

Withdrawal/Redaction Sheet

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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)
002. list	re: IAWG meeting (1 page)	06/20	P3/b(3)
003. list	re: contact info [partial] (1 page)	n.d.	P3/b(3)
004. list	re: Interagency Working Group [partial] (1 page)	12/02/1996	P3/b(3)
005. list	re; Human Radiation Contact List [partial] (1 page)	05/13/1996	P3/b(3)

COLLECTION:

Clinton Presidential Records
Domestic Policy Council
Elizabeth Drye
OA/Box Number: 10455

FOLDER TITLE:

Agendas/Briefing Papers

2014-0046-S

rc1440

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

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PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

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INTERAGENCY WORKING GROUP

CIA: PEREIRA, JOHN.....

(b)(3)

0013

DEFENSE: BAILEY, CLAUD..... 703-442-5675 [fax 847-0898] ✓
 PIERRE, JOAN MA..... 703-325-7302 [fax 325-2959] ✓
 SOPER, GORDON..... 703-697-5561 [fax 695-0476] ✓

ENERGY: AZIM, LORI..... 586-5319 [fax 586-0956] ✓
 GALSON, STEVEN..... 586-7700 [fax 586-9626] ✓
 MELAMED, ELLY..... 586-6857 [fax 586-2368] ✓
 NORDHAUS, BOB..... 586-5966 [fax 586-1499] ✓
 O'TOOLE, TARA..... 586-6151 [fax 586-0956] ✓
 SCHIAVO, LISA..... 586-5289 [fax 586-1499] ✓

-9552, 2268

EPA: FRANK, BILL..... 564-2584 [fax 501-0069] ✓

JUSTICE: GLYNN, PAT..... 616-4200 [fax 616-4473] ✓
 PLAZA, EVA..... 514-3309 [fax 514-8071] ✓

HHS: BALDWIN, WENDY... 301-496-1096 [fax 402-3465] ✓
 ELLIS, GARY..... 301-496-7005 (#205) [fax 402-2071] ✓

NASA: FERGUSON, EARL..... 358-4538 [fax 358-3038] ✓
 NICOGOSSIAN, ARNAUD 358-0215 [fax 358-4174] ✓
 STOKLOS, JANIS... 358-2209 [fax 358-3038] ✓

OMB: GLAUTHIER, T.J..... 395-4561 [fax 395-4639] ✓
 MACRIS, ERIC..... 395-4706 [fax 395-4817] ✓

OSTP: LEVINSON, RACHEL.. 456-6137 [fax 456-6027] ✓

VA: DEVESTY, BOB..... 273-8453 [fax 273-9080] ✓
 MATHER, SUSAN..... 273-8575 [fax 273-9079] ✓
 QTCHIN, NEIL..... 273-8578 [fax 273-9078] ✓
 GATHY Collier 273-7226

WH: CAPLAN, PHIL..... 456-2702 [fax 456-2215] ✓
 DRYE, ELIZABETH.... 456-2216 [fax 456-7028] ✓
 NEUWIRTH, STEVE.... 456-7903 [fax 456-1647] ✓
 REGAS, DIANE..... 456-5589 [fax 456-7028] ✓

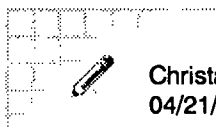
David Fein

RM 213

456-6219

Paul

616-4448



Christa Robinson
04/21/97 03:49:23 PM

Record Type: Record

To: See the distribution list at the bottom of this message

cc:

Subject: POTUS Schedule

4/21 Tomorrow POTUS goes to North Dakota to visit flood relief sites.
4/23 **Tape National Service Video**
FLOTUS Reading is Fundamental Event
CWC Vote Event
4/24 Press interviews, ENDA photo-op
4/25 Visit with Hashimoto
4/26 **Radio Address on America Reads & AmeriCorps reading tutors.**
4/27-28 **Service Summit**
5/1 Foreign Policy Speech (tentatively scheduled)
5/2 FDR Memorial Event
Tape Radio Address tbd
5/5-12 SOUTH AMERICA TRIP
5/14 Possible Press Conference
5/13-23 **Possible Legal Immigrant Benefits Event**
5/15 **Possible Police Officers Memorial Speech**
5/16 **Possible Tuskegee Meeting**
Tape Radio Address tbd
5/17 White House News Photographers' Assoc. Dinner
5/18 **Morgan State Commencement Speech (tentatively scheduled)**
5/19 **Welfare to Work Foundation launch (tentatively scheduled)**
5/20 **Possible Education Town Hall**
5/21 **US Conference of Mayors Drug Summit**

Message Sent To:

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002. list	re: IAWG meeting (1 page)	06/20	P3/b(3)
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IAWG Mtg. 6/20

<u>Name</u>	<u>Agency / Title</u>	<u>Phone / Fax</u>
Elizabeth Dye	WH/DPC Chief of Staff	456-5573 / 6-7028
ERIC MACRIS	OMB Budget Examiner	395-4706 / -4817
DIANE REGAS	WH/DPC senior Policy anal.	456-5589 - 7028
Eva Plaza	DOJ Dep. Asst Attorney Gen.	514-3309 / 8071
Tara O'Toole	DOE Asst. Sec. Env. Safety/Health	202-586-6151
Elly Mounmed	DOE Asst. Dir. of Environmental Health	202-586-6857
Gordon K. Soper	DoD Prin. Dep. ATSD(NCB)	(703)697-5561; 5-0476
GARY B. ELLIS	NIH Director, OPAR	301-496-7005; 402-2071
PAT GLYNN	DOJ Director, Toxic Branch	202-616-4291 616-4473
RACHEL LEVINSON	OSTP LIFE SCIENCES	202-456-6137 456-6027
Jonathan Foster	OSTP Deputy Director for Management and General Counsel	456-2735 456-6019
Cassie Gilson	OSTP Legal Intern	456-6078 60027
JOHN PEREIRA	CIA Chief, Historical Review Group	(b)(3)
LORI AZIM	DOE	202-586-5319/0956
KATHY COLLIER	VA/COMPENSATION CONSULTANT	202-273-7226 / 202-275-1729
Susan Mather	VA Chief Public Health & Env. Hazards Officer	202-273-8575 / 202-273-9080
JANIS STOKLOS	NASA HEAD, SP. RES. IN REPROD. MED.	202-353-2209 / 3038
Patricia Norris	NBAE Communications Director	(301)402-6466, 402-2071
Paul Yanowitz	DOJ Attorney, Civil Div.	(202) 616-4448
Phil Capen	WH	456-2702 / 456-2215

Fred Baldwin 301-496-1046

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(over 7
 pan
 Carmen - DOD
 Mansfield - CIA
 John - HHS
 Angelo - ?

Name

Agency

Phone [003]

John Pereira
 Janis Stoklosa
 Patrick Glynn

CIA
 WASA
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Carmen McDougall
 Gary Ellis

Joe March
 Mike Mansfield
 Carol Forman
 Toby Graff

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 CIA
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 616-2765 - 574-7971
 690-7854 - 690-5673

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e-mail: macris_e@a1.eop.gov

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Harold Gracey ph: 202-273-4808 fax: 202-273-4877

Neil Otchin ph: 202-565-7057 fax: 202-565-7572

WH: Phil Caplan ph: 202-456-2702 fax: 202-456-2215

e-mail: caplan_p@a1.eop.gov

EPA: William Frank ph: 202-564-2584 fax: 501-0069

e-mail: frank.william@epamail.epa.gov

note: main contact is listed first, although this is not necessarily the most senior member of the IAWG staff for that agency; where e-mail is available for the main contact, it is included.

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C004]

CIA: PEREIRA, JOHN.....

(b)(3)

DEFENSE: BAILEY, CLAUD..... 703-442-5675
 PIERRE, JOAN MA..... 703-325-7302
 SOPER, GORDON..... 703-697-5561

[fax 847-0890] ✓

[fax 325-2959] ✓

[fax 695-0476] ✓

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 GALSON, STEVEN..... 586-7700
 MELAMED, ELLY..... 586-6857
 NORDHAUS, BOB..... 586-5966
 O'TOOLE, TARA..... 586-6151
 SCHIAVO, LISA..... 586-5289

[fax 586-0956] ✓

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[fax 586-2268] ✓

[fax 586-1499] ✓

[fax 586-0956] ✓

[fax 586-1499] ✓

EPA: FRANK, BILL..... 564-2584

[fax 501-0069] ✓

JUSTICE: GLYNN, PAT..... 616-4200
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[fax 616-4473] ✓

[fax 514-8071] ✓

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[fax 456-2215] ✓

DRYE, ELIZABETH..... 456-3016 5573

[fax 456-7028] ✓

NEUWIRTH, STEVE..... 456-7903

[fax 456-1647] ✓

REGAS, DIANE..... 456-5589

[fax 456-7028] ✓

~~Daniel F...~~

456-6247

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Human Radiation Contact List

[005]

Interagency Working Group

CIA: John Pereira

(b)(3)

DOD: Claud Bailey

ph: 703-442-5675

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e-mail: james.mccullough@cpqm.saic.com

Joan Ma Pierre

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fax: 703-325-2959

Gordon Soper

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DOE: Elly Melamed

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Lori Azim

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Lisa Blatt

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Steve Galson

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Robert Nordhaus

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Tara O'Toole

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DOJ: Pat Glynn

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Eva Plaza

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HHS: Gary Ellis

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fax: 301-402-2071

e-mail: ge4l@nih.gov

Wendy Baldwin

ph: 301-496-1096

fax: 301-402-3469

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

09-May-1996 04:56pm

TO: Phillip M. Caplan

FROM: Diane Regas
 Domestic Policy Council

CC: Elizabeth E. Drye
CC: Stephen R. Neuwirth

SUBJECT: Radiation

Today's discussion was very helpful. Elizabeth and I plan to spend next week getting up to speed and beginning to sketch out what needs to be in a closing "package" on this issue. The week of the 20th we would like to set up 2 or 3 individual meetings with key staff from DOE, DOD, HHS... We would then like an interagency meeting on May 29 to discuss next steps. Soon after that we would plan to call a Asst. Secretary level meeting to move forward.

What are your reactions to this plan?

Can you get us a contact list (unless you've sent it to E. already)?

Can you call a May 29th meeting, or should we?

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

23-May-1996 09:36am

TO: (See Below)

FROM: Phillip M. Caplan
Office of the Staff Secretary

SUBJECT: Human Radiation Interagency Working Group Meeting

There will be an working group meeting on Thursday, June 6 at 11:00 am in Room 472, OEOB.

Elizabeth Drye and Diane Regas, both of DPC, have begun the process of running an interagency policy process in order to come to closure on several of the outstanding issues related to the Advisory Committee's recommendations.

Please RSVP to my office at 62702.

Thanks.

Distribution:

TO: Stephen R. Neuwirth
TO: T J Glauthier
TO: Tracey E. Thornton
TO: Eric L. Macris
TO: Rachel E. Levinson

CC: Elizabeth E. Drye
CC: Diane Regas
CC: Carol H. Rasco

Fax Cover Sheet

=====

Please Deliver to:

Elizabeth Drye

*Elly
- Loretta
- Rachael*

Fax #: 94567028

Company: DPC

From:

AZIM, LORI

Fax #: 000-000-0000

Phone:

Pages: 28.

=====

Message:

This is the resend you requested of the materials for today's IAWG conference call on 202-287-1007 at 10 AM. This fax includes the newly revised DRAFT PRELIMINARY White Paper and a one-pager containing the agenda/topics for today's call. Questions, call Elly, Lori or Loretta at 202-586-6151.

This fax was sent using Castelle's FaxPress network fax server.

**INTERAGENCY WORKING GROUP STAFF
PRELIMINARY DRAFT RESPONSE TO THE
RECOMMENDATIONS OF THE
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS**

BACKGROUND

The Advisory Committee on Human Radiation Experiments (ACHRE), chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January, 1994. Acting in cooperation with Federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the Committee was charged to provide expert advice to the Cabinet-level Interagency Working Group (IAWG) on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The Committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

FINAL REPORT OF THE ADVISORY COMMITTEE

The Committee's report began by identifying the ethical standards that applied to the government and to the medical and research professions in the post-war period. Several "case studies" were then reviewed in detail, including the injections of plutonium into 18 hospital patients during World War II, research with prisoners, and research funded by the military on patients who had previously been exposed to total body irradiation in clinical settings. Intentional environment releases of radioactivity were also reviewed.

The Committee also considered issues related to some radiation exposures associated with government activities that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing. why

Finally, the Committee reviewed 125 current or recent Federally-funded studies (not limited to radiation research) and interviewed patients at selected hospitals in order to gauge the adequacy of procedures for obtaining informed consent from subjects and evaluating research risks and to sample attitudes toward human subject research.

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The Advisory Committee's recommendations fall into three major areas: biomedical experiments and population exposures (1944-1974); current human subject protection; and secrecy and openness.

BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES

Recommendation 1: Apology and compensation for three specific experiments where secrecy was involved and thus, individuals were denied the opportunity to pursue alleged grievances. These experiments involved Department of Energy (DOE) predecessor agencies and contractors only.

Recommendation 2: Apology and compensation where harm can be established, and where there was no prospect of direct medical benefit to the subject of the experiment. Several experiments and categories of experiments were proposed as candidates by the Committee.

Summary Response: The agencies involved, in coordination with the Department of Justice, are engaged in ongoing discussions with numerous claimant representatives concerning compensation issues.

Recommendation 3: Apology (without compensation) for experiments in which subjects were wronged but not harmed, i.e. where no consent or inadequate consent was obtained or the selection of the subjects constituted an injustice. One experiment was proposed as a candidate with the indication that there may be many others.

Summary Response: At the ceremony in which Dr. Faden presented him the report, President Clinton formally apologized on behalf of the government to the victims of human radiation experiments.

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Recommendation 4: No need for subject notification and medical follow-up with criteria for subsequent notification if new experiments come to light. These criteria included both the level of risk from radiation exposure and the potential benefit from medical follow-up in exposed individuals.

Summary Response: (revised) The IAWG staff has generally agreed with the Advisory Committee that no further response is warranted at this time and that the criteria set forth by the Committee are appropriate for evaluating future cases. This recommendation has generated a great deal of controversy among stakeholders, which was expressed at the Stakeholders Workshop on February 26, and 27, 1996 held by the IAWG. Although it is difficult to generalize about the diversity of views presented at the Workshop, the stakeholders generally seemed to want some form of notification along with medical care provided by physicians of their own choice, rather than medical follow-up by the government. They viewed the latter as a continuation of suspect government activities.

In addition, at hearings on human radiation experiments held by the Senate Committee on Governmental Affairs on March 12, 1996, Senator Glenn suggested that subjects may want to be notified whether or not they were harmed.

In response, the IAWG staff has further discussed and reviewed its response to this recommendation. Many staff members have pointed out that the entire human radiation experiments effort as carried out by the Federal agencies has involved a public notification process, though generally not at the level of individual participants. Lists of experiments have been made public as has a large volume of documents. The whole process has received extensive publicity.

In one example, the National Aeronautics and Space Administration (NASA) sent a detailed letter notifying all current and former NASA employees, contractors and grantees about the human research radiation review.

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Headquarters, the nine NASA Field Installations, and the Jet Propulsion Laboratory participated in this notification. These avenues of notification included those universities and institutions at which human radiation research was performed through NASA grants. Additional notification was accomplished through various NASA alumnae associations and professional organizations. At the same time, NASA did not and does not retain any administrative or individual medical records of human radiation research subjects.

In addition, through the Interagency Helpline, individuals who thought they may have been involved in experiments have had their case reviewed by the appropriate agency. In response to these inquiries, for example, DOE has notified a number of individuals that they appear to have been participants in a human radiation experiment in which DOE had some involvement.

Several agencies have been reviewing this issue of notification in specific areas. *

Treatment with Nasopharyngeal (NP) Radium during Military Service

DOD
NOTIFICATION

The Departments of Defense (DOD) and Veterans Affairs (VA) have been considering a relatively large group which has attracted public attention: the servicemen who received NP irradiation during and immediately following World War II. Nasopharyngeal irradiation was considered accepted medical treatment at the time, and records identifying that individual treatment took place are difficult to locate. DOD has been able to locate names of a few servicemen receiving this treatment and in these cases has sent a letter informing the servicemen of this fact and providing a fact sheet about the therapy.

The VA, along with the Centers for Disease Control (CDC) and Yale University, co-sponsored a workshop on the public health response to NP irradiation which was held in New Haven, Connecticut in September 1995. Consensus did not support medical screening of symptomatic individuals but recommended that individuals treated with NP radium inform their health care

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providers for consideration when they were examined or evaluated. VA officials have published information on NP radium treatments in medical journals and sent information to veterans' service organizations for their newsletters.

The VA and CDC are planning a satellite teleconference in September 1996 to provide health professionals information about this issue. Currently, veterans treated with NP radiation do not have special eligibility for VA care. A current bill (HR #2080), if enacted, would provide priority eligibility to veterans treated with NP radium in service. A VA legislative proposal also currently under consideration would make veterans treated with NP radium eligible for the VA's Ionizing Radiation Program. *legislate*
** check w/ L. Corman*

Alaskan Natives

A number of Alaskan Natives were involved in the U.S. Air Force Arctic Aeromedical Laboratory Iodine-131 thyroid test, which took place in 1956 and 1957. Although both the Advisory Committee and the Institute of Medicine (IOM) determined that there was no evidence of lifetime risk to the participants in these tests, notification and follow-up of the juvenile participants was recommended by the latter as prudent. The Air Force is currently determining appropriate follow-on concerning the minors involved in the Iodine-131 study. In general, the Air Force and the Radiation Experiments Command Center (RECC) are following up on the recommendations of the IOM in its recent report concerning the Iodine-131 experiments involving Native Alaskans. Efforts are ongoing to locate documents about experiments involving Native Alaskans and to identify the six Native Alaskans and six soldiers whose names were omitted from the study report. *DoD*

DOE Efforts

In addition to the subjects of the plutonium injection experiments, whose next-of-kin, where located, were notified, DOE is trying to identify whether there are

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any other subjects for whom it has information that would make notification possible. Although the agency does not currently believe that this information is available, a letter has been sent to all DOE facilities at which human radiation experiments were identified, asking them to provide detailed information about the kind of individual information available, if any, relating to the subjects, the feasibility of notification and whether any kind of notification process has already taken place. DOE has carefully considered the issues raised by notification and the agency's continuing concerns about the value and feasibility of this process were included in the testimony of Dr. Tara O'Toole before the Senate Committee on Governmental Affairs on March 12, 1996.

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Testimony

Recommendation 5: Working with Congress to amend the Radiation Exposure Compensation Act of 1990 (RECA) to cover other exposed populations, including citizens exposed around the Hanford site.

Summary Response: (revised) The IAWG staff agrees with the Advisory Committee's concern about treating exposed populations fairly. Studies are underway that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats, and Oak Ridge. If information is forthcoming showing increased cancer resulting from the operation of DOE facilities, the government will work with Congress to amend existing laws to cover those affected. The GAO has been provided with a list of all studies currently in process.

finis?

- GAO
file

Recommendation 6: (revised) Updating the epidemiologic tables that govern relief for veterans and improving the administration of the current laws governing compensation.

VA

Summary Response: The VA has established a Task Force led by the Undersecretary for Benefits to evaluate the likelihood of injury due to exposure to ionizing radiation. Representatives are included from the Departments of

- No 2nd meeting
NIA hasn't put forth adequate person -
NIA individual
not updating EPI tables.

Draft Federal response to ACHRE Recs. 5/8/96. This document is strictly for discussion purposes only. It was prepared by staff at various agencies and has not been fully approved by these agencies. All responses are preliminary.

Dr. John Boyle -
approved / appears
to be reviewing.
long following up w/ NIA
of orphan drug act.

Harold Grace
CS

John Vogel

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~~Defense (DOD) and Health and Human Services (HHS):~~ The Task Force is also evaluating the efficacy of the current law and regulations relating to compensation of veterans whose illnesses or deaths may be attributable to their radiation exposures while in military service. The report is expected to be completed in the late spring or early summer of 1996. Specifically, the report will recommend the most feasible way to accomplish updating the epidemiologic tables; describe the administration of laws governing compensation of Atomic Veterans; and if appropriate recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

*DOD

Recommendation 7: Working with Congress to possibly amend the Radiation Exposure Compensation Act of 1990 (RECA) relating to uranium miners. The changes would involve a widening of eligibility for compensation and a loosening of documentation requirements.

Summary Response: A committee of government scientists and attorneys with appropriate experience and expertise was established to review the provisions in RECA that relate to compensation for uranium miners. The committee also reviewed the Department of Justice's (DOJ) implementing regulations under RECA to ensure that they are not unduly restrictive. The committee consists of four scientists from the National Institute of Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI), and three attorneys from DOJ. The committee report is in the process of completion.

The committee has agreed on a series of recommendations that propose significant and substantial modification to the statutory compensation criteria for lung cancer and nonmalignant respiratory diseases, and to the regulations that govern proof of these diseases. In a few instances, it has recommended that statutory criteria be modified but has not proposed specific alternative criteria. This was the case where, in the time allotted, the Committee was unable to locate sufficient reliable data to analyze or because the appropriate solution ultimately depends on a purely policy judgement.

RECA review committee - status of legislative changes.

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Recommendation 8: Continuing the current medical monitoring and treatment program for citizens of the Marshall Islands as long as any member of the exposed population remains alive. In addition, consideration should be given to adding the populations of other exposed atolls to the south and east; to involving the Marshall Islanders in the design of any further medical research conducted on them; and establishing an independent panel to review the adequacy of the current monitoring and treatment program.

Summary Response: (revised) Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other northern Marshall Island atolls were a factor of 30-90 times less than at Rongelap and about 10-25 percent of those at Utirik based upon external dose measurements and on estimates of thyroid doses. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by DOE and managed by CDC. If new data is developed to indicate that residents of atolls south and east of Bikini other than Rongelap and Utirik are at increased health risk, Congress would need to consider expanding the current medical surveillance program. *time frame?*

The planned Joint Commission for Accreditation of Healthcare Organizations (JCAHO) review of the DOE Marshall Islands Program, administered by the Brookhaven National Laboratory, has recently been suspended. At the request of the Government of the Republic of the Marshall Islands (RMI), the mechanism for such a review is being reevaluated based on further input from RMI. Discussions with the RMI Ambassador to the United States have taken place and RMI has requested a broader review that might be done by the National Research Council/National Academy of Sciences. The Department is considering the use of a Blue Ribbon Panel as another possible mechanism for this review.

Representatives of RMI participated in the February Stakeholders Workshop and DOE is generally working with RMI representatives to determine how to enhance the program to better meet their current needs. *STATUS?* DOE is also in the

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process of locating additional documentation requested by RMI and facilitating their access to material already located.

CURRENT HUMAN SUBJECT PROTECTION (revised)

Overview: Responses to these recommendations involve a wide range of approaches, some of which are activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that are being implemented in the near term while others will require preliminary groundwork prior to full implementation. A third group of responses involve referring certain recommendations to the National Bioethics Advisory Commission (NBAC), an independent body established by the President through Executive Order 12975 on October 3, 1995. (Presidential appointments to NBAC are pending.)

In general, agency activities in response to these recommendations fall into the following categories:

- Referring specific Advisory Committee recommendations to NBAC which will provide expert advice on issues of bioethics;
- Developing educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in non-Federally funded research with the ethical considerations in conducting research involving human subjects;
- Implementing training programs within Federal agencies to educate senior level officials on regulations and policies governing human subjects research;

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- Reminding institutions conducting Federally funded research of their ongoing responsibilities with respect to Institutional Review Board (IRB) review;
- Pooling resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the government's system for the protection of human subject, and to establish processes for oversight or review of compliance;
- Considering the proposal of legislation to remedy some of the gaps in the current system for protecting human subjects;
- Implementing educational workshops and an active dialogue with international partners with whom Federal agencies cooperate in human research to develop common ethical principles and to ensure the rights of human subjects are protected, e.g. specific activities proposed by NASA.

How to maintain

Individual Recommendations and Summary Responses:

Recommendation 9: Efforts to ensure centrality of ethics in the conduct of human subjects research.

Summary Response - mechanism?

Summary Response: NBAC will provide advice and make recommendations to the National Science and Technology Council and other appropriate government entities in the areas of bioethical issues arising from research on human biology and behavior and the clinical applications of that research. NBAC will also identify broad principles to govern the ethical conduct of research. The IAWG staff has identified activities carried out in recent years to address this issue as well as major new efforts to upgrade or expand these

applicability, includes

NBAC

- 4-5 agencies mentioned
intro

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activities that will be carried out by HHS, DOE, DOD, and NASA.
Some of these are discussed below.

In addition, the National Institutes of Health (NIH) is leading an interagency initiative to fund the development of new knowledge related to the informed consent process. Despite the vigor with which all parties embrace the informed consent process, little is actually known or understood about it. Much of the Advisory Committee's commentary on current human subjects research was centered on informed consent, and NIH, NASA, VA, DOE, and DOD are committed to supporting research that will more fully illuminate the process. A Request for Applications (RFA) is in preparation, and Fiscal Year 1997 monies are intended to support this RFA.

- what types of questions

getting \$
A who has signed on dotted line?
(Can will make it happen)

Recommendation 10: Changes IRBs in five critical areas: better focus on studies that pose more than minimal risk; better mechanisms for providing information to potential subjects that distinguishes research from treatment; realistically explain benefits, and clearly describe the potential for discomfort and pain; better mechanisms for providing information to potential subjects on sponsors and purposes of the research; better mechanisms for providing information to potential subjects on financial implications; and recognition that the IRBs must determine if the quality of the science justifies the risk.

Agency

→ **Summary Response:** The IAWG staff has agreed that agencies will instruct IRBs to be responsive to these recommendations and will provide oversight and review to ensure compliance. The IAWG staff will work with NBAC and the National Science and Technology Council in carrying out these recommendations.

NBAC

The Office of Protection from Research Risks (OPRR) leads a national educational effort to showcase the Advisory Committee's message. OPRR collaborates closely with Public Responsibility in Medicine & Research (PRIM&R), a Boston-based private, nonprofit organization, to stage an annual

OPRR?

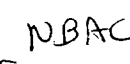
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public meeting for individuals interested in the governance of human subjects research. More than 600 people attended the October 1995 PRIM&R meeting, at which the Advisory Committee recommendations were presented for the first time to the IRB community. OPRR has scheduled presentations and discussions of the recommendations at national workshops in Atlanta, Oklahoma City, Honolulu, Peoria, and Houston. The November 1996 PRIM&R annual conference in San Diego is expected to address IRB implementation of the recommendations. The recent placement of the Advisory Committee report on the World Wide Web makes it possible for IRBs to examine its full text.

In October, 1995, the Food and Drug Administration (FDA) issued a major, 154-page revision of its "Information Sheets for Institutional Review Boards and Clinical Investigators," to take account of the latest thinking and to provide guidance to IRBs.

OPRR and FDA make extensive use of public meetings, forums, hearings, FAX call, and electronic media to address evolving issues on human subject protections. OPRR and FDA actively identify and mail to IRBs and other interested parties copies of Federal Register notices and "Dear Colleague" letters regarding human subject protections.

Recommendation 11: A mechanism for the continuing interpretation of ethical rules in a public forum. 

Summary Response: It is expected that NBAC will develop and maintain a forum for implementing this continuing review and interpretation of ethical rules. *principles.* 

Recommendation 12: Improving the rights and interests of military personal with respect to human subject research by reviewing policies and procedures,

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educating officers and investigators, maximizing voluntariness, and maintaining a registry of volunteers.

Summary Response: DOD has agreed to a number of specific steps including revising directives or Military Department regulations to meet these proposals and incorporating appropriate training into courses for commanders and senior leadership as well as those involved in human subjects research. In the summer of 1996, DOD will publish a revised human subject protection regulation that will include policy changes recommended by the Advisory Committee. For example, new policy will preclude officers and non-commissioned officers from playing a role in selecting volunteers for military tests to avoid undue command influence.

STATUS

Recommendation 13: Improving the current Federal system for protecting the rights and interests of human subjects in the areas of oversight, sanctions, and scope.

Summary Response: In addition to Federal agencies undertaking specific activities in response to this recommendation, some of which are described below, it is expected that NBAC will fully address this recommendation in carrying out its responsibilities.

are already

oversight, sanctions

NBAC

Recommendation 14: Resolving the longstanding issue of whether and how all persons injured in the future from Federally-funded research should be compensated.

NBAC (prospective)

Summary Response: The IAWG staff recommends to NBAC that it begin an early assessment of compensation for research injury. Despite being addressed twice before by the HEW Secretary's Task Force (1977) and the President's Commission (1982), a definitive resolution of the long-standing social policy issue remains elusive.

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NBAC Update: The principal response of the Executive Branch to the Advisory Committee findings and recommendations was the creation of NBAC. As a first priority, NBAC shall direct its attention to protection of the rights and welfare of human research subjects. Human radiation experiments, per se, are not referenced in NBAC's charter.

Although its chartering was catalyzed by the Advisory Committee report, NBAC in fact represents the reinstitution by the President of an entity that has been absent since 1983. That entity is a national, deliberative body of private citizens that provides advice and recommendations to the government on bioethical issues arising from research on human biology and behavior, and the applications of that research. As such, NBAC can be expected to pursue various issues identified in these Committee recommendations based on their merits, as judged by NBAC.

The President is expected to appoint the NBAC membership soon, with meetings to begin in mid-1996. Reports provided to NBAC by agencies that carry out current human research will permit NBAC to begin a critical assessment of the implementation of the 1991 Federal Policy for the Protection of Human Subject ("Common Rule"). Such independent analysis is critically needed, five years after the promulgation of the regulations.

At the March 12th hearing, both the Chairman and the Ranking Minority Member of the Senate Committee on Governmental Affairs expressed concerns about human subjects protections in non-Federally-funded research -- a specific Advisory Committee concern as well. The Advisory Committee had called for the IAWG to take steps to ensure that all human subjects are adequately protected, and the IAWG staff will work closely with the Senate Committee as it pursues this issue. NBAC can also be expected to address this issue.

IAWG on
an
(permanent)

Current Agency Activities: As part of the Executive Order, all agencies that are involved in current human subject research (not only those agencies

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represented on the IAWG) were required to review this research in the light of the Advisory Committee recommendations and report to NBAC. DOE, DOD, DHHS, NASA, VA, CIA, and DOJ (along with many other agencies) are providing NBAC with reports that are fully responsive to the President's October 3, 1995 Executive Order. The following are some specific activities that have been undertaken by IAWG agencies in relation to, or as a result of, this review.

The Department of Energy:

- Developed a newly revised handbook on protecting human subjects which is in pre-publication review. The handbook specifically addresses issues raised by the Advisory Committee on informed consent and classified research.
- Has begun a program of regular site visits to its facilities performing human subjects research, for education and review. Each site will be visited approximately once every three years.
- Requested all DOE laboratories to provide a sample of current informed consent documents. These will be reviewed by a team charged with improving and monitoring the quality of these documents.
- Requested all laboratories to provide plans that detail local activities to improve the human subjects research review system.
- Issued a brochure to educate the DOE community on human subjects protection, updated its human subjects research database, held its annual human subjects workshop and created a World Wide Web Home Page on human subject programs.

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The Department of Defense:

- Reviewed in detail DOD's existing policies and procedures for the protection of human subjects of research and has undertaken extensive revision of DOD Directive 3216.2, "Protection of Human Subjects in DOD Supported Research."
- Proposed changes to current policies that would:
 - Adopt investigator assurances of familiarity with the Nuremberg code, the Belmont Report, the Common Rule and related requirements;
 - Incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals;
 - Include specific language in the revised directive that would emphasize the expedited review process for certain categories of minimal risk research that are detailed in the Common Rule (32 CFR 219);
 - Require education in human subjects regulations in the executive level of training for commanders and senior civilians who may be involved in human subjects research and for individual investigators, IRB members, research administrators, and support personnel; and
 - Ensure that officers and senior NCOs in the chain of command not be present during research recruitment briefings of personnel under their command, and that an ombudsman be present at group recruitment briefings.

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The National Aeronautics and Space Administration:

- Established an external Bioethics Policy Task Force to review all NASA human use research policies and procedures, chaired by Baruch Brody, Ph.D., Leon Jaworski Professor of Biomedical Ethics and Director of the Center for Ethics, Medicine and Public Issues at Baylor College of Medicine. The final report of the Task Force was provided on February 14, 1996. In collaboration with the Task Force, NASA enhanced the conduct of human subjects research so that it satisfies the requirements both of the Federal Common Rule and of the highest principles of research ethics.
- Updated the NASA Management Instruction (NMI) on the conduct of Human Research, issued on August 8, 1995, to reflect the Federal Common Rule and incorporate the relevant recommendations reflected in the Advisory Committee's final report. NASA Headquarters has also established a process for oversight and assurance.
- Conducted internal reviews at Headquarters, Johnson Space Center, and Ames Research Center to ensure that elements of the Common Rule and Advisory Committee recommendations were incorporated into agency and Center instructions.
- Because much of its future space research will be conducted with its partners on the International Space Station, has conducted the first in a series of forums to inform NASA's international biomedical community on issues related to the ethics of human subjects research. These workshops will effect a transnational understanding of the sensitivity to ethical issues in human research and ensure that all international partners support common ethical principles regarding the protection of human subjects. A common consent form for use on the international space station was agreed upon and will undergo periodic review.

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- Initiated ethics forums on the Common Rule and protection of human subjects for its domestic biomedical research community.

The Central Intelligence Agency:

- Obtained the services of a prominent ethicist from the academic community to become a permanent voting member of the Agency's Human Subject Research Panel (HSRP).
- Revised agency regulations to indicate that all research carried out or sponsored by the Agency that utilizes human subjects shall be brought to the HSRP for approval. The Chairman must certify as exempt or approve a research proposal before it can proceed, and final approval rests with the Agency Director.
- Disseminated an Agency Bulletin to all employees specifying the rationale and function of the panel and necessity of referring human subject research to it for approval.
- Revised the Agency's Contracting Manual to guarantee that HSRP approval is obtained prior to approval of any contract involving human subject research.

The Department of Health and Human Services:

- Designated the Office for Protection from Research Risks, National Institutes of Health, to coordinate the preparation of the NBAC report with information drawn from the Public Health Service agencies and other operating divisions.
- Began activities to improve the procedures for protecting human subjects; for example, CDC is developing an on-line education system in research integrity and ethics that will be mandatory for investigators.

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- Ensured that FDA will respond to NBAC, not only as part of the Department, but also in its capacity as a regulator of research done by private industry.

Other Agencies:

- VA has planned IRB site visits to review procedures and their Office of Research and Development is reviewing its policy manual to identify any needed revisions.
- The Department of Education anticipates reporting to NBAC on ongoing training activities, and efforts to disseminate information through guidance documents and establish networks within that Department.
- The Environmental Protection Agency (EPA) is planning to issue an internal order implementing the Common Rule.
- The Consumer Product Safety Commission is updating and changing its internal documents and policies.

SECRECY AND OPENNESS

Recommendation 15: a) No waiver of informed consent for classified research and informing the potential subjects of the identity of the sponsoring agency and that classified research is involved and b) For classified research, establishing an independent panel, whose records are permanent, to review scientific merit, risk/benefit, consent, and whether subjects need a security clearance.

Summary Response: (revised) The IAWG staff proposes that the President and/or Agency Head direct all departments and agencies that, effective immediately, there will be no waivers of informed consent for Federally funded classified research. Also, in all Federally funded classified research, two

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additional elements of information be provided when consent is sought from potential human subjects: 1) the identity of the sponsoring Federal agency and 2) a statement that the project involves classified information.

NBAC should then evaluate whether the Federal rules governing human subjects protection should be revised to codify these directives. NBAC

The IAWG staff is reluctant to propose creating a new oversight body for 15(b) but proposes to use the current IRB system which already must include at least one member not affiliated with the institution. The IRBs could be directed to ensure that participation of non-government persons in reviewing the classified research by establishing a dedicated panel or ensuring that all IRB members have the necessary clearances.

Recommendation 16: a) Review by an independent panel of any planned environmental release where any aspect involves secrecy and b) Environmental oversight of classified programs (now done by EPA) should include keeping review records permanently and reporting to Congress.

Summary Response: (revised) EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. There is concern that creating a new regulatory entity would add to the bureaucratic complexities of ensuring environmental safety.

EPA's ability to oversee classified operations to assure compliance with environmental laws could be improved through implementation of "a program directed at the oversight of classified programs, with suitably cleared personnel," as stated in Recommendation 16b. The narrative accompanying Recommendation 16b correctly states that all Federal agencies are obligated by Executive Order 12088 to comply with environmental laws and fully cooperate with EPA, and State, Interstate, and local agencies to prevent, control, and abate

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environmental pollution, regardless of whether the activities of regulated Federal agencies are classified.

1. While EPA currently does oversee all Federal government operations, whether classified or not, through its enforcement program, which assures compliance with environmental laws by Federal agencies, EPA does not have as yet a systematic information gathering, coordination, or reporting process specifically related to issues of national security and/or activities subject to the Federal government's information secrecy program under Executive Order 12356.
2. In May 1995, EPA and the Air Force signed a Memorandum of Agreement assuring environmental compliance at a secret operating location known as the "Operating Location Near Groom Lake". Discussions are now taking place between EPA and the Air Force to establish through a second, broader Memorandum of Understanding an EPA operational enforcement capability over all classified Air Force projects. EPA's goal is to take lessons learned from reaching such a Memorandum of Understanding to then discuss comparable issues with other affected agencies.
3. In the past, EPA and state inspectors have obtained, on a case by case basis, appropriate clearances for access to national security information and facilities. To operate an effective enforcement capability over classified projects, EPA is considering systematically identifying cleared personnel and to seek from the operating Federal agencies through a series of Memoranda of Understanding the appropriate "need to know" access. This new process would assure that EPA could handle most environmental compliance matters through administrative processes in classified settings.

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The National Environmental Policy Act (NEPA) directs Federal agencies to prepare an environmental impact statement for "major Federal actions significantly affecting the quality of the human environment." Section 309 of the Clean Air Act directs EPA to review Federal proposals for legislation, regulations and major federal actions significantly affecting the quality of the human environment and comment in writing.

The Council on Environmental Quality regulations state that "...[e]nvironmental assessments and environmental impact statements (EIS) which address classified proposals may be safeguarded and restricted from public dissemination in accordance with agencies' own regulations applicable to classified information." (Section 1507.3(c))

Under the aforementioned provisions, EPA has reviewed classified documents that have been prepared to comply with NEPA. This happens occasionally, not frequently. EPA staff that are assigned as liaisons to the DOD and DOE hold the appropriate security clearances and, in the event it becomes necessary to review a classified NEPA document, the individual typically goes to the offices of the lead agency and reviews the classified material there. EPA has seen no need to establish a system to document this procedure, and does not have any evidence that federal actions are not being appropriately reviewed in the NEPA review process.

Typically the documents that are reviewed are support documents to the EIS, which is public, and the documents have not presented data that suggest environmental impacts other or in addition to those presented in the public sections of the EIS. Should the reviewer determine that a problem exists, that problem would be surfaced to EPA senior management holding the necessary security clearance, and the issue would be further discussed with the lead agency.

EPA does not now keep a record of which EISs have classified sections. However, should it prove desirable, EPA could add this information to its

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existing tracking system. It should be noted, however, that EPA only knows about classified sections if the lead agency notifies it that they exist. With regard to reports to Congress, EPA has no reason to believe at this time that there is either a significant workload for review or significant adverse environmental effects likely to occur.

EPA's recommendation for NEPA document review is that each Federal agency should be responsible for overseeing its own handling of classified material. EPA should continue to review at a lead agency's request classified documents associated with the NEPA process. To that end, staff assigned to work with the DOD and DOE should have the relevant security clearances. It should continue to be the lead agency's responsibility, however, to trigger such a review. EPA does not have the authority to compel, or the access to discover, the existence of classified documents. Should it be deemed advisable, EPA could modify its tracking systems to include the existence of classified documents associated with a particular EIS or, if necessary, totally classified documents that are not officially filed with EPA or made public.

Recommendation 17: Ensuring historical records are organized and accessible by 1) hastening movement of records to Archives; 2) making indexes and finding aids readily available; 3) improving public access to records in the custody of agencies; 4) maintaining records of document destruction; and 5) reviewing policies governing access to records of grantees and contractors.

Summary Response: (revised) For 1, 2, 3, and 5, the IAWG staff agrees with moving aggressively down the path to openness exemplified by this project and will work to make government records more accessible including using new technology to enhance access. For 4, the IAWG staff would propose making the records themselves of classified human subject research permanent and the records of destruction of all human subject research permanent.

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Current Agency Activities: IAWG members have initiatives underway to ensure that information retrieved for the human radiation experiments project is readily available to the public, and to respond to specific Advisory Committee recommendations on openness.

The Department of Energy:

- The Department has produced three publications which include background information, record series descriptions, topical essays, a list of over 400 experiments, and oral histories. Most of this information, along with over 250,000 scanned historical documents, is located on the Internet, with paper copies of all documents at the Coordination and information Center (CIC) in Nevada.
- In response to Advisory Committee recommendations, DOE is
 - Negotiating the transfer of over 3,000 cubic feet of records to the National Archives; and
 - Actively making finding aids to records still in agency custody more readily available to the public, and has prepared records access guidance. To date, finding aids from Headquarters records and a number of filed sites have been placed in public reading rooms across the DOE complex.
- The Department continues to update its World Wide Web site on the Internet with additional documents of interest and recently added three new experiments to its experiment list.

The Department of Defense:

- The Department is preparing a guide similar to the DOE *Roadmap* that will describe DOD documents found during the human radiation records

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search, and will identify and list human ionizing radiation experiments conducted or sponsored by the DOD. It will also include information on DOD events that were not human radiation experiments but were specifically included by the DOD in its search efforts, such as atmospheric releases. Scheduled availability is summer 1996.

- The documents will be available on the Internet and hard copies will be deposited at the CIC. DOD has also declassified many documents identified in the search for human radiation experiments and is also planning to transfer them to OpenNet, an Internet source for recently declassified documents.
- DOD has taken the lead in an interagency effort to create a home page, on the model of DOE's, with access to documents located by all agencies as part of this project.
- DOD is expediting its response to Freedom of Information Act requests concerning human radiation experiment subjects.

The National Aeronautics and Space Administration:

- NASA will maintain a permanent collection of human radiation experiment records and database at Johnson Space Center and a process for submission of a response to requests for information has been developed.
- The agency is also working to make radiation research documents available on the Internet. The agency is creating a NASA Radiation Review Homepage which summarizes the agency's search and findings.

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The Central Intelligence Agency:

- The CIA is transferring approximately 1,000 pages of declassified documents and a CIA Inspector General report on human subject research procedures to the National Archives. The documents will also be available on the Internet.
- The agency is reviewing for declassification a few documents relevant to the MKULTRA program that had not been previously declassified and released. An independent review of the CIA's record system has been undertaken by the National Archives and will be completed in approximately six months.

Health and Human Services and Veterans Affairs:

- These agencies are preparing documents for availability on the Internet sometime in the spring or summer of 1996. Paper copies have been transferred to the National Archives.

Recommendation 18 : a) Review of CIA recordkeeping by CIA Inspector General or other groups with special attention to facilitating public access and b) Priority given to declassification of CIA historical records such as MKULTRA.

Summary Response: The National Archives has begun a scheduled review of CIA's records management program, including records access issues and the CIA has agreed to give top priority to declassification of human subjects research records.

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Attached is a revised version of the draft whitepaper, incorporating the material recently provided by the agencies. This is a draft of a draft! Please let me have any suggestions for revisions, additions, or changes that you may have.

The teleconference is Thursday at 10:00 and the number is 202 287 1007. The GAO will NOT be participating in this teleconference. After some discussion it was agreed that it would be preferable to have a teleconference for only the IAWG staff before we include the GAO, since we have not talked with one another for a number of weeks. In addition, several congressional staffers - Chris Kline from Senator John Glenn's Office and John Root from Senator Ted Steven's Office - have also asked to be included on this call with the GAO. We will try to set up this call for sometime next week.

The following is a proposed agenda for the teleconference.

1. Individual agency updates and discussion/comments on the redrafted White Paper.
2. Update/Discussion on issues of notification and compensation
3. Update by Phil Caplan on White House initiatives in relation to HRE.
4. Discussion of phone call to be held next week with GAO and congressional staff.
5. Discussion of next steps to be taken by IAWG staff.

Fax Cover Sheet

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Please Deliver to:

Diane Regas
Elizabeth Drye

Fax #: 94567028
Company: White House

From:

AZIM, LORI

Fax #: 000-000-0000
Phone:

Pages: 11

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Message:

Attached are materials for Interagency
Working Group. More information will
be forthcoming as we get it. FYI -
I do not yet have a copy of the agenda
for Thursday, June 20th's meeting. Call
if you have questions at 202-586-5319.
Have a good week!

This fax was sent using Castelle's FaxPress network fax server.

From: Elly Melamed
Department of Energy

Date: June 14, 1996

Subject: Briefing Paper on the Marshall Islands (Recommendation 8)

Background

The Advisory Committee recommended continuing current DOE surveillance program for Marshallese exposed to fallout from US atomic tests as long as the exposed population remains alive; reviewing the program to determine if other atolls should be added; and establish ~~an~~ independent panel to review the current program for providing medical care to the exposed population; and involve the Marshallese in the design of any further medical research. ✓

The Department of Energy recognizes the difficulties and inequities in the current program of medical care for the Marshall Islands and fundamentally agrees with all these recommendations. *specific?* ✓

The fundamental problem is additional funding: the Department has no additional funds available to allocate to this program. New efforts will have new costs and the Marshallese are already concerned that the current program is not funded at a sufficient level.

The Marshallese assert that they do not seek additional surveillance of additional atoll populations; they are interested in more local control of services provided by DOE and DOE and an extensive expansion of medical care facilities and services available in the Marshall Islands, including construction of a new hospital. The need for medical care is not directly linked to past radiation exposures.

- If the medical care program were to be significantly expanded, DOE is concerned that it is not the appropriate agency to undertake a broad medical delivery effort; other agencies have more expertise and experience in this matter. There are indications that the Marshallese agree with this position.
- There are complicated scientific, logistic, and financial questions in terms of expanding the current program that would need to be considered by Congress, the Department of Energy and the Department of the Interior.
- DOE would like the review panel to be a "blue ribbon group" that focuses on the current program and how to help build infrastructure and self-sufficiency for the Marshallese medical program. The Marshallese want ~~study~~ a National

Academy of Sciences study which would be more expensive, take longer and retrospectively consider the past program rather than on future options.

plus

Actions Taken

- DOE has been aggressively meeting with the Marshallese and has affirmed its plans to continue the current program, its willingness to support efforts to review the issue of adding further atolls, to establish an independent panel to review the direction and scope of the surveillance program and to work with the Marshallese to involve them in any decision making and to allocate funds according to their priorities. The Marshallese have been responsive to these assurances.
- DOE has also met with Department of Interior staff who administer the medical care services to the Marshallese in efforts to better coordinate US efforts and answer the needs of the Marshallese.
- DOE is willing to expand the surveillance program if appropriate funds are available from Congress; such funds cannot simply be transferred from existing DOE health and safety programs. A Senate hearing scheduled for June 22, 1996 will explore existing DOE and DOI programs, the Marshallese requests and attendant costs in more detail.
- DOE is concerned about the expense and the length of time involved in a study by the National Academy of Science. New funds would have to be provided by Congress for such a study to avoid compromising the current medical program.

Options

1. Let the Congressional inquiries play out, continue active negotiations with the Marshallese that would support the Marshallese desire for more local control of program directions and implementation, but do not advance legislation calling for a greatly expanded budget and health care program in the absence of Congressional Initiative.

- Pro
- Would continue to provide medical care to the acutely exposed population under the Department of Energy's (DOE's) program.
 - Would meet DOE's current Congressional mandate.
 - Would allow Congress to decide on eligibility criteria for inclusion in the program.

- Would leave Congress in the position of deciding what level of funding is needed to meet the concerns expressed.
- Would enable DOE to continue to build on improved relationships with the RMI.
- Con - Would not address the RMI coverage concerns expressed during the Advisory Committee's review.
- Would leave a poorly functioning Department of Interior (DOI) medical care delivery system intact for the bulk of the Marshallese populations also exposed to some fallout dose, while continuing to provide high quality medical care to a very few.

2. Administration submission of legislation supporting Marshallese desire for medical coverage of all Marshallese believed to be exposed and who are experiencing radiation related health effects. (Assumes adding patients to the current DOI 177 Health Care Program and increasing patient care levels to \$5,000/patient/year.)

- Pro - Would continue in the spirit of trying to find an equitable way to deal with the U.S. Government moral commitment to provide at least a minimal level of primary medical care to all deserving Marshallese citizens.
- Would honor Departmental commitments to work toward a solution that can ameliorate, in some fashion the inadequate status of medical care delivery in the Marshall Islands.
- Offers the opportunity to bring in a federal agency more qualified to provide health care delivery program of this magnitude.
- Con - Would cost the Administration some \$17.5M annually to add just the 3,500 Bikini and Enewetak proposed by Amendment 4039 to S. 1804, or
- If the additional populations of Ailuk, Likiep and Wotho (some 1900 additional) are added, costs would be driven to \$66.9M annually. This assumes treatment of the some 13,370 patients (11,470 plus 1,900).

**From: Elly Melamed
Department of Energy**

Date: June 14, 1996

Subject: Briefing Paper on Notification (Recommendation 4)

BACKGROUND

The President's charge to the Advisory Committee on Human Radiation Experiments was that: "If required to protect the health of individuals who were subjects of a human radiation experiment, or their descendants, the Advisory Committee may recommend to the Human Radiation Interagency Working Group that an agency notify particular subjects of an experiment, or their descendants, of any potential health risk or the need for medical follow-up."

In response to this charge, and using a traditional public health approach, the Advisory Committee analyzed in detail a subset of human radiation experiments involving children that they judged to represent the highest risk incurred from radiation exposure and the potential benefit of medical followup. They found that almost all of the experiments involved small radiation doses with a remaining lifetime risk of cancer of less than 1/1000, a minimal level compared with normal risk of dying of cancer. Many experiments involved tracer doses, similar to those used in medical diagnostic procedures today.

With regard to brain, head, and neck cancers among children and military personnel exposed to nasopharyngeal radium treatments, the ACHRE did find that these subjects exceeded the 1/1000 threshold for lifetime cancer risk but they found neither an accepted nor a recommended screening procedure for these tissues.

Therefore, the Advisory Committee recommended against notification and medical monitoring for subjects of biomedical human radiation experiments; it also cited potential risks and adverse effects of a widespread notification process.

Nonetheless, radiation stakeholders and possibly some members of Congress believe the government should track all experiments back to individual subjects, notify subjects of their past involvement in experiments, and provide medical care to these subjects.

Some stakeholders do not accept the risk analyses underlying the ACHRE recommendation. In addition, some stakeholders believe the government should provide medical care to subjects regardless of the ability of medical monitoring

10-20 JUN 11 1330 TELNO: 000-000-0000 0000 PAGE: 0/11

focused on preventing or mitigating currently recognized consequences of radiation exposure.

FEASIBILITY AND UTILITY ISSUES

The Interagency Working Group has strong concerns that notification is impractical, and unlikely to confer benefits, or to satisfy the groups who are requesting it. It is worth noting that the Administration's charge to the Interagency Working Group did not specify that individuals should be located and notified; the Varney Memo simply instructed agencies to locate records about experiments.

In many cases, documents do not identify subjects by name. In some instances, it may be possible to uncover subjects' names through elaborate records searches (e.g., by hand-review of all medical records of Brookhaven Hospital) but it will be extremely difficult or impossible to trace and actually locate people.

Meaningful notification would require a contemporary dose analysis and presentation of risk which is complicated and expensive; data is often inadequate to carry this out.

At least at DOE sites, many subjects knew they were involved in experimental studies; it is unclear how they would benefit from the notification process or whether these are the subjects the stakeholders are trying to reach.

The universe of records relating to individuals to which the government has access is limited; many stakeholders, for example, have indicated that their greatest concern is records of private hospital and universities where confidentiality and privacy rules prohibit government access.

In addition to risks and adverse effects identified in the notification process by the Advisory Committee, there is the strong possibility for invasions of personal privacy.

DOE polled all eight of its sites at which verified experiments took place; all provided data and made the judgement that further notification efforts were not worthwhile; they generally characterized the potential process as a high cost, low yield endeavor.

ADMINISTRATION ACTIONS TO ENSURE OPENNESS

The entire human radiation experiments process was predicated on openness and providing as much information to the public as possible about this chapter of cold war history.

All Advisory Committee meetings were open; some were held outside of Washington; stakeholders were asked to participate at the open forums.

Agency search efforts and methods were fully described and available for public review.

A telephone Helpline for those who thought they were potentially subjects of experiments was established at the beginning of the project; agencies responded directly to these individuals who identified themselves through this process.

Agencies provided close to a thousand cubic feet of records to the Advisory Committee; all records located for this project are available to the public at the National Archives in College Park. DoD and DOE records are also available at the Coordination and Information Center in Nevada.

All agencies are in the process of making their documents available on the Internet World Wide Web with full text searching across agency collections; all will continue to make information available as it is located.

AGENCY-SPECIFIC ACTIONS

Individual agencies effectively tailored notification and search efforts and products to meet their individual situations and histories; examples of specific activities follow.

The Department of Energy:

- Produced three publications - a Roadmap, a List of Experiments, and an Oral History - and made over 250,000 documents available on the Internet World Wide Web.
- Notified next of kin for 14 of the 18 plutonium injection subjects; others could not be located. In response to Helpline requests, notified 15 individual subjects and next of kin that they were involved in human radiation experiments involving DOE and its predecessors. The cases of 3,100 additional people who wrote or phoned were intensively researched and supplied with specific information. Many thousands of other callers were referred to other agencies or received responses that did not require research.
- Is developing a workshop for stakeholders on how to research individual information across the government and using other private and public sources.

The Department of Defense:

- Is producing a publication documenting its search and is leading the interagency effort to put all documents on the Internet.
- Is also working through a caseload of 5,992 inquiries of which some have been closed out and some referred to other agencies; 997 are currently undergoing active research.
- In response to an Institute of Medicine report on thyroid tests involving Alaskan Natives, which recommended notification and follow-up of the juvenile participants, the Air Force determining appropriate follow-on and working to identify six Alaskans and six soldiers whose names were omitted from the report.
- Is working with the Veterans Administration to provide information to the medical and veterans communities about the veterans who received nasopharyngeal irradiation; some names have been located and efforts are being made to find additional information in order to notify these subjects. The effort is proceeding because there is some concern that such treatment incurred increased risk of head and neck cancer and even though these radiation treatments were conventional medical practice at the time, and there is no established means of preventing such cancers.

Other agencies:

- The Department of Veterans Affairs (VA) has responded to approximately 1,450 inquiries; VA also identified and reviewed the protocols for 53 research projects, determining that all doses were tracer levels.
- Health and Human Services (HHS) responded to the 88 individuals who wrote to the agency, of which eight had records at the National Institute of Health (NIH) Clinical Center; a physician from the NIH Clinical Center's Nuclear
- Medicine Department reviewed each case, explained the extent of exposure, and offered an evaluation of risk.

WHAT ARE THE GOVERNMENT'S OPTIONS?

1. The government can attempt to carry out the individual notification effort that the stakeholders and some Members of Congress would like to see done.

Pro: This effort would please the stakeholders who would see it as a good faith gesture whatever the outcome.

This may satisfy some of the concerns of Congress who feel that regardless of harm, subjects would want to know about their involvement.

Con: This effort would be extremely expensive, and is likely to be of limited value; the stakeholders would probably be disappointed with what is ultimately achieved.

The expert group set up by the President to make a judgement on this issue rejected this approach.

Benefits are unclear and potential exists for adverse reactions and invasions of privacy.

2. The government can accept the recommendation of the Advisory Committee and reject any additional notification efforts.

Pro: This is the simplest, least expensive approach and is consistent with conventional public health practice and with the expert Advisory Committee process set up by the President.

Con: This may produce adverse publicity if the Government is perceived as being unresponsive to a vocal constituency with longstanding and strongly expressed grievances.

Congress may possibly mandate some form of additional notification activity.

3. The government can fundamentally accept the Advisory Committees recommendation but also (a) carefully frame its response to make clear that a great deal has already been done that is part of a general openness/public notification process and (b) make a strong case for the difficulties and adverse impact of this process.

Pro: This allows the Government to make the choice that seems most consistent with the evidence available and the process established, but also attempts to mitigate negative political consequences and to more fully publicize and explain the actual issues involved - (there are not "thousands" of experiments that require notification).

Con: Stakeholders may be unwilling to accept anything less than an all out notification effort and Congress may still mandate some form of notification.

4. The government can do (3) above, but in addition investigate the possibility of offering Medicare coverage to members of certain groups who are not yet eligible for this coverage. Three potential groups are the atomic veterans, the uranium miners, and the Nevada test site downwinders. All three of these groups have been formally recognized in legislation as subject of government sponsored radiation exposure. A very rough estimate of the numbers are: atomic veterans - approximately 400,000, approximately 200,000 of whom are believed to be ineligible for Medicare at this time; Nevada downwinders - approximately 19,000; and atomic veterans - approximately 18,000.

Pro: Avoids the problems of notification but provides medical coverage, a crucial issue for stakeholders, to three important groups.

May ultimately be more satisfying to stakeholder groups than biomedical experiments notification since it involves more subjects.

Represents a genuine attempt by the government to find compassionate ways to respond to stakeholder concerns.

Con: Potentially expensive.

May not be politically feasible given the current sensitivity with Medicare.

**From: J. Patrick Glynn
Department of Justice (DOJ)**

Date: June 13, 1996

Subject: DOJ Response (Recommendation 2) (From 2/16/96 Draft Response)

Recommendation 2: Apology and compensation where harm can be established, and where there was no prospect of direct medical benefit to the subject of the experiment. Several experiments and categories of experiments are proposed as candidates by the Committee.

Summary Response: As recommended by the Advisory Committee, in coordination with the Department of Justice (DOJ), and to the extent permitted by law, subjects (or their surviving immediate family members) will be offered reasonable financial compensation for human radiation experiments in which a government agency was involved in actions falling within the Advisory Committee criteria:

1. Experiments in which excessive secrecy deprived individuals of the opportunity to pursue potential grievances;
2. Experiments in which there was no prospect of direct medical benefit to the subject and physical injury resulted; or
3. Experiments in which interventions considered controversial at the time were presented as conventional or standard practice and physical injury resulted.

A streamlined administrative process, based on Federal Tort Claims Act procedures or other applicable law, will be used to offer compensation as part of a settlement of relevant claims. Maximum effort will be made to avoid lengthy litigation, including use of alternative dispute resolution, such as mediation or arbitration, where appropriate. The amount of compensation will be based on the extent of physical injury to the subject, the nature of the experiment, and the degree of government involvement. As needed, agencies will seek expert advice on scientific and medical issues. If compensation cannot be offered under existing law in any case under the stated criteria, the Administration will work with Congress to seek legislative relief in appropriate cases.

Fax Cover Sheet

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Please Deliver to:

Diane Regas ✓
Elizabeth Drye

Fax #: 94567028
Company: White House

From:

AZIM, LORI

Fax #: 000-000-0000
Phone:

Pages: 11

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This fax was sent using Castelle's FaxPress network fax server.

**From: Elly Melamed
Department of Energy**

Date: June 14, 1996

Subject: Briefing Paper on the Marshall Islands (Recommendation 8)

Background

The Advisory Committee recommended continuing current DOE surveillance program for Marshallese exposed to fallout from US atomic tests as long as the exposed population remains alive; reviewing the program to determine if other atolls should be added; and establish an independent panel to review the current program for providing medical care to the exposed population; and involve the Marshallese in the design of any further medical research.

The Department of Energy recognizes the difficulties and inequities in the current program of medical care for the Marshall Islands and fundamentally agrees with all these recommendations.

The fundamental problem is additional funding: the Department has no additional funds available to allocate to this program. New efforts will have new costs and the Marshallese are already concerned that the current program is not funded at a sufficient level.

The Marshallese assert that they do not seek additional surveillance of additional atoll populations; they are interested in more local control of services provided by DOE and DOE and an extensive expansion of medical care facilities and services available in the Marshall Islands, including construction of a new hospital. The need for medical care is not directly linked to past radiation exposures.

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- There are complicated scientific, logistic, and financial questions in terms of expanding the current program that would need to be considered by Congress, the Department of Energy and the Department of the Interior.
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Actions Taken

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1. Let the Congressional inquiries play out, continue active negotiations with the Marshallese that would support the Marshallese desire for more local control of program directions and implementation, but do not advance legislation calling for a greatly expanded budget and health care program in the absence of Congressional Initiative.

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**From: Elly Melamed
Department of Energy**

Date: June 14, 1996

Subject: Briefing Paper on Notification (Recommendation 4)

BACKGROUND

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The expert group set up by the President to make a judgement on this issue rejected this approach.

Benefits are unclear and potential exists for adverse reactions and invasions of privacy.

2. The government can accept the recommendation of the Advisory Committee and reject any additional notification efforts.

Pro: This is the simplest, least expensive approach and is consistent with conventional public health practice and with the expert Advisory Committee process set up by the President.

Con: This may produce adverse publicity if the Government is perceived as being unresponsive to a vocal constituency with longstanding and strongly expressed grievances.

Congress may possibly mandate some form of additional notification activity.

3. The government can fundamentally accept the Advisory Committees recommendation but also (a) carefully frame its response to make clear that a great deal has already been done that is part of a general openness/public notification process and (b) make a strong case for the difficulties and adverse impact of this process.

Pro: This allows the Government to make the choice that seems most consistent with the evidence available and the process established, but also attempts to mitigate negative political consequences and to more fully publicize and explain the actual issues involved - (there are not "thousands" of experiments that require notification).

Con: Stakeholders may be unwilling to accept anything less than an all out notification effort and Congress may still mandate some form of notification.

4. The government can do (3) above, but in addition investigate the possibility of offering Medicare coverage to members of certain groups who are not yet eligible for this coverage. Three potential groups are the atomic veterans, the uranium miners, and the Nevada test site downwinders. All three of these groups have been formally recognized in legislation as subject of government sponsored radiation exposure. A very rough estimate of the numbers are: atomic veterans - approximately 400,000, approximately 200,000 of whom are believed to be ineligible for Medicare at this time; Nevada downwinders - approximately 19,000; and atomic veterans - approximately 18,000.

Pro: Avoids the problems of notification but provides medical coverage, a crucial issue for stakeholders, to three important groups.

May ultimately be more satisfying to stakeholder groups than biomedical experiments notification since it involves more subjects.

Represents a genuine attempt by the government to find compassionate ways to respond to stakeholder concerns.

Con: Potentially expensive.

May not be politically feasible given the current sensitivity with Medicare.

**From: J. Patrick Glynn
Department of Justice (DOJ)**

Date: June 13, 1996

Subject: DOJ Response (Recommendation 2) (From 2/16/96 Draft Response)

Recommendation 2: Apology and compensation where harm can be established, and where there was no prospect of direct medical benefit to the subject of the experiment. Several experiments and categories of experiments are proposed as candidates by the Committee.

Summary Response: As recommended by the Advisory Committee, in coordination with the Department of Justice (DOJ), and to the extent permitted by law, subjects (or their surviving immediate family members) will be offered reasonable financial compensation for human radiation experiments in which a government agency was involved in actions falling within the Advisory Committee criteria:

1. Experiments in which excessive secrecy deprived individuals of the opportunity to pursue potential grievances;
2. Experiments in which there was no prospect of direct medical benefit to the subject and physical injury resulted; or
3. Experiments in which interventions considered controversial at the time were presented as conventional or standard practice and physical injury resulted.

A streamlined administrative process, based on Federal Tort Claims Act procedures or other applicable law, will be used to offer compensation as part of a settlement of relevant claims. Maximum effort will be made to avoid lengthy litigation, including use of alternative dispute resolution, such as mediation or arbitration, where appropriate. The amount of compensation will be based on the extent of physical injury to the subject, the nature of the experiment, and the degree of government involvement. As needed, agencies will seek expert advice on scientific and medical issues. If compensation cannot be offered under existing law in any case under the stated criteria, the Administration will work with Congress to seek legislative relief in appropriate cases.

DATE:

ASSISTANT SECRETARY
OFFICE OF ENVIRONMENT, SAFETY AND HEALTH
U.S. DEPARTMENT OF ENERGY
1000 INDEPENDENCE AVENUE, S.W.
WASHINGTON, D.C. 20585

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TO: I A W G STAFF / WHITE HOUSE ATTENDEES

FROM: ELLY MELAMED

NO. OF PAGES TO FOLLOW: 4

☐ For your information☐ Please call upon receipt☐ As requested☐ For review and comment☐ Original copy to follow via mail

COMMENTS/MESSAGES:

MARSHALL ISLANDS PIECE FOR

FRIDAY MEETING.

**From: Elly Melamed
Department of Energy**

Date: June 27, 1996

Subject: Revised Briefing Paper on the Marshall Islands (Recommendation 8)

Background

The Advisory Committee made four recommendations concerning the Marshall Islands:

- 1) to continue the current DOE surveillance program limited to those Marshallese exposed to fallout from US atomic tests, as long as the exposed population remains alive;
- 2) to review the program to determine if other atolls should be added;
- 3) to establish an independent panel to review the current program for providing medical care to the exposed population;
- 4) to involve the Marshallese in the design of any further medical research.

Malaysian

DOE agrees with each of these recommendations. The first and the last are, and will continue to be, carried out. The fundamental problem in terms of expanding the program is one of funding: the Department does not have the resources to expand the medical care program; nor does it have funds to do the type of independent study that the Marshallese have requested. New efforts will have new costs and the Marshallese are already concerned that the current program is not funded at a sufficient level.

The Current Medical Program

There are currently three separate and distinct programs that provide medical care to the Marshallese. The Department of Energy recognizes the difficulties and inequities in the quality of care each program provides.

DOE Program. DOE supports a special, intensive medical program which at present serves the 133 individuals from the atolls of Rongelap and Utirik who were inadvertently exposed to high amounts of atmospheric fallout from the Castle BRAVO test in 1954. The objective of this program is to thoroughly assess the health of these individuals that who may have problems related to radiation exposure from the Castle BRAVO test. This is a high quality medical program that uses the best and latest examination and laboratory techniques. The Department offers these examinations twice a year, utilizing a team of US physicians from Brookhaven National Laboratory, academic centers, and Federal agencies such as the PHS and DOD.

177 Health Care Program (four atoll program). Supported through the Department of Interior, this program was created to provide *year-round general* medical care and treatment to residents of the four atolls most directly affected by the *overall* U.S. weapons testing program in the South Pacific. It now provides care for approximately 11,500 individuals with a total annual budget of \$2.0 million, or roughly \$174 per patient per year. Additional people have been added, including children, without increasing the level of funding.

Marshallese Program. The Government of the Republic of the Marshall Islands has a general Ministry of Health medical delivery system operating primarily out of hospitals in Majuro and Ebeye. This program, we believe, is in need of improvements as it struggles under the burden of a lack of sufficiently trained personnel and crumbling facilities. The Marshallese would like better health for those covered by this RMI system, especially for those who live in the atolls of Ailuk, Likiep, and Wotho.

The Marshallese are interested in more local control of services provided by DOE and an extensive expansion of medical care facilities and services available in the Marshall Islands, including construction of a new hospital. This need for medical care is real and is not directly linked to past radiation exposures.

If the medical care program were to be significantly expanded, DOE is concerned that it is not the appropriate agency to undertake a broad medical delivery effort; other agencies have more expertise and experience in this matter. There are indications that the Marshallese agree with this position.

There are complicated scientific, logistic, and financial issues that need to be addressed before the U.S. can agree to expanding the current program. There are no indications that Congress intends to act to expand the DOE program or the four atoll program, although they would like to see this latter work more effectively.

Issues Involving the Review Panel

The Marshallese would like DOE to fund a study that would be performed by the National Academy of Sciences and would retrospectively consider the past program rather than focus on future options. This would be an expensive and time-consuming undertaking. DOE would prefer to set up a "blue ribbon group" that would focus on the current program and how to help build infrastructure and self-sufficiency for the Marshallese medical program. In addition, DOE does not have sufficient funds to underwrite an NAS study.

Actions Taken

DOE has been actively working with the Marshallese and has affirmed its plans to continue the current program, its willingness to support efforts to review the issue of adding further atolls, and its desire to establish an independent panel to review the direction and scope of the surveillance program. DOE has also agreed to work with the

Marshallese and involve them in any decision making and to allocate funds according to their priorities. The Marshallese have been responsive to these assurances.

DOE has also met with Department of Interior staff who administer the medical care services to the Marshallese in efforts to better coordinate US efforts and answer the needs of the Marshallese.

If the DOE program were expanded to include the 3500 Bikini and Enewetak populations, it is anticipated, based on Straub Clinic older adult care costs, that it would cost at least \$5000 per patient per year. Approximately \$4500 would be needed to provide the medical care and another \$500 in logistics costs would be required to get patients to appropriate medical care facilities. Thus a program of this magnitude would likely cost about \$17.5 million annually. This budget could be higher if medical referrals facilities outside the Marshall Islands are needed. Such a program would best be executed through a Public Health Service contract and administered by a medical care delivery entity.

Options

1. Let the Congressional inquiries play out, continue active negotiations with the Marshallese that would support the Marshallese desire for more local control of program directions and implementation, but do not advance or propose legislation calling for a greatly expanded budget and health care program in the absence of Congressional Initiative.

- Pro
 - Would continue to provide medical care to the acutely exposed population under the Department of Energy's (DOE's) program.
 - Would meet DOE's current Congressional mandate.
 - Would allow Congress to decide on eligibility criteria for inclusion in the program.
 - Would leave Congress in the position of deciding what level of funding is needed to meet the concerns expressed.
 - Would enable DOE to continue to build on improved relationships with the RMI.
- Con
 - Would not address the RMI coverage concerns expressed during the Advisory Committee's review.
 - Would leave a poorly functioning "177" medical care delivery system intact for the bulk of the Marshallese populations also exposed to some fallout dose, while continuing to provide high quality medical care to a very few.

What's the problem

2. Propose legislation supporting Marshallese desire for medical coverage of all Marshallese believed to be exposed and who are experiencing radiation related health effects. (Assumes adding patients to the current DOI 177 Health Care Program and increasing patient care levels to \$5,000/patient/year.)

- Pro
- Would continue in the spirit of trying to find an equitable way to deal with the U.S. Government moral commitment to provide at least a minimal level of primary medical care to all deserving Marshallese citizens.
 - Would honor Departmental commitments to work toward a solution that can ameliorate, in some fashion the inadequate status of medical care delivery in the Marshall Islands.
 - Offers the opportunity to bring in a federal agency more qualified to provide health care delivery program of this magnitude.
- Con
- Would cost the Administration some \$17.5M annually to add just the 3,500 Bikini and Enewetak proposed by Senator Murkowski (Amendment 4039 to S. 1804) which proposes to add the 3500 Marshallese to the current DOE Medical Program, or
 - If the additional populations of Ailuk, Likiep and Wotho (some 1900 additional people) are added, costs would be driven to \$66.9M annually. This assumes treatment of the some 13,370 patients (11,470 plus 1,900).

DATE:

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TO:

IAWG STAFF / WHITE HOUSE ATTENDEE

FROM:

ELIX MELAMED

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ATTACHED, W PREPARATION FOR THE FRIDAY
MEETING IS ① MATERIAL FROM DOE ON NP
RADIUM THERAPY ② ADDITIONAL INFO FROM
DOE ON URANIUM MINERS. MARSHALL
ISLANDS INFO WILL FOLLOW. ALSO, UPDATED
WHITE PAPER WILL BE DISTRIBUTED
AT THE MEETING. CALL IF QUESTIONS.
202 586-6757



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

*CDC rec TS
no notification*

JUN 27 1996

RECC

**MEMORANDUM FOR INTERAGENCY WORKING GROUP
ATTN: ELLY MELAMED**

SUBJECT: Treatment of Aerotitis Media in Submariners and Aircrews

Background on Nasopharyngeal (NP) Radium Therapy

During the 1920s, physicians at Johns Hopkins University developed a new technique using radium which enabled them to successfully treat children for hearing impairment caused by chronic inflammation of the middle ear (otitis media). Called nasopharyngeal (nose and pharynx) therapy, this procedure involved routing a radium tipped applicator through the nasal passage, positioning it adjacent to the eustachian tube and leaving it in place for several minutes before removal. Treatments were routinely repeated over a period of months as determined by tissue response to the therapy.

Both civilian and military facilities used this procedure from the late 1920s until the 1960s. In the early 1940s military medical personnel performed NP radium therapy on Navy submariners/aviators and Army Air Force aviators as a treatment for inflammation of the middle ear due to pressure changes (aerotitis media) and upper respiratory infections. This therapy was particularly valuable during World War II and played a significant role in keeping air crews and submariners available for duty. However, one major epidemiological study suggests that treated individuals may be at increased risk for the development of head and neck malignancies. It is also possible that the treatment may result in other types of diseases such as endocrine disorders.

*Recovery
power*

DOD actions to date

- On 31 March 1994, the Bureau of Medicine and Surgery (BUMED) Supplemental Report on Human Radiation Experiments identified a study using nasopharyngeal irradiation on Submariners, labeled "Study #SMRL-01". It identified a test population 732 but provided no further personal identifying data.
- On 30 April 1996, the original log book of the Aerotitis Media Study was located at the Medical Research Laboratory in New London, Connecticut.
- The DOD is in the process of analyzing this log. A meeting was held between DOD and VA on 31 May 1996 to start efforts of further identifying and following up on participants of this study. The DOD agreed to develop a database of the individuals listed in the log book.
- The DOD identified 1611 names in the log book who may have been involved in the research. The Nautilus Submarine Museum in Groton, Connecticut has copies of student data cards for the time frame in question. The DOD sent researchers there 12-25 June 1996 to identify possible matches. There were 1039 possible matches (965 enlisted and 74 officer). This corresponds to a 65% match of log names with student data cards.

- The DOD will take this list of matches and attempt to locate corresponding service and medical records at the National Personnel Record Center. These records will be reviewed and the information passed to the VA for further follow-up.

VA actions to date

- The VA co-sponsored (with the CDC and Yale University) a workshop entitled "The Public Health Response to Nasopharyngeal Irradiation" held in New Haven CT on 27-28 September 1995.
- The VA's Environmental Epidemiology Service (EES) examined the feasibility of an epidemiological study of Navy personnel treated with radium. Prior to the discovery the researcher's log book, this was not considered feasible.
- VA officials authored or co-authored articles in major medical publications (including the Journal of the American Medical Association and the Morbidity and Mortality Weekly Report) to inform health professionals about NP radium.
- Information on NP radium has been sent to major veterans service organizations for publication in their newsletters.

VA actions in progress

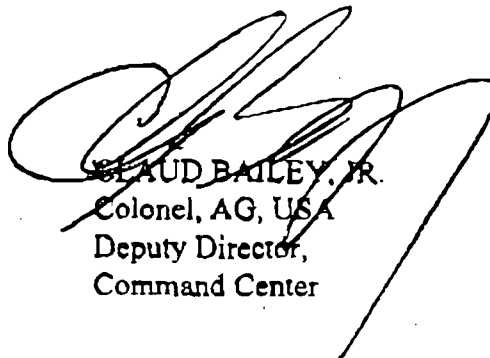
- A legislative proposal has been drafted which will make veterans treated with NP radium in the service eligible to participate in the VA's Ionizing Radiation Registry Examination program and have priority eligibility for treatment of conditions possibly related to radiation exposure. *Spencer*
- VA's EES is examining the feasibility of an epidemiological study of Army Air Force veterans treated with NP radium.
- The VA is collaborating with the CDC to present a satellite teleconference on NP radium to further inform health professionals. This is scheduled for 5 September 1996

Follow-up VA actions

- In light of the recent retrieval of the Navy log book, VA's EES will re-examine the feasibility of an epidemiological study of Navy personnel treated with NP radium.
- VA will also re-examine the feasibility of notification of individual veterans treated with NP radium.

FOR THE DIRECTOR:

besand logbook



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

RECOMMENDATIONS REGARDING THRESHOLD EXPOSURE CRITERIA FOR URANIUM MINERS WITH LUNG CANCER

1. Background of Problem:

The Radiation Exposure Compensation Act (RECA) presently requires uranium miners seeking compensation for lung cancer to meet minimum radon progeny exposure thresholds; the thresholds vary by the smoking status of the miner and the age of the miner at the time of diagnosis of lung cancer (attained age). The RECA Committee has proposed new threshold exposure criteria, using the latest scientific data and analytical methods. The new criteria indicate that the relative risk of lung cancer due to radon progeny decreases with attained age, and decreases as time since last exposure increases. As a consequence, the new eligibility criteria for miners who developed lung cancer over the age of 60 and who have been out of the miners for more than 20 years are significantly higher than the present statutory criteria. Most (though not all) of the miners who are applying for compensation now (or who have applied since 1991) fall into the affected group. The practical consequence is that any miner in the affected group applying today likely will be denied compensation.

2. Basis for Modifying Proposed Criteria:

Although the RECA Committee recognized the consequences of the new lung cancer compensation criteria, it specifically avoided modifying the criteria to account for political or other policy-based factors. The recommended criteria simply represent the Committee's best "technical" judgment where the line for compensation should be drawn, based on the premise that Congress sought in the Act to compensate only those miners whose lung cancer more likely than not was the result of their exposure to radon progeny in the course of their employment in underground uranium mines.

There are a number of reasons that justify the Administration in modifying the proposed criteria to ease or eliminate any added burden to eligibility imposed on miners now contracting lung cancer.

a. First, and foremost, the criteria proposed by the Committee do not account for uncertainties associated with the data. The Committee did take into account the uncertainty due to the statistical sampling process. However, the Committee did not factor in the potential error due to inaccuracy or imprecision of the underlying data. In the case of the exposure-based criteria, that uncertainty is likely to be significant; the historical radon measurements in the mines are widely believed to be

inaccurate and imprecise measures of claimants' exposures in many cases.¹

b. Second, the RECA is designed to provide compassionate payments to persons presumably injured as a result of the government's proven failure to protect its citizens. It is remedial legislation -- as such, the risk of uncertainty should be imposed on the government, and the benefit of the doubt given to the aggrieved parties (the miners).

c. Third, the new criteria, to the extent they raise the threshold requirements for compensation, run counter to settled expectations in the affected communities. While citizens generally have no enforceable or politically plausible "right of expectation" in government legislation, in this case the affected communities may have effectively been "duped" into not challenging earlier the analytical process employed by the Committee. The criticisms presented to Congress and the Advisory Committee did not explicitly note the likelihood that some criteria would rise under a more rigid scientific analysis. Moreover, the new methodology was not discussed in detail before congressional committees or the Advisory Committee, so neither claimants nor their advocates realistically could have been prepared for what they will surely see as a breach of good faith. Because the government made no effort to advise them of this outcome, and instead allowed optimistic expectations to solidify, the claimants and their advocates have had no opportunity to advocate to the Advisory Committee or the IAWG some policy-based parameters to guide the Committee's investigation.

3. Possible Alternative Criteria

a. Allow claimants to qualify under either the present statutory criteria or the newly proposed criteria

Under this proposal, no claimant will be adversely affected by the new criteria. The Program will use that set of criteria that sets the lowest threshold standard for the claimant, based on their smoking history, age, and mining history. This proposal will maximize the number of claimants who will be eligible for compensation.

Though this will solve the problem in practice, it is theoretically objectionable. First, the new criteria were developed because it was agreed that the present criteria do not

¹ Of course, any error associated with the mine exposure data is eliminated by using criteria based on employment duration. The employment data, however, has an associated error not accounted for.

accurately quantify the risk of lung cancer to uranium miners, and thus do a poor job of effecting congressional intent -- getting the money to deserving claimants. The lack of a firm scientific foundation for the criteria -- likely the result of political compromise -- was the impetus behind the Advisory Committee's Recommendation 7 and the creation of the RECA Committee. If we continue to use the present criteria, even partially, we create a system that is prone to the same criticism that led to the current undertaking.

Second, if we use the present criteria for some miners, we sanction a set of standards we acknowledge do not accurately quantify the risks to miners, and thus do not accurately effect congressional intent. Indeed, allowing a claimant to qualify based on the "old" standards where the new standards are higher has the effect of compensating a claimant our best information indicates does not deserve compensation.

Third, if we use both set of criteria, we create a problem of comparability within the class of miners. Miners who opt to use the present standards where they are more liberal than the new criteria will be compensated though the probability of causation is less than fifty percent. On the other hand, many miners will use the new criteria because for their age, smoking status and employment history, these criteria are lower than the present statutory criteria. The new criteria, however, embody the fifty percent probability standard. Thus, some miners are compensated only if they meet the fifty percent probability, while other miners for whom the present criteria are more advantageous are compensated at a lower standard of probability.

b. Grandfather in all claimants with claims that are pending or accrued as of some date

Under this proposal, any claimant who has a claim pending with the program or whose claim has "accrued" as of some date would be entitled to use the present statutory criteria, if they are more advantageous. The question here is how to define when a claim "accrues." One definition is when the compensable disease was or could have been diagnosed -- i.e., when the claimant develops the disease. By setting the date for a change in the standards some period of time after the amendment of the Act (i.e., two years), you can provide a window of comfort to ensure you include claimants whose lung cancer is manifesting presently, and avoid violating reasonable expectations among many claimants.

This proposal, however, will not help claimants who develop lung cancer some years in the future, and who perceive that they have been unfairly treated. Claimants are thus divided into two groups with differing threshold standards, depending solely on the quixotic factor of when their disease manifested (a factor already accounted for in the development of the criteria).

c. Modify the criteria tables to account for additional uncertainties in the data

The Committee's recommended criteria factor into account uncertainties in the statistical process by developing "levels of assurance," described above. The Committee did not take into account the uncertainty associated with the underlying data. It is probable that the confidence intervals calculated to account for this uncertainty will be greater for the more recent miners because the Colorado cohort is weighted toward older, more highly exposed miners. Thus, there is some theoretical justification for giving a larger "break" to miners who were exposed later and to smaller amounts -- which will be many of the miners now coming down with lung cancer.

While this approach is theoretically defensible and has the virtue of being, like the criteria themselves, "science-based," it may not be practical. Confidence intervals reflecting the uncertainty associated with radon progeny exposure estimates cannot be calculated. There are a host of uncertainties associated with this estimate process, and statistical models to determine the error are only now being developed. In the words of one of the statisticians on the Committee, the problem is "not trivial."

Additionally, dropping the exposure criteria for some miners will not work for the employment-based standards, which the Committee strongly recommends be used in conjunction with the exposure-based criteria. The employment data is much more precise than the mine data, so there is little uncertainty, yet the employment-based criteria for older miners are still quite high.

d. Propose criteria based on a different standard of causation

As noted above, the Committee developed the new criteria based on the premise that Congress intended to compensate claimants whose lung cancer more likely than not was caused by exposure to radon progeny during employment in underground mines. Lowering the standard of causation to a figure less than 50% will result in lower threshold exposure or employment duration criteria. The Administration can propose to Congress that the Act be amended to establish a lower causation standard given the uncertainties associated with the data and the recognized injustice done to the miners. This approach could be part of a broader effort to deal with the recognized "comparability problem" -- the compensation criteria in the Act effectively set three different probabilities of causation for the three eligible classes, with the uranium miners required to meet the highest standard.

This approach may well be unwarranted because it asks Congress to redebate one of the fundamental propositions underlying the Act. The legislative history suggests that there is some strenuous opposition to any scheme that explicitly purports to compensate individuals where the probability of causation is less than 50%. Reopening this debate, in light of recent data on the relative risks to the downwind and onsite participant populations, might jeopardize the compensation scheme for these two groups and would create extensive collateral political problems.

600 million

- OMA Jack Lewin -

ACHRE Recommendation Follow-up
December 3, 1996

Introduction

Status of Pending Actions

Report Responding to ACHRE

Summary

Outstanding issues

Process for interagency approval

- Fund has dispersed \$148 million

Legislation

Radiation Exposure Compensation Act - \$5. million

VA Bill *Verify - that OMB cleared.*

Possible Glenn bill

Regulations

DOJ Regulations on RECA

Presidential memorandum on Classified Research

Next Steps

Public Stakeholders

Congressional Committees

Press event (timing, participation, outline)

modifications to EO

- Stronger stmt on rarity
- Annual to

Lay out -

- Ex. summary
- Things that this didn't address. —

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THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS.

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Kathy Paroff

AGENDA

Interagency Working Group on Human Radiation Experiments

June 6, 1996

open issues
legislation
Is there someone -
Volunteer

- I. Introductions
- II. Short Term Objectives -- Goals and Timeframes
- III. Identification of Outstanding Issues in Key Areas
 - a. Notification - - V.
 - b. Compensation
 - c. Expectations for NBAC
 - d. Uranium Miners
 - e. Marshall Islanders ←
f. ~~NP~~ NP ←
- IV. Process for Resolving Issues.

g. atomic vets.
h. other

o sub
o

F

Agenda
Interagency Working Group on Human Radiation Experiments
June 20, 1996, 2:30-4:00

- I. National Bioethics Advisory Committee- Rachel Levinson,
Jon Foster
- . Status and content of announcement
 - . ACHRE recommendations identified as possible referrals to NBAC:
 - Recommendation 9:** NBAC's role in establishing strategies to ensure the centrality of ethics in human subject research.
 - Recommendation 10:** NBAC's role in changing IRB's.
 - Recommendation 11:** Ongoing public forum needed to discuss ethical issues raised by human experimentation.
 - Recommendation 13:** NBAC's role in improving oversight, sanctions, and scope of human subjects protections.
 - Recommendation 14:** NBAC's role in future compensation for research injury.
 - Recommendation 15:** NBAC's role in deciding whether federal rules should be changed to codify "no waivers" of consent.
- II. Uranium Miners (Recommendation 7) - Paul Yanowitch
- III. Public Involvement in follow-up to ACHRE
- IV. Next Steps
- . . Next meeting schedule and agenda (proposed: atomic veterans; Marshall islanders; nasopharyngeal radiation)

AGENDA

Interagency Working Group on Human Radiation Experiments

June 6, 1996

I. Introductions

II. Short Term Objectives -- Goals and Timeframes

III. Identification of Outstanding Issues in Key Areas

- a. Compensation *DOJ*
- b. Notification *Tara O'Toole*
- c. Expectations for NBAC
- d. Uranium Miners - *Justice (Paul)*
- e. Marshall Islanders - *DOE*
- f. Nasopharyngeal Radiation *DOH - CDC* *Gordon*
- g. Atomic Veterans *DOH - VA*
- h. Other

IV. Process for Resolving Issues.

17th 18th

Fax Cover Sheet

=====

Please Deliver to:

Diane Regas
Elizabeth Drye

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Company: White House

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Phone:

Pages: 2

=====

Message:

*****URGENT!!!*****

I've attached the agenda for today's IAWG meeting at OEOB. Diane Regas submitted the agenda. Hope we will see you there. Call with questions 202-586-5319. Have a great morning!

This fax was sent using Castelle's FaxPress network fax server.

Agenda
Interagency Working Group on Human Radiation Experiments
June 20, 1996, 2:30-4:00

I. National Bioethics Advisory Committee - Jon Foster

Status and content of announcement

ACHRE recommendations identified as possible referrals to NBAC:

- * Recommendation 9: NBAC's role in establishing strategies to ensure the centrality of ethics in human subject research.
- * Recommendation 10: NBAC's role in changing IRB's.
- * Recommendation 11: Ongoing public forum needed to discuss ethical issues raised by human experimentation.
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- * Recommendation 14: NBAC's role in future compensation for research injury.
- * Recommendation 15: NBAC's role in deciding whether federal rules should be changed to codify "no waivers" of consent.

II. Uranium Miners (Recommendation 7) - Justice

III. Public Involvement in follow-up to ACHRE

IV. Next Steps

Next meeting schedule and agenda (proposed: Atomic Veterans; Marshall Islanders; nasopharyngeal radiation)

Agenda
Interagency Working Group on Human Radiation Experiments
July 9, 1996, 10:30-12:00

- I. Atomic Veterans (VA)
- II. Waivers of Consent for Classified Research (HHS)
- III. Next Steps
 - . Next meeting July 16, 10:30 and agenda (proposed: notification; IRBs)

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DEPARTMENT OF THE ARMY
U. S. ARMY CLAIMS SERVICE
OFFICE OF THE JUDGE ADVOCATE GENERAL
FORT GEORGE G. MEADE, MARYLAND 20755-5360

REPLY TO
ATTENTION OF:

APR 16 1996

Eastern U.S. Torts Branch

Mr. Robert Newman
Attorney at Law
1014 Vine Street, Suite 2520
Cincinnati, Ohio 45202

Dear Mr. Newman:

This letter is in reference to the Standard Form (SF) 95 (Claim for Damage, Injury, or Death), submitted to the Department of Defense (DOD) on January 18, 1996, in the total amount of \$100,000,000, on behalf of the claimants listed in enclosure 1. The SF 95 states that it is on behalf of representatives of 44 people who were subjects of human radiation experiments at the Cincinnati General Hospital from 1960 to 1972, with which were associated a series of DOD contracts. With respect to the basis of the claim, the SF 95 refers to the Second Amended Consolidated Class Action Complaint, "In Re: Cincinnati Radiation Litigation," United States District Court, Southern District of Ohio, Western Division, Case No. C-1-94-126. That complaint was against a number of parties, not including the U.S. Government. The SF 95 seeks to assert claims under the Federal Tort Claims Act (FTCA) for compensation from the U.S. Government for the claimants. The U.S. Army Claims Service is responsible for evaluating your submissions.

It is the policy of the DOD to evaluate any claims for compensation arising from certain human radiation experiments under two parallel sets of standards: 1) standards based on the recommendations of the Advisory Committee on Human Radiation Experiments; and 2) normal FTCA standards. These are described below, followed by an initial response to the SF 95.

Standards Based on Recommendations of the Advisory Committee on Human Radiation Experiments.

Recommendation 2 in the October 1995 Final Report of the Advisory Committee on Human Radiation Experiments stated:

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The Advisory Committee recommends to the Human Radiation Interagency Working Group that for subjects of human radiation experiments that did not involve a prospect of direct medical benefit to the subjects, or in which interventions considered to be controversial at the time were presented as conventional or standard practice, and physical injury attributable to the experiment resulted, the government should deliver a personal, individualized apology and provide financial compensation to cover relevant medical expenses and associated harms (pain, suffering, loss of income, disability) to the subject or surviving immediate family members.

Final Report, p. 803. The Advisory Committee also recommended that certain human radiation experiments be considered as candidates for remedies under this recommendation. These included total-body irradiation (TBI) experiments,

should it be determined that TBI was considered at the time to be a controversial treatment for patients with 'radioresistant' tumors, and it was not presented as such to potential subjects, and should a determination of harm attributable to the experiments be made.

Id., p. 804.

In consultation with the Department of Justice and other agencies represented on the Interagency Working Group, DOD will use the administrative claims process of the FTCA, 28 U.S.C. § 2672, to consider compensation claims based on governmental involvement under the standards recommended by the Advisory Committee, and will seek to resolve those claims in a just and compassionate manner. A claimant who is dissatisfied with the outcome of this process retains the option, to the extent allowed by law, to pursue a claim in federal court, but the avoidance of lengthy litigation is a key objective of the administrative process. An offer of compensation under this process must be based on the authority of the FTCA; if FTCA prerequisites cannot be met in a particular case, possibilities for legislative relief may need to be considered.

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Normal FTCA Standard.

Because FTCA jurisdictional authority must be established in order for compensation to be offered through the administrative process, and because, in the absence of a satisfactory administrative resolution, litigation may follow, all human radiation experiment claims will also be analyzed under the normal FTCA standards. Under the FTCA, there are a number of jurisdictional requirements, defenses, and other provisions that must be considered. These include, but are not limited to:

- o a sum certain claimed for each individual, 28 U.S.C. §§ 2401, 2675(b); 28 C.F.R. § 14.2;
- o evidence of a representation agreement from each claimant authorizing an attorney and/or other representative to file a claim on the claimant's behalf, 28 C.F.R. § 14.3;
- o filing of an administrative claim within two years after the claim accrues, 2 U.S.C. § 2401(b);
- o exclusion of claims arising from actions of any government contractor, 28 U.S.C. § 2671; and
- o exclusion of claims arising out of performance of discretionary functions, misrepresentations, or certain other grounds, 28 U.S.C. § 2680.

In considering certain human radiation experiment claims under the standards of the Advisory Committee's recommendation, the United States does not waive any rights or defenses under the FTCA.

Response to SF 95, as filed.

With the above as background, the response to your SF 95 follows. As an initial matter, the SF 95, as filed, does not constitute a valid claim under the FTCA. As noted above, a sum certain must be claimed for each individual. Moreover, you did not provide evidence of a representation agreement from each of the claimants authorizing you to file claims on their

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behalf. As a result of these deficiencies in the SF 95, this Service does not consider the claim to be properly filed. To remedy these deficiencies, this Service recommends that each claimant submit a separate claim. The claimant should sign the SF 95. However, a representative is authorized to sign for a claimant, provided the representative includes a power of attorney or other document authorizing the representative to act for the claimant. Also, if a claimant is acting in the role of an executor of an estate, that person must include proof that he or she is the legal representative of the estate. Finally in this vein, a proper jurisdictional basis must be established, including a showing of compliance with the statute of limitations.

In addition to these procedural matters, your submission did not include sufficient factual information to permit analysis. For the United States to consider a claim under the standards of the Advisory Committee's recommendation, at a minimum, evidence of the following will be needed for each claimant:

- o that the TBI provided to the subject was presented to that subject as conventional or standard practice;
- o that there was physical injury to the subject attributable to the TBI;
- o that there were compensable damages based on medical expenses, pain and suffering, loss of income, or disability, and that those damages are quantified;
- o that the claimant is the subject or a surviving immediate family member; and
- o that the compensation sought from the government is commensurate with the government involvement in the experiment.

At enclosure 2 is a copy of 28 C.F.R. Part 14, the Department of Justice regulations for administrative claims under the FTCA. This may be of assistance to you in filing these claims. Please especially note section 14.4, which details the types of evidence

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necessary to substantiate claims. If you have any questions concerning the administrative claims process, please feel free to call Captain James F. McConnon, Jr. of this Service at (301) 677-7009, extension 238.

Please be assured of the commitment of the Department of Defense to vigorously pursue the reasonable resolution of claims arising from the Cincinnati human radiation experiments.

Sincerely,



Francis R. Moulin
Colonel, U.S. Army
Chief, Tort Claims Division

Enclosures