes should be part of the final report and those that should not be part of the report, e.g. purely occupational exposures.

Dr. Thomas said the Scope subcommittee should become dormant and members should be

reassigned to other projects.

Mr. Guttman said the public will want from the Committee's work at least an index of identified experiments and the staff will pursue the data necessary to construct the Committee's database. Dr. Royal observed that the Committee staff need to concentrate on filling in gaps in some representative experiments at an early date, so that the Committee can determine what experiments or categories will provide sufficient evidence for the Committee to reach informed conclusions about research practices, and about how and where to target its resources.

Dr. Katz suggested that the staff prepare a report for members outlining options for sampling and fleshing out records of experiments that are of primary interest to the Committee. Drs. Faden and Thomas said the experiment sampling paradigm would be generated from the intensive study of the experiments identified as of interest to the American people and the Committee.

Dr. Macklin said that there must be commensurate criteria to define Committee conclusions for 1993 protocols and older Cold War experiments.

Committee Discussion: Restructuring of Subcommittees. *Dr. Faden.*

Committee members discussed assigning members to working groups to focus on particular tasks. Members agreed to the following working groups, with the provision that roles may change as the work of the Committee progresses:

Biomedical Research: Drs. Stevenson and Royal, co-chairs; Drs. Faden, Glatstein, Oleinick, Russell and Thomas.

Intentional Releases and Exposures/Experiments of Opportunity: Drs. Oleinick and Thomas, co-chairs; Drs. Katz and Macklin and Mr. Feinberg.

Oral History: Dr. Lederer, chair; Drs. Macklin and Russell.

Outreach: Dr. Tuckson, chair; Dr. Macklin, Ms. Norris, Dr. Royal.

Subject Interviews: Dr. Faden, chair; Dr. Lederer.

Protocol Review: Drs. Katz and Macklin; Dr. Glatstein, Ms. Norris and Dr. Royal. Drs. Faden, Stevenson and Thomas were added to work on the methodology required to launch the study. The subcommittee was charged with reporting on the methodology phase of the project at the Committee's September meeting.

Dr. Faden said that absent members (Ms. King, Dr. Tuckson and Mr. Feinberg) would be consulted about their assignments and that staff would be named to work on specific projects associated with the subcommittees.

The subcommittees on intentional releases and biomedical research were given oversight responsibility for deciding how much documentary research will be necessary to elucidate subjects of interest to the Committee.

Experiments of opportunity would go to the intentional release subcommittee. That would include the cases of the uranium miners, atomic veterans, Marshall Islanders and downwinders, as well as Green Run and Dugway environmental releases.

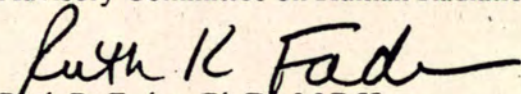
Mr. Caplan closed the meeting at 3 p.m.

Appendix A

Persons signed in to attend all or part of the meeting included: Oscar Rosen, National Association of Atomic Veterans; Laura Wilson, Association of American Universities; Tom Smith, National Association of Radiation Survivors; Patricia Olson, Senate Veterans Affairs Committee; Martha Glock, National Library of Medicine; Marcia Haggard; Dennis Nelson, Task Force for Environmental Awareness; Jackie Kittrell, American Environmental Health Studies Project; Sandra Reid, Oak Ridge Health Liaison; Amy Hall, NIH; Gwendon Plair, CROCSP; Joan McCarthy, NCRV/S; Fred Allingham, NARS; Allan Murray, Embassy of Australia; Chris Kline, Senate Government Affairs; Heather Shepherd, Congressman Shepherd's office; Robert de Vesty, Veterans Affairs; Jennifer Schiller, Daryl Kimball, Physicians for Social Responsibility; Paul Barton, Gannett News Service; Albert Lukban, Washington Monthly; Marilyn J. Siegel, Washington University; Rachel Rubey, Essential Information; Jack Bartley, Lawrence Berkeley Laboratory; Irene Stith-Coleman, Congressional Research Service; Janis Stohlar, NASA; Anuj Goel, Congressman Portman's office; Marty Gensler, Senator Wellstone's office; R. David Thomas Jr., Virginia C. Thomas, R.D. Thomas & Co.; Michael Mayes, Office of Management and Budget; Michael S. Yesley, Los Alamos National Laboratories; Ed Allen, GAO; Susan Prather, Van Ness Feldman; Geoffrey Sea, Leiff, Cabraser & Heimann; Jeff Trey, DoE; Linda Chase, House Committee on Natural Resources; John Howell, NASA; Melissa Burnside, Erin Brummett, VCU; Ann Hopkins; Amy McClain, University of Cincinnati; Stan Ammons, AAMC; Fred Bonkovsky, NIH; Margaret Furman; Kathleen Tucker, Health and Energy Institute; Charles Pope, Knight-Ridder; Jim Wells, GAO; Carol Stevens, Detroit News; Lee Davidson, Deseret News; Kevin Robbins, Scripps Howard; Earl Lane, Newsday; Tod Ensign, On Guard; Rick Nelson, David Shapinsky, ABC; Craig Lobdell, DoE; Kathy Rizzo, AP; Scott Armstrong, ABC; Beverly Orndorff, Richmond Times-Dispatch; Brad Flowers, Washington Times; Douglas Pasternak, U.S. News and World Report; Christina McKenna, WRIC-TV, Richmond.

APPROVAL

The above minutes represent an accurate account of the July 25-26 meeting of the Advisory Committee on Human Radiation Experiments.


 Ruth R. Faden, Ph.D., M.P.H.
 Chair



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

Minutes: September 12-13.

September 12, 1994

Attending: Ruth Faden, Eli Glatstein, Jay Katz, Pat King, Susan Lederer, Ruth Macklin, Lois Norris, Nancy Oleinick, Henry Royal, Philip Russell, Mary Ann Stevenson, Duncan Thomas, Reed Tuckson.

Philip Caplan, Special Assistant to the President for Cabinet Affairs and the designated federal official of the Advisory Committee, opened the meeting in the Federal Room of the Ramada Plaza Hotel, 10 Thomas Circle, Washington, D.C. Dr. Faden briefed members on the agenda for the meeting.

Staff Report: Introductions and Current Assignments. *Jeffrey Kahn.*

Dr. Kahn introduced new members of the staff: Robin Cochran, Gail Javitt, John Kruger, and newly retained consultant Suzanne White-Junod.

Approval of Minutes

Members approved the minutes of the meeting of July 25-26 without objection.

Staff Report: Update on Ethics Policies and Procedures. *Jonathan Moreno.*

Dr. Moreno briefed the Committee on the debate in the Department of Defense's Committee on Medical Sciences over informed consent rules. The staff outlined the discoveries of the debate prior to adoption of the 1953 Wilson memorandum establishing the Nuremberg Code as Department of Defense policy, and the process by which policies were developed following the Wilson memorandum.

A significant addition to this history was the surgeon general's 1962 interpretation that testing and operation of prototype equipment was outside the normal duties of soldiers, and thus apparently fell under the Wilson rule.

Dr. Moreno discussed efforts to fill out the documentary record on the context of debates within the government on informed consent issues, and the role of legal liability concerns in the debate. Implementation of the Wilson directive continues to be a focus of document searches, as



does the explication of ethical issues with respect to intentional releases and experiments of opportunity.

Members discussed questions of intent as guides to ethical judgements, and legal liability concerns as a motivating factor for keeping exposures secret.

Dr. Russell observed that much that the military did in the postwar world involved trying new methods of organization, of tactics and of weaponry to adapt to changing times. He noted that different agencies of the Department of Defense were likely to define experimentation and maneuvers, such as those that took place at the Nevada Test Site, in sharply different ways.

Dr. Royal noted that the Committee has a limited time frame for discovery and a wide range of experiments, therefore the Committee must make hard decisions about what to pursue in depth. He noted that bringing these issues to light in a public forum may be a significant contribution even where the Committee does not have the resources to exhaust the topic.

Members questioned Dr. Moreno on the differences between experimentation and training of soldiers; on the moral issues raised in the Committee on Medical Sciences; and whether rules such as those contained in the Wilson memorandum were followed in day-to-day operations of armed services or research agencies.

Professor King said the question of motivation for policies is of less interest than the acceptable outcomes of the policies.

Staff Report: Human Experimentation in Connection with Atomic Bomb Tests. *Gregg Herken and Dan Guttman.*

Dr. Herken summarized the history of atomic weapons tests within the continental United States, a total of more than 900 tests until 1963. He traced the differences between the military and the Atomic Energy Commission on troop exposure rules, leading to military agencies taking responsibility for radiological safety in the maneuvers. Mr. Guttman said that the Joint Panel on the Medical Aspects of Atomic Warfare appears to be increasingly central to the question of human subject experiments at weapons sites.

Mr. Guttman said records indicate that vision tests were included in the biomedical component of the tests in 1951-53, and studies at Walter Reed Army Institute of Research were conducted in connection with the Teapot test series in 1955. The tests were discussed in Congressional testimony in 1959. Tests involving cloud fly-throughs grew out of a 1948 accidental exposure of an aircrew. Mr. Guttman said many questions remain about what procedures were used in the operations; what other ethical debates occurred; and, what group or groups inherited responsibility for the planning after the Joint Panel was discontinued in 1953.

Members discussed how to define biomedical experimentation in the weapons testing program, including psychological testing in troop maneuvers. Dr. Macklin suggested that exemptions from the Wilson policy for occupational exposures may have allowed the Department of Defense to avoid acknowledging that it was conducting research. Dr. Oleinick noted the repeated exposures as part of the cloud fly-throughs, and suggested that a reasonable question is how many were necessary.

Dr. Russell observed that the military was having parallel discussions about combat effectiveness at the time, and Dr. Royal said that measuring radiation dosages may suggest an

appropriate concern for pilot safety.

Staff Report: Management Theme/Pilot Case Study. Oak Ridge and Los Alamos. *Donald Weightman and Barbara Berney.*

Mr. Weightman discussed goals of in-depth looks at key institutions involved in radiation research. Staff work in this area is intended to show how decisions were carried out in the field, why specific projects were undertaken or rejected, and get a range of perspectives on how work was actually done across a variety of types of work at the time. He traced findings about gallium 72 studies in 1950-53 at Oak Ridge Institute for Nuclear Studies.

Oversight roles for the gallium studies were more difficult to assess in light of gaps in the records of various committees. Dr. Royal noted that a stable isotope of gallium is routinely used today in diagnostics, and Mr. Weightman said that point addresses the issue of knowledge -- the gallium 72 study didn't work out but may have expanded the base of knowledge that aided in development of subsequently successful interventions. Not enough information is available to determine the scope of toxicity studies.

Dr. Macklin asked about the distinction between waivers and consent forms at Oak Ridge. Jonathan Harkness of the staff reported that a 1958 Irving Ladimer thesis explained that Oak Ridge brochures explicitly required a commitment to a period of research as a condition of hospital admission.

Dr. Berney discussed Los Alamos research focusing on weapons development, the principal mission of the facility, and protection of the workforce of the weapons facilities. A number of intentional releases took place, but frequently with minimal exposures to human beings.

A number of sets of experiments conducted in Los Alamos had wider implications: experiments with chelation agents and experiments with radioactive iodine were among the portfolio. There is currently no evidence of motivation other than basic science for extensive tracer experiments and metabolism studies.

Many employees were used as experimental subjects, and some of them report that they were knowledgeable and consenting volunteers. When employee volunteers reached limits of permissible exposure, Los Alamos turned to outside institutions like the Kiwanis Club. Need for secrecy militated against use of outsiders at the weapons complex, but there is little information about how or whether indigent patients at the hospital or other subjects were informed of experimentation. A process was established to approve experimental proposals, but records are not clear on informed consent issues.

Dr. Royal said that a CNN documentary aired this spring included interviews with experiment subjects who are children of researchers. Dr. Faden said the staff would seek a tape for the Committee.

Staff Report: Update on Agency Data Collection Efforts. *Ruth Faden.*

Dr. Faden reported on the status of agency record searches in the National Aeronautics and Space Administration, Departments of Veterans Affairs, Health and Human Services and

Defense. Dr. Faden noted that Denise Holmes has found new information in the Stafford Warren papers in Los Angeles, and the material will be digested for the next meeting. Dr. Faden said the Defense Nuclear Agency in particular has found significant new records, and Health and Human Services has devoted more staff to records searches in the Cold War period. Charles McCarthy has joined the staff as a consultant to assist in the Health and Human Services research.

The Department of Energy has begun contacting universities involved in plutonium injections, but also has reported that records of the AEC/Energy Intelligence Division are likely to have been destroyed. Energy and Defense have facilitated the flow of formerly declassified material.

Mr. Stern reported on the data collection efforts at the Central Intelligence Agency. The CIA had previously reported to the Committee that it could find no records of CIA-sponsored experiments involving human experimentation with ionizing radiation, or records relating to experimentation by other agencies. New records from the Defense Department indicate that the CIA was an associate member of the Defense Department's Committee on Medical Sciences, and representatives of the CIA appear to have attended meetings of that Committee and the Joint Panel on the Medical Aspects of Atomic Warfare relating to human experimentation. The Committee has asked the CIA to pursue this new information by searching for relevant documents.

Subcommittee Report: Oral History. *Susan Lederer.*

Dr. Lederer briefed members on the questions for the oral history project, which is expected to gain IRB approval by the end of September. She emphasized the effort to gain perspectives from practitioners in different types of research, e.g., surgical research, infectious diseases, military medicine.

Members made suggestions about phrasing of questions and suggested inquiring about experimentation with children of interviewees as subjects. Dr. Lederer said the questions may be revised after initial experiences with interviews, and Dr. Katz suggested that the first transcript be promptly circulated to members for feedback on additional questions that might be added.

Subcommittee Report: Protocol Review. *Ruth Macklin.*

Dr. Macklin said the subcommittee's report includes the addition of a review of journal articles on research involving more than minimal risk. Members agreed that the study ought to include review of comparable studies involving agents other than radiation.

Dr. Kahn reported on the gathering of abstracts from agencies. Health and Human Services provided significant material. NASA has not sent the abstracts requested, the Department of Energy has provided abstracts, Veterans Affairs provided little information to date, and the Department of Defense reported that its abstracts will have been provided by September 13.

Dr. Macklin outlined the considerations for selection of protocols to be surveyed and the criteria for assessing the protocols. The process will include the request of information from the IRBs involved in protocols of interest.

She added that the study will allow for a comparison of radiation research with other human research.

Members discussed motivations for patients to engage in studies or in control groups, in the case of those for whom treatment is not indicated; definitions of clinical practice, risk factors and disadvantaged populations.

Professor King questioned the usefulness of a review of journal articles, and a decision on the issue was postponed until the next conference call of the Protocol Review Subcommittee, in which Dr. Thomas and Professor King would join.

Professor King noted that time frames should be included with every subcommittee report because of the time pressures facing the Committee.

Subcommittee Report: Outreach. *Reed Tuckson.*

Dr. Tuckson reported on the Outreach subcommittee's plans for an extended public comment period at the October meeting in San Francisco. The first panel hearing was set for October 21 in Cincinnati, coinciding with the meeting of the Task Force on Radiation and Human Rights.

Dr. Tuckson praised the assistance of the Task Force in the work of the Committee. The subcommittee will continue to look for ways to further collaborate with the Task Force and others.

The subcommittee proposed panel hearings in Spokane, Washington, Monday, November 21; Santa Fe or Albuquerque, New Mexico, Monday, January 30; Nashville, Tennessee, Friday, March 24.

Professor King emphasized that the public hearings be seen as open to all points of view, gathering information to generate a range of perspectives for the Committee.

She suggested that the March 24 meeting may be late for input, and the subcommittee agreed.

The staff will consider, after the interim report is released, whether a summary or fact sheet should be distributed after each Committee meeting to keep interested parties informed of Committee activities.

Members agreed to contact Communications Director Stephen Klaidman with dates on which they can participate in panel hearings.

Public Comment

Ruth Blaz, Hollywood, Fla. Mrs. Blaz addressed the Committee about the medical problems her son has endured since a 1947 radiation treatment. She read into the record a statement by her son, Joel Blaz. Mrs. Blaz made copies of her son's medical records available to the Committee.

Cliff Honicker, Environmental Health Studies Project, Knoxville, Tenn. Mr. Honicker presented a series of documents regarding postwar federally funded experiments at the Medical College of Virginia, which had been the subject of presentations at the July 25-26 meeting. Mr. Honicker said he would share copies of the documents with the Committee.

Mrs. Frances Brown, Southwick, Mass. Mrs. Brown told the Committee of her late husband's experience as a navigator who flew through clouds at weapons tests. She said Colonel Brown was assigned the duty and was given no protective clothing; he died of cancer in 1983.

Tod Ensign, Citizen Soldier, New York, N.Y. He urged the Committee to pursue more information about groups of volunteer officers who were placed near atomic blasts. He said that volunteer officers were too near ground zero for other than physical-effects experimentation.

Mr. Ensign said the Committee should recommend compensation for persons who can demonstrate radiogenic cancers as a consequence of federally funded exposures.

Pat Broudy, National Legislative Director, National Association of Atomic Veterans. Mrs. Broudy presented to the Committee a set of documents relating to radiation exposures at Marshall Islands and Nevada atomic tests.

September 13, 1994

Attending: Ruth Faden, Kenneth Feinberg, Eli Glatstein, Patricia King, Susan Lederer, Ruth Macklin, Lois Norris, Nancy Oleinick, Henry Royal, Philip Russell, Mary Ann Stevenson, Duncan Thomas.

Subcommittee Report: Subject Interview. *Ruth Faden.*

Dr. Faden said the subject interview program is under review by the Office of Management and Budget, as required by the Paperwork Reduction Act. The subcommittee will conduct three sessions with oncology specialists to solicit ideas about how to better conduct the project. The Committee agreed that in the interest of time minor changes in the project suggested by the specialists panels could be incorporated into the project without bringing the matter back to the full Committee.

Subcommittee Report: Intentional Releases. *Duncan Thomas and Nancy Oleinick.*

Dr. Oleinick reported that data gathering continues. The subcommittee is looking with special interest into following up documents relating to human experiments during atomic bomb tests, particularly what troops were told and how data from exposures were evaluated. Indoctrination materials and reports of what was learned are of interest.

The subcommittee proposed using the 1965 KIWI nuclear rocket test at Los Alamos as a case study. The test provides considerable available information, involved a number of agencies, and included at least some surveying of exposure to pilots of airplanes flying through clouds.

Dr. Thomas said the volunteer observer program at weapons tests deserves close study.

Dr. Oleinick said the Committee's purposes require the targeting of its research as narrowly as possible to generate enough information to evaluate how biomedical tests were carried out and how the knowledge gained was used by government or scientists. Dr. Faden said the Committee's charge requires a focus on issues involved in human subject experimentation, rather than being drawn too far afield.

Subcommittee Report: Biomedical Experiments. *Mary Ann Stevenson and Henry Royal.*

The subcommittee reported that it has worked with analyses of dosimetry contributed by staff and members, but the subcommittee feels that the available dose information is generally insufficient to evaluate the level of risk in many experiments. Ethical evaluations of experiments, as a general rule, are not likely to be easily determined on the basis of clear examples of inappropriate dosages.

The subcommittee proposed circulating a document which summarizes different points of view about the information available from case studies of total body irradiation and plutonium injection experiments. The Committee approved the proposal.

Dr. Macklin questioned how researchers made ethical decisions in the 1940s and 1950s, if today's knowledge does not make clear what dosages are dangerous. She said that medical professionals should have acted with great caution and a more conservative approach to dose levels. Dr. Stevenson said that there was a much more substantial body of knowledge about high-dose effects soon after exposure, but much less sophisticated knowledge of radiogenic carcinogenesis, although some information was available to researchers and their government employers. Dr. Royal observed that the fundamental reason for research is to probe the unknown.

Briefing: Radiation Dosages. *Henry Royal.*

Dr. Royal briefed members on how doses are estimated, how radiation affects different organs, and how experimental exposures might be evaluated. He noted how difficult it is to do dose reconstruction, and listed areas of concern in the record of the Cincinnati and plutonium injection experiments before the Committee.

Members questioned Dr. Royal about the determination of levels of risk in occupational exposures; harm and benefit ratios; medical uncertainty and its impact on research decisions.

Committee Discussion: Harms and Risk.

Members discussed how judgments could be rendered in cases where experimental subjects were exposed to little or no measurable risk of harm. Mr. Feinberg said that a lack of a clear dividing line on harms may make a difference in how Committee members approach their judgment about remedies.

While risk is most often calculated in terms of excess deaths, Dr. Macklin said that remediable injury may be defined in other terms. Dr. Royal said that there are calculations that can be made about the detrimental effects of exposures other than fatal effects, but that the decrement is very small in the type of exposures common in medical research.

Dr. Stevenson said the limited time available to the Committee for its work suggests that complex dose reconstructions must be limited to cases where there is good reason to believe such a study is necessary.

Staff Report: Classification of Documents. *Don Weightman.*

Mr. Weightman briefed members on plans to review classified material and decide whether to target specific documents or collections for agency declassification efforts. Only two staff and one Committee member have obtained security clearances so far.

Members with clearances may be asked to participate in document reviews from time to time.

Staff Report: Draft Interim Report Outline. *Anna Mastroianni.*

Anna Mastroianni reported that a staff draft of the interim report will be circulated to members for review before the October meeting. Dr. Faden said that the report is a progress report and will not draw conclusions about issues before the Committee.

Mr. Guttman said the report must include a projection of whether the Committee's work will be concluded on time. Professor King said the report should try to project a plan for completion of the project in April. Dr. Faden said that the Committee may need an additional few months to complete its final report.

Members suggested a separate section in the outline that would describe the interaction with agencies; and members suggested the draft include categories that group Committee activities in relation to general subjects that may be reflected in the final report.

Public Statement

Dr. Faden noted, in the interest of openness, that three members of the Committee -- Drs. Glatstein, Royal and Stevenson -- are members of the American College of Radiology. She also noted that Dr. Royal is listed as a coauthor with Eugene Saenger of articles on Chernobyl exposures, but that Dr. Royal and Dr. Saenger worked independently as part of an International Atomic Energy Agency study project. Dr. Royal submitted a letter for the record outlining the circumstances of the Chernobyl study, and Dr. Faden said the instances do not represent a conflict of interest for the purposes of the Committee.

Committee Discussion: Goals and Priorities. *Ruth Faden.*

Members discussed outstanding issues remaining to be decided at this meeting, falling generally into contemporary and Cold War sampling methods.

Contemporary period. Dr. Faden summarized the 1993 protocol review as the Committee's major study to meet the Committee's charge to review the ethics of a sample of existing human radiation research.

She said the journal review proposal would remain open to decision by the subcommittee with input of other members. Members agreed without objection.

1942-74 period. Dr. Faden said the Committee's work to date suggested numerous potentially profitable lines of inquiry.

These included: a case study of an institution or institutions, such as Oak Ridge; intensive study of controversial experiments and those intentional releases listed in the Committee charter; a sample of the extensive listing of biomedical experiments, e.g., learning everything possible about

the total body irradiation experiments; sampling or selecting studies of subject groups of interest, e.g., children or pregnant women; sampling or selection of experimental groups by the source of funding.

Members discussed strategies of how to generate useful information about the different categories of studies; the need to speak to issues raised in the public mind because of controversy surrounding some experiments; the need to link search priorities to prospective recommendations in the final report; and how to grapple with issues of management and funder influence in the direction of experiments.

Dr. Faden said a consensus suggests doing one intensive study of a national laboratory and one intensive study of a veterans hospital/university site, such as the University of California at Los Angeles. Professor King asked that the staff be directed to develop a recommendation about whether to undertake a third study, either another national laboratory or a special institution like the School of Aviation Medicine. Dr. Faden said that, in the interest of saving time, there may be a fax-poll of members about appropriate institutions for in-depth study.

Several members said that the role of children as subjects should be given major emphasis in the final report. Professor King and Dr. Stevenson were asked to work with Dr. Sandra Thomas of the staff to determine whether sufficient information will be available to support such a study.

Dr. Faden asked members to rank their suggested priorities among the potential lines of inquiry discussed for the 1942-74 period. Members discussed the resources of time and staff available for various options, which were ranked as follows: 1. Well-publicized Studies/Charter-stipulated Releases. 2. Institutional Case Studies (2). 3. Sampling/Selection within Biomedical Groups (Total body irradiation; biodistribution; tracers; radiation therapy and diagnosis; experiments of opportunity); 4. Sampling/Selection by Subjects: Children. 5. Sampling/Selection by Agency: Funding.

Dr. Faden summarized the discussion as authorizing the staff to proceed with a detailed proposal for two institutional case studies, with perhaps a third to be determined. The staff was directed to circulate a list of heavily publicized experiments which require detailed analysis. Members agreed to the need to address issues raised by intentional releases in the Committee charter. In cases where there are heavily publicized experiments to deal with, every effort will be made to provide as much background as possible to provide a context for judging the appropriateness of the activities.

To be pulled together before the next meeting is a report on children as a special case study, and Dr. Thomas and Dr. Berney of the staff were asked to consider an appropriate way to sample the world of biomedical experiments provided by government agencies.

Dr. Faden said that for the moment, subcommittees would continue in their present structure, in addition to the subcommittee on Subject Selection/Children, on which would serve Dr. Faden, Professor King, Dr. Stevenson and Dr. Lederer.

Mr. Caplan closed the meeting at 3 p.m.

Meeting of October 11-13
Tuesday, October 11, 1994

Attending: Ruth Faden, Susan Lederer, Ruth Macklin, Lois Norris, Nancy Oleinick, Henry Royal, Philip Russell, Mary Ann Stevenson, Duncan Thomas, Reed Tuckson.

As the designated Federal official, Executive Director Dan Guttman opened the meeting at 2 p.m. Tuesday, October 11, at the Press Club, 555 Post Street, San Francisco. Dr. Faden briefed the public about the background of the Committee. Dr. Faden noted that the meeting is in San Francisco to hear from citizens who might be unable to go to Washington, D.C., where Committee meetings are usually held.

Dr. Faden noted that Drs. Eli Glatstein and Jay Katz, and Professor Patricia King were unable to attend the meeting. Mr. Ken Feinberg joined the Committee on Wednesday.

Subcommittee Report: Oral Histories. *Susan Lederer.*

Dr. Lederer said two interviews have been completed and are being transcribed and submitted for approval to interviewees; these will be distributed to members for comments and suggestions. The interviews may help to provide a fuller portrait of ethical practices in 1944-74 by the November meeting. Dr. Lederer said there are opportunities to follow up with questions to interviewees.

Mr. Guttman reported that interviews conducted by the staff to investigate specific experiments would also ask about the core concerns in the oral history project.

Dr. Thomas asked that a full list of interviewees from both projects be provided by the staff. Dr. Lederer said that interviews conducted by government agencies would be obtained where they can assist the Committee's efforts.

Subcommittee Report: Subject Interviews. *Ruth Faden.*

Jeremy Sugarman reported on the interview project, which has benefited from consultations with three panels of medical professionals. Sites will be selected that include a major research medical university, Veterans Health Administration hospital, community hospital, a national laboratory or research facility, and/or a military hospital.

Dr. Sugarman said the Committee has obtained Office of Management and Budget clearance under the Paperwork Reduction Act, and received information from funding agencies needed for selecting institutions. The Department of Energy expects its procurement paperwork to be done soon.

Dr. Faden said the institutional review boards' clearance at participating institutions will be done as quickly as possible. She said there was a gratifying level of support from physicians consulted about the process.

Subcommittee Report: Research Proposal Review. *Ruth Macklin.*

Dr. Macklin reported that after lengthy discussion the subcommittee, joined by Professor King and Dr. Thomas, decided against identifying research projects for review based on an analysis of the published literature. Dr. Macklin briefed members on the review of research proposals. Members agreed to include proposals involving tissue samples drawn for research after the subjects were exposed to ionizing radiation.

At the suggestion of Dr. Thomas, members agreed to a strategy of quota sampling, in which proposals initiated as early as 1990 may be included in order to obtain an adequate number of proposals in each category of interest. Specifically, the Committee agreed to anchor the study in FY93 and work outward to reach a goal of at least five studies in each cell of the sampling chart presented by the subcommittee.

Members discussed composition of teams for review of proposals. Dr. Macklin said that as many Committee members as possible should begin working on the review so that the Committee as a whole can reach informed conclusions. Dr. Thomas said it is important that multiple reviewers identify the relevant issues so that fairness can be assured.

Dr. Macklin suggested that a pilot of a few proposals be done as soon as possible to provide guidance about time required for the reviews and what difficulties arise in the process.

Subcommittee Report: Outreach. *Reed Tuckson.*

Dr. Tuckson noted that the Committee and staff work required in a West Coast meeting, and the extension of the meeting to involve four hours of public comment on October 12, demonstrates the importance the Committee assigns to outreach. He reported that Dr. Faden and others met with the editorial board of the San Francisco Chronicle, and that members would be asked to visit editorial boards in other cities to ensure that the public is aware of the Committee's work.

He reported that small panel meetings are scheduled for Cincinnati on October 21, Spokane on November 21 and Albuquerque/Santa Fe on January 30. He said the staff continues to work daily with interested parties to maximize communication and cooperation.

Committee Discussion: Agency Updates. *Ruth Faden.*

Dr. Faden reported that the Committee continues to receive a substantial amount of cooperation from agencies in their searches for relevant information, although she noted that most

public discussion tends to focus on remaining difficulties. These include working closely with the Department of Energy to complete descriptions of record collections, and with the Department of the Army to get records from key headquarters, including the Chemical Corps, as well as documentation from experiments already identified.

The Department of Health and Human Services is working on a more useful list of experiments from its radiation study division from 1944-74, and reports from the Clinical Center from 1954-74. The Committee has asked NASA for its list of experiments and supporting documentation, and the agency expects to complete that task, originally scheduled for September 23, at some date in November. The Department of Veterans Affairs has had limited success in finding relevant Central Office documents, and it will be shifting its focus to key field sites.

Subcommittee Report: Biomedical Research. Selection of Case Studies. *Duncan Thomas and Barbara Berney.*

Dr. Berney reported that the staff and subcommittee have concluded that random sampling of experiments is not useful as a strategy because of the fragmentary nature of much of the data from experiments of 1944-74. The subcommittee recommended that experiments be grouped into categories for purposes of intensive study, and members debated the rationale for grouping experiments together. Mr. Guttman and Dr. Faden noted that a great deal of discovery remains to be done within proposed categories.

Members discussed at length the ethical issues brought into focus by the categories proposed, and the evidence available to deal with the issues in each category. Members approved four categories:

Biodistribution experiments, such as plutonium injections and other experiments related to the toxicology of transuranic elements. Experiments in this area include uranium injections in comatose patients and tests of chelating agents.

Total body irradiation (TBI) experiments in Cincinnati and elsewhere.

Experiments involving or affecting children and pregnant women, as at Nashville, Boston and elsewhere.

Radioisotope research with both therapeutic and diagnostic intentions, and which may have involved fallout research.

Members deferred approval of a fifth category, boron neutron capture therapy, until a full presentation can be made at the November meeting. Members agreed to discuss on October 13 the category of testicular and other partial-body irradiation that was performed without therapeutic intent, as in the Washington and Oregon prisoner experiments.

October 12, 1994

Attending: Ruth Faden, Ken Feinberg, Susan Lederer, Ruth Macklin, Lois Norris, Nancy Oleinick, Henry Royal, Philip Russell, Mary Ann Stevenson, Duncan Thomas, Reed Tuckson.

Public Comment Period

Dr. Faden briefed members of the audience on the work of the Committee. The Committee heard from the following persons during its extended public comment session:

Mrs. Nancy Lynch, Santa Barbara, California. She briefed members on the case of her late husband, involved in Operation Teapot in 1955. She said the first victim of radiation experiments is the truth, and explained her difficulties in getting records and satisfaction from government agencies.

Dr. Thomas questioned Mrs. Lynch about reasons for denial of VA claims, and Dr. Tuckson asked her to send the Committee more information on that issue because of its potential relevance to the work of the remedies subcommittee.

Mrs. Jackie Maxwell, Menlo Park, California. She testified concerning the genetic defects suffered by her children with her late husband, a prisoner of war forced to work in the immediate fallout of Hiroshima in 1945.

Mr. Vernon Sousa, San Francisco. A veteran of the Defense Atomic Support Agency, Mr. Sousa said that test events at Sandia base have been covered up by the government. Dr. Tuckson questioned Mr. Sousa about the secrecy rules in effect at the time of the incidents, and Ms. Norris inquired about service and medical records.

Mrs. Gwynne Burroughs, Chico, California. Mrs. Burroughs spoke to the Committee about medical problems she ascribed to exposure as a child at Sandia base in the late 1950s.

Mr. Israel Torres, Nipomo, California. Mr. Torres told members of his experiences as a Marine at Camp Desert Rock atomic weapons tests. He said that he was the subject of extensive medical monitoring following the tests.

Mrs. Audrey Hack, Union City, California. The widow of a Marine who served in Nagasaki in 1945, Mrs. Hack commended the Committee for its research and urged the Committee to add to its membership a victim of radiation exposure. She said that the Committee's experts should also include some members from universities with no history of involvement in radiation research.

Mr. Richard Harley, Bakersfield, California. Mr. Harley is a Navy veteran of the first H-bomb test in 1952 and detailed his medical and psychological difficulties since.

Mr. Donald Arbitblit, San Francisco. Attorney for the plaintiffs in the class action lawsuit about Vanderbilt tracer experiments, Mr. Arbitblit provided the Committee with statements and a videotaped deposition regarding the case. He asked the Committee to urge Vanderbilt University to release names of all patients who may have been subjects in the 1945-47 experiments at the university's clinic.

Geoffrey Sea, Oakland. Mr. Sea, a radiological health physicist working on the Vanderbilt litigation for the plaintiffs, stated that he was speaking as an individual and founder of International Radiation Injury Survivors. He urged members to pursue vigorously evidence of exposures that may have been covered up by government agencies.

Mr. Harold Bibeau, Portland, Oregon. Mr. Bibeau briefed members on his experience as a subject in the Oregon prison experiments. Members questioned Mr. Bibeau about issues of consent and disclosure by the investigator, the late Dr. Carl Heller.

Mrs. Cherie Anderson and Mr. Tom Wilson, Placerville, California. Mrs. Anderson and Mr. Wilson briefed the members on problems with radium treatments that occurred in childhood. They urged members to find why the government approved such therapies, why they were

discontinued, and how these experiences helped define what is experimental and what is a typical medical procedure.

Michael Yesley, Los Alamos National Laboratory (LANL). Mr. Yesley briefed members on informed consent policies at LANL discovered by the laboratory's Human Studies Project Team. Dr. Royal asked Mr. Yesley to provide a tape of a CNN report which included interviews with children tested. In response to a question from Mr. Guttman, Mr. Yesley said he had no information about destruction of records at Los Alamos Medical Center.

Lynn Stenbridge, Hanford Education Action League (HEAL), Spokane. She briefed members on the Green Run and other exposures at Hanford and urged the Committee to make every effort to bring to light still-classified documents regarding the exposures. She also urged that the Committee recommend a formal apology to citizens by the government of the United States.

Trisha Pritikin, Berkeley, California. A Hanford downwinder, Ms. Pritikin provided the Committee with documentation about finding further information on Hanford releases. She urged the Committee to recommend remedies for downwinders that include medical monitoring, no-cost health care and compensation for pain and suffering.

Lois Camp, Hanford Downwinder Health Effects Group. Mrs. Camp briefed members on health issues related to the downwind exposures and urged close study of research involving students in Richland-area public schools. She urged the Committee to see that all health-related information is immediately declassified. She praised the work of the Committee but added that its work could be improved by the addition of persons immediately affected by experiments and exposures.

Darcy Thrall, Richland, Washington. Ms. Thrall related her experiences as a schoolchild involved in an apparent research study in Richland. She reported threats and other harassment as a result of publicly raising questions about the purpose of these unexplained activities.

Dr. Bernard Lo, San Francisco. Dr. Lo, professor of medicine at the University of California at San Francisco, reported on the efforts of the UCSF committee to investigate experiments performed under the university's auspices. He said the UCSF committee will make its findings public and available to the Advisory Committee. Members questioned Dr. Lo about ethical standards and the search process by the UCSF committee.

Jackie Cabasso, Oakland, California. The director of the Western States Legal Foundation, which advises nuclear and environmental activists, Ms. Cabasso urged the Committee to use an expansive definition of "experiment" because of the wide range of radiation exposures.

Marylia Kelly, Livermore, California. Mrs. Kelly, representing a Livermore citizens group, called for the Committee to recommend a comprehensive sampling program around nuclear facilities. She stated that many radiation exposures were for experimental purposes, whether in a clinical setting or in an environmental release.

Dr. Faden thanked members of the public for their presentations and asked that they communicate with staff members to provide additional documentation for the Committee.

Staff Report: Case Study, Plutonium Injections. Gregg Herken and Jonathan Moreno.

Dr. Herken outlined the story of the 1946-47 series of transuranic injections. He reported

on the distinction drawn in an interview with one of the researchers, Patricia Durbin, between the case of Cal-1, in wartime, and the cases Cal-2 and Cal-3. While Cal-1 could be described as science in service to the state, the two later cases were said by Dr. Durbin to be research efforts to find "the magic bullet" against cancer. Other injections through 1950 were argued as fitting into the second category. All occurred after elaboration of some consent standards by the Atomic Energy Commission.

Dr. Moreno discussed the ideas of clinical research standards relative to subjects under current human subjects protection regulations (45 CFR 46). He described the staff's exercise of developing the historical story as well as determining whether today's rules would permit the same experiments.

Members discussed issues of consent; the lack of prior review of experiments; the apparent lack of reliable diagnoses, and the highly public nature of the trip from Australia taken by Cal-2.

Members said the process of discussing the plutonium experiments was helpful and Dr. Faden said that the November meeting would include more discussion about ethical standards and retrospective judgments. Dr. Royal asked that papers be made available to members as early as possible in the process.

Staff Report: Institutional Case Study Selection. *Donald Weightman and Barbara Berney.*

Mr. Weightman presented the staff recommendations that Oak Ridge National Laboratories and the University of California's San Francisco Bay area institutions be selected as institutional case studies. He noted that research regarding other institutions which are being studied by staff (such as Los Alamos and the School of Aviation Medicine) would generate valuable material, and that those efforts would continue, but that the study of the interplay of institutional processes and research development would be concentrated at Oak Ridge and San Francisco.

Mr. Weightman said Oak Ridge's history represents a sizeable number of experiments and considerable mass of associated institutions and agencies. There is some documentation there as well about evolving levels of institutional review of human experimentation. Records review at the University of California complex in the Bay area includes institutions where the records search is well-advanced but significant questions remain to be answered.

Mr. Weightman also cautioned that neither time nor staff exists for a comprehensive look at such large institutions. Work would be targeted on specific times and experiments and determining how management and operational systems worked. The goal is a "vertical slice" through chains of command, funding sources, and research management at the experiment level.

Members approved the staff recommendation.

October 13, 1994

Attending: Ruth Faden, Ken Feinberg, Susan Lederer, Ruth Macklin, Lois Norris, Nancy Oleinick, Henry Royal, Philip Russell, Mary Ann Stevenson, Duncan Thomas, Reed Tuckson.

Subcommittee Report: Remedies. *Kenneth Feinberg.*

Mr. Feinberg presented a staff report outlining what has been enacted by Congress to compensate persons involved in mass exposures. The responses by Congress have been generally designed to remedy harms resulting from environmental releases; there is little precedent for those designed to deal with individual cases of radiation experimentation. There are a few examples of private legislation for particular cases, as in CIA experimentation involving LSD. The government tends to create statutory presumptions for cause, but compensation tends to be limited, almost on the model of workers compensation, Mr. Feinberg said.

Mr. Feinberg noted that most people who apply for claims are denied, and the claimants tend not to be happy with the programs.

The remedies subcommittee hopes to bring additional reports before the full Committee at the November or December meetings.

Dr. Thomas asked that staff inquire about the reasons that many claimants are denied under existing programs. He said that many common cancers are excluded from compensation because of cost, even though there is much evidence, as in the case of lung cancer, that specific cancers are associated with radiation exposure. Dr. Thomas said the radioepidemiologic tables have not been updated for ten years, and the remedies recommendations might well include a strong recommendation that the tables be updated.

Mr. Feinberg noted that an expansion of the presumptions in the black lung legislation resulted in compensation to more people than are known to have worked in the mines.

Subcommittee Report: Intentional Releases. *Nancy Oleinick and Duncan Thomas.*

Dr. Oleinick said that gaps in information remain a serious problem in assessing even the 13 intentional releases listed in the Committee's charter. Secrecy remains a serious problem. Dr. Oleinick asked that staff prepare a report on classification and why events of 50 years ago remain secret. Questions to be addressed should include why medical records from biomedical experiments remain secret and whether such events could occur today. Dr. Thomas said time is pressing for decisions on what secret documents to see and how to go about getting them.

Dr. Thomas recommended that a Green Run discussion at the November meeting be structured along the lines of the plutonium injections presentation on October 12.

Dr. Thomas said the Committee should also begin to think about the ethical principles involved in intentional releases. Disclosure issues may loom larger than informed consent in the clinical sense. Risk/benefit analysis includes the risk to populations rather than individuals. Dr. Thomas said that he will research the draft guidelines being considered by groups like the International Society of Environmental Epidemiology.

The concomitant issues include environmental impact statements. Today's regulations allow for secret EIS documents in cases of national security. The issues include whether a Green Run could occur today.

Dr. Thomas noted that there are much different perceptions of threat and national necessity in the post-Cold War era.

Members approved the subcommittee proposal to hear a November report in which members could assess whether the Green Run could occur today and whether the actions were appropriate by today's standards.

Committee Discussion: Interim Report. *Anna Mastroianni.*

Members were asked for their changes to the draft interim report circulated by Ms. Mastroianni. The report is to be released on Friday, October 21.

The section on boron neutron capture will be deleted from the interim report pending the November meeting. Members agreed that all should review the report on selection of case studies in biomedical research.

Issues targeted for revision included references to dose reconstructions; public policy on intentional releases; isotopes picked for inclusion in specific sections; total body irradiation; exploitable populations. Members discussed the categorization of research involving healthy adults in various circumstances, e.g. soldiers, prisoners. Members approved five general categories for investigation of biomedical experiments: external radiation with patients (formerly the TBI group, expanded to include partial-body irradiation); research with healthy adults (group to include research involving prisoners, military personnel, students and employees); children; radioisotopes; biodistribution.

Members asked that decisions taken in the October meeting be incorporated into the intentional releases section and the discussion of research proposal reviews.

Members asked that there be a strong statement that the archive to be left by the Committee is an important legacy. Records management details were included in an appendix.

Committee Discussion: Strategies and Direction. *Ruth Faden.*

Dr. Faden proposed groupings of members to both direct the staff and keep members informed between meetings. Dr. Royal asked that weekly or otherwise regular mailings would be made to members to keep them informed of the trend of discussions in other subcommittees.

Continuing are subcommittees dealing with intentional releases; outreach; remedies; oral history; research subject interviews and research proposal reviews. Five categories of biomedical research were discussed as potential working groups, and there are two institutional studies regarding Oak Ridge and the UC Bay-area complex.

Members discussed the idea of an ethical criteria subcommittee that would generate the criteria by which retrospective ethical judgments are made.

Members agreed to divide themselves into the following new subcommittees: ethical criteria; UCSF/Bay area case study; Oak Ridge case study; external radiation with patients (formerly the TBI group, now expanded to include partial-body irradiation); research with healthy adults (group to include research involving prisoners, military personnel, students and employees); children; radioisotopes; biodistribution. Dr. Faden also noted that all members will review contemporary research proposals at the same time.

Members organized themselves as follows:

Oral History. Lederer, Macklin, Russell.

Subject Interviews. Faden and Lederer.
Research Proposal Review. Katz, Macklin, Faden, Glatstein, Norris, Royal, Stevenson, Thomas.

Ethical Criteria. Macklin, Norris, Thomas.
Bay Area Case Study. Lederer, Stevenson.
Oak Ridge Case Study. Oleinick, Lederer, Russell.
Biomedical Experiments/Biodistribution. Royal.
Biomedical Experiments/External Radiation With Patients. Stevenson.
Biomedical Experiments/Radiation Research with Healthy Adults. Macklin, Stevenson, Royal, Thomas, Norris.
Biomedical Experiments/Research Involving or Affecting Children. Macklin, King, Stevenson.

Biomedical Experiments/Radioisotopes. Oleinick, Royal.
Intentional Releases and Exposures/Experiments of Opportunity. Oleinick, Thomas, Feinberg, Katz, Macklin.

Outreach. Tuckson, Macklin, Norris, Royal.

Remedies. Feinberg, King, Thomas.

Dr. Faden said absent members would be consulted about their choices. She said that the Committee should consider a few extra hours of scheduled discussions at each meeting, and the Committee agreed.

Mr. Guttman, acting as the designated federal official, closed the meeting at 11:30 a.m.

APPROVAL

The minutes above for the October meeting of the Advisory Committee on Human Radiation Experiments are correct and approved by members.

Ruth R. Faden
Chair

Minutes of November 14-15, 1994 Meeting

Tuesday, November 14, 1994

Attending: Ruth Faden, Kenneth Feinberg, Eli Glatstein, Jay Katz, Pat King, Ruth Macklin, Lois Norris, Nancy Oleinick, Henry Royal, Philip Russell, Mary Ann Stevenson, Duncan Thomas, Reed Tuckson.

Philip Caplan, special assistant to the President for Cabinet Affairs, opened the meeting at 9 a.m. in the Ballroom of the Renaissance Techworld Hotel, 999 Ninth Street NW, Washington, D.C. Dr. Faden briefed members on the objectives of the meeting and noted that the Public Comment Period would be held on Wednesday morning.

Approval of Minutes

The Committee approved the minutes of the October 11-13 meeting as drafted.

Agency Updates

Dr. Faden briefed members on the continuing dialogue with agency search teams. She reported that the staff plans to meet soon with the Central Intelligence Agency. Records reviews continue at the National Archives and at the Department of Energy complex at Oak Ridge.

She reported that large and important collections remain to be reviewed from the Department of Defense, and that the Department of the Army has agreed to review Chemical Corps records.

The inspector-general of the Department of Veterans Affairs has become involved in the search for records of the atomic medicine division in VA. The Department of Health and Human Services has engaged a contractor to search for additional data on lists of experiments sponsored by the radiation studies section before 1974. Records of intramural research at the National Institutes of Health Clinical Center should soon be available on an electronic database.

Dr. Faden noted that all agencies have been cooperative in efforts to provide research proposals from the 1990s for Committee sampling of contemporary studies.

Staff Report: Subject Interview Study. *Jeremy Sugarman and Nancy Kass.*

Dr. Sugarman reported on the subject interview study, including criteria for selection of institutions. Dr. Sugarman will be identifying experts in each region who can participate in multicenter investigations. Each investigation will be submitted to a local IRB. A modified task order for contractors and a general budget has been presented to administrative officials of the

Department of Energy.

Dr. Kass said that focus groups have helped to develop instruments for the subject interviews. A draft instrument should be available by the March meeting of the Advisory Committee. The goal of the project is to conduct about 150 shorter interviews at each institution, leading to the selection of 10 to 15 subjects for in-depth questioning.

Dr. Sugarman emphasized that the staff and Committee are working against a deadline and said that every effort will be made to expedite the budgetary and IRB processes.

Staff Report: Introduction of New Staff. *Jeffrey Kahn.*

Dr. Kahn introduced new staff and consultants to the Committee. These included Consultants Steve Goodman and John Till, Research Analyst Wilhelmine Miller, Research Associates Valerie Hurt and Pat Perentesis.

Briefing: Historical Relativism and Retrospective Moral Judgment. *Ruth Macklin.*

Dr. Macklin briefed members on standards of judgment of historical events, outlining a spectrum of possibilities ranging from the strict view that actions may be assessed in the context of what agents ought to have known, and a more lenient view that judgment may be based only on prevalent standards of the times. She outlined three examples of ways retrospective moral judgments may be framed between the two extremes: (1) judgments based on the articulated if not widely accepted views of the time, e.g. abolition in the 1850s; (2) judgments based on known principles or ideals accepted in other spheres but not necessarily in the field under scrutiny, e.g. a right to privacy recognized before its elaboration on sexual matters in the *Griswold* decision; (3) known principles or ideals to which lip service has been paid in a society which does not in fact follow the same standards in practice, e.g. the written consent standard of the Nuremberg Code.

She said the Committee's task included not only deciding which criteria to use, but also decisions about to whom and where in an organization the criteria might apply. One important guide might be to search for analogies elsewhere in medicine than radiation research, e.g. the longstanding practice of infectious disease researchers involving themselves as subjects in studies.

Committee members discussed at length the distinction between a judgment that wrong actions were taken and that agents of the action were in fact morally culpable. Other issues raised included the diffusion of ethical standards through societies and professions, and the varying levels of sophistication by which ethical issues are addressed; the importance of policy pronouncements like the Defense Department's adoption of the Nuremberg Code in 1953; accountability in government; and the importance of greater or lesser physical risk in research.

Staff Report: Case Study of Radiation Research with Health Adults. *Jon Harkness and Stephen Klaidman.*

Mr. Klaidman reported on the origins and development of testicular radiation experiments in Oregon and Washington state prisons. He said new documentation has been recently made available from state archives, including documents on why state prison officials ended access to

prisoners for experimentation. The documents give insights into the quality of the ethical debate, especially 1969-70 concerns about quality of consent on the part of prison volunteers.

Dr. Harkness said experimentation on prisoners was approved by the American Medical Association under a committee headed by Andrew Ivy in the wake of the Nuremberg trials. Many prisoners historically were eager to participate, and white prisoners were predominantly used because of racist tendencies to reserve such "privileges" for whites.

He traced the development of national concern about prison experiments and the development of federal regulations for prison experimentation.

Dr. Katz observed that consent is the prominent issue, as investigator Carl Heller conceded in a federal court deposition that he did not wish to frighten subjects with warnings about cancer risk. Dr. Macklin and Dr. Russell said the prison experiments require Committee scrutiny because of questions about consent.

Dr. Oleinick said an interesting component of the prisoner story is the debate over standards for neutron experiments as against the standards for X-ray experiments. Dr. Royal said the imagery of irradiating testicles would make the experiments unlikely to be approved today, although the risk of harm would probably not be very different from permissible studies.

Dr. Glatstein said the prison studies are practically all that is available today on the effects of radiation on testicular function and fertility, and that large-animal studies were unlikely to have yielded data useful for understanding human functions.

Members discussed goals of discussion of case studies and the value of guidelines arising from past experience, and questioned Mr. Feinberg about the legal implications of the discussion.

Subcommittee Report: Cincinnati Panel Meeting. *Reed Tuckson.*

Dr. Tuckson said the Cincinnati meeting was an important contribution to the Committee's outreach efforts to institutions and advocacy organizations.

Dr. Tuckson said a key concern was the lack of information about patient care reported by family members of subjects of the Cincinnati General Hospital experiments. Family members also questioned the validity of end-state prognoses cited by investigators who selected the subjects for the study. Assurances were received from the University of Cincinnati that all records would be made available to families or survivors.

The panel, consisting of Dr. Tuckson, Dr. Stevenson and Mrs. Norris, also heard from veterans of atomic weapons tests, some of whom raised concerns about the interaction between the military and the Veterans Administration in determination of disability benefits. Some comments, about exposures in the atomic weapons industry, raised issues that may not be within the Committee's scope, but contribute to the overall story, Dr. Tuckson said. Tissue sampling programs were criticized by a labor union representative.

Dr. Tuckson said the Outreach subcommittee strongly recommends that a similar meeting be held in Tennessee in the spring. Members expressed concern that the panel hearings not raise expectations of remedy in all subjects brought before them. Dr. Faden said an important element of advance work for the panel meetings is to make clear where the Committee is in its work and how its mandate is limited.

The Committee continues to seek first-hand accounts from survivors and family members

to contribute to its deliberations. Appropriate follow-up, such as helping subjects or family members to get medical records, is an important priority, Dr. Tuckson said.

Members approved the suggestion of a panel meeting in Tennessee.

Staff Report: Case Study of External Radiation Research with Patients. *Gary Stern and Ron Neumann.*

Mr. Stern and Dr. Neumann reported on the approximately 20 pre-1974 total-body irradiation (TBI) studies, with nine involving treatment of radioresistant cancers, with eight of the nine funded at least in part by the government. Military and aerospace authorities sought TBI data because of concerns about exposure of service personnel or civilians to atomic warfare. TBI was also of importance in the debate over development of a nuclear engine for aircraft.

Members discussed at length questions of consent, in particular whether Department of Defense policies should have applied to the Cincinnati research. Members also discussed the goals and objectives of the Cincinnati studies, as well as the written protocols, or lack thereof, for the work. Dr. Neumann and Mr. Stern outlined the evolution of consent forms in the Cincinnati studies.

Update: Research Involving or Affecting Children. *Sandra Thomas.*

Dr. Thomas briefed members on the existence of an estimated 100 radiation experiments involving pregnant women and healthy children. Most were identified through searches of public literature.

Update: Ethics Criteria. *Jeffrey Kahn.*

Dr. Kahn told members that a paper on retrospective ethical judgment will be distributed soon to members in preparation for the December meeting.

Update: Institutional Case Studies. *Dan Guttman.*

Mr. Guttman reported on progress of case studies in Northern California and Oak Ridge, and on other staff research at Los Alamos and elsewhere.

Update: Biodistribution. *Barbara Berney.*

Dr. Berney said identified experiments involving the transuranics and chelating agents are being thoroughly researched. Oral interviews with investigators at key institutions, and research into archives, are planned.

November 15, 1994

Attending: Ruth Faden, Kenneth Feinberg, Eli Glatstein, Jay Katz, Patricia King,

Ruth Macklin, Lois Norris, Nancy Oleinick, Henry Royal, Philip Russell, Mary Ann Stevenson, Duncan Thomas.

Subcommittee Report: Remedies. *Ken Feinberg.*

Mr. Feinberg briefed members on the subcommittee report. The subcommittee recommended that the goal of the Committee should be to draft remedies guidelines, for ultimate consideration by policymakers. Mr. Feinberg said a blueprint is the goal, to lay out a series of options for Congress or the Executive Branch to address areas of concern. The subcommittee recommended that any remedies recommendations should distinguish among the types of experiments, recognizing that experiments may have involved individuals or mass exposures, but he noted the prospect of divisiveness if recommendations make invidious distinctions among classes of victims.

Mr. Feinberg noted that, in law, it is difficult to impose culpability for acts done in the past in conformity with existing standards. He said that a key question is whether or to what extent recommended remedies should embrace the kind of retrospective moral judgment discussed earlier in the meeting by Dr. Macklin.

Mr. Feinberg said it is unlikely the Committee will be able to make judgments of medical causation of harms, given the passage of time and the limits of evidence and of Committee resources. Some presumptions about wrongs are likely to be necessary, but fashioning remedies for cases of violation of the personal integrity of patients, as in absence of consent, is likely to be very difficult.

While retributive justice may be difficult to fashion in a remedies chapter, Mr. Feinberg said it is his personal view that the Committee should consider a prospective remedy, such as guidelines for future violations of ethical standards.

Dr. Thomas, a member of the subcommittee, expressed the view that remedies may be different for different types of experiments or intentional releases, and that the Committee may wish to recommend revisions in legislation previously adopted by Congress.

Members discussed issues arising from the report, including the applicability of remedies guidelines to other types or research; the utility of medical monitoring in dealing with mass exposures; the scope of recommendations and fears of raising high expectations for substantial monetary compensation; the need for work on the conceptual framework for remedies.

Public Comment Period.

Mrs. Marcia Haggard, Silver Spring, Maryland. Mrs. Haggard related her experience with medical problems arising some 50 years after radium treatment on a childhood hemangioma. She urged the Committee to recommend followup for radium treatment victims.

Dr. Kathy Platoni, Beaver Creek, Ohio. Dr. Platoni reported on the death of her father, Eugene Platoni, and her own extensive medical problems arising from what he believed was exposure to radiation in Navy service. Her father told the family before his death that he had witnessed the atomic explosions at Hiroshima and Nagasaki.

Dr. Dennis Nelson, Kensington, Maryland. A retired military scientist and downwinder,

Dr. Nelson reported on the heavy fallout exposure in St. George, Utah, after the 1953 Shot Harry nuclear test. He criticized the Atomic Energy Commission and the government generally for failing to respond to medical problems suffered by downwinders.

Dr. Nelson offered a statement from the Task Force on Radiation and Human Rights urging the Committee to make recommendations for remedies.

Mayor George N. Ahmaogak and Mr. Rossman E. Peetok, of the North Slope Borough Assembly, Alaska. Mr. Peetok testified, through an interpreter, of medical problems of Wainwright, Alaska, residents who participated in a U.S. Army Aeromedical Laboratory I-131 study. Mayor Ahmaogak said Alaskans involved in Operation Chariot were subjected to intentional releases at Cape Thompson as well as experimental ingestion of radionuclides. The studies were conducted without informed consent, which was compromised by language barriers between the Inuit and researchers.

The mayor asked that the Committee look into the series of exposures and particularly inquire into the impact on a minority population. Members questioned the mayor about the communications or lack thereof that surrounded the tests, and the authority of village elders to provide informed consent.

Briefing: Environmental Dosimetry. *John Till.*

Dr. Till, head of the Hanford Dose Reconstruction Project, briefed members on the difficulties of reconstructing dose from environmental releases of radionuclides. He described the process of calculating dose from historical records, which are often in a chaotic condition. He said the project has found no dose estimates made at the Hanford site until the 1980s.

Staff Report: Case Study, Intentional Releases (Green Run). *Dan Guttman, Mark Goodman and Patrick Fitzgerald.*

Dr. Goodman briefed the Committee on the history of the Green Run and Professor Fitzgerald discussed the ethics analysis. Dr. Goodman discussed applicable environmental laws that might allow agencies to conduct a test similar to a Green Run today. The National Environmental Policy Act allows secret tests and the Clean Air Act allows the President to authorize exemptions to the act, without prior review, so long as Congress is notified annually.

Professor Fitzgerald discussed ethical concerns raised by the Green Run. Under today's laws, national security considerations can override Clean Air or other environmental laws, and decisions can be made in secret. Questions raised by the analysis include whether public or Congressional review is ethically necessary in cases of intentional releases conducted for national security reasons.

Dr. Royal recommended Justice Stephen Breyer's book on environmental regulation. Dr. Macklin said the traditional assessment of harms and benefits may not be a useful approach in intentional releases, but Professor Fitzgerald noted that the traditional method is what is pragmatically applied, below criticality thresholds, in today's exposure guidelines for the Department of Energy.

Dr. Glatstein questioned why part of the Green Run documents remain classified, and Mr.

Guttman noted that Senator Glenn of Ohio has written to the Department of Defense posing the same question. Members discussed dispatching cleared staff to review the classified portions of the documents. Members agreed that a member, other than Dr. Faden or Dr. Russell, should also review the material when appropriate clearances are obtained.

Subcommittee Report: Research Proposal Review Project. *Ruth Macklin, Sara Chandros and Gail Geller.*

Ms. Chandros and Ms. Geller briefed members on efforts to implement a quota sampling program for all categories of the proposal review. She said the staff is awaiting Department of Defense extramural proposals. Members discussed and suggested improvements to the review form.

Dr. Macklin asked that the Committee authorize the subcommittee to work out details about the form, and members agreed.

Committee Discussion: Strategy and Discussion. *Ruth Faden.*

Dr. Faden proposed that the December meeting be given over, other than the public comment period, to discussion of large and complex questions: retrospective moral judgments; remedies; interpretation of pre-1974 policies; interpretation of pre-1974 practices; national security and secrecy. The goal is a tentative working framework linking ethics criteria and remedies.

Dr. Faden said a super-subcommittee might be formed as a result of the combination of ethics criteria and remedies subcommittees, so that discussion papers for the December meeting can represent a crystallization of views in both areas. The super-subcommittee would also oversee the continuing research into pre-1974 ethics policies. Dr. Katz suggested that the staff prepare a report on what projects can be successfully completed to meet the Committee's charge.

Members also agreed to combine for purposes of guiding staff work the subcommittees overseeing Oak Ridge and Northern California case studies, and the subcommittees overseeing biodistribution and biomedical experimentation. A single subcommittee would also deal with external radiation for healthy adults and ill patients. Consideration of national security and secrecy issues will be overseen by the intentional releases subcommittee.

Members asked Dr. Faden to circulate a revised roster of subcommittees to members.

Dr. Faden said that members will be polled to see if an additional half-day of deliberations can be added to the regular meeting schedule in 1995.

Mr. Caplan closed the meeting at 5 p.m.

THE WHITE HOUSE
WASHINGTON

December 5, 1994

Anna Mastroianni
Advisory Committee on Human Radiation Experiments
1726 M Street NW
Suite 600
Washington, D.C. 20036

Dear Anna:

The White House Counsel received the attached FOIA request. After speaking with the Counsel's office, we thought it was appropriate for you to respond as the minutes are readily available from your office.

Please don't hesitate to call if you have any questions.

Thank you.

A handwritten signature in black ink, appearing to read 'Phil Caplan', with a stylized flourish extending to the right.

Phil Caplan
Special Assistant to the President for Cabinet Affairs

cc: Marvin Krislov
Assistant Counsel to the President

THE WHITE HOUSE
WASHINGTON

DATE: 12/2/94

TO: Phil Caplan

FROM: Marvin Krislov
White House Counsel
Room 128, OEOB, x7900

- ☐ FYI
- ☐ Appropriate Action
- ☒ Let's Discuss
- ☐ Per Our Conversation
- ☐ Per Your Request
- ☐ Please Return
- ☐ Other

WHITE HOUSE CORRESPONDENCE TRACKING WORKSHEET

☐ O - OUTGOING☐ H - INTERNAL☒ I - INCOMINGDate Correspondence Received (YY/MM/DD) 94 / 10 / 05Name of Correspondent: Patrick Small☐ MI Mail Report

User Codes: (A) _____ (B) _____ (C) _____

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Office/Agency (Staff Name)	Action Code	Tracking Date YY/MM/DD	Type of Response	Code	Completion Date YY/MM/DD
<u>CUMIKVU</u>	ORIGINATOR	<u>94, 10, 05</u>		<u>C</u>	<u>94, 10, 05</u>
<u>CUAT16 (Krisht)</u>	Referral Note: <u>A</u>	<u>94, 10, 05</u>			<u>1 / 1</u>
	Referral Note:				<u>1 / 1</u>
	Referral Note:				<u>1 / 1</u>
	Referral Note:				<u>1 / 1</u>
	Referral Note:				<u>1 / 1</u>

ACTION CODES:

A - Appropriate Action
 C - Comment/Recommendation
 D - Draft Response
 F - Furnish Fact Sheet
 to be used as Enclosure

I - Info Copy Only/No Action Necessary
 R - Direct Reply w/Copy
 S - For Signature
 X - Interim Reply

DISPOSITION CODES:

A - Answered
 B - Non-Special Referral
 C - Completed
 S - Suspended

FOR OUTGOING CORRESPONDENCE:

Type of Response = Initials of Signer
 Code = "A"
 Completion Date = Date of Outgoing

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5600 FISHERS LANE
RM 13C-24 PARKLAWN BLDG
ROCKVILLE, MD 20857

8/4/94

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PLEASE REFER TO OUR CONTROL NUMBER IN YOUR REPLY.

COPY OF THE MINUTES FOR THE HUMAN RADIATION EXPERIMENTS ADVISORY COMMITTEE MEETING HELD ON 4/21-22/94.

Sincerely,

A handwritten signature in black ink, reading "Patrick L. Small". The signature is written in a cursive style with a large, stylized "P" and "S".

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

May 6, 1994

MEMO FOR: Ms Christine Varney and Mr Phil Caplan

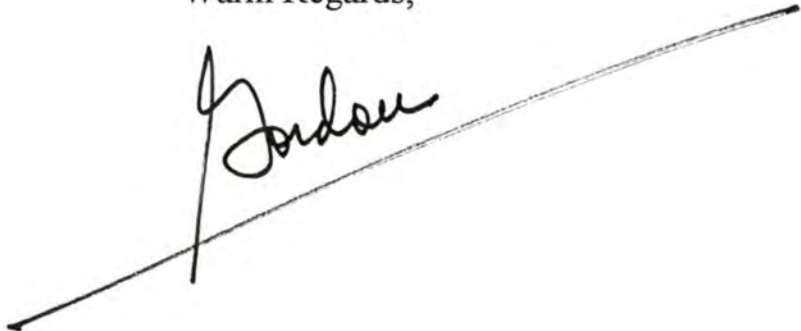
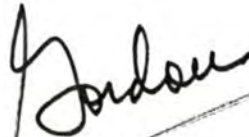
SUBJECT: Minutes of the first meeting of the Advisory
Committee 21-22 April 1994

Christine/Phil:

I've attached for your review and information an executive summary (Tab 1) and a longer version (Tab 2) of the Advisory Committee meeting 21-22 April 1994. These summaries were prepared by our folks at the DoD Radiation Experiments Command Center (RECC) who attended the meetings.

If you have any questions or comments, please let me know.

Warm Regards,



Clinton Presidential Records Digital Records Marker

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1

Divider Title: _____

**EXECUTIVE SUMMARY
MEETING OF THE
ADVISORY COMMITTEE ON
HUMAN RADIATION EXPERIMENTS
21-22 APRIL 1994**

1.1 GENERAL

The Presidential Advisory Committee on Human Radiation Experiments conducted its first of two scheduled meetings on 21 April 1994 at the Ramada Hotel, Thomas Circle, Washington, DC. The Committee is chaired by Dr. Ruth Faden and consists of 14 other members drawn from the fields of ethics (4--including Dr. Faden), history (1), law (1), epidemiology (10), radiation therapy/nuclear medicine (3), nonradiation/public health (1), military medicine (1--civilian), radiation biology (1), general science (1), and a citizen representative.

2.1 MEETING, 21 APRIL 1994

2.1.1 PURPOSE

The first day's meeting had several purposes. One was to provide the Committee with general information on the Government's efforts to date. Another was to allow the Committee to discuss its role, organization, and operations. A third was to permit the Committee to get to know one another and the Committee staff. A fourth was to receive input from the public.

2.1.2 GOVERNMENT BRIEFINGS

The Committee was briefed by three groups from within the Government.

2.1.3 ADMINISTRATION

The first group was represented by Ms. Christine Varney, Secretary to the Cabinet, who explained the Administration's views and expectations. Ms. Varney said that the Committee's work was critical for the President and Administration because it exemplified the Administration's commitment to openness and forthrightness in the Government. She also said that the issues that the Committee will examine had far reaching policy implications and that it had "license to hold the Government's feet to the fire."

2.1.4 INTERAGENCY WORKING GROUP

2.1.4.1 GENERAL. The Interagency Working Group (IWG) was the Government's second set of briefers. In attendance were the Secretaries of Energy; Health and Human Services; and Veterans Affairs; the Deputy Secretary of Defense; the Deputy Director, Central Intelligence Agency; and the Director, National Aeronautics and Space Administration (NASA).

2.1.4.2 BRIEFINGS. Each IWG member briefed the Committee on their department's or agency's efforts to locate documents and determine the extent of human radiation experimentation conducted or sponsored. The Committee was also informed of the current status of department efforts, and presented issues for their consideration. A short question and answer session between the Committee and IWG followed the completion of all the IWG briefings.

2.1.4.3 SIGNIFICANT POINTS/ISSUES. Significant points made by IWG members, and issues that arose from their statements and the question and answer period include:

- a. The departments/agencies have been responsive and proactive in their efforts to discover the extent of human radiation experimentation.
- b. The IWG members have committed a large of amount of resources to this wide-ranging effort and have identified an enormous number of sources.
- c. Because of the size and scope of this effort the IWG members need Committee guidance on where to focus their efforts.
- d. The Committee's efforts will help restore faith in Government, science, and research.

2.1.5 CONGRESS

2.1.5.1 GENERAL. Congress was the third Government entity to be heard. Senator Glenn and Representative Markey, both with long histories of involvement on this issue, made statements before the Committee and answered questions from them.

2.1.5.2 POINTS. Several points were raised by Senator Glenn and Representative Markey:

- a. The Committee's work was important and it was essential that the Government "come clean" about its involvement.
- b. Do not let retroactive justifications like, things were done for a "larger purpose," sway the Committee's judgement.
- c. Keep an open mind on the scope of the inquiry. If justified, consider examining experimentation in other areas, such as chemical and biological agents.
- d. The Committee's efforts will have legislative implications, especially in relation to compensation, medical follow-up, and use of humans in research.
- e. Expansion of the definition of an experiment to include other groups or types of research. Marshall Islanders and atomic veterans were specifically mentioned.

2.1.6 COMMITTEE DISCUSSIONS

Interspersed with information sessions were discussion periods in which the Committee addressed organizational and procedural issues.

2.1.6.1 DISCUSSION TOPICS. A wide range of topics and issues were addressed:

- a. **The types of experiments/research that should be included in the definition of an experiments.** This was a central point of the discussion because it will help define the scope of the Committee's efforts, and a strategy and process to conduct an examination. It will also allow the Committee to provide guidance to departments/agencies. This, in turn, will allow departments/agencies to better focus their efforts. It appears that, at least initially, the Committee is inclined to expand the definition of an experiment.
- b. **Methods to identify specific experiments to review.** Some suggestions were to categorize experiments by: dosage, purpose, targeting of vulnerable populations, informed consent, studies that have survivors, and secret studies.
- c. **The need for the Committee to evaluate or review the department or agency record review process.** An adjunct issue was that it was important that the public's acceptance of the Committee's findings was not influenced by a perception that the Committee relied on "cooked data" from the departments/agencies.
- d. **The requirement for the Committee to conduct "public outreach" and the means by which the Committee can reach the public.** The only publicity the initial meeting received was a notice in the *Federal Register*.

2.1.7 PUBLIC OUTREACH

The need for a better public outreach strategy was revealed when only one citizen took advantage of the public comment period which was the day's last session. An individual from Washington, DC spoke on behalf of himself and 35 other families whose relatives were subjects of research at the University of Cincinnati Medical Center in the 1960's and 1970's. He spoke to the Committee about the experiments and the efforts to gather information, and pleaded with the Committee to involve the families in their deliberations. He also responded to questions from the Committee.

3.1 MEETING, 22 APRIL 1994

3.1.1 GENERAL

The second day of the meeting included briefings by department and agency representatives on the Human Radiation Experimentation Search Group (HRESG), a question and answer period after the briefings, and a continuation of the Committee's discussion of internal matters.

3.1.2 HRESG BRIEFINGS

The HRESG briefed the Advisory Committee on the status of their document retrieval and data collection effort. Several key issues were raised: first, the Administration was adamant in going through this process in an open and forthright manner. Second, the record identification and collection effort was a massive and time-consuming endeavor. Third, the agencies needed guidance from the Advisory Committee on how to focus their search.

3.1.2 QUESTION AND ANSWER PERIOD

The question and answer period was marked by several basic categories of questions asked by the Committee members. First, how did the Interagency Working Group (IWG) decide what to include in the Advisory Committee's brief and was there a way for the Committee to expand its brief? The search group responded that the Committee's brief was designed to include only human radiation experimentation to keep the size of the search manageable and that the Committee was able to expand its brief to include the Marshall Islanders and other issues, if it desired.

Second, what methodology did the agencies use in deciding what experiments to include and which to exclude from their searches? The agencies responded that the general effort was to be inclusive, however, some agencies had defined their search more narrowly than others.

Third, what steps are being taken to validate the search process used by each agency? The search group responded that the process was being validated by rigid oversight and the establishment of centralized command centers to coordinate agency actions.

3.1.3 COMMITTEE DISCUSSIONS

The afternoon session was largely devoted to resolving organizational problems that the Advisory Committee was experiencing. It was decided that the Committee would try to meet every three weeks for the next several months and a system of tutorials for the mutual education of Committee members would be presented at the public hearings.

Substantively, the Committee decided to obtain information on several experiments to use as "pilot cases" for the purpose of familiarizing the Committee members with the issues involved and the type of records available. A subcommittee was also tasked to develop an information retrieval form for the purpose of standardizing the experiment information each agency would be forwarding to the Committee.

4.1 GENERAL OBSERVATIONS

The Committee is a diverse and talented group and its first meeting suggests that its "group forming" efforts will occur on two levels: The first will be the open, formal process that is exemplified by the chairperson having each member introduce himself/herself to the group or asking for tutorials from Committee members on their areas of expertise. On the second level a less formal process will occur to which each member will bring their expertise,

prejudices, agendas, and personalities. For example, throughout the open discussions periods one member advocated expanding the definition of an experiment by including environmental releases.

The Committee appears quite eager to expand its brief. This may change as the Committee becomes more informed on the scope of its present responsibilities.

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MEMORANDUM FOR RECORD

1. Presidential Advisory Committee on Human Radiation Experiments Meeting, 21-22 April 1994, Washington, DC.

The Presidential Advisory Committee on Human Radiation Experiments conducted its first meeting on 21-22 April 1994 in the Federal Hall Room of the Ramada Hotel, Thomas Circle, Washington, DC. The Committee Chairperson is Dr. Ruth Faden. A list of Committee members is at Tab A. At Tab B is the agenda for each day of the meeting.

2. Summary, Advisory Committee Meeting, 21 April 1994.

- a. The meeting was called to order by Ms. Christine Varney, Secretary to the Cabinet, at approximately 9:35 a.m.
- b. In her opening statement Ms. Varney welcomed the Committee and those others present, and described the Committee members as expert medical doctors, lawyers, clinicians, and ethicists. She then related the Committee's purpose, mission, responsibilities. Ms Varney said:
 - (1) One mission was to provide expert advice to the Interagency Working Group.
 - (2) The Committee's work was critical for the President and the Administration. The Committee was an example of the Administration's commitment to the public to be open and forthright on the issues.
 - (3) The Committee's task was not easy, but it was a worthwhile endeavor. Later, Ms. Varney said that the Committee had "a difficult but do-able job."
 - (4) The Interagency Working Group (IWG) had conducted several meetings with Congress.
 - (5) The Committee is to develop the criteria to analyze and judge the experiments, and, in accordance with that criteria, to consider if
 - (a) The experiments had a clear purpose.
 - (b) The experiments were appropriate.
 - (c) The research met [medical, legal, ethical] standards.
 - (d) There were any wrongs committed.

- (6) The Committee was to examine experiments from 1944 to 1974. After 1974 they were to review and sample research to evaluate the Government's application of the Federal guidelines.
 - (7) The Committee's work will be closely observed. The issues that it encounters, and the Committee's resolution of these issues will have far-reaching policy implications.
 - (8) They have "license to hold the Government's feet to the fire."
- c. After Ms. Varney concluded her remarks, the Committee was sworn in.
 - d. Following this formality the Committee Chairperson, Dr. Ruth Faden, stated, "we are now official," and then made her opening remarks.
 - (1) She extended a formal welcome and stated that she was honored by the responsibility and takes the public's trust seriously.
 - (2) Dr. Faden then provided an orientation on the structure and flow of the meeting. She outlined five objectives for the Committee's initial sessions:
 - (a) To get the Committee and its staff to know each other.
 - (b) To develop an understanding of the Committee's relationship to the Administration and to Government agencies.
 - (c) To acquaint the Committee with congressional interest in this issue. Senator Glenn and Representative Markey were scheduled to appear during the afternoon session. (Note: There was a name tag made up for Senator Kennedy, but for some unannounced reason he did not appear.)
 - (d) To define and refine the Committee's mission, which is critical.
 - (e) To define how the Committee will function (frequency of meetings, internal organization [subcommittees], priorities, and procedures). This was to be discussed in depth on Friday, 22 April 1994. Dr. Faden also said that, throughout its deliberations, public comment would be a critical component of the Committee's proceedings.
 - (3) Dr. Faden then asked the Committee members and primary staff to introduce themselves. Committee and staff members then introduced themselves, provided a synopsis of their background, stated what expertise they brought to Committee, and in some cases related specific issues that were of particular interest to them. Some areas of specific interest identified by Committee members were informed consent, use of human subjects in research, the effects on radiation on humans, and human

experimentation ethics. One member (Mr. Feinberg) was the court-appointed master for the Agent Orange settlement. After the introductions, Dr. Faden noted the excellent credentials of the Committee and staff.

- f. Following a short break, the meeting reconvened at 10:17 a.m. to hear the statements of the Interagency Working Group (IWG). Presenting statements were Secretary of Energy O'Leary, Secretary of Health and Human Services Shalala, Attorney General Reno, Secretary of Veterans Affairs Brown, Deputy Secretary of Defense Deutch, Deputy Director of the CIA Admiral Studeman, and NASA Director Golden. A note-based summary of their remarks follows.

Secretary of Energy O'Leary

- (1) Secretary O'Leary thanked the Advisory Committee for agreeing to serve and said that they were being asked to give more time and effort than they could imagine. Secretary O'Leary then provided background information on her decision to make the experimentation information public.
- (2) The Secretary said that in late November she first heard that the *Albuquerque Tribune* was going to publish stories on the Government's role in human radiation experimentation over the last 50 years and that DOE was going to be asked to release information about human radiation experiments. While considering her response, she thought of the people who lived by DOE facilities, who did not trust the Department or its science, and the thousands that she had talked to who had no faith in their Government. After considering the issue, and what she thought the Government should be, Secretary O'Leary made the decision to release the information.
- (3) She said that she did not expect the firestorm that followed or the questions that subsequently arose about science and technology. As this reaction developed the need for someone or something to stand between the Government and the public became evident. During this period Dr. Faden was one of those from whom she sought advice.
- (4) Secretary O'Leary then described the issues/questions that she thought the Committee needed to address.
 - (a) What is the whole story regarding the Government's role in human radiation experimentation? (A point echoed by Senator Glenn.)
 - (b) Were all the experiments ethical?
 - (c) Were the experiment subjects adequately informed?
 - (d) Was anyone harmed as a result of the experiments?

- (e) Were vulnerable populations selected?
 - (f) Is compensation to experiment participants appropriate?
 - (g) What considerations will be given to the scientists and researchers who conducted the experiments?
 - (h) Will the Committee's findings possibly harm the nation's research base?
 - (i) To reassure the public on the diagnostic and practical benefits of radiation.
 - (j) What can be learned from the review that can be applied as a guide for the future? This is another recurring theme of the Committee meeting.
- (5) Secretary O'Leary explained that the Committee members were selected because they were eminent in their field. She also said because of the Committee's efforts the Government teeters on the edge of an opportunity to restore public confidence.
- (6) The Secretary closed by stating that she did not regret her decision.

Secretary of Health and Human Services Shalala

- (1) Secretary Shalala was next and started her remarks by expressing her admiration for Secretary O'Leary's leadership on this issue. She said that it was important to get to the bottom of the experiments. Also at stake was the integrity of the Government and science. Secretary Shalala then related that as one of those who are trying to sell the President's health plan across the country she observed that the people were skeptical of what goes on in Washington. She further stated that she takes this very seriously, as does the President.
- (2) The Secretary then described her Department's actions on the matter. On 27 January 1994, Secretary Shalala signed a memorandum that directed the Department of Health and Human Services (HHS) to search its records. Also, as the largest supporter of the biomedical research in the nation, HHS wrote to 27,000 research institutions and universities asking them to preserve their files from the period under investigation. The most difficult cases were those from the early portion of the period. The records search was difficult, and complicated by the fact that many titles and abstracts do not tell if the research was conducted on humans.

- (3) As an indication of HHS's serious view of these matters, Secretary Shalala stated that senior HHS officials who report directly to her are directing the Department's efforts. She then tried to convey a sense of the magnitude of the Committee's task by stating some of the issues. These included
 - (a) The need to focus the HHS effort. What discriminators should be employed to better focus the search--vulnerable populations? high dosages?
 - (b) The need to be careful not to give the idea that all radiation uses are bad.
 - (c) The need to educate the public on the benefits of radiation. She estimated that three quarters of the research at the National Institutes of Health (NIH) employed radiation or radioactive material.
 - (d) She also noted elsewhere in her discussion that there are an enormous number of files to examine at the NIH.
- (4) The Secretary noted that the first regulations on human use in research were promulgated by the NIH in 1953 and were followed in 1974 by the Department of Health, Education and Welfare (HEW) guidelines.
- (5) Secretary Shalala ended her remarks by reaffirming HHS's commitment to support the Advisory Committee efforts and pledged her Department's openness and enthusiasm to the project.

Attorney General Reno

The Attorney General stated she was pleased to be at the meeting and echoed the praise of Secretary O'Leary. She said that the Committee's determination of the ethical criteria will shape the Administration's response and reiterated the theme of openness in Government. The Attorney General described the Justice Department's role in the IWG's efforts as one that offered assistance and counsel to IWG members. Attorney General Reno also reaffirmed the IWG commitment to a thorough investigation. She then described the Justice Department's actions to discover its role, if any, in radiation research. Similar to other agencies, the Department of Justice conducted a records search. Of particular interest was the possible participation of Federal prisoners in research. Because of revelations concerning use of state prisoners, she specifically directed the Bureau of Prisons to search its records for Federal prisoner involvement. Attorney General Reno reported that no records were found.

Secretary of Veterans Affairs Brown

Secretary Brown publicly thanked Secretary O'Leary and stated that he could not condone some of what occurred in the past. He reported on Department of Veteran's Affairs (DVA) efforts and stated that the DVA had learned much and still had much to learn. Secretary Brown stated that many of the earliest uses of nuclear medicine were developed in

VA hospitals and it was on VA hospitals that the DVA focused its search. He then related some statistics to impart a sense of the scope of the search, reported that some studies had been uncovered, and that he did not know if all the studies met medical and ethical standards. Secretary Brown also related that in the late 1940's the VA established an Atomic Medicine Division and that initially its existence was classified. Secretary Brown stated that he did not know why the Division's existence was initially classified or that if, because of its classification, it violated the veteran's trust. He ended by pledging his and his Department's support for the Advisory Committee's efforts.

Deputy Secretary of Defense Deutch

Deputy Secretary Deutch acknowledged Secretary O'Leary's efforts and also the role of Christine Varney. He made the point to the Advisory Committee that it was hearing from an interagency group whose efforts were coordinated and not from individual departments with individual efforts (a point reinforced later by Ms. Varney). The Committee's task was important and the issues they will confront include the credibility of science, how scientist's operate, and the evaluation of past scientific practices. Deputy Secretary Deutch described the Department of Defense's efforts. He highlighted the establishment of the Steering Committee in January 1994 and revealed that the Department had identified 1,749 experiments--the great majority of which were clinical procedures. He also noted the establishment of the Radiation Experiments Command Center (RECC) to collect and analyze data. Deputy Secretary Deutch ended his remarks by stating that in the mid-1970's the Department established practices for the protection of human subjects that compared favorably with the practices used at other institutions.

Deputy Director of the CIA Admiral Studeman

Admiral Studeman stated that there was no evidence that the Central Intelligence Agency (CIA) conducted experiments. He then described how the CIA arrived at this conclusion. It has appointed a central working group that meets weekly to oversee the Agency's efforts. They reviewed documents from the 1970's Rockefeller and Church Commissions inquiries into Agency activities. It also conducted a records search and interviewed 30 specific individuals.

NASA Director Golden

Director Golden thanked everybody on the Committee and stated that the National Aeronautics and Space Administration (NASA) supported the open approach taken by the Administration and Committee. Director Golden then said that the Committee's efforts will help restore hope in the future. He then went on to describe NASA's search efforts--retiree interviews, data base searches, and literature reviews. He also added that NASA is using a more comprehensive experiment definition than the one contained in the 19 January 1994 White House Memorandum. This definition includes the injection of radioisotopes into healthy individuals to study bodily functions.

- f. Director Golden's remarks were the last prepared statement from the IWG. Dr. Faden thanked them and then opened the meeting for a short period of questions. Several important issues were raised during the question and answer period:
- (1) The importance of defining the types of radiation experiments the Committee wants to examine as a means to focus the departments' efforts. Defining what type research or experiments should be included within the definition of an experiment occupied the committee for the rest of the day.
 - (2) A member asked if the search, thus far, revealed that more experiments were done without informed consent than with informed consent. Informed consent will be an important issue for the Committee.
 - (3) The inquiry motivated agencies to conduct internal reviews of current practices.
- g. Several general points were revealed by the prepared statements and the questions and answers.
- (1) The agencies tried to provide the Committee a sense of the scope and size of their efforts. At this juncture the Committee members seemed to be satisfied with what they heard.
 - (2) The IWG members also wanted to impress upon the Committee that they were responsive and that their efforts to date reflected that fact
 - (3) A significant point raised by IWG members was the need for guidance on the scope, focus, and depth of their inquiries. The IWG appears to be waiting for instructions from the Committee on what direction to follow.
 - (4) The point was repeatedly made that Committee efforts were important to help restore faith in the Government, in science, and in research activities.
- h. After the IWG had completed its presentation, the Committee then turned its attention to organizational matters. Two sessions (one morning session and one afternoon session) were scheduled for this day and what follows is a summary of discussions during both sessions.
- (1) At the start of the morning session Dr. Faden stated that, in this phase, the Committee would begin to refine its mission. A more refined mission will enable the Committee to provide needed guidance to the IWG. She then outlined her perception of the Committee's tasks, duties, and some of the issues confronting the group.

- (2) Dr. Faden identified three tasks.
 - (a) The committee would establish the ethical and scientific standards by which to evaluate the experiments being reviewed. Other subtasks/issues included the establishment of the cultural and scientific context for the experiments; the dangers/problems of historical relativism; and the requirement for the Committee to be able to defend its adopted position.
 - (b) The Committee will have to review specific experiments. The exact experiments to be reviewed will have to be decided in accordance with the criteria established by the Committee. Once the review experiments have been identified, they will have to be evaluated against Committee standards for appropriate medical follow-up; the need for official apologies; and the need for developing groundwork for compensation and other possible legislative remedies.
 - (c) The Committee also had an obligation to look at and comment on the current situation which seemed to imply a review of current policies, procedures, and research.
- (3) Dr. Faden identified the Committee's duties as
 - (a) To the American public which appeared to imply the responsibility to discover the extent of radiation experimentation, evaluate the Government's efforts, and to provide remedies for wrongs discovered
 - (b) To improve public confidence in science, especially uses of radiation
 - (c) To assist in reestablishing trust in Government
 - (d) To the subjects and their families
 - (e) To be fair to the medical and scientific communities.
- (4) Themes that will guide the Committee's work
 - (a) The influence of research ethics in the experiments, especially regarding the issues of
 - 1 Subject selection
 - 2 Informed consent
 - 3 The ethical implications of a scientist in the service of the Government
 - 4 The ethics of research when its primary purpose is not to advance human health

- (b) The proper role of secrecy in an open society especially as it pertains to scientific research
 - (c) Within the context of science when can a citizen's rights be set aside.
- (5) Following Dr. Faden's remarks the Committee began discussing some of these points, along with others that developed from the interchange of ideas between members.
- (a) There was a short discussion concerning consensus. As a method to address procedural and organizational matters, one member asked if the Committee will try to force consensus or allow dissent within the group. In response another member stated that, if possible, the Committee should strive for consensus because dissent would weaken the force of the Committee's report. The issue was raised, briefly, that the Committee will have to establish a method to arrive at consensus and/or handle dissent. This is one of many such internal issues the Committee will have to decide.
 - (b) The issue that was by far the center of much of the discussion, and one that the Committee kept returning to was what types of experiments should be include within the definition of an experiment. This appeared to be because an accepted definition, supplemented by specific criteria, will provide them the means to tailor their approach and better focus the scope and thrust of their inquiries.

The Committee's charter includes the definition of a human radiation experiment contained in the 19 January 1994, White House Memo that has been guiding the IWG efforts. However, a sense of the Committee's morning and afternoon discussion is that they do not seem to want to be particularly bound to the limitations of that definition. For example, in the morning discussion a member stated that environmental experiments (other than those already identified) that would fall outside of a strict or normal research protocol should be included. Another suggested that unscientific, unstructured, and deliberate exposure of servicemen should be included.

- (c) The Committee also discussed various strategies to define the scope of inquiries. This is a key point. The IWG needs guidance because they have identified an enormous number of records, but someone needs to provide them direction on where to focus and prioritize their efforts. Several suggestions were offered, all suggestions were discussed but nothing was decided. The methods suggested were

- 1 To establish a dose level and examine experiments that employed doses above that level

- 2 To identify experiments funded by Government agencies but conducted by others
- 3 Experiments conducted by an agency in its own facilities utilizing its own personnel
- 4 To study experiments conducted for a military purpose versus those conducted for health concerns
- 5 To identify those that targeted vulnerable populations
- 6 To use informed consent as a discriminator
- 7 To select studies in which there are still survivors because of concern for future generations
- 8 To study research that was done in secret
- 9 To develop a sampling strategy based on some of the above.

A general consensus seemed to emerge that the Committee should try a variety of approaches, strategies, or mechanisms to accomplish its mission.

- (d) The Committee also discussed the need for public outreach. The only publicity the meeting received was a notice in the *Federal Register* and the success of that might be measured by the fact that only one person spoke during the public comment portion of the agenda over the two days of the meetings. One member suggested that the Committee may want to consider three outreach approaches. The first was to contact subjects and bring them to Washington to appear before the Committee, or have the Committee go to them. Another was to solicit advocacy groups from each side of the issue(s) and have them appear before the Committee. A third was to provide an unstructured opportunity for public comment. All of these were well received by the Committee, however, a more basic issue was a way to publicize the Committee's efforts. The Committee and its staff will develop approaches to this issue.
- (e) Several interrelated issues were also discussed. One involved the question whether the Committee had a responsibility to review the departmental record review process. The consensus was that an early review of the process should take place to ensure that the departmental reviews were procedurally appropriate and that the integrity of the records was preserved. Dr. Faden asserted that this procedural review was important because the public's perception of the Committee's work will be based on the premise that it (the Committee) was not provided "cooked data" by the Government agencies and that the Committee had made a thorough review of these activities. This issue confronted the Committee with problems similar to those associated with defining the scope of the inquiry, i.e., should they sample, what should they sample, and how do they define the criteria for sampling. No decisions were made on how to conduct a review. There was also discussion of why the Committee

was to study experiments from 1944 to 1974, and then sample after 1974. The Committee understood the significance of the 1974 HEW regulations, however, they did not see them as infallible and, in their view, Government research conducted after 1974 was not exempt from their scrutiny. This issue was also related to defining the inquiries scope.

- (f) There was concern expressed that Committee might promise more than it could deliver. A way suggested to preclude this possibility was for the Committee to be clear on what it can accomplish, and then to leave a good legacy.
- (g) The idea of the Committee's legacy was raised in various guises. This most often was in the form of discussing compensation, medical follow-up for experiment subjects, or laying the groundwork so that these could occur.
- (h) Other issues briefly discussed and not resolved include
 - 1 The need for the Committee members to provide tutorials on their particular area of technical/professional expertise for the benefit of other Committee members
 - 2 The possible problem of assuring scientists/researchers that they would be shielded from civil or criminal liability that might result from testimony before the Committee
 - 3 The suggestion that historians be brought before the Committee to provide historical context, and the possibility that the Committee staff start assembling a library.
- (i) Several Committee members suggested books to be read for background. One was entitled *Radioactivity and Health: A History*. Another book identified by title was *The Clouds of Secrecy*. A third book, generally described and without a title, was one by a Professor Wingate on the operations of the Atomic Casualty Commission in Japan after World War II. Also, one Committee staff member wrote a book entitled *Health in the Headlines*.
- i. Many of the ideas and themes discussed by the Committee were echoed in the appearances of Senator John Glenn and Representative Edward Markey.
 - (1) In his statement Senator Glenn presented his view of the Government's role and Congress's role in this area. The Committee has an important task to help the Government come clean for this phase of its history. Although he supported the nuclear weapons buildup, it was inconceivable that some things were done. He said that, "the Russians are coming," attitude created an atmosphere in which things were done that were unconscionable. It was up to the Committee to provide guidance to the

IWG and to Congress. He stated that when experiments were conducted clear ethical guidelines established and urged the Committee not to accept the justification that if mistakes were made they can be excused because the experiments were done for a larger purpose. Senator Glenn then provided a brief description of his involvement with the issue. He offered the Committee copies of the reports that his Senate committee has produced on this subject. The offer was accepted. Senator Glenn also urged the Committee to work with the GAO and use the expertise that it has developed during the course of its investigations. He urged the Committee to keep an open mind about the scope of its work and to consider new items when found. He cited the Marshall Islanders and Atomic Veterans as two examples of those excluded by the present scope of the definition who should be considered for inclusion. He also urged the Committee to be willing to look into other areas of chemical and biological experimentation. He stated that the Committee's work will have policy implications and it was likely that the Committee's deliberations will lead to compensation for the subjects of experiments and legislation on the use of human subjects in research. The Committee had a tough job, the volume of documents was large and the bureaucratic obstacles were daunting.

- (2) Representative Markey summarized his statement because he had to return to the House for a vote. He started off by saying that the revelations grabbed attention but that there was a need to focus on a remedy for past errors. Consequently, he was introducing legislation to address medical follow-up and compensation, and to force DOE to identify experiments that were of little or no benefit. He cited his involvement in the publishing of the 1986 report which revealed the use of citizens in ionizing radiation research and the lack of informed consent. He commended Secretary O'Leary's forthrightness and his concern was the agencies work with Congress to address past abuses. He then reviewed issues raised by the release of papers on the plutonium studies:
 - (a) The number of patients involved remains an open question.
 - (b) There is the possibility that the plutonium experiments were part of wider, coordinated Government research effort.
 - (c) What were the medical and ethical standards the Atomic Energy Commission (AEC) used in the late 1940's? Evidence suggests that the AEC had standards in place for a short time. What caused the standards to be changed or violated?
 - (d) What was the full extent of the follow-up in the 1980's for one plutonium patient? Evaluate its applicability for today.

- (3) Representative Markey urged the Committee to look at its role expansively and requested that it consider two particular areas. The first area was compensation standards. The second area was expansion of the investigation into experiments with biological and chemical agents.
- (4) After the completion of the prepared statements there was a short question and answer session. The questions and responses which were noted are listed below.
 - (a) Senator Glenn was asked how the Committee could involve the General Accounting Office (GAO) in its process. The Senator responded that, as a first step, the Committee should get GAO reports, review them, and use the attached bibliographies as research aids. He also said that as the Committee's investigation evolved, if more GAO support or involvement was desired the issue will have to be addressed at that time.
 - (b) Both Senator Glenn and Representative Markey were asked if they thought that the worst of the experiments have been exposed. Senator Glenn responded that at each step of his investigation he thought the worse had come out and there was not anything else, but he was proven wrong. Representative Markey believed that there was ample reason to believe that there is more to know.
 - (c) Representative Markey had to return to the House for a vote. Senator Glenn responded to at least two additional questions. He was asked for advice on what the Committee should do about recommending policies to the President and Congress. Senator Glenn stated that they needed to look at the worst examples and consider remedies and compensation. He also told the Committee not to feel constrained by the year time limit that is in their charter.
 - (d) When asked about including Marshall Islanders in the definition, the Senator stated that the available data supports the view that a deliberate decision was made to move them back onto the island to observe the effects of radiation on the population. In his view this was a deliberate radiation experiment and should fall within the Committee's purview.
- j. After the appearance of Senator Glenn and Representative Markey the Committee resumed its discussion of organizational issues. The issues discussed in this session are included in paragraph 2h.
- k. This session was followed by period set aside for comments from the public. The only individual that availed himself of the opportunity was an individual from Washington, DC. He stated that his mother was a patient at the Cincinnati General Hospital in the mid-1960's and was a subject of the research conducted

by Dr. Eugene Saenger. The individual represented 36 families of Saenger patients who had recently (on or about 16 April 1994) formed a support group. He stated that they were very concerned that their voices be heard and they wondered why their relatives were exposed to radiation which, in many cases, shortened their lives and affected their quality of life. He asked that they please be involved in the Committee's efforts and said that they had uncovered much information.

He shared some of that information with the Committee. He described his mother's experience, alleged that NIH ended funding for or refused to fund the research in 1969 because of concerns about informed consent, and raised a point that Dr. Saenger advised Dr. John Northrup, Deputy Director, Defense Nuclear Agency (DNA) in 1972 to change the word "experiment" to "research" in a statement that Dr. Northrup drafted in anticipation of being required to appear before Congress to explain the DNA's involvement with Dr. Saenger.

The Committee had several questions. He was asked about the details of the experiments and described the facts as he understood them. He was asked how he, and others, discovered information, and he described their efforts. Because of the alleged involvement of NIH in a DoD-sponsored project an issue arose concerning agency co-funding/co-sponsoring. Dr. Faden informed the Committee that the Committee would be receiving information on the Saenger research from DoD and HHS. The Committee completed its first day of work at approximately 3:45 p.m.

3. Summary, Advisory Committee Meeting, 22 April 1994.

- a. The Friday, 22 April 1994 meeting began with one-half hour devoted to a review of the previous day's activities. During this period several issues were raised for discussion in the afternoon session. Issues were
 - (1) The Committee needed to establish the scope and limitations of its own brief.
 - (2) The Committee needed to discuss and then issue directions to the IWG concerning the record collection process.
 - (3) The Committee should obtain information from several experiments that can be used as a "pilot project" to familiarize the Committee members with what they are dealing with and what the data looks like. (The Committee agreed to this proposal and decided the specific experiments would be chosen in the afternoon session.)
 - (4) The Committee needed to reach closure on the issue of advocacy and its impact on the public meetings.

- (5) The Committee needed to use the electronic media to generate more public involvement in this issue. A member suggested that perhaps a PBS documentary could be generated.
 - (6) The Committee needed to know what ethical standards the agencies used as guidance over the decades and whether that standard was comparable to ones used elsewhere.
 - (7) A member suggested that the Committee get copies of a report he had read in the 1950's put out by the Inspector General of the Navy on the ethics of human use in experiments.
 - (8) The Committee must find out what efforts are underway to cross-reference people that are contacting the agencies with specific experiments.
 - (9) The Committee should obtain the reports on those experiments that have already been reviewed by the agencies so that the Committee does not waste its time duplicating actions already taken.
 - (10) One member questioned whether the members of the Committee will get transcripts or summaries of the Committee meetings.
- b. Following the Committee's discussion period the representatives from the Interagency Search Group (ISG) briefed the Committee on departmental document retrieval and data collection efforts. The first briefer was Dr. Tara O'Toole from the Department of Energy (DOE).
- (1) First, Dr. O'Toole gave an overview of DOE's actions since Secretary O'Leary's 7 December 1993 revelation that the Government was involved in human radiation experimentation.
 - (a) 7 December 1993 -- Secretary O'Leary reveals that the Government was involved in human radiation experimentation. Soon after, DOE called in an ethicist (Dr. Ruth Faden) to help determine what the next step should be.
 - (b) 3 January 1994 -- An Administration meeting was held in the Old Executive Office Building with all branches of the Government that could have been involved in human radiation experimentation. At this meeting it was determined to be inclusive and look at all ionizing radiation experimentation. It was also decided to designate a panel of experts to thoughtfully review the available information. The decision was made to convene this independent panel of experts rather than a stakeholder panel because of the enormous scope of the endeavor. An inclusive stakeholder panel would have been far too large. The scope of the issue was narrowed to exclude occupational exposure, the Marshall Islanders, and "downwinders" because the size

of the review with these groups included would have become unmanageable. These groups were also being taken care of by other programs.

- (2) Dr. O'Toole then described DOE's records retrieval process. She related that the record retrieval process had been ongoing since February 1994. A record collection center was established to coordinate search activities and provide a common storage facility for pertinent records. Phase I of the search was to comprehensively inventory and locate relevant records. Phase II was to focus the search to obtain the documents that would be needed for any further review.
- (3) Dr. O'Toole also described what the Interagency Working Group (IWG) wants from Advisory Committee:
 - (a) The Committee must tell the story of human radiation experimentation.
 - (b) The Committee must tell the public what role the Government had in this process.
 - (c) Guidance from the Committee must be forthcoming to focus and prioritize the records search.
 - (d) The Committee must affirm or deny the Government's good efforts to collect all the pertinent records.
 - (e) The Committee should develop guidelines on how to apply the its findings so the public can have faith that the Government is always acting beyond reproach.
- c. The second briefing was by Dr. Steven Galson from DOE who provided more details on DOE's record retrieval process.
 - (1) Dr. Galson stated that DOE guidance was issued in early January and record retrieval teams were sent out from headquarters to the field. DOE was in the process of visiting six facilities and expected to be finished by the end of May. The information developed from these visits was being processed for the Committee's use.
 - (2) He then outlined the results of the DOE's efforts. Dr. Galson said that 231 boxes of records had been examined totaling 94,000 records. Only four percent of the documents examined were found to be relevant. To date, DOE had received 329 congressional inquiries and 4,680 letters from the public (of which 500 were forwarded to other agencies). DOE had generated 3,951 responses to these inquiries. The helpline had received 21,000 calls of which 14,000 calls were relevant. To date \$3.68 million

had been spent on the search process and an estimated \$23.98 million would be expended to complete the search process.

- (3) DOE representatives raised several concerns, issues and problems that they anticipated or had already experienced.
 - (a) How are documents to be released to the public? Privacy concerns would have to be taken into consideration before many documents could be publicly released.
 - (b) DOE is experiencing a culture shift from secrecy to openness and problems endemic to this shift would impact the record retrieval process.
 - (c) The DOE employees with the best experience to conduct the review were, in some cases, involved in some way with the experiments and conflict of interest was a growing possibility.
 - (d) When this process is complete, DOE wants public trust in the scientific establishment to be maintained.
- d. The next briefing was by Dr. D. A. Henderson of the Department of Health and Human Services (HHS).
 - (1) Dr. Henderson stated that HHS had been involved in this issue for a long time. HHS issued regulations governing human subject protection in the early 1950's and these regulations were updated in the late 1960's.
 - (2) HHS tried to develop a record search strategy. It would be impossible to review all the records on this issue (some documents have been identified and are being reviewed). It was hoped that caller information from the helpline would open new avenues of research, but this did not occur. HHS interviewed former employees that might have been involved in human radiation experimentation, but this yielded little useful information. An on-line review of grants revealed 160,000 possible human radiation experiments from 1964 onward (records of grants issued before 1964 are only available in a card catalog which was not searched). The information provided by this search indicated only the title of the experiment and the amount of the grant. In most case there was no way of knowing whether the experiments involved humans. An on-line review of literature provided 400 to 500 titles for one year alone which was an unmanageable number.

- (3) Other approaches were needed to make this task manageable. The present approach was too intensive and ultimately unproductive. The Advisory Committee should identify the agencies that are likely to have participated in human radiation experimentation and focus the effort on those agencies. If the Committee can categorize experiments and narrow the field this would aid the search immensely.
- e. Harold Gracey from Department of Veterans Affairs (DVA) was the next briefer.
- (1) From the beginning DVA's search had focused logically on the Veterans Health Service. DVA runs 172 medical centers of which 132 have nuclear medicine divisions. DVA has run into some difficulties because only 49 of the 172 medical centers have copies of the protocols to do radiology research. Only 54 of the 172 medical centers have documents related to this research. Only 24 of the 172 medical centers have the names of patients involved in research.
 - (2) DVA is trying to coordinate with DOE and the Department of Defense (DoD) to keep a high degree of commonality in the record retrieval process. An effort had been made to contact researchers associated with DVA in this area. The DVA has received approximately 8,000 calls on human radiation experimentation, of which only 800 are actually possible human radiation experiments. Of the 800 referrals from the helpline only 150 are actually possible human radiation experiments.
 - (3) To date DVA was using established resources with no additional outside contractors. No special center had been established to coordinate DVA's activities, but because of the scope of the task the time was soon approaching when that would be necessary. Mr. Gracey indicated DVA would like the Committee to provide a focus and prioritization for the record search.
- f. Dr. Gordon Soper represented the Department of Defense.
- (1) Dr. Soper abbreviated his presentation in the best interests of time.
 - (2) Hundreds of personnel were involved in the DoD-wide search of many record facilities.
 - (3) He highlighted the commitment of the senior people in DoD and introduced Rear Admiral Wisely and Colonel Bailey.
 - (4) The Navy had identified 700 experiments to date including Operation Hydra II.
 - (5) The Army had identified approximately 932 experiments to date.

- (6) The Air Force had identified 106 experiments to date.
 - (7) The Defense Agencies (Defense Nuclear Agency and Armed Forces Radiobiology Research Institute) had identified 11 experiments to date.
 - (8) The number of total identified DoD experiments to date: 1,749.
 - (9) Dr. Soper emphasized that DoD had decided from the onset to be inclusive in its search and to make sure it's record search was an open one.
 - (10) Dr. Soper indicated that DoD wanted the same type of guidance from the Committee as the other agencies, including priorities for record retrieval and a firmer definition of the population criteria.
- g. Mr. Crease from the Central Intelligence Agency (CIA) followed Dr. Soper.
- (1) Mr. Crease related that the CIA did a computerized search of its on-line records from its data base of 34 million documents. The search took one month. An additional half million older documents were reviewed by hand. One hundred twenty people were involved in this process (not necessarily full-time), and their efforts were managed by a working group. No documents were found on any CIA involvement with human ionizing radiation experiments.
 - (2) The reason the CIA was even looking was because the initial research protocol for the mind altering program of the 1950's and 1960's mentioned radiation as one possible avenue of research. Fifty people involved in the mind altering program were interviewed and no recollection of any use of radioactive material was uncovered. In the past the data base system had not performed perfectly and had given the Agency problems. Because of this the CIA would continue to pursue the search.
- h. Mr. Harry Holloway of the National Aeronautics and Space administration (NASA) was the final briefer.
- (1) Mr. Holloway said that NASA's search process had involved interviews, record center searches, literature searches, the processing helpline calls, and research by NASA historians. Nine-hundred and fifty man-hours had been expended on the search, including 18 interviews with past NASA officials.
 - (2) To date NASA had received 20 letters on human radiation experimentation. The literature search identified 213 articles. Astronaut studies were considered by NASA to be occupational studies and were thus not under the purview of the Committee.

- (3) Several issues were identified by NASA as needing resolution:
- (a) A good definition of human radiation experimentation was needed. For example, should clinical experiments that followed sound standards be included?
 - (b) How will responsibility be assigned when more than one agency shares involvement in an experiment?
 - (c) Should data collected unethically be quarantined?
- i. The briefings were followed by a question and answer period. The first two questions were not recorded.
- (1) Duncan Thomas: Why were the Marshall Islanders excluded from the Committee purview?
- O'Toole*: If the Committee felt the need to, it could change its charter to add additional responsibilities. However, the Marshall Islanders were not being neglected. For example, action was being taken on Capitol Hill. DOE would provide as much information as the Committee desired. The idea was not to sidetrack the progress being made on the Marshall Island's issue by lumping it together with human radiation experimentation. The issue of the Islanders was progressing independently.
- (2) Duncan Thomas: He wanted more details on the helpline. Is there a protocol on how the operators of the helpline ask questions? How is cross referencing being done?
- Galson*: There is an established protocol and format for asking questions. If the information provided by the caller is not pertinent to human radiation experimentation then the information is forwarded to the appropriate DOE division or other agency for action.
- (3) Susan Lederer: Have there been any calls to the helpline about human experimentation other than radiation experimentation and, if so, what is done with that information?
- Galson*: The helpline focused only on recording human radiation experimentation. He had no numbers on nonradiation experimentation.
- Soper*: Many of the helpline calls forwarded to DoD had in fact been referred to the Nuclear Test Personnel Review (NTPR) for action.
- Gracey*: Agreed with Soper that 90 percent of the helpline calls forwarded to DVA were later referred to NTPR.

- (4) Susan Lederer: Has DOE followed up on the issue of radioactive isotope shipments to research facilities to determine if this was an avenue of finding human radiation experiments?

Mr. Jim Weir (in charge of the DOE records search): Yes, that had been followed up and to date one research facility had been identified.

- (5) Reed Tuckson: Any thought given to one department heading the records search for another department? What is being done to ensure that the record search process being used is uniformly the best process?

O'Toole: Because of time restraints the specifics of the answer would be filtered through the staff, but each agency was carrying out its own search because it knows best where to look for information and who to question about possible avenues of research. The agencies were sharing lessons learned and passing information along by means of the Interagency Working Group

- (6) Reed Tuckson: What is being done to validate the search process being conducted by each agency?

O'Toole: For DOE, teams were sent out from Washington, DC to double check the searches conducted in the field. Command centers were also established to coordinate activities and the IWG was rigidly supervising the record review process.

- (7) Dan Guttman: Can the Committee have access to CIA personnel to put the human radiation experiments conducted into an international perspective appropriate for the timeframe the experiments took place?

Crease: Yes.

- (8) Patricia King: Was there any attempt to look for CIA involvement overseas. In the search did the CIA differentiate between foreign and domestic or classified and unclassified?

Crease: No distinction was made concerning either location or security clearance.

- (9) Jay Katz: No question, just wanted the CIA to keep a record of all personnel involved in the record search so that the Committee could have access to those people if needed.

- (10) Ken Feinberg: If, at the end of this long process, it is determined that the Government had acted improperly, is the Government skirting the issue of remedy?

O'Toole: The IWG was already looking at past models of compensation. The Committee would also be asked for its recommendations on this matter. She also pointed out that Congress was certainly not skirting the issue, as several pieces of legislation had been entered dealing with compensation.

- (11) Ruth Macklin: The Committee Charter specifies "intentional" experiments not "accidental" exposure. Can the Committee look into accidental exposures?

O'Toole: Yes. When the Committee's charter was drawn up it was intended that accidental exposures be included in the Committee's purview.

- (12) Ruth Macklin: Directed to Dr. Soper. Regarding Hydra II, what was being studied and what records are available?

Soper: Underwater shock effect with radioactive tracer elements.

- (13) Ruth Macklin: Were any incentives given to the "Tribal Elders" to get access to the population? (This was in reference to the Alaskan Natives study conducted in 1957 by the United States Air Force.)

Soper: Not that he knew of.

- (14) Ruth Faden: Why was "Green Run" included under the Committee's purview?

O'Toole: It was part of the GAO study and had not been looked at in depth to date. The Government did not want to look like it was trying to cover something up by means of exclusion.

Soper: DoD was spooked by the prospect of purposely excluding something so it tried to err on the side of inclusion.

- (15) Nancy Oleinick: Would search have included all experiments, both foreign and domestic?

Various: Yes.

- (16) Mary Anne Stevenson: Comment: The Committee would need a standardized format to receive information from the agencies. Directed to *Henderson, HHS*, What plans did HHS have to look at the pre-1964 information that is not computerized?

Henderson: Many problems existed, including the fact that few records have been kept because of standard record destruction procedures.

- (17) Mary Anne Stevenson: Directed to *Galson, DOE*: Who triaged helpline calls and decided if the caller's information was relevant or not? What happened to the information if it was not relevant?

Galson: Nobody was being abandoned. If the call was not relevant to human radiation experimentation it was referred to the proper agency to deal with.

- (18) Patricia King: Comment: She had trouble with the word "intentional" used in the Committee charter. She is interested in motivation and impact. She wants accidental exposures included. How did each agency decide how the search would be targeted? Defined? Minimized? She is afraid that the agencies might have excluded something that should be included.

Henderson: HHS has not included in its search some experiments that included intentional ionizing radiation exposure.

King: This answer "frightened" her. Makes it more important to look at agency procedures.

- j. The question and answer period was followed by a discussion of Committee strategy and direction. This session focused on four topics.

- (1) Pilot cases: The afternoon session began with a discussion of which experiments the Committee wanted to use as pilot experiments. The purpose of the pilot experiments is to allow the Committee members to familiarize themselves with the issue they are dealing with and the types of records that are going to be available. The Committee decided to focus on the Saenger experiment, the plutonium injections experiments, and the "Green Run" experiment. Patricia King questioned the wisdom of using the most controversial cases as pilot cases. The pilot case should be for the Committee to evaluate and develop methodological approaches, not to make judgments. Ms. King suggested a "random selection of events." Dr. Faden allowed that both approaches could be used -- some "big" cases and a random selection of other cases. Ms. King expressed her feeling that approaching the controversial cases initially would run the danger of creating a "media circus" before the Committee members had the opportunity to develop a base of knowledge and information from which to make informed decisions.

- (2) Meeting Schedule: A discussion of how often the Committee should meet brought forth two proposals: to meet every two weeks or every three weeks. Meeting every two weeks was deemed to be excessively time consuming for the staff which would be spending too much time gearing up and then gearing down from public hearings. It was decided to attempt to meet every three weeks, but to make sure that the Committee met at

least every four weeks. This would be the schedule for the next several months.

- (3) Tutorials: A system of tutorials was established during which various members of the Committee would give a presentation on a particular pertinent issue. These presentations were scheduled to be given during the public sessions. Several presentations were tasked, including the effects of radiation on humans; the history of ethics in human experimentation, and a presentation on the history of the regulation of human radiation experimentation.
- (4) Scope and Priorities: Because of time restraints this portion of the discussion was not fully threshed out. The idea was to develop a practical scope for the Advisory Committee with an eye toward giving instructions to the agencies. An abbreviated "wish list" of information was developed before it was decided to establish a "forms subcommittee." The subcommittee was tasked to produce a draft document for the purpose of requesting information on a particular experiment from the agencies.

Some of the information Committee members indicated they wanted on the form was

- Status of subjects (volunteer versus patient)
- Which radioactive isotope was used and what quantity
- What was the subject's body weight (if isotope used)
- Age of subjects
- An identification of whether the study was confidential or published
- An identification to indicate whether the subjects were from a vulnerable population (vulnerable population was not fully described, but included the mentally handicapped, pregnant women, and children)

The Committee ended its second day at 2:30 p.m.

Brian H. Thompson
Research Section
DoD RECC

Thomas A. Popa
Research Section
DoD RECC

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ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

PUBLIC MEETING

APRIL 21-22, 1994

TENTATIVE AGENDA

Thursday, April 21, 1994

- 9:30 am Call to Order
 Christine Varney, Secretary to the Cabinet
- Welcome and Introductions
 Ruth Faden, Chair
- 9:50 am Introductory Comments on Committee Mission
 Ruth Faden
- 10:00 am Initial Committee Discussion of Mission
 Moderator: Ruth Faden
- 10:45 am Break
- 11:00 am Briefing by Interagency Working Group
- 12:00 pm Lunch
- 1:15 pm Introductory Comments
 Ruth Faden
- 1:30 pm Comments by Congressional Representatives
- 2:00 pm Continued Committee Discussion of Mission
 Moderator: Ruth Faden
- 3:00 pm Break
- 3:15 pm Public Comment Period
- 5:00 pm Meeting Adjourned

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

PUBLIC MEETING

APRIL 21-22, 1994

TENTATIVE AGENDA

Friday, April 22, 1994

- | | |
|----------|---|
| 9:00 am | Opening Remarks
Ruth Faden |
| 9:05 am | Committee Discussion
Moderator: Ruth Faden |
| 9:30 am | Briefing by Interagency Working Group: Document Retrieval and Data
Collection Efforts |
| 10:30 am | Break |
| 10:45 am | Briefing by Interagency Working Group: Document Retrieval and Data
Collection Efforts (Continued) |
| | Committee Question and Answer Period
Moderator: Ruth Faden |
| 11:45 am | Committee Staff Structure and Organization
Dan Guttman, Executive Director |
| 12:15 pm | Lunch |
| 1:30 pm | Discussion of Committee Strategy and Direction
Moderator: Ruth Faden |
| 3:00 pm | Meeting Adjourned |

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RUTH R. FADEN

CHAIR, ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Biographical Sketch

Ruth R. Faden, Ph.D., M.P.H., is Professor of Health Policy and Management in the School of Hygiene and Public Health, Johns Hopkins University. Dr. Faden is also Senior Research Scholar at the Kennedy Institute of Ethics, Georgetown University.

Dr. Faden is Director of the Program in Law, Ethics, and Health of Johns Hopkins' School of Public Health. She is the author of many books and journal articles on biomedical and research ethics, health policy, and health behavior, including A History and Theory of Informed Consent, co-authored with Tom L. Beauchamp, Ph.D. In addition to her extensive publications, Dr. Faden has served on numerous national task forces and committees.

Dr. Faden holds a Bachelor of Arts in American Civilization from the University of Pennsylvania and a Master of Arts in Humanities from the University of Chicago. She received a Masters in Public Health (M.P.H.) and a Doctorate (Ph.D.) in Attitudes and Behavior from the University of California-Berkeley.

ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS

Ethicists

Ruth R. Faden, Ph.D., M.P.H. - Professor of Health Policy and Management and Director, Program in Law, Ethics and Health, Department of Health Policy and Management, Johns Hopkins University, Baltimore, Maryland; Senior Research Scholar, Kennedy Institute of Ethics, Georgetown University, Washington, District of Columbia.

Ruth Macklin, Ph.D. - Head, Division of Philosophy and History of Medicine, Professor of Bioethics, Shoshanah Trachtenberg Frackman Faculty Scholar in Biomedical Ethics, Department of Epidemiology and Social Medicine, Albert Einstein College of Medicine, Bronx, New York.

Patricia A. King, J.D. - Professor of Law, Georgetown University Law Center, Washington, District of Columbia; Adjunct Professor, Department of Health Policy and Management, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, Maryland.

Jay Katz, M.D. - Elizabeth K. Dollard Professor Emeritus of Law, Medicine and Psychiatry, Harvey L. Karp Professorial Lecturer in Law and Psychoanalysis, Yale University, New Haven, Connecticut.

Historian

Susan E. Lederer, Ph.D. - Associate Professor, Department of Humanities, The Milton S. Eisenhower Medical Center, Pennsylvania State University, Hershey, Pennsylvania.

Attorney

Kenneth R. Feinberg, J.D. - Kenneth R. Feinberg & Associates, Washington, District of Columbia; Adjunct Professor of Law, Georgetown University Law Center, Washington; Member, Presidential Commission on Catastrophic Nuclear Accidents, 1989-90.

Epidemiologist

Duncan Thomas, Ph.D. - Professor, Preventive Medicine, University of Southern California School of Medicine, Los Angeles, California.

Clinicians, Radiation Therapy/Nuclear Medicine

Eli J. Glatstein, M.D. - Professor and Chairman, Department of Radiation Oncology, Simmons Cancer Center, Southwestern Medical Center, University of Texas, Dallas, Texas.

Henry D. Royal, M.D. - Associate Director, Division of Nuclear Medicine, Mallinckrodt Institute of Radiology, Professor of Radiology, Washington University School of Medicine, St. Louis, Missouri.

Mary Ann Stevenson, M.D., Ph.D. - Assistant Professor of Radiation Oncology, Joint Center for Radiation Therapy, Deputy Chief, Department of Radiation Oncology, New England Deaconess Hospital, Harvard Medical School, Boston, Massachusetts.

Clinician, Non-Radiation/Public Health

Reed V. Tuckson, M.D. - President, Charles R. Drew University of Medicine and Science, Los Angeles, California.

Military Medicine Specialist

Philip K. Russell, M.D. - Professor of International Health, School of Hygiene and Public Health, Johns Hopkins University, Baltimore, Maryland.

Radiation Biologist

Nancy L. Oleinick, Ph.D. - Professor of Radiation Biology and Biochemistry, Environmental Health Science and Oncology, School of Medicine, Director, Division of Biochemistry and Oncology, Department of Radiology, Case Western Reserve University, Cleveland, Ohio.

General Scientist

Frank Press, Ph.D. - Fellow, Cecil and Ida Green Fellowship, Carnegie Institution of Washington, Washington, District of Columbia; former President, National Academy of Sciences.

Citizen Representative

Lois L. Norris - Community Representative, Institutional Review Board, University of Nebraska; retired Second Vice President, Omaha National Bank and Omaha National Corporation, Omaha, Nebraska.

DAN GUTTMAN

EXECUTIVE DIRECTOR, ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS STAFF

Biographical Sketch

Dan Guttman has been a partner at Spiegel & McDiarmid, a Washington, D.C. law firm which represents public agencies, workers and consumers in energy, communication and environmental matters, and human rights issues. He has assisted local governments and worker representatives in the ongoing conversion of the nuclear weapons complex, and Nye County, Nevada, the site of the proposed nuclear waste repository.

Following graduation in 1971 from Yale Law School, he co-authored the Ralph Nader sponsored book, The Shadow Government: The Government's Multibillion Dollar Giveaway of its Decisionmaking Powers to Private Management Consultants, "Experts," and Think Tanks. He served as special counsel to Senator David Pryor in the oversight and investigation of the Federal use of private expertise in the performance of the basic work of government.

He participated on the National Academy of Public Administration's Standing Panel on Executive Organization and Management, and was the recipient of a German Marshall Fund grant to advise on energy conservation in Czechoslovakia.

He has written for publications including The New Republic, The Washington Monthly, Public Power, and The Harvard Journal on Legislation. He served as research assistant to Andy Rooney in the production of "Mr. Rooney Goes to Washington," an award winning CBS news documentary.

He was graduated *phi beta kappa* with highest honors from the University of Rochester in 1968.

**ADVISORY COMMITTEE
ON HUMAN RADIATION EXPERIMENTATION
STAFF**

Biographical Sketches

Anna Mastroianni, J.D.

Director of Committee Affairs

Deputy Staff Director

Senior Policy and Research Analyst

Before joining the Advisory Committee staff, Ms. Mastroianni was a study director in the Division of Health Sciences Policy of the National Academy of Sciences' Institute of Medicine. In that position, she most recently directed a study evaluating legal and ethical issues relating to the inclusion of women in clinical studies. Ms. Mastroianni practiced health care law in Washington, DC, in addition to serving as a legal consultant to the National Research Council's Committee on Contraceptive Development. She received her Juris Doctor and undergraduate degrees from the University of Pennsylvania. Her research interests include legal and ethical issues in the "right to die" area. She currently studies health policy at the Johns Hopkins University School of Hygiene and Public Health, and is a member of the Department of Health and Human Services Advisory Workshop on Women in Medicine.

Jeffrey Kahn, Ph.D., M.P.H.

Acting Staff Director

Senior Policy and Research Analyst

In addition to his Committee duties, Jeffrey Kahn is Assistant Professor of Bioethics and Associate Director for Graduate Studies in the Center for the Study of Bioethics of the Medical College of Wisconsin (MCW). His administrative responsibilities at MCW include directing the College's Master's program in Bioethics. Before joining the faculty at MCW, Dr. Kahn was Assistant Professor of Medical Humanities at East Carolina University School of Medicine, in Greenville, North Carolina. Dr. Kahn's background includes study in both science and the humanities, with a Bachelor degree in Microbiology from the University of California Los Angeles, a Masters in Public Health from the Johns Hopkins University School of Hygiene and Public Health (Health Policy), and a Doctorate (Ph.D.) in Philosophy from Georgetown University, where he studied Bioethics at the Kennedy Institute of Ethics. Dr. Kahn does research and publishes in a variety of areas, including theoretical bioethics, ethics and genetics, dental ethics, ethical issues in health policy, and research ethics. His experience outside the academic setting includes hospital ethics committee memberships and consultations, along with review of proposed human and animal research.

**ADVISORY COMMITTEE
ON HUMAN RADIATION EXPERIMENTATION
STAFF**

Biographical Sketches

Stephen Klaidman

Director of Communications

In addition to his Committee duties, Stephen Klaidman is currently a visiting professor of journalism at the Pennsylvania State University and a fellow of the Kennedy Institute of Ethics, Georgetown University. He began his career in academia after 23 years as a journalist with The New York Times, The Washington Post, and the International Herald Tribune. Mr. Klaidman has been a columnist, editorial writer, reporter, and editor. He has been a senior associate of the Institute for Health Policy Analysis at Georgetown, director of the Undergraduate Values Project also at Georgetown, and is currently an Associate in the Department of Health Policy and Management at Johns Hopkins University. He is the author of Health in the Headlines (Oxford, 1991) and The Virtuous Journalist (Oxford, 1987, with Tom L. Beauchamp). Mr. Klaidman has been a Guest Scholar at the Woodrow Wilson Center, where he won First Prize in the Media Studies competition in 1989. In 1992 he won the Lowell Mellett Award for improving journalism through critical evaluation.

Jeremy Sugarman, M.D., M.P.H., M.A.

Senior Policy and Research Analyst

In addition to his Committee duties, Jeremy Sugarman is an Assistant Professor and Co-Director of the Program in Medical Ethics in the Division of General Internal Medicine, Senior Fellow in the Center for the Study of Aging and Human Development, and Assistant Research Professor in the Center for Health Policy Research and Education at Duke University Medical Center. He received his medical degree and residency training at Duke and went on to pursue formal training in medical ethics at Georgetown University, where he received his Master of Arts in Philosophy. Dr. Sugarman also received training in empirical research at the Johns Hopkins University School of Hygiene and Public Health, where he received a Masters in Public Health. Dr. Sugarman is board-certified in Internal Medicine and is a practicing physician at the Duke Medical Center. He has consulted for the U.S. Congress' Office of Technology Assessment on its Defensive Medicine and Use of Medical Technologies Project. His primary research interests relate to the moral issues associated with physician-patient communication, such as advance directives, informed consent, and shared medical decisionmaking.